Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

30 April 2014*

(Combined Nomenclature — Tariff headings — Medicaments within the meaning of heading 3004 — Notion — Nutritional preparations intended to be administered only enterally under medical supervision to persons undergoing medical treatment — Beverages within the meaning of heading 2202 — Notion — Nutritional liquids intended to be administered enterally and not to be drunk)

In Case C-267/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Hoge Raad der Nederlanden (Netherlands), made by decision of 19 April 2013, received at the Court on 15 May 2013, in the proceedings

Nutricia NV

v

Staatssecretaris van Financiën,

THE COURT (Sixth Chamber),

composed of A. Borg Barthet, President of the Chamber, S. Rodin (Rapporteur) and F. Biltgen, Judges,

Advocate General: E. Sharpston,

Registrar: A. Calot Escobar,

after considering the observations submitted on behalf of:

— Nutricia NV, by B. Boersma, adviser,

— the Netherlands Government, by M. Bulterman and B. Koopman, acting as Agents,

— the European Commission, by H. Kranenborg and B.-R. Killmann, acting as Agents,

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

gives the following

* Language of the case: Dutch.

Judgment

1 This request for a preliminary ruling concerns the interpretation of the terms ‘medicaments’ and ‘beverages’ within the meaning of the Combined Nomenclature 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 (EC) No 1549/2006 of 17 October 2006 (OJ 2006 L 301, p. 1) (‘the CN’).

2 The request has been made in proceedings between Nutricia NV (‘Nutricia’) and the Staatssecretaris van Financiën (State Secretary for Finance) concerning Binding Tariff Informations (‘BTIs’) relating to the classification of products used to feed patients enterally.

Legal context

3 CN heading 2106 reads as follows:

‘2106 – Food preparations not elsewhere specified or included.’

4 CN heading 2202 and subheadings 2202 10 00, 2202 90 and 2202 90 10 read as follows:

‘2202 – Waters, including mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured, and other non-alcoholic beverages, not including fruit or vegetable juices of heading 2009:

2202 10 00 – Waters including mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured

2202 90 – Other:

2202 90 10 – – Not containing products of headings 0401 to 0404 or fat obtained from products of headings 0401 to 0404

– – Other, containing by weight of fat obtained from the products of headings 0401 to 0404.’

5 In Part Two of the CN, Chapter 22, entitled ‘Beverages, Spirits and Vinegar’, provides in note 1:

‘This chapter does not cover:

...

(e) medicaments of heading 3003 or 3004’.

6 Commission Regulation (EEC) No 184/89 of 25 January 1989 concerning the classification of certain goods in the combined nomenclature (OJ 1989 L 23, p. 19), describes the goods under subheading 2202 90 10 as containing the following:

‘A liquid preparation containing sodium and calcium caseinates, soya protein, soya lecithin, maize oil, soya oil, medium-chain triglycerides, maltodextrins, minerals, vitamins and water capable also of being administered by enteral tube.’

7 Heading 3004 and subheadings 3004 50 and 3004 50 10 are worded as follows:

‘3004 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:

…

3004 50 — Other medicaments containing vitamins or other products of heading 2936

3004 50 10 — Put up in forms or in packings of a kind sold by retail’.

8 In Part Two of the CN, Chapter 30, entitled ‘Pharmaceutical Products’, states in note 1:

‘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 …’.

9 Additional note 1 to Chapter 30 provides:

‘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 abovementioned conditions of (a), (c) and (d).

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.’

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

10 On 10 May 2007, Nutricia applied to the relevant tax inspectorate (‘the inspectorate’) for five BTIs in respect of five different types of products used to tube-feed patients (‘the products in question’). In its application, it suggested that the products in question should be classified under CN subheading 3004 50 10.

11 On 28 August 2007, the inspectorate issued Nutricia with the BTIs for which it had applied, in which the products in question are classified under CN subheading 2202 90 10. In those BTIs the products are described in the following terms:

‘A light brown-coloured liquid preparation, being a tube feed for the dietary treatment of disease-related malnutrition, which must — as indicated — be administered to patients only under medical supervision.

Among other ingredients, the liquid preparation contains proteins, vitamins, carbohydrates, fats, dietary fibres and minerals.

The liquid preparation contains no fats derived from milk and the sucrose content (including the invert sugar or isoglucose content, expressed as sucrose) is <0.1% by weight.

The liquid preparation is produced for retail sale, supplied with directions for use in several languages and packaged in a 500 ml plastic pouch with a special tube connection.’

