OPINION OF ADVOCATE GENERAL
LÉGER
delivered on 3 March 2005 [1]

1. Must foodstuffs for infants and young children bear labelling stating that the foodstuffs have been produced from certain genetically modified organisms ('GMOs') if, as a result of adventitious contamination, the foodstuffs contain material derived from such organisms in proportions not exceeding 1%?

2. That, in essence, is the question referred by the Consiglio di Stato (Italy) in the context of proceedings in which the legality of a ministerial decree is in issue.

3. With this question, the Court is called upon to clarify the scope ratione materiae of certain provisions 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, [2] as amended by Commission Regulation No 49/2000 of 10 January 2000. [3]

I — Legal framework

A — *The Community legislation*

4. Numerous measures of secondary law have been adopted with regard to the labelling of foodstuffs. Some of them apply to all foodstuffs and thus have general and horizontal effect, while others apply only to certain foodstuffs and therefore constitute specific measures.

1 — Original language: French.

2 — OJ 1978 L 159, p. 4.

3 — OJ 2000 L 6, p. 13 ('Regulation No 1139/98, as amended').

1. General legislation on the labelling of foodstuffs

5. General legislation on the labelling of foodstuffs has been in existence since the adoption of 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. [4]

6. In the words of the third recital in the preamble, the purpose of this directive was to enact Community rules of a general nature applicable horizontally to all foodstuffs put on the market.

7. Accordingly, Article 3 of the said directive laid down the principle that the labelling of foodstuffs was to show a number of particulars, which were exhaustively listed, including a list of ingredients.

8. However, this principle was subject to a number of modifications. Article 4 of the directive allowed Community provisions applicable to specified foodstuffs to derogate from the requirement to include certain particulars on the labelling, including the requirement for a list of ingredients, [5] or, conversely, allowed such provisions to require additional particulars to those exhaustively listed in Article 3 of the directive. [6] Article 4 also allowed the Member States to lay down such labelling requirements where there were no Community measures to that effect, subject to compliance with certain conditions. [7]

9. All these provisions of Directive 79/112 were restated in essence by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. [8] This is the directive which was in force when the decree of the Minister of Health No 371 of 31 May 2001 [9] was published on 16

4 — OJ 1979 L 33, p. 1.

5 — See Article 4(1) of Directive 79/112.

6 — See the first subparagraph of Article 4(2) of the same directive.

7 — See the second subparagraph of Article 4(2) of the said directive.

8 — OJ 2000 L 109, p. 29. Directive 2000/13 merely codifies Directive 79/112, which it repeals, as the latter was amended several times.

9 — GURI No 241, 16 October 2001, p. 4 ('the contested Decree').

October 2001, which is the relevant date, in the context of the main proceedings, for assessing the legality of the said decree.

2. Special measures on the labelling of foodstuffs

10. Pursuant to Article 4 of Directive 79/112, a specific measure was adopted for foodstuffs for infants and young children and another for foodstuffs produced from GMOs.

(a) Measures on the labelling of foodstuffs for infants and young children

11. Article 7(1) of 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 [10] provides that Directive 79/112 applies to the products referred to in Article 1 of Directive 89/398, which include products for infants and young children (in good health).

12. Article 3(1) of Directive 89/398 lays down the principle that the nature or composition of the products concerned must be such that the products are appropriate for the particular nutritional use intended. In this connection, Article 4(1) envisages the adoption of specific directives for the foodstuffs covered by Directive 89/398, in particular with regard to their nature or composition, the quality of raw materials and the labelling of such foodstuffs.

13. Two specific directives were adopted on the basis of Article 4(1):

— Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae, [11] and

10 — OJ 1989 L 186, p. 27.

11 — OJ 1991 L 175, p. 35. 'Infant formulae' are defined as foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons (see Article 1(2)(c)). 'Follow-on formulae' are defined as foodstuffs intended for particular nutritional use by infants aged over four months (and under the age of 12 months) and constituting the principal liquid element in a progressively diversified diet of this category of persons (see Article 1(2)(d)). Directive 91/321 covers 'infant formulae' and 'follow-on formulae' made from cows' milk proteins and soya proteins alone or in a mixture (second recital of preamble).

— Commission Directive 96/5/EEC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children. [12]

14. Article 3(1) and (2) of Directive 91/321 provides that infant formulae and follow-on formulae are to be manufactured from protein sources defined in the annexes to that directive and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data. In the same way, Article 5(1) adds that only certain substances (listed exhaustively in Annex III to the directive) may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy their nutritional requirements. [13] It is stated that the purity criteria for these substances will be stipulated at a later stage.

