



HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE

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23rd Session
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O. Eng.

Brussels, 22 February 2001.

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

(Item III.B.3 on Agenda)

I. INTRODUCTION

1. The Secretariat received, on 16 February 2001, a proposal with regard to Chapter 38 from the US Administration. The proposal is reproduced in the Annex to this document.

II. SECRETARIAT COMMENTS

2. Due to the recent arrival of the proposal, the Secretariat considers that it would be appropriate to have a preliminary discussion only at the 23rd Session of the Review Sub-Committee.

III. CONCLUSION

3. The Sub-Committee is invited to examine the proposal from the US Administration taking into account the comments by the Secretariat in paragraph 2 above.

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File No. 2844

**US proposal to amend the Nomenclature and Explanatory Notes
to heading 38.21**

1. According to US industry sources, the culture media industry has experienced significant and fundamental technology changes since the text of heading 38.21 was first written. Culture media are most commonly used to grow cells that, in turn, produce viruses, proteins and other metabolites for medical research applications or pharmaceutical manufacture.
2. When heading 38.21 was written, researchers and pharmaceutical companies were typically growing the viruses that they needed for drug research or manufacture in micro-organisms (**prokaryotic cells**¹), such as bacteria. However, over the past 30 years, scientists have discovered that many cell-based products, such as viruses and proteins, were expressed much better and more efficiently when produced in higher **eukaryotic cells**².
3. Scientists have learned that the bacterial (prokaryotic) cells traditionally used to grow viruses and express proteins did not process the proteins in the same way as the mammalian cells. Specifically, some proteins would not express properly unless they were “folded” properly, and the proteins would “fold” properly only if they were expressed in eukaryotic cells. Moreover, for a number of proteins that have proven effective for therapeutic purposes, certain series of sugars must be added that can only be provided by eukaryotic cells.
4. Owing to these fundamental and important discoveries, researchers and pharmaceutical manufacturers have converted over time to using eukaryotic cells for many of their activities. As a consequence, producers of prepared culture media have developed new, more advanced products to meet the evolving needs of the industry.
 - (a) Proposal to amend the text of heading 38.21
5. In order to reflect this evolution of the culture media industry, and given the apparently limited scope of present heading 38.21, the US Administration proposes that the text of heading 38.21 be amended to specify clearly that it covers culture media used for producing both prokaryotic and eukaryotic cells. In this connection, the US proposes the following text :

¹ Prokaryotic cells, or prokaryotae, are defined by Dorland's Illustrated Medical Dictionary (27th Edition) as “consisting of cellular organisms that lack a true nucleus (the bacteria).”

² Eukaryotic cells, or eukaryotes, are defined by Dorland's as organisms “whose cells have a true nucleus, i.e., one bounded by a nuclear membrane, within which lie the chromosomes combined with proteins, and that exhibit mitosis; eukaryotic cells also contain many membrane-bound compartments (organelles) in which cellular functions are performed. The cells of higher plants and animals, fungi, protozoa and most algae are eukaryotic.”

Heading 38.21.

1. Heading text.

Delete and substitute :

“Prepared culture media for the development of prokaryotic and eukaryotic cells.”

(b) Proposals to amend the Explanatory Note to heading 38.21

In addition to reflecting the proposed legal amendment in the Explanatory Notes, the US Administration proposes that the following amendments be incorporated in the Explanatory Note to heading 38.21.

Page 577. Heading 38.21. New fifth paragraph.

Insert the following new fifth paragraph :

“This heading also covers prepared culture media intended for the growth, development and maintenance of eukaryotic cells (e.g., mammalian (including human), avian, insect and fish cells). Such media often contain organic salts, amino acids, vitamins, carbohydrates and other metabolites and macromolecular constituents required for cell growth and biological function.”

Page 578. Heading 38.21. First paragraph.

Insert the following new last sentence :

“They may also be put up in bulk containers, of plastics or of stainless steel.”
