European Court of Justice, 29 April 2004, Commission v Germany

PHARMACEUTICAL LAW

Food preparations containing three times more vitamins than the recommended daily amount

- **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).**

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European Court of Justice, 29 April 2004

(V. Skouris, J.N. Cunha Rodrigues, R. Schintgen, F. Macken and N. Colneric)

JUDGMENT OF THE COURT (Sixth Chamber)

29 April 2004 (1)

(Failure of a Member State to fulfil obligations – Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC) – Directive 65/65/EEC – Food preparations containing three times more vitamins than the recommended daily amount – Preparations lawfully marketed as food supplements in the Member State of exportation – Preparations classified as medicinal products in the Member State of importation – 'Medicinal product' – Obstacle – Justification – Public health – Proportionality – Admissibility of the application)

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,

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 – B1, B2, B6, B12 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-0000, 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□0000, 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 (VanBennekom, cited above, paragraphs 15, 30, 31 and 38; Case 35/85 Tissier [1986] ECR 1207, paragraph 22; and Case C-219/91 TerVoort [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; VanBennekom, cited above, paragraph 37; Commission v Denmark, cited above, paragraph 42; and Case C-24/00 Commission v France [2004] ECR I-0000, 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; VanBennekom, 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; VanBennekom, 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.

OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 16 May 2002 (1)

Cases C-387/99

Commission of the European Communities

v

Federal Republic of Germany

and C-150/00

Commission of the European Communities

v

Republic of Austria

supported by

Kingdom of Denmark

Republic of Finland

(Failure to fulfil obligations – Article 28 EC – National administrative and legal practice according to which certain vitamin and mineral preparations that are lawfully manufactured or marketed in other Member States as food supplements are regarded as being medicinal products)

I – Introduction

1. In Case C-387/99 the Commission requests the Court to declare that by classifying as medicinal products vitamin and mineral preparations which are lawfully produced or marketed 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 (German Food Association), the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC (ex Article 30 of the EC Treaty).

2. In Case C-150/00 the Commission requests the Court to declare that by classifying vitamin and mineral preparations as medicinal products where they exceed the basic daily amount and, more generally, when they contain vitamins A, D and K or mineral substances in the chromate group, without demonstrating that the increased vitamin content or the vitamins or minerals content poses a serious danger to health, the Republic of Austria has failed to fulfil its obligations under Article 28 EC.

II – The legal background

A – Community Law

3. Pursuant to Article 28 EC quantitative import restrictions and all measures having equivalent effect are prohibited between Member States. In accordance with Article 30 EC the provisions of Article 28 EC are not to preclude prohibitions or restrictions on imports justified, among others, on the grounds of the protection of health and life of humans.

B – National Law

Case C-387/99

4. Paragraph 1, first subparagraph, of the German law on foodstuffs and consumer goods (Duitse Lebensmittel- und Bedarfgegenständegesetz) (hereafter 'LMBG') defines food as products destined for human consumption. Paragraph 2, first subparagraph, of the law on medicinal products determines when a product is to be designated as a medicinal product. In the event that a product fulfils both a food and a medicinal requirement, the circumstances of the particular case at issue determine classification as either a foodstuff or a medicinal product. In reaching this classification the generally prevailing objective opinion of the average consumer is decisive.

5. Paragraph 47a of the LMBG lays down the principle of mutual recognition between the Member States. According to this paragraph the principle of mutual recognition does not apply to an approval procedure for foodstuffs, if under German law the product in question is a medicinal product. Only in an approval procedure for medicinal products could the therapeutic efficacy of the product concerned be demonstrated with any certainty.

– Case C-150/00

6. Under Paragraph 18, first subparagraph, of the Austrian Foodstuffs Law (Lebensmittelgesetz) (hereafter 'LMG') foodstuffs must be declared to the competent authorities before they are placed on the market. In accordance with Paragraph 18, second subparagraph, the authorities must give notice of any eventual ban on marketing a product as a foodstuff within three months. The competent authorities must institute an administrative procedure within the period mentioned in Paragraph 18, second subparagraph, to investigate the declaration. This investigation results in an expert's report that is communicated to the applicant, who has two weeks to react to it.

III – Facts and procedure

Case C-387/99

7. On 7 April 1998 the Commission sent the Federal Republic of Germany a letter of formal notice, because the Commission considered that the practice followed by the German administrative authorities and courts whereby vitamin and mineral preparations, lawfully manufactured or marketed as food supplements in other Member States, were designated as medicinal products when they contain over three times the recommended daily amount, was incompatible with the principle of the free movement of goods enshrined in Article 28 EC.

