JUDGMENT OF THE COURT (Sixth Chamber)
18 May 2000 *

In Case C-107/97,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Tribunal de Grande Instance, Grasse, France, for a preliminary ruling in the criminal proceedings pending before that court against

Max Rombi,

Arkopharma SA, party liable at civil law,

third parties:

Union Fédérale des Consommateurs 'Que choisir?',

and

Organisation Générale des Consommateurs (Orgeco), Union Départementale 06,

on the interpretation of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27),

* Language of the case: French.

THE COURT (Sixth Chamber),

composed of: R. Schintgen, President of the Second Chamber, acting as President of the Sixth Chamber, G. Hirsch (Rapporteur) and H. Ragnemalm, Judges,

Advocate General: N. Fennelly,
Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

— Mr Rombi and Arkopharma SA, by A. Deur, of the Nice Bar, and G. Vandersanden, of the Brussels Bar,

— the French Government, by K. Rispal-Bellanger, Head of Subdirectorate in the Legal Directorate of the Ministry of Foreign Affairs, and R. Loosli-Surrans, Chargé de Mission in that Directorate, acting as Agents,

— the Commission of the European Communities, by R.B. Wainwright, Principal Legal Adviser, and M. Shotter, a national civil servant on secondment to the Commission's Legal Service, acting as Agents, assisted by H. Lehman, of the Paris Bar,

having regard to the Report for the Hearing,

after hearing the oral observations of Mr Rombi and Arkopharma SA, the French Government and the Commission at the hearing on 2 July 1998,

after hearing the Opinion of the Advocate General at the sitting on 22 October 1998,

gives the following

Judgment

1 By judgment of 19 July 1996, received at the Court Registry on 14 March 1997, the Tribunal de Grande Instance (Regional Court), Grasse, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) five questions on the interpretation of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27).

2 The questions have been raised in criminal proceedings against Mr Rombi, the chairman and managing director of Arkopharma SA, and Arkopharma SA itself as the party liable at civil law (together 'Arkopharma'). Arkopharma is charged with adulterating foodstuffs intended for human consumption and with having marketed adulterated foodstuffs in contravention of Articles L 213-1 and L 213-3 of the French Code de la Consommation (Consumer Protection Code).

Adulterated ('*falsifiées*') foodstuffs means foodstuffs which do not comply with the rules in force.

3 The various products marketed by Arkopharma contain an amino acid derivative, L-carnitine, as a significant ingredient, in doses which are not permitted under French legislation in foodstuffs intended for particular nutritional uses.

The legal framework

Community law

4 Directive 89/398/EEC recast Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (OJ 1977 L 26, p. 55).

5 Article 1(2) of Directive 89/398 provides that:

'(a) Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed

nutritional purposes and which are marketed in such a way as to indicate such suitability.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

(i) of certain categories of persons whose digestive processes or metabolism are disturbed; or

(ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or

(iii) of infants or young children in good health.'

6 Article 2 of Directive 89/398/EEC restricts use of the description 'dietetic' or 'dietary' to the products referred to in Article 1(2)(b)(i) and (ii).

7 Under the first subparagraph of Article 4(1) of Directive 89/398/EEC, specific provisions applicable to the groups of foods for particular nutritional uses listed in Annex I to the Directive are to be laid down by means of specific directives. The list includes, in particular, at 4, 'Low-energy and energy-reduced foods intended for weight control' and, at 8, 'Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen'.

8 The following directives have been adopted pursuant to Article 4(1) of Directive 89/398/EEC: Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (OJ 1991 L 175, p. 35), amended by Commission Directive 96/4/EC of 16 February 1996 (OJ 1996 L 49, p. 12, hereinafter 'Directive 91/321/EEC'); Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ 1996 L 49, p. 17), and Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ 1996 L 55, p. 22).

9 The second subparagraph of Article 4(1) of Directive 89/398/EEC provides that those specific directives may include, in particular, essential requirements as to the nature or composition of the products belonging to one of the groups of foods listed in Annex I, as well as a list of additives. Article 4(2) provides that a list is to be adopted of substances for specific nutritional purposes, such as vitamins, mineral salts, amino acids and other substances to be added to foodstuffs intended for particular nutritional uses.

