European Court of Justice, 9 June 2005, HLH Warenvertriebs – Orthica v Deutschland

PHARMACEUTICAL LAW

Distinction between medicinal products and food additives

- **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 ac-cordance with the method by which it is used, with water or with yoghurt.**
- **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.**
- **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.**
- **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 ca-pacities 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, correct-ing 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.**
- **that a product which constitutes a medicinal product within the meaning of Directive 2001/83 may be imported into another Member State only upon ac-quisition 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.**
- **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.**
- **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.**
- **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.**
- **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 signifi-cant 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 de-termining the extent of human consumption of that food or food ingredient.**
- **that a national court cannot refer questions on the clas-sification of products to the European Food Safety Authority. An opinion delivered by that Authority, pos-sibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evi-dence that that court should take into consideration in the context of that dispute.**

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European Court of Justice, 9 June 2005
(P. Jann, N. Colneric, J.N. Cunha Rodrigues, M. Ilešič and E. Levits)
JUDGMENT OF THE COURT (First Chamber)
9 June 2005 (*)
(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)
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,
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 con-

sumption 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 yo-

ghurt, 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.

OPINION OF ADVOCATE-GENERAL GEELHOED

delivered on 3 February 2005 (1)
Case C-211/03
HLH Warenvertriebs GmbH
v
Federal Republic of Germany
(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))
(Interpretation of Articles 28 EC and 30 EC, of 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, and of 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 – A Member State treats a product, Lactobact omni F0S, as a medicinal product, whereas in another Member State it is marketed as a food supplement)
Case C-299/03
Orthica BV
v
Federal Republic of Germany
(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))
(Interpretation of Articles 28 EC and 30 EC, of 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, and of 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 – A Member State treats a product, C 1000 (1000 mg Vitamin C with Bioflavonoid complex), as a medicinal product, whereas in another Member State it is marketed as a food supplement)
Case C-316/03
Orthica BV
v
Federal Republic of Germany
(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))
(Interpretation of Articles 28 EC and 30 EC, of 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, and of 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 – A Member State treats a product, OPC 85, as a medicinal product, whereas in another Member State it is marketed as a food supplement)
Case C-317/03
Orthica BV
v
Federal Republic of Germany
(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))
(Interpretation of Articles 28 EC and 30 EC, of 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, and of 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 – A Member State treats a product, Acid free C 1000, as a medicinal product, whereas in another Member State it is marketed as a food supplement)
Case C-318/03
Orthica BV
v
Federal Republic of Germany

(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))

(Interpretation of Articles 28 EC and 30 EC, 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 of 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, and of 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 – Member State treats a product, E 400 (natural Vitamin E), as a medicinal product, whereas in another Member State it is marketed as a food supplement)

I – Introduction

1. The facts on which these cases are based are relatively straightforward. All the cases concern products marketed in the Netherlands as food supplements. The applicants in the main proceedings asked the competent German authority for permission to import these products and place them on the market. Their requests were refused, on the one hand, because the product in question had to be treated as a medicine rather than a food and, on the other, because there were other compelling public health reasons why the product should not be allowed onto the market.

2. In all these cases, the Oberverwaltungsgericht für das Land Nordrhein□Westfalen (Higher Administrative Court for the Land of Nordrhein-Westfalen), which must rule on the appeal against the decisions to refuse admission, has submitted to the Court a series of questions concerning the interpretation of the relevant Community law. As these questions are largely, though not wholly, identical, in what follows I shall deal with them in groups.

3. The legal problems underlying these cases form the subject of a by now extensive Court case-law, beginning with the Van Bennekom judgment and recently supplemented by the Commission v Denmark and Commission v Netherlands judgments. (2)

II – The relevant legislation

A – Community law

4. Article 1 of Regulation (EC) No 258/97 (3) of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ('Regulation No 258/97') reads as follows:

'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.

…'

5. According to the first paragraph of Article 2 of Regulation (EC) No 178/2002 (4) 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 ('Regulation No 178/2002') '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'. However, subparagraph (d) of the same article explicitly states that medicinal products within the meaning of Directives 65/65/EEC and 92/73/EEC do not fall within this definition of food. The abovementioned directives can now be found as a single text in Directive 2001/83.

6. According to Article 1(2) of Directive 2001/83/EC (5) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ('Directive 2001/83') for the purposes of the Directive 'medicinal product' means, firstly, 'any substance or combination of substances presented for treating or preventing disease in human beings' and, secondly, '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'.

7. Article 1(1) of Directive 2001/83 stipulates that 'proprietary medicinal product' shall be taken to mean 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'.

8. Article 2(a) of Directive 2002/46/EC (6) 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 ('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 … marketed in dose form …'. Nutrients are vitamins or minerals (Article 2(b) of Directive 2002/46).

9. Article 1 of this directive expressly states that the directive does not apply to medicinal products as defined by Directive 2001/83.

10. Article 15 of Directive 2002/46 requires Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this directive by 31 July 2003.

B – National law

11. Paragraph 47a of the Lebensmittel- und Bedarfgegenständegesetz (Law on foodstuffs and consumer products, 'the LMBG') provides 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 Federal Ministry of consumer protection and food safety has not published a decision of general application in the Bundesanzeiger (Official Gazette) approving 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 by the Federal Ministry of consumer protection and food safety with the agreement of the Federal Ministry of economic affairs and export controls 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 party 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. The application shall be dealt with within a reasonable time. If a final decision on the application has not been made within 90 days, the applicant shall be informed of the reasons for the delay.

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.'

12. The first sentence of Paragraph 73(1) of the German Arzneimittelgesetz (Law on medicinal products, hereinafter 'the AMG') provides 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 a country that is not a Member State of the European Community or another State party to the European Economic Area Agreement, the recipient must possess authorisation under Paragraph 72.

...'

III – Background and the questions referred for a preliminary ruling

National procedure

13. In 1995 and 1996, HLH Warenvertriebs GmbH (hereinafter 'HLH') and Orthica BV (hereinafter 'Orthica') unsuccessfully applied to the Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (Federal Ministry of Consumer Protection, Food and Agriculture), the competent authority at the time, for a decision of general application under Paragraph 47a of the LMBG. Their intention was to place on the German market a number of products which in the Netherlands were authorised as food supplements.

14. The products in question were:

– in Case C□211/03: 'Lactobact omni FOS' (in powder form, one gram of the powder containing at least 1 000 000 000 organisms from the following six bacterial strains: Lactobacillus acidophilus, Lactococcus lactis, E. faecium, Bifidobacterium bifidum, Lactobacillus casei, and Lactobacillus thermophilus. The recommended daily amount is approximately 2 g (about one level teaspoon), dissolved while stirring in half a glass of water or yoghurt, or twice that where the need is greater and in the first four weeks of use);

– in Case C□299/03: 'C□1000' (in tablet form, composed of 1 000 mg of vitamin C, 30 mg of citrus bioflavonoids, hesperidin rutin complex and other ingredients, the recommended amount being one tablet per day);

– in Case C□316/03: 'OPC 85' (in tablet form, composed of 50 mg extract bioflavonol, procyanidine oligomer and other ingredients, the recommended amount being one tablet per day);

– in Case C□317/03: 'Acid Free C□1000' (in tablet form, composed of 1 110 mg calcium ascorbate, 1 000 mg vitamin C, 110 mg calcium and other ingredients, the recommended daily amount being one tablet);

– in Case C□318/03: 'E□400' (in tablet form, composed of 268 mg vitamin E, the recommended amount being one tablet per day).

