JUDGMENT OF THE COURT (Grand Chamber)

12 July 2005 *

In Joined Cases C-154/04 and C-155/04,

REFERENCES for a preliminary ruling under Article 234 EC from the High Court of Justice England and Wales, Queen's Bench Division (Administrative Court), made by decisions of 17 March 2004, received at the Court on 26 March 2004, in the proceedings

The Queen, on the application of:

Alliance for Natural Health (C-154/04),

Nutri-Link Ltd

v

Secretary of State for Health

* Language of the case: English.

and

The Queen, on the application of:

National Association of Health Stores (C-155/04),

Health Food Manufacturers Ltd

v

Secretary of State for Health,

National Assembly for Wales,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmermans, A. Rosas, K. Lenaerts (Rapporteur), Presidents of Chambers, C. Gulmann, A. La Pergola, J.-P. Puissochet, R. Schintgen, J. Klučka, U. Lõhmus, E. Levits and A. Ó Caoimh, Judges,

Advocate General: L.A. Geelhoed,
Registrar: K. Sztranc, Administrator,

having regard to the written procedure and further to the hearing on 25 January 2005,

after considering the observations submitted on behalf of:

— the Alliance for Natural Health and Nutri-Link Ltd, by K.P.E. Lasok QC, A. Howard and M. Patchett-Joyce, Barristers,

— the National Association of Health Stores and Health Food Manufacturers Ltd, by R. Thompson QC and S. Grodzinski, Barrister,

— the United Kingdom Government, by M. Bethell, acting as Agent, and C. Lewis, Barrister,

— the Greek Government, by N. Dafniou and G. Karipsiadis, acting as Agents,

— the Portuguese Government, by L. Fernandes, acting as Agent,

— the European Parliament, by M. Moore and U. Rösslein, acting as Agents,

— the Council of the European Union, by E. Karlsson and E. Finnegan, acting as Agents,

— the Commission of the European Communities, by J.-P. Keppenne and M. Shotter, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 5 April 2005,

gives the following

Judgment

1 These references for a preliminary ruling concern the validity of Articles 3, 4(1) and 15(b) 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 references were made following applications brought (i) on 10 October 2003 by the National Association of Health Stores and Health Food Manufacturers Ltd (Case C-155/04) and (ii) on 13 October 2003 by the Alliance for Natural Health and Nutri-Link Ltd (Case C-154/04) seeking leave for judicial review of the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003 ('the Food Supplements Regulations'). Those two sets of regulations transpose Directive 2002/46 into the law of England and Wales.

Law

3 Directive 2002/46, adopted on the basis of Article 95 EC, 'concerns food supplements marketed as foodstuffs and presented as such', as is clear from Article 1(1) of the directive.

4 According to the first recital of the preamble to the directive, '[t]here 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'.

5 The second recital of the preamble to the directive states:

'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.'

6 The 5th recital states that '[i]n 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'.

7 It is clear from the 6th, 7th and 8th recitals to the directive that, given the wide range of nutrients and other ingredients which might be present in food supplements, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts, the Community legislature gave priority to laying down measures for vitamins and minerals used as ingredients in food supplements. It is stated that other Community rules for nutrients other than vitamins and minerals, and for other substances with a nutritional or physiological effect used as ingredients in food supplements, are to be adopted at a later stage once adequate and appropriate scientific data are available and that until those Community rules are adopted national rules concerning those nutrients and substances can continue to be applied in compliance with the provisions of the EC Treaty.

8 The 9th, 10th, 11th and 12th recitals to Directive 2002/46 are worded as follows:

'(9) Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Controversy as to the identity of those nutrients that could potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.

(10) There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties.

(11) The chemical substances used as sources of vitamins and minerals in the manufacture of food supplements should be safe and also be available to be used by the body. For this reason, a positive list of those substances should also be established. Such substances as have been approved by the Scientific Committee on Food, on the basis of the said criteria, for use in the manufacture of foods intended for infants and young children and other foods for particular nutritional uses can also be used in the manufacture of food supplements.

(12) In order to keep up with scientific and technological developments it is important to revise the lists promptly, when necessary. Such revisions would be implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.'

9 For the purposes of Directive 2002/46 'food supplements' is defined by Article 2(a) of the directive as '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'.

10 Article 2(b) of the directive defines 'nutrients' as vitamins and minerals.

11 Under Article 3 of Directive 2002/46, Member States are to ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in the directive.

12 Article 4 of Directive 2002/46 provides:

'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.

...

5. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 13(2).

6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

(a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.

7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.

... '

13 Article 11 of Directive 2002/46 provides:

'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.'

14 Article 13 of the Directive is worded as follows:

'1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 ... (hereinafter referred to as "the Committee").

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

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

15 Article 14 of Directive 2002/46 provides:

'Provisions that may have an effect upon public health shall be adopted after consultation with the European Food Safety Authority.'

16 Article 15 of the directive provides:

'Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 July 2003. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

(a) permit trade in products complying with this Directive, from 1 August 2003 at the latest;

(b) prohibit trade in products which do not comply with the Directive, from 1 August 2005 at the latest.

