JUDGMENT OF THE COURT (Sixth Chamber)
29 April 2004 *

In Case C-387/99,

Commission of the European Communities, represented by C. Schmidt, acting as Agent, with an address for service in Luxembourg,

applicant,

v

Federal Republic of Germany, represented by W.-D. Plessing, acting as Agent, assisted by J. Sedemund, Rechtsanwalt,

defendant,

supported by

Kingdom of Denmark, represented by J. Molde, acting as Agent, with an address for service in Luxembourg,

* Language of the case: German.

and by

Republic of Finland, represented by T. Pynnä and E. Bygglin, acting as Agents, with an address for service in Luxembourg,

interveners,

APPLICATION for a declaration that, by classifying as medicinal products vitamin and mineral preparations which are lawfully produced or marketed as food supplements in the other Member States where they contain three times more vitamins and minerals than the daily amount recommended by the Deutsche Gesellschaft für Ernährung, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC),

THE COURT (Sixth Chamber),

composed of: V. Skouris, acting as the President of the Sixth Chamber, J.N. Cunha Rodrigues, R. Schintgen, F. Macken (Rapporteur) and N. Colneric, Judges,

Advocate General: L.A. Geelhoed,
Registrar: H. von Holstein, Deputy Registrar,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 21 February 2002,

after hearing the Opinion of the Advocate General at the sitting on 16 May 2002,

gives the following

Judgment

1 By application lodged at the Court Registry on 8 October 1999, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by classifying as medicinal products vitamin and mineral preparations which are lawfully produced or marketed as food supplements in the other Member States where they contain three times more vitamins and minerals than the daily amount recommended by the Deutsche Gesellschaft für Ernährung ('the German Food Association'), the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC).

Community legislation

2 Under the first subparagraph of Article 1(2) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-66 (I), p. 24), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) (hereinafter 'Directive 65/65'), a medicinal product is 'any substance or combination of substances presented for treating or preventing disease in human beings or animals' ('presentation' medicinal product). Under the second subparagraph of the same provision, likewise considered as a medicinal product is 'any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals' ('function' medicinal product).

3 The first paragraph of Article 3 of Directive 65/65 provides:

'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [OJ 1993 L 214, p. 1] ...'

4 The third paragraph of Article 4 of Directive 65/65 states the particulars and documents which are to accompany the application for a marketing authorisation.

5 Under Article 5 of Directive 65/65:

'The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.

Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4.'

6 It is common ground that, on the relevant date of this action, namely at the end of the two-month period laid down in the reasoned opinion of 30 December 1998, there were no provisions in Community legislation laying down the conditions under which nutritive substances such as vitamins and minerals may be added to foodstuffs for general consumption.

7 As regards foodstuffs intended for particular nutritional uses, some of these have been covered by directives adopted by the Commission on the basis of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27).

Pre-litigation procedure

8 The Commission received complaints that, once imported into Germany, food preparations legally produced or marketed as food supplements in other Member States were classified as medicinal products where they contained three times more than the daily amount of vitamins and minerals recommended by the German Food Association.

9 Regarding that administrative practice ('the German practice') as contrary to Article 30 of the Treaty, the Commission sent a letter of formal notice to the German Government on 7 April 1998.

10 On 12 June 1998, the German Government replied that the presumption that a food preparation constitutes a medicinal product where it contains three times more vitamins and minerals than the daily amount recommended by recognised scientific bodies was justified. It explained that that presumption applied only to water-soluble vitamins, since liposoluble vitamins, considered more dangerous, had to fulfil stricter criteria.

11 Finding that the 'triple amount' rule was of general application and considering that the stricter criteria for liposoluble vitamins had not been made clear, the Commission sent a reasoned opinion to the Federal Republic of Germany on 30 December 1998 calling on it to comply therewith within two months of its notification.

12 By letter of 14 April 1999, the German Government, while acknowledging the need to assess on a case-by-case basis and according to the characteristics of the product whether a product is a medicinal product within the meaning of Directive 65/65, reiterated that the German practice complied with Community law.

13 It is in those circumstances that the Commission brought this action.

14 By orders of 7 April and 10 May 2000, the Kingdom of Denmark and the Republic of Finland were given leave to intervene in support of the submissions of the Federal Republic of Germany.

