Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

15 December 2016*

(Reference for a preliminary ruling — Combined Nomenclature — Classification of goods — Food supplements falling under heading 2106 — Active ingredient as the essential component — Possible classification in Chapter 30 of the Combined Nomenclature — Goods presented and marketed as medicinal products)

In Case C-700/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Vrhovno sodišče (Supreme Court, Slovenia), made by decision of 10 December 2015, received at the Court on 31 December 2015, in the proceedings

LEK farmacevtska družba d.d.

v

Republika Slovenija,

THE COURT (Sixth Chamber),

composed of E. Regan, President of the Chamber, J.-C. Bonichot and S. Rodin (Rapporteur), Judges,

Advocate General: M. Bobek,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— LEK farmacevtska družba d.d., by P. Pensa, odvetnik, and J. Zaplotnik, odvetnica,

— the European Commission, by A. Caeiros and M. Žebre, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: Slovenian.

Judgment

1 The present reference for a preliminary ruling concerns the interpretation of the Combined Nomenclature of the Common Customs Tariff ('the CN'), set out in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1987 L 256, p. 1), as amended by Commission Regulation (EU) No 1006/2011 of 27 September 2011 (OJ 2011 L 282, p. 1) ('Regulation No 2658/87').

2 The reference was submitted in the course of proceedings between LEK farmacevtska družba d.d. ('Lek') and the Republika Slovenija concerning decisions in respect of tariff classification of three products named 'Linex', 'Linex Forte' and 'Linex Baby Granulat'.

Legal context

The HS

3 The Customs Cooperation Council, now the World Customs Organisation (WCO), was established by the convention establishing that body, concluded in Brussels on 15 December 1950. The Harmonised Commodity Description and Coding System ('the HS') was drawn up by the WCO and established by the International Convention on the Harmonised Commodity Description and Coding System ('the HS Convention') concluded in Brussels on 14 June 1983 and approved, with its amending protocol of 24 June 1986, on behalf of the European Economic Community by Council Decision 87/369/EEC of 7 April 1987 (OJ 1987 L 198, p. 1).

4 Under Article 3(1) of the HS Convention, each Contracting Party undertakes to ensure that its customs tariff and statistical nomenclatures will be in conformity with the HS, to use all the headings and subheadings of the HS without addition or modification, together with their related codes, and to follow the numerical sequence of that system. Each Contracting Party also undertakes to apply the General Rules for the interpretation of the HS and all the section, chapter and subheading notes of the HS, and not to modify their scope.

5 The WCO is to approve, under the conditions laid down in Article 8 of the HS Convention, the Explanatory Notes and Classification Opinions adopted by the HS Committee.

6 The Explanatory Note relating to HS heading 21.06 is worded as follows:

'Provided that they are not covered by any other heading of the Nomenclature, this heading covers:

…

(B) Preparations consisting wholly or partly of foodstuffs, used in the making of beverages or food preparations for human consumption. The heading includes preparations consisting of mixtures of chemicals (organic acids, calcium salts, etc.) with foodstuffs (flour, sugar, milk powder, etc.), for incorporation in food preparations …

…

The heading includes, inter alia:

…

(16) Preparations, often referred to as food supplements, based on extracts from plants, fruit concentrates, honey, fructose, etc., and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put up in packagings with indications that they maintain general health or well-being. Similar preparations intended for the prevention or treatment of diseases or ailments are excluded (heading 30.03 or 30.04).'

The CN

7 The CN, which was established by Regulation No 2658/87, is based on the HS and reproduces the headings and subheadings of the HS to six digits, with only the seventh and eighth figures creating further subheadings which are specific to it.

8 The eighth recital of Regulation No 2658/87 (the ninth recital in the Slovenian language version of that regulation) states:

'Whereas it is essential that the [CN] and any other nomenclature wholly or partly based on it, or which adds subdivisions to it, should be applied in a uniform manner by all the Member States; whereas provisions to this effect must be able to be adopted at Community level; whereas, furthermore, the Community provisions ensuring uniform application of the [CN] of the Common Customs Tariff contained in Decision 86/98/ECSC are applicable to products falling within the province of the Treaty establishing the European Coal and Steel Community; …'

9 Heading No 2106 of the CN covers 'food preparations not elsewhere specified or included'.

10 Chapter 30 of the CN relates to pharmaceutical products. Note 1(a) to that chapter is worded as follows:

'This chapter does not cover:

(a) foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV)'.

