OPINION OF ADVOCATE GENERAL JÄÄSKINEN
delivered on 17 December 2009[1]

1. In these proceedings, the Court is asked to rule on several questions relating to the existence and, where relevant, to the scope of the powers of the Member States as far as concerns food supplements, where the Commission fails to adopt implementing measures for setting the maximum amounts of nutrients present in food supplements.

2. In that regard, I note that the legislature sought to achieve complete harmonisation as regards the vitamins and minerals which may be used in the manufacture of food supplements. However, that harmonisation is incomplete in practice, since the Commission has failed to adopt the necessary implementing measures. That situation is a source of legal uncertainty for the undertakings concerned and causes problems in the application and transposition process for the competent authorities of the Member States. It is therefore for the Court to seek a balance between the requirement for the free movement of the goods in question and the need to protect public health in this unprecedented legal context.

3. The French Conseil d'État (Council of State) has posed a series of questions to the Court concerning the interpretation of Articles 5, 11(2) and 12 of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[2] ('Directive 2002/46'), and Articles 28 EC and 30 EC.

4. This reference arises in the actions for misuse of powers brought before the referring court between 11 and 24 July 2006 by Solgar Vitamin's France and seven other claimants, all active in the food supplements sector ('Solgar and Others'), and in the action brought on 28 July 2006 by the Syndicat de la

1 — Original language: French.

2 — OJ 2002 L 183, p. 51.

Diététique et des Compléments Alimentaires ('the Syndicat') against the interministerial order of 9 May 2006 on nutrients permitted for use in the manufacture of food supplements ('the order of 9 May 2006').

I – Legal framework

A – *European Union law*

5. According to Article 1(1) of Directive 2002/46, the Directive concerns food supplements marketed as foodstuffs and presented as such.

6. Recitals 1, 2, 5, 13, 14 and 16 in the preamble to Directive 2006/46 are worded as follows:

'(1) There is an increasing number of products marketed in the Community as foods containing concentrated sources of nutrients and presented for supplementing the intake of those nutrients from the normal diet.

(2) Those products are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.

...

(5) In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.

...

(13) Excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.

(14) When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.

...

(16) The adoption of the specific values for maximum and minimum levels for vitamins and minerals present in food supplements, based on the criteria set out in this Directive and appropriate scientific advice, would be an implementing measure and should be entrusted to the Commission.'

7. Article 2 of Directive 2002/46 provides:

'For the purposes of this Directive:

(a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

(b) "nutrients" means the following substances:

(i) vitamins,

(ii) minerals.'

8. Article 3 of Directive 2002/46 is worded as follows:

'Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive.'

9. Article 4(1), (2) and (4) of Directive 2002/46 provide:

'1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.

2. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 3.

...

4. For those substances listed in Annex II for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.

...'

10. Article 5 of Directive 2002/46 is worded as follows:

‘1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.

2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2).’

11. Article 11 of Directive 2002/46 states:

‘1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are

applicable in the absence of Community acts adopted under this Directive.'

3. If the Commission considers that amendments to this Directive or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure referred to in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.'

12. Under Article 12 of Directive 2002/46:

'1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.

13. Article 13(1) of Directive 2002/46 provides that the Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by 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 [3] ('the Committee').

14. Where reference is made to Article 13(2) of Directive 2002/46, Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [4] ('the Comitology Decision')

3 — OJ 2002 L 31, p. 1.
4 — OJ 2002 L 184, p. 23.

shall apply. Article 5 of the Comitology Decision governs regulatory procedure.

15. Recital 16 in the preamble to Regulation No 178/ 2002 states:

'Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.'

B – *National law*

16. The purpose of Decree No 2006-352 of 20 March 2006 concerning food supplements ('the Decree') is inter alia to transpose Directive 2002/46 into French law.

17. Article 2 of the Decree states that the term 'nutrients' within the meaning of the Decree includes vitamins and minerals.

18. Under Article 5 of the Decree:

'The nutrients defined in Article 2(2) may be used in the manufacture of food supplements only under the conditions laid down by order of the ministers responsible for consumer affairs, agriculture and health. That order establishes:

1. The lists of nutrients which may be used;

2. The identity and purity criteria which they are required to satisfy;

3. The acceptable maximum amounts and, if appropriate, required minimum amounts;

4. The list of nutrients which may be used until 31 December 2009.'

19. Under Article 15 of the Decree:

'The person responsible for the first marketing of a food supplement which does not fall within the procedure laid down in Article 16 shall inform the General Directorate for Competition Policy, Consumer Affairs and Fraud Control that his product is being marketed by submitting a sample of its labelling.

The composition of the product as described on the labelling must satisfy the conditions laid down by the provisions of Article 3(1).

An order issued by the ministers responsible for consumer affairs, agriculture and health shall specify the procedure for giving that notification.'

20. Under Article 16 of the Decree:

'The first placing on the French market of a food supplement containing a substance having a nutritional or physiological purpose, a plant or plant preparation, which is not listed in the orders provided for in Articles 6 and 7 but is lawfully manufactured or marketed in another Member State of the European Community or another State party to the Agreement on the European Economic Area, gives rise to the following procedure:

1. An importer or manufacturer established in the territory of a Member State of the European Community or of another State party to the Agreement on the European Economic Area must notify the General Directorate for Competition Policy, Consumer Affairs and Fraud Control.

…

5. Permission to market may be refused on the basis of:

…

(b) … scientific data, issued inter alia by the French Food Safety Agency, showing that the product involves a risk to health.

…'

21. The order of 9 May 2006, which was adopted pursuant to that decree, establishes inter alia a list of the vitamins and minerals which may be used in the manufacture of food supplements, and the maximum daily doses for that use.

22. Under Article 3 of the order of 9 May 2006:

'Use of the vitamins and minerals listed in Annex II must not result in the daily portions listed in Annex III to this order being exceeded, in the light of the manufacturer's recommended daily portion of the product as indicated on the labelling.'

23. As regards fluoride, Annex III to the order of 9 May 2006 sets the maximum daily dose of that mineral at 0 mg.

II – The facts in the main proceedings and the questions referred for a preliminary ruling

24. In the proceedings pending before the Conseil d'État, the applicants have contested the lawfulness of the order of 9 May 2006 submitting inter alia that it is incompatible with European Union law and, more specifically, with Articles 28 EC and 30 EC and Directive 2002/46.

25. Solgar and Others and the Syndicat maintained inter alia before the national court that Directive 2002/46 precluded any national measure designed to set maximum and minimum amounts of vitamins and minerals present in food supplements.

26. In addition, the applicants in the main proceedings allege that the French authorities set the maximum daily doses without having regard to the daily portion recommended by the manufacturer and without taking into account the upper safe limits established by scientific risk assessment and differences in

the degrees of sensitivity between different consumer groups.