10 Under Article 9 of Directive 89/398/EEC various specific provisions apply to the placing on the market of foodstuffs intended for particular nutritional uses which

do not belong to one of the groups listed in Annex I. Essentially, those specific provisions make the placing on the market of the foodstuffs concerned subject to a requirement to notify the competent authorities.

11 Article 10 of Directive 89/398/EEC provides:

'1. Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Directives adopted in implementation of this Directive.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of Directives adopted in implementation of this Directive.'

12 While Article 15(1) of Directive 89/398/EEC sets out the timetable for the adoption of national measures implementing the Directive in order to permit trade in products complying with the Directive and prohibit trade in products not complying with it, Article 15(2) states that 'Paragraph 1 shall not affect those

national provisions which in the absence of the Directives referred to in Article 4 apply to certain groups of foodstuffs intended for particular nutritional uses.'

National law

13 In France, Decree No 91-827 of 29 August 1991 on foodstuffs intended for particular nutritional uses (*Journal Officiel de la République Française* (JORF) of 31 August 1991, hereinafter 'Decree No 91-827') is intended to transpose Directive 89/398/EEC. It reproduces the majority of the provisions of Directive 89/398/EEC including, in particular, in Article 1 the definition of foodstuffs for particular nutritional uses found in the Directive.

14 The first paragraph of Article 9 of Decree No 91-827 repeals Decree No 81-574 of 15 May 1981 applying the Law of 1 August 1905 on misrepresentation and adulteration of products or services relating to foodstuffs and drinks intended for particular nutritional uses (JORF of 17 May 1981 and corrigendum of 27 June 1981, hereinafter 'Decree No 81-574'), which transposed into French law Directive 77/94/EEC. The second paragraph of Article 9 of Decree No 91-827 nevertheless provides that the Orders relating to products intended for particular nutritional uses adopted pursuant to legislation prior to the Decree are to remain in force to the extent that they do not conflict with Decree No 91-827.

15 The Order of 4 August 1986 on the use of additives in the manufacture of foods intended for particular nutritional uses (JORF of 30 August 1986, hereinafter 'the Order of 4 August 1986') was adopted pursuant to Decree No 81-574. It sets out the conditions in which the use of additives is authorised in the manufacture of foodstuffs intended for particular nutritional uses and, in particular, the permitted maximum doses of additives.

16 Under Article 4(2) of the Order of 4 August 1986 L-carnitine, which is classed as an additive for nutritional purposes, is permitted only (i) in the manufacture of foodstuffs for infants and young children in doses comparable to the natural dosage normally present in breast milk but not exceeding 15.4 mg per litre of the reconstituted product and (ii) in the manufacture of foodstuffs intended for particular nutritional uses other than foodstuffs intended for infants and young children, the maximum dose being 100 mg per 1 000 kilocalories of the product.

17 In addition, French legislation prohibits the addition of L-carnitine to normal foodstuffs.

The dispute in the main proceedings and the questions referred for a preliminary ruling

18 Arkopharma has been prosecuted in the Tribunal de Grande Instance, Grasse, for having manufactured and placed on the market various products, including 'Arkotonic Gélules', 'Turbodiet 300', 'Turbodiet Fort', 'Elle Carnitine Gélules' and 'Elle Carnitine Forte', which contain L-carnitine in doses exceeding those permitted by French legislation applying to foodstuffs for particular nutritional uses.

19 Arkopharma has contended in its defence that, as a result of Directive 89/398/EEC having been incompletely transposed, French law is in conflict with Community law. Decree No 91-827 provides that the Orders on products intended for particular nutritional uses which were adopted prior to Directive 89/398/EEC remain in force to the extent that they are not in conflict with the Directive. This way of legislating constitutes an infringement of the obligation to transpose Directive 89/398/EEC inasmuch as keeping the Order of 4 August 1986 in force in this way conflicts with the rules laid down at Community level by Directive 89/398/EEC and, at the national level, by Decree No 91-827.

