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

In Case C-150/00,

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

applicant,

v

Republic of Austria, represented initially by H. Dossi and subsequently by C. Pesendorfer, acting as Agents, with an address for service in Luxembourg,

defendant,

* Language of the case: German.

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 vitamin and mineral based preparations as medicinal products where the quantity of vitamin compound exceeds the simple daily amount, and, more generally, where those preparations contain vitamins A, D or K or minerals in the chromate group, without demonstrating that the higher amount of vitamins or their vitamin or mineral content poses a serious health risk, the Republic of Austria has failed to fulfil its obligations under Article 28 EC,

THE COURT (Sixth Chamber),

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

Advocate General: L.A. Geelhoed,
Registrar: M.-F. Contet, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 7 March 2002,

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

gives the following

Judgment

By application lodged at the Court Registry on 19 April 2000, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by classifying vitamin and mineral based preparations as medicinal products where the quantity of vitamin compound exceeds the simple

daily amount, and, more generally, where those preparations contain vitamins A, D or K or minerals in the chromate group, without demonstrating that the higher amount of vitamins or their vitamin or mineral content poses a serious health risk, the Republic of Austria has failed to fulfil its obligations under Article 28 EC.

Relevant provisions

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 1965-1966 (I), p. 24), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('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 3 September 1999, 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).

National legislation

8 It is apparent from the Austrian legislation that products which may be ingested by humans are divided into foodstuffs, consumable products (such as food supplements) and medicinal products. Under Paragraph 3 of the Lebensmittelgesetz (Austrian Law on Foodstuffs; 'LMG') consumable products ('Verzehrprodukte') are products which are intended to be eaten, chewed or drunk by human beings, without being absorbed principally for nutritional or curative purposes.

9 A two-stage examination is carried out in order to ascertain if a product should be regarded as a foodstuff, a consumable product or a medicinal product. First it is determined if the product is absorbed principally for nutritional or gustatory purposes. If that is not its function, as in the case of food supplements, it is then determined if it is a medicinal product.

10 Paragraph 18(1) of the LMG provides that a declaration must be sent to the competent authorities before a consumable product is placed on the market. Pursuant to Paragraph 18(2) of the LMG, the competent authorities are to notify immediately, and at the latest within three months, the prohibition on placing on the market of a product declared as a consumable product which does not satisfy the requirements of the LMG. It is for the competent authorities to initiate a full

administrative procedure within the period laid down in Paragraph 18(2) of the LMG. Under this procedure, the application is examined by experts in pharmacy who draw up a report. The results of the report are notified to the applicant, who has the opportunity to respond within a period of two weeks, and a prohibition notice is issued as necessary.

Pre-litigation procedure

11 The Commission received complaints that, once imported into Austria, consumable products containing vitamins or minerals were classified as medicinal products where their vitamin content, other than vitamins A, D or K, or mineral content, other than those in the chromate group, exceeded the simple daily amount. As for consumable products containing vitamins A, D or K or minerals in the chromate group, those were systematically classified as medicinal products, regardless of their content of nutritive substances.

12 Considering that administrative practice ('the Austrian practice') contrary to Articles 30 and 36 of the EC Treaty (now, after amendment, Articles 28 EC and 30 EC), the Commission sent the Austrian Government a letter of formal notice on 6 November 1998.

13 The Austrian Government replied by letters of 15 January and 18 February 1999. It communicated a list, referred to as 'guidelines' ('the guidelines'), stating that preparations containing vitamins A, D or K or minerals in the chromate group are to be classified as medicinal products and stating the maximal value from which a preparation containing other vitamins and minerals must be classified as a medicinal product. It explained that those guidelines do not contain classification criteria for experts, but a simple description of experience relating to the classification of products. It was a guide intended for those making a product

declaration and an aid for the competent public authorities — when the product in question does not exceed the maximal values stated, the informant does not have to present other documents; on the other hand, when the product exceeds those values, the informant must adduce proof that it does not pose a health risk, failing which the product will be regarded as a medicinal product.

14 The Austrian Government also claims that the maximal values appearing on the list differ according to the vitamin or mineral in question. They correspond to the simple daily amount, which was chosen as a delimiting criterion in order to obtain values which are readily understandable. However, in respect of vitamin C, the maximal content was set at 100 mg, that is to say a value higher than the simple daily amount. In addition, any preparation containing vitamins A, D or K is classified as a medicinal product. According to the Austrian Government, its classification practice is based on the objective medicinal effect, in particular in the therapeutic field.

