JUDGMENT OF THE COURT (First Chamber)

9 June 2005 *

In Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03,

REFERENCES under Article 234 EC for a preliminary ruling, made 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, 11 and 24 July 2003, in the proceedings

HLH Warenvertriebs GmbH (C-211/03),

Orthica BV (C-299/03 and C-316/03 to C-318/03)

v

Bundesrepublik Deutschland,

* Language of the case: German.

intervener:

Der 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,

Advocate General: L.A. Geelhoed,
Registrar: K. Sztranc, Administrator,

having regard to the written procedure and further to the hearing on 9 December 2004,

after considering the observations submitted on behalf of:

— HLH Warenvertriebs GmbH and Orthica BV, by M. Forstmann and T. Büttner, Rechtsanwälte,

— the Bundesrepublik Deutschland, by G. Preußendorff and U. Stöhr, acting as Agents,

— the Spanish Government, by L. Fraguas Gadea and F. Díez Moreno, acting as Agents,

— the Swedish Government, by K. Wistrand, acting as Agent,

— the Commission of the European Communities, by M.-J. Jonczy and H. Krämer, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 3 February 2005,

gives the following

Judgment

1 The requests for a preliminary ruling relate to the interpretation of Articles 28 EC and 30 EC, Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 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 (OJ 2001 L 311, p. 67), 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. 1) and 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).

2 Those requests were submitted in the context of proceedings brought by HLH Warenvertriebs GmbH ('HLH') and Orthica BV ('Orthica') against the Bundesrepublik Deutschland concerning the classification of certain products as food supplements or as medicinal products for the purposes of being marketed on German territory.

Law

Community legislation

3 Article 1(1) and (2) of Regulation No 258/97 provides:

'1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.'

4 Article 3(1) and (2) of Regulation No 258/97 is worded as follows:

'1. Foods and food ingredients falling within the scope of this Regulation must not:

— present a danger for the consumer,

— mislead the consumer,

— differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

2. For the purpose of placing the foods and food ingredients falling within the scope of this Regulation on the market within the Community, the procedures laid down

in Articles 4, 6, 7 and 8 shall apply on the basis of the criteria defined in paragraph 1 of this Article and the other relevant factors referred to in those Articles.

...'

5 Article 1(1) of Directive 2001/83 defines a 'proprietary medicinal product' as '[a]ny ready-prepared medicinal product placed on the market under a special name and in a special pack'.

6 For the purposes of Article 1(2) of that directive, 'medicinal product' means, first, '[a]ny substance or combination of substances presented for treating or preventing disease in human beings' and, second, '[a]ny 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'.

7 Article 6(1) of Directive 2001/83 provides:

'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 [Council] Regulation No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal

products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)].'

8 Article 26 of that directive provides:

'The marketing authorisation shall be refused if, after verification of the particulars and documents listed in Articles 8 and 10(1), it provides that:

(a) the medicinal product is harmful in the normal conditions of use, or

(b) that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or

(c) that its qualitative and quantitative composition is not as declared.

Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Articles 8 and 10(1).'

9 Article 29(1) and (2) of that directive provide:

'1. Where a Member State considers that there are grounds for supposing that the marketing authorisation of the medicinal product concerned may present a risk to public health, it shall forthwith inform the applicant, the reference Member State which granted the initial authorisation, any other Member States concerned by the application and the Agency. The Member State shall state its reasons in detail and shall indicate what action may be necessary to correct any defect in the application.

2. All the Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. However, if the Member States have not reached agreement within the time limit referred to in Article 28(4) they shall forthwith refer the matter to the [European] Agency [for the Evaluation of Medicinal Products, established by the first paragraph of Article 49 of Regulation No 2309/93] with regard to the Committee [for Propriety Medicinal Products, established by Article 27(1) of Directive 2001/83]'s reference for the application of the procedure laid down in Article 32.'

10 Article 2 of Regulation No 178/2002 states:

'For the purposes of this Regulation, "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.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

"Food" shall not include:

...

(d) medicinal products within the meaning of Council Directives 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20) and 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8);

...'

