JUDGMENT OF THE COURT (Third Chamber)

29 April 2010 *

In Case C-446/08,

REFERENCE for a preliminary ruling under Article 234 EC from the Conseil d'État (France), made by decision of 17 December 2007, received at the Court on 9 October 2008, in the proceedings

Solgar Vitamin's France,

Valorimer SARL,

Christian Fenioux,

L'Arbre de Vie SARL,

Source Claire,

* Language of the case: French.

Nord Plantes EURL,

RCS Distribution,

Ponroy Santé,

Syndicat de la Diététique et des Compléments Alimentaires

v

Ministre de l'Économie, des Finances et de l'Emploi,

Ministre de la Santé, de la Jeunesse et des Sports,

Ministre de l'Agriculture et de la Pêche,

intervening parties:

Syndicat de la Diététique et des Compléments Alimentaires,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, R. Silva de Lapuerta (Rapporteur), G. Arestis, J. Malenovský and T. von Danwitz, Judges,

Advocate General: N. Jääskinen,
Registrar: R. Grass,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Solgar Vitamin's France, Valorimer SARL, M. Fenioux, L'Arbre de Vie SARL, Source Claire, Nord Plantes EURL, RCS Distribution and Ponroy Santé, by P. Beucher, avocat,

— the Syndicat de la Diététique and des Compléments Alimentaires, by J.-C. André, avocat,

— the French Government, by G. de Bergues, A. Adam and R. Loosli-Surrans, acting as Agents,

— the Polish Government, by M. Dowgielewicz, acting as Agent,

— the Commission of the European Communities, by L. Pignataro-Nolin and M. Owsiany-Hornung, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 17 December 2009,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 5, 11 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 (OJ 2002 L 183, p. 51).

2 The reference was made in the course of proceedings between Solgar Vitamin's France, Valorimer SARL, Mr Fenioux, L'Arbre de Vie SARL, Source Claire, Nord Plantes EURL, RCS Distribution and Ponroy Santé ('the applicants in the main proceedings') and the Syndicat de la Diététique et des Compléments Alimentaires ('the SDCA') against the Ministère de l'Économie, des Finances et de l'Emploi (Ministry for the Economy, Finance and Employment), the Ministère de la Santé, de la Jeunesse et des Sports (Ministry for Health, Youth and Sport) and the Ministère de l'Agriculture et de la Pêche (Ministry for Agriculture and Fisheries), concerning the inter-ministerial decree of 9 May 2006 relating to nutrients which may be used in the manufacture of food supplements (JORF of 28 May 2006, p. 7977, 'the decree of 9 May 2006').

Legal context

European Union legislation

3 According to Recitals 1, 2, 5, 13, 14 and 16 in the preamble to Directive 2002/46:

‘(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.'

4 Article 1(1) of Directive 2002/46 provides:

'This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.'

5 Article 2 of Directive 2002/46 is worded as follows:

‘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.’

6 Article 3 of Directive 2002/46 provides:

'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.'

7 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).'

8 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 EC 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.'

9 According to 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.

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.'

10 Article 13 of Directive 2002/46 provides:

'1. 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 [OJ 2002 L 31, p. 1] ("the Committee").

2. Where reference is made to this paragraph, 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 (OJ 1999 L 184, p. 23)] shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468 shall be set at three months.

3. The Committee shall adopt its rules of procedure.'

11 Pursuant to the first paragraph of Article 15 of Directive 2002/46, Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with that directive by 31 July 2003. They were to immediately inform the Commission thereof.

12 Annexes I and II to Directive 2002/46 list respectively '[v]itamins and minerals which may be used in the manufacture of food supplements' and '[v]itamin and mineral substances which may be used in the manufacture of food supplements'.

National legislation

13 Adopted in accordance with Article 5 of Decree No 2006-352 of 20 March 2006 on food supplements (JORF of 25 March 2006, p. 4543), the decree of 9 May 2006 sets out, inter alia, a list of vitamins and minerals which may be used in the manufacture

of food supplements and the maximum daily dose which must not be exceeded when those supplements are taken.

14 As regards fluorine, Annex III to the decree of 9 May 2006 sets its maximum daily dose at 0 mg.

The dispute in the main proceedings and the questions referred for a preliminary ruling

15 By the applications lodged on 11, 13, 17, 18, 24 and 28 July 2006 before the national court, the applicants in the main proceedings and the SDCA sought the annulment of the decree of 9 May 2006. The SDCA also intervened in support of the applicants in the main proceedings.

16 In particular, the applicants in the main proceedings and the SDCA submit that Directive 2002/46 precludes any national measure designed to set maximum and minimum amounts of vitamins and minerals present in food supplements.