15. On the same lines, Article 6(1) of Directive 91/321 requires infant formulae and follow-on formulae to contain no substance in such quantity as to endanger the health of infants. In this connection, it is envisaged that, where necessary, the maximum levels of any such substance will be stipulated at a later date.

16. In addition to the provisions concerning the production and composition of foodstuffs for infants, Directive 91/321 provides, in Article 7(2), that the labelling of such foodstuffs must show a number of particulars in addition to those laid down by Directive 79/112. [14] The additional particulars relate to the vitamin content, content of proteins, lipids and glucides, and the energy value and instructions for use of such foodstuffs.

17. All those provisions were in substance repeated by Directive 96/5 with regard to processed cereal-based foods and foods for infants (of less than 12 months) and young children (of one to three years of age).

12 — OJ 1996 L 49, p. 17. 'Processed cereal-based foods' comprise: simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids, cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,pastas which are to be used after cooking in boiling water or other appropriate liquids, rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids (Article 1(2)(a)). 'Baby foods' cover foods other than 'processed cereal-based foods' (Article 1(2)(b)). 'Infants' are children under the age of 12 months and 'young children' are children aged between 1 and 3 years (Article 1(4).

13 — These are requirements relating to mineral substances, vitamins, amino acids, other nitrogen compounds and other substances having a particular nutritional purpose.

14 — In this connection, the sixth recital in the preamble to Directive 91/321 states that the general rules concerning the labelling of foodstuffs laid down by Directive 79/112 apply to the specific foodstuffs covered by Directive 91/321 (infant formulae and follow-on formulae).

18. Directives 91/321 and 96/5 were amended by Directives 1999/50/EC [15] and 1999/39/EC [16] respectively. The latter were adopted on the basis of Article 6 of Directive 91/321 and Article 6 of Directive 96/5 respectively, pursuant to the precautionary principle. [17] They added to the said Article 6 provisions concerning pesticides in order to limit their presence in foodstuffs for infants and young children. [18]

(b) Rules on the labelling of foodstuffs produced from GMOs

19. The basic rules concerning the labelling of foodstuffs produced from GMOs were laid down by Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. [19]

20. The main aim of those rules was to set up a common procedure for the marketing for the first time, on the Community market, of products containing or made from GMOs. In the framework of this procedure, the trader concerned was required to inform the Member State in question of his proposal to place such a product for the first time on the Community market from the territory of that State. The notification was to include the proposed labelling of the product, indicating the presence of GMOs among other mandatory particulars. This mandatory statement was then to be shown on the labelling once the marketing decision was taken if, following an appraisal of its harmlessness, the product was deemed not to be harmful to human health or to the environment. [20]

15 — Commission Directive of 25 May 1999 (OJ 1999 L 139, p. 29).

16 — Commission Directive of 6 May 1999 (OJ 1999 L 124, p. 8).

17 — See, to that effect, the first and fourth recitals in the preambles to Directives 1999/39 and 1999/50.

18 — Directives 1999/39 and 1999/50 lay down the principle that the foodstuffs to which they refer must not contain residues of pesticides at levels exceeding 0.01 mg/kg of the product to be consumed. The directives also provide that certain pesticides must not be used in agricultural products intended for the production of those foodstuffs because the absorption of such pesticides (even within the said limits) is likely to exceed the daily permissible dose for infants and young children. I should point out that these provisions concerning certain pesticides were supplemented by two Commission directives adopted on 10 February 2003: Directive 2003/13/EC amending Directive 96/5 (OJ 2003 L 41, p. 33) and Directive 2003/14/EC amending Directive 91/321 (OJ 2003 L 41, p. 37). In view of the risk of accidental contamination to which those foodstuffs are subject because of the presence of those pesticides in the environment, Directives 2003/13 and 2003/14 set up a presumption that the pesticides are considered not to have been used if their residues do not exceed a level of 0.003 mg/kg. It is stated that this level is considered to be the limit of quantification of the analytical methods and that it will be kept under regular review in the light of technical progress.

19 — OJ 1990 L 117, p. 15. This directive was subsequently repealed by Directive 2001/18/EC of the European Parliament and of the Council, of 12 March 2001 (OJ 2001 L 106, p. 1). The repeal did not take effect until 17 October 2002, that is to say, after the relevant date for the purpose of the main proceedings, so that Directive 90/220 was then still applicable.

