



HARMONIZED SYSTEM  
REVIEW SUB-COMMITTEE

NR0256E1

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25<sup>th</sup> Session  
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O. Eng.

Brussels, 31 January 2002.

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

(Item III.A.19 on Agenda)

Reference documents :

NR0154E1 (RSC/23)  
NR0165E2, Annex D/3 (RSC/23 - Report)  
NC0368E1 (HSC/27)

NC0430E2, Annex F (HSC/27 - Report)  
NS0044E1 (SSC/17)  
NS0060E2 (SSC/17 - Report)

I. BACKGROUND

1. The 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 are used in a manner similar to those for higher organisms (eukaryotic cells), and may contain some of the same ingredients, there are 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.
3. 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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4. He also 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.
5. Accordingly, the Delegate of Canada 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.
6. 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.
7. 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 6 above (see Annex D/3 to Doc. NR0165E2).
8. The Sub-Committee examined this question at its 17<sup>th</sup> Session on the basis of Doc. NS0044E1.

## II. DISCUSSION AT THE 17<sup>TH</sup> SESSION OF THE SCIENTIFIC SUB-COMMITTEE

### Paragraph 16.1 of Doc. NS0044E1

9. 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.
10. 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 of Doc. NS0044E1

11. 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

12. 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.
13. 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.

III. SECRETARIAT COMMENTS

14. As regards paragraph 13 above, the McGraw-Hill ENCYCLOPEDIA of SCIENCE and TECHNOLOGY, volume 11, page 141 states :

"Modern microbiology continued to evolve from bacteriology by encompassing the identification, classification, and study of the structure and function of a wide range of microorganisms. ... Modern microbiology includes protozoa, algae, fungi, viruses, rickettsia, and parasites as well as bacteria ..."

15. The New Encyclopedia Britannica states :

"**Microbiology**, scientific study of microorganisms, a diverse group of simple life forms including protozoans, algae, molds, bacteria, and viruses (Vol. 8, page 101).

As microbiology eventually developed into a separate science, it was found that microbes comprise a very large group of extremely diverse organisms; thus, microbiology became subdivided into various disciplines - e.g., bacteriology, protozoology and virology. ... It (Microbiology) encompasses the study of bacteria, rickettsiae, small fungi (e. g., yeast and molds), algae and protozoans, as well as problematical forms of life such as viruses (Vol. 14, page 1118)."

16. The Secretariat would note that based on the above information, the term "micro-organisms" appears to cover viruses.
17. Based on the above information it appears that with regard to the US and Canadian proposal to amend the text of heading 38.21, there was consensus in the SSC that the amendment would involve a widening of the scope of the heading. There was also a strong feeling on the part of some delegates that the precise scope of the heading would be made unclear and that the heading could be widened to such an extent as to cover certain products currently classified in Chapter 4.
18. For that reason, those delegates suggested that there was a need to define the intended scope of revised heading 38.21 by means of a legal Note. The Secretariat would tend to agree and would, therefore, invite the proponents of the amendment to put forward the text of a possible legal Note to define the scope of the proposed new heading text, i.e., "Prepared culture media".

III. CONCLUSION

19. The Sub-Committee is invited to consider the views expressed by the Scientific Sub-Committee as mentioned in paragraphs 9 to 13, taking into account the comments of the Secretariat in paragraphs 14 to 18 above, and to decide whether the proposed heading text "prepared culture media" should be supplemented by a definition in the form of a legal Note.

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