The action

Arguments of the parties

15 The Commission claims that the triple amount rule applied by the German authorities is contrary to Article 30 of the Treaty and to the case-law of the Court, in particular to Case C-227/82 *Van Bennekom* [1983] ECR 3883. According to that case, the classification of each vitamin as a medicinal product must be carried out on a case-by-case basis, having regard to its pharmacological properties to the extent that they have been established in the present state of scientific knowledge. The triple amount rule applies to any vitamin preparation where it contains three times the recommended daily amount of vitamins. It does not therefore take account of the pharmacological properties of each vitamin and therefore infringes

Community law. The degree of harmfulness of vitamins varies. The same general abstract approach for all vitamins, which inevitably applies the strictest criterion, goes beyond what is necessary to achieve the objective of protection of health permissible under Community law and thus is not proportionate.

16 According to the Commission, a more suitable rule would be, for example, to lay down for each vitamin, on the basis of its properties, a multiplication factor or threshold value above which it is classified as a medicinal product.

17 As a preliminary point, the German Government raises the inadmissibility of the action on the ground that it relates to all vitamin and mineral preparations, without distinction or reference to any specific case.

18 According to the German Government, the case-law of the Court states that an application for failure to fulfil obligations must indicate the specific grounds for complaint on which the Court is asked to rule and to state the facts and circumstances at the origin of the infringement. However, that requirement has not been satisfied here. First, the Commission does not state clearly for which vitamins and minerals a threshold value above the amount authorised in Germany would be just as appropriate for the purposes of the protection of public health. Secondly, the Commission does not state which vitamin or mineral preparations are the subject-matter of the present action. Therefore, the Court is not in a position to determine whether the Federal Republic of Germany has exceeded its discretion in specific cases.

19 On the merits, the German Government pleads first that in infringement proceedings it is for the Commission to prove the existence of the alleged infringement. In this instance, it is for the Commission to show that, in specific cases, the German authorities have gone beyond the discretion they have pursuant

to Directive 65/65 and Article 36 of the EC Treaty (now, after amendment, Article 30 EC) when they classify a product as a medicinal product and have applied the term medicinal product incorrectly. However, the Commission has not adduced proof of this. On the contrary, as regards the preparations which have been the subject-matter of two preliminary proceedings brought prior to the present action, the German Government has justified their classification as medicinal products.

20 The Commission cannot argue solely that in other Member States those same preparations are not medicinal products. In the absence of full harmonisation, the classification of a product as a medicinal product may vary from one Member State to another (Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, paragraphs 15 to 17). The fact that a product is not a medicinal product in one Member State cannot prevent its being classified in that category in another Member State, in the light of its pharmacological properties (Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 27).

21 The German Government next disputes the Commission's statement that the German practice does not take account of the properties of vitamin or mineral preparations for the purposes of classifying them as medicinal products.

22 First, the triple amount rule does not apply to all vitamins and minerals. As regards vitamins, a distinction is made between water-soluble and liposoluble vitamins. Accordingly, the triple amount rule does not apply to liposoluble vitamins A and D, which pose higher risks to health and for which the straightforward daily amount acts as the threshold value between foodstuffs and

medicinal products. That rule applies only to water-soluble vitamins — B_1, B_2, B_6, B_{12} and C, vitamin PP, folic acid, pantothenic acid and vitamin H — and also acts as the guideline for liposoluble vitamins E and K, which are comparable in that respect. As regards minerals, the triple amount rule is not used either.

23 Secondly, the triple amount rule is only one of a number of guidelines to determine whether a vitamin preparation should be classified as a medicinal product. It does not relieve the German authorities of the need to examine both the concrete properties of the preparation and the image presented to consumers of that product for the purposes of its classification as a medicinal product. Thus in respect of the preparations at issue in the two abovementioned preliminary procedures, in certain cases the triple amount rule was not applied; in other cases, classification of the preparation as a medicinal product was based on the presence of substances other than vitamins or minerals considered harmful; in yet other cases, classification as a medicinal product was based on the fact that the preparation was a 'presentation' medicinal product as provided for in Directive 65/65.

