JUDGMENT OF THE COURT (First Chamber)

15 November 2007 *

In Case C-319/05,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 19 August 2005,

Commission of the European Communities, represented by B. Stromsky and B. Schima, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Federal Republic of Germany, represented by M. Lumma and C. Schulze-Bahr, acting as Agents,

defendant,

* Language of the case: German.

THE COURT (First Chamber),

composed of P. Jann, President of the Chamber, R. Schintgen, A. Borg Barthet (Rapporteur), M. Ilešič and E. Levits, Judges,

Advocate General: V. Trstenjak,
Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 19 April 2007,

after hearing the Opinion of the Advocate General at the sitting on 21 June 2007,

gives the following

Judgment

1 By its application, the Commission of the European Communities seeks a declaration from the Court that, by classifying as a medicinal product a garlic preparation in capsule form which does not fall under the definition of a medicinal product by presentation, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 EC and 30 EC.

Legal background

Directive 2001/83/EC

2 The second to the fifth recitals in the preamble to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) state:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.'

3 Under Article 1(2) of Directive 2001/83, 'medicinal product' must be construed as meaning:

'Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product ...'

4 Article 2 of Directive 2001/83 provides:

'The provisions of this Directive shall apply to industrially produced medicinal products for human use intended to be placed on the market in Member States.'

5 According to Article 6(1) of Directive 2001/83:

'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.'

Directive 2002/46/EC

6 Under Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51), 'food supplements' means:

'... foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities'.

7 Under Article 2(b) of Directive 2002/46, 'nutrients' means the following substances:

'(i) vitamins;

(ii) minerals'.

8 Article 11 of Directive 2002/46 provides:

'(1) Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit

or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

(2) Without prejudice to the EC Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.'

Regulation (EC) No 178/2002

9 According to Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), 'food' (or 'foodstuff') means:

'... any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

...'.

10 Article 14(7) to (9) of Regulation No 178/2002 provide:

'7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.'

Pre-litigation procedure

11 The Commission received a complaint from an undertaking whose application for authorisation to import and market a garlic preparation in capsule form was refused by the Federal Ministry for Health on the ground that the product was not a foodstuff but a medicinal product.

12 The product concerned is marketed under the designation 'garlic extract powder capsule'. According to the information provided by the parties, it is an extract obtained using ethanol and incorporated in an excipient (lactose) for the technological purpose of spray drying. Each capsule contains 370 mg of garlic powder extract with an allicin content of between 0.95% and 1.05%, which is the equivalent of 7.4 g of fresh raw garlic.

13 After a lengthy informal exchange, the Commission sent a letter before action of 24 July 2001 to the Federal Republic of Germany in which it concluded that the classification of the garlic preparation concerned as a medicinal product on the basis of a justification such as that put forward when the complaint was being investigated was not compatible with the principle of free movement of goods under Article 28 EC and Article 30 EC and the relevant case-law. The Federal Republic of Germany replied to the letter of formal notice on 5 October 2001.

14 In its reasoned opinion of 17 December 2002, the Commission called on the Federal Republic of Germany to put an end, within two months of receiving the reasoned opinion, to the administrative practices according to which products composed of dried garlic powder which are clearly not labelled or presented as medicinal products are treated as such.

15 Since the Federal Republic of Germany, in its response to the reasoned opinion, stated that the classification of the product concerned as a medicinal product had been re-examined and had to be maintained, the Commission decided to bring the present proceedings.

The action

Arguments of the parties

16 The Commission observes, first of all, that, in addition to protecting human health, the Community provisions relating to medicinal products are intended to safeguard the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general and of the term medicinal product in particular cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.

17 The Commission then submits that, in order to classify the product concerned as a medicinal product by virtue of its function, account must be taken not only of the pharmacological effects but also the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 29).

