WORLD CUSTOMS ORGANIZATION
ORGANISATION MONDIALE DES DOUANES
Established in 1952 as the Customs Co-operation Council
Créée en 1952 sous le nom de Conseil de coopération douanière

HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE
-
28th Session
-

NR0447E1
(+ Annex)

O. Eng.

Brussels, 30 July 2003.

POSSIBLE AMENDMENT OF NOTE 4 (c) TO CHAPTER 30

(PROPOSAL BY THE EC)

(Item III.B.2 on Agenda)

I. BACKGROUND

1. On 3 June 2003, the Secretariat received the following Note from the EC regarding the possible amendment of Note 4 (c) to Chapter 30. The EC requested the submission of the proposal for consideration by the 28th Session of the Review Sub-Committee.

II. NOTE FROM THE EC

2. "The EC has examined the classification of a number of products generally referred to as "mesh" :

Product A
Knitted mesh, for surgical use in hernia operations. The mesh is made of polyester or polypropylene. It is available in squares or rectangles of various sizes, put up in sterile packets. The mesh is cut to the required size by the surgeon, and remains in the body permanently.

Product B
Absorbable knitted mesh for use in hernia surgery or to help prevent haematomas. The mesh is made from polyglactin 910 (a copolymer consisting of 90% glycolide and 10% lactide). The mesh is available in rectangles of various sizes, put up in sterile packets. It is cut to the required size by the surgeon, and is absorbed by the body within 56 to 70 days.

Product C
Partially-absorbable knitted mesh for use in hernia surgery or to reduce the formation of conjunctive tissue and scarring. The mesh consists of 56% polyglactin 910 and 50% polypropylene. It is available in squares or rectangles of various sizes, put up in sterile

Note : Shaded parts will be removed when documents are placed on the WCO documentation database available to the public.

File No. 2990

packets. The mesh is cut to the required size by the surgeon. The polyglactin is absorbed by the body, while the polypropylene remains in the body permanently.

Product D
Absorbable anti-adhesions barrier used in gynaecological pelvic surgery to separate adjacent tissue surfaces during reperitonisation and avoid pelvic adhesions. The barrier consists of a knitted mesh obtained by the controlled oxygenation of regenerated cellulose. It is rectangular in shape, exists in various sizes, and is put up in sterile packets. The mesh is cut to the required size by the surgeon, and is absorbed by the body within four weeks.

Product F
A rectangular sheet of microporous polytetrafluoroethylene. This product is put up in sterile packets, and is used during surgical operations to repair local lesions or separate organs which must not be allowed to stick to each other. The product sometimes has to be cut to size before use.

Examination of classification

3. Various headings could be taken into consideration when the classification of these products is concerned : headings 39.21, 30.05, 30.06, 60.02 and 90.21.

4. We consider that these products could be excluded from heading 30.06 by Note 4 to Chapter 30. Heading 90.21 also seems to be ruled out, because these meshes are neither artificial parts of the body, nor appliances which are implanted in the body to compensate for a defect or disability. In addition, some of these products must be cut to size by the surgeon; this means that they cannot fall in the category of “other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability”. These arguments could also apply to products A, B and C described above. This leaves us with headings 39.21, 30.05 and 60.02 as possibilities.

5. Product F could fall in heading 39.21 with reference to its constituent material. The product in question is a permanent mesh used in hernia operations. Products A, B, C and D fulfil a function similar to that of product F, and it therefore appears that they should also be classified with reference to the same criterion, i.e., constituent material, which would lead to their classification in heading 60.02. However, the fact that products B and D are absorbable raises certain questions about them vis-à-vis the other products. Product D is for use in “gynaecological pelvic surgery” and not in hernia operations.

6. There could also be reasons for classifying these products in heading 30.05, as they seem to behave inside the body in the same way as certain dressings or bandages used externally, in the sense that by their structural presence (which, in some cases, is temporary), they have a prophylactic/therapeutic effect. Nowhere in the legal texts of the Nomenclature and the corresponding Explanatory Notes is it specified that the products of this heading must be applied to the outside of the body.

Conclusion

7. The EC does not consider it necessary to have the above-mentioned products classified, and is not asking that this be done. These examples, described in general terms, have been given merely in order to explain the proposal and the reasoning behind it.

