JUDGMENT OF THE COURT (Second Chamber)

26 May 2005 *

In Case C-132/03,

REFERENCE for a preliminary ruling under Article 234 EC from the Consiglio di Stato (Italy), made by decision of 28 January 2003, received at the Court on 25 March 2003, in the proceedings

Ministero della Salute

v

Coordinamento delle associazioni per la difesa dell'ambiente e dei diritti degli utenti e dei consumatori (Codacons),

Federconsumatori,

intervening parties:

Lega delle Cooperative,

* Language of the case: Italian.

Associazione Italiana Industrie Prodotti Alimentari (AIIPA),

Adusbef,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans (Rapporteur), President of the Chamber, C. Gulmann and R. Schintgen, Judges,

Advocate General: P. Léger,
Registrar: M. Múgica Arzamendi, Principal Administrator,

having regard to the written procedure and further to the hearing on 9 June 2004,

after considering the observations submitted on behalf of:

— Coordinamento delle associazioni per la difesa dell'ambiente e dei diritti degli utenti e dei consumatori (Codacons), by C. Rienzi and F. Acerboni, avvocati,

— Associazione Italiana Industrie Prodotti Alimentari (AIIPA), by G. Ferrari and F. Capelli, avvocati,

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

— the Commission of the European Communities, by I. Martínez del Peral and A. Aresu, acting as Agents.

after hearing the Opinion of the Advocate General at the sitting on 3 March 2005,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 2(2)(b) of Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (OJ 1998 L 159, p. 4), as amended by Commission Regulation (EC) No 49/2000 of 10 January 2000 (OJ 2000 L 6, p. 13; hereinafter 'Regulation No 1139/98').

2 The reference was made in proceedings between Coordinamento delle associazioni per la difesa dell'ambiente e dei diritti degli utenti e dei consumatori (Codacons) (Coordination of the associations for the protection of the environment and of users' and consumers' rights; 'Codacons') and the Ministero della Salute (Ministry of Health).

3 Those proceedings concern an application for annulment of Decree No 371 of the Minister for Health of 31 May 2001 implementing Commission Directive 1999/50/EC of 25 May 1999 amending Directive 91/321/EEC on infant formulae and follow-on formulae (GURI No 241 of 16 October 2001, p. 4; 'Decree No 371/2001'). The effect of the decree is that the presence of genetically modified organisms ('GMOs') in a proportion not exceeding 1% of the ingredients making up baby foods and follow-on formulae, caused by adventitious contamination, need not be indicated on the labelling of those foods and formulae.

Law

Community legislation

Community legislation on the labelling of foodstuffs produced from GMOs

4 Regulation No 1139/98 sets out the particulars which it is mandatory to include on the labelling of foods and food ingredients obtained from GMOs.

5 The fourth recital in the preamble to Regulation No 1139/98 states that differences between the measures adopted by certain Member States in respect of the labelling of foods and food ingredients produced from GMOs are liable to impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market and that it is therefore necessary to adopt uniform Community labelling rules for those products.

6 The fifth and sixth recitals to the regulation state:

'... 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), lays down, in Article 8, additional specific labelling requirements in order to ensure proper information for the final consumer; whereas those additional specific labelling requirements do not apply to foods or food ingredients which were used for human consumption to a significant degree within the Community before the entry into force of Regulation (EC) No 258/97 and are for that reason considered not to be novel;

... in order to prevent distortions of competition, labelling rules for the information of the final consumer based on the same principles should apply to foods and food ingredients consisting of or derived from GMOs which were placed on the market before the entry into force of Regulation (EC) No 258/97 pursuant to a consent given under [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)] and to foods and food ingredients which are placed on the market thereafter'.

7 According to Article 1(1) of Regulation No 1139/98, the regulation applies to foods and food ingredients produced from the following GMOs:

— soya beans covered by Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soya beans (*Glycine max L.*) with increased tolerance to the herbicide glyphosate, pursuant to Directive 90/220 (OJ 1996 L 107, p. 10), and

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

8 Under Article 2(3) of Regulation No 1139/98, those labelling rules consist, in essence, of the addition of the words 'produced from genetically modified soya' or 'produced from genetically modified maize', as appropriate.