20 In those circumstances the Tribunal de Grande Instance, Grasse, decided to stay the proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'1. Can a Member State correctly transpose a Community directive where, in the national transposing measure, it maintains in force previous provisions adopted on the basis of repealed national legislation transposing a previous, repealed directive, indicating in the new transposing measure merely that those provisions remain in force to the extent that they do not conflict with the new national legislation?

2. Do Articles 10(2) and 15(2) of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27) authorise a State to continue to apply rules which predate the Directive and the measure transposing it?

3. Does the classification, by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the [Member] States [relating to foodstuffs intended for particular nutritional uses], of foodstuffs intended for particular nutritional uses into nine groups (referred to in Annex I thereto), which are

to be the subject of specific directives, and into foodstuffs not falling within those groups, for which there is no provision for such directives, allow a Member State to apply rules founded on a classification based on a distinction between dietary products and dietetic products or on a distinction between foodstuffs for infants and young children and foodstuffs other than those intended for infants and young children?

4. Do Articles 10(2) and 15(2) of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, which do not affect the application of national measures in the event that specific directives as provided for in Article 4 of the Directive are not adopted, preclude individuals from relying on the provisions of the Directive in order to challenge the detailed measures of transposition adopted by the Member States and to have them declared inapplicable by the national courts to the extent that they conflict with the provisions of the Directive?

5. Does not the fact that foodstuffs are controlled within the framework of Community directives imply that [Member] States must, when carrying out such control, observe the general Community principles, in particular the protection of legitimate expectations?'

Admissibility of the questions referred for a preliminary ruling

21 The French Government considers that the questions referred to the Court are inadmissible on the ground that the products containing high doses of L-carnitine which are marketed by Arkopharma are food supplements. On that basis, they cannot be classed as foodstuffs intended for particular nutritional uses within the meaning of Directive 89/398/EEC and, as a result, do not fall within the ambit of the Directive. Therefore, the Court's answer is not necessary in order to decide the main action.

22 That argument cannot be accepted. The Court has consistently held that it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court (see, *inter alia*, Case C-387/93 *Banchero* [1995] ECR I-4663, paragraph 15, and Case C-105/94 *Celestini* v *Saar-Sektkellerei Faber* [1997] ECR I-2971, paragraph 21). Consequently, where the questions submitted by the national court concern the interpretation of Community law, the Court is, in principle, bound to give a ruling (see, *inter alia*, Case C-415/93 *Union Royale Belge des Sociétés de Football Association and Others* v *Bosman and Others* [1995] ECR I-4921, paragraph 59).

23 The Court has also consistently held that, when applying national law, whether the provisions in question were adopted before or after a directive, the national court called on to interpret the directive is required to do so as far as possible in the light of the wording and purpose of the directive in order to achieve the result pursued by the directive and thereby comply with the third paragraph of Article 189 of the EC Treaty (now the third paragraph of Article 249 EC) (see, in particular, Case C-106/89 *Marleasing* v *La Comercial Internacional de Alimentación* [1990] ECR I-4135, paragraph 8, and Case C-355/96 *Silhouette International Schmied* v *Hartlauer Handelsgesellschaft* [1998] ECR I-4799, paragraph 36).

24 In view of those judgments, it is clear that the interpretation of Directive 89/398/EEC sought by the national court is not manifestly unnecessary for a decision in the main action, if only inasmuch as an interpretation is necessary in order to ascertain whether the products at issue in the main proceedings fall within the scope of Directive 89/398/EEC.

25 Consequently, the questions referred by the national court must be held to be admissible.

The first, second and third questions

26 By these questions, which it is appropriate to consider together, the national court is asking essentially whether, having regard, in particular, to Articles 10(2) and 15(2), Directive 89/398/EEC precludes Member States from maintaining in force after the transposition of the Directive previous legislative provisions, such as those at issue in the main proceedings, which apply to additives authorised in the manufacture of foodstuffs intended for particular nutritional uses even when those provisions are based on a system of classification other than the one used in the Directive.