11 Directives 65/65 and 92/73, referred to in the preceding paragraph, were codified by Directive 2001/83.

12 Regulation No 178/2002 provides, in Article 14, entitled 'Food safety requirements':

'1. Food shall not be placed on the market if it is unsafe.

...

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with a 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 with prejudice to the Treaty, in particular Articles 28 and 30 thereof.'

13 Article 1 of Directive 2002/46 provides:

'1. This Directive concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.

2. This Directive shall not apply to medicinal products as defined by Directive 2001/83 ...'

14 Article 2(a) of Directive 2002/46 defines 'food supplements' as '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 ...'. 'Nutrients' are defined in Article 2(b) of that directive as vitamins and minerals.

15 According to Article 5(1) of that directive:

'1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

(a) supper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.'

16 Article 12(1) and (2) of that directive is worded as follows:

'1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing

Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.'

17 The first paragraph of Article 15 of Directive 2002/46 provides that Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with that directive by 31 July 2003.

National legislation

18 Paragraph 47a of the Law on food and consumer products (Lebensmittel- und Bedarfsgegenständegesetz; 'the LMBG') is worded as follows:

'(1) By way of derogation from the first sentence of Paragraph 47(1), products to which the present Law applies, which are lawfully manufactured and marketed in another Member State of the Community, or another State party to the European Economic Area Agreement, or which come from a non-member country and are lawfully marketed in a Member State of the Community, or in another State party to the European Economic Area Agreement, may be imported and placed on the domestic market, even if they do not comply with the legislation concerning foodstuffs currently in force in the Federal Republic of Germany. The first sentence does not apply to products which

1. contravene the prohibitions laid down in Paragraphs 8, 24 or 30 or

2. do not comply with other legal provisions adopted for the purposes of protecting public health, in so far as the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Ministry for Consumer Protection and Food Safety) has not published a decision of general application in the *Bundesanzeiger* (Official Gazette) approving the marketing of those products in Germany.

(2) Decisions of general application, in accordance with the second sentence of Paragraph 1, point 2, shall be adopted ... provided that there are no compelling health protection reasons not to do so. They shall be applied for by the person intending to import the products into the country. When assessing the risks that a product poses to health, the Federal Ministry must take into consideration international research findings and, in the case of foodstuffs, nutritional habits in the Federal Republic of Germany. Decisions of general application, pursuant to the first sentence are to operate for the benefit of all importers of the products concerned from other Member States or other States Parties to the Agreement on the European Economic Area.

(3) An exact description of the product and the available documents that are required for the decision shall be attached to the application. ...

(4) If some foodstuffs are not covered by the provisions of this Law or of the implementing regulations, this must be stated in an appropriate manner if it is necessary to protect the consumer.'

19 Paragraph 73 of the Law on Medicinal Products (Arzneimittelgesetz) is worded as follows:

'(1) Medicines subject to authorisation or registration may be imported into the territory in which this law is applicable — with the exception of tax-free areas other than the island of Helgoland — only if they have been authorised or registered for circulation in the territory or if they have been exempted from authorisation or registration, provided that:

1. if the product is imported from a Member State of the European Community or another State Party to the European Economic Area Agreement, the recipient must be a pharmaceutical company, a wholesaler, a veterinary surgeon or a pharmacist; or

2. if the product is imported from [another country], the recipient must possess authorisation under Paragraph 72.

...'

Main proceedings and questions referred to the Court

20 In 1995 and 1996 HLH and Orthica requested the Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (Federal Ministry for Consumer Protection, Food and Agriculture), which at the material time had competence for the facts of the main proceedings, to adopt a general decision pursuant to Article 47 of the Food Act, as they intended to import into Germany certain products marketed as food supplements in the Netherlands and to place them, in that category, on the German market. The products in question were as follows:

— for the purposes of Case C-211/03, Lactobact omni FOS in powdered form; one gram of powder contains at least 1 000 000 000 organisms from the following bacterial strains: lactobacillus acidophilus, lactococcus lactis, E. faecium, bifidobacterium bifidum, lactobacillus casei and lactobacillus thermophilus; the recommended consumption is approximately 2 g per day, dissolved in half a glass of water or with yoghurt, although the dose is doubled where the need is greater and during the first four weeks of taking it;