15 Finding that the Austrian practice showed a certain degree of consistency and generality and considering that it was incompatible with the principle of the free movement of goods, the Commission sent the Republic of Austria a reasoned opinion on 3 September 1999, calling on it to comply within two months of its notification.

16 By letter of 28 October 1999, the Austrian Government replied that the Austrian practice was consistent with the case-law of the Court. It maintained that a full administrative procedure must take place when a product is declared as a consumable product. In order to dispel the Commission's reservations, it stated that the guidelines were not decisive in the classification of products.

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

18 By order of 27 October 2000, the Kingdom of Denmark and the Republic of Finland were given leave to intervene in support of the submissions of the Republic of Austria.

The action

Arguments of the parties

19 According to the Commission, the Austrian practice under which vitamin and mineral based preparations are classified as medicinal products where their vitamin or mineral content exceeds the simple daily amount or where they contain vitamins A, D or K or minerals in the chromate group is contrary to the principle of the free movement of goods enshrined in Articles 28 EC and 30 EC.

20 Relying on Case 21/84 *Commission* v *France* [1985] ECR 1355, the Commission claims that that practice shows a sufficient degree of consistency and generality for the Court to make a finding of incompatibility with Article 28 EC.

21 According to the Commission, it is settled case-law that, in order for obstacles to trade between Member States stemming from disparities between national provisions to be acceptable, those provisions must be justified as being necessary

to fulfil the grounds referred to in Article 30 EC or essential requirements and be proportionate to the objective pursued, and that objective must not be capable of being achieved through measures less restrictive of trade between Member States.

22 The Commission notes that the Court has found that vitamins may not, as a general rule, be regarded as medicinal products where they are consumed in small quantities, but that vitamin preparations used for therapeutic purposes, generally in high dosages, against certain illnesses are unquestionably medicinal products (Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraphs 26 and 27). National rules which regard as medicinal products vitamin preparations with a high concentration are however justified under Article 30 EC on grounds connected with the protection of health, but the Member State must none the less observe the principle of proportionality. In this connection, 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 (*Van Bennekom*, paragraph 40).

23 Concerning, first, vitamins other than vitamins A, D and K and minerals other than those in the chromate group, the Austrian practice under which a consumable product having a vitamin or mineral content above the simple daily amount is normally classified as a medicinal product is inconsistent with the principle of proportionality, since it does not take account of harmful effects of excessive consumption, the extent of which varies according to the type of vitamin or mineral (*Van Bennekom*, paragraph 36).

24 Less restrictive rules would determine, for each type of vitamin and mineral, a value from which that substance could be classified as a medicinal product. Such rules would observe the requirement set out in paragraph 29 of *Van Bennekom*

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.

25 Further, the Austrian practice does not take account of the fact that it is for the Member State to show that the marketing of each product creates a serious risk to public health (*Van Bennekom*, paragraph 40). It is true that the Austrian Government stated that higher concentrations may be authorised when the informant adduces proof that they do not create a public health risk. However, it did not refer to any actual case in which an authorisation had been granted for a concentration higher than the simple daily amount, and the Commission does not know of any. In any event, it is for the Member State to determine the risk connected with the higher concentration, and the informant cannot be required to show that its product is harmless.

26 The Commission takes the view that, even if the Austrian Government contended in its reply to the reasoned opinion that the guidance to applicants in classifying products is not decisive and is not of a binding nature, that assertion does not dispel in any way its doubts as to the Austrian practice. First, it is not the existence of guidance to applicants which is the subject-matter of these infringement proceedings, but the manner in which consumable products are classified by the Austrian authorities under a practice which is sufficiently consistent and general. Therefore, it is immaterial to state that that guidance is not decisive. Secondly, assuming that the Austrian practice has changed, it is for the Austrian Government to show exactly how the new classification system is applied. The Austrian Government cannot merely claim that the relevant factors were taken into consideration. The Commission cannot withdraw the present infringement proceedings without having sufficient proof.