27. It is against that background that the Conseil d'État decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must Directive 2002/46/EC of 10 June 2002, and in particular Articles 5(4) and 11(2) thereof, be interpreted as meaning that, although in principle it is for the Commission to determine the maximum amounts of vitamins and minerals present in food supplements, the Member States remain competent to adopt legislation in this field so long as the Commission has not adopted the necessary Community measure?

(2) If that question is answered in the affirmative:

(a) If the Member States are required, in order to set those maximum amounts, to comply with the provisions of Articles 28 EC and 30 EC, must they also be guided by the criteria laid down in Article 5 of Directive [2002/46], including the requirement for a risk assessment based on generally accepted scientific data, in an area in which there is still relative uncertainty?

(b) May a Member State set maximum levels when it is impossible, as in the case of fluoride, to calculate precisely the intake of vitamins and minerals from other dietary sources, mains water in particular, for each consumer group and on a territory-by-territory basis? May it in that case set a zero level where risks are known to exist, without resorting to the safety procedure provided for in Article 12 of Directive [2002/46]?

(c) When setting maximum levels, if it is possible to take into account differences in the degrees of sensitivity of different consumer groups, as provided for in Article 5(1)(a) of Directive [2002/46], can a Member State also take into account the fact that a measure addressed solely to sections of the population who are particularly exposed to risk, appropriate labelling for example, might dissuade that group from using a nutrient that would be beneficial to it

in small amounts? Might taking into account that difference in sensitivity result in the application to the entire population of the maximum level appropriate for sensitive sections of the population, in particular children?

(d) To what extent may maximum levels be set in the case where no safe limits have been laid down because there is no established danger to health? More generally, to what extent and in what circumstances might the weighting of criteria to be taken into account lead to the setting of maximum levels that are significantly lower than the safe limits accepted for those nutrients?'

III – The power of the Member State to legislate

A – *Preliminary observations*

28. Before examining the questions raised by the national court, I should like to point out that, in their written observations, Solgar and Others claim that the order of 9 May 2006 is unlawful inter alia because there is no mutual recognition procedure in respect of food supplements using vitamins and minerals from another Member State. I consider that Article 16 of the Decree excludes from the scope of the 'simplified' procedure laid down by that article food supplements lawfully marketed in another Member State using nutrients whose values exceed the limits set by the order of 9 May 2006.

29. However, in the order for reference, the Conseil d'État considered that the problem of the mutual recognition of nutrients was not the subject-matter of the proceedings before it. Therefore, although I think the exact scope of the term 'use' in Article 3 of the order is uncertain, [5] I shall not pursue the matter.

B – *The absence of measures implementing Directive 2002/46*

30. As regards the first question, the opinions expressed by the parties which submitted

5 — Indeed, the question arises whether that term covers both manufacture and marketing or only manufacture.

written observations in these proceedings may be divided into two groups.

31. On the one hand, Solgar and Others and the Syndicat suggest that the Court reply to the effect that, even if the Commission has not adopted the necessary measure, the Member States are not competent to adopt national legislation such as that at issue in the main proceedings.

32. On the other hand, the Commission and the French and Polish Governments take the view that Directive 2002/46 is to be interpreted as meaning that, if measures setting the amounts provided for in Article 5(4) of the directive are not adopted, the Member States remain competent to set the thresholds for vitamins and minerals.

33. After recalling the rules governing the procedure laid down for the adoption of the measures in question, it is necessary to examine the effects of the Commission's failure to adopt the measures at issue.

34. It is apparent from Article 5(4) of Directive 2002/46 that the maximum and minimum amounts of vitamins and minerals should be adopted in accordance with the regulatory procedure laid down in Article 5 of the Comitology Decision.

35. Under that procedure, the Commission submits to the committee referred to in Article 13(1) of Directive 2002/46 a draft of the measures to be taken, on which the committee delivers its opinion. In the present case, the matter has not yet even been referred to the committee. [6] In its observations, the Commission refers briefly to the progress made in that regard. In spite of the adoption of a discussion paper in 2006 [7] and discussions held with the Member States and the interested parties in 2007 and 2008, it appears that no draft of measures has yet been adopted. [8]

36. Indeed, when Directive 2002/46 was adopted, the legislature did not set a time-limit for the adoption of implementing measures pursuant to Article 5(4) of Directive 2002/46. That approach seems to me appropriate in the light of the difficulty in setting minimum and maximum amounts of

6 — As regards the progress made by the Commission, see the reply given by Androula Vassiliou, European Commissioner for Health, to Written Question No E-4319/09 of 14 September 2009, posed by Marina Yannakoudakis (ECR) to the Commission (http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2009-4319&language=EN).

7 — http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

8 — Apparently, the Commission also failed to exercise its right to take the initiative in proposing amendments to the directive at issue. However, it seems to me, that in the light of the difficulties found, it should have taken that action.

vitamins and minerals, which therefore took a considerable time.

37. In any event, I note that Directive 2002/46 was adopted on 10 June 2002. The Member States were required to bring into force the necessary laws, regulations and administrative provisions by 31 July 2003 and to apply them in such a way as to permit trade in products complying with Directive 2002/46 from 1 August 2003 at the latest, and to prohibit trade in products not complying with Directive 2002/46 from 1 August 2005 at the latest. [9]

38. Clearly, in the absence of a Commission measure setting maximum and minimum amounts of vitamins and minerals present in food supplements, the European Union legal order concerning food supplements has, as the law now stands, a real lacuna. By not adopting the necessary measures, the Commission has not exercised its powers to implement the provisions of Directive 2002/46, even though the time-limit for the Member States to transpose that directive expired some years ago.

39. There is no doubt that Article 5(4) of Directive 2002/46, while empowering the Commission to define the maximum and minimum amounts of vitamins and minerals, also imposes on it an obligation to define the scope of the directive. In the absence of such definition, the term 'product which complies with this Directive' is in practice impossible to apply, at least uniformly. It is conceivable that the absence, in Article 5 of Directive 2002/46, of a provision comparable to that in Article 4(4) of Directive 2002/46, is the indirect expression of the legislature's intention to require the Commission to adopt its decision, at the latest, at the end of the transposition period, that is to say, in August 2003.

40. Since it is impossible for the Member States to complete the transposition procedure, this situation seems to me unacceptable from a legal point of view. The absence of implementing measures renders the approximation of the national laws at issue ineffective and untransparent both for the Member States and for the manufacturers, as well as for the consumers. Also, the effectiveness of the relevant provisions of Directive 2002/46 is negated.