— for the purposes of Case C-299/03, C 1000 in tablet form containing, in particular, 1 000 mg of vitamin C, 30 mg of citrus bioflavonoids, hesperidin rutin complex and other ingredients; the recommended consumption is one tablet per day;

— for the purposes of Case C-316/03, OPC 85 in tablet form containing, in particular, 50 mg of extract of bioflavonol — oligomere procyanidine; the recommended consumption is one tablet per day;

— for the purposes of Case C-317/03, Acid Free C-1000 in tablet form containing, in particular, 1 110 mg of ascorbate of calcium — 1 000 mg of vitamin C and 110 mg of calcium; the recommended consumption is one tablet per day;

— for the purposes of Case C-318/03, E-400 in tablet form, containing 268 mg of vitamin E; the recommended consumption is one tablet per day.

21 The Bundesministerium für Gesundheit (Federal Ministry for Health), which in the meantime had become competent for such matters, refused to adopt the decisions of general application requested and, in substance, provided the following reasons for its refusal:

— in Case C-211/03, that the product in question was not a foodstuff but a medicinal product, since the bacterial cultures used form part, individually or in combination, of the composition of gastro-enterological remedies;

— in Cases C-299/03 and C-317/03, that the product was not a foodstuff of current consumption, since the dose of vitamin C currently recommended in Germany was exceeded by at least 13 times following ingestion of one tablet per day and since the requirements of health protection precluded the product being placed on the market;

— in Case C-316/03, that the bioflavonoids contained in the product, in isolated form, did not primarily correspond to the aims of food or pleasure, but must be

regarded as substances having a pharmacological effect and the requirements of protection of health precluded such a product being placed on the market;

— in Case C-318/03, that the ingestion of a single tablet per day meant exceeding by at least 22 times the dose of vitamin E currently recommended in Germany and the results of recent studies indicated that a prolonged and high intake of vitamin E could have harmful effects for health, so that the uncertainties in the matter precluded the product being placed on the market.

22 HLH and Orthica brought actions before the Verwaltungsgericht (Administrative Court) Köln against the refusal to adopt decisions of general application for the products referred to at paragraph 20 of this judgment. That court dismissed the actions by a number of judgments, on the ground that the products concerned were not foodstuffs but medicinal products.

23 HLH and Orthica appealed against those judgments before the Oberverwaltungsgericht (Higher Administrative Court) für das Land Nordrhein-Westfalen.

24 That court considers that its decision on appeal depends on the interpretation of a number of provisions of Community law, in particular Articles 28 EC and 30 EC, Regulation No 258/97, Directive 2001/83, Regulation No 178/2002 and Directive 2002/46.

25 It was in those circumstances that the Oberverwaltungsgericht für das Land Nordrhein-Westfalen decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling in Case C-211/03:

'1. (a) Is the contested product "Lactobact omni FOS" a foodstuff (perhaps in the form of a food supplement) or a medicinal product? Is this classification binding on all the Member States?

(b) Is it relevant when classifying the product that, according to the directions for use, it is intended to be dissolved in water or in yoghurt? Or is the condition in which it is imported the determining factor?

(c) If the Court of Justice concludes that the product in question is medicinal, but that in those Member States where it has hitherto been regarded as a foodstuff it should continue to be a foodstuff, that raises problems for the referring Chamber such as those underlying Question 2(f), in conjunction with question 2(c). Reference is made to those questions and the observations thereon and an answer is requested.

(d) If "Lactobact omni FOS" is a foodstuff (food supplement), is it then a novel food within the meaning of Regulation ... No 258/97 ...? What is the relationship between the various legal bases?

2. In the event that — as has been the case hitherto — Question 1(a) to (d) is to be answered not by the Court of Justice but by the national courts, guidance is

none the less sought on how correctly to resolve Question 1(b) from a Community law standpoint, in so far as Community law is applicable.

In addition, the following questions arise:

(a) (i) Is the contested product to be classified according to the first and second paragraphs of Article 2, in conjunction with point (d) of the third paragraph of Article 2 of Regulation No 178/2002 ... or — once the period for transposition expires on 31 July 2003 — according to Directive 2002/46 ... , and if so according to which parts of the directive?