20 — The risk to human health or to the environment could also be taken into account once the product was placed on the market. Where a Member State had valid reasons for considering that a product which had already been marketed presented such a risk, it was open to the Member State in question to restrict or ban the use or the sale of the product provisionally in its territory, provided that the Commission and the other Member States were informed so that a decision on the matter could be taken.

21. These provisions of Directive 90/220 were very largely repeated by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. [21]

22. The labelling requirements of Regulation No 258/97 became applicable to certain specified products irrespective of the date on which they were placed on the market (that is to say, before or after the said regulation came into force). [22]

23. Regulation No 1813/97, which was adopted for that purpose, was repealed and replaced by Regulation No 1139/98. The question referred relates to the latter regulation, as amended, and seeks to clarify its scope ratione materiae.

24. On the same lines as Regulation No 1813/97, Regulation No 1139/98 applies (in the words of Article 1(1)) to foods and food ingredients which are to be delivered as such to the final consumer and are produced, in whole or in part, from genetically modified soya beans covered by Decision 96/281 or from genetically modified maize covered by Decision 97/98.

25. Article 2(1) of Regulation No 1139/98 lays down the principle that the foodstuffs falling within the scope of the regulation are subject to additional specific labelling requirements. These are set out in Article 2 (3) and aim to ensure that the consumer is informed as to the origin of the ingredients from which the foodstuffs concerned are made, by including (in the list of ingredients required by Directive 79/112 or in relation to it) words such as 'produced from genetically modified soya' or 'produced from genetically modified maize'.

21 — OJ 1997 L 43, p. 1. The scope of this regulation as regards the products affected is wider than that of Directive 90/220 because it covers foods and food ingredients containing or consisting of GMOs within the meaning of the said directive, as well as foods and food ingredients produced from, but not containing, GMOs (Article 1(2)(a) and (b)).

22 — This follows from Commission Regulation (EC) No 1813/97 of 19 September 1997 concerning the compulsory indication on the labelling of certain foodstuffs produced from GMOs of particulars other than those provided for in Directive 79/112 (OJ 1997 L 257, p. 7). This regulation applied to the labelling of foodstuffs or food ingredients made from genetically modified 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 resistance to the herbicide glyphosate, pursuant to Council Directive 90/220 (OJ 1996 L 107, p. 10), or made from genetically modified 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 Council Directive 90/220 (OJ 1997 L 31, p. 69).

26. However, Article 2(2) of the same regulation provides that certain foodstuffs (although produced from GMOs) are not subject to the additional specific labelling requirements if they finally contain neither protein nor DNA resulting from genetic modification after undergoing processing. [23]

27. Commission Regulation (EC) No 49/2000 of 10 January 2000, which amended Regulation No 1139/98, added another situation (the opposite of that referred to above) in which the additional labelling requirements are excluded. This is the situation referred to in the first sentence of Article 2(2)(b) of Regulation No 1139/98, as amended, and it is the situation to which the question from the national court in particular relates.

28. It is the situation where material derived from the GMOs referred to in Article 1(1) of Regulation No 1139/98, together with any material derived from other GMOs (placed on the market in accordance with Regulation No 258/97), is present in the food ingredients or foodstuffs containing a single ingredient, where their presence results from adventitious contamination and is limited to a small amount (not exceeding 1% of the ingredients considered individually or of a foodstuff containing a single ingredient).

29. As indicated in the fourth and eighth recitals in the preamble to Regulation No 49/2000, the phenomenon of adventitious contamination may occur during the cultivation, harvest, transport, storage and processing of ingredients or foodstuffs, that is to say, from one end of the production chain to the other.

30. The second subparagraph of Article 2(2)(b) of Regulation No 1139/98, as amended, stated that '[i]n 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 genetically modified organisms (or produce thereof) referred to in the previous paragraph as a source'.

31. In other words, in that situation the ingredients and foodstuffs in question were not considered as having been produced from GMOs, so that it was unnecessary to include any wording in that connection on the labelling.

23 — This situation is explained by the fact that proteins or DNA resulting from genetic modification may have been destroyed in the successive stages of processing (see the 17th recital in the preamble to the said regulation).

32. Subsequently to the relevant date for the purpose of the main proceedings, the 1% tolerance level specified in Article 2(2)(b) of Regulation No 1139/98, as amended, was reduced to 0.9%. [24]

B — *The national measures*

33. Article 4(1) of the Decree of the Minister of Health No 500, of 6 April 1994, [25] which was intended, inter alia, to implement Directive 91/321, provides that 'infant formulae shall be manufactured from protein sources defined in the annexes to [the Decree] 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'.

34. The contested Decree added the following provisions 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'. These are the provisions in issue in the main proceedings.

