JUDGMENT OF THE COURT

9 September 2003 *

In Case C-236/01,

REFERENCE to the Court under Article 234 EC by the Tribunale amministrativo regionale del Lazio (Italy) for a preliminary ruling in the proceedings pending before that court between

Monsanto Agricoltura Italia SpA and Others

and

Presidenza del Consiglio dei Ministri and Others,

on the interpretation and validity of the first subparagraph of Article 3(4) and the first paragraph of Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1), and on the interpretation of Article 12 thereof,

* Language of the case: Italian.

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, J.-P. Puissochet and C.W.A. Timmermans (Rapporteur) (Presidents of Chambers), C. Gulmann, D.A.O. Edward, A. La Pergola, P. Jann, V. Skouris, S. von Bahr, J.N. Cunha Rodrigues and A. Rosas, Judges,

Advocate General: S. Alber,
Registrar: L. Hewlett, Principal Administrator,

after considering the written observations submitted on behalf of:

— Monsanto Agricoltura Italia SpA and Others, by E.A. Raffaelli, G.F. Ferrari and P. Todaro, avvocati,

— the Italian Government, by I.M. Braguglia, acting as Agent, assisted by M. Fiorilli, avvocato dello Stato,

— the Norwegian Government, by B. Ekeberg, acting as Agent,

— the European Parliament, by C. Pennera and G. Ricci, acting as Agents,

— the Council of the European Union, by A. Lo Monaco and F.P. Ruggeri Laderchi, acting as Agents,

— the Commission of the European Communities, by M. Shotter and A. Aresu, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Monsanto Agricoltura Italia SpA and Others, the Italian Government, the Parliament, the Council and the Commission at the hearing on 24 September 2002,

after hearing the Opinion of the Advocate General at the sitting on 13 March 2003,

gives the following

Judgment

1 By order of 18 April 2001, received at the Court on 19 June 2001, the Tribunale amministrativo regionale del Lazio (Regional Administrative Court, Lazio) referred to the Court for a preliminary ruling under Article 234 EC four questions on the interpretation and validity of the first subparagraph of Article 3(4) and the first paragraph of Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1), and on the interpretation of Article 12 thereof.

2 Those questions were raised in proceedings brought by Monsanto Agricoltura Italia SpA, established in Lodi (Italy), Monsanto Europe SA, established in Brussels (Belgium), Syngenta Seeds SpA (formerly Novartis Seeds SpA), established in Origgio (Italy), Syngenta Seeds AG (formerly Novartis Seeds AG), established in Basel (Switzerland), Pioneer Hi Bred Italia SpA, established in Malagnino (Italy) and Pioneer Overseas Corporation, established in Des Moines (USA), which are companies involved in the development of genetically modified food plants for use in agriculture, and the Associazone Nazionale per lo Sviluppo delle Biotecnologie (Assobiotec) (National Association for the Development of Biotechnology) against the Presidenza del Consiglio dei Ministri, the Ministero della sanità, the Consiglio dei Ministri, the Presidente del Consiglio dei Ministri, the Ministero per le politiche comunitarie, the Istituto superiore di sanità and the Consiglio superiore de sanità regarding a measure suspending the trade in and use of certain transgenic products in Italy.

Legal framework

Community legislation

Directive 90/220/EEC

3 Under Article 2(1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15), 'organism' means any biological entity capable of replication or of transferring genetic material, and '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.

4 Article 11(5) of that directive, in conjunction with Article 11(1) thereof, provides that no product containing GMOs may be released into the environment before the competent authority of the Member State in which the product is to be placed on the market for the first time has given its written consent following a notification made to it by the manufacturer or the importer into the Community.

Regulation No 258/97

5 The second recital in the preamble to Regulation No 258/97 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'.

6 Article 1(1) and (2) of Regulation No 258/97 provides:

'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;

...'

7 Article 3 of Regulation No 258/97 states:

'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 shall apply...

...

4. By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1(2)(b), (d) and (e) 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 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.'

8 Article 5 of Regulation No 258/97 provides:

'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*.

With respect to labelling, the provisions of Article 8 shall apply.'

9 Article 8(1) of Regulation No 258/97 provides:

'Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

— composition,

— nutritional value or nutritional effects,

— intended use of the food,

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.

A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.

In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;

(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

...'

10 Article 11 of Regulation No 258/97 states:

'The Scientific Committee for Food shall be consulted on any matter falling within the scope of this regulation likely to have an effect on public health.'

11 Article 12 of Regulation No 258/97 is worded as follows:

'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 Article 13 of Regulation No 258/97 provides:

'1. Where the procedure defined in this article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, 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.'

Recommendation 97/618/EC

13 On 29 July 1997 the Commission adopted, under Article 4(4) of Regulation No 258/97, Recommendation 97/618/EC 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 No 258/97 (OJ 1997 L 253, p. 1). In Part I of the Annex to that recommendation, which sets out recommendations concerning the scientific aspects of information necessary to support applications

for the placing on the market of novel foods and novel food ingredients, Section 3, point 3.3, headed 'Substantial equivalence', states:

'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.

The application of the principle of substantial equivalence can be extended to the evaluation of foods from novel sources and processes. Substantially equivalent [novel foods and novel food ingredients] are thus comparable, in terms of safety, to their conventional counterpart. Substantial equivalence may be established either for the whole food or food component including the introduced "new" change, or it might be established for the food or food component except for the specific "new" change introduced. If a [novel food or novel food ingredient] 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 [novel food or novel food ingredient] should be evaluated on the basis of its unique composition and properties.

...'

14 In Section 3 of the Annex, point 3.7, headed 'Toxicological requirements', states:

'In principle, the toxicological requirements for [novel foods and novel food ingredients] need to be considered on a case-by-case basis. In establishing the need 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 [novel food or novel food ingredient], in which case any further assessment of safety should focus specifically on these traits;

...'

15 Part I of the Annex to Recommendation 97/618 includes a section 5, the purpose of which is to provide, by way of guidance, structured schemes identifying the

types of information which are likely to be required to establish the safety of particular classes of novel foods and food ingredients. Point IV of that section, headed 'Effect of the genetic modification on the properties of the host organism', states:

'The information gathered through this scheme focuses on the effects of the genetic modification on the properties of the GMO compared to the host organism. It differentiates between intended and unintended effects. In the latter case, special attention should be given to any nutritional, toxicological and microbiological impact on the foods.