18 With regard to the pharmacological effects, the Commission does not dispute the fact that the product in question may serve to prevent arteriosclerosis, but points out that that effect may be achieved by taking a dose equivalent to 4 g of raw garlic each day. Therefore, where a product which is claimed to be a medicinal product does nothing more than a conventional foodstuff, it is clear that its pharmacological properties are insufficient for it to be accepted as a medicinal product. According to the Commission, a product which has no more effect on the body than a foodstuff has not reached the threshold above which it must be regarded as a medicinal product by function. In other words, substances which do not have a significant effect on the body and strictly speaking modify the way in which it functions cannot be treated as medicinal products.

19 The Commission takes the view that the product concerned might at best be regarded as a food supplement within the meaning of Article 2(a) of Directive 2002/46, that is to say as a foodstuff which is a concentrated source of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form. It states, nevertheless, that the attempt to deny that the product concerned is a foodstuff certainly does not justify its classification as a medicinal product.

20 As regards the classification of a product as a medicinal product by virtue of its presentation, the Commission submits that that must be done on a case-by-case basis according to the specific characteristics of the product. A product might be regarded as a medicinal product by virtue of its presentation if its form and the

manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and the information provided with it reference is made to research by pharmaceutical laboratories or to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product in question (Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 41).

21 The Commission states that, in this case, the preparation is not presented or recommended for treating or preventing disease, either on the label, on the information printed on the packaging, or in any other way. Neither can the product's external packaging be regarded as typical of medicinal products. The capsule form is the only specific characteristic of the product that relates to medicinal products, although external form alone cannot be an exclusive and decisive indicator. No other element in this case indicates that the product is a medicinal product by virtue of its presentation. The Commission takes the view that consumers know exactly what is contained in the capsules, namely garlic, which they know as a foodstuff. Consumers can also see that the product does not make reference to any therapeutic effect.

22 Finally, the Commission states that it is possible for Member States, under national law, to submit a product which is not a medicinal product within the meaning of Directive 2001/83 to the rules applying to medicinal products provided, however, that the measures to safeguard public health are proportionate (see Case C-387/99 *Commission* v *Germany* [2004] ECR I-3751, paragraph 72). In this case, the Federal Republic of Germany has not provided evidence that the prohibition on marketing the product concerned as a food supplement and the obligation to obtain authorisation for medicinal products are actually necessary for the protection of public health.

23 For its part, the Federal Republic of Germany submits that only the provisions of Community law specific to medicinal products apply to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product (Joined Cases C-211/03, C-299/03 and

C-316/03 to C-318/03 *HLH Warenvertrieb and Orthica* [2005] ECR I-5141, paragraph 43). It submits that, according to the case-law of the Court, the priority accorded to the regime governing medicinal products follows from Article 2, third paragraph, subparagraph (d) of Regulation No 178/2002 and from Article 1(2) of Directive 2002/46, which both exempt medicinal products from the scope of the rules on foodstuffs and on food supplements. That interpretation is also confirmed by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34) which inserts into Directive 2001/83 a new version of Article 2, according to paragraph 2 of which, in cases of doubt, where a product is also covered by other Community legislation — such as the rules governing foodstuffs — it is always the provisions of Directive 2001/83 that apply.

24 The Federal Republic of Germany submits that the garlic preparation in question is a medicinal product by function, primarily because it has pharmacological properties to which considerable importance is attached. In order to determine those pharmacological properties, the Federal Republic of Germany states that it is not only the effects of that preparation on health in general which is important, but also its pharmacological effectiveness (Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 17). In this case, the product in question has therapeutic effects which prevent lesions occurring in the human body, and more specifically prevents arteriosclerosis. The Federal Republic of Germany relies on several studies and scientific reports in support of its argument.

25 In answer to the Commission's argument that the effects of the preparation concerned on arteriosclerosis are limited, the Federal Republic of Germany states that neither Directive 2001/83 nor the case-law of the Court indicates a 'materiality threshold' according to which a specific level of pharmacological effects has to be proven. Therefore, if pharmacological effectiveness is accepted in this case, it is irrelevant whether there is a slight or material reduction in the risk of arteriosclerosis.