II — Facts and main proceedings

35. Following the entry into force of the contested Decree, an action for its annulment was brought with regard to those of its provisions which supplemented Article 4(1) of Decree No 500/1994.

36. The action was brought by the Coordinamento delle associazioni per la difesa dell'ambiente e dei diritti degli utenti e consumatori (Coordination of the associations for the protection of the environment and of users' and consumers' rights) [26] on the ground that the contested Decree was illegal in so far as, by referring to the application of Regulation No 49/2000, the contested Decree allowed infant formulae to contain up to 1% of material derived from GMOs and not to state this in the wording on their labelling.

24 — This follows from 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). Article 12(2) of this regulation (which repeals Regulation No 1139/98 and Regulation No 49/2000) states that the specific labelling requirements which it lays down do not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of each ingredient, provided that this presence is adventitious or technically unavoidable. Article 12(4) adds that lower thresholds may be established to take into account advances in science and technology.

25 — GURI No 189, 13 August 1994, p. 3 ('Decree No 500/1994').

26 — 'Codacons'.

37. By judgment of 14 May 2002, the Tribunale amministrativo regionale del Lazio annulled the disputed provisions of the contested Decree only in so far as, according to that court, they derogated from the specific rules on the labelling of infant formulae and follow-on formulae by providing that, in the event of the adventitious contamination of such products, it is not mandatory to indicate on their labelling the presence of material derived from GMOs in a proportion of not more than 1%. [27]

38. The court of first instance ruled to that effect on the ground that baby foods for infants and follow-on formulae are subject to special labelling rules (laid down by Directives 91/321 and 96/5) differing from the general rules of Directive 79/112, to which Regulation No 49/2000 refers, so that the derogation from the obligation concerning labelling laid down by that regulation, in the event of adventitious contamination not exceeding 1%, is not to apply to products for infants or young children.

39. The Ministero della Salute (Italian Ministry of Health) lodged an appeal against the judgment with the Consiglio di Stato. According to the order for reference, the appeal relates only to the part of the judgment which led to the annulment of the contested national provisions.

40. In support of the appeal, the Ministero della Salute claimed that none of the directives concerning baby foods for infants contains rules on indicating the presence of GMOs on the labelling. Only Regulation No 1139/98, as amended, has provisions on the subject. It followed that the labelling rules in Article 2(2)(b) of that regulation were intended to apply to baby foods.

41. The Associazione Italiana Industrie Prodotti Alimentari ('AIIPA') (Italian Association of Food Product Industries) intervened in support of the Ministero della Salute. Adusbef and Federconsumatori also intervened in the proceedings, in support of Codacons.

III — The question referred

42. In view of the arguments put forward by the parties, the Consiglio di Stato decided to

27 — On the other hand, the court of first instance held that the contested provisions were lawful in so far as they allowed foodstuffs for infants and young children to contain material derived from GMOs, in a proportion not exceeding 1%, as a result of adventitious contamination.

stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 2(2)(b) of Regulation (EC) No 1139/98, as amended by Article 1 of Regulation (EC) No 49/2000, 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 genetically modified organisms in a proportion of no more than 1% be indicated on the labelling?'

IV — Discussion

44. In order to reply to this question, I shall examine, first, the wording of the first subparagraph of Article 2(2)(b) of Regulation No 1139/98, as amended, second, the general scheme of the regulation in conjunction with all the Community measures dealing with the labelling of foodstuffs within the framework of which this regulation falls, third, the aims of the same regulation and, fourth, the requirements arising from the precautionary principle.

A — *The wording of the first subparagraph of Article 2(2)(b) of Regulation No 1139/98, as amended*

43. In essence, the national court's question seeks to ascertain whether the provisions of Article 2(2)(b) of Regulation (EC) No 1139/98, as amended, must be interpreted as meaning that they are to apply to foodstuffs intended for infants and young children.

45. I should point out that the first subparagraph of Article 2(2)(b) of Regulation No 1139/98, as amended, provides that 'the *specified foodstuffs* shall not be subject to the additional specific labelling requirements where: ... 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'. [28]

28 — Emphasis added.

46. The specified foodstuffs referred to by the foregoing provisions are defined in Article 1(1) of Regulation No 1139/98, as amended, as 'foods and food ingredients which are to be delivered as such to the final consumer or mass caterers ... produced, in whole or in part, from: genetically modified soya beans covered by Decision 96/281/EC [or] genetically modified maize covered by Decision 97/98/EC'.