17 In any event, they challenge the detailed rules for setting maximum daily doses of vitamins and minerals which may be used in the manufacture of food supplements, provided for by the decree of 9 May 2006.

18 In those circumstances the Conseil d'État decided to stay its proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Must Directive [2002/46], 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?'

The questions referred for a preliminary ruling

The first question

19 By its first question, the national court asks essentially whether Directive 2002/46 must be interpreted as meaning that the Member States remain competent to adopt legislation on the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements so long as the Commission has not already laid down those amounts.

20 It is clear from Article 5(4) of that Directive that the maximum and minimum amounts of vitamins and minerals which may be used in the manufacture of food supplements are laid down by the Commission according to the procedure referred to in Article 13(2) thereof.

21 It is established that the Commission has not yet laid down those amounts.

22 In that connection, the Court has already held that, according to Article 11(2) of Directive 2002/46, in the absence of specific European Union rules laid down in that directive, national rules may be applied without prejudice to the provisions of the Treaty (see Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 84).

23 Accordingly, without prejudice to the EC Treaty, where the Commission has not adopted measures under Article 5(4) of that directive laying down the maximum and minimum amounts of vitamins and minerals which may be used in the manufacture of food supplements, national provisions setting those amounts are applicable.

24 In those circumstances, the answer to the first question is that Directive 2002/46 must be interpreted as meaning that, without prejudice to the Treaty, the Member States remain competent to adopt legislation on the maximum and minimum amounts of vitamins and minerals which may be used in the manufacture of food supplements so long as the Commission has not laid down those amounts in accordance with Article 5(4) of that directive.

Question 2(a)

25 By Question 2(a), the national court asks essentially whether, in addition to the obligation to comply with Articles 28 EC and 30 EC, the Member States must 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 setting

the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements.

26 Although the Member States remain competent to adopt legislation on those amounts so long as the Commission has not set them in accordance with Article 5(4) of that directive, the fact remains that, in the exercise of that competence, they must comply with the law of the European Union.

27 In that connection, it must be recalled that the obligation of a Member State to take all the measures necessary to achieve the result prescribed by a directive is a binding obligation imposed by the third paragraph of Article 249 EC and by the directive itself (Case C-129/96 *Inter-Environnement Wallonie* [1997] ECR I-7411, paragraph 40).

28 The result prescribed by Directive 2002/46 would not be achieved if the Member States failed to take account of the criteria laid down in Article 5 thereof, when they set those amounts themselves, while waiting for the Commission to lay down the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements pursuant to Article 5(4).

29 Article 5(1) and (2) of Directive 2002/46 constitutes a fundamental provision with respect to setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements, since it lists the criteria which must be taken into account in order to set those amounts.

30 Those criteria are derived from a risk analysis, within the meaning of Regulation (EC) No 178/2002, which, according to Article 1(2) thereof, is intended to apply to all measures concerning food safety, including those taken by the Member States.

31 Furthermore, it is clear from Article 5(1) and (2) of Directive 2002/46, read in conjunction with Recitals 13 and 14 thereof, that setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements on the basis of those criteria is intended to protect human health.

32 In those circumstances, the answer to Question 2(a) is that, in addition to the obligation to comply with Articles 28 EC and 30 EC, the Member States must also be guided by the criteria laid down in Article 5(1) and (2) of Directive 2002/46, including the requirement for a risk assessment based on generally accepted scientific data, in setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements, while waiting for the Commission to lay down those amounts pursuant to Article 5(4).

Question 2(b)

33 By Question 2(b), the national court asks essentially whether, where it is impossible to calculate precisely the intake of vitamins and minerals from other dietary sources, a Member State may, where risks are known to exist, set at zero the maximum levels of a mineral which may be used in the manufacture of food supplements, without resorting to the procedure provided for in Article 12 of Directive 2002/46.

34 That question, reflecting the assessment of the referring court which is based on the premise that it is impossible to calculate precisely the intake of fluoride from various dietary sources, results from the fact that by the decree of 9 May 2006 the French authorities set the maximum daily amount of that mineral at 0 mg.

35 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 their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the European Union (Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 42, and Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 49).

36 That discretion relating to the protection of public health is particularly wide where it is shown that there is still uncertainty 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 diet, the composition of which cannot be foreseen or monitored (*Commission* v *Denmark*, paragraph 43, and *Commission* v *France*, paragraph 50).

