



HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE

NR0222E1

-
25th Session
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O. Eng.

Brussels, 29 January 2002.

STUDY OF POSSIBLE AMENDMENTS TO HEADING 30.01
WITH REGARD TO HUMAN ORGANS, TISSUES, ETC.
(Item III.A.12 on the Agenda)

Reference documents :

NR0184E1 (RSC/24)
NR0205E2, Annex D/2 (RSC/24 - Report)

I. BACKGROUND

1. At its 24th Session (September 2001), the Sub-Committee discussed the possible amendment of the HS Nomenclature with regard to human body parts on the basis of Doc. NR0184E1.
2. The Director began the discussion by explaining that during the HS seminars conducted by the Secretariat several administrations had indicated that there was international trade in human cadavers and body parts (organs, tissues, etc.) and had raised questions as to their classification. He also noted that research in stem cells to develop new therapies for certain diseases was growing. He was therefore of the view that it was important to determine whether the Nomenclature should be amended to clarify the classification of these products, which were legitimately conveyed internationally.
3. With regard to human cadavers, many delegates indicated that they were not objects of trade and, in the interest of human dignity, they should not be considered as goods covered by the Harmonized System. They therefore preferred the status quo and to make no reference to human cadavers in the Harmonized System.
4. One delegate indicated that, even for transplant purposes, cadavers were not transported as such but that only tissues, organs, etc., that were recovered immediately after death, were transported under very specific means and conditions. He also explained that, in view of Item (D) (3) of the Explanatory Note to heading 30.01, human organs, etc., recovered from cadavers, for transplant, should be classified in heading 30.01.

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5. With regard to organs, tissues, etc. meant for research and medical studies, two delegates expressed the view that they should also be covered by heading 30.01, and agreed that the text of the heading may need to be changed in this regard.
6. The Sub-Committee finally agreed to maintain the status quo with regard to human cadavers and therefore directed that no further action should be taken. With regard to human organs, tissues, stem cells, etc., it agreed that the Secretariat should continue its study of possible amendments to heading 30.01, taking into account the comments made by delegates during the meeting.
7. The Secretariat accordingly wrote to administrations requesting their comments with regard to this study as well as any information in respect of laws concerning trade in human body parts (organs, tissues, stem cells, etc.) and any legitimate trade in these products. The following responses have been received.

II. COMMENTS BY ADMINISTRATIONS

China

8. “Human cadavers and body parts used in transplants and something alike are new commodities that more and more appear in the international trade and can be predicted to get a upgrowing volume due to the maturation of physical technology and rapid progress of therapeutic science. We think these commodities are quite reasonable to be reflected in the Harmonized System. The limitation or supervision to these commodities by specific laws in some countries could not become the barriers for adding new subheadings for them. The main question is that we could not get a more precise volume data of these commodities and could not know how fast volume growth will take place. We suggest that the Secretariat do some investigation of this matter first. And we think it is also appropriate now to prepare adding new subheadings only for body parts used in transplants that will have a considerable volume within several years as a result of needs of organic operation and development of clone technique. Obviously these kinds of commodities should be classified in heading 30.01.”

South Africa

9. “This Administration has received inquiries at various stages relating to the classification of specifically human remains. To date there has been nothing forthcoming about “body parts” as such. The only option that this Administration could consider up until this point has been heading 05.11, for want of a more appropriate heading. This has raised some ethical questions, especially as regards dignity of human bodies being “imported”, normally for burial purposes. There have been objections to human remains being seen as “commodities” for classification purposes. Yet from the Nomenclature point of view, it would be essential if provision had to be made for the classification thereof. The same problem with regard to “organs” or other “body parts” is not foreseen, especially for transplant, or other surgical procedures, as this would be for the preservation of life, and these “parts” would not be privy to the same sensitivity, than that concerning human remains.

10. There is no reference in the South Africa Customs and Excise Act to importations of this nature, and no specific legislation has been promulgated in this regard. To the best of this Administration's knowledge, there have never been trade inquiries, relating to the importation of items currently being discussed, on a commercial level.
11. As so aptly put by the Secretariat, this is very likely to be changed in the foreseeable future, and this Administration would welcome a proposal for provisions to be made for these items. This administration would support the use of heading 30.01 in this regard, as it seems to be the logical heading to use. The fact that bones, organs and other human or animal tissues for pharmaceutical use are already provided for in this heading strengthens this conviction. The current wording of heading 05.11 definitely does not seem appropriate, seeing as it relates either to "animal products not elsewhere specified or included", or alternatively "dead animal of chapters 1 to 3, unfit for human consumption". It is not thought appropriate that human body parts should under any circumstances be referred to as either animal products, nor as dead animals. The inclusion of the phrase "unfit for human consumption" with the latter compounds this view, as it conjures up grisly imagery."

Azerbaijan Republic

12. "With respect to the laws concerning the matter in question we would like to inform you that presently there is the law of the Azerbaijan Republic No. 726-10 of 28 October 1999 on "Transplantation of human organs and tissues" in force. Basing on the modern scientific developments and medical experience this Law regulates issues on transplantation of human body organs and tissues. According to Article 17 of the Law, human body organs or tissues can not be the objects of purchase and sale. Therefore, natural and juridical persons engaged in trade of these products bear the responsibility in accordance with the legislation. However, these provisions of the Law do not cover the transplant materials and preparations made of the tissue components.
13. The legitimate international trade in human body parts (organs, tissues, etc.) requires their HS classification. We therefore consider it appropriate for heading 30.01 to be amended in respect of these products."