47. This definition is not based on any criterion as to age or the state of development or health of the final consumer. It follows that, for the application of Article 2 (2)(b) of Regulation No 1139/98, as amended, it is immaterial that the foodstuffs in question are intended for infants or young children.

48. It must therefore be concluded that nothing in the wording of those provisions precludes Article 2(2)(b) of Regulation No 1139/98, as amended, from applying to foodstuffs to be given as such to infants and young children if the foodstuffs in question have been produced, wholly or in part, from the GMOs covered by Decisions 96/281 and 97/98.

49. In my view, this conclusion is not affected by the general scheme of Regulation No 1139/98, as amended.

B — *The general scheme of Regulation No 1139/98, as amended*

50. There is nothing in Regulation No 1139/98 or Regulation No 49/2000 to indicate that foodstuffs for infants and young children are excluded from the scope of those regulations or at least from that of Article 2(2)(b) of Regulation No 1139/98, as amended.

51. It is true that Article 2(4) of Regulation No 1139/98 (which was not amended by Regulation No 49/2000) provides that 'this Article [in particular, paragraph 2(b)] shall be without prejudice to the other requirements of Community law concerning the labelling of foodstuffs'.

52. This wording means that the *specific* rules on the labelling of foodstuffs in Article 2 of Regulation No 1139/98, as amended,

apply to the foodstuffs covered by that regulation, provided that they do not disregard or impair the application of other relevant rules in force, in particular other *specific* rules,[29] such as those concerning foodstuffs for infants and young children.

53. However, it must be said that application of the specific labelling rules of Article 2 of Regulation No 1139/98, as amended, does not disregard or impair the application of the rules of Directives 91/321 and 96/5 for the labelling of foodstuffs for infants and young children.

54. As the Ministero della Salute and the Commission have correctly observed, neither Directive 91/321 nor Directive 96/5 contains provisions requiring the labelling of foodstuffs for infants and young children to state that material derived from GMOs is present in those foodstuffs or that they have been made from such material.[30]

55. In my view, the absence of such provisions cannot be accounted for by the notion that the directives concerned in any event prevent such foodstuffs from containing material derived from GMOs and that consequently it is unnecessary to lay down any requirement at all for labelling on that point.

56. The fact is that Article 5 of both Directive 91/321 and Directive 96/5 merely provides that only certain substances suitable for particular nutritional use by infants or young children may be used in the manufacture of foodstuffs intended for them. In this connection, it is envisaged that the

29 — This is necessarily the case with regard to the *general* rules for the labelling of foodstuffs laid down by Directive 79/112 and subsequently by Directive 2000/13. The mandatory particulars listed in Article 2 of Regulation No 1139/98 (for the labelling of foodstuffs produced from GMOs) merely supplement those laid down by one or the other of those directives, pursuant to the first subparagraph of Article 4(2) thereof (see points 8 to 10 of this Opinion). It follows that, manifestly, a derogation from the additional labelling requirement (under Article 2(2)(b) of Regulation No 1139/98, as amended) in no way affects the application of the general rules for the labelling of foodstuffs, laid down successively by Directives 79/112 and 2000/13.

30 — Although those directives require the labelling of foodstuffs for infants and young children to show certain mandatory particulars, the particulars differ from those required by Regulation No 1139/98. As I have shown in points 16 and 17 of this Opinion, the mandatory particulars required by the directives relate to, for example, the vitamin content, content of proteins, lipids and glucides, and the energy value and instructions for use of such foodstuffs. Such particulars relate to points other than that concerning the presence of material derived from GMOs. Furthermore, as the various mandatory particulars (prescribed, on the one hand, by Directive 91/321 or Directive 96/5 and, on the other, by Regulation No 1139/98) are not inconsistent among themselves, they can all be shown together.

purity criteria for those substances will be stipulated at a later stage. Following the same principle, Article 6 of both directives merely provides that the foodstuffs concerned are not to contain any substance in such quantity as to endanger the health of infants or young children. Here again, all that is anticipated is that, if necessary, the maximum levels of each substance will be stipulated at a later date.

57. It cannot be inferred from those provisions that foodstuffs for infants or young children are not to contain even the slightest trace of material derived from GMOs.

58. Furthermore, to this day, unlike in the case of pesticides, [31] no maximum level has been laid down, on the basis of Article 6 of Directives 91/321 and 96/5, for limiting the presence of material derived from GMOs in foodstuffs for infants and young children.

59. It is in the light of these considerations that it is necessary to interpret the silence of Directives 91/321 and 96/5 with regard to the scope of the obligation to indicate, on the labelling of foodstuffs for infants and young children, the presence of GMOS or material derived from GMOs. The only inference that can be drawn from such silence is that the directives lay down no particular labelling requirement of that kind.