11 CN heading 3004 reads as follows:

'Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale'.

12 Additional Note 1 to Chapter 30 of the CN reads as follows:

'Heading 3004 includes herbal medicinal preparations and preparations based on the following active substances: vitamins, minerals, essential amino acids or fatty acids, in packings for retail sale. These preparations are classified in heading 3004 if they bear on the label, packaging or on the accompanying user directions the following statements of:

(a) the specific diseases, ailments or their symptoms for which the product is to be used;

(b) the concentration of active substance or substances contained therein;

(c) dosage; and

(d) mode of application.

This heading includes homeopathic medicinal preparations when they meet the conditions of (a), (c) and (d) mentioned above.

In the case of preparations based on vitamins, minerals, essential amino acids or fatty acids, the level of one of these substances per recommended daily dose indicated on the label must be significantly higher than the recommended daily allowance to maintain general health or well-being.'

Regulation (EC) No 1264/98 and Implementing Regulation (EU) No 727/2012

13 Point 5 of the Annex to Commission Regulation (EC) No 1264/98 of 17 June 1998 concerning the classification of certain goods in the Combined Nomenclature (OJ 1998 L 175, p. 4), classifies under CN heading 2106 food supplements in capsules containing malto-dextrin (70%), magnesium stearate (3%) and ascorbic acid (0.5%) with added lactic ferments (*Bifidobacterium breve* and *B. longum*, *Lactobacillus acidopbilus* and *L. rhamnosus*, approximately 1 billion per gram).

14 The Annex to Commission Implementing Regulation (EU) No 727/2012 of 6 August 2012 concerning the classification of certain goods in the Combined Nomenclature (OJ 2012 L 213, p. 5) classifies under CN heading 2106 cultures of micro-organisms presented in gelatine capsules, put up for retail sale. The content of each capsule consists of the following components (% by weight), namely *L. rhamnosus* (3.36), *L. acidophilus* (3.36) *L. plantarum* (0.84), *B. lactis* (0.84), maltodextrine (50.6), micro-crystalline cellulose (10), corn starch (30), magnesium stearate (1). According to the label the product is presented as a food supplement for human consumption.

Directive 2001/83/EC

15 Recitals 2 to 5 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 (OJ 2001 L 311, p. 67), as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) ('Directive 2001/83') are worded as follows:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.'

16 Article 1(2) of Directive 2001/83 states as follows:

'For the purposes of this Directive, the following terms shall bear the following meanings:

…

2. Medicinal product:

(a) any substance or combination of substances presented for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'

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

17 Lek is a Slovenian company that manufactures pharmaceutical products. On 4 September 2012, the Generalni carinski urad Carinske uprave Republike Slovenije (Directorate-General of the Customs Authority of the Republic of Slovenia) issued three binding tariff information decisions for goods with the trade names 'Linex', 'Linex Forte' and 'Linex Baby Granulat'. The goods at issue may be described as follows.

18 First, the product named 'Linex' is a solid gelatine capsule packed with specific probiotic bacteria with a vehicle (an excipient) and intended for use against digestive disorders. Each capsule contains at least 1.2 x 10^{7} units of live, lyophilised lactobacillales, of the *Lactobacillus acidophilus* type of the species *Lactobacillus gasseri*, *Bifidobacterium infantis* and *Enterococsus faecium* strains, with a vehicle consisting of a mixture of magnesium stearate, lactose, dextrin and potato starch. Each capsule contains more than 5% glucose or starch by weight. The product is packaged in a form intended for retail sale, in an aluminium blister pack of 16 capsules enclosed in a cardboard box.

19 Next, the product named 'Linex Forte' is also a capsule containing at least two billion lactobacillales forming live, lyophilised colonies of the *Lactobacillus acidophilus* and *Bifidobacterium animalis subsp. lactis* strains in the proportion of 1:1, with a vehicle consisting of a mixture of glucose, microcrystalline cellulose, potato starch, inulin, oligofructose and magnesium stearate. Each capsule contains more than 5% glucose or starch by weight. The product is packaged in a form intended for retail sale, in an aluminium blister pack of 16 capsules enclosed in a cardboard box.

20 Finally, the product named 'Linex Baby Granulat' is presented in granular form, packaged in sachets of 1.5g. Each sachet contains at least one billion bacteria forming live, lyophilised colonies of the *Bifidobacterium* (*Lactobacillus acidophilus* and *Bifidobacterium animalis subsp. lactis*) strain, with a vehicle consisting of maltodextrin. Each sachet contains more than 5% glucose or starch by weight. The product is packaged in a form intended for retail sale, in a cardboard box containing 10 sachets.