27 In so far as the first question raises the issue, in particular, of whether Directive 89/398/EEC has been correctly transposed into national law, it must be noted that the Court cannot, in proceedings under Article 177 of the Treaty, rule on the validity of a measure of national law from the point of view of Community law, as it might in proceedings under Article 169 of the EC Treaty (now Article 226 EC) (see Joined Cases C-74/95 and C-129/95 *X* [1996] ECR I-6609, paragraph 21).

28 Nevertheless, a question as to whether a directive has been correctly transposed into national law seeks, essentially, to ascertain whether the national legislation as it stands after the transposition is valid because it is compatible with the directive. National legislation will not be compatible with the directive and, therefore, valid unless transposition has been correctly effected.

29 Although the Court has consistently held that it does not have jurisdiction within the framework of Article 177 of the EC Treaty to rule on the compatibility of a provision of national law with Community law, it may nonetheless provide the national court with all the criteria of interpretation of Community law which may enable the national court to assess that compatibility for the purposes of

deciding the case before it (see Case C-241/89 *SARPP* v *Chambre Syndicale des Raffineurs et Conditionneurs de Sucre de France and Others* [1990] ECR I-4695, paragraph 8).

30 An interpretation of Directive 89/398/EEC for the purposes of replying to the questions reformulated in paragraph 26 above is thus likely at the same time to provide the national court with all the criteria it needs to enable it to decide whether the relevant national legislation is compatible with the Directive.

31 Consequently, it is sufficient to consider the questions as redrafted without dealing separately with the question as to whether Directive 89/398/EEC has been correctly transposed.

The scope of Directive 89/398/EEC

32 Before answering the first three questions as reformulated in paragraph 26 above, it is necessary to ascertain whether Directive 89/398/EEC is capable of applying to products such as those marketed by Arkopharma and containing high doses of L-carnitine.

33 The French Government maintains that the products marketed by Arkopharma are food supplements, which are defined as products composed of, *inter alia*, nutritional additives intended to supplement food for normal consumption in order to compensate for real or imagined deficiencies in the daily diet. They are classed under national law as foodstuffs and are subject, on that basis, to general legislation applying to all foodstuffs. More particularly, the French Government

claims that L-carnitine is authorised as an additive for nutritional purposes in only two categories of foodstuffs intended for particular uses, namely, under Article 4 of the Order of 4 August 1986, in products for infants and young children and in dietetic products for adults, but that it does not fall within the scope of any harmonised Community rules.

34 Arkopharma takes the view that the products it markets fall primarily within group 8 in Annex I to Directive 83/398/EEC, or in group 4 of the same Annex. At the hearing it stated that its products might also fall within group 5, 'Dietary foods for special medical purposes', without, however, giving any reasons as to why they should belong to this group.

35 As a preliminary point, it is apparent from the reasoning in the judgment making the reference that the Tribunal de Grande Instance, Grasse, considers that L-carnitine is a nutrient and that the products containing it and marketed by Arkopharma are food supplements. It is not disputed in this respect that the products marketed by Arkopharma containing high doses of L-carnitine constitute foodstuffs.

36 Therefore in the circumstances of the present case it is irrelevant that in different doses, combined with other substances and with different packaging, L-carnitine could be regarded as an additive or even a medicine.

37 Article 1(1) of Directive 89/398/EEC concerns foodstuffs intended for particular nutritional uses. Under Article 1(2)(a) foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed

in such a way as to indicate such suitability. Under Article 1(2)(b) a particular nutritional use must fulfil the particular nutritional requirements of certain categories of persons.

38 It is not disputed that the products marketed by Arkopharma have, in their capacity as food supplements, a particular set of ingredients including high doses of L-carnitine and can thus be clearly distinguished from foodstuffs for normal consumption. The first of the conditions laid down in Article 1(2)(a) of Directive 89/398/EEC is thus met in the present case.