...'

17 Pursuant to Article 16, Directive 2002/46 entered into force on 12 July 2002, the day of its publication in the *Official Journal of the European Communities*.

18 Directive 2002/46 contains two annexes drawing up lists concerning the '[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' ('the positive lists').

The main actions and the question referred to the Court

19 The claimants in Case C-154/04 are a Europe-wide association of manufacturers, wholesalers, distributors, retailers and consumers of food supplements and a small specialist distributor and retailer of food supplements in the United Kingdom.

20 The claimants in Case C-155/04 are two trade associations representing around 580 companies, the majority of which are small firms which distribute dietary products in the United Kingdom.

21 All the claimants in the main actions maintain that the provisions of Article 3 in conjunction with those of Article 4(1) and Article 15(b) of Directive 2002/46 are incompatible with Community law and must consequently be declared invalid. Those provisions, which prohibit with effect from 1 August 2005 the marketing of foodstuffs which do not comply with the directive, were transposed into national law by the Food Supplements Regulations.

22 The High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), granted permission to apply for judicial review and decided to stay the proceedings and to refer to the Court the following question, cast in identical terms in both these cases:

'Are Articles 3, 4(1), and 15(b) of Directive 200[2]/46/EC invalid by reason of:

(a) the inadequacy of Article 95 EC as a legal basis;

(b) infringement of (i) Articles 28 EC and 30 EC and/or (ii) Articles 1(2) and 24(2)(a) of Council Regulation (EC) No 3285/94 (of 22 December 1994 on the common rules for imports and repealing Regulation (EC) No 518/94 (OJ 1994 L 349, p. 53));

(c) infringement of the principle of subsidiarity;

(d) infringement of the principle of proportionality;

(e) infringement of the principle of equal treatment;

(f) infringement of Article 6(2) [EU], read in the light of Article 8 and Article 1 of the First Protocol to the European Convention on Human Rights, and of the fundamental right to property and/or the right to carry on an economic activity;

(g) infringement of Article 253 EC and/or the duty to give reasons?'

23 By order of the President of the Court of 7 May 2004, the national court's applications to apply to the present cases the accelerated procedure provided for in Article 104a of the Rules of Procedure were dismissed. By the same order, Cases C-154/04 and C-155/04 were joined for the purposes of the written and oral procedure and judgment.

The question referred to the Court

Part (a) of the question

24 By part (a) of its question, the national court is asking whether Articles 3, 4(1) and 15 (b) of Directive 2002/46 are invalid on the ground that Article 95 EC does not afford them an appropriate legal basis.

25 The claimants in Case C-154/04 submit that the prohibition arising from those provisions of Directive 2002/46 does not contribute to improving the conditions for the establishment and functioning of the internal market. On the assumption that the reason for the prohibition lies in public-health considerations, reliance on Article 95 EC constitutes a misuse of powers since, under Article 152(4)(c) EC, the Community has no power to harmonise national legislation on human health.

26 The claimants in Case C-155/04 claim, first, that Articles 3, 4(1) and 15(b) of Directive 2002/46 are contrary to the principle of the free movement of goods within the Community, a principle with which the Community legislature must comply when exercising its powers under Article 95 EC (see Case C-51/93 *Meyhui* [1994] ECR I-3879, paragraphs 10 and 11). Second, the provisions entail direct and immediate restrictions on trade with third countries and should thus have been adopted on the basis of Article 133 EC.

27 In that regard, it must be borne in mind that, as provided for by Article 95(1) EC, the Council of the European Union, acting in accordance with the procedure referred to in Article 251 EC and after consulting the European Economic and Social Committee, is to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

28 By virtue of the Court's case-law, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 95 EC (see, to that effect, Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419, paragraph 84), it is, however, otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the

functioning of the internal market (Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 30, and Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 29; see also, to that effect, *Germany* v *Parliament and Council*, paragraph 95, and Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 60).

29 It also follows from the Court's case-law that, although recourse to Article 95 EC as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them (*Arnold André*, paragraph 31, and *Swedish Match*, paragraph 30; see also, to that effect, Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, paragraph 35, *Germany* v *Parliament and Council*, paragraph 86, Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraph 15, and *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 61).

30 The Court has also held that, provided that the conditions for recourse to Article 95 EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62, *Arnold André*, paragraph 32, and *Swedish Match*, paragraph 31).

31 It must be noted in that regard 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 that Article 95(3) EC explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62, *Arnold André*, paragraph 33, and *Swedish Match*, paragraph 32).

32 It follows from the foregoing that when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products, which bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the Community, Article 95 EC authorises the Community legislature to intervene by adopting appropriate measures, in compliance with Article 95(3) EC and with the legal principles mentioned in the Treaty or identified in the case-law, in particular the principle of proportionality (*Arnold André*, paragraph 34, and *Swedish Match*, paragraph 33).