9 — Also, under Article 4(6) of Directive 2002/46, until 31 December 2009, Member States could allow in their territory, in certain circumstance, the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II.

41. Therefore, the submission of Solgar and Others and the Syndicat, that the Member States are not competent to adopt national legislation such as that at issue in the main proceedings [10] even though the Commission has not adopted the required measure, cannot be upheld. That interpretation conflicts with the first subparagraph of Article 152(1) EC, Article 95(3) EC, [11] and also with recital 13 in the preamble to Directive 2002/46. What is in issue, in fact, are substances the excessive consumption of which may have harmful effects for human health, and some substances included in the 'positive' list in Annex I to Directive 2002/46, such as fluoride or chromium, may even prove to be toxic if their safe limit is exceeded.

42. Therefore, in the specific context of food law and pending action on the part of the Commission, I consider that this lacuna in the legislation of the European Union may, and indeed must, be supplied by the addressees of Directive 2002/46, namely the Member States.

43. I consider that there are two legal grounds on which to justify this conclusion. The first consists in a reference to Article 11(2) of Directive 2002/46. The second may be based on the case-law concerning the application of Articles 28 EC and 30 EC.

C – *The applicability of Article 11(2) of Directive 2002/46*

44. In their written observations submitted to the Court, the Commission and the French Government pointed out that, with regard to the setting of thresholds for vitamins and minerals, Directive 2002/46 does not provide, in contrast to Article 4(4) concerning the purity criteria for the substances listed in Annex II, for the application of national rules until the Community specifications have been adopted.

45. In that regard, it should be pointed out that Directive 2002/46 provides, first, in Article 3, that only food supplements which

10 — Some authors also consider that the national maximum amounts infringe Directive 2002/46: Hagenmeyer, M., 'Mad about the Food Supplements, "Nahrungsergänzungsmittelverordnung" – The German implementation of Directive 2002/46/EC and its national peculiarities', *European Food and Feed Law Review*, 1/2006, pp. 25 to 32, especially p. 29.

11 — It is apparent from the case-law that 'the first subparagraph of Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, and Article 95(3) EC explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed'. See to that effect Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 62; Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 33; and Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 32.

comply with Directive 2002/46 may be marketed within the European Union. Secondly, it is apparent from Article 11(1) of Directive 2002/46 that Member States may not prohibit or restrict trade in products which comply with the directive and with acts of the European Union adopted to implement it. That provision refers to all the products mentioned in Article 1 of Directive 2002/46, namely food supplements marketed as foodstuffs and presented as such.

46. Under Article 11(2) of Directive 2002/46, this prohibition imposed on the Member States from restricting trade in products which comply with Directive 2002/46 does not affect national provisions which are applicable in the absence of acts of the European Union adopted in accordance with Directive 2002/46.

47. It is also apparent from Article 11(2) that the power accorded to the States to enact national provisions in the absence of European Union measures is limited, in particular by the obligation to comply with the principle of the free movement of goods.

48. Indeed, the Court has already held, as regards Article 11(2) of Directive 2002/46, that when that provision is read in conjunction with recital 8 in the preamble to the directive, it becomes clear that its purpose is to preserve, until specific European Union rules are adopted, the application, in compliance with the Treaty, of national rules concerning nutrients other than vitamins and minerals or other substances with nutritional or physiological effect used as ingredients in food supplements. [12]

49. The Court also stated that Article 11(2) of Directive 2002/46 is thus directed solely at food supplements containing nutrients or substances not falling within the material scope of the directive. [13]

50. However, in the present case, I consider that it is necessary to extend the scope of Article 11(2) of Directive 2002/46 by an interpretation closer to the literal meaning of that provision. I therefore suggest that the words 'in the absence of Community acts adopted under this Directive' be interpreted as referring also to the lack of measures to be adopted by the Commission in order to specify the maximum and minimum amounts of vitamins and minerals in accordance with

12 — Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraph 59.

13 — *Ibidem*, paragraph 60.

Article 5(4) of Directive 2002/46. I also consider that, pending the adoption of implementing measures by the Commission, certain Member States have, in practice, followed that interpretation. [14]

51. I therefore consider that Article 11(2) of Directive 2002/46 confers a power on the Member States to act if the European Union fails to adopt implementing measures. Thus, in my view, the Member States are authorised to specify the maximum amounts of vitamins and minerals.

52. I also consider that this power of the Member States is essential in the light of the need to protect human health which governs the legislation on food supplements, as is pointed out in recital 13 in the preamble to Directive 2002/46. Also, the Member States have scientific data, established at national level, which may be used for the benefit of the population pending the adoption of the necessary measures at European Union level. Finally, I note that several Member States have already adopted legislative measures or have established recommendations in order to identify the thresholds of nutrients present in food supplements. [15]

D – *Recourse to Article 30 EC as legal basis for the residual competence of the Member States*

53. If the Court is not prepared to depart from the interpretation of the scope of Article 11(2) which it accepted *obiter dicta* in the judgment in *Alliance for Natural Health and Others*, [16] I believe it is possible to reach the same conclusion following an alternative line of reasoning.

54. In that regard, I would point out that, in its judgment in *Denkavit Futtermittel*, the Court held that Article 36 of the EEC Treaty (now, after amendment, Article 30 EC) is not designed to reserve certain matters to the

14 — Hauer, C. et al., 'Country Reports', *European Food and Feed Law Review*, 1/2006, pp. 47 to 65; Chaldoupis, C.A. and Dekleva, T., 'The Implementation of the Food Supplement Directive 2002/46 in Greece', *European Food and Feed Law Review*, 5/2006, pp. 302 to 305; Hagenmayer, M., 'Mad about the Food Supplements', *European Food and Feed Law Review*, 1/2006, pp. 25 to 32. See also the replies of the Member States and of the various bodies concerning the setting of amounts of vitamins and minerals: http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm. This phenomenon was also pointed out by the Commission, which gave an assurance that it would take scrupulous account of existing national laws. See the Commission's joint reply to the letters addressed to Markos Kyprianou, European Commissioner for Health and Consumer Protection, regarding the setting of maximum levels for the preparation of food supplements: http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/coll_answer_fr.pdf

15 — *Ibidem*.

16 — Paragraph 59.

exclusive jurisdiction of Member States but only permits national laws to derogate from the principle of the free movement of goods to the extent to which such derogation is and continues to be justified for the attainment of the objectives referred to in that article. [17]

55. It is apparent from the case-law that when, in application of Article 95 EC, directives provide for the harmonisation of the measures necessary to guarantee the protection of animal and human health, recourse to Article 30 EC is no longer justified and the appropriate checks must be carried out and the protective measures adopted within the framework outlined by the harmonising directives. [18]

56. When the question concerns harmonisation at European Union level, the national measures relating thereto must be assessed in the light of the provisions of that harmonising measure and not those of the EC Treaty. [19]

57. In the present case, it is apparent, inter alia, from recitals 2 and 5 in the preamble to Directive 2002/46, that the directive is intended to reconcile the objectives of protection of human health and the free movement of food supplements containing substances defined in the annexes to the directive.