12 In order to justify that classification, the inspectorate stated that it ‘is determined by General Rules 1 and 6 for the interpretation of the [CN], Note 1(a) to Chapter 30 and the texts of CN codes 2202, 2202 90 and 2202 90 10 (see Case C-130/02 [*Krings* EU:C:2004:122]). … Regulation (EEC) No 184/89 … Laboratory analysis dated 15 August 2007 ...’.

13 Following confirmation of the BTIs by the inspectorate after an objection had been lodged by Nutricia, the latter brought an action before the Rechtbank te Haarlem (District Court, Haarlem), which, by decision of 2 June 2009, declared the action to be unfounded. Nutricia lodged an appeal before the Gerechtshof te Amsterdam (Regional Court of Appeal, Amsterdam), which upheld that decision in its judgment of 28 April 2011. Finally, Nutricia lodged an appeal on a point of law with the referring court against that judgment.

14 The referring court observes that, in order for a product to be capable of being classified under heading 3004, the case-law of the Court makes it clear that it is of crucial importance that that product should have therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or that it is capable of being applied in the prevention or treatment of diseases or ailments. Given that the products in question produce effects on the treatment and prevention of disease-related malnutrition, it follows that they should not be classified under that heading. However, the referring court expresses doubts as to that conclusion.

15 The referring court thus notes in particular that the products in question are not intended to be drunk, which precludes their classification under heading 2202. Moreover, those products are intended exclusively to be administered to persons who are receiving medical treatment for a disease or ailment, and to whom they are given by means of a stomach tube as part of the control of that disease or ailment. It states that it is clear from the case-law of the Court that the ‘administration by artificial means’ of products which, because of their objective characteristics, are by their nature intended for medical use, means that the classification should be made under heading 3004.

16 In those circumstances, the Hoge Raad der Nederlanden, having doubts as to the correct interpretation of the CN, decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘1. Must the term “medicament” for the purposes of CN heading 3004 be interpreted as also including food preparations such as the [products at issue], which are intended exclusively to be administered enterally (by means of a stomach tube) under medical supervision to persons who

are undergoing medical treatment for a disease or ailment and who have the product administered to them as part of the control of that disease or ailment in order to control or prevent malnutrition?

2. Must the concept of "beverages" for the purposes of CN heading 2202 be interpreted as including liquid foodstuffs such as the [products at issue], which are not intended to be drunk but are to be administered enterally (by means of a stomach tube)?'

Consideration of the questions referred

The first question

17 By its first question, the referring court asks, in essence, whether CN tariff heading 3004 must be interpreted as meaning that the term 'medicaments', for the purposes of that heading, includes food preparations intended exclusively to be administered enterally under medical supervision to persons who are receiving medical care if, as part of the control of the disease or ailment affecting them, that product is administered to them in order to control or prevent their malnutrition.

18 In order to reply to that question, it must be noted that CN heading 3004 includes '[m]edicaments … consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses … or in forms or packings for retail sale'.

19 It must be stated at the outset that the Court has consistently held 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 found in their objective characteristics and properties as defined in the wording of the relevant CN heading and of the section or chapter notes (see, inter alia, Case C-459/93 *Thyssen Haniel Logistic* EU:C:1995:160, paragraph 8 and the case-law cited, and Case C-291/11 *TNT Freight Management (Amsterdam)* EU:C:2012:459, paragraph 30).

20 In that regard, the Court has already been called on a number of occasions to reply to questions concerning the interpretation of the term 'medicaments' in relation to the classification of goods in the CN. In accordance with settled case-law, in order to classify products in Chapter 30 of the CN, it is necessary to examine whether those products have clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or whether they are capable of being applied in the prevention or treatment of diseases or ailments. Even where the product in question does not have an intrinsic therapeutic effect, but is used in the prevention or treatment of a disease or ailment, it must, provided that it is specifically intended for such a use, be regarded as having been prepared for therapeutic use (see, inter alia, *TNT Freight Management (Amsterdam)* EU:C:2012:459, paragraphs 40 and 42).

21 It is apparent from the case-law cited in the two preceding paragraphs that the intended use of a product may constitute an objective criterion for classification if it is inherent to the product, and that inherent character must be capable of being assessed on the basis of the product's objective characteristics and properties (see, inter alia, *Krings* EU:C:2004:122, paragraph 30 and the case-law cited). According to the case-law of the Court, a product which, on account of its objective characteristics and properties, is clearly intended for medical use may be classified in Chapter 30 of the CN (see *Thyssen Haniel Logistic* EU:C:1995:160, paragraph 14, and *TNT Freight Management (Amsterdam)* EU:C:2012:459, paragraph 41).