GM plants

The principles for evaluating GM plants and their products are similar to those valid for non-GM plants and their products. The safety evaluation of a GM plant may be a simpler task than the evaluation of a novel non-GM plant, if the non-modified organism is a traditional food plant and the alteration has occurred by means of a precisely defined process of genetic modification. In this case, the safety assessment can focus on the results of the genetic modification.

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 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 toxicological 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 a genomic rearrangement, will influence the overall outcome of the genetic modification. A knowledge of the normal toxin production in 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.

...'

National legislation

16 The Decree of the President of the Council of Ministers of 4 August 2000 on the precautionary suspension of the trade in and use of certain transgenic products within national territory under Article 12 of Regulation No 258/97 (GURI No 184 of 8 August 2000, p. 9) (hereinafter 'the Decree of 4 August 2000') states:

'1. Trade in and use of the transgenic maize products Bt-11, MON 810 and MON 809... shall be suspended in accordance with the preamble.

2. The present decree shall be published in the *Gazzetta ufficiale della Repubblica italiana* and shall immediately be notified to the European Commission and to the other Member States.'

The main proceedings and the questions submitted for a preliminary ruling

17 In response to 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 Council Directive 90/220 (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 Council Directive 90/220 (OJ 1998 L 131, p. 32), which were adopted under that directive, the French authorities and the United Kingdom authorities gave their consent for the placing on the market by some of the companies which are applicants in the main proceedings or by connected companies of genetically modified maize grain of the line Bt-11 — a genetic modification rendering the maize resistant to insects, and MON 810 — a genetic modification providing the maize with increased tolerance to a herbicide, respectively. Decisions 98/292 and 98/294 specifically mention that those two Member States gave their consent without prejudice to other Community legislation, in particular Regulation No 258/97.

18 On 10 December 1997, 30 January 1998 and 14 October 1998, notifications under the simplified procedure for placing novel foods or novel food ingredients on the market, laid down in Article 5 of Regulation No 258/97 (hereinafter 'the simplified procedure'), were made to the Commission by or on behalf of certain of the companies which are applicants in the main proceedings. Those notifications related to the placing on the market of novel foods or novel food ingredients derived from the maize lines Bt-11, MON 810 and MON 809 (hereinafter 'the novel foods'), such as cornflour.

19 Those notifications were accompanied by opinions delivered in September 1996 by the Advisory Committee on Novel Foods and Processes (hereinafter 'the ACNFP'), a competent body within the meaning of Articles 3(4) and 4(3) of Regulation No 258/97 established in the United Kingdom, and sent to the undertakings concerned by the United Kingdom authorities by letter of 14 February 1997. In the opinions, the ACNFP essentially concluded that the derived foods in question were substantially equivalent to products derived from conventional maize and were 'safe for use in food'.

20 Those notifications were subsequently forwarded to the Member States on 5 February, 6 February and 23 October 1998, respectively. They were also published in summary form in the *Official Journal of the European Communities* (OJ 1998 C 200, p. 16 and OJ 1999 C 181, p. 22).

21 The Commission and the Member States had agreed within the framework of the Standing Committee for Foodstuffs no longer to apply the simplified procedure to novel foods derived from GMOs which contain transgenic protein, with effect from January 1998.

22 By letters of 23 November 1998, 4 February 1999 and 2 April 1999 to the Commission, the Italian health ministry alleged that the use of the simplified procedure for the purpose of placing on the market novel foods or novel food ingredients derived from maize lines Bt-11, MON 809 and MON 810 was improper. The ministry asked to see the documentation relating to that procedure, as well as the toxicological and allergenicity assessments. The Commission forwarded those letters to the undertakings concerned, so that they could respond directly to the Italian authorities.

23 By letter of 23 December 1999 sent to the member of the Commission in charge of health and consumer protection (hereinafter 'the competent Commissioner'), the ministry, referring to a report by the association Verde Ambiente e Società and relying in addition on an opinion by the Consiglio superiore de sanità (Italian federal board of health) of 16 December 1999, again raised an objection to the use of the simplified procedure in the present case on the ground, *inter alia*, that the novel foods were not 'substantially equivalent' to existing foods.

24 According to that letter, preventive measures had to be taken to ensure that the novel foods were safe and that their potential health risks were rigorously assessed before they were placed on the market. The ministry also asked the Commission to reconsider allowing free circulation of those foods and, more generally, the adequacy of the simplified procedure for the purpose of excluding any risk to consumer health.

25 By letter of 10 March 2000, the President of the Commission replied that it had been adequately established in the present case that the condition of substantial equivalence was satisfied and that recourse to the simplified procedure was therefore justified. He added that the Commission had decided to propose an amendment of the legislation at issue in order to clarify it and make it more transparent.

26 By letter of 5 June 2000 to the President of the Commission and the competent Commissioner, the ministry repeated its objection to the use of the simplified procedure in the present case and, in addition, expressed the wish that the procedure no longer be used for transgenic foods because of the ambiguity of the concept of substantial equivalence.

27 In a first opinion dated 4 July 2000, the Istituto superiore di sanità (Italian federal institute of health), which comes under the Italian Ministry of Health, arrived at the same conclusions as those of the Consiglio superiore di sanità, set out in its opinion of 16 December 1999, on which the ministry had relied.

28 By letter of 10 July 2000 the competent Commissioner replied to the letter of 5 June 2000 that it was appropriate to carry out a full review of the legal framework relating to novel foods. He also stated that he had forwarded the appropriate information to the Scientific Committee for Food for the purpose of a full assessment.

29 In a second opinion, dated 28 July 2000, the Istituto superiore di sanità noted the presence in the foods at issue of proteins derived from genetic modifications, at levels from 0.04 to 30 parts per million. It found that the novel foods were in general substantially equivalent to their traditional counterparts as regards their micronutritive and macronutritive value, while adding that for certain (micro)components the documentation provided did not contain any data comparing the novel foods to their traditional counterparts.

30 It concluded that, 'in the light of current scientific knowledge, the consumption of the GMO foods set out in the table does not appear to present any danger to human and animal health'.

31 Referring to its correspondence with the Commission and to those scientific opinions, the Italian Government adopted the Decree of 4 August 2000, which is explicitly based on Article 12 of Regulation No 258/97.