8. The Commission was of the opinion that the practice concerned constituted a trade barrier that could not be justified in terms of public health or the protection of consumers on the basis of Article 30 EC, since the practice was contrary to the principle of proportionality. The German practice did not take into account the fact that when amounts are increased the harmfulness threshold for vitamins is not reached at the same rate for all vitamins. The Commission maintains that such a view, whereby the strictest standard is applied to all vitamins, is disproportionate to the goal of protecting human health.

9. In reaction to the formal notice the German Government defended the German practice in a letter dated 12 June 1998, by stating that this practice was justified in terms of the protection of the consumer. On 30 December 1998 the Commission sent a reasoned opinion, to which the German Government responded in a letter dated 14 April 1999. The German Government maintained its viewpoint that the practice followed by the German administrative authorities and courts was in conformity with Community law.

10. On 8 October 1999 the Commission brought an action before the Court. By orders of 7 April and 10 May 2000 the Kingdom of Denmark and the Republic of Finland respectively were granted leave to intervene in support of the forms of order sought by the Federal Republic of Germany.

11. Written observations from the German Government, the Danish Government, the Finnish Government and the European Commission have been lodged at the Court. The German Government and the European Commission expounded their arguments at the hearing of 21 February 2002.

Case C-150/00

12. On 6 November 1998 the Commission sent the Republic of Austria a letter of formal notice, because the Commission considered that the practice followed by the Austrian administrative authorities and courts of designating vitamin and mineral preparations as medicinal products and the application of Paragraph 18 of the LMG regarding the notification procedure for foodstuffs were incompatible with the principle of the free movement of goods as enshrined in Articles 28 and 30 EC and in the case-law of the Court.

13. In letters dated 15 January and 18 February 1999 respectively, the Austrian Government submitted a list that serves as the guideline for applicants in notification submissions. The list also aids the competent authorities in the assessment procedure. The Austrian Government states that this list sets out a threshold limit for each individual vitamin, namely the recommended daily amount, above which a product containing this substance would be considered a medicinal product. If the vitamin content is below the threshold then the product is considered to be a foodstuff. In the event that the threshold limit is exceeded it is the applicant's duty to demonstrate that a particular vitamin preparation does not present any danger to health. The Austrian Government states that products containing vitamins A, D and/or K are classified as medicinal products because of the risks attached to overdosing. The Austrian Government also points out that the threshold limits on the list vary according to the vitamins and the amounts indicated. Furthermore, the basic daily amount serves only as a delimitation criterion.

14. In the reasoned opinion sent on 3 September 1999 the Commission maintained its grounds for complaint, with the exception of the objection regarding Paragraph 18 of the LMG. In response to this the Austrian Government stated in a letter dated 28 October 1999 that the practice followed by its administrative authorities and courts was in accordance with the case-law of the Court.

15. On 19 April 2000 the Commission brought an action before the Court. By order of 27 October 2000 the Kingdom of Denmark and the Republic of Finland were granted leave to intervene in support of the form of order sought by the Republic of Austria.

16. Written observations were submitted by the Austrian, Danish and Finnish Governments and by the European Commission. The oral proceedings in this case took place on 7 March 2002.

IV – Arguments of the parties

Case C-387/99

17. The Commission is of the opinion that the classification as medicinal product of all vitamin and mineral preparations when they contain over three times the daily amount, without taking into account the pharmacological properties of each of the vitamins, is too general. In this regard the Commission refers to Van Bennekom (2) in which the Court gave general indications, on the basis of which the dividing line between medicinal products and foods can be drawn.

18. Among other things the Commission refers to the paragraphs in which the Court states that in general vitamins may not be regarded as medicinal products when they are consumed in small quantities, inasmuch 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. (3) In the event that vitamin or multivitamin preparations are used for therapeutic purposes, usually in high amounts, then they will of course be classified as medicinal products. The Court ruled, in the case concerned, that the classification of a vitamin as a medicinal product must be carried out case by case, having regard to the pharmacological properties of each such vitamin to the extent to which they have been established in the present state of scientific knowledge. (4)

19. The Commission considers that the classification as medicinal product of all vitamin and mineral preparation, when they contain over three times the daily amount is in contradiction with the scientifically proven fact that when amounts are increased, the harmfulness threshold for vitamins is not reached at the same time for all vitamins. In this connection the Court considered in Sandoz (5) that an excessive consumption of vitamins over a prolonged period may have harmful effects, the extent of which varies according to the type of vitamin, there being generally a greater risk with vitamins soluble in fat than with those soluble in water. The Court also stated that in particular high dose vitamins appear to represent a real danger to health. According to the Commission, to regard all vitamins in global/abstract terms, in such a way as necessarily to apply the strictest criterion, is to go beyond 'what is necessary' in order to achieve the goal of health protection as recognised under Community law.