24 Thirdly, the recommended daily amount is determined individually for each vitamin on the basis of its individual characteristics. Therefore, the triple amount rule leads to results which also take into account those characteristics.

25 Finally, the German Government contends that the German practice is justified in the light of the objective of the protection of public health.

26 It notes that, in accordance with settled case-law (*Van Bennekom*, cited above, paragraphs 26 and 27), the classification of vitamin preparations as foodstuffs or medicinal products depends in principle on the dosage. The German practice,

which makes a distinction between low dosage, subject to legislation governing foodstuffs, and high dosage, subject to legislation governing medicinal products, therefore complies with the case-law of the Court. Its validity is also confirmed by Case C-328/97 *Glob-Sped* [1998] ECR I-8357 in which the Court held that a product with a high vitamin C content should be classified as a medicinal product in the Combined Nomenclature.

27 Furthermore, scientific assessments to lay down 'maximum values' above which there is a health risk have not yet been completed for the majority of vitamins and minerals, and there are considerable uncertainties in the field. Therefore, the German Government believes that, in accordance with the case-law of the Court stating that it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection of health and life of humans they intend to ensure (Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 16), the Federal Republic of Germany is at liberty to lay down a maximum limit ensuring that food supplements which are freely sold do not contain amounts of vitamins or minerals which could be harmful to consumers.

28 The German Government states that the Commission has not indicated the dosage above which a distinction could be made between a food supplement and a medicinal product and that certain Member States have adopted stricter recommendations than those of the German Food Association. It contends that it may not be inferred from scientific knowledge that the triple amount rule is wrong from the dietary or health point of view.

29 In its reply, the Commission notes that the infringement does not relate to the classification of any particular preparation but to the administrative practice of automatically classifying a preparation as a medicinal product where it contains three times more vitamins or minerals than the recommended daily amount.

According to the Commission, that practice goes beyond what is necessary in terms of the protection of public health, since it is not carried out on a case-by-case basis and therefore is disproportionate and illegal. Moreover, it is immaterial for the outcome of this action that the application of that practice can sometimes lead to acceptable results in scientific terms, since the practice is in any event unlawful.

30 The Commission states that the triple amount rule is open to criticism only where the proportion of vitamins is chosen as the decisive criterion in classifying a preparation as a medicinal product. It cites specific cases in which that was the case. By contrast, that rule is not open to criticism where the classification of foodstuffs as medicinal products is based on their presentation or the presence of prohibited substances.

31 Referring to the case-law of the Court (*Van Bennekom*, paragraph 28; *Delattre*, paragraph 27; and *Commission* v *Germany*, paragraphs 15 and 16, all cited above), the Danish Government submits first that the Member States have a broad margin of discretion when they classify a product as a foodstuff or as a medicinal product.

32 Secondly, it is apparent from Case 174/82 *Sandoz* [1983] ECR 2445, paragraphs 11 and 16 to 18, and *Van Bennekom*, cited above, paragraphs 36 to 38 and 41, that, in the light of the risks to human health of excessive consumption of vitamins and having regard to the recognised discretion of the Member States to decide what degree of protection of health and life of humans they intend to ensure, when, as in this case, there are uncertainties in the state of scientific research, the Member States may prohibit the sale or storage for the purpose of distribution of vitamin preparations from another Member State which have a high degree of concentration, provided that marketing authorisations are granted when they are compatible with the requirements of the protection of health.

33 The Danish Government concludes that the triple amount rule applied by the German authorities complies with Articles 30 and 36 of the Treaty, in particular with the principle of proportionality, given that it is not possible, as scientific knowledge now stands, to lay down critical quantities and concentrations.

34 Relying on the *Van Bennekom* judgment cited above, the Finnish Government submits first that the Member States may lay down limits for vitamins and minerals above which preparations are classified as medicinal products provided that they come within the definition of a medicinal product within the meaning of Directive 65/65. In this connection, the Finnish Government takes the view that preparations with a vitamin or mineral content in excess of the recommended daily amount or the reference intake values for a population fall within the definition of a medicinal product because such preparations are intended to either prevent diseases or restore, improve or modify organic processes. On the other hand, preparations with a vitamin or mineral content below those values are foodstuffs.

