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HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE
-
37th Session
-

NR0741E1a
(+ Annex)

O. Eng.

Brussels, 28 April 2008.

POSSIBLE AMENDMENTS OF THE NOMENCLATURE

(PROPOSAL BY THE RESEARCH GROUP FOR BIOLOGICAL ARMS CONTROL)

(Item III.A.15 on Agenda)

Reference document :

NR0713E1a (RSC/36)
NR0722E1b, Annex E/1 (RSC/36 – Report)
NC1264E1a (HSC/41)
NC1310E1b, Annex F/3 (HSC/41 – Report)

I. BACKGROUND

1. At its 36th Session, the Review Sub-Committee examined a proposal by the Research Group for Biological Arms Control of the University of Hamburg (Germany) to provide separately in the Nomenclature for certain "biological dual-use items". The Sub-Committee instructed the Secretariat to prepare a list of proposed items to be provided for separately in the HS, and to present this list to the HS Committee for classification in March 2008. The Secretariat, as far as possible, would indicate its view on the classification of these items in order to support the work of the HS Committee. After that, on that basis a new working document, the Review Sub-Committee would consider the consequences of the proposal at its next Session in May 2008.

2. The Secretariat had suggested HS classifications of the proposed items and the results were indicated in Doc. NC1264E1a. In a number of cases, where it had not been possible to assign one HS classification, more than one HS code had been indicated. The Harmonized System Committee, at its 41st Session, and on the basis of Doc. NC1264E1a, examined the classification of the proposed items to be provided for separately in the HS. The comments in respect of the classification suggested by the Secretariat were set out in Annex F/3, paragraph 7, of NC1310E1b (HSC/41 – Report). It is to be noted that these comments did not relate to specific products, but were based on the generic descriptions of the products, and that the classification of the listed items would only serve as an indication.

File No. 3144

II. SECRETARIAT COMMENTS

3. The Secretariat has prepared and appended the possible amendments of the Nomenclature for the proposed items to be provided for separately in the HS (see Annex to this document).

4. Besides a number of observations submitted by the Research Group for Biological Arms Control of the University of Hamburg (Germany) (hereafter : Research Group), no information or comments have been received by the Secretariat during the intersession.

5. In respect of the issues raised during the examination of the classification of the proposed items at the 41st Session of the HS Committee, and on the basis of the observations received from the Research Group, the Secretariat notes the following (in the order of the Nomenclature):

Heading 38.21

6. As regards the possible separate subheadings for prepared culture media of heading 38.21, the Research Group proposed to provide separately for prepared culture media for production purposes on the one hand, and prepared culture media for diagnostic purposes on the other hand.

7. The Research Group has submitted the following comments :

Growth media for diagnostic purposes - what is the trade value ?
Average prices from just under 100 €/kg to 400 €/kg. Specific types may be much more expensive. Production media is on sale already for under 2 €/kg also for smaller packages, i.e., one gallon. Probably much cheaper when traded in larger packages as 100 kg or more.

How does it differ from growth media for production ?
Diagnostic media are often readily prepared on substrates, and traded in rather small packages. Diagnostic growth media contains at least one antibiotic or antifungal. Production media is in contrast traded as bulk ware (often 5 litre canisters or even tanks) and is not specific to the growth of one or few micro-organisms (respectively does not abolish or inhibits the growth of specific micro-organisms).

What is the trade volume for growth media ?
The Research Group will contact EuropaBio (the European Biotechnology Lobby group) to ask them for expertise on the traded volumes of all items on the list. For growth media an internet research resulted in finding a high number of supplier companies in all larger European States.

Heading 38.22

8. Regarding the possible classification under heading 90.27 of detection assays for micro-organism and toxins, including immunological and gene probe assays, it was indicated at the HS Committee's 41st Session that the equipment might not fall under Chapter 90 at all.

9. The Research Group has submitted the following comments :

Are detection assays pharmaceuticals, i.e. chemicals; or are they equipment?
A detection assay is the totality of antibodies, chemicals (if the assay does not work with an antibody test, but by analysing the DNA of the micro-organism) and hardware. The hardware can be a rather simple (plastic) stick containing the antibody substrate, or polymerase chain

reaction (PCR) machinery.

10. Given the fact that these detection assays would consist of specially designed reagents, the Secretariat has inserted a possible new subheading for these detection assays under heading 38.22, instead of heading 90.27.

Heading 39.26

11. The Secretariat has added heading 39.26 to the list of possible headings for positive pressure air-fed suits and half-suits for protection from exposure to hazards such as pathogens. Consequently, a subheading for these goods under heading 39.26 has been inserted in the list with possible amendments of the Nomenclature.

Heading 40.15

12. As regards the possible new subheading for rubber gloves for Class III and IV safety cabinets, the Research Group has not been able to find specific characteristics (e.g., thread/winding for the connection to the safety cabinet) for this kind of glove.

13. The Secretariat has found information on the Internet which shows that rubber gloves for Class III Biologically safety cabinets (sometimes called “glove boxes”) could be presented as single piece leak-tested long-sleeved gloves of Neoprene™ synthetic rubber, with assemblies to connect to the safety cabinet.

Heading 62.10

14. Following the comments of the HS Committee at its 41st Session, the Secretariat has also prepared a possible new subheading within present HS subheading 6210.10 for positive pressure air-fed suits, not incorporating breathing apparatus.

Heading 70.19

15. Although it had been indicated at the HS Committee’s 41st Session, that HEPA (High Efficiency Particulate Air), ULPA (Ultra Low Penetration Air) or SULPA (Super-ULPA) filters might also be classified outside subheading 7019.32, depending on the structure of the filters, the Secretariat has not received any further information on the classification of these filters.