32 In the preamble to that decree, the Italian Government stated that the absence of the information which it had requested several times and the referral to the Scientific Committee for Food for the purpose of reassessing the effects of GMOs on consumer health and on the environment constituted a sufficient basis for requiring suspension of the marketing and use of GMO maize whose modified elements had been observed to persist in foods, pending the necessary verification as regards the composition of those elements.

33 Pursuant to Article 12(1) of Regulation No 258/97, the Italian Government sent a copy of the Decree to the Commission and to the other Member States on 7 August 2000.

34 As it had stated in its letter of 10 July 2000, the Commission consulted the Scientific Committee for Food in accordance with Article 11 of Regulation No 258/97, submitting to it the question whether the abovementioned opinions of 16 December 1999 of the Consiglio superiore di sanità and of 28 July 2000 of the Istituto superiore di sanità provided specific or other grounds for considering that the use of the novel foods at issue endangers human health.

35 In its opinion of 7 September 2000, that scientific committee expressed the view that the information presented by the Italian authorities did not provide specific scientific grounds for considering that the use of the novel foods at issue endangers human health.

36 In the light of that opinion, the Commission on 18 October 2000 referred to the Standing Committee for Foodstuffs a draft decision contesting the Decree of 4 August 2000, in accordance with Article 12(2) of Regulation No 258/97.

37 According to the minutes of the committee meeting which took place on 18 and 19 October 2000:

'... a number of Member States expressed concerns about the application of the simplified procedure to products derived from GMOs and insisted that this problem should be addressed before a decision on the Italian Decree [of 4 August 2000] could be taken. Clarification of the application of substantial equivalence to GM derived products such as GM maize products was needed, and this could be done, it was noted, under Article 3(4) of [Regulation No 258/97].'

38 The Commission was of the opinion that it was not necessary to invite the committee to deliver a formal opinion.

39 To date, the Decree of 4 August 2000 has not been the subject of any measure taken by the Commission pursuant to Article 12(2) of Regulation No 258/97.

40 On 13 November 2000, the applicants in the main proceedings brought an action before the Tribunale amministrativo regionale del Lazio against the defendants in the main proceedings, essentially seeking:

— the annulment of the Decree of 4 August 2000 in so far as it temporarily suspends the trade in and use of the novel foods within Italian territory, and of all preliminary, related or subordinate measures or courses of action expressly referred to in that decree, and

— full compensation for the damage which they have suffered, in the form of a grant of judicial authorisation to market those products.

41 In view of the arguments advanced before it, the national court considers that in the present case the use of the simplified procedure does not appear to be justified, since the novel foods are not substantially equivalent to existing foods.

42 According to that court, it follows in particular from Recommendation 97/618, specifically from Section 3, points 3.3 and 3.7, and Section 5, point IV, of Part I of the annex thereto, that all the elements of equivalence must be taken into account. It considers that in the present case the applicants in the main proceedings have not cast any serious doubt on the fact that the novel foods contain transgenic protein which expresses the inserted genes. It therefore follows that the substantial equivalence of those foods cannot be established, since they differ in their composition from existing foods.

43 The national court is of the opinion that the possible consequences of that procedural irregularity should be considered, in particular as regards the power of the Member States to adopt measures relating to foodstuffs introduced in their territory as the result of an improper procedure of that kind.

44 As regards the recourse by the Italian Republic to Article 12 of Regulation No 258/97, the national court considers that that provision includes a safeguard clause which gives specific expression to the precautionary principle (see, as regards Article 11 of Directive 90/220, Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651, paragraph 44).

45 The court observes that, since it seems to follow from the wording of Article 5 of Regulation No 258/97 that the use of the simplified procedure does not imply that the Commission has authorised the placing on the market of the foods at issue, the Member State may, in accordance with the precautionary principle, exercise the competence which it derives from Article 12 of that regulation, even when evidence which may prove that those foods endanger human health and the environment is not available or not yet available to it.

46 The national court takes the view that if the simplified procedure implied tacit consent by the Commission for the placing on the market of foods which are the subject of a notification, the question of the lawfulness of the Commission's consent would then arise.

47 In addition, if Regulation No 258/97 had to be interpreted to mean that the use of the simplified procedure was justified in the present case, the question would also arise whether that regulation is compatible with Articles 153 EC and 174 EC and with the principles of proportionality and 'reasonableness'.

48 In those circumstances, the Tribunale amministrativo regionale del Lazio decided to stay proceedings and to submit several questions to the Court for a preliminary ruling. Those questions have not been set out separately. Nevertheless, the following questions may be deduced from the grounds of the order for reference:

(1) Is the first subparagraph of Article 3(4) of Regulation No 258/97 to be interpreted as meaning that foods and food ingredients covered by Article 1(2)(b) of the Regulation may be considered substantially equivalent

to existing foods or food ingredients and may therefore be placed on the market by means of the simplified procedure, following 'notification', even if those foods and food ingredients contain residues of transgenic protein?

(2) If the answer to the first question is negative and use of the simplified procedure is therefore impermissible in the present case, what are the consequences, in particular 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 specific expression in Article 12 of Regulation No 258/97, and for the allocation of the burden of proof as regards risks to human health or the environment arising from the new product?

(3) Does it affect the answer to the second question if the simplified procedure is found to entail tacit consent by the Commission for the placing on the market of the products concerned in that the Member State concerned must first challenge the lawfulness of that tacit consent?

(4) If the answer to the first question is affirmative, is Article 5 of Regulation No 258/97 compatible with Articles 153 EC and 174 EC and 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 informed participation of the Member States and of their scientific bodies, although such involvement is necessary in light of the requirement for protection of those values, as

shown by the normal procedure provided for in Article 6 et seq. of the Regulation, and

— such a simplified procedure can be used, solely in order to speed up and simplify administrative action, for the placing on the market of foods and food ingredients in respect of which, since they contain transgenic protein, information is not available concerning all the implications of placing them on the market for the health of consumers, human consumption and the environment, as can be generally deduced from Recommendation 97/618?

The first question

49 By its first question, the national court essentially asks whether the first subparagraph of Article 3(4) of Regulation No 258/97 is to be interpreted as meaning that the presence in novel foods of residues of transgenic protein at certain levels precludes those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those novel foods on the market.

Observations submitted to the Court

50 The applicants in the main proceedings claim that Regulation No 258/97 allows novel foods to be placed on the market under the simplified procedure if they do not contain GMOs and are substantially equivalent to existing foods.