37 Furthermore, it must be recalled, as held in paragraphs 24 and 32 of this judgment, that, so long as, in accordance with Article 5(4) of Directive 2002/46, the Commission has not laid down the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements, the Member States remain competent to set those amounts and that, in the exercise of that competence, they must, in particular, be guided by the criteria laid down in Article 5(1) and (2).

38 Pursuant to Article 3 of Directive 2002/46, only food supplements which comply with the rules laid down in that directive may be marketed in the European Union.

39 Furthermore, according to Article 11(1) of that directive, the Member States must not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in food supplements which comply with that directive and, where appropriate, with acts of the European Union adopted in order to implement it.

40 The Member States retain only limited possibilities of restricting the marketing of such food supplements. Article 12 of Directive 2002/46 provides that where a Member State, as a result of new information or of a reassessment of existing information made since that directive or one of the implementing European Union acts was adopted, has detailed grounds for establishing that a food supplement endangers human health though it complies with the directive or those European Union acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory.

41 Therefore, the application of Article 12 of Directive 2002/46 is subject to the implementation of that directive and, in particular, to Article 5 thereof, that is the laying down of the maximum amounts by the Commission referred to by the latter.

42 Since the Commission has not yet laid down the maximum amounts, Article 12 is not applicable.

43 In that connection, it must be recalled that the maximum amounts referred to in Article 5 of Directive 2002/46 must be set on the basis of the criteria in that provision.

44 In that context, it cannot be excluded that the taking into account of one or more of the criteria in Article 5(1) and (2) of Directive 2002/46 may lead to the maximum amount of a vitamin or mineral which may be used in the manufacture of food supplements being set at a very low level or even at zero, despite the fact that that vitamin or mineral is one which may be used in the manufacture of food supplements listed in Annex I to that directive.

45 In particular, Article 5(1)(b) of Directive 2002/46 provides that the maximum amounts per daily portion of consumption as recommended by the manufacturer is to be set taking into account the intake of vitamins and minerals from other dietary sources.

46 That provision therefore requires that, in a situation such as that at issue in the main proceedings in which, when setting the maximum amount of fluoride which may be used in the manufacture of food supplements it is, according to the national court, impossible to determine precisely the intake of fluoride from other dietary sources, account must be taken of the fact that there is a genuine risk that that intake will exceed the upper safe limit established for that mineral.

47 In such a situation, taking account of such a risk may have the result that the maximum amount of fluoride which may be used in the manufacture of food supplements is set at a zero level.

48 In those circumstances, the answer to Question 2(b) is that Directive 2002/46 must be interpreted as meaning that in a situation such as that in the main proceedings where, when setting the maximum amount of a mineral which may be used in the

manufacture of food supplements, it is impossible to calculate precisely the intake of that mineral from other dietary sources, and so long as the Commission has not laid down the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements in accordance with Article 5(4) of that directive, a Member State may, if there is a genuine risk that that intake will exceed the upper safe limit established for the mineral in question, and provided that Articles 28 EC and 30 EC are respected, set the maximum amount at a zero level without resorting to the procedure laid down in Article 12 of that directive.

Question 2(c)

49 By Question 2(c), the national court asks essentially whether, as Article 5(1)(a) of Directive 2002/46 provides that when setting the maximum amount of vitamins and minerals which may be used in the manufacture of food supplements it is necessary to take account of the varying degrees of sensitivity of different consumer groups, a Member State may, in setting those amounts, also take account of the fact that a measure addressed solely to a group of consumers who are particularly exposed to risk, such as appropriate labelling, might dissuade that group from using a nutrient that would be beneficial to it in small amounts and whether taking into account that difference in sensitivity might result in the application to the entire population of the maximum level appropriate for sensitive sections of the population, in particular children.

50 In that connection, it must be stated at the outset that the fact that appropriate labelling might dissuade the group of consumers to which it is addressed from using a nutrient beneficial to it in small doses does not appear among the criteria mentioned in Article 5(1) and (2) of Directive 2002/46 which must be taken into account in setting the maximum amounts of vitamins and mineral which may be used in the manufacture of food supplements.

51 On the other hand, it must be recalled that appropriate labelling, informing consumers about the nature, the ingredients and the characteristics of fortified foodstuffs, can enable consumers who are at risk from excessive consumption of a nutrient added to those products to decide for themselves whether to use them (*Commission* v *France*, paragraph 75), and that that solution is consonant with the protection of public health without imposing serious restrictions on the free movement of goods (see *Commission* v *Germany*, paragraph 95).

52 In the same way, it is clear from Recital 5 in the preamble to Directive 2002/46, that adequate and appropriate labelling helps to ensure a high level of consumer protection and to facilitate their choices.