20. On the basis of the above the Commission concludes that the practice followed by the German administrative authorities and courts with regard to vitamin and mineral preparations is incompatible with Article 28 EC.

21. The German Government questions at the outset the admissibility of the Commission's action. It puts forward the argument that in its request the Commission does not specify which vitamin and mineral preparations the complaint concerns. By not referring to a concrete situation the action relates to all vitamin and mineral preparations. Furthermore, the Commission has not summarised the facts upon which the action is based. The Commission has limited itself to the argument that the vitamin and mineral preparations were lawfully marketed as food supplements in other Member States, without establishing whether this classification is in conformity with Community law.

22. With regard to the distinction between medicinal products and foodstuffs the German Government points out that according to Article 1(2), first subparagraph, of Directive 65/65/EEC (6) medicinal product means 'any substance or combination of substances presented for treating or preventing disease in human beings or animals', and according to the second subparagraph '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' are likewise to be considered medicinal products. Furthermore, the German Government notes that the Court has already stated that the aforementioned directive provides two definitions of the term medicinal product: one definition 'by virtue of its presentation' and one definition 'by virtue of its function'. (7) A product is a medicinal product if it falls under either one of these definitions. According to the German Government it follows from this that the classification as medicinal product is not only designed to protect public health but also to protect the consumer.

23. The German Government observes that the Court has also stated that, so long as harmonisation of the measures necessary to ensure the protection of health is not complete, differences in the classification of products as between Member States may continue to exist. (8) In these circumstances, it is for the national authorities to determine, subject to review by the courts, for each product, whether or not it constitutes a medicinal product. The German Government further asserts that according to the settled case-law of the Court the fact that a product is qualified as being a foodstuff in one Member State does not preclude its being treated as a medicinal product in the another Member State if it possesses the relevant characteristics. (9)

24. The German Government draws attention to the fact that in an action for failure to fulfil obligations, the burden of proof lies with the Commission, who must demonstrate that in that particular case a Member State has wrongly classified a product as a medicinal product. The German Government considers that the Commission has not proven that the German authorities exceeded their power of assessment, in classifying the vitamin and mineral preparations as medicinal products. The Commission has simply asserted that the vitamin and mineral preparations were not classified as medicinal products in other Member States, without demonstrating that the manufacture and marketing of these products in the other Member States was legal. In addition the Commission has not indicated the dosage above which a product is considered a medicinal product nor the dosage above which vitamin and mineral preparations are a danger to health.

25. With regard to the rule concerning the tripling of the daily amount the German Government maintains that this rule is not the sole criterion and that it only serves as a guideline. The Government denies that this rule is applied to all vitamin and mineral preparations. In this respect it refers to the distinction that is made between vitamins soluble in water and those soluble in fat. The rule concerned is only applicable to vitamins B1, B2, B6, C, niacin, folic acid, pantothenic acid and biotin. The rule serves as a guideline for the fat soluble vitamins E and K and does not apply to the fat soluble vitamins A and D, which pose a greater risk to health and for which therefore the normal daily amount applies. With regard to the latter vitamins the action is consequently inadmissible.

26. Furthermore, the German Government is of the opinion that the rule concerning the tripling of the daily amount is justified on the basis of the protection of the consumer, because vitamin and mineral preparations can be classified as medicinal products by virtue of their presentation or by virtue of their function. In this context the German Government refers to Van Bennekom (10) and Glob-Sped. (11) In the latter judgment it was decided that a product with a high vitamin C content must be classified as a medicinal product.

27. The Commission states in its reply that it is indeed for the Member States, in the absence of harmonisation and in so far as uncertainties persist in the present state of scientific research, to decide what degree of protection of the health and life of humans they intend to assure. However, in doing so they must

have regard to the requirements of the free movement of goods within the Community. In particular the proportionality principle must be taken into account.

28. The Commission then states that should it indeed be the case, as the German Government claims in its defence, that the rule concerning the tripling of the daily amount is not applicable to mineral substances, trace elements and vitamins A and D, then it will withdraw its complaint on this issue. The Commission's objection would then concern vitamins B1, B2, B6, C, niacin, folic acid, pantothenic acid, biotin and vitamins E and K.

29. According to the Commission the German Government has not justified the rule concerning the tripling of the daily amount by demonstrating that the aforementioned vitamins constitute a health risk on the basis of their specific pharmacological properties at certain concentrations. A mere statement that the rule concerned is not the only criterion used for the classification as medicinal product is insufficient.

