Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

12 July 2012*

(Common Customs Tariff — Combined Nomenclature — Tariff headings 3002 and 3502 — Blood albumin prepared for therapeutic or prophylactic uses — Processing of the product)

In Case C-291/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Hoge Raad der Nederlanden (Netherlands), made by decision of 13 May 2011, received at the Court on 9 June 2011, in the proceedings

Staatssecretaris van Financiën

v

TNT Freight Management (Amsterdam) BV,

THE COURT (Third Chamber),

composed of K. Lenaerts, President of the Chamber, R. Silva de Lapuerta, E. Juhász, G. Arestis (Rapporteur) and D. Šváby, Judges,

Advocate General: E. Sharpston,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— the Netherlands Government, by C. Wissels and B. Koopman, acting as Agents,

— the European Commission, by M. van Beek and L. Bouyon, 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 reference for a preliminary ruling concerns the interpretation 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 1789/2003 of 11 September 2003 (OJ 2006 L 281, p. 1) ('the CN'), in particular Notes 1(g) in Chapter 30 of the CN and 1(b) in Chapter 35 thereof.

2 The reference has been made in proceedings between the Staatssecretaris van Financiën (Secretary of State for Finance) and TNT Freight Management (Amsterdam) BV ('TNT') concerning the payment of customs duties claimed from TNT for the import of blood albumin.

Legal context

The harmonised system

3 The International Convention on the Harmonised Commodity Description and Coding System ('the HS'), and the Protocol of Amendment thereto ('the Convention on the HS'), concluded at Brussels on 14 June 1983, were approved on behalf of the European Economic Community by Council Decision 87/369/EEC of 7 April 1987 concerning the conclusion of the International Convention on the Harmonised Commodity Description and Coding System and of the Protocol of Amendment thereto (OJ 1987 L 198, p. 1).

4 Under Article 3(1)(a) of the Convention on the HS, each Contracting Party undertakes to ensure that its customs tariff and statistical nomenclatures will be in conformity with the HS, to use all of 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. The same provision provides that 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 the scope of the sections, chapters, headings and subheadings.

5 Under Article 6(1) of the Convention on the HS, a committee entitled 'the Harmonised System Committee', composed of representatives of each Contracting Party, was set up within the Customs Cooperation Council. One of the tasks of the Committee is to propose amendments to that convention and to prepare explanatory notes, classification opinions and other advice on the interpretation of the HS.

6 The explanatory note of the HS relating to heading 3002 states that that heading includes blood albumin (for example human blood albumin obtained by fractioning the plasma of whole human blood) prepared for therapeutic or prophylactic uses (heading 3502).

7 The explanatory note in the HS relating to heading 3502 states in point 1 that albumins covered by that chapter are animal or vegetable proteins which are used in particular in the preparation of glues, foodstuffs or pharmaceutical products. It is also clear from that note that blood albumin prepared for therapeutic or prophylactic use is excluded from heading 3502.

The Combined Nomenclature

8 Regulation No 2658/87 established the CN, which takes six-digit headings and subheadings from the HS, only the seventh and eighth digits forming subdivisions that are specific to it.

9 For the purpose of the regulation at issue in the main proceedings, the versions of the CN applicable are those resulting from Commission Regulation (EC) No 2031/2001 of 6 August 2001 amending Annex I to Regulation No 2658/87 (OJ 2001 L 279, p. 1), Commission Regulation (EC) No 1832/2002 of 1 August 2002, amending Annex I to Regulation No 2658/87 (OJ 2002 L 290, p. 1), and Commission Regulation (EC) No 1789/2003. As regards the present case, the relevant provisions of those three versions are identical.

10 In order to ensure as far as possible a uniform application of the Common Customs Tariff, the World Customs Organisation inserted into the HS a set of binding preliminary provisions, which were set out at European Union level in the general rules for the interpretation of the Combined Nomenclature. Those rules, which appear in Part One, Title I, Section A, of the CN, provide:

'Classification of goods in the [CN] shall be governed by the following principles:

1. The titles of sections, chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes and, provided such headings or notes do not otherwise require, according to the following provisions.

…

6. For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, mutatis mutandis, to the above rules, on the understanding that only subheadings at the same level are comparable. For the purposes of this rule, the relative section and chapter notes also apply, unless the context requires otherwise.'