15. The Bundesministerium für Gesundheit (Federal Ministry of Health), the competent authority at the time, refused to adopt a decision of general application on the following grounds:

– in Case C□211/03, by pointing out that the product was not a food supplement but a preparation containing isolated bacterial cultures with medicinal properties;

– in Cases C□299/03 and C□317/03, by pointing out that taking one tablet results in the daily amount recommended in Germany being exceeded by a factor of more than 13, so that the product cannot be regarded as a foodstuff for general consumption and therefore, for compelling health-protection reasons, should not be marketed;

– in Case C□316/00, by pointing out that the bioflavonoids contained in the product, in isolated form, do not have nutrition or pleasure as their primary function and should be regarded as a substance with a pharmacological effect and, for compelling health-protection reasons, should not be marketed;

– in Case C□318/03, by pointing out that taking one tablet results in the dose of vitamin E recommended in Germany being exceeded by a factor of 22 and that recent studies suggest that the increased ingestion of vitamin E over a prolonged period of time has an injurious effect on health, so that the scientific uncertainty in this area militates against the product being marketed.

16. HLH and Orthica contested these refusals. The Verwaltungsgericht (Administrative Court) decided that the products were not foodstuffs but medicinal products and dismissed the applications.

17. The abovementioned parties then appealed to the Oberverwaltungsgericht für das Land Nordrhein□Westfalen which considers that its decision will depend on the interpretation of a number of provisions of European law and has therefore referred the following questions to the Court for a preliminary ruling.

Questions referred for a preliminary ruling

'Question A

– Question A I (in all cases)

Is the contested product … a foodstuff (perhaps in the form of a food supplement) or a medicinal product? Is this classification binding on all the Member States?

– Question A II (in Case C□211/03)

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?

– Question A III (in Case C□211/03) and Question A II (in Cases C□299/03 and C□316/03 to C□318/03, inclusive)

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 the questions in B VI, in conjunction with those in B III. Reference is made to those questions and the observations thereon and an answer is requested.

– Question A IV (in Case C□211/03)

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?

Question B

In the event that – as has been the case hitherto – the questions posed in section A above are to be answered not by the Court of Justice but by the national courts, guidance is sought on how to resolve the following questions.

– Question B I (a) (in all cases)

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?

– Question B II (in Case C□211/03) and Question B 2 II (a) (in Cases C□299/03 and C□316/03 to C□318/03, inclusive)

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 the Basic Regulation, to be defined for the purposes of Community law? In particular, does the definition include a requirement that there be a health risk?

– Question B II (b) (in Cases C□299/03 and C□316/03 to C□318/03, inclusive)

Now that Directive 2001/83 has, by the second sentence of Article 1(2) (on "functional" medicinal products), introduced the term "physiological functions", the further question arises as to the meaning of that term and its relation to the term "pharmacological effect".

– Question B III (in all cases)

Does the view expressed by the Court of Justice in Case 227/82 Van Bennekom [1983] ECR 3883, paragraph 39, 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 the product at issue here, and does the Court of Justice adhere to its view in the light of subsequent Community law?

– Question B IV (a) (in all cases)

In so far as the term "health risk" is relevant to the questions in sections II or III, 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? How are the words "reference intakes of vitamins and minerals for the population" within the meaning of Article 5 of the Food Supplements Directive to be defined?

– Question B IV (b) (in all cases)

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?

– Question B V (a) (in all cases)

If a product may be marketed in at least one other Member State as a foodstuff, is the fact that there is no "nutritional need" for that product in Germany significant in terms of the freedom to market the product in Germany?

– Question B V (b) (in all cases)

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?

– Question B VI (in all cases)

If in regard to the questions posed in section III 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 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,

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

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

– Question B VII (in Case C□211/03)

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 (the referring court) concerning 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 "not hitherto been used … 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"?

– Question B VIII (in Case C□211/03) and Question B VII (in Cases C□299/03 and C□316/03 to C□318/03, inclusive)

If the Court declines itself to reply to the questions posed in section A, may the national court then direct questions on the classification of products to the European Food Authority and to what extent are any guidelines provided by that authority binding on the national court?'

Proceedings before the Court

18. In the proceedings before the Court, HLM, Orthica and, moreover, the Commission, the German Government, the Spanish Government and the Swedish Government submitted written observations. A hearing was held on 9 December 2004.

IV – Analysis

Preliminary remarks

19. The context within which the questions reproduced above arose is volatile in more than one respect.

20. In terms of economics, the development of food technology has led to the appearance on the market of an ever-widening range of novel foods, alongside the traditional foodstuffs with their time-honoured ingredients. Novel not only in recipe and composition but also because they may be enriched with active substances, such as vitamins, bacteria or minerals, and marketed as a specific category of products, such as food supplements. With regard to medicines, the progress of pharmaceutical technology has had similar consequences and, in particular, the development of biotechnology is expected to result in far-reaching changes.

21. From the scientific standpoint, the situation is even more fluid. The discoveries leading to new foods and medicinal products are paralleled by improvements in our understanding of the risks attached to the consumption of certain foods and the administration of certain medicines. Sometimes it may be a question of the intake of a specific substance or ingredient, or the composition of an entire food package may, from the public health standpoint, give cause for concern.

22. As for the law, the situation is in flux because the public interest involved in the consumption of foods and medicinal products is forcing the legislature to keep the legislation abreast of both developments in the marketplace and trends in technical and scientific

thinking. The Community legislature, in particular, has the additional task of ensuring the free movement of these products, the necessary harmonisation between the national legal systems and the necessary convergence in their application. This dual responsibility has resulted in a large body of directives and regulations (see below).

23. As a consequence of the activities of, in particular, the Community legislature, since the abovementioned Van Bennekom judgment the legislative context within which the Court must arrive at its decisions has radically changed. Although the principles established by the Court in that judgment are still valid, the space within which those principles must be applied has become ever more tightly hedged about by subordinate Community legislation. As we shall see, this applies to the legislation on medicinal products even more than to that on foods.

24. In conclusion, I would draw attention to a special feature of the implementation of the Community food and medicinal products legislation. The responsibility lies, in the first instance, with the competent national authorities, the Community bodies playing a supporting or complementary role, which is more developed in the medicinal product than in the food sector. This parallel responsibility, within the common market, of the competent national authorities, which under the Community legislation are allowed a certain discretion, means that divergent opinions are still possible with respect to the authorisation of foods and – to a lesser extent – medicinal products. As the present cases clearly show, the resulting hindrances to trade repeatedly give rise to new questions of law.