58. Accordingly, the Court has already held that the prohibition on marketing food supplements which do not comply with Directive 2002/46, supplemented by the obligation of the Member States under that directive to permit trade in food supplements complying with the directive, has the objective of removing barriers resulting from differences between the national rules on vitamins, minerals and vitamin or mineral substances authorised or prohibited in the manufacture of food supplements, whilst ensuring, in accordance with Article 95(3) EC, a high level of human health protection. [20]

59. With regard to the setting of limits applicable to the vitamins and minerals present in food supplements, Article 5(1) of

17 — Case 251/78 *Denkavit Futtermittel* [1979] ECR 3369, paragraph 14.

18 — See to that effect *Denkavit Futtermittel*, paragraph 14.

19 — See Case 227/82 *van Bennekom* [1983] ECR 3883, paragraph 35; Case C-150/88 *Eau de Cologne & Parfümerie-Fabrik 4711* [1989] ECR 3891, paragraph 28; Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9; Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32; Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 *HLH Warenvertriebs and Orthica* [2005] ECR I-5141, paragraphs 58 and 59; and Case C-257/06 *Roby Profumi* [2008] ECR I-189, paragraph 14.

20 — *Alliance for Natural Health and Others*, paragraph 105.

Directive 2002/46 determines the general parameters according to which the maximum amounts of vitamins and minerals listed in Annex I must be set.

60. The adoption on the basis both of the criteria established by Directive 2002/46 and of appropriate scientific data of the specific values corresponding to the maximum and minimum limits of vitamins and minerals present in food supplements was entrusted, as an implementing measure, to the Commission.

61. However, as the Commission has not set the limits in question, the harmonisation carried out by Directive 2002/46 cannot, at this stage, be regarded as exhaustive.

62. Consequently, in the light of the case-law above, the Member States remain competent to adopt measures necessary for the protection of human health, particularly where they provide for measures designed to prevent the use of excessive, even toxic, amounts of vitamins and minerals in food supplements.

63. Moreover, in that context, the Court has already held that such a discretion relating to the protection of public health is particularly wide where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances, such as vitamins, which are not as a general rule harmful in themselves but may have special harmful effects solely if taken to excess as part of the general nutrition, the composition of which cannot be foreseen or monitored. [21]

E – *Conclusion on the first question raised*

64. Therefore, in the light of all the foregoing, I, for my part, can only conclude that, where the Commission fails to adopt the implementing measures provided for in Article 5(4) of Directive 2002/46, the Member States remain competent to adopt measures designed to set maximum amounts of vitamins and minerals,

21 — Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 43.

in compliance with the principles laid down in Articles 28 EC and 30 EC.

IV – The extent of the competence of the Member States to set maximum and minimum amounts of vitamins and minerals

A – *General observations*

65. Although it is accepted that the Member States remain competent, in the present case, to adopt the maximum amounts of vitamins and minerals present in food supplements, it is important to point out that, in the exercise of that competence, they are none the less not exempt from complying with the general principles of European Union law.

66. As regards the extent of the obligations of the Member States during the various stages in the transposition of a directive, it is settled case-law that, before the expiry of the transitional period, the Member States must take the measures necessary to ensure that the result prescribed by the directive is achieved at the end of that period, and must refrain from taking any measures liable seriously to compromise the result prescribed by the directive. [22]

67. The Court has also ruled on the transitional provisions laid down by the directives and applicable after the expiry of the transposition period. [23] After concluding that the provisions concerned were not to be interpreted as constituting a 'standstill' obligation, [24] the Court held that the rules laid down in *Inter-Environnement Wallonie* apply to transitional periods during which the Member States may continue to apply their national systems, even though they do not comply with the directive under consideration. [25]

22 — Case C-129/96 *Inter-Environnement Wallonie* [1997] ECR I-7411.

23 — Case C-316/04 *Stichting Zuid-Hollandse Milieufederatie* [2005] ECR I-9759 and Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-8339.

24 — See Case C-316/04 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 40, and Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 40.

25 — See Case C-316/04 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 42, and Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie*, paragraphs 42 to 44. Since Article 4(1) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) required as a condition of authorisation of such a product by a Member State that its active substances are listed in Annex I to the directive, and that any conditions laid down therein are fulfilled, national authorisation systems could not fully implement the directive until that annex had at least some content (see the Opinion delivered by Advocate General Jacobs in Case C-316/04 *Stichting Zuid-Hollandse Milieufederatie*, point 33). At the time of the adoption of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1), the annexes to the directive were empty.

68. Indeed, according to the Court, the Member States' right to amend their systems for authorisation during the transitional period cannot be regarded as unlimited. [26]

69. I consider that the same reasoning must apply a fortiori to a situation such as the one in this case, resulting from the Commission's failure to adopt measures to implement the directive, above all since the binding effects of Directive 2002/46 for the Member States became complete and definitive at the end of the transposition period.

70. I therefore consider that the conclusion should be that it follows from the combined application of the second paragraph of Article 10 EC and the third paragraph of Article 249 EC, as well as from Directive 2002/46 itself, that, if the Commission fails to adopt implementing measures relating to the setting of minimum and maximum amounts of vitamins and minerals present in food supplements, the Member States must adopt any measures necessary to preserve the effectiveness of the provisions of Directive 2002/46 and refrain from adopting provisions such as to compromise the result prescribed by that directive.

71. Next, I would point out that, within the framework of food law conceived as an intersectoral policy, it is necessary to weigh up the different interests, namely consumer protection, health protection and environmental protection.

72. As far as concerns food supplements, it is in particular the principles of consumer protection and health protection which are involved. This specific area of food law constitutes the expression of the requirements of the first subparagraph of Article 152(1) EC, which provides that a high level of human health protection shall be ensured in the definition and implementation of all European Union policies and activities, and of Article 95(3) EC, which expressly requires that a high level of health protection is ensured in the harmonisation carried out. [27]

73. Also, as the Commission pointed out in a 1997 communication, experience shows 'that food safety is not only of concern to the consumer, but is also at the very root of a proper functioning of the market. Food safety is

26 — Case-316/04 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 41, and Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 41.