33 Depending on the circumstances, those appropriate measures may consist in requiring all the Member States to authorise the marketing of the product or products concerned, subjecting such an obligation of authorisation to certain conditions, or even provisionally or definitively prohibiting the marketing of a product or products (*Arnold André*, paragraph 35, and *Swedish Match*, paragraph 34).

34 It is in the light of those principles that it is necessary to ascertain whether the conditions for recourse to Article 95 EC as legal basis were satisfied in the case of the provisions to which the national court's question refers.

35 According to the second recital to Directive 2002/46, food supplements were regulated, before the directive was adopted, by differing national rules liable to impede their free movement and thus have a direct impact on the functioning of the internal market.

36 As the European Parliament and the Council have noted in their written observations, those statements are borne out by the fact that prior to the adoption of Directive 2002/46 a number of cases were brought before the Court which related

to situations in which traders had encountered obstacles when marketing in a Member State other than their State of establishment food supplements lawfully marketed in the latter State.

37 Furthermore, at point 1 of the Explanatory Memorandum to the proposal for a directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (COM(2000) 222 final, presented by the Commission on 10 May 2000 (OJ 2000 C 311 E, p. 207)), it is stated, as the Greek Government, the Council and the Commission have pointed out in their written observations, that before that proposal was presented the Commission services had received 'a substantial number of complaints from economic operators' on account of the differences between national rules which 'the application of the principle of mutual recognition did not succeed in overcoming'.

38 In those circumstances action on the part of the Community legislature on the basis of Article 95 EC was justified in relation to food supplements.

39 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46, which give rise to a prohibition, with effect from 1 August 2005 at the latest, on marketing food supplements which do not comply with the directive, could be adopted on the basis of Article 95 EC.

40 In view of the cases cited at paragraphs 30 and 31 of this judgment, the fact that human health considerations played a part in the formulation of the provisions concerned cannot invalidate the foregoing assessment.

41 As regards the argument of the claimants in Case C-155/04 that Articles 3, 4(1) and 15(b) of Directive 2002/46 should be based on Article 133 EC, it must be stated that the fact that those provisions may incidentally affect international trade in food supplements does not make it possible validly to challenge the fact that the primary objective of those provisions is to further the removal of differences between national rules which may affect the functioning of the internal market in that area (see, to that effect, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 96).

42 Consequently, Article 95 EC constitutes the only appropriate legal basis for Articles 3, 4(1) and 15(b) of Directive 2002/46.

43 It follows that those provisions are not invalid by reason of lack of an appropriate legal basis.

Part (b) of the question

44 By part (b) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of infringement of Articles 28 EC and 30 EC and/or infringement of Articles 1(2) and 24(2)(a) of Regulation No 3285/94.

45 In both the present cases the claimants in the main actions submit that the prohibition arising from the provisions with which the question referred to the Court is concerned constitutes a restriction on intra-Community and international trade in food supplements hitherto lawfully put into circulation.

46 The claimants in Case C-155/04 add that neither Article 30 EC nor Article 24(2)(a) of Regulation No 3285/94 can justify the sudden introduction of a restriction on trade in products whose safety had never before been put in doubt.

Articles 28 EC and 30 EC

47 It must be observed that by virtue of settled case-law the prohibition of quantitative restrictions and of all measures having equivalent effect, laid down in Article 28 EC, applies not only to national measures but also to measures adopted by the Community institutions (see Case 15/83 *Denkavit Nederland* [1984] ECR 2171, paragraph 15, *Meyhui,* paragraph 11, Case C-114/96 *Kieffer and Thill* [1997] ECR I-3629, paragraph 27, and *Arnold André,* paragraph 57).

48 Nevertheless, as Article 30 EC provides, Article 28 EC does not preclude prohibitions or restrictions justified, inter alia, on grounds of protection of the health and life of humans (see *Arnold André,* paragraph 58, and *Swedish Match,* paragraph 60).

49 The provisions of Article 3 in conjunction with those of Article 4(1) and 15(b) of Directive 2002/46 constitute a restriction covered by Article 28 EC. By prohibiting the marketing in the Community of food supplements containing vitamins and minerals, or vitamin and mineral substances, not included on the positive lists, those provisions are capable of restricting the free movement of food supplements within the Community.

50 As the Advocate General has stated at point 40 of his Opinion, it is clear from the preamble to Directive 2002/46, and in particular from the 5th, 9th, 10th and 11th recitals thereto, that the Community legislature gives, as the rationale for the prohibition, considerations related to the protection of human health.

51 It remains necessary to ascertain whether the measure is necessary and proportionate in relation to the objective of protecting human health.

52 With regard to judicial review of those conditions, the Community legislature must be allowed a broad discretion in an area such as that involved in the present case, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. Consequently, the legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (see *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 123).

53 In the present cases, the claimants in the main actions submit that the prohibition at issue is neither necessary nor proportionate in relation to the objective put forward.

54 First, they deny that the prohibition is necessary. They maintain to that end that Articles 4(7) and 11(2) of Directive 2002/46 give the Member States the power to restrict trade in food supplements which do not comply with the directive. A Community prohibition is thus superfluous.