Case C-150/00

30. The Commission is of the opinion that the practice followed by the Austrian administrative authorities and courts of classifying vitamin and mineral preparations as medicinal products, when they exceed the basic daily amount and, more generally, when they contain vitamins A, D and K or mineral substances from the chromate group, is in conflict with Articles 28 and 30 EC and with the case-law of the Court. In view of the absence of harmonisation in the area of food supplements Articles 28 and 30 EC are applicable in the present case. Furthermore, referring to Commission v France (12) the Commission states that an administrative practice that shows a certain degree of generality and consistency constitutes a measure prohibited under Article 28 EC. According to the Commission the Austrian practice constitutes such a prohibited measure.

31. The Commission notes that obstacles to free movement within the Community resulting from disparities between the national laws must be accepted in so far as such rules may be recognised as being necessary in order to satisfy mandatory requirements relating in particular to consumer protection or the protection of health and life of humans. Such obstacles are only admissible if the national rule is proportionate to the aim in view. If a Member State has a choice between various measures to attain the same objective it should choose the means which least restricts the free movement of goods. (13)

32. According to the Commission the Austrian practice does not take into account the fact that not all vitamins and minerals are equally harmful. A less restrictive rule would provide for the fixing of a threshold for each individual vitamin or mineral substance, above which a preparation containing this substance would be classified as a medicinal product. The Commission therefore considers that the basic daily amount is too rigid a criterion. In addition the Commission notes that the practice referred to disregards the fact that the Member State concerned must demonstrate for each individual product that its being placed on the market poses a serious threat to health. In this connection the Commission refers to the argument of the Austrian Government that a higher concentration (than the basic daily amount) is allowed if the person submitting the request demonstrates that no risk to health is posed. The Commission considers it unacceptable that the applicant is required to provide the evidence of harmlessness, because in the absence of critical limits established by the scientific committees, it is the Member State that must prove that higher concentrations pose a threat to health.

33. The Commission also objects to the fact that under the Austrian practice products that contain vitamins A, D or K or mineral substances from the chromate group are automatically classified as medicinal products, without it being demonstrated that this classification is justified in terms of health protection.

34. The Austrian Government is of the opinion that the Commission's interpretation of the term medicinal product is not in conformity with Community law. In this context the Austrian Government refers to Article 1(2) of Directive 65/65 where this term is defined. (14) The Austrian Government considers that in view of the fact that the directive provides two definitions of the term medicinal product, one definition 'by virtue of its presentation' and one definition 'by virtue of its function', the risk to health is not a criterion in determining whether a product should be deemed to be a medicinal product.

35. The Austrian Government also recalls that in Van Bennekom (15) it was decided that it is for the national authorities to demonstrate in each case that their rules are necessary to give effective protection to the interests referred to in Article 30 EC and, in particular, to show that the marketing of the product in question creates a serious risk to public health. According to the Austrian Government this does not mean that vitamin and mineral preparations may be classified as medicinal products only when they pose a serious health risk. It further adds that it would appear from the judgment cited that in view of the uncertainties inherent in scientific assessment, a national rule applying the procedures foreseen in Directive 65/65 to vitamin or mineral preparations presented in a pharmaceutical form or in high concentrations is in principle justified in terms of the protection of human health within the meaning of Article 30 EC.

36. The Austrian Government denies that as a result of the rule concerning the basic daily amount products are automatically classified as medicinal products. According to the Austrian Government the administrative practice takes into account the pharmacological properties of each individual vitamin. An assessment of the properties of the product concerned takes place in each individual case. This assessment also takes account of the nature and the manner of marketing, the application and the pharmaceutical form or the form of the medicinal products. In the light of Van Bennekom, (16) the Austrian practice at issue also complies with the principle of proportionality. The Austrian Government believes that it cannot be concluded from Van Benne-

kom that every vitamin preparation must be approved as a foodstuff.

V – Observations of the interveners

37. I shall deal with the observations submitted in the present cases by the Danish and Finnish Governments together, since the arguments of both Governments in the two cases are largely the same.

38. The Danish Government observes that in Denmark a provision exists that is similar to the rules at issue regarding the tripling of the daily amount and the basic daily amount. In the same way as the German and Austrian rules, the Danish legislation is aimed at protecting the consumer from harmful effects of high levels of vitamins and minerals in food supplements. The Danish Government points out that it is generally recognised that an overdose of both water and fat soluble vitamins can have harmful effects.

39. Furthermore, the Danish Government points out that the risk of interaction between various vitamins can lead to serious disturbances. In this connection the Danish Government cites a number of vitamins that in high doses and when used simultaneously can cause disturbances. In view of the fact that it is not possible in the present state of scientific knowledge to determine which vitamins or minerals could be harmful when the recommended daily amount is exceeded, the Danish Government considers it justified to adopt a restrictive approach with regard to the levels of vitamins and minerals permitted in food supplements.