9 Regulation No 1139/98 provides, however, for an exception to those labelling rules where the presence of material derived from the GMOs concerned is adventitious, provided that the presence does not exceed a *de minimis* threshold or tolerance level.

10 According to the 14th recital to Regulation No 1139/98, such adventitious contamination cannot be excluded. The fourth recital to Regulation No 49/2000 states that adventitious contamination may occur, for example, during cultivation, harvest, transport, storage or processing.

11 Thus, Article 2(2)(b) of Regulation No 1139/98 provides:

'The specified foodstuffs shall not be subject to the additional specific labelling requirements where:

...

(b) material derived from the [GMOs] referred to in Article 1(1), together with any material placed on the market pursuant to Regulation (EC) No 258/97 derived from other [GMOs], is present in their food ingredients or the food comprising a single ingredient in a proportion no higher than 1% of the food ingredients individually considered or food comprising a single ingredient, provided this presence is adventitious.

In order to establish that the presence of this material is adventitious, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid using the [GMOs] (or produce thereof) referred to in the previous paragraph as a source.'

12 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;

(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex IA, Part 1, of Directive 90/220/EEC.'

13 Regulation No 1139/98 was repealed and Article 8(1)(d) of Regulation No 258/97 was deleted by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).

14 Articles 12 to 14 of Regulation No 1829/2003, which became applicable with effect from 18 April 2004, lay down specific labelling requirements for foodstuffs which contain, or are produced from, GMOs and an exemption from those requirements in cases of adventitious or accidental contamination by GMOs not exceeding a *de minimis* threshold of 0.9%.

General Community legislation on the labelling of foodstuffs

15 The third and fourth recitals in the preamble to Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ 1979 L 33, p. 1) state that:

'... the purpose of this directive should be to enact Community rules of a general nature applicable horizontally to all foodstuffs put on the market;

... rules of a specific nature which apply vertically only to particular foodstuffs should be laid down in provisions dealing with those products'.

16 The sixth recital to the directive states that:

'... the prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer'.

17 Article 3 of Directive 79/112 includes an exhaustive list of the particulars which are compulsory on the labelling of foodstuffs.

18 The first subparagraph of Article 4(2) of Directive 79/112 states that:

'Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars in addition to those listed in Article 3 must appear on the labelling.'

19 Directive 79/112 was repealed and replaced by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 (OJ 2000 L 109, p. 29), which entered into force on 26 May 2000.

Community legislation on foodstuffs for the particular nutritional use of infants and young children

20 The second and third recitals in the preamble to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27) state that the directive is a first stage in the removal of obstacles to the free movement of foodstuffs for particular nutritional uses resulting from differences in national laws and that, at the current stage, the purpose of the approximation of national laws proposed is to draw up a common definition, to determine measures enabling the consumer to be protected against fraud concerning the nature of the products and to adopt rules to be complied with in labelling the products in question.

21 The fourth recital in the preamble to Directive 89/398 states that:

'... the products covered by this Directive are foodstuffs the composition and preparation of which must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended; ... it may be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to achieve the specific nutritional objective'.

22 Article 1(2) of Directive 89/398 provides:

'(a) Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

...

or

(iii)of infants or young children in good health.'

23 Under Article 4(1), first subparagraph, of Directive 89/398, specific provisions applicable to the groups of foods for particular nutritional uses appearing in Annex I are to be laid down by means of specific directives. Those groups include, at point 1, 'Infant formulae', at point 2,'Follow-up milk and other follow-up foods' and, at point 3,'Baby foods'.

24 Pursuant to Article 4(1)(f) of Directive 89/398 those specific directives may cover, in particular, provisions regarding labelling, presentation and advertising of products belonging to any of the groups of foodstuffs referred to in Annex I to the directive.

