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Notice for the OJ

JUDGMENT OF THE COURT OF JUSTICE

(First Chamber)

of 9 June 2005

in Joined Cases C-211/03, C-299/03 and C-316/03 to C 318/03 (References for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen): HLH Warenvertriebs GmbH, Orthica BC v Federal Republic of Germany ¹

(Free movement of goods - Distinction between medicinal products and food additives - Product marketed as a food additive in the Member State of origin but treated as a medicinal product in the Member State of import - Marketing authorisation)

(Language of the case: German)

In Joined Cases C-211/03, C-299/03 and C-316/03 to C 318/03: references for a preliminary ruling under Article 234 EC, by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany), by decisions of 7 May and of 4, 3, 7 and 8 July 2003 respectively, received at the Court on 15 May and 11 and 24 July 2003, in the proceedings pending before that court between **HLH Warenvertriebs GmbH** (C-211/03), **Orthica BV** (C-299/03 and C-316/03 to C-318/03) and the **Federal Republic of Germany**, intervener: **Vertreter des öffentlichen Interesses beim Oberverwaltungsgericht für das Land Nordrhein-Westfalen**, the Court (First Chamber) composed of P. Jann, President of the Chamber, N. Colneric, J.N. Cunha Rodrigues (Rapporteur), M. Ilešič and E. Levits, Judges; L.A. Geelhoed, Advocate General, K. Sztranc, Administrator, for the Registrar, gave a judgment on 9 June 2005, the operative part of which is as follows:

The classification of a product as a medicinal product or as a foodstuff must take account of all the characteristics of the product, established both in the initial stage of the product and where it is mixed, in accordance with the method by which it is used, with water or with yoghurt.

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 constitutes an additional set of rules in relation 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, the application of which is precluded to the extent to which a Community rule, such as that directive, contains specific provisions for certain categories of foodstuffs.

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.

The pharmacological properties of a product are the factor on the basis of which the authorities of the Member States must ascertain, 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/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. The risk that the use of a product may entail for health is an autonomous factor that must also be taken into consideration by the competent national authorities in the context of the classification of the product as a medicinal product.

A product which constitutes a medicinal product within the meaning of Directive 2001/83 may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that directive, even where it is lawfully marketed as a foodstuff in another Member State.

The concept of 'upper safe levels' in Article 5(1)(a) of Directive 2002/46 is of no importance for the purposes of drawing a distinction between medicinal products and foodstuffs.

In the context of an evaluation by a Member State of the risks that foodstuffs or food supplements may constitute for human health, the criterion of the existence of a nutritional need in the population of the Member State may be taken into consideration. However, the absence of such a need does not in itself suffice to justify, either under Article 30 EC or under Article 12 of Directive 2002/46, a complete ban on marketing foodstuffs or food supplements lawfully manufactured or placed on the

market in another Member State.

The fact that the discretion enjoyed by the national authorities as regards the establishment of an absence of nutritional need is subject to only limited review by the courts is compatible with Community law, on condition that the national procedure for judicial review of the decisions in that regard taken by those authorities enables the court or tribunal seised of an application for annulment of such a decision effectively to apply the relevant principles and rules of Community law when reviewing its legality.

Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients is to be interpreted as meaning that a food or a food ingredient has not been used for human consumption to a significant degree within the Community if, when all the circumstances of the case are taken into account, it is established that that food or that food ingredient has not been consumed in a significant quantity by humans in any of the Member States before the reference date. 15 May 1997 is the reference date for the purpose of determining the extent of human consumption of that food or food ingredient.

A national court cannot refer questions on the classification of products to the European Food Safety Authority. An opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute.

¹ - OJ C 200 of 23.08.2003 OJ C 275 of 15.11.1003