60. I conclude from this that the possibility of derogating, on the basis of Article 2(2)(b) of Regulation No 1139/98, as amended, from the specific labelling requirement connected with the presence (in certain foodstuffs) of material derived from GMOs has, in reality, no effect on the application of the specific labelling rules of Directives 91/321 and 96/5.

61. In addition, contrary to what Codacons appears to suggest, the fact that Article 2(2)(b) of Regulation No 1139/98, as amended, constitutes a derogation from the specific labelling obligation (laid down in Article 2(1) and amplified in Article 2(3)) and must therefore be interpreted strictly does not mean that foodstuffs for infants and young children must be excluded from the scope of the derogation on the strength of that argument alone.

31 — See point 18 of this Opinion.

62. To accept the contrary would amount to making additions to the wording of the first subparagraph of Article 2(2)(b). As I have just pointed out, Article 2 expressly provides that it applies to 'specified foodstuffs'. However, as we have also just seen, this term implicitly, but necessarily, covers foodstuffs for infants and young children (assuming, it must be remembered, that such foodstuffs are produced from the GMOs referred to by Decisions 96/281 and 97/98). To exclude such foodstuffs from the scope of Article 2(2)(b) would therefore be more of a legislative exercise that an exercise of pure interpretation.

63. Therefore, in my view the general scheme of Regulation No 1139/98, as amended, does not preclude the application of Article 2(2)(b) of that regulation to foodstuffs for infants or young children.

64. To my mind, the same conclusion follows from an examination of the aims of the regulation.

C — The aims of Regulation No 1139/98, as amended

65. As the Court observed in its judgment in Case C-316/01, Regulation No 1139/98 has a dual purpose. [32]

66. First, according to the fourth recital in the preamble, the regulation aims to remove potential obstacles, arising from differences in national measures relating to labelling, to the free movement of foods and food ingredients produced from GMOs. Secondly, according to the ninth recital, the same regulation aims to inform the final consumer of any characteristic or food property which renders a food no longer equivalent to an existing food inasmuch as it has been produced from GMOs.

67. The pursuit of those two objectives resulted in the adoption of uniform rules for the labelling of foodstuffs and food ingredients made from certain GMOs (which were marketed by virtue of Decisions 96/281 and 97/98). Accordingly, the 12th recital in the

32 — *Glawischnig* [2003] ECR I-5995, paragraph 30. See, to the same effect, the Opinion of Advocate General Tizzano in the same case, point 32.

preamble to Regulation No 1139/98 states that it is necessary to ensure that the labelling requirements are no more burdensome than necessary but sufficiently detailed to supply consumers with the information they require.

68. Regulation No 49/2000, which amended Regulation No 1139/98, takes the same approach. Like the latter, it aims to reconcile the different interests involved, namely those of the industry in question and those of consumers.

69. In providing that a derogation may be made from the specific labelling requirements laid down by Regulation No 1139/98 in the event of adventitious contamination in a proportion not exceeding 1%, Regulation No 49/2000 gives expression to the Community legislature's concern to take into account the efforts made by the industry to avoid using certain GMOs as a raw material in its products, while safeguarding so far as possible the legitimate interest of consumers in being given information.

70. The scope of Article 2(2)(b) of Regulation No 1139/98, as amended, must be ascertained in the light of this dual purpose and the corresponding concern of the Community legislature to reconcile the different interests involved.

71. With regard to the industry in question, it goes without saying that it is very much in the interest of manufacturers that Article 2 should be regarded as intended to apply to foodstuffs for infants and young children.

72. Any reference to GMOs on the labelling is likely to give rise to an instinctive reaction of rejection on the part of consumers since the foodstuffs in question are intended for that particular section of the population. The situation is probably the same even if the labelling also states that the presence in those foodstuffs of material derived from such organisms is purely adventitious and is limited to a proportion not exceeding 1%.

73. To require manufacturers to affix such labelling, in the event of adventitious contamination limited to that amount, would quite obviously be contrary to their interests especially as, precisely in that case, they

would have taken particular care to avoid such contamination. To impose such a requirement would tend to restrict the free movement of foodstuffs for infants and young children.

74. In contrast, so far as consumers are concerned, the protection of their interests militates in favour of a stricter obligation for the labelling of foodstuffs for infants and young children, which would be necessary even in the case of limited adventitious contamination.