8. In order to secure the uniform and correct classification of these products, and bearing in mind their nature, the EC proposes that Note 4 (c) to Chapter 30 be amended to read as follows :

Amendment of Note 4 (c) to Chapter 30

"Sterile absorbable haemostatic products used for surgical or dental purposes; sterile adhesion barriers, whether or not absorbable, used in surgery to prevent the sticking together of human or animal tissue; sterile absorbable surgical or dental yarns."

III. SECRETARIAT COMMENTS

9. In the proposal above, the EC suggests to amend Note 4 (c) to Chapter 30 with a view to redrafting and extending the current text of this Note. Taking into account the architecture of heading 30.06 and the fact that its scope is explicitly defined by Note 4 to Chapter 30, the proposed amendment would, in fact, broaden the scope of heading 30.06. The proposed new commodities to be included in heading 30.06 are sterile adhesion barriers used in surgery to prevent the sticking together of human or animal tissues and sterile absorbable surgical or dental yarns. Due to their character and their use in surgery, they could be regarded as a kind of pharmaceutical goods.

10. Generally, although not literally, the texts of subheadings within heading 30.06 follow the wording and structure of Note 4 to Chapter 30. At subheading level, Items (a), (b) and (c) of this Note are grouped together in subheading 3006.10. In this context, if Note 4 (c) were to be amended as proposed by the EC, the text of subheading 3006.10 should also be amended accordingly. The EC may, however, wish to explain what the intention of its proposal is in this respect.

11. The current text of Note 4 (c) reads : “sterile absorbable surgical or dental haemostatics”. The EC suggests to replace this expression with : “sterile absorbable haemostatic products used for surgical or dental purposes”, which appears to be synonymous with the existing text. If the scope of the two expressions would, in fact, not be different, the question arises whether such amendment would be necessary and whether the current expression could be used in the first part of proposed new Note 4 (c). The Sub-Committee may therefore wish to ask the EC to explain whether the proposed new wording referred to above is meant to be synonymous with the existing text or is aimed to broaden its scope.

12. In the last part of the proposed amendment, the EC suggests that “sterile absorbable surgical or dental yarns” be added to proposed new Note 4 (c). In this connection, the Secretariat would like to point out that Note 4 (a) to Chapter 30 mentions similar goods, e.g., sterile surgical catgut and similar sterile suture materials. Sterile absorbable surgical or dental yarns could, in the Secretariat’s view, fall in this category. The EC may wish to give more precise information about these products, their characteristics and the way they are used (e.g., as suture materials or for other purposes). Then, it would be up to the Sub-Committee to decide whether it is necessary to mention “sterile absorbable surgical or dental yarns” in proposed new Note 4 (c) to Chapter 30.

13. The proposed amendment would extend the scope of heading 30.06, and thus would involve a transfer of products. At this point, the Secretariat has not commented on these potential transfers since the classification of the examples mentioned above has not been requested to be examined. However, at a later stage, and once the EC proposal has been

accepted, the need for classification of some of these products may arise in order to identify all possible transfers in the correlation tables between HS 2002 and HS 2007.

14. On the basis of the EC proposal, the Secretariat has prepared the possible amendment of Note 4 (c) to Chapter 30 which is set out in the Annex to this document. In English, the word “tissue” is used in plural in order to align the English on the French. The expression “sterile absorbable haemostatic products used for surgical or dental purposes” has been placed in square brackets together with the corresponding current text of Note 4 (c) to Chapter 30; thus offering the “*status quo*” as an alternative to the first part of the proposed text. The last part of the proposed text referring to “sterile absorbable surgical or dental yarns” has also been placed in square brackets.

15. In conclusion, the Secretariat would ask the Sub-Committee to express its views as to whether the proposed amendment of Note 4 (c) to Chapter 30 would be acceptable and what action should be taken vis-à-vis a possible amendment of subheading 3006.10.

IV. CONCLUSION

16. The Sub-Committee is invited to examine the proposal of the EC to amend Note 4 (c) to Chapter 30 as set out in the Annex to this document, taking into account the Note by the EC, the Secretariat’s comments and the alternative proposals in paragraphs 10 to 14 above.

* * *