25. Below, I shall start by giving an account of the relevant existing Community law on foods and medicinal products. I shall then describe the problem of the demarcation line between the Community legislation on medicinal products and that on foods, as largely solved in the meantime by the Community legislature and the Court. Since the questions referred for a preliminary ruling cover territory which has been in part completely and in part incompletely harmonised, it may be useful to give a comprehensive overview of the relevant provisions of the trade-restrictive measures of Member States that have been justified on grounds of public health. I shall round off my general remarks with a brief account of certain elements of the Court's recent case-law which could be helpful in seeking answers to the questions posed. My analysis draws upon the Community legislation as it now stands, since in its order for reference the national court explains that it too will base its final decision in the main proceedings on the current legislation.

26. It will be possible to answer the grouped questions fairly concisely since the most important building blocks will already have been laid in my general commentary. To spare the reader the intellectual tedium of a long and repetitive exposition, I shall simply refer to the paragraphs of this Opinion in which the proposed answers to the various questions have already been formulated.

Medicinal products

27. The first harmonisation measures to remove hindrances to the free movement of medicinal products can be found in Directive 65/65/EEC. (7) This Directive represented only the first step toward complete harmonisation. (8) The method employed consisted in formulating Community definitions for the concepts of medicinal product and proprietary medicinal product and in harmonising the national procedures for authorising the marketing of such products.

28. Over the years, Directive 65/65 was frequently amended and supplemented and, in 2001, for the sake of greater transparency, this extensive body of legislation was reorganised and codified in a single text, Directive 2001/83, the 'Community code relating to medicinal products for human use'. It is illustrative of the rapid evolution of this branch of legislation that less than three years later the Community code was extensively amended by Directive 2004/27/EC. (9) In fact, the time-limit for transposing the latter directive has not yet expired.

29. The current definition of 'medicinal product' can be found in Article 1.2 of Directive 2001/83. Just like the earlier description in Directive 65/65, it is in two parts. A substance is a medicinal product if it is presented for treating or preventing disease in human beings (definition 'by virtue of presentation') and it is a medicinal product if it can be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (definition 'by virtue of function'). If a product can be made to fit within this two-part definition, then under Community law it is a medicinal product.

30. The case-law shows that the notion of 'presentation' of a product should be given a broad interpretation. (10) It includes not only products presented for treating or preventing disease within the meaning of the medicinal products directive, but also products that create the impression in the averagely well-informed consumer that they possess such therapeutic or prophylactic properties. Products to which the definition is applied by virtue of their 'function' must first be subjected to a detailed technical and scientific investigation. In its case-law the Court has mentioned the following criteria which may be taken into consideration in determining whether a product is covered by this part of the definition: the pharmacological properties of the product concerned 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. (11)

31. If a product falls within the Community definition of a medicinal product, then for market access purposes the provisions of Directive 2001/83 apply. According to the directive, a medicinal product may be placed on the market only if an authorisation has been issued (Article 6). There are two kinds of authorisation: a centralised Community authorisation based on Regulation (EEC) No 2309/93, (12) and a decentralised national authorisation, the procedure for which is gov-

erned by national provisions harmonised under Directive 2001/83. For medicinal products that fall within the regulation, authorisation must be requested from the European Agency for the Evaluation of Medicinal Products. The authorisations issued by the Agency are valid for the entire Community. However, the scope of this procedure is restricted to a few categories of medicinal products listed in the annex to the regulation. Thus, for most medicinal products applications for authorisation must be addressed to the competent authority of the Member State concerned. The requirements for applying for an authorisation can be found in Article 8 of Directive 2001/83, and the grounds for refusal, exhaustively listed, in Article 26. Article 27 et seq. lays down the important principle of the mutual recognition of authorisations. In principle, the Member State of destination must recognise the authorisation issued in the Member State of origin, unless the Member State in which recognition is being requested considers that placing the product concerned on the market may present a risk to public health. In these circumstances, it is first necessary to follow the procedure laid down in Article 29, which requires the Member States concerned to endeavour to reach agreement. If that does not seem possible, then the Article 32 procedure must be followed. This may lead to a definitive ruling on the application by the Commission.

32. From the content and system of Directive 2001/83 it follows that medicinal products are now subject to a regime which combines a high level of health protection with extreme freedom of inter-State trade in medicinal products. In its written observations the Swedish Government has stated that for medicinal products harmonisation is now complete. This view is shared by the applicants in the main proceedings. The observations of the Spanish Government suggest that, in its view, the sector in question is still only partially harmonised. The Commission takes a slightly divergent position. In its opinion, the special provisions for the products covered by the Community definition of medicinal products are now largely governed by Community law. Accordingly, Member States should still be able to adopt measures relating to medicinal products autonomously, under Article 30 EC, only to the extent that they concern aspects not dealt with by Directive 2001/83, such as the way in which medicinal products may be marketed.

33. I am inclined to share the Commission's view. The system established by Directive 2001/83 is conclusive where the definition of the notion of medicinal product is concerned; it exhaustively regulates marketing authorisations and the vital – from the standpoint of inter-State trade – issue of mutual recognition, while laying down a sound procedure for resolving differences of opinion between Member States concerning the health risks of permitted medicinal products. Within this framework, Member States are required to formulate their views on health protection in conformity with the detailed provisions of the directive. Only in circumstances which clearly fall outside the scope of the directive is there still room for autonomous national measures under Article 30 EC.

34. It follows that in describing products as 'medicinal products' Member States are bound by the exhaustive definition in Article 1(2) of Directive 2001/83. The national courts have exclusive jurisdiction to review the decisions of the national competent authorities concerning the description of products as medicinal products. In so doing, the national courts should take into account the case-law of the Court in which the definition is further interpreted.

35. The case-law clearly brings out the twofold ratio legis underlying Directive 2001/83. On the one hand, the legal regime for medicinal products should be more rigorous than that for food, since their use in consumption may present particular risks. (13) On the other hand, there must be sufficient assurance that products which claim to have medicinal properties do indeed have those properties. (14) The existence of both particular risks and therapeutic efficacy must be demonstrated on the basis of data supported by sound scientific research.

36. In my opinion, there are three objections to too broad an interpretation and application of the definition of medicinal product. First of all, the concept of 'medicinal product' would cease to have any differentiating effect if it were to include products whose properties and action did not justify their being classified as such. This would harm rather than serve the interests of human health. Secondly, it could result in the specific Community regulations for certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory object. I am thinking, inter alia, of Regulation No 258/97 concerning novel foods and novel food ingredients and Directive 2002/46 on food supplements. Thirdly, a 'stealthy' extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods.

37. This does not exclude minor differences between Member States in the practical application of Directive 2001/83. Nevertheless, whenever a Member State proceeds to treat as medicinal a product that elsewhere in the Community is regarded as a foodstuff or a special food, it should justify its decision with objective scientific data.

Food

38. Meanwhile various Community rules have also been established for food. These include, on the one hand, general or horizontal rules which in principle apply to all foods and, on the other, specific rules which apply to particular categories of 'sensitive' foods.

39. Regulation No 178/2002 has as its primary objective the approximation of the concepts, principles and procedures of the food laws of the Member States so as to form a common basis for measures governing food taken in the Member States and at Community level. This harmonisation is still in the initial stage. Although the most important concepts, such as the concept of food, have now been harmonised, it appears from the preamble to the regulation, in particular, re-

cital (5), that the adaptation of conflicting provisions in the existing legislation, at both national and Community level, will still take some time. In any event, the existing principles must be brought into compliance with the principles laid down in Articles 5 to 10, inclusive, of the regulation by 1 January 2007. The latter form a horizontal framework for the further regulation of the sector.