40. With regard to the distinction between medicinal products and food supplements, the Danish Government also refers to Directive 65/65. (17) The Danish Government states that it would appear from the settled case-law of the Court that the 'presentation' criterion used in the directive is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective, or do not have the effect which their presentation might lead to expect, in order to preserve consumers not only from harmful or toxic medicinal products as such, but also from a variety of products used instead of the proper remedies. (18) Consequently a product that is expressly represented or recommended as having therapeutic or prophylactic properties should be considered to be a medicinal product 'by virtue of its presentation', even when no actual therapeutic effect is known.

41. Referring to Van Bennekom (19) the Danish Government states that it is impossible in the present state of scientific knowledge to determine whether the criterion of concentration alone is always sufficient in order to be able to establish whether a vitamin preparation constitutes a medicinal product. Still less is it possible to specify the level of concentration above which a vitamin preparation falls within the definition of a medicinal product. It is apparent from the settled case-law of the Court (20) that the fact that a product is not considered to be a medicinal product in one particular Member State is not relevant in determining whether or not the product concerned can be classified as a medicinal product. In this context the Danish Government refers to the wide discretion of the Member States with regard to the degree of protection they wish to provide for the health and the life of humans.

42. Finally, the Danish Government states that the rules regarding the tripling of the daily amount and the basic daily amount are in conformity with the principle of proportionality. The Danish Government considers the burden of proof, which requires that the Member States demonstrate that the national rule regarding maximum limits does not go further than what is necessary to protect human health, to be lower as a result of the scientific uncertainty regarding the level at which a threat to human health arises.

43. The Finnish Government argues that it is for the Member States to lay down rules regarding the maximum permitted levels of vitamins and minerals in foodstuffs, in view of the fact that no Community provisions exist in that area. Consequently, the Finnish Government considers that in the present cases the maximum limits laid down for vitamins and minerals do not conflict with Community law.

44. The Finnish Government states that in the majority of Member States these maximum limits are established with the cooperation of food scientists and medical experts, taking into account both the pharmacological effects of a particular substance and the protection of consumer health. In these circumstances it is up to the Member States to determine in specific cases whether certain vitamins and mineral preparations should be classified as medicinal products within the meaning of Directive 65/65.

45. The Finnish Government goes on to state that even if Article 28 EC were applicable, the German and Austrian practices are justified in terms of the protection of consumers and of health. Inasmuch as the incorrect use of vitamins and minerals can pose a threat to public health, vitamin and mineral preparations which exceed the recommended daily amount should be classified as medicinal products.

VI – Assessment

Introduction

46. The cases at issue concern the compatibility with Articles 28 and 30 EC of German and Austrian administrative practices applied to vitamin or mineral enriched food supplements. The public health interests presented by these cases are not at issue. The criticism of the Commission is essentially directed at the manner in which the Germans and Austrians have set standards.

Admissibility

47. Before going into the substance of the cases it is first necessary to consider the admissibility aspect. The German Government disputes the admissibility of the Commission's action. The German Government has argued that the Commission's action against Germany does not specify the vitamin and mineral preparations to which the complaint relates and that the complaint is not substantiated by reference to a concrete example.

48. In both cases the Commission's objection relates to practices followed by the administrative authorities and courts. It is settled case-law that these practices may also be the subject of an infringement procedure.

(21) In the present cases I believe that the Commission has stated the object of the procedure in sufficiently clear terms. The cases do not concern a specific vitamin or mineral preparation but rather a practice followed by the administrative authorities and courts whereby food supplements are 'automatically' deemed to be medicinal products if a certain limit is exceeded, thereby ignoring the fact that the harmful effects (or the therapeutic aspects) which can occur when an overdose is taken, vary from one vitamin or mineral preparation to another. It is also settled case-law that in proceedings for failure to fulfil an obligation, it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled. (22) Whether the Commission has sufficiently demonstrated the alleged failure is an issue that should be dealt with in the consideration of the substance of the case.

On the substance of the case

49. The key question posed in both cases is whether a national legal or administrative rule setting a general upper limit for the presence of vitamins and minerals in food supplements is justified in terms of the protection of public health, and, if it is justified, whether it is also proportional.

50. Both cases concern vitamin and mineral preparations that are lawfully marketed as food supplements elsewhere in the Community. Nor is it disputed that a great variety of vitamins and minerals are covered by a general standard in Germany and Austria. A recommended daily amount is applied to each vitamin and mineral. The general standard then states that this value may not be exceeded by a factor of three or a factor of one respectively. As a result preparations that are lawfully marketed as foodstuffs elsewhere in the Community may not be marketed as such in Germany and Austria. This results in a quantitative import restriction within the meaning of Article 28 EC. However, Article 30 EC provides a ground for justification for national measures that aim to protect public health. In this regard a number of preconditions must be met.