55 First of all, it must be stated that Article 4(7) of Directive 2002/46 — as is clear from its actual wording and from the legislative history of the directive — is intrinsically linked to Article 4(6) of the directive, as was confirmed at the hearing by the Parliament, the Council and the Commission.

56 It follows that the power of the Member States laid down in Article 4(7) of Directive 2002/46 to continue to apply, in compliance with the rules of the Treaty, existing national restrictions or bans on trade in food supplements containing vitamins and minerals or vitamin and mineral substances not included on the positive lists is merely the corollary of a Member State's ability under Article 4(6) to allow in its territory until 31 December 2009 the use of such constituents on the conditions set out in that provision.

57 As the Advocate General has observed at point 22 of his Opinion, the purpose of Article 4(7) of Directive 2002/46 is solely to provide that Member States other than a State which allows on its territory, within the limits and in compliance with the conditions set out in Article 4(6), the use in the manufacture of food supplements of vitamins, minerals or vitamin or mineral substances not included on the positive lists, do not have to allow imports into their own territory of food supplements containing such ingredients.

58 The argument of the claimants in the main actions which is founded on Article 4(7) of Directive 2002/46 thus does not give grounds for concluding that the prohibition at issue is unnecessary.

59 Next, as regards Article 11(2) of Directive 2002/46, when that provision is read in conjunction with the 8th recital to the directive, it becomes clear that its purpose is to preserve, until specific Community 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.

60 Article 11(2) of Directive 2002/46 is thus directed solely at food supplements containing nutrients or substances not falling with the material scope of the directive. Consequently, it is of no relevance for the purpose of ascertaining whether the prohibition in Articles 3, 4(1) and 15(b) of the directive is necessary.

61 Second, the claimants in the main actions maintain that the prohibition is disproportionate.

62 They submit in that regard that the positive lists are inadequate. That is because the list of substances in Annex II to Directive 2002/46 was compiled on the basis not of the criteria pertaining to safety and bioavailability set out in the 11th recital in the preamble to the directive but of lists identifying ingredients authorised in the manufacture of food for particular nutritional purposes. It follows that the prohibition affects a large number of nutrients which are none the less suitable for a normal diet and are currently manufactured and marketed in certain Member States and which have hitherto not been shown to represent a risk to human health. The prohibition in Directive 2002/46 is also unjustified and disproportionate in the case of vitamins and minerals in natural forms, although they are usually found in the normal diet and are better tolerated by the body than vitamins and minerals from synthetic sources.

63 It must be stated, at the outset, that if the various recitals in the preamble to Directive 2002/46 are read together, it is apparent that the directive concerns food supplements containing vitamins and/or minerals derived from a manufacturing process using 'chemical substances' (11th recital), and not food supplements whose ingredients include 'amino acids, essential fatty acids, fibre and various plant and herbal extracts' (6th recital), whose conditions for use consequently remain 'until ... specific Community rules are adopted' within the scope of 'national rules', 'without prejudice to the provisions of the Treaty' (8th recital).

64 Next, it must be noted that the positive lists correspond, as the claimants in Case C-155/04 have observed, to the list of substances included in the categories 'vitamins' and 'minerals' in the Annex to Commission Directive 2001/15/EC 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).

65 As is stated in the 4th recital in the preamble to Directive 2001/15, the selection of the substances identified in the annex to the directive took into account criteria of safety and availability for use by humans, criteria referred to in the 11th recital to Directive 2002/46.

66 As is clear when the 10th and 11th recitals to Directive 2002/46 are read together, the fact that a certain number of chemical substances used as ingredients in food supplements marketed in some Member States are currently not authorised at European level is explained by the fact that the substances at issue in the main actions had not, at the time when the directive was adopted, received a favourable evaluation, from the point of view of the criteria of safety and bioavailability, from the competent European scientific authorities.

67 The information provided by the claimants in the main actions in their written observations about certain vitamin or mineral substances not included on the positive list in Annex II to Directive 2002/46 is not such as to cast doubt on the merits of that explanation. It is apparent from it that at the time when the directive was adopted those substances had not yet been evaluated by the Scientific Committee on Food or that, at the very least, the committee continued to entertain serious doubts, in the absence of adequate and appropriate scientific data, regarding their safety and/or their bioavailability.

68 In those circumstances and in view of the need for the Community legislature to take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health (see, to that effect, Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 64, and Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 100, and Case C-41/02 *Commission* v *Netherlands* [2004] ECR I-11375, paragraph 45), the authors of Directive 2002/46 could reasonably take the view that an appropriate way of reconciling the objective of the internal market, on the one hand, with that relating to the protection of human health, on the other, was for entitlement to free movement to be reserved for food supplements containing substances about which, at the time when the directive was adopted, the competent European scientific authorities had available adequate and appropriate scientific data capable of providing them with the basis for a favourable opinion, whilst giving scope, in Article 4(5) of the directive, for obtaining a modification of the positive lists by reference to scientific and technological developments.