25 Article 7 of Directive 89/398 provides:

'1. ... Directive 79/112 ..., as last amended by Directive 89/395/EEC, shall apply to the products referred to in Article 1, under the conditions set out below.

...

3. The labelling of products for which no specific Directive has been adopted in accordance with Article 4 must also include:

...

4. The particular labelling requirements for those products for which a specific Directive has been adopted shall be laid down in that Directive.'

26 The following directives were adopted under Article 4(1) of Directive 89/398: Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (OJ 1991 L 175, p. 35), as amended by Commission Directive 1999/50/EC of 25 May 1999 (OJ 1999 L 139, p. 29; 'Directive 91/321') and Commission

Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ 1996 L 49, p. 17), as amended by Commission Directive 98/36/EC of 2 June 1998 (OJ 1998 L 167, p. 23) and Commission Directive 1999/39/EC of 6 May 1999 (OJ 1999 L 124, p. 8; 'Directive 96/5').

27 According to Article 1(2)(a) and (b) of Directive 91/321 and Article 1(4) of Directive 96/5, 'infants' means children under the age of 12 months and 'young children' means children aged between 1 and 3 years.

28 Directives 91/321 and 96/5 lay down rules on composition and labelling in relation to (i) infant formulae and follow-on formulae for infants in good health and (ii) processed cereal-based foods and baby foods for infants and young children.

National legislation

29 Article 3(2) of Italian Decree No 128 of the President of the Republic of 7 April 1999 implementing Directives 96/5 and 98/36/EC on processed cereal-based foods and baby foods for infants and young children (GURI No 109, of 12 May 1999, p. 5, 'Decree No 128/1999') provides:

'... The foodstuffs in question ... shall not contain pesticide residues in excess of 0.01 mg/kg nor shall they contain genetically modified substances.'

30 Article 4(1) of Decree No 500 of the Minister for Health of 6 April 1994 implementing Commission Directives 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae and Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries (GURI No 189, of 13 August 1994, p. 3, 'Decree No 500/1994') provides:

'Infant formulae shall be manufactured from protein sources defined in the annexes to Decree No 128/1999 and in accordance with the requirements which they contain, and from other food ingredients whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.'

31 Decree No 371/2001 added the following sentence to Article 4(1) of Decree No 500/1994:

'In any case, the use of products derived from [GMOs] is excluded, subject to any derogation provided for by Regulation (EC) No 49/2000.'

Facts and the question referred to the Court

32 By judgment of 14 May 2002, the Tribunale amministrativo regionale del Lazio annulled Decree No 371/2001 to the extent to which it provided that the presence of GMOs in a proportion not exceeding 1% of the ingredients making up baby foods for infants and follow-on formulae, caused by adventitious contamination, need not be indicated on the labelling of such food and formulae.

33 One of the findings in that judgment was that the exemption from the labelling requirement laid down by Decree No 371/2001 was contrary to Article 3(2) of Decree No 128/1999 and that it was not required under Regulation No 49/2000, since the latter does not apply to baby foods for infants and young children.

34 According to that court, Directive 91/321 established a special regime for, inter alia, the labelling of baby foods for infants and young children. That regime derogates from the general Community regime on the labelling of foodstuffs laid down by Directive 79/112 in that it imposes requirements which are stricter than the general principle that the consumer should be given full and accurate information.

35 That interpretation of Community law is compelling not only because it reflects the logic of the system but also on account of the precautionary principle, a general principle of Community law, which demands the best possible information.

36 However, the judgment dismissed the application as to the remainder, holding that Decree No 371/2001 is lawful in so far as it allows baby foods for infants and follow-on formulae to contain material derived from GMOs in a proportion no higher than 1%.

37 On 25 June 2002, the Ministero della Salute appealed against that judgment to the Consiglio di Stato, seeking to have the judgment set aside in so far as it annulled Decree No 371/2001.

38 The Ministero della Salute maintained, inter alia, in support of its appeal that none of the specific directives on foodstuffs intended for infants or young children contain rules concerning the indication on the labelling of the adventitious presence of material derived from GMOs in such foodstuffs.