40. One of the main objectives of Regulation No 178/2002 is to assure a high level of protection of human health. This is made clear at various points in the regulation, notably in Articles 1(1), 5(1), 6(1) and 7(1). The achievement of this objective depends upon the fulfilment of the food safety requirements laid down in Article 14(1) to (6). (15) In the context of the present cases, Article 14(7) to (9) assumes special importance. Article 14(7) establishes the principle that food that complies with specific Community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned. Article 14(8), however, introduces an exception to this principle by stipulating that the conformity of a food with specific provisions applicable to that food shall not bar the competent national authorities from taking appropriate measures to impose restrictions on its being placed on the market, where there are reasons to suspect that the food is nevertheless unsafe. Article 14(9) establishes the principle that 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 without prejudice to the Treaty, in particular Articles 28 EC and 30 EC. I shall return to these provisions of Article 14, which are of particular importance in the present context.

41. From the key paragraphs of Regulation No 178/2002 quoted above it appears that the general principles and requirements of this regulation presuppose specific harmonising provisions for certain categories of foods or ingredients thereof. Meanwhile, a number of such specific harmonisation measures containing substantive provisions for particular groups of foods have been adopted. In this context Directive 2002/46 and Regulation No 258/97 are of special relevance.

42. Directive 2002/46 meets the need for specific legislation for food supplements. Only food supplements that satisfy the provisions of this directive can be placed on the market. For the moment, the substantive scope of the directive is restricted to certain nutrients (vitamins and minerals). Thus, only the minerals and vitamins on the positive list appended to the directive (Annexes I and II) can be used for the manufacture of food supplements. The – restrictive – regime of this directive is subject to a transition period. Articles 12 and 13 of the directive are of particular interest. Under Article 12, where a Member State, as a result of new information or of a reassessment of existing information made since the directive or one of the implementing acts was adopted, has detailed grounds for establishing that a product to which the directive applies endangers human health, though it complies with the regulations, that Member State may temporarily suspend or restrict application of the provisions in question within its territory and then inform the Commission and the other Member States thereof. The Commission must take the appropriate measures having regard to the procedure of Article 12(2) and (3) and, where necessary, Article 13(2).

43. Regulation No 258/97 contains specific Community provisions concerning novel foods and novel food ingredients. In particular, it concerns, in summary, the following categories:

– foods and food ingredients containing or consisting of genetically modified organisms;

– foods and food ingredients produced from, but not containing, genetically modified organisms;

– foods and food ingredients with a new or modified primary molecular structure;

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

– foods and food ingredients isolated from plants and animals;

– foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to changes in the composition or structure of the foods or food ingredients.

44. Before such products can be marketed, they must undergo a standard safety check in accordance with a Community procedure. The Member State in which the product is placed on the market for the first time makes the initial assessment. This assessment is carried out in close cooperation with the Commission, the other Member States and the Standing Committee for Foodstuffs. In this regulation too, the assurance of a high level of protection is one of the main objectives, as is apparent from Article 3(1). Articles 12 and 13 of the regulation contain provisions which are similar but not wholly identical to those of Articles 12 and 13 of Directive 2002/46.

45. All this can be summarised as follows: at Community level, Regulation No 178/2002 introduced a system of generic Community requirements establishing the general principles with which both national and Community food regulations must comply. For sensitive foods and food ingredients, which present special dangers and risks, in an ongoing process of substantive harmonisation an ever-increasing number of specific Community regulations, intended to remove obstacles to free movement and assure a high level of health protection, are being introduced.

46. As the Commission and the Governments of Spain and Sweden have pointed out, harmonisation in the extensive food sector is still far from complete and the Member States have retained greater discretion than in the medicinal products sector while striving for a level of food safety which, in their view, ensures adequate protection for human health. However, from what has already been said it appears that this conclusion is too general and needs to be refined as the general principles laid down in Regulation No 178/2002 are further implemented at national and Community level and as

specific harmonisation measures for the foods and food ingredients concerned are introduced.

47. In fact, now that Regulation No 178/2002 expressly stipulates that both Community and national food laws must assure a high level of protection and that the decisions of the competent bodies must be based on sound scientific risk analyses and, where justified, take the precautionary principle into account, it will be more difficult for Member States to resort to Article 30 EC on the grounds of health protection. They will have to show that although products may have been authorised elsewhere in the common market, with due regard for the principle of a high level of health protection and the precautionary principle, they nevertheless present unacceptable dangers and risks to health. Where it may be assumed that the approval of the products concerned in the Member State of production is also based on a thorough scientific investigation, the second expert opinion required to make a case under Article 30 will have to be very convincing.

48. If they succeed in making it seem plausible that dangers or substantial risks to health do indeed exist, then, in accordance with the settled and recently reaffirmed (16) case-law of the Court, the restrictive measures proposed will have to comply with the principle of proportionality. That means that the measures must be appropriate, not go beyond what is strictly required by the interest to be protected and be proportional to the objective pursued, in the sense that the objective could not have been attained by measures which are less restrictive of intra-Community trade.

49. However, where foods and food ingredients which form the subject of specific Community regulations are concerned, Member States are no longer free, in the presence of supposed dangers or risks to health, to resort to Article 30 EC without taking more restrictive measures. Thus, they will have to act in accordance with the procedures of the Community regulations concerned, as for example laid down in Articles 12 and 13 of Regulation No 258/97. In the absence of such special procedures, they will have to act in accordance with the more generic provisions of Article 14(7) and (8) of Regulation No 178/2002.

50. In conclusion, I should also point out that the European Union's developing food law is characterised by the coexistence of the national competent bodies of the Member States and the competent Community bodies. Given the ever more extensive cross-border production and distribution chains for foodstuffs, this is creating a twofold interdependency. On the one hand, as they increase in length and complexity, the above-mentioned chains are becoming increasingly vulnerable to unilateral constraints and restrictions. On the other hand, they allow dangers and risks to health to spread rapidly over the territory of the Union. This is forcing the authorities to cooperate, both horizontally between national bodies and vertically between national and Community bodies. These obligations are partially specified in the relevant regulations and, to the extent that they are not, they follow from the principle of cooperation in good faith laid down in Article 10 EC. (17)

Demarcation issues

51. The existence of Community definitions for medicinal products and food does not mean that no demarcation issues will arise. These issues can be divided into two categories.

52. Firstly, static demarcation issues. These arise whenever, with respect to its objectively ascertainable characteristics, a product falls both under the definition of medicinal product as described in Article 1(2) of Directive 2001/83 and under the definition of food given in Article 2 of Regulation No 178/2002. If it does, then under Article 2(d) of Regulation No 178/2002 that regulation will not apply. A comparable provision is contained in Article 1(2) of Directive 2002/46. Where there are no such express prioritising provisions, as in Regulation No 258/97, it must be assumed that if a product can be considered to be a medicinal product and a novel food or novel food ingredient, Directive 2001/83 applies. However, as a special category of foods, novel foods and food ingredients also fall under the general definition of food in Regulation No 178/2002. Thus, they are also subject to Article 2(d) of that regulation. This was very recently reconfirmed by the Community legislature and clarified in Directive 2004/27 amending Directive 2001/83. This added a second paragraph to Article 2 of Directive 2001/83 to the effect that in cases of doubt, where a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of the medicinal products legislation apply. Although the period allowed for the transposition of the amending directive has not yet passed – it expires on 30 October 2005 – I consider this addition significant within the present context as it makes explicit what according to legislation and case□law (18) is already valid law.