39 The third condition laid down by Article 1(2)(a) of Directive 89/398/EEC is also met, inasmuch as the products at issue in the main proceedings are marketed, as is apparent from the particulars provided by Arkopharma and which have not been contested, as performance-enhancing products for sportsmen or as slimming aids.

40 By contrast, the French Government claims that the products at issue in the main proceedings are not suitable for the nutritional purposes that Arkopharma claims they are and that, as a result, they do not meet the second condition laid down by Article 1(2)(a) of Directive 89/398/EEC. It also maintains that they do not fulfil the particular nutritional requirements of certain categories of persons, contrary to the requirements of Article 1(2)(b)(i) and (ii) of Directive 89/398/EEC.

41 The objection raised by the French Government does not automatically exclude the products marketed by Arkopharma from the scope of Directive 89/398/EEC. First, it is evident from Articles 3(1), 11 and 12 of Directive 89/398/EEC that the

Directive applies at least as long as it is not proven that the products concerned are not suitable for the particular nutritional needs for which they are intended: Article 3 sets out the requirement that the products must be suitable, by their nature or composition, for the particular nutritional use intended and the other articles set out various measures which may be taken in the event of a breach of that requirement.

42 Second, in the context of Article 177 of the Treaty, it is for the national court alone to ascertain whether the products at issue in the main proceedings are actually suitable for the nutritional purposes that Arkopharma claims they are, that is, whether they do facilitate weight loss or are, in the case of sportsmen, performance-enhancing.

43 Consequently, Article 1(2) of Directive 89/398/EEC must be interpreted as meaning that food supplements such as those at issue in the main proceedings, which contain L-carnitine in high doses and which are marketed on the basis that they are suitable for a particular nutritional purpose, fall within the scope of the Directive unless the national court establishes that they are not suitable for the nutritional purposes that the manufacturer claims they are or that they do not fulfil the particular nutritional requirements of one of the categories of persons referred to in Article 1(2)(b)(i) and (ii) of the Directive.

The interpretation of Directive 89/398/EEC

44 It is apparent from the wording of Articles 10(2) and 15(2) that national legislation such as the legislation at issue in the main proceedings will not be affected by Directive 89/398/EEC if neither it nor the directives adopted pursuant to it, in particular the specific directives referred to in Article 4(1), contain rules on additives authorised in general in the manufacture of foodstuffs or groups of

foodstuffs intended for particular nutritional uses or, more generally, on the composition of those types of foodstuffs.

45 Therefore, it is necessary to consider whether Directive 89/398/EEC itself or any directive adopted pursuant to it, in particular a specific directive covered by Article 4(1), includes any such rules.

46 According to the second and third recitals in the preamble to Directive 89/398/EEC, it constitutes an initial stage in the removal of obstacles to the free movement of foodstuffs intended for particular nutritional uses resulting from different national laws and, at that stage, the approximation of national laws provided for by the Directive is intended to result in the drawing up of a common definition, the determination of measures enabling the consumer to be protected against fraud concerning the nature of the products and the adoption of rules to be complied with in labelling the products in question.

47 However, Directive 89/398/EEC does not itself regulate either additives authorised in general in the manufacture of this type of foodstuffs or substances with specific nutritional purposes to be added to such foodstuffs and does not include any specific requirements as to their composition.

48 As regards foodstuffs intended for particular nutritional uses in general, it should be noted that Article 4(2) of Directive 89/398/EEC provides for the adoption of a list of substances with specific nutritional purposes, such as vitamins, mineral salts and amino acids. Leaving aside the question of whether L-carnitine can be categorised as an amino acid by virtue of being an amino acid derivative, it is apparent from the documents before the Court and from the observations of Arkopharma and the French Government that the relevant list has not yet been adopted.

49 First, in respect of foodstuffs intended for particular nutritional uses not belonging to any of the groups in Annex I to Directive 89/398/EEC, no regulation is anticipated on authorised additives in particular and the composition of those foodstuffs in general, other than the adoption of the list of substances with nutritional purposes referred to in paragraph 48 hereof.