(ii) If the first and second paragraphs of Article 2 in conjunction with point (d) of the third paragraph of Article 2 of ... Regulation [No 178/2002] apply, the following question arises: is it the case that it is no longer the product's main (objective) purpose that is the decisive factor, but rather that a product which meets the criteria for both a food and a medicine is, legally speaking, always — and only — a medicinal product? How material for these purposes is the type of product and how material the individual product?

(b) How is the term "pharmacological effect", which is critical for the purposes of classification, inter alia, under the first and second paragraphs of Article 2, in conjunction with point (d) of the third paragraph of Article 2 of ... Regulation [No 178/2002], to be defined for the purposes of Community law?

In particular, does the definition include a requirement that there be a health risk?

(c) Does the view expressed by the Court of Justice at paragraph 39 of its judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883 on the general classification of vitamin preparations, in which it said that it must be possible to import a product that may be marketed as a food in the Member State in which it was manufactured by the granting of a marketing authorisation if, even though it is regarded as a medicine in the Member State of import, a marketing authorisation is compatible with the requirements of health protection, also apply to probiotic products of the kind at issue here, and dose the Court of Justice adhere to its view in the light of subsequent Community law?

(d) (i) In so far as the term "health risk" is relevant to Question 2(b) and (c), or to other applicable Community law, such as Articles 28 EC and 30 EC:

Is the relevant threshold the "upper safe level" or should it be reduced, say, because the substances in question are also ingested with food and/or because — at least where they are taken long-term — regard may have to be had to the various consumer groups and their different sensitivities?

(ii) Is it an infringement of Community law for the specialist authorities to have a discretion under national law to determine (individual) upper safe levels

and any (individual) reductions that is subject to only limited review by the courts?

(e) (i) If a product may be marketed in at least one other Member State as a foodstuff, is the fact that the competent German authority essentially says that in Germany there is no "nutritional need" for that product significant in terms of the freedom to market the product as a foodstuff (food supplement) in Germany?

(ii) If so, is it compatible with Community law for the authority to have a discretion under national law that is subject to only limited review by the courts?

(f) If in regard to Question 2(c) the Court confirms the judgment in *Van Bennekom* and there is no incompatibility in this case with the requirements of health protection, how can the request for marketing authorisation be successfully pursued? Can a decision of general application under Paragraph 47a of the LMBG be refused, without Community law being infringed, on the basis that in the German classification system a product is medicinal, whereas it can be marketed as a foodstuff in the Member State where it was manufactured? Is it compatible with Community law, and in particular with Articles 28 EC and 30 EC, not to apply the rule in Paragraph 47a of the LMBG to such medicinal products analogously? If not, can the German State, without thereby infringing Community law, evade an obligation which a German court intends to impose on it to adopt a decision of general application under Paragraph 47a of the LMBG (applied analogously) if it, or the authority responsible for food but not

medicines, objects that, because in the German classification system the product is medicinal, no decision of general application under paragraph 47a of the LMBG (analogously) may be adopted:

(i) because the body competent to adopt decisions of general application under Paragraph 47a of the LMBG is not competent for medicines also;

(ii) because the product is not authorised as a medicine?

(g) If as a result of the Court's replies it transpires that the product in question is a foodstuff (including, possibly, a food supplement) but is in any event not a medicine, questions will arise for the Chamber on the applicability of ... Regulation [No 258/97], which takes precedence over Paragraph 47a of the LMBG, and the effect of which may be to remove any interest in legal protection in this case. The Chamber therefore asks:

How is the phrase "which have not hitherto been used for human consumption to a significant degree" in Article 1(2) of ... Regulation [No 258/97] to be interpreted? Is it sufficient that the Netherlands Official Gazette of 16 February 1995 declared trading in a probiotic similar to the contested product called "Ecologic 316" to be permissible and that, according to the invoice of 20 May 1996, a delivery of Ecologic 316 was made to the applicant, or alternatively what are the minimum requirements that must be met in order for there to have been

use to a significant degree hitherto for the purposes of Article 1(2) of ... Regulation [No 258/97]? What is the starting point for interpreting the words "not hitherto"?