27 — In the words of recital 8 in the preamble to Regulation No 178/2002, the Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally. See also *Alliance for Natural Health and Others*, paragraph 31.

therefore not only a prerequisite for protecting consumer health but will also serve the interests of producers and those involved in processing and marketing of foodstuffs and relevant agricultural products.' [28]

74. Also, scientific assessment is a fundamental feature of a system which seeks to reconcile the objectives of freedom of movement and technical innovation, since both objectives involve risks which need to be analysed. [29]

75. It is in the light of the aforementioned points that the following questions referred by the national court must be analysed.

B – *Question 2(a)*

76. In connection with this question, the Court will find it necessary to identify the provisions which a Member State must take into account when setting maximum amounts of vitamins and minerals present in food supplements. The national court is asking, in effect, whether a Member State must be guided, as well as by Articles 28 EC and 30 EC, by the criteria in Article 5 of Directive 2002/46.

77. I note that all the parties which have submitted written observations agree that this question should be answered in the affirmative.

78. In that regard, it should be pointed out that Article 5 of Directive 2002/46 lays down three criteria for setting maximum amounts of vitamins and minerals present in food supplements:

— upper safe levels (Article 5(1)(a) of Directive 2002/46);

— intake of vitamins and minerals from other dietary sources (Article 5(1)(b) of Directive 2002/46);

28 — Commission communication of 30 April 1997 entitled 'Consumer health and food safety' (COM(97) 183 final, p. 6).

29 — Risk analysis has three parts: assessment, management and communication – see Article 6 of Regulation No 178/2002.

— reference intakes [30] of vitamins and minerals for the population (Article 5(2) of Directive 2002/46).

79. It is apparent from the case-law cited above that the obligation of a Member State to take all the measures necessary to achieve the result prescribed by a directive is binding. [31] It follows that at the end of the transposition period, if the Commission has not adopted implementing measures, the Member States must adopt the measures necessary to ensure that the result prescribed by the directive will be achieved and refrain from taking provisions such as to compromise that result.

80. Since Article 5 of Directive 2002/46 is a key provision as regards the setting of maximum amounts of vitamins and minerals, the Member States cannot, pending the adoption of an act of the European Union, disregard the criteria it contains without compromising the objectives which Directive 2002/46 seeks to achieve.

81. In that regard, it is also necessary to refer to the principles governing food law and, in particular, to the objective of protecting human health which underlies inter alia the provisions of Article 5 of Directive 2002/46.

82. Indeed, in order to ensure that food supplements present no risk to health, Directive 2002/46 ensures a rigorous procedure for determining the harmlessness of those products and adequate information for the consumer. These two aspects are the essential principles of any assessment of the preparations at issue.

83. I note that, in the *Stichting Zuid-Hollandse Milieufederatie* cases mentioned above, the Court pointed out the importance of taking into account the effects on human health of measures adopted by a Member

30 — It is apparent from the Commission's observations that 'reference intakes' of vitamins and minerals may also be called 'recommended daily amounts'. The Commission states that they are established according to the needs of a population or category of population. In general, in order that those intakes may cover the nutritional needs of the majority of the population, they are set so as to exceed the average needs of two standard deviations. In other words, they take account of the individual variation of needs and are placed below the average so as to cover the needs of individuals who are +2 standard deviations from the average need. Accordingly, with these intakes, it is possible to cover the needs of 97,5% of the population and to limit to 2,5% of the population the risk of not covering its needs.

31 — Case 51/76 *Verbond van Nederlandse Ondernemingen* [1977] ECR 113, paragraph 22; Case 152/84 *Marshall* [1986] ECR 723, paragraph 48; Case C-72/95 *Kraaijeveld and Others* [1996] ECR I-5403, paragraph 55; and *Inter-Environnement Wallonie*, paragraph 40.

State during the transitional period prescribed by Directive 2002/46. [32]

84. Moreover, Article 5 is a provision of general application which concerns scientific risk assessment. This criterion is among the principles also laid down in Article 6 of Regulation No 178/2002, under which, in order to achieve the general objective of a high level of protection of human health and life, food law is to be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

85. Indeed, Regulation No 178/2002, as *lex generalis*, applies in so far as Directive 2002/46, as *lex specialis*, does not apply. [33]

86. Nevertheless, as the Commission points out, the analysis of the three criteria in Article 5 of Directive 2002/46 constitutes 'a risk assessment' within the meaning of Regulation No 178/2002, which, under Article 1(2) thereof, is designed to apply to any measures concerning food safety adopted at both European Union level and Member State level.

87. Finally, it may be argued that, in the light of the exceptional circumstances arising from the Commission's failure to adopt implementing measures, the Member States are temporarily replacing the Commission for the purposes of setting the maximum amounts of vitamins and minerals present in food supplements. They must therefore be guided by the criteria in Article 5 of Directive 2002/46 and, in that connection, to limit the negative effects of the absence of implementing measures at European Union level in order to achieve the objectives pursued by Directive 2002/46.

88. In the light of all the foregoing, I suggest that Question 2(a) be answered to the effect that, in adopting measures to define the maximum amounts of vitamins and minerals present in food supplements, the Member States are required not only to comply with Articles 28 EC and 30 EC but also to be guided by the criteria in Article 5 of Directive 2002/46.

32 — Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie*, paragraph 48.

33 — See the Opinion of Advocate General Geelhoed in *HLH Warenvertriebs and Orthica*, point 76.

C – *Question 2(b)*

89. By this question, the national court wishes to know whether, if it is impossible, as in the case of fluoride, to calculate precisely the intake of vitamins and minerals from other dietary sources, a Member State may, where risks exist, fix the maximum amounts of a mineral at a zero level, without resorting to the safety procedure provided for in Article 12 of Directive 2002/46.

90. All the parties which have submitted written observations, with the exception of the French Government, maintain that setting a zero level amounts to introducing an absolute prohibition on using fluoride which is nevertheless included in the positive list of vitamins and minerals which may be used in the manufacture of food supplements. They argue that it follows that a Member State taking such action thus restricts the scope of Directive 2002/46. Consequently, the parties in question consider that a Member State may not set a maximum amount at zero without resorting to the safety procedure provided for in Article 12 of Directive 2002/46.

91. I consider that this view is consistent and it is doubtless easily justifiable in the light of the general principles applicable to the free movement of goods. I wonder, however, whether such an approach is an oversimplification of the terms of the dispute in question. According to this argument, a Member State could avoid being criticised for excluding a substance from the scope of Directive 2002/46 merely by setting values close to zero, more or less notional values, as for example a maximum value of 0,01 mg for fluoride.

92. In my view, this practice conflicts with the provisions of Article 5 of Directive 2002/46. As I have pointed out above, the national authorities must be guided by the criteria laid down in that article.