11 Part Two of the CN includes Chapter 30, entitled 'Pharmaceutical products', which includes heading 3002, which is worded as follows:

3002	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products:
3002 10	Antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes:
3002 10 10	– Antisera
	Other:
3002 10 91	Haemoglobin, blood globulins and serum globulins
	Other:
3002 10 95	Of human origin
3002 10 99	Other
3002 20 00	Vaccines for human medicine
3002 30 00	Vaccines for veterinary medicine
3002 90	Other:
3002 90 10	Human blood
3002 90 30	animal blood prepared for therapeutic, prophylactic or diagnostic uses;

12 It is clear from Note 1(g) in Chapter 30 of the CN that the latter does not include 'blood albumin not prepared for therapeutic or prophylactic uses (No 3502)'.

13 Heading 3502 in Chapter 35 of the CN, entitled 'Albuminoidal Substances; Modified Starches; Glues; Enzymes', is worded as follows:

3502	Albumins (including concentrates of two or more whey proteins, containing by weight more than 80% whey proteins, calculated on the dry matter), albuminates and other albumin derivates:
	Egg albumin:
	…
3502 20	Milk albumin, including concentrates of two or more whey proteins:
	…
3502 90	Other:
	Albumins, other than egg albumin and milk albumin (lactalbumin):
3502 90 20	Unfit, or to be rendered unfit, for human consumption
3502 90 70	Other
	…

14 It is clear in particular from Note 1(b) in Chapter 35 of the CN that the latter does not cover 'blood fractions (other than blood albumin not prepared for therapeutic or prophylactic uses), medicaments or other products of Chapter 30'.

15 Pursuant to the second indent of Article 9(1)(a) and Article 10 of Regulation No 2658/87, the Commission is to adopt explanatory notes of the CN after examination by the Tariff and Statistical Nomenclature Section of the Customs Code Committee. The explanatory notes contain the following information:

'3002 10 95 Other

and

3002 10 99 These subheadings include 'normal' sera, plasma fibrinogen, fibrin and, provided that it is prepared for therapeutic or prophylactic uses, blood albumin (for example, obtained by fractioning the plasma of human blood).

Blood albumin not prepared for therapeutic or prophylactic uses is, therefore, excluded (Note 1(g) to this chapter) (heading 3502).'

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

16 In 2002, 2003 and 2004, TNT lodged a number of declarations for the release into free circulation as goods designated as 'Bovuminar Cohn Fraction V ph. 7.0'. It was a blood albumin derived from bovine animal blood obtained by processing blood plasma through the addition of ethanol and salts and by adjusting the acidity level ('the product at issue'). According to the information provided by the referring court, that product is not suitable for human or animal consumption. It is used as a growth medium for cells and constitutes one of 14 components in the preparation of certain specific proteins, also called antibodies, which are used in the treatment of certain illnesses and complaints.

Furthermore, it is clear from that information that the price of that product on the market is approximately USD 600 per kilogramme, where as blood albumin used in the food industry is USD 6 per kilogramme.

17 In those declarations, TNT had chosen, as regards the product at issue, subheading 3002 10 10 of the CN, which gave rise to an exemption from customs duties for the release into free circulation of that product.

18 Following a declaration made on 19 December 2004, a sample of that product was analysed. It follows from the report written on the basis of that analysis that that sample consisted of blood albumin in the form of a beige powder containing flakes and that there were no indications that the product had been prepared for therapeutic or prophylactic purposes. According to that report, the label affixed to the product mentioned that it could be used for research and further manufacturing use only and that it was not intended for human or animal consumption. As a result of that analysis, tariff subheading 3502 90 70 of the CN was adopted for the product at issue and TNT was therefore requested to pay customs duties corresponding to a notice of assessment of 25 July 2005.

19 Since the complaint lodged against that request for payment was rejected, TNT brought an action before the Rechtbank te Haarlem (Court of First Instance, Haarlem).

20 That court upheld the action and annulled the request for payment. The customs administration brought an appeal against the Rechbank te Haarlem's decision before the Gerechtshof te Amsterdam (Court of Appeal, Amsterdam) which confirmed that decision.

21 The Gerechtshof te Amsterdam took the view that the use of the product at issue as a growth medium for cells was inherent in that product and that another use, even if it were possible, was not, in any event, of a nature and extent such as to influence the classification of that product in the CN. That court held that, although the product at issue did not itself have a therapeutic or prophylactic effect, it was essential to the production of antibodies which had a therapeutic effect and that it was therefore prepared for a therapeutic use within the meaning of Note 1(g) of Chapter 30 of the CN. That court also held that that product should be classified under subheading 3002 90 of the CN.

