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Press and Information

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Judgment of the Court of Justice in Case C-319/05

Commission of the European Communities v Federal Republic of Germany

GARLIC EXTRACT POWDER CAPSULES ARE NOT MEDICINAL PRODUCTS

Requiring marketing authorisation as a medicinal product for garlic capsules constitutes an obstacle to the free movement of goods not justified on health protection grounds.

The German authorities refused to allow the importation and marketing of "garlic extract powder capsules" on the ground that they constituted not a foodstuff but a medicinal product.

Taking the view that classification of the product amongst medicinal products was incompatible with the principle of the free movement of goods, the Commission brought an action against the Federal Republic of Germany before the Court of Justice for failure to fulfil obligations.

The concept of a medicinal product

In its judgment, the Court recalled that the Community code relating to medicinal products for human use¹ constitutes only the first stage of harmonisation, and that, in those circumstances, it is difficult to avoid the existence of differences in the classification of products between Member States. Nevertheless, a product must be regarded as a "medicinal product" if it satisfies the Community definition of that concept. A product may be a medicinal product either by presentation or by function.

Whilst presentation in capsule form is an indicator towards classification amongst medicinal products by presentation, that indicator cannot be the sole or conclusive evidence. Moreover, capsule form is not exclusive to medicinal products.

Regarding the concept of a medicinal product by function, the Court has stated that the criterion of physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements. The documents before the Court show that, apart from an excipient, "garlic extract powder capsules" do not contain any substance other than natural garlic and have no additional effects, either positive or negative, as compared to those which derive from the consumption of garlic in its natural state. By contrast, in order to correspond to the definition of a medicinal product by function, a product must have the function of preventing

¹ 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

or treating disease. Beneficial effects for health in general, such as those of garlic, are not sufficient.

The Court has therefore held that garlic extract powder capsules do not correspond to the definition either of a medicinal product by presentation or of a medicinal product by function. Therefore, they cannot be classified as a medicinal product.

Infringement of the free movement of goods

The requirement for marketing authorisation as a medicinal product constitutes a measure having equivalent effect to a quantitative restriction on importation prohibited by Community law, since it creates an obstacle to intra-Community trade in products legally marketed as foodstuffs in other Member States.

As for possible justification, the Court recalls 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 health, while taking into account the requirements of the free movement of goods. In exercising their discretion, the Member States must comply with the principle of proportionality. In this case, the requirement for authorisation cannot be justified by the arguments put forward by Germany, which relate essentially to the risks connected with taking garlic in general and do not concern the capsules in question. Moreover, other measures exist which are just as effective but less restrictive of the free movement of goods than prior authorisation.

The Court therefore holds that the Federal Republic of Germany has failed to fulfil its Treaty obligations concerning the free movement of goods.

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Available languages: BG ES CS DE EN FR HU NL PL RO SK SL

The full text of the judgment can be found on the website of the Court of Justice
<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-319/05>

It may normally be consulted from 12 hours CET on the day of delivery.

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