50 Second, Article 4(1) of Directive 89/398/EEC provides that rules concerning the composition, including any additives, of foodstuffs belonging to one of those groups will be adopted by means of specific directives but, as noted in paragraph 8 above, as Community law stands at present, only three directives have been adopted under this article and they do not apply to products such as those at issue in the main proceedings which belong to group 4 or group 8 in Annex I to Directive 89/398/EEC.

51 It must therefore be concluded that, in the absence, first, of Community rules on the authorisation of additives in general in foodstuffs intended for particular nutritional uses, and in particular on L-carnitine, and, second, of rules on the composition of such foodstuffs, Community law does not preclude national legislation on additives authorised in the manufacture of this type of foodstuff such as the legislation at issue in the main proceedings.

52 That conclusion is not affected by the alleged difference between the classification established by Directive 89/398/EEC and that used in the Order of 4 August 1986.

53 First, it must be borne in mind that national rules such as those at issue in the main proceedings must be interpreted, as far as possible, in the light of the wording and purpose of the directive in order to achieve the result pursued by the

latter (see, *inter alia*, *Marleasing*, paragraph 8, and Case C-63/97 *Bayerische Motorenwerke (BMW) and BMW Nederland* v *Deenik* [1999] ECR I-905, paragraph 22).

54 Thus, in its interpretation of national legislation using, in particular, a classification based on the difference between dietetic products and dietary products, the national court must take account of the definition laid down in Article 1(2) of Directive 89/398/EEC and of the possibility under Article 2(1) of the Directive of characterising products as 'dietetic' or 'dietary'.

55 Second, as regards more specifically the difference between the Community classification and the national classification, it should be noted that Directive 89/398/EEC is based, in the first place, on the difference between foodstuffs belonging to one of the groups listed in Annex I to the Directive, in respect of which Article 4(1) of the Directive provides for a list of additives to be adopted, and other foodstuffs, in respect of which no specific rules on additives are provided.

56 In the second place, Directive 89/398/EEC draws a distinction between additives and substances for nutritional purposes. Article 4(2) of the Directive provides that a list of the latter is to be adopted which will apply in respect of all foodstuffs covered by Directive 89/398/EEC.

57 However, the national legislative provisions at issue in the main proceedings, leaving aside the difference between dietetic and dietary products, are based on the twofold distinction between, on the one hand, additives for technological purposes and additives for nutritional purposes and, on the other hand, between

foodstuffs for infants and young children and other foodstuffs intended for particular nutritional uses.

58 Leaving aside the fact that it is apparent from Annex IV to Directive 96/5/EC and Annex III to Directive 91/321/EEC (mentioned in paragraph 8 above), which were adopted pursuant to Article 4(1) of Directive 89/398/EEC, that L-carnitine is considered under the scheme of Directive 89/398/EEC, not as an additive, but as a nutritional substance, the classification in Directive 89/398/EEC does not preclude, in a case such as that at issue in the main action, national rules based essentially on the distinction, first, between additives for technological purposes and additives for nutritional purposes and, second, between foodstuffs for infants and young children and other foodstuffs intended for particular nutritional uses, unless the classification in the Directive had the effect of authorising the use of L-carnitine by persons prevented by national law from using it or of authorising it in doses prohibited by national law, or vice versa.

59 In the absence of any directives other than those already adopted pursuant to Article 4(1) of Directive 83/398/EEC and mentioned in paragraph 8 above, nothing permits the conclusion to be drawn, nor is it alleged by the parties, that in the present state of Community law the difference between the Community classification and the national classification leads to such a result.

60 Consequently, as Community law presently stands, Directive 89/398/EEC and the directives adopted pursuant to it do not prevent Member States from maintaining in force after the transposition of Directive 89/398/EEC prior national legislative provisions such as those at issue in the main proceedings which apply to additives authorised in the manufacture of foodstuffs intended for particular nutritional uses, even if those provisions are based on a classification other than that used in Directive 89/398/EEC.

