OPINION OF ADVOCATE GENERAL GEELHOED
delivered on 16 May 2002 [1]

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.

1 — Original language: Dutch.

B — *National Law*

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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.

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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

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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.

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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

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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.

2 — Case 227/82 [1983] ECR 3883.

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.

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.

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.

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.

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 B_1, B_2, B_6, 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.

10 — Cited in footnote 2.

11 — Case C-328/97 [1998] ECR I-8357.

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 B_1, B_2, B_6, 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.

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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

12 — Case 21/84 [1985] ECR 1355.

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

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

14 — See point 22 of this opinion.

15 — Cited in footnote 2.

16 — Cited in footnote 2.

also complies with the principle of proportionality. The Austrian Government believes that it cannot be concluded from *Van Bennekom* 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.

17 — Cited in footnote 6.

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

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.

19 — Cited in footnote 2.

20 — *Delattre*, cited in footnote 7.

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.

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.

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

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.

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.

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

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

27 — Cited in footnote 2.

28 — For further detail on this aspect see point 22 of this opinion.

29 — Cited in footnote 5.

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 above-mentioned 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.

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.

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

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.

(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 prepara-

tion 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:

In 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.