27 In fact, the Commission takes the view that the Austrian practice has not changed. The Court held in *Van Bennekom* that the distinction between foodstuffs and medicinal products must be made on the basis of the pharmacological properties

of each vitamin. The observations of the Austrian Government do not show clearly to what extent the option chosen by the national authorities, which is clearly based on the dietary and physiological daily amount of vitamins and minerals, reflects the Court's findings on the pharmacological properties of the vitamins. The criterion used as the basis for the Austrian practice, which is founded on the dietary and physiological values, is more restrictive than the option accepted by the Court.

28 According to the Commission, the use of fixed values by committees of scientific experts such as the Scientific Committee for Food instituted by Commission Decision 74/234/EEC of 16 April 1974 (OJ 1974 L 136, p. 1) to establish a distinction between foods and medicinal products is compatible with the case-law of the Court. The thresholds set by the committees of experts for vitamins and minerals already contain safety factors which reflect the harmfulness of the different substances. The Commission cites the example of vitamin C, for which the simple daily amount is established at 100 mg whereas, according to a report of the Scientific Committee for Food on nutritive substances and energy consumption in the European Economic Community of 11 December 1992, the absorption of a 1 000 mg quantity does not pose serious danger to health.

29 Secondly, in respect of vitamins A, D and K and minerals in the chromate group, consumable products containing those nutritive substances are systematically classified as medicinal products. It is true that that distinction takes account of the assessment of the Court that harmfulness varies from one vitamin to another. However, the grounds connected to the protection of health justifying that classification are not clear.

30 The Austrian Government maintains that there is no Community provision on harmonisation of the classification of vitamin preparations or preparations containing minerals as foodstuffs or medicinal products and contends that, by complaining that the Austrian authorities classify vitamin preparations or

preparations containing minerals as medicinal products without establishing the existence of a serious risk to public health, the Commission is relying on a meaning of medicinal product which does not reflect the definition given in Directive 65/65. Contrary to the claims of the Commission, the possibility of a serious risk to health is not a criterion for classifying a product as a medicinal product. The criterion is the existence or otherwise of a pharmacological effect. The definition of medicinal product given by the Austrian provisions is in fact consistent with Directive 65/65.

11 According to the Austrian Government, the statement in paragraph 40 of the *Van Bennekom* case 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 36 of the Treaty and, in particular, to show that the marketing of the product in question creates a serious risk to public health' refers to the assessment of the proportionality of a national measure prohibiting distribution in the context of Article 36 of the Treaty. Therefore, there is no ground for inferring that vitamin preparations can be classified as medicinal products within the meaning of Directive 65/65 only when they pose a serious risk to health.

12 Given the uncertainties connected with the scientific assessment, a national rule applying the procedures provided for by Directive 65/65 to vitamin preparations presented in the shape of pharmaceuticals or having a high degree of concentration is, in principle, justified under Article 30 EC.

13 The Austrian practice, which takes account of the pharmacological properties of each vitamin in accordance with the state of scientific knowledge, is proportionate, all the more so because, in this case, there is no marketing prohibition as in *Van Bennekom*, but classification as a medicinal product.

34 The Austrian Government adds that each product is classified by the competent national authorities as a medicinal product at the end of a full administrative procedure and in a reasoned decision. An assessment of the specific nature of the product concerned and corresponding classification is carried out in each case. Not only the vitamin or mineral content but also, and above all, the nature and form of the marketing (indication), type of use, and pharmaceutical form of the product concerned (capsules, effervescent tablets, oils, etc.) are among the parameters taken into account. The guidelines are no longer used for classifying products and, in any event, they never constituted the basis of the classification nor gave the informant the burden of proof in the event that the values set therein were exceeded. Accordingly, there is no systematic classification depending on the 'simple amount' rule.

35 Referring to the case-law of the Court (*Van Bennekom*, paragraph 28; Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 27; and Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, paragraphs 15 and 16), 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.

36 Secondly, it is apparent from Case 174/82 *Sandoz* [1983] ECR 2445, paragraphs 11 and 16 to 18, and *Van Bennekom*, 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.

37 In that regard, the Danish Government notes that as the Austrian practice does not prohibit the marketing of vitamin preparations or preparations containing minerals but only classifies them as medicinal products, the Austrian authorities are not required to show in each case that the classification of those products as medicinal products is necessary to protect effectively the interests referred to in Article 30 EC and, in particular, that the marketing of those products poses a serious risk to public health.