51 The foods at issue in the main proceedings do not contain GMOs. It is not disputed that those foods, although they contain transgenic protein, cannot be classified as GMOs.

52 In addition, Regulation No 258/97 fully delegates the assessment of substantial equivalence to the scientific community. That question does not relate to an issue of interpretation of Community law but exclusively concerns the scope of a scientific concept. It follows that the Court cannot rule on that question as such in the context of a reference for a preliminary ruling.

53 The Italian Government contends that Regulation No 258/97 requires that the normal procedure referred to in Article 3(2) of that regulation (hereinafter 'the normal procedure') be complied with in so far as risk assessment is necessary. In the absence of such an assessment, the essential principle of Regulation No 258/97, namely the protection of public health, would be infringed and the foods at issue would be placed on the market unlawfully.

54 The Italian Government refers to Part I, Section 3, point 3.3 of the Annex to Recommendation 97/618, which confirms that the concept of 'substantial equivalence' is instrumental and relative in nature. That concept and, consequently, the simplified procedure apply only if the equivalence relates to all the factors identified in Regulation No 258/97 (composition, nutritional value, and so forth).

55 The Italian Government states that in the main proceedings the Istituto superiore di sanità observed the presence of transgenic protein resulting from inserted genes, nor is that presence disputed. The mere observation that in the present case there was no assessment of the safety of that presence under the normal procedure established by Regulation No 258/97, which provides for the informed participation of all the Member States, results in the simplified procedure not being applicable.

56 The Norwegian Government maintains that the presence in novel foods of foreign protein expressed by genes which are often derived from organisms from another kingdom is in itself a substantial change in the composition of the plant concerned.

57 According to the Norwegian Government, the assessment intended to establish whether foods may be characterised as substantially equivalent to other foods must also take into account the possible consequences of genetic modification.

58 In particular, the insertion of foreign genes may give rise to unpredictable effects on the composition of the plant which must be subject to a more detailed assessment as part of a comprehensive risk assessment. Those effects could be caused by the effects of the genetic insertion itself on the genes already present in the plant or could result from the interaction of products carrying a foreign gene with the components/processes of the parent line.

59 The Norwegian Government states that it follows from that observation that the presence in novel foods of foreign proteins, as is the case in the products at issue in the main proceedings, precludes those foods from being considered substantially equivalent to existing foods within the meaning of the first subparagraph of Article 3(4) of Regulation No 258/97. Moreover, were substantial equivalence to be recognised, in such circumstances, the foods at issue could be marketed without safety assessments being carried out, contrary to Article 3(1) of Regulation No 258/97. The first question must therefore be answered in the negative.

60 The Parliament maintains that it is for national courts to decide, as a question of fact, whether novel foods fall under one of the categories of food for which the

use of the simplified procedure is authorised and whether they are substantially equivalent to existing foods. It adds that it doubts that those two conditions are satisfied in the main proceedings.

61 The Commission states that at a formal level there are no legal obstacles to the use of the simplified procedure for the placing on the market of the novel foods at issue in the main proceedings.

62 It follows from both Article 3(4) of Regulation No 258/97 and Recommendation 97/618 that, during an assessment specifically intended to ascertain on the basis of current scientific knowledge whether novel foods containing transgenic protein can be considered substantially equivalent to traditional foods which do not contain them, prudence is called for, since the concept of substantial equivalence has no single definition and such an assessment implies a difficult comparison between various parameters.

63 The Commission states that at the material time — more precisely, at the time when the companies which are applicants in the main proceedings undertook technical and scientific steps in order to place the novel foods on the market under the simplified procedure — the legislative situation and the state of scientific knowledge allowed the use of the concept of substantial equivalence and, accordingly, of the simplified procedure for the purpose of placing those foods on the market, despite the presence of residues of transgenic protein.

64 However, following discussions within international scientific institutions, the significance of the concept of substantial equivalence has evolved substantially.

65 Following that critical reassessment, the Commission arrived at the conclusion that, given the current state of scientific research, it appears that foods containing transgenic protein may, in principle, no longer be considered substantially equivalent to existing foods within the meaning of the first subparagraph of Article 3(4) of Regulation No 258/97 unless a full assessment of their characteristics makes it possible to be certain beyond any reasonable doubt that all the conditions laid down in that provision are satisfied.

66 In the light of that new approach, which is based on considerations arising from prudence and the development of scientific knowledge, the Commission and the Member States agreed no longer to use the simplified procedure for such foods as from January 1998.

67 That new policy explains why, in Article 38 of its proposal for Regulation 2001/C 304 E/15 of the European Parliament and of the Council on genetically modified food and feed (OJ 2001 C 304, p. 221), presented on 30 July 2001, the Commission provided for an end to use of the simplified procedure for the foods referred to in Article 1(2)(b) of Regulation No 258/97.

68 Nevertheless, according to the Commission, use of the concept of substantial equivalence and, consequently, of the simplified procedure was justified in the present case since at the material time the Commission and the Member States had not yet adopted a more stringent approach following the critical reassessment of the issue.

69 Such an approach is, moreover, in accordance with a literal interpretation of Regulation No 258/97 and protects the expectations engendered by an objective reading thereof. In addition, the Commission points out that both the Istituto

superiore di sanità, in its opinion of 28 July 2000, and the Scientific Committee for Food, in its opinion of 7 September 2000, confirmed that the novel foods did not pose risks to health or the environment.

Findings of the Court

70 For the purpose of the simplified procedure, the condition of substantial equivalence set out in the first subparagraph of Article 3(4) of Regulation No 258/97 is assessed either on the basis of the available and generally recognised scientific evidence or, as was the case in the main proceedings, by scientific bodies which specialise in assessment of the risks generated by novel foods, namely the competent bodies of the Member States referred to in Article 4(3) of the Regulation, which act prior to the novel food being placed on the market.

71 This is a condition for applying that procedure which, if satisfied and in so far as the novel food concerned belongs to one of the categories of food which can be the subject of the procedure — a matter that is for the national court to determine as regards the foods at issue in the main proceedings — means that the risk assessment provided for under the normal procedure is not required.