The fourth question

61 By its fourth question, the national court is asking essentially whether individuals may rely on Directive 89/398/EEC in order to challenge national rules such as those at issue in the main proceedings which apply to additives authorised in the manufacture of foodstuffs intended for particular nutritional uses and which are contrary to the provisions of the Directive.

62 In this respect, it is sufficient to note that, in the absence of any provision in Directive 89/398/EEC itself, or in the directives adopted pursuant to Article 4 of that Directive, as to the composition of foodstuffs intended for particular nutritional uses or the use of additives or substances for specific nutritional purposes in the manufacture of that type of product, no relevant Community rules exist, as Community law presently stands, on which individuals may rely in order to challenge national rules on additives and substances for nutritional purposes authorised in the manufacture of foodstuffs of the kind at issue in the main proceedings.

The fifth question

63 The national court's last question asks essentially whether Member States are subject to the requirements arising from general principles recognised by Community law, in particular the principle of the protection of legitimate expectations, when they monitor the composition of foodstuffs intended for

particular nutritional uses and, in particular, the additives and substances for nutritional purposes which are included in the manufacturing process.

64 The national court has not provided any explanation of this question. Nevertheless, in view of the observations submitted by Arkopharma, which claims that it is authorised to market the products at issue in the main proceedings by virtue of Community law, and in order to give the national court an answer enabling it to resolve the proceedings which are pending before it, the question must be understood as seeking to establish whether the national authorities are restricted, for reasons relating to the protection of Arkopharma's legitimate expectations, to ensuring that the products at issue comply with Community rules relating to the use of L-carnitine.

65 The Court has consistently held that the requirements flowing from the protection of general principles recognised in the Community legal order, including the principle of the protection of legitimate expectations, are also binding on Member States when they implement Community rules, and that consequently they are bound, as far as possible, to apply the rules in accordance with those requirements. Where national rules fall within the scope of Community law and reference is made to the Court for a preliminary ruling, the Court must provide all the criteria of interpretation needed by the national court to determine whether those rules are compatible with the general principles the observance of which is ensured by the Court (see, on fundamental rights falling within those general principles, Case C-2/92 *The Queen* v *Minister of Agriculture, Fisheries and Food, ex parte Bostock* [1994] ECR I-955, paragraph 16).

66 It is true that, as Arkopharma has observed, the principle of the protection of legitimate expectations is the corollary of the principle of legal certainty which requires that legal rules be clear and precise, and aims to ensure that situations

and legal relationships governed by Community law remain foreseeable (see Case C-63/93 *Duff and Others* v *Minister for Agriculture and Food, Ireland, and the Attorney General* [1996] ECR I-569, paragraph 20).

67 However, according to the case-law of the Court, the principle of the protection of legitimate expectations may be relied on in order to challenge Community rules only to the extent that the Community itself has previously created a situation which can give rise to a legitimate expectation (see, for example, Case C-22/94 *Irish Farmers Association and Others* v *Minister for Agriculture, Food and Forestry, Ireland and the Attorney General* [1997] ECR I-1809, paragraph 19). In the case of foodstuffs intended for particular nutritional uses, Community rules have not previously created a situation which might give rise, on the part of Arkopharma, to a legitimate expectation on which Arkopharma could rely.

68 Although it is evident from the fifth recital in the preamble to Directive 89/398/EEC that the Directive is intended to promote, in particular, effective monitoring of foodstuffs intended for particular nutritional uses, it does not itself, as noted in paragraphs 44 to 59 above, lay down any requirements as to the composition of this type of foodstuffs or as to the additives and substances for nutritional purposes referred to in Article 4(2) authorised in their manufacture.

69 It follows that, leaving aside the three directives adopted pursuant to Directive 89/398/EEC, the monitoring mentioned by the national court would apply only in respect of compliance with national rules on additives and substances for nutritional purposes which are authorised in the manufacture of foodstuffs intended for particular nutritional uses.