69 It is also necessary to state in that regard that, by virtue of Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), the Community legislature is entitled to adopt the provisional risk management measures necessary to ensure a high level of health protection and may do so whilst awaiting further scientific information for a more comprehensive risk assessment, as is stated in the 10th recital to Directive 2002/46.

70 Contrary to the contention of the claimants in Case C-154/04, a negative list system, which entails limiting the prohibition to only the substances included on that list, might not suffice to achieve the objective of protecting human health. Reliance in this instance on such a system would mean that, as long as a substance is not included on the list, it can be freely used in the manufacture of food supplements, even though, by reason of its novelty for example, it has not been subject to any scientific assessment apt to guarantee that it entails no risk to human health.

71 The claimants in the main action submit that the procedures referred to in Article 4 (5) and (6) of Directive 2002/46 lack transparency because of the lack of precision in the criteria applied by the European Food Safety Authority in its examination of dossiers seeking authorisation to use a substance not included on the positive lists. The procedures thus represent a particularly heavy financial and administrative burden.

72 In that regard, a measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty.

73 Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorised substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the

procedure results in a refusal, the refusal must be open to challenge before the courts (see, by analogy, Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraphs 26, 27 and 36, and Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraphs 35, 36 and 50).

74 In the case of Directive 2002/46, the procedure accompanying the measure at issue, by which a vitamin, a mineral or a vitamin or mineral substance may be added to the positive lists, is referred to in Article 4(5) of the directive, which deals with modification of the lists.

75 It follows that, for the purposes of assessing the validity of the prohibition stemming from Articles 3, 4(1) and 15(b) of Directive 2002/46, the Court's review must concern solely the legality of the procedure referred to in Article 4(5) of the directive. A review of the validity of the procedure laid down in Article 4(6), which is designed for obtaining a temporary national authorisation and which thus pursues a different purpose from that of the procedure laid down in Article 4(5), falls, however, outside the scope of the assessment in these cases.

76 Article 4(5) of Directive 2002/46 refers to Article 13(2) of the directive, which provides, in its first subparagraph, that '[w]here reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof'.

77 As is stated in the 12th recital to Directive 2002/46, the reference to the procedure laid down in 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) meets the concern that it should be possible, when it is necessary to revise the positive lists to reflect scientific and technological developments, to use a simplified and accelerated procedure in the form of technical implementing measures for whose adoption the Commission is responsible.

78 As is shown by the 7th and 9th recitals in the preamble to Decision 1999/468, that procedure, known as 'comitology', is intended to reconcile, on the one hand, the requirement for effectiveness and flexibility arising from the need regularly to amend and update aspects of Community legislation in the light of developments in scientific understanding in the area of the protection of human health or safety and, on the other hand, the need to take account of the respective powers of the Community institutions.

79 Within the framework of the comitology procedure, provision is made, under Article 5 of Decision 1999/468, for the Commission to submit 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 must deliver its opinion 'within a time-limit which [its] chairman may lay down according to the urgency of the matter' (Article 5(2)). When the committee has delivered its opinion, it is for the Commission to adopt the measures envisaged if they are in accordance with the opinion (Article 5(3)). If that is not the case or if the committee does not deliver an opinion, the Commission must, 'without delay', submit to the Council a proposal relating to the measures to be taken and must inform the European Parliament (Article 5(4)) and the Council may act within a period of three months (Article 5(6), first subparagraph, of Decision 1999/468; Article 13(2), second subparagraph, of Directive 2002/46). If within that period the Council opposes the Commission's proposal, the Commission must re-examine its proposal and may submit the same proposal or an amended proposal to the Council or present a legislative proposal on the basis of the Treaty (Article 5(6), second subparagraph). However, if on the expiry of that period the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, those measures are adopted by the Commission (Article 5(6), third subparagraph).

80 The provisions of Article 13(2), second subparagraph, of Directive 2002/46 in conjunction with those of Article 5 of Decision 1999/468, to which Article 4(5) of Directive 2002/46 refers, ensure that once the matter has been brought before the committee by the Commission under Article 5(2) of the decision the procedure for amending the positive lists is completed within a reasonable time.

81 It would, no doubt, have been desirable, as regards the stage between the filing of a dossier seeking modification of the positive lists and the time when the matter is brought before the committee (a stage which includes, inter alia, consultation of the European Food Safety Authority as envisaged in both Article 14 of, and the 10th recital to, Directive 2002/46), for the directive to have included provisions which in themselves ensured that that stage be completed transparently and within a reasonable time.

82 The absence of any such provisions cannot, however, be regarded as such as to jeopardise the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, inter alia, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time.

83 By providing for the procedure established in Article 5 of Decision 1999/468 to apply, Article 4(5) of Directive 2002/46 also ensures that an application for inclusion on the positive lists of a vitamin, a mineral or a vitamin or mineral substance can be rejected only by a binding legal act, which may be subject to judicial review.