72 The need for the uniform application of Community law and the principle of equality require that the terms of a provision of Community law which, like Article 3(4) of Regulation No 258/97 and the concept of substantial equivalence set out therein, makes no express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an autonomous and uniform interpretation throughout the Community, which must take into account the context of that provision and the purpose of the legislation in question (see, to that effect, in particular Case C-287/98 *Linster* [2000] ECR I-6917, paragraph 43).

73 Since substantial equivalence constitutes a concept of Community law which is not defined in Regulation No 258/97, it is appropriate to examine the context of the first subparagraph of Article 3(4) of Regulation No 258/97 and the Regulation's objectives, in order to give an autonomous and uniform interpretation to that concept.

74 The twofold objective of Regulation No 258/97, which is to ensure the functioning of the internal market in new foodstuffs (the first recital in the preamble to the Regulation) and to protect public health against the risks to which they may give rise (the second recital in the preamble to the Regulation and the first indent in Article 3(1)), is an important factor supporting an interpretation according to which the concept of substantial equivalence does not preclude novel foods which display differences in composition that have no effect on public health from being considered substantially equivalent to existing foods.

75 The concept of substantial equivalence should be placed in the context of the work carried out by the international scientific institutions where it was elaborated, as set out *inter alia* in Recommendation 97/618.

76 It is true, as follows from its legal basis, namely Article 4(4) of Regulation No 258/97, that that recommendation was adopted for the purpose of clarifying the normal procedure. That explains why the requirement for a conventional toxicological evaluation referred to in Part I, Section 5, point IV of the Annex to the Recommendation (read in conjunction with points 3.3 and 3.7 of Section 3 thereof), to which the national court refers, is not relevant in the present case. The concept of substantial equivalence is there applied in the specific context of a risk analysis such as that provided for under the normal procedure.

77 The Recommendation is nevertheless useful for the purpose of defining the concept of substantial equivalence as referred to in the first subparagraph of Article 3(4) of Regulation No 258/97. It is clear from the first and second subparagraphs of Part I, Section 3, point 3.3 of the Annex that the concept does not in itself involve a safety assessment, but rather constitutes an approach for comparing the novel food with its conventional counterpart in order to determine whether it should be subject to a risk assessment as regards, in particular, its unique composition and properties. It also follows therefrom that the absence of substantial equivalence does not necessarily imply that the food in question is unsafe, but simply that it should be subject to an assessment of its potential risks.

78 In order further to define the concept of substantial equivalence, it must also be placed in the context of the process of risk analysis as commonly defined at international and Community level. As in the present case, a concept which is applied by specialised scientific bodies charged with assessing the risks inherent in novel foods is involved.

79 That concept must, more precisely, be understood as a specific method concerning novel foods, relating to the identification of hazards which comprises the first stage in scientific risk assessment, namely the identification of the biological, chemical and physical agents liable to give rise to adverse health effects which may be present in a given food or group of foods and which call for scientific assessment in order better to understand them (see to that effect, *inter alia*, the procedure manual of the Codex Alimentarius Commission of the United Nations Food and Agriculture Organisation (FAO), 12th edition, pages 51 and 52, and Annex III to the provisional communication by the Codex Alimentarius Commission of the FAO and of the World Health Organisation (WHO) CX 4/10, CL 2000/12 — GP, April 2000; Article 3(9) to (14) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures

in matters of food safety (OJ 2002 L 31, p. 1) and points 5.1.1 and 5.1.2 of and Annex III to the Communication from the Commission on the precautionary principle of 2 February 2000 (COM (2000)1); see also Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 156, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 169).

80 Since the protection of public health is a fundamental objective of Regulation No 258/97, the concept of substantial equivalence cannot be interpreted in such a way that the simplified procedure, which according to the wording of the first subparagraph of Article 3(4) of that regulation is in the nature of a derogation, amounts to a relaxation of the safety requirements which must be met by novel foods (see to that effect, in the area of proprietary medicinal products, Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, paragraph 22).

81 As to the unpredictable effects on human health which the insertion of foreign genes may produce, which are referred to by the Norwegian Government in particular, if such effects were identifiable as a danger to human health according to available scientific evidence at the time of the initial examination by the competent body, they would have to be subject to a risk assessment, and a finding of substantial equivalence would therefore be excluded.

82 Another element of the regulatory context of the concept of substantial equivalence in the first subparagraph of Article 3(4) of Regulation No 258/97 which reinforces the interpretation according to which that concept does not preclude differences in composition that are not relevant to public health is apparent on reading the second paragraph of Article 5 and Article 8 of that regulation.

83 It follows from those provisions that certain differences, *inter alia* as regards the composition of novel foods, do not prevent those foods from being deemed substantially equivalent in accordance with the first subparagraph of Article 3(4) of Regulation No 258/97, since Article 8 of that regulation, on the contrary, provides that such differences must be specifically referred to on the labelling.

84 Therefore, the answer to the first question must be that the first subparagraph of Article 3(4) of Regulation No 258/97 must be interpreted as meaning that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those novel foods on the market. However, that is not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. It is for the national court to determine whether that condition is satisfied.

The second and third questions

85 By its second and third questions, which it is appropriate to consider together, the national court in essence asks what effect the validity of the use of the simplified procedure has on the power of the Member States to adopt, on the basis of the precautionary principle and in particular of Article 12 of Regulation No 258/97, measures such as the Decree of 4 August 2000, in particular so far as concerns the onus of proving the safety of novel foods and the possibility that application of the simplified procedure implies tacit consent on the part of the Commission which must be challenged.

Observations submitted to the Court

86 According to the applicants in the main proceedings, it is clear that the conditions for applying Article 12 of Regulation No 258/97, explicitly laid down in that provision, were not satisfied in the main proceedings since the Decree of 4 August 2000 could not have been founded on any detailed grounds for considering that, in light of the available scientific information, the novel foods were dangerous for human health or the environment.

87 Therefore, by its second question, the national court in essence asks whether, if the provision envisaging use of the simplified procedure for novel foods containing transgenic protein is unlawful, Community law, and in particular the precautionary principle, allows a Member State to adopt a preventive measure suspending the marketing of those foods even where the conditions laid down in Article 12 of Regulation No 258/97 are not satisfied.

88 In that regard, the applicants in the main proceedings claim that it follows from the Court's case-law that when, as in the main proceedings, the conditions laid down in Article 12 of Regulation No 258/97 are not satisfied, neither the precautionary principle nor any other principle of Community law can justify the adoption by a Member State of preventive measures intended to suspend trade in products placed on the market, in reliance on the argument that the provision of that regulation which lays down the procedure under which marketing was carried out is invalid, as long as it has not been declared invalid in accordance with the EC Treaty. It follows that the answer to the second question must be in the negative.