53. Secondly, there are demarcation problems which are dynamic in nature. These arise whenever a product deemed in the Member State of production to be a foodstuff or special food to which specific Community provisions apply and which is treated by that Member State in accordance with Community and national food law is deemed to be a medicinal product by a Member State of destination. As I have already pointed out in paragraph 37 above, under the present system for the administration and enforcement of Community medicinal products law, differences in the interpretation and application of the substantive scope of that law are inevitable. In such cases, the characteristics of the product in question will be differently construed by the national competent authorities concerned.

54. There are two ways in which the scope for such differences of interpretation between national competent authorities is limited by the relevant Community law. Firstly, by the definitions of medicinal products, food and special foods themselves. It is forbidden to bring products within the definition of medicinal products if, on the basis of objective criteria, they do not belong in that category. I have already referred, in paragraph 36, to the disadvantages of arbitrarily broadening the scope of the definition of medicinal products.

Secondly, by the priority rule just mentioned in paragraph 52, where products objectively fall both within the definition of medicinal products and within the general definition, or one of the special definitions, of food. They must then, under the existing Community law, be treated as medicinal products.

55. In describing the Community law on medicinal products and food I have indicated that in both sectors there are procedural mechanisms for resolving differences in the interpretation of the relevant law and in its application to particular products with a view to avoiding undesirable discrepancies in the level of protection and unnecessary hindrances to inter-State trade in the products concerned. Considering the potentially serious consequences of differences in interpretation and application between national competent bodies and considering the vulnerability of the inherently complex legal systems to careless application, it seems clear that the national authorities of a Member State ought to be aware of the implications of classifying products imported into its territory differently from the competent authorities of the country of exportation. The duty of care implies that they should at least make use, as far as possible before taking their decision, of the procedures provided by Community law for avoiding trade-restrictive differences in the interpretation and application of the Community legislation concerned or limiting the damage. This holds even more true where, as a result of differing views, a product is subject to medicinal product law in one Member State whereas in others it is subject to general or specific food laws, because the applicability of medicinal product law would place much wider restrictions on the product in question.

Hindrances to trade

56. In my overview of the relevant nascent Community law on medicinal products and food, I have already touched on the hindrances to trade that can result from differing interpretations and applications of the legislation by national competent authorities. For the sake of clarity, I will now summarise the various possibilities, while at the same time indicating the general and special legislation applicable:

a. Products deemed to be medicinal products by both the Member State of production and the Member State of destination:

– with respect to those aspects of the trade in medicinal products for which Directive 2001/83 does not – yet – provide for exhaustive harmonisation, such as the rules on the way in which medicinal products are marketed, assuming they are not selling arrangements within the meaning of Keck and Mithouard, (19) Article 30 EC can be used to justify national measures provided that they meet the requirements for the application of that article which follow from the case-law;

– with respect to those aspects of the trade in medicinal products for which Directive 2001/83 provides for exhaustive harmonisation, a Member State of destination can refuse to admit medicinal products lawfully manufactured or marketed elsewhere in the European Union only on the grounds mentioned in Article 29(1) of the directive. Such a measure must be pursued under the procedures laid down in Article 29(2) and, where appropriate, Article 32 of the directive.

b. Products deemed to be food by both the Member State of production and the Member State of destination and lawfully marketed in the Member State of production, and to which no specific harmonisation provisions apply:

– the basic rule is that these are deemed to be safe when they conform to the specific provisions of the Member State in which they are marketed (first part of Article 14(9) of Regulation No 178/2002);

– however, Member States of destination may refuse admission to these products or subject them to restrictions either on health grounds under Article 30 EC or on the grounds of compelling requirements of public interest recognised in the case-law on Article 28 EC (second part of Article 14(9) of Regulation No 178/2002).

c. Products which are the subject of specific harmonisation measures and are deemed to be a food in both the Member State of production and the Member State of destination:

– the basic rule is that if these products have been approved for marketing by the national competent authorities in the Member State of production in accordance with the relevant special harmonisation measures, they may also be marketed in the Member State of destination (Article 14(7) of Regulation No 178/2002);

– if a Member State has reason to suspect that a food is unsafe, even though it conforms with the specific provisions applicable to that food, it may nonetheless take appropriate measures to impose restrictions on its being placed on the market or require its withdrawal from the market (Article 14(8) of Regulation No 178/2002). However, in this case, the specific harmonising provisions must always be consulted to establish the special rights and obligations of the Member State concerned in such circumstances (see Regulation No 258/97, Articles 12 and 13, and Directive 2002/46, Articles 12 and 13).

d. If in the Member State of production a product is deemed to be a food or a foodstuff to which specific harmonising provisions apply, but in the Member State of destination is deemed to be a medicinal product, then from the existing scheme of things it follows that:

– if on the basis of its objective characteristics the product in question must be deemed to be a medicinal product, then Directive 2001/83 applies. The Member States concerned must then, in the interests of uniform application, take the necessary steps, together with the Commission, to resolve the matter using the procedures provided for the purpose in Directive 2001/83. Meanwhile, the Member State of destination may not impose any restrictions on the product's being placed on the market over and above those that it deems strictly necessary in the interests of health;

– if there are grounds for supposing that the product in question should not, on the basis of its objective characteristics, be deemed to be a medicinal product

and specific harmonising provisions apply to that product, then in taking restrictive measures the Member State of destination should follow the special procedures laid down in the specific harmonisation provisions;

– if there are grounds for supposing that the product in question should not, on the basis of its objective characteristics, be deemed to be a medicinal product and no specific provisions apply to that product, then the Member State concerned may take appropriate measures under Article 14(9) of Regulation No 178/2002;

– if it is uncertain whether the product in question should be deemed to be a medicinal product, the Member State must proceed by analogy with the procedures described in the two previous indents. These afford it a sufficient opportunity to protect the health interests at stake, while leaving intact its entitlement to seek a solution of the classification problem under the procedures of Directive 2001/83.

Issues already resolved in the case-law

57. In answering various of the questions posed, it becomes necessary to consider how far, as a minimum, the judicial review of an assessment by the competent national food and medicinal product authorities, based on technical analyses, should be taken.

58. The Court turned its attention to this matter in the Upjohn II case. (20) This case concerned the revocation of an authorisation for the marketing of a medicinal product. The decision was based on a medico-pharmacological investigation and had to take account of issues similar to those involved in classifying a product as a medicinal product.

59. In its judgment, the Court argued that under Community law the authority concerned enjoys a wide measure of discretion in performing duties which call for technical and scientific analyses. The exercise of this discretion is subject only to a limited judicial review, in the course of which the Community judicature may not substitute its assessment of the facts for that made by the authority in question. The review should be restricted to an examination of the accuracy of the findings of fact and law made by that authority. In particular, the judicature should verify that there has been no manifest error or a misuse of powers and that the authority did not clearly exceed the bounds of its discretion. (21) The Court concluded that Community law does not require Member States to establish a procedure for judicial review of national decisions revoking marketing authorisations for medicinal products which involves a review more extensive than that carried out by the Court in similar cases.