84 It must be added in that regard that Directive 2002/46 contains nothing to compel or encourage the competent European authorities to take account, in the procedure referred to in Article 4(5) of the directive, of criteria which do not relate to the objective of protecting human health.

85 On the contrary, it is clear from the 9th recital to Directive 2002/46 that the criterion that the vitamin or mineral be normally found in, and consumed as part of, the diet is the only relevant criterion for the purposes of the list in Annex I to the directive. As the claimants in Case C-154/04 have observed, although the proposal for the directive mentioned at paragraph 37 of this judgment provided for a second criterion, namely that the vitamins and minerals in question should be 'considered essential nutrients', as is shown by the 7th recital in the preamble to the proposal, that criterion is no longer included in the 9th recital to Directive 2002/46. As regards the list in Annex II to the directive, it is apparent from the 11th recital that the only relevant criteria are those relating to the safety and bioavailability of the chemical substance in question.

86 Such statements show that the relevant criteria for the purposes of the positive lists and the application of the procedure for modification of those lists can, as conceived by the Community legislature, relate only to grounds of human-health protection, to the exclusion of considerations concerning nutritional needs.

87 It should also be stated that the criticisms made by the claimants in the main actions of the procedure for modifying the positive lists concern in essence the administrative and financial burdens involved in presenting files seeking such modifications and the way in which the criteria of safety and bioavailability set out in the 11th recital to Directive 2002/46 are applied by the European Food Safety Authority when considering individual files.

88 However, although such factors may, depending on the circumstances, be advanced in support of an action for annulment of a final decision refusing an application for modification of the positive lists or an action for damages against the European Food Safety Authority under Article 47(2) of Regulation No 178/2002, they cannot, in themselves, affect the legality of the procedure for modifying the positive lists, as the Greek Government has pointed out in its written observations.

89 It must therefore be concluded that the analysis at paragraphs 76 to 88 of this judgment has not revealed any factor of such a kind as to affect the legality of the procedure laid down in Article 4(5) of Directive 2002/46 with regard to modification of the positive lists.

90 Finally, it should be noted that, when the Community legislature wishes to delegate its power to amend aspects of the legislative act at issue, it must ensure that that power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria (see, to that effect, Case 9/56 *Meroni* v *High Authority* [1958] ECR 133, at p. 152) because otherwise it may confer on the delegate a discretion which, in the case of legislation concerning the functioning of the internal market in goods, would be capable of impeding, excessively and without transparency, the free movement of the goods in question.

91 In this instance, as has been stated at paragraphs 85 and 86 of this judgment, the 9th and 11th recitals to Directive 2002/46 state that the only relevant criteria concerning the positive lists relate, as regards vitamins and minerals, to the fact that the latter are normally found in and consumed as part of the diet and, as regards chemical substances used as sources of vitamins or minerals, to the safety and bioavailability of the substance concerned.

92 Those statements, which are closely related to the concrete expression of those criteria through the positive lists in the body of Directive 2002/46 and which should ideally have been included in the actual provisions of the directive (see, to that effect the Inter-Institutional Agreement of the European Parliament, of the Council and of the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ 1999 C 73, p. 1)), limit the Commission's power to modify the lists through their reference to objective criteria connected exclusively with public health. They show that in this instance the Community legislature laid down the essential criteria to be applied in the matter when the powers thus delegated are exercised (see, to that effect, Case 25/70 *Köster* [1970] ECR 1161, paragraph 6).

93 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of Articles 28 EC and 30 EC.

Articles 1(2) and 24(2)(a) of Regulation No 3285/94

94 It is appropriate to point out that Regulation No 3285/94 was adopted in the framework of the common commercial policy, as is apparent from its legal basis, namely Article 113 of the EC Treaty (now, after amendment, Article 133 EC).

95 The objective of the regulation is to liberalise imports of products originating in non-member States. However, it does not aim to liberalise the placing on the market of those products, which takes place after import (see Case C-296/00 *Expo Casa Manta* [2002] ECR I-4657, paragraphs 30 and 31).

96 It follows that, as the Parliament, the Council and the Commission have rightly submitted and as the Advocate General has pointed out at points 57 and 58 of his Opinion, Regulation No 3285/94 is of no relevance for the purpose of assessing the legality of Community measures whose effect is to prohibit the placing on the market within the Community of products imported from non-member States which do not satisfy the conditions laid down for such placing on the market for reasons relating to the protection of human health.

97 Furthermore, even if there were a conflict between Articles 3, 4(1) and 15(b) of Directive 2002/46 and Articles 1(2) and 24(2)(a) of Regulation No 3285/94, it would then be necessary to state that the directive was adopted on the basis of Article 95 EC and thus does not constitute a measure implementing the regulation.

98 It follows that there is no need to consider the validity of the relevant provisions of Directive 2002/46 in the light of Regulation No 3285/94.

Part (c) of the question

99 By part (c) of its question, the national court is asking whether Articles 3, 4(1) and 15 (b) of Directive 2002/46 are invalid by reason of an infringement of the principle of subsidiarity.