(h) If the Court declines itself to reply to Question 1(a) to (d), may the national court then direct questions on the classification of products or indeed scientific or methodological questions to the European Food Safety Authority and to what extent are any guidelines provided by that authority binding on the national court? Can (or must) such guidelines be reviewed by the Community judicature alone or by the referring national court also?'

26 In Cases C-299/03 and C-316/03 to C-318/03, the questions referred by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen are the same as those referred in Case C-211/03, apart from the following differences. First, in each of those cases, Question 1(a) refers by name to the product at issue in the main proceedings. Question 1(b) and (d) and Question 2(g) are referred only in Case C-211/03 and not in Case C-299/03 and C-316/03 to C-318/03. Last, in the latter cases Question 2(b) is supplemented as follows:

'Since Directive 2001/83 ... has introduced in the second sentence of Article 1(2) (concerning "functional" medicinal products) the concept of "physiological functions", the question also arises as to the significance of that concept and of its relationship with that of "pharmacological action"'.

27 The referring court further states that the grant of decisions of general application pursuant to Paragraph 47 of the LMBG is now within the competence of the newly-created Bundesamt für Verbraucherschutz und Lebensmittelsicherheit.

28 By order of the President of the Court of 22 September 2003, Cases C-211/03, C-299/03 and C-316/03 to C-318/03 were joined for the purposes of the written procedure, the oral procedure and the judgment.

The questions referred for a preliminary ruling

Question 1(b)

29 By Question 1(b), which should be examined first, the national court asks the Court, essentially, whether the method of ingesting a product is significant for its classification as a medicinal product or as a foodstuff.

30 For the purposes of determining whether a product must be classified as a medicinal product or as a foodstuff within the meaning of the Community regulations, the competent national authority 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 (see *Van Bennekom*, cited above, paragraph 29; Case C-369/88 *Delattre* [1991] ECR I-1487, paragraphs 26 and 35; Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 29; Case C-112/89 *Upjohn* ('*Upjohn I*') [1991] ECR I-1703, paragraph 23; Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, paragraph 17; and Case C-150/00 *Commission* v *Austria* [2004] ECR I-3891, paragraph 64).

31 The manner in which the product is used which must be taken into account in the context of that global examination includes, where appropriate, the fact that the product in question must, according to the method by which it is used, be mixed with water or with yoghurt. However, that factor is not decisive in itself and does not preclude the characteristics of the product in its initial state, before being mixed with water or with yoghurt, from being taken into account.

32 Consequently, the answer to Question 1(b) must be that 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.

Question 1(c)

33 As Question 1(c) merely refers to Question 2(c) and (f), it does not call for an individual answer.

Question 2(a)(i)

34 By Question 2(a)(i), the referring court seeks essentially to ascertain the relationship between Regulation No 178/2002 and Directive 2002/46.

35 It follows from the definition of food supplements in Article 2(a) of Directive 2002/46 that they constitute a special category of foodstuffs.

36 Regulation No 178/2002 represents a general rule which, in addition to establishing the European Food Safety Authority and laying down procedures in matters of food safety, lays down the general principles and requirements of food law.

37 Under Article 14(1) of Regulation No 178/2002, food is not to be placed on the market if it is unsafe and, in accordance with Article 14(2), food is to be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. Under Article 14(7), food that complies with specific Community provisions governing food safety is to be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned. However, Article 14 (8) provides that conformity of a food with specific provisions applicable to that food is not to 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.

38 It follows from the system established by Regulation No 178/2002, in particular by Article 14(1), (2), (7) and (8), that, so far as the requirements governing food safety are concerned, that regulation constitutes an additional set of rules in relation to Directive 2002/46.

39 It follows that the answer to Question 2(a)(i) must be that Regulation No 178/2002 constitutes an additional set of rules in relation to Directive 2002/46, 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.

Question 2(a)(ii)

40 By Question 2(a)(ii), the referring court asks essentially whether 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.

41 The wide definition of the word 'foodstuff' in the first paragraph of Article 2 of Regulation No 178/2002 may include medicinal products. However, it is apparent

from point (d) of the third paragraph of that article that 'food' does not cover medicinal products within the meaning of Directive 2001/83.