21 The instructions for use of all three products at issue state that the purpose of use is to prevent, and support the treatment of, diarrhoea, bloating and other digestive disorders that occur owing to disruption of the balance of the intestinal flora, bacterial or viral infections of the digestive system, or as a result of treatment with broad spectrum antibiotics or chemotherapy. Furthermore, the instructions for use state that taking probiotics or lactobacillales effectively reduces the frequency and intensity of low to moderate gastrointestinal discomfort, which occurs owing to destruction of the normal intestinal microflora. Therefore, the Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices), making its decision on the basis of the national law transposing Directive 2001/83, granted marketing authorisations as medicinal products for the three products.

22 The national customs authority classified those goods under CN heading 2106 90 98. Taking the view that the goods at issue must be classified under CN heading 3002 90 50, Lek lodged an appeal against the classification made by that authority.

23 By decisions of 28, 29 and 30 November 2012, the Finance Minister rejected the appeals against the classification made by that authority.

24 Not satisfied with the decisions of the Finance Minister, Lek requested that the administrative court of first instance rule on the tariff classification of the goods at issue, submitting that they must be classified under CN heading 3004 90 00. On 28 January 2014, that court upheld the aforementioned decisions.

25 Lek lodged an appeal on a point of law against that judgment before the referring court.

26 That court notes that the decisive criterion for classifying a product in Chapter 30 of the CN is that it should have clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or that it be capable of being applied in the prevention or treatment of diseases or ailments. According to that court, the goods at issue in the main proceedings could fulfil that criteria to the extent that they, first, treat certain digestive problems, second, their effect is concentrated on the proper functioning of the intestines and, third, they are used for the prevention or treatment of a specific condition, namely intestinal imbalances.

27 However, that court has doubts as to the classification of those goods in Chapter 30 of the CN to the extent that they contain active ingredients, namely probiotic bacteria, that are usually contained in food supplements and used generally as active ingredients which have a general positive effect on health.

28 The referring court considers that the question arising in the present case is whether a product that contains the same active ingredients as food supplements within Chapter 21 of the CN could, however, be classified in Chapter 30 of the CN owing to the fact that it is used to prevent or treat certain health conditions and is marketed as a medicinal product. Furthermore, that court refers to the consequences of the adoption of Directive 2001/83. More specifically, it considers that that directive, which aims to ensure a uniform allocation of marketing authorisations for medicinal products, could alter the findings of the Court made in the judgment of 12 March 1998, *Laboratoires Sarget* (C-270/96, EU:C:1998:103), namely that the allocation of an authorisation to be marketed as a medicinal product does not necessarily mean that the product must be classified in Chapter 30 of the CN.

29 In those circumstances the Vrhovno sodišče (Supreme Court, Slovenia) decided to stay proceedings and to refer to the Court the following questions for a preliminary ruling:

‘(1) May the provisions of Chapter 30 of the CN be interpreted as meaning that a product, whose main component is an active ingredient (probiotic bacteria) contained in food supplements classified under tariff heading 2106 90 98 CN, is not to be classified in that chapter?

(2) For a product to be classified in Chapter 30 of the CN, is it sufficient that the manufacturer presents that product, which contains an active ingredient having beneficial effects on health in general which is often found in food supplements, as a medicinal product, and markets and sells it as such?

(3) In the light of the evolution of EU law regulating the market for medicinal products, must the concept of ‘clearly defined therapeutic or prophylactic characteristics’ which, according to the settled case-law of the Court of Justice of the European Union, is a condition for classification in Chapter 30, be interpreted as corresponding to the definition of medicinal product within the meaning of the provisions of EU law relating to medicinal products for human use?

The questions referred

The third question

30 By its third question, which should be examined first of all, the referring court asks, in essence, whether CN heading 3004 must be interpreted as meaning that goods that fall within the definition of 'medicinal product' within the meaning of Directive 2001/83 must automatically be classified under that heading.

31 In that regard, it is clear, first of all, from recitals 2 to 5 of Directive 2001/83 that that directive aims to ensure the approximation of national legislation concerning medicinal products whilst ensuring the attainment of its essential aim, which is the safeguarding of public health (see, to that effect, the judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 76).