51. First of all, Community measures must be absent. Furthermore, the national measure must be targeted at a permissible goal, the measure taken must be relevant in order to achieve that goal and the measure must be indispensable and proportional. It is apparent from case-law that it is for the Member States to demonstrate that a national rule complies with the necessity criterion and is proportional to the goal targeted by the measure. (23)

52. A proposal exists 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, (24) which, although it is in an advanced stage of the adoption process, (25) has not yet been adopted. The first precondition is thus met. The German and Austrian Governments have indicated that Community legislation (Directive 65/65) does exist in the area of medicinal products. I shall return to this aspect later in my conclusions. I shall limit myself here to pointing out that this directive does not define what should be classified as a medicinal product and what as a food supplement and that therefore, in the current state of Community law, it is still possible for one Member State to classify a food supplement as a foodstuff, whilst the same food supplement is classified as a medicinal product in another Member State.

53. There can be no doubt that in the present case a public health interest exists, namely the protection of the consumer against the possible effects on health that the excessive consumption of vitamins and minerals could have. As such this interest justifies that the Member States take appropriate measures. The Court allows Member States a wide discretion in the adoption of health protection measures, provided that no harmonised measures exist, the state of scientific knowledge still leaves questions open and these measures deal effectively and in a proportional way with the interest to be protected. (26)

54. Both the Austrian and German legislation and practice establish general upper limits for the presence of vitamins and minerals in food supplements and provide that preparations which exceed this upper limit are to be classified as medicinal products and must therefore comply with the procedural approval conditions arising from national medicinal product legislation as harmonised by Directive 65/65.

55. Although a ban on the marketing of food supplements containing levels of vitamins or minerals above a certain general limit is undoubtedly useful and effective, and has the attraction of simplicity, nevertheless one should question whether such a measure does not go beyond what is strictly necessary.

56. A simple general rule has the advantage that it is transparent for the sellers and can be easily carried out and enforced by the public authorities. The disadvantage of such a rule is that it can exclude products from being marketed as foodstuffs, without it being established that they are, or could be, a real danger to health. Both the German administrative practice and the Austrian legislation have such far-reaching consequences, since they both classify products as medicinal products, and therefore exclude them from being foodstuffs, despite the fact that such a classification does not necessarily follow from the medicinal products directive.

57. The next question that arises is whether a comparable level of health protection can be offered by more appropriate means, without this having such serious consequences for the free movement of goods. The answer is in the affirmative as shall be demonstrated below.

58. In Van Bennekom (27) the Court held that the consequence of general legislation, namely that large groups of products are classified as medicinal products when they are not, is disproportionate and that therefore an assessment must be carried out case by case as to whether the products concerned really do pose health risks.

59. In this respect the Court adopted the following line of reasoning: that generally vitamins in low concentrations cannot be classified as medicinal products

(paragraph 26), whereas with regard to vitamins in high concentrations this may well be the case (paragraph 27); that in the present state of scientific knowledge the criterion of concentration alone is insufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product, still less therefore to specify the level of concentration above which such a vitamin preparation would fall within the Community definition of a medicinal product (paragraph 28); and that consequently an assessment must be carried out case by case as to whether a vitamin preparation is to be classified as a medicinal product (within the meaning of the second part of the definition in Directive 65/65). (28)

60. Then in paragraphs 32 to 41 of this judgment the Court tests the relevant national legislation against Articles 28 and 30 EC, taking it for granted that certain vitamin and mineral preparations do not fall under the Community definition of medicinal product. The Court refers to the fact that it has already had occasion to affirm in Sandoz (29) that the excessive consumption of vitamins over a prolonged period may have harmful effects, the extent of which varies according to the type of vitamin, there being generally a greater risk with vitamins soluble in fat than with those soluble in water and that it is principally in high concentrations that vitamins constitute a risk to health. The Court then refers to a consistent line of decisions in which it has stated that, in so far as uncertainties persist in the present state of scientific research, it is for the Member States, in the absence of harmonisation, to decide what degree of protection of health and life of humans they intend to ensure. These principles also apply to substances such as vitamins, which are not as a general rule harmful but may have special harmful effects if taken to excess, provided that the principle of proportionality is observed. It is for the national authorities to demonstrate in each case that their rules are necessary and, in particular, to show that the marketing of the product in question creates a serious risk to public health. (30)

61. The Court is not alone in adopting a 'case by case' approach; the proposal for a directive on food supplements also adopts such an approach. In accordance with this directive maximum amounts must be established per vitamin and mineral. The development of Community law therefore appears to be based on a standard applicable per vitamin or mineral. In the light of case-law and the development of Community law as apparent from the proposed directive, each Member State would have to demonstrate that a differentiated approach was not possible with regard to the preparations concerned. (31)

62. Likewise in the light of the abovementioned case-law and legal developments the Member States are still obliged to demonstrate, where possible, on a case by case basis, which standards may justifiably be applied to the dosage in order to protect public health.