22 It must be added that the Court has already held, relying on the actual wording of heading 3004, that the fact that products are put up in measured doses or that they are packaged for retail sale constitutes a condition of the application of that provision (see order in Case C-40/06 *Juers Pharma* EU:C:2007:2, paragraph 23 and the case-law cited).

23 It is also important to note that the question of whether or not an illness is recognised in a measure of EU law other than those that refer to classification in the CN is not a decisive factor for the classification of a product under heading 3004 thereof (see, to that effect, order in Case C-206/03 *SmithKline Beecham* EU:C:2005:31, paragraph 44).

24 In the action in the main proceedings, it is apparent from the documents before the Court that the products in question are used for tube-feeding in the treatment of malnutrition connected with diseases or ailments, and that they may be administered to patients only under medical supervision by means of a stomach tube. It follows that such products are intended to be used in the prevention or treatment of a disease or ailment and that they are clearly intended for medical use.

25 It is also important to bear in mind that the additional note relating to heading 3004 states clearly that that heading includes herbal medicinal preparations and preparations based on active substances (vitamins, minerals, essential amino-acids or fatty acids) in packings for retail sale, which must be classified in that heading if they bear statements relating to the product in question on the label or packaging.

26 It is, admittedly, true that note 1(a) to Chapter 30 of the CN, which excludes from that chapter food preparations and supplements and beverages other than nutritional preparations for intravenous administration, is a valid aid to interpreting the CN. In this regard, the Court has already held on a number of occasions that both the notes which head the chapters of the Common Customs Tariff and the explanatory notes to the Harmonised Commodity Description and Coding System drawn up by the Customs Cooperation Council, now the World Customs Organisation, may be regarded as useful aids to interpreting that tariff (see Case C-395/93 *Neckermann Versand* EU:C:1994:318, paragraph 5; Joined Cases C-59/94 and C-64/94 *Pardo & Fils* and *Camicas* EU:C:1995:326, paragraph 10; and Case C-338/95 *Wiener SI* EU:C:1997:552, paragraph 11).

27 However, it should be stressed that the explanatory notes drawn up in relation to that harmonised system by the World Customs Organisation and in relation to the CN by the European Commission are interpretative in character and do not have legally binding force (see, inter alia, Case C-396/02 *DFDS* EU:C:2004:536, paragraph 28; Case C-15/05 *Kawasaki Motors Europe* EU:C:2006:259, paragraph 37 and the case-law cited; and Case C-312/07 *JVC France* EU:C:2008:324, paragraph 37).

28 In this regard it must be noted that it is clear from the actual wording of note 1(a) to Chapter 30 of the CN that dietetic foods or beverages, other than nutritional preparations for intravenous administration, which, without being part of the daily diet, are nevertheless used purely for feeding purposes are excluded from that chapter.

29 In the present case, it should be stressed that, according to the description given by the referring court, the products in question contain active substances, they are put up for retail sale, they are supplied with directions for use in several languages and are packaged in plastic pouches containing 500 ml of product with a special tube connection.

30 Moreover, having regard to the objective properties of the products at issue, in particular the fact that they are put up for retail sale, that they are used within a medical environment and that they are intended to be administered to patients through a stomach tube under medical supervision with the aim of preventing or treating malnutrition connected with diseases or ailments, it must be concluded that those products are prepared for therapeutic or prophylactic uses within the meaning of tariff heading 3004.

31 Accordingly, the answer to the first question is that CN tariff heading 3004 must be interpreted as meaning that the term 'medicaments' within the meaning of that heading includes food preparations intended exclusively to be administered enterally (by means of a stomach tube) under medical supervision to persons who are receiving medical care, provided that that product is administered, as part of the control of the disease or ailment affecting them, in order to prevent or control their malnutrition.

The second question referred for a preliminary ruling

32 In view of the answer to the first question, there is no need to reply to the second question referred by the national court.

Costs

33 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:

Tariff heading 3004 of the Combined Nomenclature 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 (EC) No 1549/2006 of 17 October 2006, must be interpreted as meaning that the term 'medicaments' within the meaning of that heading includes food preparations intended exclusively to be administered enterally (by means of a stomach tube) under medical supervision to persons who are receiving medical care, provided that that product is administered, as part of the control of the disease or ailment affecting them, in order to prevent or control their malnutrition.

[Signatures]