35 Secondly, the Finnish Government submits that, assuming that Article 30 of the Treaty applies, the German practice is justified in terms of the protection of public health or the health of consumers.

36 In its submissions on the statements in intervention, the Commission states that, subject to express confirmation by the German Government during the oral procedure that preparations containing vitamins A and D or those containing minerals are not subject to the triple amount rule, it will limit its action to the classification of preparations containing water-soluble vitamins or the liposoluble vitamins E and K.

37 As regards those preparations, the Commission claims that, notwithstanding that the Member States are at liberty, in the absence of harmonisation, to lay down what degree of protection of public health they intend to ensure, they may not jeopardise the free movement of goods by determining the risk posed by vitamins on the basis of one and the same factor. There is no automatic link between the level of the recommended daily amount and the potential danger of a vitamin. Thus it is known that a large dose of vitamin C is fairly harmless, unlike, for example, a large dose of liposoluble vitamins E and K. The Commission adds that, if the German authorities applied the limits above which there may be a risk to health, referred to in the report of the Scientific Committee for Food (notice of 11 December 1992), or the maximum daily limits referred to in the report of the German Food Association published in 2000, no complaint would be made against them.

38 According to the Commission, while for some vitamins and minerals the maximum harmless quantity is slightly higher than the daily recommended amount, by contrast, for other vitamins that limit lies greatly above that amount, which means that the maximum limit which must not be exceeded cannot be laid down for all vitamins on the basis of the triple amount rule.

Findings of the Court

Admissibility

39 The Commission has stated specific grounds for complaint against the Federal Republic of Germany on which the Court is to rule, and has set out the facts and circumstances of the infringement.

40 The letter of formal notice and the reasoned opinion as well as the application clearly set out the subject-matter of the dispute, which does not relate to the classification as medicinal products of specific vitamin preparations but to the German practice of automatically classifying vitamin preparations as medicinal products where they contain three times the daily recommended amount, regardless of the vitamin in their composition.

41 The Commission has also expressly stated that its action is not intended to move the Court to intervene in the scientific debate on the laying down of threshold values above which vitamins should be considered as medicinal products, but relates solely to the failure of the German practice to take into account the pharmacological properties specific to each vitamin, which are not the same for all vitamins.

42 The case-law of the Court (see, to that effect, Case 21/84 *Commission* v *France* [1985] ECR 1355, paragraphs 13 and 15; Case C-187/96 *Commission* v *Greece* [1998] ECR I-1095, paragraph 23; and Case C-185/96 *Commission* v *Greece* [1998] ECR I-6601, paragraph 35) shows that an administrative practice can be the subject-matter of an action for failure to fulfil obligations when it is, to some degree, of a consistent and general nature.

43 In this case, according to the defence of the German Government, when a vitamin preparation contains three times the recommended daily amount it is automatically classified as a medicinal product by the German authorities pursuant to the triple amount rule, even if there are no other grounds for that classification, such as the presence of substances, other than vitamins, considered to be harmful or the fact that the preparation is a 'presentation' medicinal product for the purposes of Directive 65/65.

44 In those circumstances, the plea of inadmissibility raised by the German Government must be rejected.

Substance

45 It must be stated as a preliminary point that during the oral procedure the Commission discontinued the action in so far as it concerns the classification as medicinal products of vitamin preparations containing vitamins A and D and preparations containing minerals, in view of the German Government's explanation, during these proceedings, that the triple amount rule is not applied to them. The action now concerns therefore only the classification of preparations containing vitamins other than vitamins A and D.

46 In those circumstances, reference will be made in the rest of this judgment only to vitamins other than vitamins A and D and to preparations containing them.

47 Furthermore, it should be stated at the outset that the complaint of the Commission relates only to the automatic classification of vitamin preparations as medicinal products on the sole ground that they contain more than three times the recommended daily amount. In particular, the Commission is not alleging that the German authorities regard as medicinal products preparations presented as having curative or preventive properties in relation to human diseases, irrespective of their vitamin content, and which hence fall within the definition of 'presentation' medicinal product.