100 In both these cases, the claimants in the main actions submit that the provisions interfere unjustifiably with the powers of the Member States in a sensitive area involving health, social and economic policy. The claimants in Case C-154/04 add

that the Member States are the best placed to determine, on their respective markets, the public health requirements which would justify a barrier to the free marketing of food supplements on their national territory.

101 In that regard, it is appropriate to recall that the principle of subsidiarity is set out in the second subparagraph of Article 5 EC, which provides that the Community, in areas which do not fall within its exclusive competence, is to take action only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

102 Paragraph 3 of the Protocol on the application of the principles of subsidiarity and proportionality, annexed to the Treaty, states that the principle of subsidiarity does not call into question the powers conferred on the Community by the Treaty, as interpreted by the Court of Justice.

103 As the Court has already held, the principle of subsidiarity applies where the Community legislature makes use of Article 95 EC, inasmuch as that provision does not give it exclusive competence to regulate economic activity on the internal market, but only a certain competence for the purpose of improving the conditions for its establishment and functioning by eliminating barriers to the free movement of goods and the freedom to provide services or by removing distortions of competition (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 179).

104 In deciding whether Articles 3, 4(1) and 15(b) of Directive 2002/46 comply with the principle of subsidiarity, it is necessary to consider whether the objective pursued by those provisions could be better achieved by the Community.

105 In that regard, it must be stated that the prohibition, under those provisions, on marketing food supplements which do not comply with Directive 2002/46, supplemented by the obligation of the Member States under Article 15(a) of the directive to permit trade in food supplements complying with the directive (see, by analogy, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 126), 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.

106 To leave Member States the task of regulating trade in food supplements which do not comply with Directive 2002/46 would perpetuate the uncoordinated development of national rules and, consequently, obstacles to trade between Member States and distortions of competition so far as those products are concerned.

107 It follows that the objective pursued by Articles 3, 4(1) and 15(b) of Directive 2002/46 cannot be satisfactorily achieved by action taken by the Member States alone and requires action to be taken by the Community. Consequently, that objective could be best achieved at Community level.

108 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of subsidiarity.

Part (d) of the question

109 By part (d) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the principle of proportionality.

110 The claimants in the main actions maintain that those provisions constitute a disproportionate means of achieving the intended objective. The arguments put forward in support of that claim are those set out at paragraphs 54, 62, 70 and 71 of this judgment.

111 However, it is clear from the analysis set out at paragraphs 55 to 60, 63 to 70 and 72 to 92 of this judgment that Articles 3, 4(1) and 15(b) of Directive 2002/46 are measures appropriate for achieving the objective which they pursue and that, given the obligation of the Community legislature to ensure a high level of protection of human health, they do not go beyond what is necessary to attain that objective.

112 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of proportionality.

Part (e) of the question

113 By part (e) of its question, the national court is asking whether Articles 3, 4(1) and 15 (b) of Directive 2002/46 are invalid by reason of an infringement of the principle of equal treatment.

114 The claimants in both actions submit that those provisions infringe that principle because certain substances which do not satisfy the criteria set out in the 11th recital to Directive 2002/46 were included on the positive lists without having been subject to additional tests, whereas burdensome requirements are imposed on manufacturers of food supplements containing non-authorised substances in order to prove that the abovementioned criteria have been met. They add that there is no objective justification for that difference in treatment, the lists not having been compiled on the basis of the criteria laid down by the Directive.

115 In that regard, it is appropriate to bear in mind that, by virtue of settled case-law, the principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (see Joined Cases C-184/02 and C-223/02 *Spain and Finland* v *Parliament and Council* [2004] ECR I-7789, paragraph 64; *Arnold André*, paragraph 68, and *Swedish Match*, paragraph 70).

116 As the United Kingdom Government, the Parliament and the Commission have observed in their written observations, the vitamin and mineral substances which are not included on the positive list in Annex II to Directive 2002/46 are not in the same situation as those which are included on it. In fact, unlike the latter substances, those that are not included on the list, had not, at the time when the directive was adopted, been subject to a scientific evaluation by the competent European authorities so as to ensure their conformity with the criteria of safety and bioavailability referred to in the 11th recital to the directive.

117 Since each substance has, as is stated in those observations, its own characteristics, a substance which had not yet been evaluated in accordance with those criteria could not be treated in the same way as a substance included on the positive lists.

118 That difference in situations therefore permitted a difference in treatment, and an infringement of the principle of equal treatment cannot be successfully pleaded.

119 It follows from the foregoing that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the principle of equal treatment.

Part (f) of the question

120 By part (f) of its question, the national court is asking whether Articles 3, 4(1) and 15 (b) of Directive 2002/46 are invalid by reason of infringement of Article 6(2) EU, read in the light of Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 ('the ECHR') and Article 1 of the First Protocol to the Convention, and of the fundamental right to property and/or the right to carry on an economic activity.

