



HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE

NR0276E1
(+ Annexes I and II)

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26th Session
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O. Eng.

Brussels, 8 July 2002.

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

(Item III.A.6 on Agenda)

Reference documents :

NR0154E1 (RSC/23)	NS0044E1 (SSC/17)
NR0165E2, Annex D/3 (RSC/23 - Report)	NS0060E2 (SSC/17 - Report)
NC0368E1 (HSC/27)	NR0256E1
NC0430E2, Annex F (HSC/27 - Report)	NR0265E3, Annex C/18 (RSC/25 -Report)

I. BACKGROUND

1. The Review Sub-Committee, at its 23rd 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 heading text could be modified to read "Prepared culture media for the development of living cells".

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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 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 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 17th Session on the basis of Doc. NS0044E1. The discussion at that Session has been reproduced in Annex I to this document.
7. At the 25th 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.
8. 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.
9. 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.
10. Finally, the 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.

III. SECRETARIAT COMMENTS

11. The new US proposal as mentioned above, which is reproduced in Annex II to this document as Option 1, is aimed at covering culture media used for the development and maintenance of all living cells and viruses. Since the proposal covers animal or plant cells, which are not covered by the present wording of heading 38.21, it would widen the scope of heading 38.21, entailing a transfer of prepared culture media for the development or maintenance of plant or animal cells from outside of heading 38.21. However, the proposed text would reflect the state of current technological developments and the Secretariat supports this approach.

12. As regards the possible transfer of culture media used for preparing yogurt falling in Chapter 4, the Secretariat considers that the above-mentioned amendment of heading 38.21 would not cause any transfer in this respect since the scope of the heading with regard to culture media used for the development of micro-organisms has remained unchanged. Nevertheless, if the Sub-Committee wishes, a legal Note defining the scope of the heading could be drafted.

13. As regards the question of whether viruses were covered by the term "micro-organisms", in view of the fact that the term "viruses" is already used in the current Explanatory Note to heading 38.21, and on the basis of information given in technical literature (see paragraphs 14 and 15 of Doc. NR0256E1), the Secretariat considers that the term "micro-organisms" covers viruses and therefore, the **US** proposal is well based. The Secretariat also considers that the **US** proposal could be modified as follows by deleting the reference to "including viruses" (Option 2) :

"Prepared cultured media for development of micro-organisms or for the development or maintenance of plant or animal cells."

14. However, at the 25th Session of the Review Sub-Committee, one delegate expressed his 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". Taking into account the above arguments, the Secretariat would like to make another alternative proposal as follows (Option 3) :

"Prepared culture media for development of micro-organisms, viruses and the like or for the development or maintenance of plant or animal cells."

This text should allay any concerns regarding the scope of the term "micro-organisms".

15. Nevertheless, if the Sub-Committee still remains of the view that the above texts do not solve the problem of whether micro-organisms cover viruses, the Secretariat has proposed yet another alternative text (Option 4) :

"Prepared culture media for the development or maintenance of prokaryotic or eukaryotic cells and viruses".

This text should cover all living cells, including animal and plant cells and micro-organisms and viruses and the objective of the **US** proposal should be achieved.

16. The new **US** proposal and the Secretariat's three alternative proposals are set out in Annex II to this document.

III. CONCLUSION

17. The Sub-Committee is invited to examine the proposals set out in Annex II to this document, taking into account the comments of the Secretariat above.

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DISCUSSION AT THE 17TH SESSION OF THE SCIENTIFIC SUB-COMMITTEE

Paragraph 16.1 of Doc. NS0044E1

1. Many delegates were of the view that the proposed text would widen the scope of present heading 38.21 by transferring culture media for developing and maintaining cultures of higher organisms to that heading. Although the composition and use of such media was very similar to the media described in the current Explanatory Note to heading 38.21, they were not presently covered by this heading. They supported the US proposal, taking into account the recent development of technology in this field.
2. Several other delegates were of the view that the expression “prepared culture media” as proposed was extremely vague and would make it difficult to distinguish between the products falling in the proposed revised heading 38.21 and other media, e.g., those used for preparing yoghurt, which would fall in Chapter 4, and therefore preferred the status quo. If the proposed wording were to be adopted, a legal Note defining the scope of the heading would need to be inserted.

Paragraph 16.2

3. Although certain delegates supported the proposed text of the Explanatory Note since it reflected the recent development of technology, the Sub-Committee did not examine this question in detail in view of divergence of opinions as mentioned in paragraph 10 above.

Paragraph 16.3

4. The Sub-Committee was of the view that the definitions of procaryotic and eucaryotic cells provided in paragraph 9 of Doc. NS0044E1 were well founded.
5. In this connection, certain delegates were of the view that the term “micro-organisms” appearing in present heading 38.21 did not cover viruses. According to them, viruses were not living organisms and therefore, they considered that even the present Explanatory Note to heading 38.21 exceeded the scope of the legal text.

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