53 As regards the possibility, given the varying degrees of sensitivity of different consumer groups, of applying to the whole population a maximum amount appropriate for a sensitive group of consumers, such as children, it must be observed that that difference constitutes a criterion which, under Article 5(1)(a) of Directive 2002/46, must be taken into account in the course of a scientific risk assessment designed to establish the upper safe limits for vitamins and minerals.

54 In exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health or to satisfy overriding requirements regarding, for example, consumer protection. They must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of trade within the European Union (see *Commission* v *Denmark*, paragraph 45, *Commission* v *France*, paragraph 52, and *Commission* v *Germany*, paragraph 87).

55 Furthermore, it is for the national authorities to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in Article 30 EC and, in particular, that the marketing of the products in question poses a real risk to public health (see, to that effect, *Commission* v *Denmark*, paragraph 46, and *Commission* v *France*, paragraph 53).

56 It must therefore be established that, in the light of national nutritional habits and taking account of the results of international scientific research, a measure which applies to the entire population a maximum amount appropriate for a group of sensitive consumers, such as children, is necessary in order to ensure the protection of the health of the persons belonging to that group, since the marketing of food supplements whose content in nutrients exceed that maximum amount poses a real risk to public health, and that that objective cannot be attained by measures which are less restrictive of trade within the European Union.

57 In that context, it is for the national court to examine, in particular, whether appropriate labelling informing consumers about the nature, the ingredients and the characteristics of the food supplements concerned constitutes a measure which is sufficient to ensure the protection of the health of those persons, in particular in order to avoid the harmful effects relating to an excessive consumption of the nutrients concerned.

58 In that connection, in addition to the criteria mentioned in paragraphs 51 and 55 of this judgment, it must be recalled that Recital 6 in the preamble to Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters (OJ 2003 L 126, p. 34) states, that in order to protect infants and young children, who are the most sensitive to the risk of fluorosis, a reference, which can be

easily seen by consumers, must be made on the label where the fluoride content of a natural mineral water exceeds the guide value for fluoride in drinking water recommended by the World Health Organisation.

59 Article 4(1) of Directive 2003/40 provides that natural mineral waters with a fluoride concentration exceeding 1,5 mg/l must bear on the label the words 'contains more than 1,5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age'. Article 4(2) adds that that reference on the label must be placed in immediate proximity to the trade name and in clearly visible characters.

60 In that context, it must also be recalled that, although the criterion of the nutritional need of the population of a Member State can play a role in its detailed assessment of the risks which the addition of nutrients to foodstuffs may pose for public health, the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States (*Commission* v *Denmark*, paragraph 54, *Commission* v *France*, paragraphs 59 and 60, and Joined Cases C-211/03, C-299/03, C-316/03 and C-318/03 *HLH Warenvertriebs and Orthica* [2005] ECR I-5141, paragraph 69).

61 In those circumstances, the answer to Question 2(c) is that Article 5 of Directive 2002/46 must be interpreted as meaning that the fact that appropriate labelling might dissuade the group of consumers to which it is addressed from using a nutrient beneficial to them in small doses is not a relevant criterion for setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements. The taking into account of the varying degrees of sensitivity of different consumer groups allows a Member State to apply a maximum amount appropriate for a specific group of consumers, such as children, to the whole population only

if that measure is limited to what is necessary to protect the health of the persons belonging to that group, and only if that measure is proportionate to the objective it pursues, and that objective cannot be attained by measures which are less restrictive to trade within the European Union, which is a matter to be ascertained by the national court.

Question 2(d)

62 By Question 2(d), the national court asks essentially whether the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements may be set even though, in the absence of any known risk to health, the upper safe limits have not been determined with respect to those nutrients and, more generally, to what extent and under what conditions it is possible to set those maximum amounts at a level significantly lower than the upper safe limit laid down for those nutrients.

63 It must be recalled, as held in paragraph 32 of this judgment, that setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements must be based on the criteria in Article 5(1) and (2) of Directive 2002/46.

64 In that connection, according to Article 5(1)(a) those amounts are set per daily portion of consumption as recommended by the manufacturer, taking into account the 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.

65 It is clear that setting those amounts must in particular be based on consideration of the upper safe limits established, for the vitamins and minerals concerned, following a scientific assessment of the risks to human health based on the relevant scientific data and not on purely hypothetical considerations.

66 Setting maximum amounts for vitamins and minerals which may be used in the manufacture of food supplements where, in the absence of a proven risk to human health, upper safe limits have not been established for those nutrients after such a scientific assessment, does not satisfy that requirement.

