

Marketing Authorisation: Distinction Between Food Additives and Medicinal Products

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The case HLH Warenvertriebs GmbH and another v Germany (Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03) was decided by the Court of Justice of the European Communities (First Chamber).

The applicants, HLH Warenvertriebs GmbH and another, intended to import into Germany and market certain products that were on the market as food supplements in the Netherlands. They planned to market the products also as food supplements. The applicant applied for marketing authorisation to market the products in Germany as food supplements. The applicants requested the German federal ministry for consumer protection, food and agriculture to adopt a general decision concerning marketing authorisations, pursuant to national law. The German Federal Ministry refused and they brought proceedings before the regional administrative court against this refusal. The court dismissed their actions. The main ground on which the proceedings were dismissed was that the products were medicinal products, not foodstuffs.

The applicants appealed to the higher administrative court. This court then stayed proceedings and referred the case to the Court of Justice of the European Communities ("European Court") for a preliminary ruling regarding the interpretation of a number of provisions of Community law, in particular:-

Novel foods and novel food ingredients (Parliament and Council Regulation (EC) 258/97);

Articles 28 and 30 of the EC Treaty;

The Community code relating to medicinal products for human use (Parliament and Council Directive (EC) 2001/83);

The general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Parliament and Council Regulation (EC) 178/2002); and The approximation of the laws of the member states relating to food supplements (Parliament and Council Directive (EC) 2002/46).

The European Court decided:

In order to classify a product as a medicinal product or as a foodstuff, all the characteristics of the product had to be taken into account as established in the initial stage of the product i.e. where it was mixed, the method by which it was used and whether with water or with yoghurt.

Regulation 178/2002 (No 4 above) constituted an additional set of rules in relation to Council Directive (EC) 2002/46 (No 5 above).

It was only the provisions of Community law specific to medicinal products which applied to a product that satisfied equally the conditions for classification as a foodstuff and the conditions for classification as a medicinal product.

The competent authorities in member states had to:-

use the pharmacological properties of a product to ascertain, in the light of the potential capacities of the product, whether it might, for the purposes of the second subparagraph of art 1(2) of directive 2001/83 (No 3 above), be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

establish the risk to health of human beings of using this product in the context of the classification of the product as a medicinal product.

A product which constituted a medicinal product within the meaning of directive 2001/83 (No 3 above) might 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 was lawfully marketed as a foodstuff in another member state.

The concept of 'upper safe levels' in art 5(1)(a) of directive 2002/46 (No 5 above) was not of importance for the purposes of drawing a distinction between medicinal products and foodstuffs.

In evaluating the risks that foodstuffs or food supplements might constitute for human health by a member state, the member state has to take into account whether there is a nutritional need in the population of that member state. However, the absence of such a nutritional need did not in itself justify, either under art 30 EC (No 1 above) or under art 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.

Article 1(2) of regulation 258/97 (No 1 above) should be interpreted to mean that a food or a food ingredient had not

been used for human consumption to a significant degree within the Community if, when all the circumstances of the case were taken into account, it was established that that food or food ingredient had not been consumed in a significant quantity by humans in any of the member states before the reference date.

A national court could not directly refer questions regarding the classification of products to the European Food Safety Authority (EFSA). If the EFSA delivered an opinion, say, in a case forming the subject-matter of a dispute pending before a national court, this might constitute evidence that the national court could take into consideration in the context of that dispute.

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