63. Incidentally I would comment upon the fact that there are situations in which general rules could be acceptable for certain groups or categories of products. This is especially so when the products belonging to such a category or group pose the same or very similar risks to health. In such a situation an assessment per group or category is acceptable and the advantage of more transparency and limited implementation and enforcement burdens outweighs the more graduated consequences for the free movement of goods.

64. Neither the German Government nor the Austrian Government have been able to demonstrate that a less restrictive rule, whereby the preparations concerned would be evaluated either on a case to case basis or by group or category, would not be possible.

65. Nor do the remaining arguments presented in both proceedings convince me.

66. I do not consider the Austrian Government's argument that the product can at least still be marketed as a medicinal product to be valid. In fact, for traders, the classification as a medicinal product or as a foodstuff has consequences for their market behaviour. The sale, distribution and advertising of medicinal products are subject to far stricter rules than that of foodstuffs. Furthermore, in the context of Directive 65/65 to obtain approval as a medicinal product expensive testing is necessary. According to the German practice, it is even possible that vitamin and mineral preparations cannot be marketed as medicinal products because they have no therapeutic efficacy.

67. The German and Austrian Governments also refer to the broad interpretation that the Court has given to the 'presentation criterion'. Indeed the medicinal products directive does not only pertain to medicinal products having a genuine therapeutic effect (definition 'by virtue of its function'), but also to medicinal products which are not sufficiently effective or do not have the effect which their presentation might lead consumers to expect (definition 'by virtue of its presentation'). In the context of consumer protection the Court has interpreted the term 'presentation' in a broad sense.

68. Vitamin and mineral preparations are often presented in the form of tablets or capsules. However, it should not be assumed on the basis of this fact alone that they are medicinal products. Since, if this were the case, certain foodstuffs that are traditionally presented in a similar form to pharmaceutical products would also be covered. (32) In this respect, as the Bundesgerichtshof has also remarked, it is the therapeutic or prophylactic efficacy that is of primary importance. (33) Moreover the consumer can be informed of the recommended daily amount, the maximum, the aim and the use of the food supplement via labelling or the insert leaflet.

69. With regard to the customs classification and the argument of the German Government based on Glob-Sped (34) the following reference in that judgment seems to me to be relevant:

'21. Chapter 30 of the Explanatory Notes to the combined nomenclature of the European Communities (OJ 1994 C 342, p. 1) also states, under "General", that:

"The description of a product as a medicament in Community legislation (other than that relating specifically to classification in the combined nomenclature) or in the national legislation of the Member States, or in

any pharmacopoeia, is not the deciding factor in so far as its classification in this chapter is concerned."'

70. I am of the opinion that it can be deduced from this that the classification of a product as a medicinal product for customs purposes does not necessarily mean that a similar product should also be classified as a medicinal product within the meaning of the medicinal products directive.

71. I consider the implicit argument of the German and Austrian Governments, that the Commission should have indicated which standards they should have applied, to be untenable. The Commission does not have the competence to prescribe how the Member States are to make use of their discretionary competences under Article 30 EC. It must ensure that these competences are used in accordance with Community law. Furthermore, the Commission duly indicated the method of regulation that it would consider in this instance to be in conformity with the Community principle of proportionality, namely a method which took into account the fact that, when amounts are increased, the harmfulness thresholds are different depending on the vitamin or group of vitamins.

72. Finally, on this point, I would state that the Danish Government's opinion that the burden of proof for the Member States should be more limited in the event of scientific uncertainty regarding the level at which the risk of harm arises, and that consequently Member States are within their rights in adopting general and strict approval standards, cannot be accepted as such. This uncertainty still allows for the possibility of a differentiated approach with regard to the maximum levels justified per vitamin or group of vitamins in the light of those uncertainties.

73. Finally, it should be noted that from a comparison of the two systems at issue, it appears that there are several possible opinions with regard to the desired level of protection and also accordingly as regards the consequences for intracommunity trade. It is evident that the German authorities favour a rule that would forbid doses exceeding three times the recommended daily amount for the majority of the vitamin and mineral preparations concerned; the Austrian authorities believe that the threshold should be placed at doses exceeding the single daily amount. In addition, the Austrian authorities consider that preparations containing Vitamin A, D and/or K should be classified automatically as medicinal products, regardless of their dose; the same applies to mineral substances from the chromate group. The German authorities believe that a preparation that contains vitamin A or D is to be classified as a medicinal product only if the preparation contains in excess of the single recommended daily amount.