121 In both cases the claimants in the main actions maintain that there is such an infringement. They submit that Directive 2002/46 is an unjustified and disproportionate impairment of the ability of manufacturers of food supplements to pursue their activities, which have hitherto been carried on entirely lawfully, and of the individual right to freedom of choice as regards food products.

122 In that regard, it must first be observed that Article 6(2) EU provides: 'The Union shall respect fundamental rights, as guaranteed by the [ECHR] and as they result from the constitutional traditions common to the Member States, as general principles of Community law'.

123 Article 8 of the ECHR entitled 'Right to respect for private and family life' provides, at paragraph (1), that '[e]veryone has the right to respect for his private and family life, his home and his correspondence' and, at paragraph (2), that '[t]here shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

124 The fact that Articles 3, 4(1) and 15(b) of Directive 2002/46 may deprive people of the right to consume food supplements which do not comply with the directive cannot be regarded as amounting to a breach of respect for private and family life.

125 Article 1 of the First Protocol to the ECHR states, under the heading 'Protection of Property':

'Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties.'

126 It is clear from settled case-law that the right to property, with which the provisions reproduced in the preceding paragraph are concerned, and likewise the freedom to pursue an economic activity, form part of the general principles of Community law. However, those principles are not absolute but must be viewed in relation to their social function. Consequently, the exercise of the right to property and the freedom to pursue an economic activity may be restricted, provided that any restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute in relation to the aim pursued a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (see, inter alia, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 15, and Case C-200/96 *Metronome Musik* [1998] ECR I-1953, paragraph 21).

127 It is the case here that the prohibition on the marketing and placing on the Community market of food supplements which do not comply with Directive 2002/46 is capable of restricting the freedom of manufacturers of those products to carry on their business activities.

128 Nevertheless, their right to property is not called into question by the introduction of such a measure. No economic operator can claim a right to property in a market share, even if he held it at a time before the introduction of a measure affecting the market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances (Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 79, and *Swedish Match*, paragraph 73). Nor can an economic operator claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by measure taken by the Community institutions within the limits of their discretion will be maintained (Case 52/81 *Faust* v *Commission* [1982] ECR 3745, paragraph 27, and *Swedish Match*, paragraph 73).

129 As has been stated above, the prohibition arising from Articles 3, 4(1) and 15(b) of Directive 2002/46 is intended to protect human health, which is an objective of general interest. It is not evident that the prohibition is inappropriate in relation to that objective. In those circumstances, the obstacle to the freedom to pursue an economic activity which a measure of that kind represents cannot be found, in the light of the aim pursued, to constitute a disproportionate impairment of the right to exercise that freedom or to the right to property.

130 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of infringement of Article 6(2) EU, read in the light of Article 8 of the ECHR and Article 1 of the First Protocol thereto, the fundamental right to property or the right to pursue an economic activity.

Part (g) of the question

131 By part (g) of its question, the national court is asking whether Articles 3, 4(1) and 15(b) of Directive 2002/46 are invalid by reason of an infringement of the obligation to state reasons laid down in Article 253 EC.

132 The claimants in Case C-154/04 maintain that no reasons are given for the prohibition arising from those provisions, which, in their submission, amounts to an infringement of Article 253 EC.

133 In that regard, it should be observed that, although the reasoning required by Article 253 EC must show clearly and unequivocally the reasoning of the Community authority which adopted the contested measure so as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review, it is not required to go into every relevant point of fact and law (Case C-122/94 *Commission* v *Council* [1996] ECR I-881, paragraph 29).

134 Furthermore, the question whether a statement of reasons satisfies the requirements must be assessed with reference not only to the wording of the measure but also to its context and to the whole body of legal rules governing the matter in question. If the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for each of the technical choices made by the institution (see, inter alia, Case C-100/99 *Italy* v *Council and Commission* [2001] ECR I-5217, paragraph 64).

135 Here, the 9th recital to Directive 2002/46 explains that the vitamins and minerals affected by the prohibition are those which are not normally found in, or consumed as part of, the diet.

136 As regards existing vitamin and mineral substances covered by the prohibition, the 10th and 11th recitals to Directive 2002/46 clearly disclose that such a measure relates to the general concern, expressed in the 5th recital to the directive, to ensure a high level of protection for consumers by authorising the placing on the market only of products which are safe for human health and is explained by the fact that the substances concerned had not, at the time when the directive was adopted, been evaluated by the Scientific Committee on Food by reference to the criteria of safety and bioavailability on the basis of which the positive list in Annex II to the directive was drawn up.

137 It follows that Articles 3, 4(1) and 15(b) of Directive 2002/46 are not invalid by reason of an infringement of the obligation to state reasons laid down in Article 253 EC.

138 In view of all the foregoing considerations, the answer to the question referred to the Court must be that examination of the question has revealed no factor of such a kind as to affect the validity of Articles 3, 4(1) and 15(b) of Directive 2002/46.

Costs

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

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

Examination of the question referred to the Court has revealed no factor of such a kind as to affect the validity of Articles 3, 4(1) and 15(b) 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.

[Signatures]