26 The Federal Republic of Germany also submits that the origin of the substances cannot be decisive in order to define a medicinal product, and states that the Court has held that vitamins in a particular form and in high doses could be classified as medicinal products (see Case 227/82 *van Bennekom* [1983] ECR 3883, paragraph 27, and *Commission* v *Germany*, paragraph 56). The fact that vitamins also occur in many foodstuffs thus does not prevent their classification as medicinal products. The same must apply to garlic and allicin, the active substance contained in it. Therefore, it is ultimately irrelevant whether or not an active substance with pharmacological properties also occurs in a foodstuff.

27 The preparation concerned also has pharmacological properties that could cause health risks if taken (see *Commission* v *Germany*, paragraph 82). The fact that the consumption of certain other foodstuffs may also have negative effects on health cannot call into question the status of medicinal product. The Federal Republic of Germany states, however, that it is above all the pharmacological and/or therapeutic effects which play a crucial role.

28 With regard to the methods of use, the Federal Republic of Germany states that the fact that the product concerned is offered for sale in capsule form also suggests that it should be classified as a medicinal product by function.

29 As to the definition of medicinal products by presentation, the Federal Republic of Germany submits that a product may be regarded as such if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product.

30 In this case the form of capsule used suggests that it is intended to be marketed as a medicinal product, although the Federal Republic of Germany accepts that the external form alone cannot be a decisive indicator for classification as a medicinal product (see *Delattre*, paragraph 38).

31 Furthermore, the Federal Republic of Germany points out that there are a large number of medicinal products containing active substances such as garlic bulb powder or oil on the German market, packaged in exactly the same way as the preparation concerned. The fact that they are all classified as medicinal products leans, according to commercial usage and consumer expectations, in favour of classification of the product in question as a medicinal product by virtue of its presentation.

32 The Federal Republic of Germany also infers from the case-law of the Court that the national authorities have a broad discretion when deciding classification (see *HLH Warenvertrieb and Orthica*, paragraph 56). The Commission has not satisfied the burden of proof as it has not established that the exercise of discretion by the German authorities in classifying the preparation concerned as a medicinal product was defective.

33 Alternatively, the Federal Republic of Germany states that in the event that the Court takes the view that the principle of free movement of goods is applicable and considers the classification of the product in question as a medicinal product to be a restriction on that principle, the decision is justified in any event in order to protect an overriding public interest, namely the protection of public health.

Findings of the Court

34 It is clear from Articles 2 and 6(1) of Directive 2001/83 that no industrially produced medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State or an authorisation has been granted in accordance with Council 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).

35 It follows that if a product produced industrially comes within the definition of medicinal product in Article 1(2) of Directive 2001/83, 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-150/00 *Commission* v *Austria* [2003] ECR I-3887, paragraph 57).

36 Furthermore, although the essential purpose of Directive 2001/83 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 such products (see, to that effect, *Commission* v *Austria*, paragraph 58).

37 In those circumstances, 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 medicinal products or

foodstuffs between Member States. Thus, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product (see *HLH Warenvertrieb and Orthica*, paragraph 56).

38 The fact remains that a product which satisfies the definition of 'medicinal product' within the meaning of Directive 2001/83 must be held to be a medicinal product and be made subject to the corresponding rules even if it comes within the scope of other, less stringent Community rules (see, to that effect, Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 19 and the case-law cited).

39 In those circumstances it is appropriate to determine, first of all, whether the product concerned is a medicinal product within the meaning of Directive 2001/83.

40 Under the first subparagraph of Article 1(2) of Directive 2001/83, a medicinal product is '[a]ny substance or combination of substances presented for treating or preventing disease in human beings', and according to the second subparagraph thereof, '[a]ny substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings' is likewise to be considered a medicinal product.

41 The directive thus gives two definitions of medicinal product, one 'by presentation' and one 'by function'. A product is a medicinal product if it falls within either of those definitions (*HLH Warenvertrieb and Orthica*, paragraph 49).

