



HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE

-
19th Session
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NR0012E1
(+Annex)
O. Eng.

H11-3

Brussels, .

POSSIBLE AMENDMENT TO HEADING 38.22 TO CLARIFY

THE CLASSIFICATION OF CRMs

(Item II.A.12 on Agenda)

Reference document :

40.211 (SSC/11)
40.460 Annex A/9 (SSC/11 – Report)
40.412 paragraphs 24 and 25 (HSC/18)
40.600 Annex D, paragraphs 16 and 17 (HSC/18 – Report)
40.758 (SSC/12)
40.870 Annexes A/12 and C/4 (SSC/12 – Report)
40.918 (HSC/19)
41.100 Annexes D/3 and K/6 (HSC/19 – Report)
41.343 (HSC/20)
41.682 (HSC/20)
41.600 Annex F/22 (HSC/20 – Report)
41.808 (RSC/17)
41.920 (Annex B/9 (RSC/17 – Report)
42.045 (HSC/21)
42.100 Annexes H/6 and L/5 (HSC/21- Report)
42.500 Annex B/1 (RSC/18 – Report)
42.406 paragraph 34 (HSC/22)
42.750 paragraph 29 (HSC/22 – Report)

I. BACKGROUND

1. At its 18th Session, the Review Sub-Committee examined the question of amending the legal texts for future classification of all Certified Reference Materials (CRMs) in heading 38.22. The Sub-Committee agreed, in principle, that CRMs (chemical and non-chemical; for values of physical properties and concentrations) should be grouped in heading 38.22 for the future. In this connection, the Secretariat was instructed to prepare draft amendments to the Nomenclature and, if appropriate, to the Explanatory Notes on the basis of the EC's texts in paragraphs 5 and 11 of Doc. 41.808 and taking account of the views expressed in the Sub-Committee, for examination at the next session. Administrations

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were invited to submit comments to the Secretariat as soon as possible on the precise scope to be defined, as well as the concept of certification.

II. SECRETARIAT COMMENTS

2. As of mid-January 1999, the Secretariat had not received any comments from administrations concerning this subject.
3. For ease of reference, the EC's texts in paragraphs 5 and 11 of Doc. 41.808 are reproduced below :

"A Certified Reference Material is a reference material which is accompanied by a certificate which indicates the values of the certified properties, methods used to determine the values and the degree of certainty associated with each value."

"Heading No. 38.22 includes Certified Reference Materials, which are not to be classified in any other heading of the Nomenclature."
4. The Secretariat would clarify that, in the light of the Sub-Committee's recent discussions about the materials to be classified as CRMs in new heading 38.22, the new heading 38.22 should include the following CRMs :
 - (i) Chemical CRMs, whether they react or do not react chemically with the materials being tested; and
 - (ii) Non-chemical CRMs for values of physical properties (e.g., thermal properties, particle and surface properties, ion activity, electrical properties, viscometric properties, etc.) and concentrations (proportions).
5. In this connection, it should be noted that the Harmonized System Committee (22nd Session) agreed, when examining the possible amendment of the present Explanatory Note to heading 38.22, that non-chemical CRMs and chemical CRMs which do not react chemically with the materials being tested were not classifiable in heading 38.22, since the terms "reagents" in that heading text did not apply to them but to chemical CRMs which react chemically with materials being tested (see Annex H/6 to Doc 42.100. HSC/21 – Report).
6. The Secretariat would therefore suggest amending the text of heading 38.22 to include CRMs (chemical and non-chemical) and that the CRMs be defined in the legal Note. As suggested by the EC in its proposal (see paragraph 11 of Doc. 41.808), there should also be a special legal provision to exclude, for example, milk powder put up as a CRM from Chapter 4 and to classify such products in heading 38.22. In this regard, the definition of CRMs and the special provision could be drafted on the basis of the EC's texts in paragraph 3 above. The Secretariat would also suggest that the scope of new heading 38.22 be clarified by amending the Explanatory Note to heading 38.22.
7. With regard to the special legal provision (see paragraph 6 above), one delegate stated at the last session that his Administration could accept the classification of all CRMs in heading 38.22, with the exception of products of Chapter 28 or 29 and products which would be considered laboratory instruments of Chapter 90. In this connection, another delegate noted that, if products such as those mentioned above were to be excluded, the legal Note should make that clear (see paragraphs 2 and 5 of Annex B/1 to Doc. 42.500, Report – RSC/18). If the Sub-Committee agrees with this, the special legal provision should be

drafted with the exception of the products of Chapter 28 or 29 and the laboratory instruments of Chapter 90.