89 The Italian Government contends that Article 12 of Regulation No 258/97 confirms the instrumental and relative character of the concept of substantial equivalence as recognised by the Commission in Recommendation 97/618.

90 The Italian Government maintains that the Member State which suspends the marketing authorisation for a novel food must furnish a reasoned assessment of that food in order to challenge the prior assessment, issued by a technical body other than that on which the Member State is relying, and that the Commission, together with the Member States and in accordance with Article 13 of Regulation No 258/97, in turn evaluates the technical conclusions of the competent authority of the Member State which has suspended the marketing and use of that food.

91 The simplified procedure does not require the Commission to verify the notification of the novel food or novel food ingredient. Such a check is therefore not a precondition for the validity of the notification, so that it does not appear possible to regard such a procedure as a complex measure or as a unilateral measure subject to conditions of applicability.

92 The Italian Government accordingly concludes that how the notification of the placing on the market of a novel food is classified is not relevant to whether to acknowledge the power of the Member States to suspend an authorisation pending a safety assessment of that food, carried out with the informed participation of all the Member States, in accordance with Article 13 of Regulation No 258/97.

93 The Norwegian Government maintains that when a Member State, such as the Italian Republic in the main proceedings, has an objection to novel foods being considered substantially equivalent to existing foods within the meaning of the first subparagraph of Article 3(4) of Regulation No 258/97, that issue must, pursuant to the second subparagraph of that provision, be determined in accordance with the procedure laid down in Article 13 of the Regulation. In those circumstances, each Member State may invoke that procedure.

94 A Member State which disagrees with a decision relating to substantial equivalence taken following that procedure may rely on Article 12 of Regulation No 258/97 in so far as the conditions required under that article are satisfied.

95 The Norwegian Government also contends that a Member State may legitimately have recourse to Article 12 of Regulation No 258/97 if it has preliminary scientific indications which provide reasonable grounds for concern that a novel food is potentially dangerous to human health or the environment. According to the Norwegian Government, a prudent approach is all the more necessary since a relatively new scientific field is involved, where knowledge of the potential effects of GMOs remains limited.

96 In the light of the conditions and the particular procedure laid down in Article 12 of Regulation No 258/97, the decision as to whether the use of that provision by a Member State is or is not justified is not a matter for a national court.

97 Finally, the Norwegian Government maintains that the absence of a reaction from the Commission under the simplified procedure cannot be construed as tacit consent to the marketing of a novel food since its role in that procedure is limited to receiving, forwarding and publishing notifications of the placing on the market of novel foods.

98 The Council states that the legal nature of the simplified procedure is of no importance for the purpose of applying the safeguard clause laid down in Article 12 of Regulation No 258/97, since on the basis of that article the Member States may at any time, and regardless of the procedure under which the placing on the market of novel foods was authorised, suspend trade in those foods on the basis of detailed grounds.

Findings of the Court

99 It is appropriate to consider these questions taking into account the fact that it is for the national court and not the Court of Justice to decide whether, in the main proceedings, the novel foods are substantially equivalent to existing foods, in the light, *inter alia*, of the ruling on the interpretation of Community law provided in the present judgment in answer to the first question.

100 As regards the legal nature of the simplified procedure, the absence of a reaction by the Commission when that procedure is implemented cannot be characterised

as tacit consent on its part to the marketing of novel foods since its role in such a procedure is limited to receiving, forwarding and publishing notifications of the placing on the market of those novel foods. If the use of the simplified procedure is not warranted because of a lack of substantial equivalence between novel foods and existing foods, a Member State can have recourse to the safeguard clause provided in Article 12 of Regulation No 258/97 in so far as the conditions for its application are met and is not first required to challenge the lawfulness of any, even tacit, consent by the Commission.

101 As regards the determination of substantial equivalence under the simplified procedure, the first subparagraph of Article 3(4) of Regulation No 258/97 requires that this be carried out before the placing on the market of the novel food, but the second subparagraph of Article 3(4) and Article 13 of the Regulation provide for the possibility of verifying the existence of such substantial equivalence at Community level.

102 It is not in dispute that, in the main proceedings, the Italian Republic had recourse to the safeguard clause without the Community procedure specifically designed to verify the advance determination of substantial equivalence, envisaged in the second subparagraph of Article 3(4) and Article 13 of Regulation No 258/97, having first been applied.

103 Nevertheless, that fact cannot in itself affect the validity of recourse to the safeguard clause. In accordance with Articles 12(2) and 13 of Regulation No 258/97, the grounds for the measure adopted by the Member State on the basis of the safeguard clause, including those relating to the rule of substantial equivalence, can be verified at Community level by applying the same procedure as that referred to by the second subparagraph of Article 3(4) of the Regulation, namely the procedure laid down in Article 13 thereof.

104 The applicability of Article 12 is not affected by the type of procedure which was followed prior to the placing on the market of the novel foods — namely the simplified procedure or the normal procedure — or, in principle, by the validity of the procedure which was followed.

105 However, it cannot be excluded that, in a case where the simplified procedure was applied wrongly given that differences between the composition of a novel food and that of an existing food did not warrant the conclusion that those products are substantially equivalent in view of the risk to public health that those differences entail, demonstration of the existence of such risks may, where relevant, justify the adoption of a safeguard measure on the basis of Article 12(1) of Regulation No 258/97.

106 If the twofold objective of Regulation No 258/97, namely ensuring the functioning of the internal market in novel foods and protecting public health against the risks to which those foods may give rise, is not to be adversely affected, protective measures adopted under the safeguard clause may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified (see to that effect, as regards a non-harmonised field, the judgment of the EFTA Court in Case E-3/00 *EFTA Surveillance Authority* v *Norway*, EFTA Court Reports 2000-2001, p. 73, paragraphs 36 to 38).

107 Such protective measures, notwithstanding their temporary character and even if they are preventive in nature, can be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary in order to ensure that novel foods do not present a danger for the consumer, in accordance with the first indent of Article 3(1) of Regulation No 258/97.

108 As regards the burden of proof on the Member State concerned under Article 12(1) of Regulation No 258/97, that provision requires the Member State to have 'detailed grounds' for considering that the use of a novel food endangers human health or the environment.

