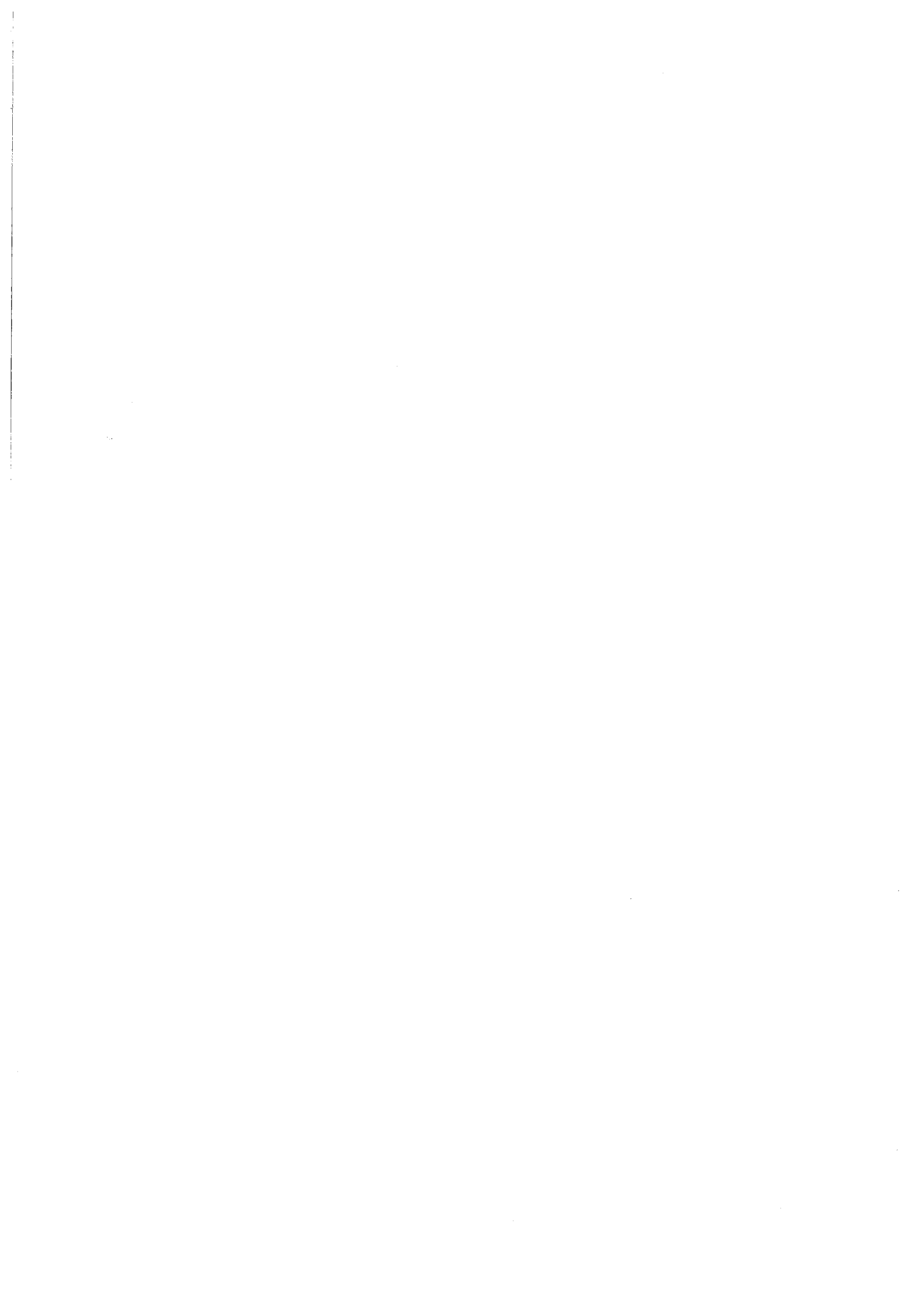


ANNEX 1

EU: Case C-319/05 *Commission v Germany*



EU: Case C-319/05
Celex No. 605J0319

European Union Cases

Court of Justice

Judgment of the Court (First Chamber) of 15 November 2007. Commission of the European Communities v Federal Republic of Germany. Failure of a Member State to fulfil its obligations - Article 28 EC and Article 30 EC - Directive 2001/83/EC - Garlic preparation in capsule form - Preparation legally marketed as a food supplement in a number of Member States - Preparation classified as a medicinal product in the Member State of importation - Definition of 'medicinal product' - Obstacle - Justification - Public health - Proportionality. Case C-319/05.