8. As the EC also suggested in paragraph 11 of Doc. 41.808, it seems necessary to avoid such a provision conflicting with other legal requirements. The Secretariat would therefore propose adding the expression “regardless of the terms of any other headings or any other Section and Chapter Notes” to the new provision. The special provision would read as follows :

“With the exception of the products of Chapter 28 or 29 and the laboratory instruments of Chapter 90, heading No. 38.22 includes certified reference materials, which are not be classified in any other heading of the Nomenclature regardless of the terms of any other headings or any other Section and Chapter Notes.”

9. On the above basis, the Secretariat has prepared and appended draft texts for amending the Nomenclature and the Explanatory Notes.

III. CONCLUSION

10. Taking into account the Secretariat’s above comments, the Review Sub-Committee is requested to examine the draft texts for amending the Nomenclature and the Explanatory Notes proposed by the Secretariat.

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ANNEXE

PROJET D'AMENDEMENTS DE LA NOMENCLATURE ET DES NOTES EXPLICATIVES

CONCERNANT DES MRC

(Point II.A.12 de l'ordre du jour)

ANNEX

DRAFT AMENDMENTS TO THE NOMENCLATURE AND EXPLANATORY NOTES

CONCERNING CRMS

(Item II.A.12 on Agenda)

ARTICLE 16 PROCEDURE

A. AMENDMENTS TO THE NOMENCLATURE

CHAPTER 38.

Note 1. Item (a) (4).

Delete and substitute :

“(4) Products specified in Note 4 (a) or 4 (c) below;”

New Notes 2 and 3.

Insert the following new Notes 2 and 3 :

- “2.- For the purpose of heading No. 38.22, the expression "certified reference materials" means reference materials which are accompanied by a certificate which indicates the values of the certified properties, methods used to determine the values and the degree of certainty associated with each value.
- 3.- With the exception of the products of Chapter 28 or 29 and the laboratory instruments of Chapter 90, heading No. 38.22 includes certified reference materials, which are not to be classified in any other heading of the Nomenclature regardless of the terms of any other headings or any other Section and Chapter Notes.”

Renumber present Note 2 as 4.

Heading 38.22.

Delete and substitute :

“38.22 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading No. 30.02 or 30.06, and certified reference materials.”

B. AMENDMENTS TO THE EXPLANATORY NOTES

CHAPTER 38.

Page 553. Note 1. Item (a) (4).

Delete and substitute :

“(4) Products specified in Note 4 (a) or 4 (c) below;”

Page 553. New Notes 2 and 3.

Insert the following new Notes 2 and 3 :

- “2.- For the purpose of heading No. 38.22, the expression "certified reference materials" means reference materials which are accompanied by a certificate which indicates the values of the certified properties, methods used to determine the values and the degree of certainty associated with each value.
- 3.- With the exception of the products of Chapter 28 or 29 and the laboratory instruments of Chapter 90, heading No. 38.22 includes certified reference materials, which are not to be classified in any other heading of the Nomenclature regardless of the terms of any other headings or any other Section and Chapter Notes.”

Renumber present Note 2 as 4.

Page 578. Heading 38.22.

1. Heading text.

Delete and substitute :

“38.22 Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading No. 30.02 or 30.06, and certified reference materials.”

2. First paragraph. First sentence.

Delete and substitute :

"This heading covers **diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, other than** diagnostic reagents of **heading 30.02** or diagnostic reagents designed to be administered to the patient and blood grouping agents of **heading 30.06**, and **certified reference materials.**"

3. Third paragraph. First Sentence.

Delete and substitute :

"The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents."

4. New fourth paragraph.

Insert the following new fourth paragraph :

“With the exception of the products of Chapter 28 or 29 and the laboratory instruments of Chapter 90, this heading includes certified reference materials, which are not to be classified in any other heading of the Nomenclature regardless of the terms of any other headings or any other Section and Chapter Notes.

The certified reference materials of this heading are reference materials prepared for the calibration of an apparatus, the assessment of a measurement method or the assignment of values to a material. These reference materials may consist of the following :

- (a) Substrate materials containing added analytes, the concentration of which has been accurately determined ;
- (b) Unmixed materials, the concentration of certain components of which has been accurately determined (e.g., the protein and fat content of milk powder);
- (c) Materials, whether natural or synthetic, certain properties of which have been accurately determined (e.g., tensile strength, specific gravity)

These reference materials have to be accompanied by a certificate which indicates the values of the certified properties, methods used to determine the values and the degree of certainty associated with each value."

5. Last paragraph. First Sentence.

Delete and substitute :

"The heading also excludes the following reagents, whether or not put up in forms for use as diagnostic or laboratory reagents :"