39 It follows that the only provisions to apply are those laid down by Regulation No 1139/98 and consequently those provisions, including those relating to the tolerance level introduced by Regulation No 49/2000, apply to all foodstuffs and therefore also to foodstuffs intended for infants or young children.

40 The Associazione Italiana Industrie Prodotti Alimentari (AIIPA) (Italian Association of food producers) ('AIIPA') intervened in the appeal in support of the Ministero della Salute.

41 Codacons, supported by Adusbef and Federconsumatori, interveners in the appeal proceedings, contended that the appeal should be dismissed.

42 In those circumstances, taking the view that an interpretation of Regulation No 1139/98 was necessary in order for it to reach a decision in the main action, the Consiglio di Stato decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 2(2)(b) of Regulation ... No 1139/98 ... apply also to baby foods for infants and for young children of up to three years of age, and, more specifically, in relation to such products, must the adventitious contamination by material derived from [GMOs] in a proportion of no more than 1% be indicated on the labelling?'

The question referred to the Court

43 By its question, the national court is asking essentially whether Article 2(2)(b) of Regulation No 1139/98 must be interpreted in such a way that the exemption for which it provides from the obligation, laid down by Article 2(1) and (3) of the regulation, to indicate on the labelling of foodstuffs the presence of material derived from certain GMOs where its presence has come about as the result of adventitious contamination and does not exceed a *de minimis* threshold of 1% also applies to foodstuffs intended for the particular nutritional use of infants and young children.

44 A preliminary point to be borne in mind is that as a general rule it is for the national court alone to delimit the scope of the questions which it considers it must refer to the Court.

45 It follows that the question of the lawfulness of Article 2(2)(b) of Regulation No 1139/98, raised by Codacons in the alternative (namely in the event that the Court concludes that Article 2(2)(b) also applies to foodstuffs intended for infants or young children) cannot be examined by the Court, since it clearly goes beyond the scope of the question formulated by the national court in its order for reference.

46 In order to answer the question referred to the Court, the relevant provisions of Regulation No 1139/98 must be placed in the context of all the Community legislation on the labelling of foodstuffs.

47 The second legal base cited in Regulation No 1139/98 is Article 4(2) of Directive 79/112, by virtue of which the Community provisions applicable to certain specified foodstuffs and not to foodstuffs in general may provide for other compulsory particulars in addition to those listed in Article 3 of the directive.

48 Regulation No 1139/98 thus includes provisions on labelling which, in the words of the fourth recital in the preamble to Directive 79/112, are of 'a specific nature [and] which apply vertically only to particular foodstuffs'.

49 Regulation No 1139/98 in fact applies only to certain foodstuffs, namely those obtained wholly or in part from certain genetically modified soya beans or certain genetically modified types of maize, referred to in Article 1(1) of the regulation.

50 As regards the Community legislation on foodstuffs intended for a particular nutritional use, more specifically use by infants and young children, it follows from Article 4 of Directive 89/398 that the Commission is responsible for adopting specific directives with, in particular, provisions regarding the labelling, presentation and advertising of certain products including infant formulae, follow-up milk and other follow-up foods and baby foods.

51 That is why Directives 91/321 and 96/5 were adopted, which determine the rules on the composition and labelling of infant formulae and follow-on formulae intended for use by infants in good health and processed cereal-based foods and baby foods for infants and young children.

52 The question therefore arises as to whether the specific labelling requirements of Regulation No 1139/98 also apply to foodstuffs intended for the particular nutritional use of infants and young children, with which the Community legislation mentioned at paragraphs 50 and 51 of this judgment is concerned.

53 It follows from Article 7(1) and (4) of Directive 89/398, interpreted in keeping with the fourth recital in the preamble thereto, that labelling requirements such as those laid down by Regulation No 1139/98 apply in principle to foodstuffs intended for particular nutritional uses within the scope of the directive, namely those which are intended to meet a particular nutritional purpose in respect of certain categories of persons, unless it is necessary to provide for a derogation from those requirements in order to ensure that the particular nutritional purpose in question is attained (see, to that effect, Case C-101/98 *UDL* [1999] ECR I-8841, paragraphs 15 and 18).