109 It follows that the reasons put forward by the Member State concerned, such as result from a risk assessment, cannot be of a general nature. None the less, in the light of the limited nature of the initial safety analysis of novel foods under the simplified procedure (see paragraph 79 of the present judgment) and of the essentially temporary nature of measures based on the safeguard clause, the Member State satisfies the burden of proof on it if it relies on evidence which indicates the existence of a specific risk which those novel foods could involve.

110 In addition, given that, as the national court has rightly observed, the safeguard clause must be understood as giving specific expression to the precautionary principle (see, by analogy with Article 11 of Directive 90/220, *Greenpeace France and Others*, cited above, paragraph 44), the conditions for the application of that clause must be interpreted having due regard to this principle.

111 According to the case-law of the Court, it follows from the precautionary principle that where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (see Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63, and Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99).

112 Therefore, protective measures may be taken pursuant to Article 12 of Regulation No 258/97 interpreted in the light of the precautionary principle even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data (see to that effect *Pfizer Animal Health* v *Council*, cited above, paragraphs 160 and 162, and *Alpharma* v *Council*, cited above, paragraphs 173 and 175).

113 Such measures presuppose, in particular, that the risk assessment available to the national authorities provides specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of the most reliable scientific evidence available and the most recent results of international research that the implementation of those measures is necessary in order to avoid novel foods which pose potential risks to human health being offered on the market.

114 In the light of the foregoing, the answer to the second and third questions must be that, in principle, the issue of the validity of the use of the simplified procedure laid down in Article 5 of Regulation No 258/97 for the placing of novel foods on the market does not affect the power of the Member States to adopt measures falling under Article 12 of that regulation, such as the Decree of 4 August 2000 at issue in the main proceedings. Since the simplified procedure does not imply any consent, even tacit, by the Commission, a Member State is not required to challenge the lawfulness of such a consent before adopting such measures. Nevertheless, those measures can be adopted only if the Member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case, from which it is apparent that, in the light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present danger for the consumer, in accordance with the first indent of Article 3(1) of Regulation No 258/97.

The fourth question

115 By its fourth question, the national court essentially asks whether, if the use of the simplified procedure is justified notwithstanding the presence of residues of transgenic protein in the novel foods, Article 5 of Regulation No 258/97 is valid, in particular in the light of Articles 153 EC and 174 EC, the precautionary principle and the principle of proportionality.

Observations submitted to the Court

116 First of all, the applicants in the main proceedings, the Norwegian Government, the Council and the Commission maintain that the provisions relating to the simplified procedure which are relevant in the main proceedings entail technically and scientifically complex assessments. It follows that, in the field encompassing those provisions, the Community legislature enjoys discretionary powers for the purpose of prescribing bases for action and defining the objectives pursued. Consequently, review by the Court of the exercise of that discretion must be restricted to examining whether it is vitiated by a manifest error or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion.

117 The applicants in the main proceedings claim that the simplified procedure is compatible with Articles 153 EC and 174 EC and with the principles of proportionality and 'reasonableness' and that the Community legislature in no way exceeded the discretion which it enjoys in the matter. Although based on the need for speed and administrative simplification, the simplified procedure makes it possible effectively to uphold the overriding requirements of protecting human health and the environment.

118 The applicants in the main proceedings state that, contrary to what the national court suggests, the simplified procedure ensures the informed participation of the Member States and their scientific bodies both prior to and after the placing on the market of novel foods.

119 The Norwegian Government contends that the application of the simplified procedure to novel foods containing transgenic protein such as those at issue in the main proceedings means that they may be marketed throughout the Community without safety assessments being carried out on them, notwithstanding the unpredictable effects which those foods may have as the result of the insertion of a foreign gene.

120 In those circumstances, the Norwegian Government maintains that the application of the simplified procedure for foods containing transgenic protein infringes Articles 95(3) EC, 152(1) EC, 153(1) EC and 174(2) EC and that the reference to Article 1(2)(b) of Regulation No 258/97 set out in the first subparagraph of Article 3(4) of the Regulation is consequently invalid.

121 The Parliament, the Council and the Commission state that to interpret the first subparagraph of Article 3(4) of Regulation No 258/97 as allowing the use of the simplified procedure for the authorisation of the placing on the market of novel foods containing transgenic protein does not lead to a breach of Articles 153 EC and 174 EC, and in particular of the precautionary principle. Such an interpretation therefore in no way implies that that provision is invalid inasmuch as it authorises the use of the simplified procedure for such foods.

122 The system under the simplified procedure should be considered valid in the light of both the strict conditions to which its application is subject and the other provisions of Regulation No 258/97 which provide the framework for that procedure, namely:

— the general principle laid down in Article 3(1) of Regulation No 258/97 that novel foods must *inter alia* not present a danger for the consumer (see also the second recital in the preamble to the Regulation);

— the twofold condition to which the first subparagraph of Article 3(4) of the Regulation subjects the use of the simplified procedure, namely that those foods must come within certain categories not including foods containing GMOs and must be substantially equivalent to existing foods;

— the requirement that substantial equivalence must be based on prior scientific analysis carried out by a specialised body;

— the possibility for each Member State, in accordance with the second subparagraph of Article 3(4) of Regulation No 258/97, to request verification in accordance with the procedure laid down in Article 13 of the Regulation of the existence of substantial equivalence between novel and existing foods;

— the safeguard clause laid down in Article 12 of Regulation No 258/97 which is available to Member States in order to adopt measures contesting novel foods which have been authorised for placing on the market but which prove to present risks to public health.

123 The Council states in particular that authorisation for placing a food on the market following notification under the simplified procedure does not create any legal presumption as to the safety of that food. It follows from that fundamental statement that Member States have the power to withdraw from the market at any time products which they have detailed grounds for considering harmful to health, even if their placing on the market was authorised under Regulation No 258/97.

124 It also contends that the safeguard clause laid down in Article 12 of the Regulation applies both to Commission decisions which authorise placing on the market under the normal procedure and to notifications of placing on the market sent to the Commission under the simplified procedure, even in cases where the conditions governing use of the latter procedure appear not to have been met.