75. That being so, in order to measure the exact extent of such a requirement, it is necessary to bear in mind the true purpose of a requirement for information or labelling laid down by the Community legislature.

76. Such a requirement aims to enable consumers to make their choice of one product rather than another on an informed basis, that is to say, so that they are not misled as to the characteristics of the products on offer.

77. Accordingly, in the present case the question is whether the absence, in the labelling of foodstuffs for infants and young children, of any mention of the presence of certain GMOs (the marketing of which is authorised) is capable of misleading consumers where the proportion of GMOs does not exceed 1%.

78. It has consistently been held that, to assess whether an appellation, brand name or labelling statement may mislead buyers, it is necessary to take into account the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect. [33]

79. I think this case-law can be applied to a situation where, as in the main proceedings in this case, it is necessary to decide whether labelling is misleading in so far as it does not include certain particulars.

80. Therefore the question arising is whether an average consumer who is reasonably well informed and reasonably observant

33 — See the judgments in Case C-470/93 *Mars* [1995] ECR I-1923, paragraph 24; Case C-210/96 *Gut Springenheide and Tusky* [1998] ECR I-4657, paragraph 31; Case C-303/97 *Sektkellerei Kessler* [1999] ECR I-513, paragraph 36, and Case C-465/98 *Darbo* [2000] ECR I-2297, paragraph 20.

and circumspect can expect the presence, in foodstuffs for infants and young children, of material derived from certain GMOs (the marketing of which is authorised) in a proportion not exceeding 1%, owing to adventitious contamination.

81. In my view, this may indeed be presumed. The contamination of the environment by GMOs is a well-known phenomenon and is regularly reported in the media. Moreover, it is this phenomenon which led the Community legislature to restrict significantly the deliberate release of GMOs into the environment by making it subject to various requirements in the framework of a rigorous procedure. In this connection, both Directive 90/220 and Directive 2001/18 point out that 'living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States'. [34]

82. Consequently, the contamination of the environment by GMOs is a fact which can hardly be unknown to the average consumer who is reasonably well informed and reasonably observant and circumspect. It may also be presumed that such a consumer may expect that foodstuffs for infants and young children will not be free of slight impurities or foreign substances, in spite of the efforts of the manufacturers to prevent the inclusion of material derived from such organisms in those products.

83. Therefore, even assuming that, in some cases, consumers may be unaware of this fact and may thus be misled by the absence of any reference to GMOs, that risk remains minimal and cannot therefore justify a barrier to the free movement of goods, such as would result from an obligation to affix labelling bearing a statement to that effect, where the contamination in question is adventitious and is not more than 1%. [35]

84. That conclusion is particularly compelling as the presence of material derived from GMOs, in addition to being adventitious, would be found not to exceed 1% and

34 — See the second and fourth recitals in the preambles to Directives 90/220 and 2001/18 respectively.

35 — See, to the same effect, the judgments in Case C-238/89 *Pall* [1990] ECR I-4827, paragraph 19; *Mars*, cited above, paragraph 19, Case C-51/94 *Commission* v *Germany* [1995] ECR I-3599, paragraph 34, and *Darbo*, cited above, paragraph 28.

therefore, although there is an error, it would not involve a preponderant element or an essential characteristic of the foodstuffs concerned. [36]

85. Furthermore, it is questionable whether the inclusion on the labelling of statements such as 'produced from genetically modified soya' or 'produced from genetically modified maize', in accordance with Regulation No 1139/98, is not more likely to mislead consumers than to give them objective information on the characteristics of the foodstuffs on offer. Such statements may give the impression that the foodstuffs were intentionally made from GMOs and contain a significant proportion of ingredients derived from GMOs. That would not be the case in the situation referred to in Article 2(2)(b) of Regulation No 1139/98, as amended, where there is adventitious contamination in a proportion no higher than 1%.

86. It follows from the foregoing that, in my view, the purpose pursued by the regulation of informing consumers does not prevent the waiver, provided for by Article 2(2)(b), of the labelling requirement from applying to foodstuffs for infants and young children. This is particularly true because, as we have seen, it is necessary to reconcile the aim of informing the consumer with another aim, also pursued by the regulation, namely facilitating the free movement of foodstuffs.

87. Consequently, I consider that the objectives pursued by Regulation No 1139/98, as amended, do not prevent Article 2(2)(b) thereof from applying to foodstuffs for infants and young children.

88. I therefore conclude that Article 2(2)(b) of Regulation No 1139/98, as amended, must be interpreted as meaning that it is intended to apply to foodstuffs for infants and young children.

89. In my opinion, this conclusion cannot be called into question by the requirements ensuing from the precautionary principle.