42 Likewise, Article 1(2) of Directive 2002/46 provides that that directive is not to apply to medicinal products as defined by Directive 2001/83.

43 It follows that 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 (see, to that effect, Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraphs 19 and 20).

44 That interpretation is supported by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC (OJ 2004 L 136, p. 34), although the period for transposition of that directive does not expire until 30 October 2005. That directive introduces a new Article 2 into Directive 2001/83, paragraph 2 of which is worded as follows:

'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.'

45 Consequently, the answer to Question 2(a)(ii) must be that 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.

Question 2(b)

46 By Question 2(b), the referring court is asking essentially how the concept of 'pharmacological effect' is to be defined in the context of the classification of a product as a medicinal product. It further asks whether the requirement that there be a health risk forms an integral part of that definition.

47 It should be noted that the term 'pharmacological effect' does not appear either in Regulation No 178/2002 or in Directive 2001/83 or 2002/46. In its case-law on medicinal products, on the other hand, the Court has used the expression 'pharmacological properties'. It is apparent from the order for reference that Question 2(b) is intended to refer to that case-law.

48 According to the first subparagraph of Article 1(2) of Directive 2001/83, medicinal product means 'any substance or combination of substances presented for treating or preventing disease in human beings'. According to the second subparagraph of Article 1(2), '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 to be considered a medicinal product.

49 Directive 2001/83 thus provides two definitions of medicinal product: one definition 'by presentation' and another definition 'by function'. A product is a medicinal product if it comes within one or other of those two definitions.

50 In the second definition of medicinal product, the expression 'physiological functions' corresponds to the expression 'organic functions' in the second subparagraph of Article 1(2) of Directive 65/65. As Directive 2001/83, according to the first recital thereto, is intended to bring about a codification, it must be considered that those expressions have substantially the same meaning. It follows, in particular, that the case-law on the definition of medicinal product in Directive 65/65 can be transposed to the definition set out in Directive 2001/83.

51 As stated at paragraph 30 of this judgment, for the purposes of determining whether a product comes within the definition of a medicinal product 'by function' within the meaning of Directive 2001/83, the national authorities, acting under the supervision of the courts, must proceed 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.

52 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, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

53 The risk to health, mentioned by the referring court, 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 'by function' (see, to that effect, *Commission* v *Austria*, cited above, paragraph 65).

54 The answer to Question 2(b) must be that 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, 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.

Question 2(c) and (f)

55 By Question 2(c) and (f), the referring court asks essentially whether a product which is lawfully marketed in one Member State as a foodstuff must be capable of being imported by the grant of marketing authorisation in another Member State where that product is considered to be a medicinal product and in what way a marketing authorisation may be implemented in such a case.

56 As Community law stands, it is still possible that differences will continue to exist between Member States in the classification of products as medicinal products or as foodstuffs. Thus, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product (see Case C-387/99 *Commission* v *Germany* [2004] ECR I-3773, paragraphs 52 and 53, and *Commission* v *Austria*, paragraphs 59 and 60).

57 If a product is correctly classified as a medicinal product for the purposes of Directive 2001/83, its marketing is subject to the issue of marketing authorisation pursuant to Article 6(1) of that directive. The procedure governing the issue and the effects of such authorisation are set out in detail in Articles 7 to 39 of that directive.

58 In so far as Directive 2001/83 harmonises the procedures for the production, distribution and use of medicinal products, it is no longer possible for Member States to adopt national measures which restrict the free movement of goods on the basis of Article 30 EC, in particular on grounds of the protection of health of humans (see Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251, paragraph 47 and the case-law cited).

59 Accordingly, a Member State is no longer permitted to rely on grounds of the health of humans referred to in Article 30 EC in order to make the marketing on its territory of the products referred to in Directive 2001/83 conditional on compliance with requirements associated with the actual products which go beyond the grounds for refusal set out in that directive.

60 Consequently, the answer to Question 2(c) and (f) must be that 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.

Question 2(d)(i)

61 By Question 2(d)(i), the referring court asks the Court what importance must be attributed to the concept of upper safe levels in connection with the classification of a product as a medicinal product or as a foodstuff within the meaning of the Community provisions.