16. As regards the possible separate subheadings for HEPA, ULPA and SULPA filters, the Research Group has submitted the following comments :

Are HEPA, ULPA und SULPA all made from glass fibre?
No, they can at least be made from PP, PET or PTFE fibre glass.

What is the difference between the three filter types?
The effectiveness to filter airborne particles off the air. HEPA-filters are today already used in vacuum cleaners. It is not yet checked whether these filters are of the same quality as laboratory filters, but at least they must meet the same filtering standards.
In this case ULPA and SULPA-filters, which today will be the usual equipment of new built or modernized laboratories, should be identified individually in the HS. ULPA-filters can remove from the air at least 99.999% of dust, pollen, mould, bacteria and any airborne particles with a size of 120 nanometres or larger at a specific most inauspicious air speed.
SULPA: 99.9999%.

17. Given the comments of the Research Group, the Secretariat has prepared possible amendments of the Nomenclature for the ULPA (Ultra Low Penetration Air) and SULPA (Super-ULPA) filters.

18. The Secretariat has not been able to independently confirm the criteria submitted by the Research Group regarding filtration and the aerosol particle size. The Research Group and Sub-Committee are therefore asked to confirm these criteria.

Heading 84.19

19. In respect of the possible separate subheading for double ended autoclaves, the Research Group has submitted the following comment :

What is the difference between a double ended autoclave and a pass through sterilization system?
Double ended autoclave : Build into a wall that separates the contaminated area from the outside to enable material exchanges.
Pass through sterilisation equipment is used for the sterilization of waste water or (more seldom) exhausted air (for example from fermenters). Apart from heating air or liquids, filtering and UV-radiation technologies can be used (also in combination).

20. Given the comments of the Research Group, the Secretariat has prepared possible amendments of the Nomenclature for both the double ended autoclaves and the pass through sterilisation equipment under present subheading 8419.20.

Headings 84.19, 84.21 and 84.79

21. Regarding the wording “for use with biological material”, the Research Group has submitted the following comment :

How to define "biological material", e.g. "equipment for use with biological material" ?
The phrase “(for use with) biological material” appears five times in the proposed items list and could be deleted in all cases, since the needed specifications are contained in other parts of the descriptions :
- All reciprocal shakers and shaking incubators are used for growing micro-organisms.
- “Centrifuges (…) capable of in-situ steam sterilisation in a closed state” is already the needed specification.
- Cross-flow and tangential filtration equipment“ is adequately described with the size of the filter area.
- Concerning the drying equipment, it is suggested distinguishing the dryers by the flow rate capacity (yet no threshold identified). An additional characteristic for classification could be an encapsulation of the dryer to the environment.

22. The Secretariat leaves it to the Sub-Committee to decide whether or not these words “for [use with] biological material” would be necessary to define the scope of these new proposed subheadings. Therefore, the Secretariat has left these words in the proposed texts of the subheadings but has placed this text in square brackets:

Heading 84.19

23. The Secretariat has not inserted a new possible subheading for plat inoculation chambers in heading 84.36, because scientific and industry references did not consider inoculation to include germination.

24. The Secretariat did not create detail requested for fermenters since it seems that all sizes can be considered “dual-use”. Moreover, under the present structure there would not be enough subheadings available in the range of 8419.8* for the 7 two-dash subheadings suggested.

Heading 84.24

25. The Secretariat has inserted a separate subheading for the parts of machines of new proposed subheading 8424.82, e.g., for the following specially designed components : Head Unit and Nozzle assembly of foggers.

Headings 84.37 and 84.79

26. Following the comments of the HS Committee at its 41st Session in respect of high precision milling equipment, the Secretariat has prepared a possible new subheading for this equipment within heading 84.79 only.

Heading 90.20

27. In addition to the protective suits with breathing apparatus, the Secretariat has inserted a proposed new subheading for gas masks, for protection against pathogens. The Research Group could perhaps clarify how these gas masks could be distinguished from other respirators which enable the wearer to breathe in a noxious atmosphere.

Heading 90.27

28. The Research group has not been able to provide further information on the “nose-only aerosolization equipment”. The Research Group could perhaps clarify the kind of aerosolization equipment, as well as the difference between the various types of aerosolization equipment at the Sub-Committees 37th meeting.

29. Regarding aerosol equipment, the Secretariat would like to note that devices for personal prophylaxis or therapy for medical conditions fall under heading 90.19, as aerosol therapy apparatus (see also the HS Explanatory Note to heading 90.19, page XVIII-9019-3, Item (VI)).

30. On the other hand, in the Secretariat’s view the proposed item in the list of the Research Group could include chambers designed for aerosol challenge testing with micro-organisms, viruses or toxins. Inhalation exposure technology instruments and apparatus might be a category of instruments which would rather be classified under heading 90.27. Therefore, the Secretariat has prepared a possible new subheading within present heading 90.27 for the “nose-only aerosolization equipment, excluding aerosol therapy apparatus”.

Heading 90.30

31. The Secretariat is of the view that the words “instruments and appliances” which the Secretariat has added to the text of subheading 9031.41 to match the text of proposed new subheading 9031.42 for “aerodynamic particle-sizing equipment”, do not change the scope of present subheading 9031.41.

III. CONCLUSION

32. The Sub-Committee is invited to consider the draft amendments of the Nomenclature for the items to be provided for separately in the HS in the Annex to this document, taking into account the observations submitted by the Research Group and the comments by the Secretariat above.

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