22 An appeal in cassation was brought against the judgment of the Gerechtshof te Amsterdam before the Hoge Raad der Nederlanden. According to the latter, the case-law of the Court in this area seems contradictory. On one hand, certain judgments stated that products classified in Chapter 30 of the CN must themselves have medicinal properties. On the other hand, it follows from Case C-459/93 *Thyssen Haniel Logistic* [1995] ECR I-1381 that products which lack medicinal properties but which, on account of their intended use inherent to their particular characteristics, are designed to be used for medical purposes, may be classified in Chapter 30 of the CN.

23 In those circumstances, the Hoge Raad der Nederlanden decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Should Note 1(g) to Chapter 30 [HS], read in conjunction with Note 1(b) to Chapter 35 of the [HS], be interpreted as meaning that blood albumin, which itself has no therapeutic or prophylactic effect but which has been produced with a view to, and is essential for, the preparation of products which do have a therapeutic or prophylactic effect, and which by its nature can be used only for that purpose, has been prepared for therapeutic or prophylactic uses within the meaning of that note?'

Preliminary observations

24 It must be stated that the referring court, although it refers to tariff headings in the CN in its order for reference, seeks, by its question, the interpretation of a chapter note in the HS.

25 Therefore, without there being any need to determine whether the Court has jurisdiction, in the context of the cooperation between it and the national courts under Article 267 TFEU, to rule on the interpretation of the provisions of the HS, such an interpretation is in any event unnecessary in the present case, since those provisions apply at European Union level only via the CN, which is established in the basis of the HS (see, to that effect, Case C-510/99 *Tridon* [2001] ECR I-7777, paragraph 24).

26 Therefore, that question must be regarded as referring to the interpretation of Note 1(g) of Chapter 30 of the CN, which is identical to Note 1(g) of Chapter 30 of the HS.

Consideration of the question referred for a preliminary ruling

27 By its question, the referring court asks essentially whether blood albumin which has not itself a therapeutic or prophylactic effect, but which was produced for the preparation of products which have a therapeutic or prophylactic effect and which is indispensable to it and which by its nature can only be used for that purpose was prepared for therapeutic or prophylactic use within the meaning of Note 1(g) of Chapter 30 of the CN and thereby falls within heading 3002 of the CN.

28 The Netherlands Government submits that blood albumin must itself have a therapeutic or prophylactic effect in order to be classified under heading 3002. It takes the view that that interpretation results from the case-law of the Court, in particular Joined Cases C-106/94 and C-139/04 *Colin and Dupré* [1995] ECR I-4759; Case C-328/97 *Glob-Sped* [1998] ECR I-8357; and Case C-259/00 *Biochem* [2002] ECR I-2461.

29 The Commission, however, takes the view that blood albumin which cannot be used directly for therapeutic or prophylactic purposes, but which is intended for the same purposes after being subjected to a specific preparation may be classified under tariff heading 3002 provided that that product requires more than a simple process in order to acquire therapeutic or prophylactic value.

30 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 found in their objective characteristics and properties as defined in the wording of the relevant heading of the CN and of the section or chapter notes (see, in particular, Case C-339/98 *Peacock* [2000] ECR I-8947, paragraph 9; Case C-396/02 *DFDS* [2004] ECR I-8439, paragraph 27; Case C-495/03 *Intermodal Transports* [2005] ECR I-8151, paragraph 47; and Case C-142/06 *Olicom* [2007] ECR I-6675, paragraph 16).

31 It follows, from the general rules for the interpretation of the CN Nos 1 and 6 that the classification of goods is determined for legal purposes by the terms of the headings and subheadings and by the section and chapter notes which are legally binding.

32 The Explanatory Notes drawn up by the Commission as regards the CN and by the World Customs Organisation as regards the HS may be an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force (see Case C-250/05 *Turbon International* [2006] ECR I-10531, paragraph 16).

33 For the purposes of classification under the appropriate heading, 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, *Thyssen Haniel Logistic*, paragraph 13; Case C-183/06 *RUMA* [2007] ECR I-1559, paragraph 36; and *Olicom*, paragraph 18).

34 In the present case, the product at issue is bovine blood albumin, one of the 14 components of the preparation for certain specific proteins also called 'antibodies' which are used in the treatment of certain illnesses and complaints. It has been established that that product, which is essential to the production of those antibodies, is intended for a therapeutic use.