42 In that connection, it must be observed that although the Commission expressly refers to the definition of medicinal product by presentation in its arguments, it makes no reference to the definition of medicinal product by function. In the grounds of its application, however, and throughout the pre-litigation procedure, the Commission formulated arguments relating to those definitions. In its defence, both in the pre-litigation procedure and in these proceedings, the Federal Republic of Germany also put forward arguments regarding those two definitions. Therefore, the Commission's application must be interpreted as denying the product the status of both medicinal product by presentation and medicinal product by function.

The definition of medicinal product by presentation

43 According to settled case-law, the term 'presentation' of a product must be interpreted broadly. It must be recalled, in that connection, that by basing its arguments on the criterion of the 'presentation' of the product, Directive 2001/83 intends to cover 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 consumers would be entitled to expect from the way in which they are presented. The directive thereby intends to protect the consumer not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies (*van Bennekom*, paragraph 17).

44 In that context, a product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83 when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation (see, to that effect, *van Bennekom*, paragraph 18, and *Monteil and Samanni*, paragraph 23).

45 In this case, it is clear from the file that the preparation concerned is not indicated or recommended as a product for treating or preventing disease, whether on the label, the information printed on the external packaging, or in any other way.

46 A product is also 'presented for treating or preventing disease' whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question (see, to that effect, *van Bennekom*, paragraph 18, and *Monteil and Samanni*, paragraph 23).

47 In that regard, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the 'form' must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product (see, to that effect, *van Bennekom*, paragraph 19, and *Monteil and Samanni*, paragraph 24).

48 According to the information submitted to the Court, the product concerned is a garlic powder extract marketed in capsule form. On the product's external packaging there is, inter alia, a photograph of a head of garlic next to which are two capsules.

49 In that connection, the fact, relied on by the Federal Republic of Germany, that there are a large number of products containing active substances such as garlic bulb powder or oil on the German market, packaged in a similar manner to the product

concerned and classified as medicinal products, is not sufficient to confer on that product the status of a medicinal product by presentation. The Federal Republic of Germany has not provided any specific evidence in support of that argument.

50 In those circumstances, taking account of the information before the Court, it must be held that no aspect of its packaging tends to make the product concerned resemble a medicinal product other than the photograph or of a head of garlic on the product's external packaging, as such an image also features on a number of products marketed as medicinal products in Germany. The photograph of a plant on the external packaging of a product is not, however, sufficient to inspire in a reasonably well-informed consumer confidence like that usually inspired by medicinal products.

51 Therefore, presentation in capsule form is the only aspect likely to suggest classification of the product as a medicinal product by presentation.

52 However, it must be recalled that, according to settle case-law, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered (see, to that effect, *van Bennekom*, paragraph 19, and *Delattre*, paragraph 38).

53 As the Advocate General noted, in point 51 of her Opinion, the capsule form is not exclusive to medicinal products. A large number of foodstuffs are in fact offered for sale in that form in order to facilitate their ingestion by consumers. In that

connection, it must be observed that Article 2(a) of Directive 2002/46 expressly refers, among the criteria used to define 'food supplement', to its presentation in capsule form. Consequently, that evidence alone is not sufficient to confer the status of medicinal product by presentation on the product concerned.

54 In those circumstances, it must be held that the product concerned does not satisfy the criteria laid down in the first paragraph of Article 1(2) of Directive 2001/83. Therefore it cannot be classified as a medicinal product by presentation within the meaning of that directive.

Definition of medicinal product by function

55 For the purposes of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (*HLH Warenvertrieb and Orthica*, paragraph 51).

56 In this case, in order to justify the classification of the product concerned as a medicinal product by function, the Federal Republic of Germany relies essentially on its allicin content, its effect on blood pressure and lipid levels, the capsule form used and the risks related to its ingestion.

57 It is apparent from the file that the product in question is a garlic powder extract, the allicin content of which is between 0.95% and 1.05%, each capsule containing the equivalent of 7.4 g of fresh raw garlic. Allicin, the principal active ingredient, which is obtained from crushed garlic, is the result of the transformation of alliin, an amino acid naturally present in garlic, when it is mixed with the natural enzyme allinase.

58 Therefore, it must be held that, apart from the excipient into which the garlic extract was incorporated before being powdered, the product concerned is obtained entirely from garlic, and does not contain any substance which is not itself in garlic in its natural state.

