



HARMONIZED SYSTEM  
REVIEW SUB-COMMITTEE

-  
27<sup>th</sup> Session  
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NR0343E1  
(+ Annex)

O. Eng.

Brussels, 12 February 2003.

PROPOSAL BY THE US ADMINISTRATION TO AMEND THE NOMENCLATURE AND  
EXPLANATORY NOTE TO HEADING 38.21

(Item III.A.4 on Agenda)

Reference documents :

NR0154E1 (RSC/23)	NR0256E1 (RSC/25)
NR0165E2, Annex D/3 (RSC/23 - Report)	NR0265E3, Annex C/18 (RSC/25 – Report)
NC0368E1 (HSC/27)	NR0276E1 (RSC/26)
NC0430E2, Annex F (HSC/27 - Report)	NR0332E3, Annex C/6 (RSC/26 – Report)
NS0044E1 (SSC/17)	NS0071E1 (SSC/18)
NS0060E2, Annex A/7 (SSC/17 - Report)	NS0080E2, Annex A/9 (SSC/18 - Report)

I. BACKGROUND

1. The HS Review Sub-Committee, at its 23<sup>rd</sup> Session, examined a proposal by the **US** Administration to amend the Nomenclature and Explanatory Note to heading 38.21 (see Doc. NR0154E1).
2. The Delegate of **Canada** explained that although culture media for the development of micro-organisms were used in a manner similar to those for higher organisms (eukaryotic cells), and may contain some of the same ingredients, there were differences due to the nutritional and environmental requirements of the two types of cells. Although the **US** proposal would therefore broaden the scope of heading 38.21, **Canada** felt that the proposal was logical and supported it in principle. However, he felt that further review would be required. In **Canada's** view, the proposed amendments to the Explanatory Note to heading 38.21 should include a reference to media for the development of plant cells. Furthermore, as prokaryotes and eukaryotes together encompassed all living cells, the

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heading text could be modified to read "Prepared culture media for the development of living cells".

3. The Delegate of **Canada** pointed out that present heading 38.21 included media for the development of viruses. However, since viruses were not cellular, the proposed text would not be appropriate. Furthermore, the use of the word "development" in the proposed heading text would be restrictive and would not cover culture media used to preserve living cells for later study. The inclusion of the word "maintenance" in the proposed Explanatory Note recognised that such media should also be covered. Accordingly, he suggested the amendment of the heading text to read simply "Prepared culture media" in order to cover all culture media used for the development and preservation of all living cells and viruses.
4. Another delegate suggested that, in view of the technical nature of the proposal, it would be appropriate to refer this issue to the Scientific Sub-Committee to clarify whether the scope of the heading would be widened and to obtain information on the nature of the transfers, if any. He also suggested that the Scientific Sub-Committee should provide its views on the text of the proposed Explanatory Note and the definitions of eukaryotic and prokaryotic cells.
5. The Review Sub-Committee agreed to this suggestion and decided to refer the **US** proposal and the above-mentioned **Canadian** comments to the Scientific Sub-Committee for advice on the points raised in paragraph 4 above (see Annex D/3 to Doc. NR0165E2).
6. The Scientific Sub-Committee examined this question at its 17<sup>th</sup> Session on the basis of Doc. NS0044E1. The discussion at that Session has been reproduced in Annex I to this document.
7. At the 25<sup>th</sup> Session of the Review Sub-Committee, the **US** Delegate stated that the original **US** proposal was aimed at covering culture media used for the development and maintenance of all living cells and viruses. As regards the question whether viruses were covered by the term "micro-organisms", he stated that the term "micro-organisms" was defined in differing ways in scientific literature and did not appear to be a scientific term. Since the term "viruses" already appeared in the current Explanatory Note to heading 38.21, and in view of the foregoing, he proposed the following new text for heading 38.21 : "Prepared culture media for development of micro-organisms (including viruses and the like) or for the development or maintenance of plant or animal cells". One delegate supported this new proposal.
8. Another delegate was of the view that, even among the experts in the Scientific Sub-Committee, opinions were divided as to whether viruses would be covered by the term "micro-organisms". Referring to the consensus of the Scientific Sub-Committee that the original **US** proposal and the modified **Canadian** proposal would widen the scope of present heading 38.21, he questioned whether the new **US** proposal would also widen the scope of heading 38.21, entailing a transfer of certain goods to this heading. He further stated that other media, such as those used for preparing yogurt which would fall in Chapter 4, might be transferred to heading 38.21. This would cause serious problems and, therefore, he preferred the status quo.
9. Finally, the Review Sub-Committee agreed to re-consider the possible amendment of the Nomenclature and Explanatory Note to heading 38.21 at its next session, taking into account, in particular, information from administrations on whether the proposal would widen the scope of heading 38.21 and, if so, how.