60. The Court points out, however, that any national procedure for judicial review of such decisions must enable the court, when reviewing the legality of a contested decision, to apply the relevant principles and rules of Community law.

61. In my opinion, this case-law is also applicable, mutatis mutandis, to the judicial review of national decisions concerning the classification of a product as a medicinal product. Here too, it is a question of decisions based on a technical and scientific investigation, in relation to which the national authorities have a wide measure of substantive discretion.

62. In its recent case-law the Court has considered whether the fact that the Member State of destination has no nutritional need for a product lawfully manufactured or marketed in another Member State is of importance in determining whether, on the basis of Community law, the Member State of destination is justified in prohibiting the marketing of the product in question for that reason alone.

63. In its recent judgments in Commission v Denmark and Commission v Netherlands (22) the Court went into this question in detail. In these judgments it declared that a practice of a Member State of destination which requires that the marketing of foodstuffs enriched with vitamins and minerals coming from other Member States where they are lawfully manufactured or marketed be made subject to proof of a nutritional need in the population of the Member State of destination makes the marketing of those products more difficult, if not impossible, and consequently hinders inter-State trade.

64. However, in the absence of harmonisation of standards for the products in question and to the extent that real uncertainties continue to exist in the current state of scientific research, Member States remain at liberty, under the health protection provisions of Article 30 EC, to take the measures they consider necessary to safeguard public health. This discretion is particularly wide where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances, such as vitamins, which are not as a general rule harmful in themselves but may have harmful effects if taken to excess as part of general nutrition, the composition of which cannot be foreseen or monitored.

65. According to the Court, Community law does not, in principle, preclude a Member State from prohibiting, save for prior authorisation, the marketing of foodstuffs incorporating nutrients such as vitamins and minerals other than those whose use is lawful under Community legislation. However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. Moreover, it is for the national authorities invoking Article 30 EC to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that the restrictive measures are necessary and that the marketing of the product in question poses a real risk to public health. It follows that a prohibition on the marketing of enriched foodstuffs must be based on a detailed assessment of the risk alleged by the Member State invoking Article 30 EC.

66. The object of this detailed assessment should be to appraise the degree of probability of the allegedly harmful effects from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects. Such an assessment could reveal scientific uncertainty as regards the existence and seriousness of the risks. In

such circumstances, a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until complete certainty exists as to the reality and seriousness of the risk. However, such a risk assessment, which must precede the invocation of the precautionary principle, cannot be based on purely hypothetical considerations.

67. As follows from the abovementioned case-law of the Court, a proper application of the precautionary principle presupposes, in the first place, the accurate identification of the potentially negative consequences for health of the addition of nutrients to foodstuffs and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk, because of the insufficiency, inconclusiveness or imprecision of the results of the studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.

68. In this context, the criterion of the nutritional need of the population of the Member State can play a role in its detailed assessment of the risk which the addition of nutrients to foodstuffs may pose for public health. However, the absence of such a nutritional need cannot, by itself, justify a total prohibition, under Article 30 EC, on the marketing of foodstuffs lawfully manufactured and/or marketed in another Member State.

69. In connection with this case-law of the Court, I also note that it applies, mutatis mutandis, in cases in which a Member State, rather than directly invoking Article 30 EC, invokes one of the special procedures provided for in the specific Community legislation on particular foods, such as Regulation No 258/97 or Directive 2002/46.

The questions

Question A I (all cases) and Question A IV (in Case C 211/03)

70. With these questions the national court seeks to learn whether Lactobact omni FOS, C 1000, OPC 85, Acid Free C□1000 and E□400 are foodstuffs or medicinal products and whether if Lactobact omni FOS is deemed to be a foodstuff it is a novel food within the meaning of Regulation No 258/97.

71. It is settled case-law that within the framework of preliminary ruling proceedings there is a division of functions between the Court and the national judicature. Any appraisal of the facts is the exclusive responsibility of the national court. Thus, the Court of Justice is not competent to determine the facts in the main proceedings or to apply the rules of Community law it has interpreted to national measures. (23)

72. It follows that the Court of Justice must leave these questions unanswered and that the referring court must decide them itself. In so doing it should take into account the following criteria derived from the case-law of the Court: the pharmacological properties of the product concerned 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. (24)

Question A II (in Case C 211/03)

73. The referring court asks whether the way in which a particular product is taken is relevant when classifying that product.

74. As explained in points 34 and 35 above, whether or not a particular product can be classified as a medicinal product depends on its objective characteristics, as ascertained by application of the criteria derived from the Court's case-law mentioned in point 72. The fact that the product has to be dissolved in water or in yoghurt is irrelevant. Both medicinal products and food supplements may need to be taken in this way.

Question B I (a) (in all cases)

75. This question concerning the relationship between Directive 2002/46 and Regulation No 178/2002 and the provisions that apply where a product satisfies the definition of a food as well as that of a medicinal product is dealt with at length in my preliminary analysis, in points 37 and 51 to 55 above. This leads me to propose the following answers.

76. Regulation No 178/2002 constitutes the generic horizontal legislation for foods which, in addition to establishing the European Food Safety Authority and establishing procedures in matters of food safety, lays down the general principles and requirements of Community and national food law. Directive 2002/46 lays down specific requirements for a special category of food, namely, food supplements; it constitutes lex specialis in relation to the lex generalis of Regulation No 178/2002, as is also apparent from Article 14(7), (8) and (9) of the regulation:

– If a product satisfies the definitions of medicinal product, as given in Article 1(2) of Directive 2001/83, of food, as given in Article 2 of Regulation No 178/2002, and of food supplement, as given in Article 2(1) of Directive 2002/46, then in accordance with subparagraph (d) of Article 2 of Regulation No 178/2002 and Article 1 of Directive 2002/46, these regulations will not apply to the product in question.

– However, if a product is deemed to be a food supplement within the meaning of Directive 2002/46 in the Member State in which it is manufactured or marketed but treated as a medicinal product by the competent authorities of the Member State of destination on account of the associated health risk, the latter State must follow the procedure laid down in Directive 2002/46, Articles 12 and 13, in order, in consultation with the other Member States concerned and the Commission, to reach a consensus on the classification of the product at issue and, bearing in mind any risk which consumption might entail, on protective measures.

– If a product is deemed to be a food within the meaning of Regulation No 178/2002 in the Member State in which it is manufactured or marketed but treated as a medicinal product by the competent authorities of the Member State of destination on account of the associated health risk, then the latter, in accor-

dance with the procedure laid down in Regulation No 178/2002, must consult the other Member States concerned and the Commission with a view to reaching a consensus, without prejudice to the right of the Member State, under Article 30 EC, to take the necessary reasonable measures with a view to the protection of human health.

Question B II (in all cases)

77. In asking this question, the national court seeks to know, in essence, how the term 'pharmacological effect' is to be interpreted for product classification purposes. It also inquires whether a health risk forms part of this definition.