32 Next, the classification of a product in one Member State as a medicinal product within the meaning of Directive 2001/83, does not require the competent authorities of another Member State to classify the same product as a medicinal product within the meaning of other instruments of EU law (see, to that effect, judgment of 3 October 2013, *Laboratoires Lyocentre*, C-109/12, EU:C:2013:626, paragraph 48).

33 Furthermore, it is clear from the eighth recital of Regulation No 2685/87 that the provisions of the CN must be given an identical interpretation by each of the Member States (see, to that effect, judgment of 12 March 1998, *Laboratoires Sarget*, C-270/96, EU:C:1998:103, paragraph 24).

34 Finally, it follows from the wording of Article 1 of Directive 2001/83 that a medicinal product within the meaning of that directive includes, first, any substance or combination of substances presented for treating or preventing disease in human beings and, second, 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.

35 Therefore, that definition does not require that products falling within it necessarily comply with the condition for classification in Chapter 30 of the CN, namely that they have clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or are capable of being applied in the prevention or treatment of diseases or ailments.

36 Directive 2001/83 pursues different objectives from those pursued by the CN. In order to maintain the coherence between the interpretation of the CN and that of the HS, which is established by an international convention to which the European Union is a contracting party, the fact that a product has a marketing authorisation as a medicinal product within the meaning of Directive 2001/83 cannot be decisive as regards assessing whether that product falls within the category of 'medicaments' within the meaning of CN heading 3004 (see, to that effect, judgments of 12 March 1998, *Laboratoires Sarget*, C-270/96, EU:C:1998:103, paragraph 25, and of 4 March 2015, *Oliver Medical*, C-547/13, EU:C:2015:139, paragraph 53).

37 It follows from all the foregoing considerations that the answer to the third question is that CN heading 3004 must be interpreted as meaning that goods which fall within the definition of 'medicinal product' within the meaning of Directive 2001/83 are not automatically required to be classified under that heading.

The first and second questions

38 By its first and second questions, which it is appropriate to examine together, the referring court asks, in essence, whether the CN must be interpreted as meaning that goods, such as those at issue in the main proceedings, which have beneficial effects on health and in which the essential component is an active ingredient that is found in food supplements classified under tariff heading 2106 of the CN, although they are presented by their manufacturer as medicinal products and are marketed and sold as such, may be classified under CN heading 3004 or whether they fall instead under heading 2106 thereof.

39 First, it is settled case-law that, in the interests of legal certainty and ease of verification, the decisive criterion for the classification of goods for customs purposes is in general to be sought in their objective characteristics and properties as defined in the wording of the relevant heading of the CN and in the section or chapter notes (see judgment of 17 February 2016, *Salutas Pharma*, C-124/15, EU:C:2016:87, paragraph 29 and the case-law cited).

40 Thus, the chapter notes to the CN constitute important means for ensuring the uniform application of the common customs tariff and provide, as such, useful information for its interpretation. The content of those notes must therefore be consistent with the provisions of the CN and cannot modify its scope (see judgment of 17 February 2016, *Salutas Pharma*, C-124/15, EU:C:2016:87, paragraph 30 and the case-law cited).

41 Furthermore, the explanatory notes drawn up by the Commission as regards the CN and by the WCO as regards the HS are an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force (see judgment of 17 February 2016, *Salutas Pharma*, C-124/15, EU:C:2016:87, paragraph 31 and the case-law cited).

42 In order to classify goods in Chapter 30 of the CN, it is necessary to examine whether the latter had clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or are capable of being applied in the prevention or treatment of diseases or ailments (see, to that effect, judgment of 30 April 2014, *Nutricia*, C-267/13, EU:C:2014:277, paragraph 20 and the case-law cited).

43 Furthermore, as regards CN heading 3004, it is clear from the wording of the additional note 1 to that heading that it includes herbal medicinal preparations and preparations based on an exhaustive list of active substances, namely vitamins, minerals, essential amino acids or fatty acids, provided that they also satisfy the other criteria for classification under that heading, namely that their labelling, packaging and mode of application states the diseases, ailments or symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the dose, mode of administration and, in the case of goods based on vitamins, minerals, amino acids and fatty acids, that the recommended dose is significantly higher than the recommended daily allowance.

44 To the extent that the basic component of the goods at issue in the main proceedings were cultures of micro-organisms, they do not fall under CN heading 3004, irrespective of whether they satisfy the other conditions for classification set out in additional note 1 to that heading.