54 Directives 91/321 and 96/5 do not contain specific labelling requirements relating to the presence of material derived from GMOs, which derogate, so far as foodstuffs intended for infants or young children are concerned, from those laid down by Regulation No 1139/98. Such requirements have therefore not yet been deemed necessary in order to achieve the specific nutritional objective in relation to infants and young children.

55 Accordingly, in the absence of any indication to the contrary arising from the wording, the context or the purpose of Article 2(2)(b) of Regulation No 1139/98, that provision must be interpreted as meaning that the exemption for which it provides from the specific labelling requirements laid down by the regulation also applies to foodstuffs intended for the particular nutritional use of infants and young children, to whom Directive 89/398 refers.

56 That interpretation cannot be called into question on the basis of the precautionary principle.

57 As is clear from its fourth and sixth recitals, Regulation No 1139/98 has a dual purpose: first, to remove potential obstacles to the free movement of products containing genetically modified soya and maize, and, second, to provide the final consumer with information (see, to that effect, Case C-316/01 *Glawischnig* [2003] ECR I-5995, paragraphs 30 and 31).

58 Regulation No 1139/98 is intended to add further information to that which it is already compulsory to mention on the labelling of certain foodstuffs under Directive 79/112, which was not designed as a measure for protection of the environment (see *Glawischnig*, paragraph 33).

59 Furthermore, the fifth and sixth recitals to Regulation No 1139/98 state that the additional specific labelling requirements which the regulation lays down are based on the same principles as those underlying the provisions of Article 8 of Regulation No 258/97, which are intended to ensure that the final consumer is properly informed.

60 It is also clear from those recitals that the labelling requirements apply to foods and food ingredients consisting of, or derived from, GMOs which were placed on the market before the entry into force of Regulation No 258/97, pursuant to a consent given under Directive 90/220, and to foods and food ingredients placed on the market after the entry into force of that regulation.

61 According to settled case-law, the precautionary principle presupposes that there is uncertainty as to the existence or extent of risks to human health (see, to that effect, Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 111, and the case-law cited).

62 The eighth recital to Regulation No 258/97 states that the additional specific labelling requirements laid down by the regulation are intended to ensure that the necessary information about the foodstuffs in question is available to the consumer. It adds that those foodstuffs must be safe for human health and that that assurance is to be provided for by the authorisation procedure set out in Directive 90/220 and/or by the single assessment procedure laid down by Regulation No 258/97.

63 The GMOs to which Regulation No 1139/98 refers can be placed on the market only if they have first been authorised following a risk assessment intended to ensure that, in the light of the conclusions of the assessment, they are safe for the consumer. The precautionary principle, where relevant, is part of such a decision-making process (see, to that effect, the judgment in *Monsanto Agricoltura Italia*, cited above, paragraph 133).

64 In view of all of the foregoing, the answer to the question referred must be that Article 2(2)(b) of Regulation No 1139/98 is to be interpreted as meaning that the exemption for which it provides from the obligation, laid down in Article 2(1) and (3) of that regulation, to state on the labelling of foodstuffs that material derived from certain GMOs is present, where such presence is the result of adventitious contamination and does not exceed a *de minimis* threshold of 1%, also applies to foodstuffs intended for the particular nutritional use of infants and young children.

Costs

65 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Article 2(2)(b) of Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, as amended by Commission Regulation (EC) No 49/2000 of 10 January 2000, is to be interpreted as meaning that the exemption for which it provides from the obligation, laid down in Article 2(1) and (3) of that regulation, to state on the labelling of foodstuffs that material derived from certain GMOs is present, where such presence is the result of adventitious contamination and does not exceed a *de minimis* threshold of 1% also applies to foodstuffs intended for the particular nutritional use of infants and young children.

[Signatures]