78. As the Commission has rightly pointed out, the term 'pharmacological effect' is used neither in Regulation No 178/2002 nor in Directive 2001/83 or Directive 2002/46. However, it is used in the case-law of the Court in the context of the second part of the definition of a medicinal product in Article 1(2) of Directive 2001/83 as that definition read in amended Directive 65/65. (25) Thus, the primary purpose of this question is to ascertain whether the product concerned is a medicinal product by virtue of its function, that is to say, 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 or animals.

79. I also note that the term 'physiological functions' in human beings, used in the second subparagraph of Article 1(2) of Directive 2001/83 is not essentially different from the term 'organic functions' used in its predecessor, Directive 65/65.

80. This leads me to give the following answer to the question posed:

The pharmacological effect of a product is one of the factors that must be investigated in assessing whether a product has a significant influence on the metabolism and can affect the actual functioning of the organism and thus, in the language of the second subparagraph of Article 1(2) of Directive 2001/83, 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. The risks associated with the use of the product constitute one of the factors which may be taken into account in determining whether or not it is a medicinal product. (26) However, this factor is not decisive. At least one demonstrable 'therapeutic effect' must also be present. The therapeutic efficacy must always be investigated in relation to the risk associated with the use of the product. (27)

Question B III and Question B VI (in all cases)

81. These questions are closely interrelated. From the order for reference it may be concluded that in asking these two questions the national court is seeking to learn whether Articles 28 EC and 30 EC should be understood to mean that a Member State (of destination) is precluded from prohibiting the marketing in its territory of products such as those which form part of the main proceedings when those products can be lawfully marketed as a food in the Member State in which they are manufactured.

82. I have already considered the subject-matter of these questions in detail in my preliminary analysis, in points 32 and 33 with respect to medicinal products, in points 46 to 50, inclusive, with respect to foods and in points 54 and 55 with respect to products concerning whose classification there is a difference of opinion between Member States. My findings are summarised in point 56. This leads me to propose the following answers:

(a) With respect to products deemed to be medicinal products by both the Member State of production and the Member State of destination, in so far as it is a question of aspects of the production of and trade in medicinal products for which Directive 2001/83 provides for comprehensive harmonisation, the Member State of destination may refuse to admit medicinal products lawfully manufactured or marketed elsewhere in the European Union only on the grounds mentioned in Article 29(1) of the directive. Such a measure must be pursued under the procedures laid down in Article 29 and, where appropriate, Article 32 of the directive.

(b) With respect to those aspects of the trade in medicinal products for which Directive 2001/83 does not – yet – provide for exhaustive harmonisation, such as the rules on the way in which medicinal products are marketed, assuming they are not selling arrangements within the meaning of Keck and Mithouard, Article 30 EC can be used to justify national measures, provided that they meet the requirements for the application of that article which follow from the case-law

83. If foodstuffs are lawfully marketed in the Member State of production and no specific harmonisation provisions apply, then, under the second part of Article 14(9) of Regulation No 178/2002, Member States of destination may refuse to admit them or subject them to restrictions, either on human health grounds under Article 30 EC or on the grounds of compelling requirements of public interest recognised in the case-law on Article 28 EC. These measures must always meet the requirements for their application that follow from the case-law.

84. If foodstuffs are the subject of specific harmonisation measures and are lawfully marketed in the Member State of production, then, under Article 14(8) of Regulation No 178/2002, the Member State of destination may take appropriate measures if it suspects that a food is unsafe, even though it conforms with the specific provisions for that food. However, in these cases, the specific harmonising provisions must always be consulted to establish the special rights and obligations of the Member State concerned in such circumstances.

85. If the products are deemed to be food in the Member State of production and medicinal products in the Member State of destination, then the answer is already contained in the answer to Question B I (a) (see point 76 above, second and third indents).

Question B IV (a) (in all cases)

86. With this question the national court inquires as to the significance of the term 'upper safe level' in Ar-

ticle 5(1)(a) of Directive 2002/46. The formulation of this question, which refers to Questions B II and B III, indicates that the court appears to assume that the term can play a role in differentiating between a medicinal product and a food.

87. To begin with the assumption, the term 'upper safe limit' plays no part in the process of distinguishing medicinal products from foods. This is, on the one hand, because with many foods which clearly cannot be deemed to be medicinal products it may be necessary to indicate upper safe limits in connection with the daily dose recommended by the producer and, on the other hand, because products administered in amounts far below the safe upper limit can still restore, correct or modify physiological functions in human beings and thus, in accordance with Article 1(2) of Directive 2001/83, be classified as a medicinal product. Furthermore, products that contain a concentration of active substance that clearly lies below the upper safe limit can also be presented in accordance with the first paragraph of Article 1(2) of the directive.

88. The term 'upper safe limit' must therefore be functionally interpreted irrespective of the nature of the product concerned – food or medicine. It serves as a benchmark from which the consumer can derive the information he needs to make responsible use of a product. In determining upper safe limits account must be taken, inter alia, of the so-called 'reference intakes' described in Article 5(2) of Directive 2002/46. This corresponds to the daily dose of vitamins or minerals that is sufficient for the vast majority of the healthy population.

Question B IV b (in all cases)

89. This question should be read somewhat more broadly and generally than formulated. In essence, it reduces to the classical question of how far, as a minimum, a judicial review of a decision by the competent national food or medicinal product authorities, based on technical analyses, should go.

90. The considerations set out in points 57 to 61 above call for this question to be answered as follows:

A discretion for national authorities in classifying a product as a medicine will be in accordance with Community law provided that a national procedure for the judicial review of decisions taken by those authorities in that respect enables the court seised of an action for the annulment of such a decision actually to apply, within the framework of its review of the legality of the decision, the principles and rules of Community law.

Question B V a (in all cases)

91. This question, by which the national court inquires whether the fact that there is no nutritional need for the product concerned can in itself justify a marketing ban, has also already been dealt with in my preliminary analysis (see points 62 to 69 above).

92. The answer is therefore as follows:

The criterion of the nutritional needs of the population of a Member State can play a part in the assessment by that State of the risk that products, such as those at issue in the main proceedings, may present to public health. However, the absence of such a nutritional need cannot in itself justify a total prohibition, under Article 30 EC, on the marketing of foods lawfully manufactured and/or marketed elsewhere in the European Union.

Question B V b (in all cases)

93. In posing this question the referring court wishes to learn whether the existence of a discretion for the competent national authority regarding the supposed absence of a national nutritional need is compatible with Community law. The answer to this question can easily be derived from the answers to the two previous questions.

94. The question whether or not a national nutritional need – still – exists cannot be answered without a detailed scientific investigation. The decision that the competent national bodies take on the basis of such an investigation must under Community law be subject to a judicial review that meets the requirements described in point 90 above.

Question B VII (in Case C-211/03)

95. In asking this question the referring court seeks to learn the interpretation of the condition laid down in Article 1(2) of Regulation No 258/97 according to which this regulation applies only to the placing on the market of foods which have 'not hitherto been used' for human consumption 'to a significant degree' within the Community.