93. It therefore remains to be determined whether the inclusion of the nutrient in the list in Annex I to Directive 2002/46 precludes per se a correct application of the criteria in Article 5 of the directive leading to the establishment of a zero rate in the setting of the maximum permitted amount of the mineral in question.

94. The French Government claims in that regard that a Member State is entitled to set a zero value as the maximum amount where it is known that a substance presents a risk, as in the case of fluoride, since it is impossible to calculate accurately the intake of that

substance from other dietary sources. In that situation, the Member State should not have to resort to the safety procedure laid down in Article 12 of Directive 2002/46.

95. In support of its position, the French Government refers to the studies carried out by the Agence française de sécurité sanitaire des aliments (French Food Safety Agency; 'AFSSA') which gave data concerning the concentration of fluoride in the mains water in France and identified the presence of fluoride, in variable amounts, in mineral water, fluoride salts and fluoride toothpastes and the addition of fluoride to medicines for infants and children under 12. [34]

96. In the light of the scientific opinions issued by AFSSA, [35] the Commission doubts that it is impossible, as stated in the order for reference, to calculate accurately the different intakes of fluoride. On the contrary, it considers that it is apparent that the French authorities had data which enabled them to evaluate the main sources of fluoride. At European Union level, the Commission refers to the scientific opinion of the European Food Safety Authority (EFSA) which provided data on the intakes from mineral water. [36]

97. While I accept that there are difficulties in establishing the precise intakes as regards the accumulation from various sources of fluoride for each consumer group and on a territory-by-territory basis, [37] I also consider that the French authorities had information which enabled them to identify, at least approximately, the intakes of fluoride from other dietary sources and, in particular, from mains water. I therefore interpret the position of the French authorities as meaning that the margin between the amount of fluoride from other dietary sources and the safety limit for that mineral is considered to be very small, even non-existent, in France and that, for that reason, the application of the criteria referred to in Article 5 of Directive 2002/46 permits, according to the French authorities, the setting of the maximum amount at zero.

98. As regards, more generally, the question of whether the French authorities should have had recourse to the safeguard clause

34 — See the AFSSA opinion of 12 October 2004 (referral No 2004-SA-0210).

35 — AFSSA opinion of 28 March 2003 (referral No 2003-SA-0032) and the aforementioned opinion of 12 October 2004 (referral No 2004-SA-0210).

36 — Opinion of the Scientific Panel of EFSA on Contaminants in the Food Chain on a request from the Commission related to concentration limits for boron and fluoride in natural waters (Question No°EFSA-Q-2003-2, published on 22 June 2005).

37 — See, in that regard, Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake level of fluoride (Question No EFSA-Q-2003-018) forming part of a report: *Tolerable upper intake levels for vitamins and minerals*, European Food Safety Authority, February 2006.

in the present case, the French Government explains that, since fluoride is regarded by the French authorities as falling within the category of minerals which present a particularly high risk for certain categories of the population, [38] Annex III to the order of 9 May 2006 sets the maximum daily dose of that mineral at 0 mg.

99. In addition, in its opinion, AFSSA considered that, in France, there was a risk that children and adults might exceed the safety limits for fluoride by taking food supplements containing fluoride. [39]

100. In that regard I would point out, first, that under Article 3 of Directive 2002/46, only food supplements which comply with the directive may be marketed in the European Union. Moreover, the directive provides, in Article 11(1), that Member States may not prohibit or restrict trade in those products.

101. To that end, the legislature established a positive list of vitamins and minerals and of vitamin and mineral substances which may be used in the manufacture of food supplements.

102. It is apparent from Article 12 of Directive 2002/46 that a Member State may, within the limits established by the directive, adopt temporary measures to suspend or restrict application within its territory of the provisions of Directive 2002/46 authorising the placing on the market of products which comply with it.

103. The concept of 'compliance' therefore lies at the heart of the question of the applicability of the safeguard clause. The application of that clause presupposes that the substance at issue complies with Directive 2002/46. The clause is designed to apply only if, at the outset, the substance concerned fell within the obligation of the Member States to authorise its use and marketing.

38 — On reading the AFSSA opinion of 12 October 2004 (referral No 2004-SA-0210), I find inter alia that, in the light of the increase in potential sources of fluoride which may lead to overdoses and fluorosis, AFSSA stressed the importance of controlling fluoride intake in children.

39 — According to the AFSSA studies, 15% of the French population uses mains water in which the content is over or equal to 0,3 mg/l and 3% of the population has water whose fluoride content is over or equal to 0,7 mg/l. The optimal prophylactic dose of fluoride recommended by AFSSA, in areas in which the mains water contains a level below or equal to 0,3 mg/l is 0,05 mg of fluoride/kg/day without exceeding 1 mg/day over all intakes of fluoride. AFSSA also points out that 85% of the children in France live in areas in which the fluoride content of mains water is lower than 0,3 mg/l. Accordingly, it recommends giving supplements to the children by way of medication. On the other hand, according to AFSSA, fluoride absorbed in large amounts by adults, namely in doses of over 8 mg/day, and taken over time, may be responsible for bone fluorosis.

104. In the present case, the definition of the conformity with Directive 2002/46 of a substance used in the manufacture of food supplements is not free from doubt.

105. It may be considered, first of all, that compliance may be inferred merely from the fact that a vitamin or mineral is on the positive list.

106. In that context, the setting by the French legislature, for the purposes of manufacturing food supplements, of a maximum amount of fluoride at 0 mg would lead to a unilateral exclusion from the scope of Directive 2002/46 of one of the products referred to in Article 1 of Directive 2002/46 and listed in Annex I thereto.

107. The Court has already held that the positive lists annexed to Directive 2002/46 corresponded to the list of substances included in the categories 'vitamins' and 'minerals' in the annex to Directive 2001/15/EC [40] which are the substances selected taking into account the criteria of safety and availability for use by humans, criteria referred to in recital 11 in the preamble to Directive 2002/46. [41]

108. However, in the light of the wording of Article 5(4) of Directive 2002/46, I am inclined to believe that Directive 2002/46 provides for a dual level of compliance which is reflected, on the one hand, by the inclusion of vitamins and minerals in the positive list and, on the other hand, by the subsequent setting of their maximum and minimum amounts in accordance with the criteria in Directive 2002/46. If a food supplement were to be regarded as complying with Directive 2002/46 merely because it contains only substances referred to in Annex I to Directive 2002/46, without the amounts of these substances in question being taken into consideration, there would be a risk that the freedom of movement referred to in Directive 2002/46 would extend to harmful, even toxic, preparations. However, such a situation would, in my view, be unrealistic and would run counter to the objective of Article 152 EC. That is why such an interpretation cannot be supported.

109. Therefore, as European Union law concerning food supplements now stands, it is impossible to determine whether the doses of fluoride comply with Directive 2002/46.