38 The Danish Government concludes that the Austrian practice, and in particular the use of the recommended daily amount as a criterion for the classification as foodstuffs or medicinal products of vitamin preparations or preparations containing minerals, complies with Articles 28 EC and 30 EC, 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.

39 Relying on the *Van Bennekom* judgment, 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 population reference intake values are intended to prevent, restore or modify organic processes, which is in line with the definition of medicinal product. On the other hand, preparations with a vitamin or mineral content below those values are foodstuffs.

40 Secondly, the Finnish Government submits that, assuming that Article 28 EC applies, the Austrian practice is justified in terms of the protection of public health and the health of consumers.

41 In its observations on the statements in intervention, 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, in this case the simple daily amount. 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.

Findings of the Court

42 As a preliminary point, the Austrian Government maintains that the Austrian practice is not as described by the Commission. According to the Austrian Government, it assesses the specificities of each product declared for the purposes of classification as a medicinal product or a foodstuff. The product's vitamin or mineral content is only one of the parameters taken into account. There is no systematic classification on the basis of the guidelines since the other parameters taken into account are as decisive. The guidelines have never in fact constituted the actual basis of classification and have not resulted in an applicant having to prove the properties of the product where the values provided for in the guidelines are exceeded. Moreover they have been declared inoperative following objections made by the Commission.

43 It is therefore necessary to determine whether the Austrian practice was as described by the Commission in its application at the end of the two-month period laid down in the reasoned opinion. It is irrelevant that the guidelines have been declared inoperative because, according to the Austrian Government itself, they were not binding and were merely a tool. As the Commission states, this

infringement action does not relate to the existence as such of those guidelines, but to the way in which consumable products are classified. It is therefore important to establish whether, in practice, the competent Austrian authorities continued to apply the same thresholds referred to in the guidelines for the purposes of classification of vitamin preparations or preparations containing minerals.

44 As regards, first, preparations containing vitamins A, D or K or minerals in the chromate group, it appears from the explanations of the Austrian Government in the oral procedure that the consistent practice of the Austrian authorities has not been changed and preparations are classified as medicinal products irrespective of their content of those nutritive substances.

45 As regards, secondly, preparations containing vitamins other than vitamins A, D or K or minerals other than those in the chromate group, the Austrian Government stated in its reply to the letter of formal notice of 6 November 1998 that for each vitamin a threshold is set above which a product containing that substance is regarded as a medicinal product. After stating that a normal daily diet covers the requirements of vitamins and minerals, it explained that, except for vitamin C, the simple daily amount was chosen as the delimiting criterion to establish easily understandable values and that that practice is proportionate, since it prevents vitamin overdosage. The Austrian Government also stated that, if a product has a higher vitamin content than that provided for in the guidelines, the applicant must adduce proof that there is no risk to health, failing which the product will be regarded as a medicinal product.

46 In those circumstances, the Commission was entitled to consider in its reasoned opinion that the Austrian authorities' practice of classifying as medicinal products preparations with a vitamin or mineral content in excess of the simple daily amount was established and showed a sufficient degree of consistency and

generality to be the subject of an infringement action. Finding that the Austrian Government had not furnished proof that that practice had been changed after the reasoned opinion, it brought the present action.

47 It is therefore for the Austrian Government to show that that practice has been changed within the period laid down in the reasoned opinion. It has not furnished that proof.

48 First, while it claims that the marketing as a foodstuff of a product having a higher concentration of vitamins than the simple daily amount could be authorised, it does not furnish a concrete example of such an authorisation.

49 Secondly, in the oral procedure, the Austrian Government contended that the Commission's complaint that the competent Austrian authorities classify in a general manner all vitamins on the basis of the simple daily amount is unfounded, on the ground that the thresholds for classification as a medicinal product, which correspond to those in the guidelines, are considerably higher than the recommended daily amount as laid down by the Scientific Committee for Food. However, that confirms on the contrary that those thresholds are still applicable when a product is classified as a product for consumption or as a medicinal product.

50 As for the fact that the thresholds are higher than the simple daily amount, the Austrian Government's argument cannot succeed either. It is common ground that 'the population reference intake' suggested for each nutritive substance by the Scientific Committee for Food in its notice of 11 December 1992 is not binding and that the scientific and administrative authorities of each Member State are

free to determine the recommended daily amount for their population. However, except for vitamin C, the Austrian Government has at no time during the pre-litigation procedure or at the written stage of this action disputed that the thresholds in the guidelines correspond to the daily amount as determined by Austria. As for the Commission, it has never claimed that the thresholds corresponded to 'the population reference intake' suggested by the Scientific Committee for Food.