96. This condition consists of two elements: a time element and a quantitative element. As regards the time element, the parties in the main proceedings, the Member States that have made observations and the Commission all agree that it refers to the date of entry into force of the regulation, that is, 15 May 1997. I share this view. As regards the quantitative element 'not … used … to a significant degree within the Community', opinions differ somewhat. In my view, in order to interpret this element reference should be made to the purpose of Article 1(2) of the regulation. This provision is aimed at restricting the substantive scope of the regulation to 'novel' products. In fact, a product which, when the regulation entered into force, was already being marketed in one or more Member States and thus was available to the consumer was being used for human consumption to a significant degree and thus could not be novel. It therefore seems to me that the test should be the product's being on the market, a requirement which has the additional advantage of being simple and objectively verifiable. This leads me to the following answer.

97. Foods, within the meaning of Article 1(2) of Regulation No 258/97, are not used to a significant degree within the Community, if upon the entry into force of that regulation they were not on the market in one or more Member States. The reference date for determining the degree of significance of human consumption of the food in question is 15 May 1997.

Question B VIII (in Case C 211/03) and Question B VII (in Cases C 299/03 and C 316/03 to C 318/03, inclusive)

98. What the referring court wishes to know is whether a national court is entitled to turn to the Euro-

pean Food Safety Authority for information and to what extent it is bound by any answers that body may provide. Moreover, it asks whether it can also review this information.

99. According to the Spanish Government, the national court is so entitled. According to HLM, Orthica, the Bundesamt and the Commission, it is not. In any event, a scientific report issued by the Authority at the request of a national court is not binding on that court, but is merely evidence which it can take into account under the national procedure.

100. There may be some doubt as to the admissibility of this question, since it is unclear whether it needs to be answered in order to settle the dispute in the main proceedings. Thus, it could be purely hypothetical. However, I tend to consider the question admissible since the issue of how certain products should be classified – as a medicinal product or as a food – plays a central role in the main proceedings. As the classification must be decided with reference to the definitions of Community law, it might prove useful for the national court to be able to seek information from the European Authority.

101. However, the question must be answered in the negative. According to the relevant provisions of Regulation No 178/2002, the European Food Safety Authority has, inter alia, the task of providing both the Commission and the Member States with scientific opinions, but this obligation is restricted to 'all cases provided for by Community legislation' and 'any question within its mission' (Article 23(a) of Regulation No 178/2002). In fact, at the moment, there is no Community legislation that explicitly provides for the right of national courts to ask questions. Moreover, the Community provisions applicable offer no basis for assuming the existence of an implicit right. The task of the European Food Safety Authority is restricted to providing scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety (Article 22 of Regulation No 178/2002). The answering of questions that have arisen in proceedings before a national court concerning the application of the Community law on medicinal products and foods does not form part of that task. I might also mention Regulation (EC) No 1304/2003. (28) According to Article 9 of this implementing regulation, only a government authority or authorities authorised by Member States may request scientific opinions from the Authority. This leads me to the following answer.

102. A national court may not approach the European Food Safety Authority either with questions concerning the classification of a particular product or with general scientific or methodological questions. Scientific opinions which the Authority may nevertheless have issued at the request of a judicial body of a Member State are not binding on the national court, merely constituting evidence which the court in question must take into account within the framework of national procedural law.

V – Conclusion

103. In the light of the above, I propose that the Court should answer the questions referred to it by the Oberverwaltungsgericht für das Land Nordrhein□Westfalen as follows:

Question A I (in all cases) and Question A IV (in Case C□211/03) as proposed in point 72 above.

Question A II (in Case C□211/03), as proposed in point 74 above.

Question B I (in all cases), as proposed in point 76 above.

Question B II (in all cases), as proposed in point 80 above.

Question B III and Question B VI (in all cases), as proposed in points 82, 83, 84 and 85 above.

Question B IV (a) (in all cases), as proposed in point 88 above.

Question B IV (b) (in all cases), as proposed in point 90 above.

Question B V (a) (in all cases), as proposed in point 92 above.

Question B V (b) (in all cases), as proposed in point 94 above.

Question B VII (in Case C□211/03), as proposed in point 97 above.

Question B VIII (in Case C□211/03) and Question B VII (in Cases C□299/03 and C□316/03 to C□318/03, inclusive), as proposed in point 102 above.

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1 – Original language: Dutch.

2 – Case 227/82 Van Bennekom [1983] ECR 3883; Case C-192/01 Commission v Denmark [2003] ECR I□9693; and Case C-41/02 Commission v Netherlands [2004] ECR I-11375.

3 – OJ 1997 L 43, p. 1.

4 – OJ 2002 L 31, p. 1.

5 – OJ 2001 L 311, p. 67.

6 – OJ 2002 L 183, p. 51.

7 – Directive of the Council of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ L 22, p. 369).

8 – See the preamble to this directive and, inter alia, Van Bennekom, cited in footnote 2, paragraph 31, and Case C-60/89 Monteil and Samanni [1991] ECR I□1547, paragraph 27.

9 – Directive of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34).

10 – Van Bennekom, cited in footnote 2.

11 – See Van Bennekom, cited in footnote 2, paragraph 29, and Monteil and Samanni, cited in footnote 8, paragraphs 16 and 29, together with Case C□369/88 Delattre [1991] ECR I□1487, paragraphs 21 and 29, and Case C-112/89 Upjohn I [1991] ECR I□1703, paragraph 23.

12 – Council Regulation 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).

13 – See, inter alia, Case C-219/91 Ter Voort [1992] ECR I□5485, paragraph 19; Monteil and Samanni, paragraph 16; and Delattre, paragraph 21, cited in footnote 8.

14 – See Upjohn I, cited in footnote 11.

15 – This article entered into force on 1 January 2005 (see Article 65 of Regulation No 178/2002).

16 – See Commission v Denmark and Commission v Netherlands, cited in footnote 2, and in Case C-95/01 Greeham and Abel [2004] ECR I□1333.

17 – The Court has already expressly specified the horizontal cooperation obligation as part of the principle of cooperation in good faith in Case 235/87 Matteucci [1988] ECR 5589 and Case C-165/91 Van Munster [1994] ECR I□4661.

18 – See, inter alia, Monteil and Samanni, cited in footnote 8, paragraph 15 et seq.

19 – Joined Cases C□267/91 and C□268/91 [1993] ECR I□6097.

20 – Case C□120/97 [1999] ECR I□223.

21 – See Upjohn II, paragraph 34.

22 – Cited in footnote 2.

23 – Case 13/68 Salgoil [1968] ECR 632; Case 36/79 Denkavit [1979] ECR 3439, paragraph 12; Case 235/95 Dumon and Froment [1998] ECR I□4531, paragraph 25; Case C-320/88 Shipping and Forwarding Enterprise Safe [1990] ECR I□285, paragraph 11; and Case 51/74 Van der Hulst [1975] ECR 79, paragraph 12.

24 – See the case-law cited in footnote 11 of this Opinion.

25 – See, for example, Upjohn II, cited in footnote 20, paragraph 24.

26 – See also Monteil and Samanni, cited in footnote 8, paragraph 29, and Delattre, cited in footnote 11, paragraph 35.

27 – See also recital 7 in the preamble to Directive 2001/83.

28 – Commission Regulation 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).