110. Also, at the end of the consultations held in the comitology procedure, the Commission could adopt an approach consisting in applying flexible limits, for example ranges,

40 — Commission directive of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (OJ 2001 L 52, p. 19).

41 — *Alliance for Natural Health and Others*, paragraphs 64 and 65.

taking into account the specific situation in a Member State which has claimed that there is an established risk or a considerable presence of certain minerals, by reason, inter alia, of geological factors or specific dietary factors peculiar to that Member State or to certain parts of that Member State.

111. It is also conceivable that the Commission may be required to set, on the one hand, general limits for the whole European Union and, on the other, specific limits applicable, by derogation, in certain Member States or certain areas. [42]

112. It goes without saying that the political and legal responsibility for the consequences of the necessarily discretionary nature of the decision adopted in that regard lies with the Commission.

113. Since the maximum amounts of fluoride have not yet been laid down at European Union level, I take the view that the action of the French authorities does not constitute an unlawful exclusion of fluoride from the scope of the directive.

114. Furthermore, I note that Directive 2002/46, which was adopted on the basis of Article 95 EC, is an example of harmonisation designed to achieve a high level of health and safety protection. Scientific assessment is an intrinsic part thereof.

115. Indeed, food supplements are among the 'sensitive' products with which special dangers and risks are associated. [43]

116. Therefore, Directive 2002/46 provides the opportunity to apply the safeguard clause referred to in Article 95(10) EC. That provision states that the harmonisation measures are, in appropriate cases, to include a safeguard clause authorising the Member States to take, for one or more of the non-economic

42 — See, in that regard, the reply to Written Question E-2841/09 by European Parliament Members Eija-Riitta Korhola and Dorette Corbey to the Commission referring to the particular need of the Scandinavian population for the benefit of vitamin D3 (http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2009-2841&language=EN).

43 — Opinion of Advocate General Geelhoed in *HLH Warenvertriebs and Orthica*, points 38 and 45.

reasons referred to in Article 30 of the Treaty, provisional measures subject to a European Union legal control procedure.

117. According to the case-law, the safeguard clause must be understood as giving specific expression to the precautionary principle. [44] Article 95(10) EC permits a Member State, subject to the conditions it lays down, to apply rules derogating from a harmonisation measure. [45] The Court has already held that observance of the precautionary principle is reflected in the right of any Member State provisionally to restrict or prohibit the use and/or sale on its territory of a product which has received consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment. [46]

118. These safety provisions are included in several acts of the European Union relating to food law. [47]

119. Since the harmonisation carried out by Directive 2002/46 is not complete as the law now stands, I consider that the safety procedure laid down in Article 12 of Directive 2002/46 is not designed to apply in the situation before the Court in the present case. [48]

120. However, since, in the exercise of their powers pending measures adopted by the European Union, the Member States may adopt national provisions only in compliance with Articles 28 EC and 30 EC, it is important to examine whether national legislation such as that in the case in the main proceedings complies with the principles of freedom of movement.

121. In that regard, it should be pointed out that, according to settled case-law, it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on the level of protection of human health and life they wish to ensure and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the

44 — Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 110.

45 — See to that effect Case C-41/93 *France* v *Commission* [1994] ECR I-1829, paragraph 23.

46 — See to that effect Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651, paragraph 44.

47 — Article 12 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); Article 53 of Regulation No 178/2002 to which Article 34 of 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) refers; Article 23 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1).

48 — If, however, the Court were to consider that the safety clause applied in the present case, it would be necessary to identify the event giving rise to application of the clause. Accordingly, it will have to be determined whether it should be applied merely because a Member State set a maximum level or whether the clause is designed to apply following a maximum setting at zero.

free movement of goods within the European Union. [49]

122. Therefore, the examination of the measure in question should be entrusted to the national court, pursuant to Articles 28 EC and 30 EC. It is best placed to evaluate the specific nature of the scientific data provided by the national scientific bodies in the light of the aforementioned principles. However, given that the Commission has been unable to take up a position on this matter during the years which have elapsed since the adoption of Directive 2002/46, a national court cannot be expected to carry out an in-depth examination which would yield a definitive truth on this matter, but rather to review the objectivity and neutrality of the assessment of the data during the national administrative procedures.

123. In the light of all the foregoing considerations, I propose that the answer to the question should be that in a situation such as the one at issue, in which, in the absence of implementing measures adopted by the Commission, a Member State sets a zero maximum level for a substance included in the positive list in Directive 2002/46, that Member State does not have to resort to the safeguard clause, but must nevertheless act in compliance with Articles 28 EC and 30 EC.

D – *Question 2(c)*

124. In the first part of this question, the national court asks whether, as well as taking into account differences in the degrees of sensitivity of different consumer groups, in accordance with Article 5 of Directive 2002/46, a Member State may also justify setting a maximum amount on the basis that a measure addressed solely to consumer groups who are particularly exposed to risk, such as appropriate labelling, might dissuade those consumers from using certain vitamins and minerals that would be beneficial to them in small amounts.

125. The national court then wishes to know whether taking into account that difference in sensitivity might result in the application to the entire population of the maximum

49 — Case C-88/07 *Commission* v *Spain* [2009] ECR I-1353, paragraph 86.

amount appropriate for sensitive consumer groups, in particular children. [50]

126. On this point, the opinions of the parties which have lodged written observations diverge significantly. I think this is hardly surprising, in view of the complexity of this matter. I myself have had some difficulty ascertaining its exact scope.

127. First of all, it is necessary to call in question the premiss that a measure whose aim is to protect the health of a risk group and which is reflected by appropriate labelling may have a dissuasive effect on the group in question. Indeed, it seems unlikely that, in spite of their beneficial effect when taken in low doses, those persons would cease to take certain nutrients owing to the drafting of appropriate labelling.

128. Indeed, according to the case-law, appropriate labelling, informing consumers about the nature, the ingredients and the characteristics of fortified foodstuffs, can enable consumers who risk excessive consumption of a nutrient added to those products to decide for themselves whether to use them. [51]

129. Moreover, it is apparent from recital 5 in the preamble to Directive 2002/46 that appropriate labelling helps to ensure a high level of protection for consumers.

130. As regards the generalised application, that is application to the entire population, of the maximum amount appropriate for sensitive consumer groups, I note that it is apparent from the reply to Question 2(a) that, in adopting measures setting amounts of

50 — In its observations, the French Government points out that the first part of this question refers, more particularly, to the maximum level set by the French authorities for vitamin K. The second part of this question refers to the maximum amounts set in the French legislation for vitamin B6. With regard, in particular, to vitamin K, the French Government explains that that substance constitutes a particular risk for patients undergoing anticoagulant treatment, who, as they are usually elderly, find it difficult to decipher the labels. As regards vitamin B6, the French Government points out that the Scientific Committee on Food, which was replaced by EFSA, set safety limits according to a person's body weight and therefore his age, in an opinion of 19 October 2000 (available on website: http://ec.europa.eu/food/fs/sc/scf/out80c_en.pdf). The safety limit was set at 25 mg/day for adults and 7 mg/day for children between the ages of four and six years.