European Court Reports 2007 page I-09811

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Text

1. Approximation of laws - Medicinal products for human use - Directive 2001/83 - Classification of a product as a medicinal product by presentation - Criteria

(European Parliament and Council Directive 2001/83, Art. 1(2), first para.)

2. Approximation of laws - Medicinal products for human use - Directive 2001/83 - Classification of a product as a medicinal product by function - Criteria

(European Parliament and Council Directive 2001/83, Art. 1(2), second para.)

3. Approximation of laws - Medicinal products for human use - Directive 2001/83 - Classification of a product as a medicinal product by function - Criteria

(European Parliament and Council Directive 2001/83, Art. 1(2), second para.)

4. Free movement of goods - Quantitative restrictions - Measures having equivalent effect

(Arts 28 EC and 30 EC)

SUMMARY

1. A product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83 on the Community code relating to medicinal products for human use when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, or 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.

The criteria laid down in the first paragraph of Article 1(2) of Directive 2001/83 are not satisfied by a garlic preparation in capsule form which is neither indicated nor recommended as a product for treating or preventing disease, whether on the label, the information printed on the external packaging, or otherwise, and whose packaging displays nothing capable of inspiring in a reasonably well-informed consumer confidence like that usually inspired by medicinal products, with the result that presentation in capsule form is the only aspect likely to suggest classification of the product as a medicinal product by presentation. Such a preparation cannot be classified as a medicinal product by presentation for the purposes of that directive.

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. The capsule form is not exclusive to medicinal products, given that a large number of foodstuffs

are in fact offered for sale in that form in order to facilitate their ingestion by consumers. Consequently, that evidence alone is not sufficient to confer the status of medicinal product by presentation on the product concerned. (see paras 44-46, 50-54, 78)

2. 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 on the Community code relating to medicinal products for human use, 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.

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.

However, 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.

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.

In those circumstances, and in order to preserve the effectiveness of that criterion, a product must not only have properties beneficial to health in general, but strictly speaking have the function of treating or preventing disease, especially since there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient to confer on them the status of medicinal product within the meaning of Directive 2001/83.

Finally, the fact that ingesting a product could give rise to a health risk is not an indication that it is pharmacologically effective. Whilst the health risk must be taken into consideration in the classification of a product as a medicinal product by function, it is none the less an autonomous factor.

(see paras 55, 59-61, 64-65, 69)

3. A garlic product in capsule form, whose effect on physiological functions is no more than the effects which 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 product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83. Because the mentioned risks and contra-indications related to taking garlic preparations are limited and, more importantly, are no different from those linked to taking garlic as a foodstuff, and because the criterion of the method of using of the product concerned cannot be decisive, given that capsule form is not unique to medicinal products, such a preparation cannot be classified as a medicinal product by function within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

(see paras 68, 76-78)

4. Where a Member State decides to require marketing authorisation as a medicinal product for a garlic preparation in capsule form which does not satisfy the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83 on the Community code relating to medicinal products for human use, that requirement constitutes a measure having equivalent effect to a quantitative restriction on imports,

prohibited by Article 28 EC.

By so doing, the Member State creates an obstacle to intra-Community trade in so far as such a product, legally marketed in other Member States as a foodstuff, can be marketed in the said State only after having been subjected to the authorisation procedure for placing a medicinal product on the market.

As to whether such a restriction may be justified under Article 30 EC by reasons relating to the protection of public health, it is true that Member States are entitled, 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. However, the means which they choose in that regard must be proportionate to the objective thus pursued. The issuing of a marketing authorisation under Article 8 of Directive 2001/83 is subject to particularly strict requirements, and the obligation to obtain such an authorisation before being able to market the product concerned in the territory of the Member State cannot be regarded as being in accordance with the principle of proportionality unless it is actually necessary to safeguard public health. 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.

A generic reference to the risks that consuming the product may have for health in very specific circumstances is not sufficient to justify a measure such as making the product subject to the particularly strict procedure for a marketing authorisation for a medicinal product.

(see paras 79, 81, 86-87, 89-91, 94, 97, operative part)

ISSUE 1

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,

THE COURT (First Chamber),

composed of P. Jann, President of the Chamber, R. Schintgen, A. Borg Barthet (Rapporteur), M. Ilei 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

FOUNDATIONS

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. 0067) 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. 0051), '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. 0001), '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 I1547, 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