36 — For similar reasoning, see the *Darbo* judgment, cited above, paragraph 30, and my Opinion in that case, points 51 and 73.

D — *The requirements ensuing from the precautionary principle*

90. According to Codacons, the present techniques for establishing the presence of GMOs in foodstuffs give no certainty when it comes to measuring exactly the degree to which they are present, so that today it is impossible to determine whether (in accordance with Article 2(2)(b) of Regulation No 1139/98, as amended) the presence of material derived from GMOs in foodstuffs (particularly those for infants and young children) actually exceeds 1%. [37]

91. It follows, according to Codacons, that, on the basis of the precautionary principle, Article 2(2)(b) of Regulation No 1139/98, as amended, must be interpreted as meaning that it is not intended to apply to foodstuffs for infants and young children.

92. I do not agree with that argument for the following reasons.

93. The Court has consistently held [38] that 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.

94. However, the Court has added that the risk assessment cannot be based on purely hypothetical considerations. [39]

95. In the present case, while accepting that it is not possible with present techniques to measure exactly the presence of GMOs in foodstuffs, no specific evidence has been adduced, as the case now stands, to justify a reasonable belief that the presence of such material in proportions slightly exceeding 1% may create a risk to the health of infants and young children. In this connection, although the 1% threshold laid down by Regulation No

37 — According to Codacons, there is a 30% margin of error (in present techniques for identifying the presence of GMOs in foodstuffs), so that by introducing a tolerance level of 1%, Regulation No 49/2000 actually introduced a threshold of 1.30%.

38 — See, inter alia, the judgments in Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63; Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99; Case C-236/01 *Monsanto Agricoltura Italie and Others* [2003] ECR I-8105, paragraph 111; Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraph 43; Case C-24/00 *Commission* v *France* [2004] ECR I-1227, paragraph 56, and Case C-41/02 *Commission* v *Netherlands* [2004] ECR I-11375, paragraph 52.

39 — See *Monsanto Agricoltura Italie and Others*, cited above, paragraphs 106 and 113; Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 49; *Greenham and Abel*, paragraph 43; *Commission* v *France*, paragraph 56, and *Commission* v *Netherlands*, paragraph 52, cited above.

49/2000 with regard to the labelling of foodstuffs (not their composition) was reduced to 0.9% (after the relevant date for the purpose of the main proceedings), this does not seem to me decisive in itself.

96. In addition, even assuming that such a risk exists, the appropriate conclusions should be drawn at the stage of the procedure for placing new foods and food ingredients on the market in the Community, in accordance with Regulation No 258/97. As the Commission has pointed out, that procedure entails an evaluation of the harmlessness of foodstuffs and results in a marketing authorisation only if they are deemed harmless to human health.

97. Furthermore, it must be observed that, pursuant to Article 12 of Regulation No 258/97, 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 that regulation endangers human health or the environment, that State may either *temporarily* restrict or suspend the trade in and use of the food or food ingredient in question in its territory. However, it must immediately *inform* the other Member States and the Commission thereof, giving the grounds for its decision. It is then for the Commission to take the appropriate measures, case by case.

98. As the Court observed in its judgment in the case of *Monsanto Agricoltura Italie and Others*, cited above, the safeguard clause provided in Article 12 of Regulation No 258/97 gives specific expression to the precautionary principle. The Court concluded that the principle must therefore 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. [40]

99. In my view, all those rules (concerning the placing on the market of foodstuffs containing GMOs or made from them, but not containing them) make a significant contribution to the observance of the precautionary principle.

100. In those circumstances, I do not consider it necessary to impose at a later stage, on account of the same principle, an obligation to comply with the labelling requirements of Article 2(3) of Regulation No 1139/98 in relation to foodstuffs for

40 — See paragraph 133.

infants and young children, even if such foodstuffs have been subject to a slight degree of adventitious contamination (whatever progress is made in the techniques for identifying GMOs).

101. It follows that, to my mind, the precautionary principle does not prevent Article 2(2)(b) of Regulation No 1139/98, as amended, from applying to foodstuffs for infants and young children.

102. Consequently, the reply to the question referred to the Court should be that Article 2 (2)(b) of Regulation No 1139/98, as amended, must be interpreted as meaning that it is intended to apply to foodstuffs for infants and young children.

V — Conclusion

103. In view of the foregoing, I propose that the Court give the following reply to the question from the Consiglio di Stato:

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 No 49/2000 of 10 January 2000, must be interpreted as meaning that it is intended to apply to foodstuffs for infants and young children.