59 The pharmacological properties of a product are the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (*HLH Warenvertrieb and Orthica*, paragraph 52).

60 Although, as the Advocate General observed in point 58 of her Opinion, that definition is broad enough to include products which, although they are capable of having an effect on bodily functions have in fact another purpose, that criterion must not lead to the classification as a medicinal product by function of substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (*Upjohn*, paragraph 22).

61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.

62 Such an interpretation is in accordance with the aims of Directive 2001/83 which, as is clear from the second to the fifth recitals in the preamble, seeks to reconcile the aim of protection of public health with the principle of free movement of goods.

63 Furthermore, although only the provisions of Community law specific to medicinal products apply to a product which satisfies the conditions for classification a medicinal product, even if it comes within the scope of other, less stringent Community rules (see, to that effect, *Delattre*, paragraph 22, *Monteil and Samanni*, paragraph 17, *Ter Voort*, paragraph 19, and *HLH Warenvertrieb and Orthica*, paragraph 43), it must be stated, as is shown by a reading of Article 1(2) of Directive 2001/83 in conjunction with Article 2 of Directive 2002/46, that the physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements.

64 In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease.

65 That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83.

66 In this case, the Federal Republic of Germany does not dispute that the physiological effects that it relies on, essentially with respect to the prevention of arteriosclerosis, may also be obtained by ingesting 7.4 g of garlic as a foodstuff. It is significant in that regard that the fact that the studies on which the Federal Republic of Germany bases its arguments relate both to the potential effects of ingesting garlic preparations in the form of capsules, powders or solutions, and to the potential effects of consuming garlic in its natural state.

67 It is also common ground that the disputed product does not have any additional effects as compared to those which derive from the consumption of garlic in its natural state and, as the Advocate General observed in point 62 of her Opinion, those effects should not be regarded as any greater than, or different from, those of other vegetable or animal products which are taken as part of the daily diet.

68 In those circumstances, it must be held that the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a products capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

69 Finally, and contrary to the Federal Republic of Germany's submissions, the fact that ingesting the product concerned could give rise to risks to health is not an indication that it is pharmacologically effective. It is clear from the case-law that the risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (*HLH Warenvertrieb and Orthica*, paragraph 53).

70 The assessment of the potential risks related to the use of the product concerned must be undertaken in the context of Directive 2001/83 and in the light of the principles of Community law in general.

71 As the Commission has observed, the Community provisions relating to medicinal products must ensure, in addition to the protection of human health, the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general, and the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.

72 In this case, the Federal Republic of Germany cites cases of spontaneous post-operative bleeding occurring after excessive consumption of garlic as a foodstuff or in the form of a preparation, the suppression of the effects of certain anti-retroviral drugs and an interaction with some anticoagulants.

73 In that connection, it must be observed, first of all, that those risks arise from the absorption of garlic in general and not specifically from the ingestion of the disputed preparation.

74 Furthermore, it is clear from the examples cited by the Federal Republic of Germany that it is only the interaction with certain medicinal products or excessive intake of garlic or a garlic preparation in specific circumstances such as an operation that risks to health may arise.

75 As the Advocate General observed in point 65 of her Opinion, it is clear from those examples that the risks and contra-indications related to taking garlic preparations mentioned are limited and, more importantly, are no different from those linked to taking garlic as a foodstuff.

76 As regards the criterion for the method of use of the product concerned, it cannot be decisive in this case for the reasons set out in paragraph 53 of this judgment.

77 In those circumstances, it must be held, having regard to all its characteristics, that the product concerned cannot be classified as a medicinal product by function within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

78 It is clear from all the foregoing that the product concerned does not satisfy either the definition of medicinal product by presentation or the definition of medicinal product by function. Therefore, it cannot be classified as a medicinal product within the meaning of Directive 2001/83.

Infringement of Article 28 EC and Article 30 EC

79 It is now appropriate to ascertain whether, as the Commission submits, the requirement for a marketing authorisation as a medicinal product, as it appears from the decision taken by the Federal Republic of Germany, is a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 28 EC.