48 These infringement proceedings must therefore be understood to relate to the German practice of automatically classifying as 'function' medicinal products vitamin preparations lawfully produced and marketed as food supplements in the other Member States where they contain three times the recommended daily amount.

49 It follows from Articles 2 and 3 of Directive 65/65 that no medicinal product produced industrially may be placed on the market in a Member State unless a marketing authorisation has been issued.

50 Accordingly, if a product produced industrially comes within the definition of medicinal product in Article 1(2) of Directive 65/65, the obligation on the importer of that product to obtain a marketing authorisation in accordance with that directive prior to marketing it in the Member State of importation cannot in any event constitute a restriction on trade between Member States prohibited by Article 30 of the Treaty (see, to that effect, Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraphs 48, 52 and 53).

51 Furthermore, although the essential purpose of Directive 65/65 is to remove obstacles to trade in medicinal products within the Community and although for that purpose Article 1 gives a definition of medicinal products, it nevertheless constitutes merely a first stage in the harmonisation of national legislation on the production and distribution of pharmaceutical products (see, in particular, *Commission* v *Germany*, cited above, paragraph 15).

52 As Community law stands, so long as harmonisation of the measures necessary to ensure the protection of health is not more complete, it is difficult to avoid the existence of differences in the classification of products as between Member States in the context of Directive 65/65 (see, inter alia, Case C-201/96 *LTM* [1997] ECR I-6147, paragraph 24, and Case C-270/96 *Laboratoires Sarget* [1998] ECR I-1121, paragraph 23).

53 The fact therefore that a product is classified as a foodstuff in another Member State cannot prevent its being classified as a medicinal product in the Member State of importation if it displays the characteristics of such a product (see, inter alia, *Delattre*, paragraph 27; *LTM*, paragraph 24; and *Laboratoires Sarget*, paragraph 23, all cited above).

54 In respect of vitamin preparations in particular, as the Commission acknowledged, at the relevant date of this action there were no Community harmonisation provisions on the classification of those preparations either as medicinal products or as food products.

55 Therefore it is appropriate to determine, first, if the vitamin preparations which contain more than three times the recommended daily amount are 'function' medicinal products for the purposes of the second subparagraph of Article 1(2) of Directive 65/65.

56 In so far as vitamins are usually defined as substances which, in minute quantities, form an essential part of the daily diet and are indispensable for the proper functioning of the body, they cannot, as a general rule, be regarded as medicinal products when they are consumed in small quantities. Similarly, it is a fact that

vitamin preparations are sometimes used, generally in large doses, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. In such cases, it is beyond dispute that those vitamin preparations constitute medicinal products (*Van Bennekom*, cited above, paragraphs 26 and 27).

57 In those circumstances, and in accordance with settled case-law, to determine whether vitamin preparations should be classified as medicinal products within the meaning of Directive 65/65, the national authorities, acting under the control of the court, must work on a case-by-case basis, having regard to all of their characteristics, in particular their composition, their pharmacological properties — to the extent to which they can be established in the present state of scientific knowledge — the manner in which they are used, the extent of their distribution, their familiarity to consumers and the risks which their use may entail (see, inter alia, *Van Bennekom*, cited above, paragraph 29; Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 29; Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 23; and *Commission* v *Germany*, cited above, paragraph 17).

58 Accordingly, a risk to public health is only one aspect of the product which must be taken into consideration by the competent national authorities. It is obvious that a product which does not pose a real risk to health can nevertheless have an effect on the functioning of the body. To classify a product as a 'function' medicinal product, those authorities must ascertain that it is intended to restore, correct or modify physiological functions and that it may thus have an effect on health in general (*Upjohn*, cited above, paragraph 17).

59 In this case, it must be stated that the German practice applies a general rule, applicable without distinction to all vitamin preparations regardless of the vitamin in their composition, which classifies them as medicinal products where they contain more than three times the recommended daily amount.

60 That practice does not therefore make a distinction in relation to the different vitamins in the preparations examined, even though it is common ground that no vitamin has the same effects on health in general, and, in particular, no vitamin has the same degree of potential harmfulness. As it is applicable without distinction, the triple amount rule can therefore have the effect of classifying certain vitamin preparations as medicinal products even though they are not capable of 'restoring, correcting or modifying human physiological functions'.