51 In those circumstances, the Austrian Government has not proven that the practice objected to was changed within the period laid down in the reasoned opinion, nor indeed since that date.

52 However, the Commission acknowledged, in the oral procedure and in contrast to what it had claimed until then, that the maximum vitamin C content above which a preparation is classified as a medicinal product, that is to say 100 mg, is higher than the simple daily amount for that vitamin.

53 Since the simple amount rule, the subject of this infringement action, is not applied to vitamin C, the action is in any event unfounded so far as concerns preparations containing that vitamin and no other vitamin or mineral.

54 As regards the other vitamin preparations and preparations containing minerals, it should be stated at the outset that the complaint of the Commission relates only to the systematic classification of vitamin preparations as medicinal products on the sole ground that they contain either vitamins A, D or K or minerals in the chromate group, or more than once the simple daily amount of other vitamins or

minerals. In particular, the Commission does not allege that the Austrian authorities regard as medicinal products, irrespective of their vitamin or mineral content, preparations presented as having curative or preventive properties in relation to human diseases and which hence fall within the definition of 'presentation' medicinal product.

55 These infringement proceedings must therefore be understood to relate to the Austrian practice of systematically classifying as 'function' medicinal products vitamin preparations or preparations containing minerals lawfully produced and marketed as food supplements in the other Member States where they contain either vitamins A, D or K or minerals in the chromate group, or more than once the simple daily amount of other vitamins or minerals.

56 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.

57 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 28 EC (see, to that effect, Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraphs 48, 52 and 53).

58 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*, paragraph 15).

59 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).

60 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).

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

62 Therefore it is appropriate to determine, first, if the vitamin preparations or preparations containing minerals are 'function' medicinal products for the purposes of the second subparagraph of Article 1(2) of Directive 65/65 where they contain vitamins A, D or K or minerals in the chromate group or have a vitamin or mineral content in excess of the simple daily amount.

63 In so far as vitamins or minerals 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 or preparations containing minerals 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 or mineral deficiency. In such cases, it is beyond dispute that those preparations constitute medicinal products (see, in respect of vitamins, *Van Bennekom*, paragraphs 26 and 27).

64 In those circumstances, and in accordance with settled case-law, to determine whether vitamin preparations or preparations containing minerals 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*, 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*, paragraph 17).

65 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*, paragraph 17).

66 First, in respect of vitamins other than vitamins A, C, D and K and minerals other than those in the chromate group, it must be stated that the Austrian practice applies a general rule, applicable without distinction to all vitamin preparations or preparations containing minerals and regardless of the vitamin or mineral in their composition, which classifies them as medicinal products where they contain more than once the simple daily amount.

67 Thus that practice does not make a distinction on the basis of the vitamins or minerals in the composition of the preparations under consideration, although it is common ground that no vitamin or mineral has the same effects on health in general, and in particular no nutritive substance has the same degree of potential harmfulness. Therefore the simple amount rule, in so far as it is applicable without distinction, may have the effect of classifying as medicinal products certain vitamin preparations or preparations containing minerals although they are not capable of 'restoring, correcting or modifying physiological functions in human beings'.

68 It cannot be contended that the simple daily amount has been determined individually for each vitamin and mineral on the basis of its particular characteristics, and that the simple amount rule therefore leads to results which also take account of those characteristics. Classification as a medicinal product of a vitamin preparation or a preparation containing minerals which is based solely on the recommended daily amount of the nutritive substance it contains, namely the amount which potentially covers the requirements for that substance 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 pharmaceutical properties of each vitamin preparation or preparation containing minerals. The Austrian authorities have themselves stated that, in respect of vitamin C, the threshold of 100 mg, which is higher than the simple daily amount of that vitamin, was the lowest threshold in the therapeutic range. Consequently, even though it is true that the concentration of vitamins and minerals above which a preparation is classified as a medicinal product in accordance with the simple amount rule varies according to the vitamin or mineral in question, it does not

necessarily follow that all preparations containing more than once the simple daily amount come within the definition of a 'function' medicinal product for the purposes of Directive 65/65.