45 In that regard, the fact that the goods concerned are presented and marketed as medicinal products does not call into question the finding set out in the previous paragraph. It is common ground that in neither the wording of heading 3004 nor the notes set out in the introduction to Chapter 30 of the CN for the tariff classification of products in that chapter is there any reference to the presentation of the product, and therefore such a factor is not decisive as regards classification in the CN (see order of 9 January 2007, *Juers Pharma*, C-40/06, EU:C:2007:2, paragraph 29 and the case-law cited).

46 Accordingly, it must be held, in accordance with the case-law set out in paragraphs 39 to 41 above, that additional note 1 to CN heading 3004 excludes goods such as those at issue in the main proceedings from being classified under that heading.

47 Furthermore, to the extent that note 1(a) of Chapter 30 of the CN excludes from that chapter food supplements falling under CN heading 2106, it must be determined whether the goods at issue in the main proceedings fall under that heading.

48 In that regard, it must be recalled that CN heading 2106 includes 'Food preparations not elsewhere specified or included' and also covers preparations often referred to as 'food supplements', presented in packages indicating they maintain general health or well-being (see, to that effect, judgment of 17 December 2009, *Swiss Caps*, C-410/08 to C-412/08, EU:C:2009:794, paragraph 31).

49 In addition, it is settled case law that a classification regulation is of general application in so far as it does not apply to an individual trader but, in general, to products which are the same as that examined by the Customs Code Committee. In the interpretation of a classification regulation, in order to determine its scope, account must be taken, inter alia, of its statement of reasons (see judgment of 4 March 2015, *Oliver Medical*, C-547/13, EU:C:2015:139, paragraph 55 and the case-law cited).

50 It is true that Regulation No 1264/98 and Implementing Regulation No 727/2012 are not directly applicable to the goods at issue in the main proceedings. Those goods are not identical to those covered by that regulation, since they differ in respect of their vehicles and the concentration of micro-organisms.

51 Nevertheless, the application by analogy of a classification regulation, such as Regulation No 1264/98 and Implementing Regulation No 727/2012, to products similar to those covered by that regulation facilitates a coherent interpretation of the CN and the equal treatment of traders (see, to that effect, judgment of 4 March 2015, *Oliver Medical*, C-547/13, EU:C:2015:139, paragraph 57, and the case law cited).

52 It is clear, first, from the wording of point 5 of the Annex to Regulation No 1264/98 and, second, the wording of the Annex to Implementing Regulation No 727/2012, that goods composed of various bacteria colonies and excipients are to be classified under CN heading 2106, having regard to the general rules for the interpretation of the CN, to the wording of note 1(a) of Chapter 30 and to the CN headings 2106, 2106 90 and 2106 90 98. Thus, it must be held that the goods at issue in the main proceedings have the same active ingredient as the goods classified by Regulation No 1264/98 and Implementing Regulation No 727/2012 and that the only differences between the two are the concentration of the micro-organisms and the excipients used.

53 It follows that goods, such as those at issue in the main proceedings, in which the essential component is an active ingredient that is contained in the food supplements classified under tariff heading 2106 of the CN and which have beneficial effects on health fall under CN heading 2106.

54 It follows from all the foregoing that the answer to the first and second questions is that the CN must be interpreted as meaning that goods, such as those at issue in the main proceedings, which have beneficial effects on health and in which the essential component is an active ingredient that is found in food supplements classified under tariff heading 2106 of the CN, although they are presented by their manufacturer as medicinal products and are marketed and sold as such, fall under that heading.

Costs

55 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, 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 (Sixth Chamber) hereby rules:

1. **Heading 3004 of the Combined Nomenclature of the Common Customs Tariff set out in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, as amended by Commission Regulation (EU) No 1006/2011 of 27 September 2011, must be interpreted as meaning that goods which fall within the definition of 'medicinal product', within the meaning 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, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, are not automatically required to be classified under that heading.**

2. **The Combined Nomenclature of the Common Customs Tariff set out in Annex I to Council Regulation No 2658/87, as amended by Regulation No 1006/2011, must be interpreted as meaning that goods, such as those at issue in the main proceedings, which have beneficial effects on health and in which the essential component is an active ingredient that is found in food supplements classified under tariff heading 2106 of the CN, although they are presented by their manufacturer as medicinal products and are marketed and sold as such, fall under that heading.**

[Signatures]