74. From this comparison it is apparent that the Austrian regulation and practice are stricter or more restrictive than the German. It is true that the Austrian Government has asserted that rebuttal is possible, however it has not been able to demonstrate that this is anything more than a formal possibility.

75. In any event, the Court permits differences with regard to the level of protection, provided the measure adopted to protect the interest at stake is appropriate and respects the principle of proportionality. As already observed above, neither of the regulations takes into account the fact that when amounts are increased the harmfulness threshold per vitamin or mineral is different. In both cases this is the aspect to which the Commission objects. By not taking any account of this, the German and Austrian measures go further than is necessary in order to protect the public health interest.

Conclusion

76. Therefore, I propose that the Court should:

Case C-387/99

– declare that, by classifying as medicinal products vitamin and mineral preparations which are lawfully produced and marketed 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 (German Food Association), the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC;

– order the Federal Republic of Germany to pay the costs.

In Case C-150/00

– declare that, by classifying vitamin and mineral preparations as medicinal products where they exceed the basic daily amount and more generally, without demonstrating that the increased vitamin content or the vitamins or minerals content poses a serious danger to health, the Republic of Austria has failed to fulfil its obligations under Article 28 EC;

– order the Republic of Austria to pay the costs.

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1 – Original language: Dutch.

2 – Case 227/82 [1983] ECR 3883.

3 – Van Bennekom, cited in footnote 2, paragraph 26 and following.

4 – Van Bennekom, cited in footnote 2, paragraph 29.

5 – Case C-174/82 [1983] ECR I-2445.

6 – Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ, English Special Edition 1965-66(I), p. 24.

7 – See among others Case C-369/88 Delattre [1991] ECR I-1487.

8 – See among others Case C-290/90 Commission v Germany [1992] ECR I-3317.

9 – .Delattre, cited in footnote 7.

10 – Cited in footnote 2.

11 – Case C-328/97 [1998] ECR I-8357.

12 – Case 21/84 [1985] ECR 1355.

13 – The Commission refers to Case 178/84 Commission v Germany [1987] ECR 1227.

14 – See point 22 of this opinion.

15 – Cited in footnote 2.

16 – Cited in footnote 2.

17 – Cited in footnote 6.

18 – Case C-219/91 Ter Voort [1992] ECR I-5485.

19 – Cited in footnote 2.
20 – .Delattre, cited in footnote 7.
21 – .Commission v France, cited in footnote 12.
22 – See for example Case 96/81 Commission v Netherlands [1982] ECR 1791; in Case C-159/94 Commission v France [1997] ECR I-5815; and Case C-55/99 Commission v France [2000] ECR I-11499.
23 – Settled case-law, see among others Case 104/75 De Peijper [1976] ECR 613, paragraphs 16 and 17; Sandoz (cited in footnote 5), paragraph 18; Case 247/84 Motte [1985] ECR 3887, paragraph 23; Case 304/84 Muller and Others [1986] ECR 1511, paragraph 23; Commission v Germany (cited in footnote 13), paragraphs 28 and 44; Case C-42/90 Bellon [1990] ECR I-4863, paragraph 13.
24 – COM(2000) 222 final (OJ 2000 C 311, p. 207).
25 – On 21 February 2002 the European Parliament approved the proposal at its second reading.
26 – I have already expressed my opinion that the principle of proportionality is not a static concept, but should rather be examined in the light of the intended objective, in my Opinion in Case C□121/00 Hahn [2002] ECR I-9193
27 – Cited in footnote 2.
28 – For further detail on this aspect see point 22 of this opinion.
29 – Cited in footnote 5.
30 – Cited in footnote 2, paragraph 40.
31 – The directive has not yet been adopted. However, the system that it chooses does demonstrate that other, less restrictive means are practicable. See also Case C-350/97 Monsees [1999] ECR I-2921. In this case the Court relied on an argument relating to Council Directive 95/29/EC of 29 June 1995 amending Directive 91/628 (OJ 1995 L 148, p. 52), a directive which was adopted at the time that the facts arose, but for which the time-limit for its transposition had still not expired, namely that other measures appropriate to the objective of protecting the health of animals and less restrictive of the free movement of goods were conceivable.
32 – See Van Bennekom, cited in footnote 2, paragraph 19.
33 – BGH, judgment of 25 April 2001 – 2 StR 374/00.
34 – Cited in footnote 11.