Peru

14. "Peru does not have any special legislation regulating trade on human body parts for transplants or for research purposes. However, the Health Act states that everyone has the right to receive organs or tissues from human beings, cadavers or animals to save his or her life or restore his or her health and may also donate his or her organs or tissues, subject to express written consent.
15. In those cases in which the law requires an autopsy, embalming or cremation, organs or tissues may be removed for transplanting or grafting purposes, without the need for authorisation given by the deceased while still alive or the consent of his or her relatives. Moreover, health institutions may only have these organs and tissues free of charge.
16. Although at present Peru has no special regulations for trade in human organs and tissues for transplant, it is currently importing, for example, retinas and human semen and exporting placenta for making cosmetic products. We therefore consider it desirable that the Harmonized System should clearly identify tariff classification of these products."

Federation of Russia

17. "The law Federation of Russia of 22.12.1992 No. 4180-1 "About transplantation of human organs and /or tissues" stipulates standards of State regulation and control for human organs and/or tissues intended only for transplantation.
18. The Federal law of 12.01.1996 No. 8 - Φ3 "About interment and funeral business" stipulates standards of State regulation and control for withdrawing of human cadavers organs and/or tissues. But a federal authority, which must regulate and control for this activity, is not appointed. Furthermore the above-mentioned Federal law stipulates guarantees of body (remains) interment realization.
19. Russian legislation does not provide for using subjects at issue in order to make a profit.
20. Taking into account the facts cited above and in the absence of laws stipulating standard of state regulation and control for transference through Federation of Russia frontier of human organ and/or tissues, human cadavers and their further using, the Russian Government established an interdepartmental working group. This group should devise legislative and normative acts stipulating standards of state regulation and control for withdrawing and/or using of human organs and/or tissues, embryos, placenta, the same as human cadavers, intended for scientific, medical and educational purposes. The members of the interdepartmental working group are spokesmen for interested executive organs and Academy of medical sciences Federation of Russia.
21. At present there are chances of export of human organs and tissues, brain, cadavers in accordance with contracts about scientific and technical co-operation between health services and foreign firms. The order of this co-operation is the manufacture of anatomical education supplies.
22. In view of ethical norms and importance of the considered questions we support the proposal about necessity of creating a special heading for subjects at issue. Such creation facilitates the execution of control for transference of these subjects including determination of transference purposes.
23. In our opinion, when the described question will be discussing, it will be necessary to take into account the following three categories of subject at issue :
 - I. Human organs for transplantation;
 - II. Cadavers, human organs and/or tissues, embryos, placenta, intended for scientific, medical and educational purposes;
 - III. Bodies, remains, ashes, transferred in order of interment on the territory of a foreign state in accordance with a died man's will."

Morocco

24. "This Administration proposes to maintain the status quo as regards human bodies and organs and consequently to keep the present text of heading 30.01."

III. SECRETARIAT COMMENTS

25. The Secretariat wishes to recall **first** that, as reflected in paragraph 6 above, the Sub-Committee at its last session agreed to maintain the status quo with regard to cadavers and therefore directed that no further action should be taken. The Secretariat would therefore focus on possible amendments to heading 30.01 with regard to human organs, tissues, stem cells, etc.
26. Based on the comments made by administrations, it appears that the majority is in favour of a suitable amendment of heading 30.01 to clarify the classification of human organs, tissues, stem cells, etc., in that heading.
27. To justify such an amendment, the Customs administration of **Peru** has clearly indicated that it is currently importing, for example, retinas and human semen and exporting placentas for use in the production of cosmetic products and has stressed that it is desirable to identify these products in the Harmonized System.
28. However, the above-mentioned administrations had made no comments in respect of stem cells and nor they have come out with a suitable proposal to amend the Nomenclature.
29. In view of the recent discussions and arguments on possible therapeutic applications of stem cells and organs of genetically modified animals, in both scientific and political spheres, it appears that this issue will require careful study. Since research and development work in this area is as yet very uncertain, the Secretariat feels that further studies on possible laws relating to international trade and scientific research on these products, would be useful.
30. The Secretariat is, therefore, of the view that the Sub-Committee should allow administrations and the Secretariat more time to obtain further input in order to facilitate the discussion of this issue. However, in the meantime, as a basis to begin this discussion, the Secretariat, by taking into account the comments made by administrations, proposes the following amendments to the text of heading 30.01.
- “Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; bones, organs and other tissues of human or animal origin, prepared for therapeutic or prophylactic uses and research or medical studies; other human or animal substances prepared for therapeutic or prophylactic uses and research or medical studies, not elsewhere specified or included.”
31. It would be appropriate if the Sub-Committee could discuss various products that should be covered within the scope of this heading, particularly in the context of products such as placentas for use in the production of cosmetic products (as indicated by **Peru**), and different kinds of stem cells. Furthermore, since the structure of Chapter 30 is meant for pharmaceutical products, it would be appropriate to discuss any further amendments to the legal texts, such as a new Chapter Note, in order to reflect those uses for research and medical studies. The Secretariat also suggests discussion of the necessity of creating new subheadings (as indicated by **China**).

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32. Based on the Sub-Committee's discussions, the Secretariat could prepare the consequential amendments to the Explanatory Notes.

IV. CONCLUSION

33. Taking into account of the comments made by the administrations and the Secretariat above, the Sub-Committee is invited to examine the proposed amendments to the Nomenclature as set out in paragraph 30 above.
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