125 The Commission maintains in particular that the relevant provisions of Regulation No 258/97 are not contrary to the principle of proportionality. It considers that the simplified procedure, chosen by the Community legislature from among the various possibilities open to it, offers both an easy procedure for the placing on the market of novel foods and sufficient safety guarantees as regards human health and the environment, while being consistent with the state of the scientific knowledge available at the time when the provisions relating to that procedure were adopted.

Findings of the Court

126 It is also appropriate to examine this question taking into account the fact that it is for the national court and not the Court of Justice to decide whether, in the main proceedings, the novel foods are substantially equivalent to existing foods in the light, *inter alia*, of the ruling on the interpretation of Community law provided by the present judgment in answer to the first question.

127 The fourth question concerns the validity of the simplified procedure as regards one of the conditions for its application laid down in Article 5 of Regulation No 258/97, namely that relating to substantial equivalence within the meaning of the first subparagraph of Article 3(4) of the Regulation, if it should be the case that that condition must be considered satisfied here, and to that extent concerns both those provisions.

128 In such a case, the question arises in particular whether the simplified procedure, which does not require a comprehensive risk assessment, is coupled with detailed rules sufficient to ensure a high level of protection of human health and the environment within the meaning of Articles 152(1) EC and 174(2) EC respectively and to guarantee compliance with the precautionary principle and the principle of proportionality.

129 First, as regards the argument that the simplified procedure does not require a full risk assessment for novel foods simply in order to speed up and simplify the

administrative process, the basic function of the concept of substantial equivalence should be recalled. It constitutes a specific method relating to novel foods, which is to enable identification of the dangers for human health or the environment which the differences observed between those foods and existing foods may involve. If such dangers are identifiable, the simplified procedure may not be used, since a more comprehensive risk assessment is then required, which must be carried out under the normal procedure.

130 Second, as regards the argument that the simplified procedure does not ensure the informed participation of the Member States and their scientific bodies, it is established that in the main proceedings the initial assessment of substantial equivalence was carried out by a scientific body of a Member State.

131 Moreover, that assessment comprises the first stage in a possible series of procedures during which the recognition of substantial equivalence may be re-examined — procedures which include, in addition to a specific mechanism at Community level for reviewing the determination of substantial equivalence (the second subparagraph of Article 3(4) and Article 13 of Regulation No 258/97), the possible adoption at national level of protective measures pursuant to the safeguard clause, based on as complete a risk assessment as possible by *inter alia* the scientific bodies of the Member States (Article 12(1) of the Regulation) and, finally, the verification at Community level of the justification for such measures (Articles 12(2) and 13 of the Regulation).

132 By means of those various procedures, the Community legislature has established close cooperation between the Commission and the Member States, which should offer sufficient opportunities to the latter, including their scientific bodies, to participate in the assessment and possible reassessment of the safety of novel foods.

133 As regards the precautionary principle, it is to be observed (see paragraph 110 of the present judgment) that the safeguard clause provided in Article 12 of Regulation No 258/97 gives specific expression to that principle and that the principle must therefore, where relevant, be an integral part of the decision-making process leading to the adoption of any measure for the protection of human health based on Articles 12 and 13 of that regulation. Moreover, that principle must also be taken into account where relevant under the normal procedure, *inter alia* for the purpose of deciding whether, in the light of the conclusions concerning the assessment of risk, placing on the market may be authorised without any danger for the consumer.

134 Finally, according to the case-law of the Court, in order to establish whether a provision of Community law complies with the principle of proportionality it must be ascertained whether the means which it employs are suitable for the purpose of achieving the desired objective and whether they do not go beyond what is necessary to achieve it (see, in particular, in the field of proprietary medicinal products, *Generics (UK) and Others*, cited above, paragraph 66).

135 In a sphere in which the Community legislature is called on to undertake complex assessments, judicial review of the exercise of its powers must be limited to examining whether it is vitiated by a manifest error of assessment or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion (*Generics (UK) and Others*, paragraph 67).

136 It does not appear that the simplified procedure, based *inter alia* on the condition of substantial equivalence, is inappropriate for the purpose of achieving both the objective of ensuring the functioning of the internal market in novel foods and that of protecting human health and the environment, which underlie Regulation No 258/97.

137 The procedure derogates from the normal procedure and applies only to certain types of novel foods, when the condition of substantial equivalence is satisfied, the latter not excluding differences in composition between novel foods and existing foods in so far as the differences cannot give rise to potentially harmful effects for human health.

138 In those circumstances and in the light of the fact that the recognition in advance of substantial equivalence may subsequently be reassessed by means of various procedures at both national and Community level (see paragraph 131 of the present judgment), the simplified procedure must be considered to be compatible with the principle of proportionality.

139 In the light of the foregoing, the answer to the fourth question must be that consideration of that question has disclosed no factor such as to affect the validity of Article 5 of Regulation No 258/97 as regards, *inter alia*, the condition for application of that provision relating to substantial equivalence within the meaning of the first subparagraph of Article 3(4) of the Regulation.

Costs

140 The costs incurred by the Italian and Norwegian Governments and by the Parliament, the Council and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Tribunale amministrativo regionale del Lazio by order of 18 April 2001, hereby rules:

1. The first subparagraph of Article 3(4) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients must be interpreted as meaning that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those foods on the market. However, that is not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. It is for the national court to determine whether that condition is satisfied.

2. In principle, the issue of the validity of the use of the simplified procedure laid down in Article 5 of Regulation No 258/97 for the placing of novel foods on the market does not affect the power of the Member States to adopt measures

falling under Article 12 of the Regulation, such as the Decree of 4 August 2000 at issue in the main proceedings. Since the simplified procedure does not imply any consent, even tacit, by the Commission, a Member State is not required to challenge the lawfulness of such a consent before adopting such measures. Nevertheless, those measures can be adopted only if the Member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case, from which it is apparent that, in the light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer, in accordance with the first indent of Article 3(1) of Regulation No 258/97.

3. Consideration of the fourth question has disclosed no factor such as to affect the validity of Article 5 of Regulation No 258/97 as regards, *inter alia*, the condition for application of that provision relating to substantial equivalence within the meaning of the first subparagraph of Article 3(4) of the Regulation.

Rodríguez Iglesias Puissochet Timmermans

Gulmann Edward La Pergola

Jann Skouris von Bahr

Cunha Rodrigues Rosas

Delivered in open court in Luxembourg on 9 September 2003.

R. Grass G.C. Rodríguez Iglesias

Registrar President