67 That being the case, although, in the absence of such a risk, such limits have not been established, a scientific risk assessment 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 reality and seriousness of those risks are fully demonstrated. However, the risk assessment cannot be based on purely hypothetical considerations (see, *Commission* v *Denmark*, paragraph 49, and *Commission* v *France*, paragraph 56).

68 In assessing the risk in question, it is not only the particular effects of the marketing of an individual product containing a definite quantity of nutrients which are relevant. It could be appropriate to take into consideration the cumulative effect of the presence

on the market of several sources, natural or artificial, of a particular nutrient and of the possible existence in the future of additional sources which can reasonably be foreseen (see *Commission* v *Denmark*, paragraph 50).

69 In many cases, the assessment of those factors will demonstrate that there is a high degree of scientific and practical uncertainty in that regard. A proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research (see, *Commission* v *Denmark*, paragraph 51).

70 Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided that they are non-discriminatory and objective (see, *Commission* v *Denmark*, paragraphs 52 and 53).

71 However, after the upper safe limits have been established the possibility of setting maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements at a level significantly lower than those limits cannot be excluded if the setting of those maximum amounts can be justified by taking into account the

criteria in Article 5(1) and (2) of Directive 2002/46 and that it complies with the principle of proportionality.

72 That assessment is a matter for the national court and must be carried out on a case-by-case basis.

73 In those circumstances, the answer to Question 2(d) is that Directive 2002/46 must be interpreted as meaning that it precludes the setting of maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements where, in the absence of a genuine risk to human health, upper safe limits have not been established for those vitamins and minerals, unless such a measure is justified in accordance with the precautionary principle, if a scientific risk assessment reveals that scientific uncertainty persists as regards the existence or extent of real risks to human health. After the upper safe limits have been established, the possibility of setting such maximum amounts at a level significantly lower than those limits cannot be excluded if the setting of those maximum amounts can be justified by taking into account the criteria in Article 5(1) and (2) of Directive 2002/46 and that it complies with the principle of proportionality. That assessment is a matter for the national court and must be carried out on a case-by-case basis.

Costs

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

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

1. **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 must be interpreted as meaning that, without prejudice to the EC Treaty, the Member States remain competent to adopt legislation on the maximum and minimum amounts of vitamins and minerals which may be used in the manufacture of food supplements so long as the European Commission has not laid down those amounts in accordance with Article 5(4) of that directive.**

2. **In addition to the obligation to respect Articles 28 EC and 30 EC, the Member States must also be guided by the criteria laid down in Article 5(1) and (2) of Directive 2002/46, including the requirement for a risk assessment based on generally accepted scientific data in setting the maximum amount of vitamins and minerals which may be used in the manufacture of food supplements, while waiting for the European Commission to lay down the amounts pursuant to Article 5(4).**

3. **Directive 2002/46 must be interpreted as meaning that in a situation such as that in the main proceedings where, when setting the maximum amount of a mineral which may be used in the manufacture of food supplements, it is impossible to calculate precisely the intake of that mineral from other dietary sources, and so long as the European Commission has not laid down the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements in accordance with Article 5(4) of that directive, a Member State may, if there is a genuine risk that that intake will exceed the upper safe limit established for the mineral in question,**

and provided that Articles 28 EC and 30 EC are respected, set the maximum amount at a zero level without resorting to the procedure laid down in Article 12 of that directive.

4. **Article 5 of Directive 2002/46 must be interpreted as meaning that the fact that appropriate labelling might dissuade the group of consumers to which it is addressed from using a nutrient beneficial to them in small doses is not a relevant criterion for setting the maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements. Taking account of the varying degrees of sensitivity of different consumer groups allows a Member State to apply a maximum amount appropriate for a specific group of consumers, such as children, to the whole population only if that measure is limited to what is necessary to protect the health of the persons belonging to that group and only if that measure is proportionate to the objective it pursues, and only if that objective cannot be attained by measures which are less restrictive to trade within the European Union, which is a matter to be ascertained by the national court.**

5. **Directive 2002/46 must be interpreted as meaning that it precludes the setting of maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements where, in the absence of a genuine risk to human health, upper safe limits have not been established for those vitamins and minerals, unless such a measure is justified in accordance with the precautionary principle, if a scientific risk assessment reveals that scientific uncertainty persists as regards the existence or extent of genuine risks to human health. After the upper safe limits have been established, the possibility of setting such maximum amounts at a level significantly lower than those limits cannot be excluded if the setting of those maximum amounts can be justified by taking into account the criteria in Article 5(1) and (2) of Directive 2002/46 and that it complies with the principle of proportionality.**

That assessment is a matter for the national court and must be carried out on a case-by-case basis.

[Signatures]