69 Secondly, as regards vitamins A, D or K and minerals in the chromate group, the fact that the simple daily amount rule is not applicable to preparations containing nutritive substances shows that the competent Austrian authorities have taken account of their specific characteristics.

70 In support of that classification, the Austrian Government contended in the oral procedure that, on the basis of available scientific knowledge, those nutritive substances can be regarded as dangerous in the event of overdosage, which can easily occur, so that any additional intake of those substances could be under medical supervision only. The Finnish Government also submitted that, in respect of vitamin A, the maximum safe dose is not that far from the recommended dose. Likewise, the Danish Government submitted that the difference between the quantities of liposoluble vitamins necessary for nutritive purposes and the quantities of those substances which are toxic is often slight.

71 As for vitamins A, D and K, even if they are liposoluble vitamins, which it is accepted pose a higher risk of harmfulness than water-soluble vitamins as a rule (see *Sandoz*, paragraph 11, and *Van Bennekom*, paragraph 36), the Austrian Government merely calls to mind the risk of a dangerous overdose, without stating from what quantities there is uncertainty about the harmlessness of intake of those vitamins or the nature of the risks taken if those quantities are exceeded, and without citing the scientific opinions on which it relies.

72 It is true that the Danish Government has indicated that a quantity of vitamin A corresponding to four times the recommended daily amount can be fetotoxic. However, the Austrian practice requires a marketing authorisation as a medicinal product for the marketing of any preparation containing vitamin A, irrespective of content, and therefore even when it is less than the simple daily amount.

73 It is apparent from the Austrian practice that, even if a preparation has an insufficient content of vitamin A, D or K to give rise to a risk of overdosage under normal conditions of use, that preparation is nevertheless classified as a medicinal product.

74 Therefore that practice can have the result that preparations containing vitamins A, D or K are classified as medicinal products, although the content of those nutritive substances is too small to be capable of 'restoring, correcting or modifying physiological functions in human beings'.

75 The Austrian Government also contended in the oral procedure that it is not uncommon for consumers of food supplements to take higher doses than those stated in the instructions, which increases the risk of exceeding the maximal dose. However, almost all products are potentially harmful to health if they are consumed in excessive quantities, so that in order to determine whether a product is a 'function' medicinal product the normal conditions of use should be taken into account.

76 As for minerals in the chromate group, the Danish Government stated that chromate salts (hexavalent chromium — Cr VI) are considerably more toxic than chromium salts (trivalent chromium — Cr III) and that they are not regarded as a

means of absorption of chromium in the draft document harmonising the rules on food supplements in the European Community.

77 That assertion is confirmed by the fact that Annex II to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51), which lists the vitamin and mineral substances which may be used in the manufacture of food supplements, only refers, in respect of chromium, to 'chromium (III) chloride' and 'chromium (III) sulphate'.

78 Even though that directive had not been adopted on the relevant date for the purposes of this action, it supports the analysis of the Austrian Government regarding the harmfulness of preparations containing chromate salts, irrespective of their content, and therefore their capacity to modify physiological functions in human beings.

79 In those circumstances, it is for the Commission to explain the reasons for which the Austrian authorities have, in its opinion, exceeded the bounds of their discretion in classifying preparations containing chromate salts as medicinal products (see, to that effect, *Commission* v *Germany*, paragraph 20; see also, to that effect, Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 72). Clearly, the Commission has not furnished that proof. The action is therefore unfounded so far as concerns those preparations.

80 It follows from the foregoing arguments that, except for chomate salts, the Austrian practice cannot be validated on the basis of Directive 65/65. It is therefore appropriate to determine, secondly, whether the requirement of a marketing authorisation as a medicinal product, for which the Austrian practice

provides, constitutes a measure having an effect equivalent to a quantitative restriction on imports, prohibited by Article 28 EC, and, if so, whether such a requirement may nevertheless be justified on grounds of public health referred to in Article 30 EC.

81 The prohibition on measures having an effect equivalent to quantitative restrictions laid down in Article 28 EC 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-9693, paragraph 39).

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

83 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 28 EC et seq. concerning products imported from other Member States, be subject in the domestic law of a Member State to the rules governing medicinal products (*Van Bennekom*, paragraphs 15, 30, 31 and 38; Case 35/85 *Tissier* [1986] ECR 1207, paragraph 22; and Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 42).