62 The concept 'upper safe level' is used in Article 5(1)(a) of Directive 2002/46. According to that provision, it is one of the factors to be taken into account in setting the maximum quantities of vitamins and minerals present in food supplements.

63 As such, that concept plays no part in the distinction between medicinal products and food supplements. On the one hand, it may prove necessary to lay down upper safe levels for certain foodstuffs which cannot be regarded as medicinal products. On the other hand, a product administered in quantities below any upper safe level may constitute a medicinal product either by its function or by its presentation.

64 It follows that the answer to Question 2(d)(i) must be that 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.

Question 2(d)(ii)

65 By Question 2(d)(ii), the referring court asks the Court about the discretion which the national authorities have when setting upper safe levels.

66 In view of the answer to Question 2(d)(i), there is no need to answer Question 2(d)(ii).

Question 2(e)(i)

67 By Question 2(e)(i), the referring court asks essentially whether the absence of a nutritional need in the population of a Member State means that that State is justified in prohibiting the marketing of a foodstuff or a food supplement lawfully manufactured or placed on the market in another Member State.

68 In default of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, Member States may, in certain conditions, restrict on the basis of Article 30 EC the marketing of foodstuffs lawfully marketed in another Member State on grounds of the protection of the health and life of

humans (see, to that effect, Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 42).

69 In such a context, the criterion of the nutritional need of the population of a Member State can play a role in its detailed assessment of the risks which the addition of nutrients to foodstuffs may pose for public health. However, the absence of such a need cannot, by itself, justify a total prohibition, on the basis of Article 30 EC, of the marketing of foodstuffs lawfully manufactured and/or marketed in other Member States (*Commission* v *Denmark*, cited above, paragraph 54).

70 As regards harmonisation, Directive 2002/46 brings about a certain harmonisation of national legislation on food supplements, as defined in Article 2(a) of that directive.

71 It follows from Article 3 of and the second recital to Directive 2002/46 that food supplements which comply with the rules laid down in that directive must in principle be able to be freely marketed within the Community.

72 Member States retain only limited possibilities of restricting the marketing of such food supplements. Article 12 of Directive 2002/46 provides that a Member State which intends to restrict the marketing of a product in accordance with the requirements of that directive is to establish in detail that the use of that product endangers human health. A mere statement that there is no nutritional need in the population of the Member State concerned does not suffice to demonstrate the

existence of such danger. On the other hand, it cannot be precluded that the absence of such a need may constitute one of a number of factors indicating the existence of a danger for human health.

73 It follows that the answer to Question 2(e)(i) must be that 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.

Question 2(e)(ii)

74 By Question 2(e)(ii), the referring court asks essentially whether the fact that the discretion which the authorities of a Member State enjoy when establishing an absence of nutritional need is subject to only limited review by the courts is compatible with Community law.

75 At paragraph 34 of its judgment in Case C-120/97 *Upjohn* (*'Upjohn II'*) [1999] ECR I-223, the Court held that where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the

Community judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by the authority is not vitiated by a manifest error or misuse of powers and that it clearly did not exceed the bounds of its discretion.

76 The Court concluded, at paragraph 35 of the judgment in *Upjohn II*, that Community law does not require the Member States to establish a procedure for judicial review of national decisions revoking marketing authorisations, taken under Directive 65/65 and in the exercise of complex assessments, which involve a more extensive review than that carried out by the Court in similar cases.

77 The Court none the less observed, at paragraph 36 of the judgment in *Upjohn II*, that any national procedure for judicial review of decisions of national authorities revoking marketing authorisations must enable 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.

78 Similar principles apply as regards the classification by the national authorities of a product as a medicinal product or the establishment by those authorities of any absence of nutritional need in the population of a Member State in respect of the product concerned.

79 It follows that the answer to Question 2(e)(ii) must be that 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.

Question 2(g)

80 By Question 2(g), the referring court asks the Court about the interpretation to be given to the condition laid down in Article 1(2) of Regulation No 258/97, which provides that a food or food ingredient does not fall within the scope of that regulation unless it has not hitherto been used for human consumption to a significant degree within the Community. The national court seeks essentially to ascertain the conditions from which it may be concluded that the food or food ingredient concerned has not been used for consumption to a significant degree and also the reference date for the purpose of assessing such consumption.