61 The German Government contends that, since the recommended daily amount has been individually determined for each vitamin on the basis of its particular characteristics, the triple amount rule leads to results which also take account of those characteristics.

62 However, classification as a medicinal product of a vitamin preparation which is based solely on the recommended daily amount of the vitamin it contains, namely the amount which potentially covers the requirements for that vitamin of all persons in good health in the population group under consideration, does not fully satisfy the requirement for a classification on the basis of the pharmacological properties of each vitamin preparation. Consequently, even though it is true that the concentration of vitamins above which a preparation is classified as a medicinal product in accordance with the triple amount rule varies according to the vitamin in question, it does not necessarily follow that all vitamin preparations containing more than three times the recommended daily amount come within the definition of a 'function' medicinal product for the purposes of Directive 65/65.

63 In those circumstances, it is appropriate to determine, secondly, whether the requirement of a marketing authorisation as a medicinal product, prescribed by the German practice, constitutes a measure having an effect equivalent to a quantitative restriction on imports, prohibited by Article 30 of the Treaty, and, if

so, whether such a requirement may nevertheless be justified on grounds of public health referred to in Article 36 of the Treaty.

64 The prohibition on measures having an effect equivalent to quantitative restrictions laid down in Article 30 of the Treaty relates to all rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, inter alia, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5, and Case C-192/01 *Commission* v *Denmark* [2003] ECR I-4693, paragraph 39).

65 In the present case, the German practice creates a barrier to trade, in so far as vitamin preparations lawfully marketed or produced in other Member States as food supplements cannot be marketed in Germany until they have been subject to the marketing authorisation procedure for medicinal products.

66 The Court has already ruled that a product which is not a medicinal product within the meaning of the provisions of Article 1(2) of Directive 65/65 may, subject to Article 30 et seq. of the Treaty concerning products imported from other Member States, be subject in the domestic law of a Member State to the rules governing medicinal products (*Van Bennekom*, cited above, paragraphs 15, 30, 31 and 38; Case 35/85 *Tissier* [1986] ECR 1207, paragraph 22; and Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 42).

67 In those circumstances, it is necessary to determine whether the German practice can be justified on the basis of Article 36 of the Treaty.

68 In that respect, it is for the Member States, in the absence of harmonisation and in so far as there are uncertainties in the present state of scientific research, to decide on the degree of protection of the health and life of humans they intend to ensure and on the requirement for an authorisation prior to placing foodstuffs on the market, having regard, however, to the requirements of the free movement of goods within the Community (*Sandoz*, cited above, paragraph 16; *Van Bennekom*, cited above, paragraph 37; *Commission* v *Denmark*, cited above, paragraph 42; and Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 49).

69 That discretion relating to the protection of public health is particularly important when it is established that there are uncertainties in the present state of scientific research into certain substances, such as vitamins which are not as a general rule harmful in themselves but may have particular harmful effects solely if taken to excess as part of a general diet, the composition of which is unforeseeable and cannot be monitored (*Sandoz*, paragraph 17; *Commission* v *Denmark*, paragraph 43; and *Commission* v *France*, paragraph 50, all cited above).

70 Community law does not therefore, in principle, preclude a Member State from prohibiting, save with prior authorisation, the marketing of foodstuffs incorporating nutrients, such as vitamins other than those whose addition is lawful under Community legislation (*Commission* v *Denmark*, paragraph 44, and *Commission* v *France*, paragraph 51, both cited above).

71 However, 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; they must be proportional to the

objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see *Sandoz*, paragraph 18; *Van Bennekom*, paragraph 39; *Commission* v *Denmark*, paragraph 45; and *Commission* v *France*, paragraph 52, all cited above).

72 Furthermore, since Article 36 of the Treaty provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it 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 that provision and, in particular, that the marketing of the products in question poses a real risk to public health (*Sandoz*, paragraph 22; *Van Bennekom*, paragraph 40; *Commission* v *Denmark*, paragraph 46; and *Commission* v *France*, paragraph 53, all cited above).