84 In those circumstances, it is necessary to determine whether the Austrian practice can be justified on the basis of Article 30 EC.

85 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*, paragraph 16; *Van Bennekom*, paragraph 37; *Commission* v *Denmark*, paragraph 42; and Case C-24/00 *Commission* v *France*, paragraph 49).

86 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 which 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 Case C-24/00 *Commission* v *France*, paragraph 50).

87 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 or minerals other than those whose addition is lawful under Community legislation (*Commission* v *Denmark*, paragraph 44; and Case C-24/00 *Commission* v *France*, paragraph 51).

88 However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are

less restrictive of intra-Community trade (see *Sandoz*, paragraph 18; *Van Bennekom*, paragraph 39; *Commission* v *Denmark*, paragraph 45; and Case C-24/00 *Commission* v *France*, paragraph 52).

89 Furthermore, since Article 30 EC contains an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health (*Sandoz*, paragraph 22; *Van Bennekom*, paragraph 40; *Commission* v *Denmark*, paragraph 46; and Case C-24/00 *Commission* v *France*, paragraph 53).

90 First, in respect of vitamins other than vitamins A, C, D and K and minerals other than those in the chromate group, it should be noted in the present case that the Commission alleges that the Austrian 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.

91 Although, as was noted in paragraph 87 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 or preparations containing minerals concerned as medicinal products is subject to particularly strict requirements.

92 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)).

93 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)).

94 In those circumstances, the Austrian practice may be regarded as proportionate only if the prohibition on marketing as foodstuffs the vitamin preparations or preparations containing minerals 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. The argument of the Austrian Government that that practice is necessarily proportionate on the

ground that the preparations concerned can in any case be marketed as medicinal products cannot therefore be accepted.

95 The Austrian practice makes the marketing of all preparations containing more than once the simple daily amount of those vitamins or minerals automatically subject to the issue of a marketing authorisation for medicinal products, without making a distinction by reference to the different vitamins and minerals added or, in particular, to the level of risk to public health which their addition could entail.

96 Accordingly, the systematic 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*, paragraph 56).

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

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

99 It is true that evaluation by the competent Austrian authorities of the pharmacological properties of each vitamin or group of vitamins and each mineral or group of minerals for the purposes of classification of the preparations concerned may correctly lead to the same result as the simple amount rule in some cases. However, that consideration has no bearing on the outcome of this infringement action. As was noted in paragraph 90 of this judgment, it is the systematic 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.

100 Secondly, in respect of vitamins A, D and K, as is apparent from paragraphs 71 to 74 of this judgment, the Austrian Government does not explain how, under normal conditions of use, a vitamin preparation is dangerous for health, irrespective of its content of vitamins A, D or K, so that the Austrian practice can have the result that the issue of a marketing authorisation is also required to be obtained for a preparation containing a content of vitamins A, D or K which does not pose a risk to public health.

101 The Austrian practice is therefore also disproportionate so far as concerns preparations containing vitamins A, D or K.

102 It follows from all of the foregoing considerations that, by systematically classifying as medicinal products vitamin preparations and preparations containing minerals lawfully manufactured or marketed as food supplements in other Member States where they contain either more vitamins other than vitamins A, C, D or K, or more minerals other than those in the chromate group, than the simple daily amount of those nutritive substances, or vitamins A, D or K, irrespective of

their content, the Republic of Austria has failed to fulfil its obligations under Article 28 EC. The remainder of the action is dismissed.

Costs

103 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 Republic of Austria has been unsuccessful in its main submissions, 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 systematically classifying as medicinal products vitamin preparations and preparations containing minerals lawfully manufactured or

marketed as food supplements in other Member States where they contain either more vitamins other than vitamins A, C, D or K, or more minerals other than those in the chromate group, than the simple daily amount of those nutritive substances, or vitamins A, D or K, irrespective of their content, the Republic of Austria has failed to fulfil its obligations under Article 28 EC;

2. Dismisses the remainder of the action;

3. Orders the Republic of Austria to pay the costs;

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

Skouris Gulmann Cunha Rodrigues

Macken Colneric

Delivered in open court in Luxembourg on 29 April 2004.

R. Grass V. Skouris

Registrar President