35 It should be observed that express reference to blood albumin is made in the CN. Thus, Note 1(g) of Chapter 30 thereof states that that chapter does not include 'blood albumin not prepared for therapeutic or prophylactic uses (heading 3502)'. Likewise, Note 1(b) of Chapter 35 of the CN provides that the latter does not include 'blood fractions (other than blood albumin not prepared for therapeutic or prophylactic uses), medicaments or other products of Chapter 30'.

36 The wording of those notes thus attributes a decisive importance to the intended use of the blood albumin. The latter must be prepared 'for therapeutic or prophylactic uses' in order to be classified in Chapter 30 and, more precisely, under heading 3002 of the CN.

37 In that connection, it must be held that neither the notes in the abovementioned chapters nor the explanatory notes relating to tariff headings 3002 and 3502 state that the blood albumin referred to in Note 1(g) of Chapter 30 of the CN must have an inherent therapeutic or prophylactic value.

38 Furthermore, although the case-law cited in paragraph 28 of this judgment concerns products falling within Chapter 30 of the CN which do have curative or preventive properties, that does not exclude from that chapter products which, without being inherently of a therapeutic or prophylactic nature, are intended for therapeutic or prophylactic uses after they have been the subject of a preparation.

39 Like the Commission, the expression 'prepared for' must be understood as having a twofold meaning. Thus, a product may, either by nature, be used directly for therapeutic or prophylactic purposes, or be prepared for the same purposes. Accordingly, the fact that the product at issue cannot be used directly for such purposes does not prevent it, when it goes through customs, from being regarded on the basis of its objective characteristics and properties as being prepared for therapeutic or prophylactic use.

40 In that connection, it must be stated that, in order to classify products in Chapter 30 of the CN, the Court examined whether the latter had clearly defined therapeutic or prophylactic characteristics with an effect concentrated on precise functions of the human organism or that they are capable of being applied in the prevention or treatment of diseases or ailments (Case C-201/96 *LTM* [1997] ECR I-6147, paragraphs 37 and 45, and Case C-270/96 *Laboratoires Sarget* [1998] ECR I-1121, paragraphs 39 and 48).

41 It may also be deduced from *Thyssen Haniel Logistic* that 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. In that judgment, a sterile powder was at issue which was composed of a mixture of amino acids which, after water was added, was administered in the form of infusion solutions during medical treatment. That product was therefore devoid of medicinal properties as such but was nevertheless classified in Chapter 30 of the CN on account of its intended use.

42 Therefore, it must be held that since blood albumin does not have an intrinsic therapeutic effect, but is used in the prevention or treatment of an illness or complaint, must, provided that it is specifically intended for such a use, be regarded as prepared for therapeutic use within the meaning of Note 1(g) of Chapter 30 of the CN.

43 However, the Commission's position, that only a product which has undergone a simple process in order to acquire a therapeutic or prophylactic value may be classified under tariff heading 3002, cannot be accepted.

44 Neither the CN at the material time nor the explanatory notes relating to heading 3002 and 3502 nor the case-law of the Court help in defining a 'simple process' or in determining when the processing of a product may be termed substantial.

45 Furthermore, a classification criterion such as that suggested by the Commission would neither allow nor ensure legal certainty or facilitate checks. The introduction by the Court of criteria relating to the processing of a product for therapeutic or prophylactic purposes with respect to, in particular, an area in which technology is developing, might lead to divergent assessments and thereby compromise the uniform application of the CN in the European Union.

46 It is for the referring court to undertake, on the basis of the foregoing indications, the classification of the product at issue, by verifying if, when the customs declaration was made, it appeared that, in view of its objective characteristics and properties, it was intended for the preparation of products having a therapeutic or prophylactic effect.

47 Taking account of the foregoing considerations, the answer to the question referred is that Note 1(g) of Chapter 30 of the CN, read in conjunction with Note 1(b) of Chapter 35 thereof, must be interpreted as meaning that a blood albumin which does not itself have a therapeutic or prophylactic effect, but which was produced for the preparation of products having a prophylactic or therapeutic effect, which is essential to that preparation, and which, by its nature, may only be used for that purpose, was prepared for therapeutic or prophylactic use within the meaning of that note.

Costs

48 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 (Third Chamber) hereby rules:

Note 1(g) of Chapter 30 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 1789/2003 of 11 September 2003, read in conjunction with Note 1(b) of Chapter 35 thereof, must be interpreted as meaning that a blood albumin which does not itself have a therapeutic or prophylactic effect, but which was produced for the preparation of products having a prophylactic or therapeutic effect, which is essential to that preparation, and which, by its nature, may only be used for that purpose, was prepared for therapeutic or prophylactic use within the meaning of that note.

[Signatures]