10. The Sub-Committee, at its 26<sup>th</sup> Session, examined the four options (i.e., the **US** proposal and the Secretariat's three alternative proposals) with respect to the proposed amendments to heading 38.21 set out in Annex II to Doc. NR0276B1, and invited delegates to indicate their preference among the four options.
11. Noting that, although the term "micro-organisms" was defined in differing ways in scientific literature, it was clearly stated in the current Explanatory Note to heading 38.21 that "viruses" were covered by the term "micro-organisms", one delegate was in favour of Option 1. He also indicated that his administration could accept Option 3, taking into account the fact that there was no direct reference to viruses in the current heading text. Another delegate shared this view.
12. A third delegate reiterated the view that, even among the experts in the Scientific Sub-Committee, opinions were divided as to whether viruses would be covered by the term "micro-organisms". Referring to the view expressed by several delegates at the 17<sup>th</sup> Session of SSC that the expression "prepared culture media" as proposed was extremely vague, he stated that this amendment to heading 38.21 would widen the scope of the heading and entail a transfer of certain goods to the heading. He further noted that other media, such as those used for preparing yogurt which would fall in Chapter 4, might be transferred to heading 38.21. This would cause serious problems and, therefore, he preferred the status quo, that is, no amendment of the heading text. In this connection, a fourth delegate asked for a clarification concerning the precise nature of the product of concern in Chapter 4.
13. Concerning the question of viruses, the Director pointed out that although opinions among the experts in the Scientific Sub-Committee were divided as to whether viruses would be covered by the term "micro-organisms", the term "viruses" already appeared in the current Explanatory Note to heading 38.21. He also stressed that although the Scientific Sub-Committee had already recognised that the proposed amendments to heading 38.21 would widen the scope of the heading, it still had not indicated the exact transfers to heading 38.21 entailed by the amendments. In order to assess the impact of the amendment on heading 38.21, the Director proposed that the Review Sub-Committee should ask the Scientific Sub-Committee to examine what kind of products would be transferred to new heading 38.21 from other headings. Many delegates supported this proposal.
14. No delegate supported Option 2 and the Sub-Committee finally chose Options 1, 3 and 4 as possible options for the amendment of heading 38.21. It agreed to send this issue back to the Scientific Sub-Committee with a view to clarifying the transfers to heading 38.21 under Options 1, 3 and 4, while noting that the status quo (no amendment) still remained as one of the options with regard to this question.
15. The three options, renumbered as Options 1 to 3, have been placed in square brackets, and are set out in Annex II to this document.
16. The Scientific Sub-Committee, at its 18<sup>th</sup> Session, examined the proposal to amend the nomenclature to heading 38.21 set out in the Annex to Doc. NS0071E1. The observations of the Scientific Sub-Committee are set out below.

### III. OBSERVATIONS OF THE SCIENTIFIC SUB-COMMITTEE

17. In opening the discussion on this agenda item one delegate stated that although this proposed amendment could entail the transfer of goods within the Chapter 38, i.e., a transfer from heading 38.24 to 38.21, he could not foresee any transfer from outside Chapter 38. He was of the view that there would be no transfer of media used for preparing yogurt from Chapter 4 since such media which normally is consisted of milk powder, vitamins and malt extract, were excluded from Chapter 38 by application of Note 1 (b) to that Chapter. The Sub-Committee shared his view.
18. With respect to a question raised by the **Canadian** Delegate concerning the scope of the phrase "and the like" used in the draft texts set out under Options 1 and 2 in connection with viruses, it was pointed out that bacteriophages, plasma factors and DNA cells would be covered by this phrase. The Sub-Committee recommended that this information be reflected in the Explanatory Note to heading 38.21.
19. Concerning the scope of the three proposed texts, the Sub-Committee was of the view that there was no substantial difference among them. Option 2 was, however, not supported since it could re-open the discussion as to whether or not "micro-organisms" included viruses. Option 3 was also not supported since the text was considered to be too technical.
20. After this brief discussion, the Sub-Committee recommended use of the text of Option 1, subject to certain modifications.
21. The text recommended by the Sub-Committee is set out in the Annex to this document.

### IV. CONCLUSION

22. The Sub-Committee is invited to take the observations of the Scientific Sub-Committee into consideration when examining the possible amendments of the nomenclature and the Explanatory Notes to of heading 38.21. The recommended amendments to heading 38.21 are set out in the Annex to this document.

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