51 — Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 75.

vitamins and minerals, the Member States must be guided by the criteria in Article 5 of Directive 2002/46. [52]

131. As for safe limits, these are a threshold beyond which consumption of a nutrient involves a risk to human health.

132. The view that a Member State is required to set maximum amounts at the level considered appropriate for a population at risk seems to me to run counter to the guidance contained in Article 5 of Directive 2002/46.

133. It goes without saying that a safe limit will be significantly different for children and for adults. Accordingly, a maximum amount appropriate for a particular group may prove insufficient for other consumer groups and, consequently, disproportionate to the objective pursued.

134. However, this finding is without prejudice to the adoption of specific national measures seeking to afford effective protection to a particularly sensitive group, such as children, in compliance with the principles of proportionality and precaution.

135. Consequently, I propose that this question be answered to the effect that, in setting maximum amounts of nutrients within the meaning of Directive 2002/46, the Member States cannot apply to the entire population a maximum amount appropriate for sensitive consumer groups, such as children, whose nutritional needs may prove to a large extent insufficient for the other consumer groups. Moreover, the premiss that appropriate labelling might dissuade the consumer group at risk from using certain nutrients, beneficial to them in low doses, must be ruled out as European Union law now stands.

E – *Question 2(d)*

136. By this question, the national court asks whether a Member State is entitled to set maximum amounts where, because no danger to health has been established, safe limits have not been laid down. More generally, it asks to what extent and in what circumstances a

52 — See point 78 of this Opinion.

Member State may set maximum amounts which are significantly lower than the safe limits accepted for the nutrients. [53]

137. Having regard to the structure of this question, in relation to which the opinions expressed by the parties which submitted written observations again diverged significantly, I propose to interpret it as concerning the question of the setting of maximum values, on the one hand, from the point of view of the need to adopt them in the absence of safe limits and, on the other hand, from the point of view of their nature or degree, in the presence of existing safe limits.

138. As regards the first part of the question, as I have already pointed out, [54] scientific assessment is a fundamental feature of a system which seeks to reconcile the objectives of freedom of movement and technical innovation. It goes without saying that those requirements may both involve risks which need to be analysed.

139. In my view, the absence of safe limits may reflect the current stage of scientific research without that necessarily meaning that there are risks. [55]

140. According to recital 16 in the preamble to Regulation No 178/2002, measures governing foodstuffs should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis

53 — The French Government explains, in that regard, that the question relates to two kinds of substance: those for which no safe limits have been established and those for which they have been set. According to the French Government, in the first part of its question, the national court is referring to the maximum amounts set under national law for vitamins B1, B2, B5, B8 and B12. In the second part of its question, the national court is referring to the case of vitamins B3, C and E, as well as to the case of minerals such as phosphorus, copper, manganese, potassium, selenium, chromium, and molybdenum.

54 — See point 74 of this Opinion.

55 — In that regard, I think it is useful to point out that the issues concerning vitamins and minerals are unique in relation to the conventional toxicology practices owing to the fundamental nature of those elements. Risk assessment in this area raises many difficulties which were pointed out in the observations of the French Minister for the Economy, Finance and Industry before the Conseil d'État. The minister referred inter alia to a work by S.M. Barlow et al., 'Hazard identification by methods of animal-based toxicology', *Food and Chemical Toxicology* 40, 2002, pp. 145 to 191, which states: 'Conventional toxicity studies may often be applicable to the testing of micronutrients, such as vitamins and minerals, but such studies may require unique considerations, particularly with respect to nutritional imbalance. For example, disturbances in calcium and phosphorus levels can affect bone formation … . Thus any effects seen from administration of high doses of one micronutrient might not be attributable to that substance per se but to consequential changes in related micronutrients. Interpretation of the outcome of such studies requires good nutritional as well as toxicological knowledge and the possible extension of conventional endpoints to include others might identify nutritional changes. There are also important study design considerations in relation to micronutrient dosing and the likelihood of detecting thresholds for adverse effects. This is because the margin between desirable beneficial effects and the onset of adverse effects may be very small, so smaller dose intervals may be required.'

prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.

141. It is also clear from the case-law that an assessment of the risk could reveal that scientific uncertainty persists as regards the existence or extent of real risks to human health. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the existence and gravity of those risks are fully demonstrated. However, the risk assessment cannot be based on purely hypothetical considerations. [56]

142. Setting maximum amounts in the absence of safe limits helps to constitute barriers for hypothetical reasons, since a danger to health has not been established.

143. Such a measure would also be contrary to the precautionary principle, which requires that measures adopted pending further scientific information for a more comprehensive risk assessment must be proportionate and no more restrictive of trade than is required to achieve a high level of health protection. [57]

144. In the light of the criteria in Article 5 of Directive 2002/46, it is clear that the establishment of safe limits must be based on scientific risk assessment supported by generally accepted scientific data.

145. I therefore consider that the first part of the question should be answered in the negative, without intending, however, to exclude the possibility of regular analyses and assessments of these substances present on the food supplement market.

146. As regards the second part of the question, I consider that, in the absence of implementing measures adopted by the European

56 — *Commission* v *France*, paragraph 56.

57 — See Article 7 of Regulation No 178/2002.

Union, it is possible for Member States to choose, with the guidance of the criteria in Article 5 of Directive 2002/46, to set thresholds which are significantly lower than the safe limits. As is apparent from the replies given to the preceding questions, the States are required, in so doing, to comply with the principles laid down in Articles 28 EC and 30 EC.

147. Since that choice by the national authorities will necessarily be based on scientific analyses, it is for the national court alone to determine whether the balancing of interests which led to the adoption of those measures was guided by a methodology which is acceptable in the light of the requirements of Directive 2002/46.

V – Conclusion

148. In the light of the foregoing considerations, I propose that the Court give the following replies to the questions referred by the Conseil d'État:

Where the Commission fails to adopt the implementing measures provided for in Article 5(4) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, the Member States may adopt measures designed to set maximum amounts of vitamins and minerals, in compliance with the principles laid down in Articles 28 EC and 30 EC.

In adopting the aforementioned measures in compliance with Articles 28 EC and 30 EC, the Member States are also required to be guided by the criteria laid down in Article 5 of Directive 2002/46.