81 Regulation No 258/97 is aimed at the placing on the market of novel foods and novel food ingredients, such as those containing genetically modified organisms.

82 Article 1(2) of that regulation seeks to delimit the scope of the regulation, notably by defining what is to be understood by novel foods and food ingredients. According to that definition, 'novel' food and food ingredients are those 'which have not hitherto been used for human consumption to a significant degree within the Community'.

83 That condition refers to consumption, in the sense of ingestion by humans. In order to satisfy that condition, it is sufficient that the food or food ingredient in question has not been consumed to a significant degree by humans before the reference date.

84 In order to determine whether or not such consumption has taken place, the competent authority must take all the circumstances of the case into account.

85 If the food or the ingredient in question has been marketed in one or more Member States before the reference date, that circumstance is relevant for the purposes of such an assessment.

86 The circumstances taken into consideration must relate to the actual food or ingredient under examination and not a similar or comparable food or ingredient. Where novel foods or novel food ingredients are concerned, it cannot be precluded that even apparently minor differences may have serious consequences for public health, at least until it has been established by proper procedures that the food or ingredient in question is harmless.

87 As regards the reference date which must be taken into account in order to determine the extent of the human consumption of the food or food ingredient in question, it must be held that the term 'hitherto' in Article 1(2) of Regulation No 258/97 refers to the date on which that regulation entered into force. In accordance with Article 15 of that regulation, that date is 15 May 1997.

88 Consequently, the answer to Question 2(g) must be that Article 1(2) of Regulation No 258/97 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.

Question 2(h)

89 By Question 2(h), the referring court asks in substance whether a national court may refer questions on the classification of products to the European Food Safety Authority and, if so, what the binding force of the opinions of that authority vis-à-vis the court concerned will be.

90 The tasks of the European Food Safety Authority, as defined in Articles 22 and 23 of Regulation No 178/2002, do not include responding to questions from national courts.

91 Furthermore, Article 9 of Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ 2003 L 185, p. 6) provides that each Member State is to inform that Authority of 'the government authority or authorities authorised to request scientific opinions from the Authority'. It does not appear

from the wording of that provision that the national courts are among the 'authorised' 'government authorities' to which it refers.

92 It follows that, as the Community rules stand, national courts may not refer questions on the classification of products to the European Food Safety Authority.

93 However, if that Authority gave an opinion corresponding to the subject-matter of a dispute pending before a national court, that court would have to ascribe to such an opinion the same value as that recognised to an expert report. It would then be capable of constituting evidence that the court would have to take into consideration as such.

94 The answer to Question 2(h) must therefore be that 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.

Question 1(a) and (d)

95 By Question 1(a) and (d), which must be dealt with together, the referring court asks essentially whether the products Lactobact omni FOS, C 1000, OPC 85, Acid Free

C-1000 and E-400 must be classified as foodstuffs, possibly constituting food supplements, or as medicinal products and, in the event that the product Lactobact omni FOS is a foodstuff, whether it constitutes a novel food within the meaning of Regulation No 258/97.

96 In proceedings under Article 234 EC, which are based on a clear separation of functions between the national courts and the Court of Justice, any assessment of the facts in the case is a matter for the national court. The Court therefore has no jurisdiction to give a ruling on the facts in the main proceedings or to apply the rules of Community law which it has interpreted to national measures or situations, since those questions are matters for the exclusive jurisdiction of the national court (see Case C-318/98 *Fornasar and Others* [2000] ECR I-4785, paragraphs 31 and 32).

97 It is for the referring court to classify the products at issue in the five cases before it, taking into account the elements of interpretation provided by the Court, in particular at paragraphs 30 to 32, 35 to 39, 41 to 45, 47 to 54, 56 to 60, 62 to 64 and 81 to 88 of this judgment.

Costs

98 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national courts, the decision on costs is a matter for that

court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

1. **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.**

2. **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.**

3. **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.**

4. 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.

5. 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.

6. 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.

7. 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.

8. **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.**

9. **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.**

10. **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.**

[Signatures]