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Press and Information

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Judgment of the Court of Justice in Joined Cases C-154/04 and 155/04

Alliance for Natural Health, National Association of Health Stores and Others v Secretary of State for Health

THE COURT CONFIRMS THE VALIDITY OF THE COMMUNITY DIRECTIVE ON FOOD SUPPLEMENTS

A "positive list" system is appropriate for securing the free movement of food supplements and ensuring the protection of human health

In June 2002 the European Parliament and the Council adopted a directive relating to food supplements[1]. The directive is based on Article 95 of the EC Treaty, which allows the Community to take measures to bring about the functioning of the internal market.

The directive seeks to approximate the various national rules on those products in order to ensure their free movement and, at the same time, to guarantee a high level of consumer protection. To that end, the directive establishes a "positive list" system under which only products containing substances included on the lists in the annexes to the directive can be marketed in the Community. Member States cannot prohibit or impede trade in those products. If it is safe for human health, a substance can be included on the list by decision of the Commission, assisted by a committee and by the European Food Safety Authority. Under the directive the Member States must permit, from 1 August 2003 at the latest, trade in products containing substances included on the list and prohibit, from 1 August 2005 at the latest, trade in products which do not comply with the directive.

Alliance for Natural Health (a Europe-wide association of manufacturers, wholesalers, distributors, retailers and consumers of food supplements), Nutri-Link Ltd (a small distributor and retailer), the National Association of Health Stores and the Health Food Manufacturers Association (trade associations representing around 580 companies, the majority of which are small firms which distribute dietary products in the United Kingdom) challenged the validity of the regulations transposing the directive into the law of England and Wales. They took the view that the provisions of the directive prohibiting trade in products which do not comply

[1] 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).

with the directive infringe a number of principles of Community law and were adopted on the wrong legal basis. The High Court referred a number of questions in this respect to the Court of Justice of the European Communities.

In its judgment of today **the Court** rejected the applicants' arguments and **confirmed the validity of the directive.**

The Court observed that, before the directive was adopted, food supplements were regulated by differing national rules liable to impede the free movement of those goods and the functioning of the internal market. That situation was reflected in the fact that a number of cases had been brought before the Court of Justice in which economic operators had encountered obstacles when marketing in one Member State food supplements lawfully marketed in another Member State and that the Commission had received a substantial number of complaints on account of the differences between national rules. In those circumstances, the Court concluded that the directive was properly founded on Article 95 of the Treaty.

The applicants also submitted that the directive was incompatible with the free movement of goods. The Court pointed out that certain restrictions can be justified by the protection of public health and considered the measures in question to be necessary and appropriate for the purpose of achieving that objective.

A negative list system might not suffice to achieve the same objective. Such a system could result in a substance being freely used in the manufacture of food supplements even though, for example by reason of its novelty, it had not been subject to any scientific assessment proving that it posed no risk to human health.

The Court added that a positive list system must be accompanied by a procedure which allows a given substance to be added to the lists, which is consistent with the principles of sound administration and legal certainty. Such a procedure must be accessible in that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned and must be completed within a reasonable time. An application to have a substance included on a list may be refused only on the basis of a full risk assessment, established on the basis of the most reliable scientific data available and the most recent results of international research. A refusal must also be open to challenge before the courts. Although the directive contains no provisions which in themselves ensure that the consultation stage before the European Food Safety Authority is completed transparently and within a reasonable time, the absence of any such provisions does not jeopardise the proper functioning of the procedure for modifying the positive lists within a reasonable time. However, the Court emphasised that it is the responsibility of the Commission to adopt and make accessible to interested parties the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time.