80 The prohibition on measures having equivalent effect to quantitative restrictions, set out in Article 28 EC, covers all measures which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5, and *Commission* v *Austria*, paragraph 81).

81 In this case, the Federal Republic of Germany's decision creates an obstacle to intra-Community trade in so far as the products concerned, legally marketed in other Member State as a foodstuff, can be marketed in Germany only after having been subjected to the authorisation procedure for the placing on the market of a medicinal product.

82 In that connection, the Federal Republic of Germany submits that its decision is justified by reasons relating to the protection of public health, in accordance with Article 30 EC.

83 Whilst Article 30 EC allows the maintenance of restrictions on the free movement of goods justified on grounds of the protection of the health and life of humans, which are fundamental requirements recognised by Community law, it must be recalled that that provision cannot be applied where Community directives provide for harmonisation of the measures necessary to achieve the specific objective which would be furthered by reliance upon it (see, to that effect, Case C-102/96 *Commission* v *Germany* [1998] ECR I-6871, paragraph 21).

84 In this case, it is not necessary to examine whether the product concerned may be classified as a food supplement within the meaning of Article 2 of Directive 2002/46 or as a foodstuff within the meaning of Article 2 of Regulation No 178/2002. It is sufficient to hold that, according to Article 11(2) of Directive 2002/46 and Article 14(9) of Regulation No 178/2002, in the absence of specific Community rules laid down in those provisions, national rules may be applied without prejudice to the provisions of the Treaty.

85 In those circumstances, it is appropriate to ascertain whether the German practice concerned may be justified on the basis of Article 30 EC.

86 In that connection, it must be recalled that it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the

marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community (Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 16; *van Bennekom*, paragraph 37; and Joined Cases C-158/04 and C-159/04 *Alfa Vita Vassilipoulos and Carrefour-Marinopoulos* [2006] ECR I-8135, paragraph 21).

87 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; Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 45; and Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 52).

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

89 Although, as was noted in paragraph 86 of this judgment, Community law does not, in principle, preclude a system of prior authorisation, it must however be stated that the issue of a marketing authorisation under Article 8 of Directive 2001/83 is subject to particularly strict requirements.

90 In those circumstances, the obligation to obtain a marketing authorisation for a medicinal product before being able to market the disputed product on German territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary to safeguard public health.

91 Such a restriction on the free movement of goods must therefore necessarily be based on a detailed assessment of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, *Commission* v *Denmark*, paragraph 47, and *Commission* v *France*, paragraph 54).

92 In this case, the Federal Republic of Germany merely refers to its arguments on the risks to health which derive from the preparation concerned in order to justify the restriction on the free movement of goods.

93 As was stated in paragraphs 73 to 75 of this judgment, it must be recalled, first, that those arguments relate principally to the effect of garlic taken as a foodstuff and not specifically to those of the product concerned and, second, that such risks arose in very specific circumstances.

94 The generic reference made by the Federal Republic of Germany to the risks that taking garlic may have for health in very specific circumstances is not sufficient, as the Advocate General observed in point 79 of her Opinion, to justify a measure such as making the product subject to the particularly strict procedure for a marketing authorisation for a medicinal product.

95 Furthermore, the Member State, instead of making the product concerned subject to such a procedure, could have prescribed suitable labelling warning consumers of the potential risks related to taking this product. The protection of public health would thus have been ensured without such serious restrictions on the free movement of goods (see, to that effect, Case C-17/93 *van der Veldt* [1994] ECR I-3537, paragraph 19).

96 It follows from the foregoing considerations that the Federal Republic of Germany has failed to prove that the legislation at issue is necessary in order to protect consumer health and that it goes no further than is necessary in order to achieve that aim. The decision of that Member State does not therefore satisfy the principle of proportionality.

97 It follows from all the foregoing considerations that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC.

Costs

98 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Federal Republic of Germany has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds, the Court (First Chamber) hereby:

1. **Declares that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC;**

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

[Signatures]