70 Arkopharma also claims that the power of the Member States to apply, in particular in the context of Article 10(2) of Directive 89/398/EEC, their own legislation relating to requirements as to the composition of foodstuffs intended

for particular nutritional uses and as to the additives authorised in their manufacturing process must be viewed in the light of the rules and principles governing the free movement of goods.

71 It is true that, as argued by Arkopharma, the power of Member States to regulate the composition of foodstuffs falling within the scope of Directive 89/398/EEC is subject to Articles 30, 34 and 36 of the EC Treaty (now, after amendment, Articles 28 EC, 29 EC and 30 EC) governing the free movement of goods, since national provisions covering the composition of foodstuffs intended for particular nutritional uses and additives authorised in their manufacture are capable of constituting restrictions on intra-Community trade.

72 However, in the present case, it is not apparent from the documents in the main proceedings that the activity carried on by Arkopharma involved either exporting or importing the products concerned. In such circumstances the Court is not in a position to determine whether the rules and principles relating to the free movement of goods apply to an activity of the kind at issue in the main proceedings. That decision therefore falls to the national court, which alone has jurisdiction to determine and evaluate the facts in the proceedings pending before it.

73 Consequently, the reply to be given to the fifth question is that Member States are subject, in their monitoring of the composition of foodstuffs intended for particular nutritional uses and, in particular, of additives and substances for nutritional purposes used in their manufacture, to the requirements flowing from general principles recognised by Community law, and, in particular, the principle of the protection of legitimate expectations. However, in the main proceedings the relevant Community rules could not give rise to a legitimate expectation on the part of Arkopharma on which it could reasonably rely. It is for the national court to decide whether the rules on the free movement of goods within the Community have any application to an activity such as that at issue in the main proceedings.

Costs

74 The costs incurred by the French Government and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Tribunal de Grande Instance, Grasse, by judgment of 19 July 1996, hereby rules:

1. Article 1(2) of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs

intended for particular nutritional uses must be interpreted as meaning that food supplements such as those at issue in the main proceedings, which contain L-carnitine in high doses and which are marketed on the basis that they are suitable for a particular nutritional purpose, fall within the scope of the Directive unless the national court establishes that they are not suitable for the nutritional purposes that the manufacturer claims they are or that they do not fulfil the particular nutritional requirements of one of the categories of persons referred to in Article 1(2)(b)(i) and (ii) of the Directive.

2. As Community law presently stands, Directive 89/398/EEC and the directives adopted pursuant to it do not prevent Member States from maintaining in force after the transposition of Directive 89/398/EEC prior national legislative provisions such as those at issue in the main proceedings which apply to additives authorised in the manufacture of foodstuffs intended for particular nutritional uses, even if those provisions are based on a classification other than that used in Directive 89/398/EEC.

3. In the absence of any provision in Directive 89/398/EEC itself, or in the directives adopted pursuant to Article 4 of the Directive, as to the composition of foodstuffs intended for particular nutritional uses or the use of additives or substances for specific nutritional purposes in the manufacture of that type of product, no relevant Community rules exist, as Community law presently stands, on which individuals may rely in order to challenge national rules on additives and substances for nutritional purposes authorised in the manufacture of foodstuffs of the kind at issue in the main proceedings.

4. Member States are subject, in their monitoring of the composition of foodstuffs intended for particular nutritional uses and, in particular, of additives and substances for nutritional purposes used in their manufacture, to the requirements flowing from general principles recognised by Community law, and, in particular, the principle of the protection of legitimate expectations. However, in the main proceedings the relevant Community rules could not give rise to a legitimate expectation on the part of Arkopharma on which it could reasonably rely. It is for the national court to decide whether the rules on the free movement of goods within the Community have any application to an activity such as that at issue in the main proceedings.

Schintgen Hirsch Ragnemalm

Delivered in open court in Luxembourg on 18 May 2000.

R. Grass

Registrar

J.C. Moitinho de Almeida

President of the Sixth Chamber