73 In the present case, the Commission alleges that the German practice is disproportionate, on the ground that it is not based on case-by-case analysis but on a general and systematic approach. It is therefore necessary to establish whether the objective of the protection of public health pursued by that practice could not have been attained by measures which are less restrictive of intra-Community trade.

74 Although, as was noted in paragraph 70 of this judgment, Community law does not, in principle, preclude a system of prior authorisation, the issue of a marketing authorisation for the vitamin preparations concerned as medicinal products is subject to particularly strict requirements.

75 Under Article 4 of Directive 65/65, in order to obtain a marketing authorisation, the person responsible for placing the product on the market is to attach various particulars and documents, including qualitative and quantitative particulars of all the constituents of the medicinal product (Article 4(3)), a brief description of the method of preparation (Article 4(4)), therapeutic indications, contra-indications and side-effects (Article 4(5)), posology, pharmaceutical form, method and route of administration and expected shelf life (Article 4(6)), description of control methods employed by the manufacturer (Article 4(7)), results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials (Article 4(8)). Moreover, the person responsible for placing the product on the market is to provide proof that the manufacturer is authorised in his own country to produce medicinal products (Article 4(10)).

76 Further, the rules are much more strict for medicinal products than for foodstuffs as regards distribution (see Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use (OJ 1992 L 113, p. 1)), sale (see Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use (OJ 1992 L 113, p. 5) and Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8)), and advertising (see Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13)).

77 In those circumstances, the German practice may be regarded as proportionate only if the prohibition on marketing as foodstuffs the vitamin preparations concerned and the obligation to obtain a marketing authorisation for medicinal

products are both actually necessary, in each particular case, to ensure the safeguarding of public health.

78 That practice makes the marketing of all vitamin preparations containing three times the recommended daily amount automatically subject to the issue of a marketing authorisation for medicinal products, without making a distinction by reference to the different vitamins added or in particular to the level of risk to public health which their addition could entail.

79 Accordingly, the automatic nature of that practice does not make it possible to identify and assess a real risk to public health, which requires a detailed assessment on a case-by-case basis of the effects which the addition of the vitamins in question could entail (see, to that effect, *Commission* v *Denmark*, cited above, paragraph 56).

80 The issue of a marketing authorisation for medicinal products is therefore also required to market a vitamin preparation which would not pose a real risk to public health.

81 A less restrictive measure would be to fix, for each vitamin or group of vitamins on the basis of its pharmacological properties, a threshold value above which preparations containing one of those vitamins are subject, under national law, to the rules governing medicinal products, while below that value those preparations would obtain a simple product authorisation.

82 It is true that evaluation by the competent German authorities of the pharmacological properties of each vitamin or group of vitamins for the purposes of classification of vitamin preparations may correctly lead to the same result as the triple amount rule in some cases. However, that consideration has no bearing on the outcome of this infringement action. As was noted in paragraph 73 of this judgment, it is the automatic nature of that rule and the fact that it is not based on a case-by-case analysis which are the subject-matter of this action.

83 It follows from all the foregoing considerations that, by automatically classifying as medicinal products vitamin preparations lawfully manufactured or marketed as food supplements in the other Member States where they contain three times more vitamins, other than vitamins A and D, than the daily amount recommended by the German Food Association, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the Treaty.

Costs

84 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Federal Republic of Germany has been unsuccessful, the latter must be ordered to pay the costs. In addition, under Article 69(4) of the Rules of Procedure, the Member States and the institutions which have intervened are to bear their own costs. The Kingdom of Denmark and the Republic of Finland must therefore be ordered to bear their own costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. Declares that, by automatically classifying as medicinal products vitamin preparations lawfully manufactured or marketed as food supplements in the other Member States where they contain three times more vitamins, other than vitamins A and D, than the daily amount recommended by the Deutsche Gesellschaft für Ernährung (German Food Association), the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EC Treaty (now, after amendment, Article 28 EC);

2. Orders the Federal Republic of Germany to pay the costs;

3. Orders the Kingdom of Denmark and the Republic of Finland to bear their own costs.

Skouris Cunha Rodrigues Schintgen

Macken Colneric

Delivered in open court in Luxembourg on 29 April 2004.

R. Grass

Registrar

V. Skouris

President