



SCIENTIFIC SUB-COMMITTEE

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(+ Annex)  
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14th Session  
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SC-3

Brussels, 14 December 1998.

POSSIBLE LEGAL AMENDMENTS TO CHAPTER 30 CONCERNING HORMONE  
DERIVATIVES AND ANALOGUES

(Item II.7 on Agenda)

I. BACKGROUND

1. At its 21<sup>st</sup> Session (March 1998), the Harmonized System Committee adopted, under Article 16, texts proposed by the Scientific Sub-Committee for a new Note 8 to Chapter 29 and for amendments to heading 29.37 and its Explanatory Note. These amendments concerned the classification of hormones and their derivatives and analogues. In February 1998, the Secretariat received a letter from the Asociación Latinoamericana de Integración (ALADI), concerning the present and future scope of subheading 3004.32, which was not part of the proposal to amend the Nomenclature in this regard, but which nevertheless covered medicaments, mixed or unmixed, put up in measured doses or in forms or packings for retail sale and containing adrenal cortical hormones. The comments from ALADI are excerpted below.

II. COMMENTS FROM ALADI

2. “[ALADI wondered whether] subheading 3004.32 ... would [presently] include medicaments containing adrenal cortical hormone derivatives or not. [ALADI refers to Docs. 40.765 (SSC/12) and 40.870, Annex A/5 (SSC/12 Report).] In the third paragraph, third and fourth lines [of Annex A/5, Doc. 40.870], we read : “one delegate noted that an important group of anti-inflammatory drugs was excluded from subheading 3004.32 by virtue of their being derivatives of adrenal-cortical hormones”. This is consistent with Item III (A) of the Explanatory Note to heading 29.37 (page 431), which establishes that adrenal cortical hormones are “found in the cortical zone of the adrenal glands”.
3. Thus medicaments that contain **natural** hormones would be classified in subheading 3004.32, and subheading 3004.39 would cover the majority of medicaments with hormonal activity similar to adrenal cortical hormones, all of which seems accepted by the SSC.
4. However, in the second edition of the Harmonized System Commodity Data Base ... we note that approximately 90 percent of the products listed in subheading 3004.32

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correspond to medicaments containing **derivatives** of adrenal cortical hormones, whereas no such references are found for subheading 3004.39 ... If the intention ... is to classify in subheading 3004.32 only those medicaments containing natural adrenal cortical hormones (as established by the text of subheading 3004.32 and as seems consistent with the comments of the 12<sup>th</sup> Session of the SSC), then it should be expressly noted in an Explanatory Note. Further, the references to products containing derivatives should be deleted from subheading 3004.32 in the HS Commodity Data Base.

5. However, if the intention is to classify in subheading 3004.32 all the medicaments that contain adrenal cortical hormones, natural or not, as well as their derivatives with a corticosteroid activity, as it now appears in the HS Commodity Data Base, then the text of the subheading should be amended accordingly.”

### III. SECRETARIAT COMMENTS

#### Present scope of subheading 3004.32

6. From a strictly legal point of view, it has been argued that the present scope of subheading 3004.32 covers medicaments containing natural adrenal cortical hormones only; those which are found in nature or which are reproduced by synthesis to have the same chemical structure found in the natural product. Furthermore, it would seem that medicaments containing a mixture of natural (or synthetically reproduced) hormones with derivatives would also be covered by the subheading. However, medicaments containing only derivatives or analogues of the natural product would seem to fall to subheading 3004.39.
7. The fact that the HS Commodity Data Base indicates otherwise demonstrates the fact that some administrations in the past have taken a more liberal view of the scope of subheading 3004.32, while others followed a more strictly legal interpretation. It was because of this apparent nonuniform application of the hormones provisions that led the HS Committee to adopt a new Note 8 to Chapter 29, a complete restructuring of heading 29.37 and an amended Explanatory Note for the future. However, the amendments adopted by HSC/21 did not include a corresponding amendment to subheading 3004.32.

#### Possible amendment of subheading 3004.32 for the future

8. The amendments already adopted by the Harmonized System Committee for heading 29.37 provided for the inclusion in the various subheadings for the natural hormones, as well as their derivatives and structural analogues. It would seem consistent that, at least for the future, subheading 3004.32 should also include derivatives and structural analogues. The Secretariat therefore agrees with ALADI's suggestion in paragraph 5 above that the text of subheading 3004.32 should be amended accordingly.

9. In this connection, the Secretariat would point out that the new amendments for heading 29.37 and its subheadings will no longer refer to “adrenal cortical hormones”, but instead as “steroidal hormones” and, more specifically in the Explanatory Notes, as “corticosteroid hormones”. Further, it would seem that terms “adrenal cortical” and “corticosteroid” are synonymous, so that the latter term could be inserted in the text subheading 3004.32 without affecting its scope.
10. Taking the above considerations into account, the Secretariat would suggest that the text of subheading 3004.32 could be amended to read as follows :

“Containing corticosteroids, their derivatives and structural analogues”.

Given the nonuniform application of the hormone provisions at present, this amendment could result in the transfer of derivatives and analogues from other subheadings, but given the restructuring of heading 29.37, the end result would seem desirable.

#### Other possible amendments

11. The Secretariat has reviewed other legal texts of Chapter 30 that might also be candidates for amendment in this regard. In particular, subheadings 3003.3, 3003.40 and 3006.60 might be considered for review.
12. The text of present subheadings 3003.3 and 3003.40 specify “hormones or other products of heading 29.37”, so it would seem that derivatives and analogues would be covered, at least for the future. Thus it may not be necessary to amend these subheadings. The Sub-Committee is asked to give its views in this regard.
13. Subheading 3006.60 covers products “based on hormones”, without reference to derivatives or structural analogues. The Secretariat wonders whether it might be preferable to amend this text to read “based on hormones or other products of heading 29.37”, in order to avoid any misunderstanding in the future.
14. The Secretariat has prepared these draft legal amendments, along with corresponding amendments to the Explanatory Notes, and set them out in the Annex for the Sub-Committee’s examination.

#### IV. CONCLUSION

15. The Sub-Committee is requested to give its views on the proposed amendments set out in the Annex, taking into account the comments of ALADI and of the Secretariat, above.

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Annexe au Doc. 42.197  
Annex to  
(SCS/14/fév. 99)  
(SSC/14/Feb. 99)

ANNEXE

PROJET DE REMANIEMENT DE LA NOMENCLATURE ET DES NOTES EXPLICATIVES  
CONCERNANT LES HORMONES  
(Point II.7 l'ordre du jour)

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ANNEX

DRAFT AMENDMENTS TO THE NOMENCLATURE AND EXPLANATORY NOTES  
CONCERNING HORMONES  
(Item II.7 on Agenda)

PROCEDURE DE L'ARTICLE 16

A. PROJET D'AMENDEMENTS DE LA NOMENCLATURE

CHAPITRE 30.

N° 3004.32.

Nouvelle rédaction :

“3004.32 -- Contenant des hormones corticostéroïdes, leurs dérivés et analogues structurels”.

N° 3006.60.

Nouvelle rédaction :

“3006.60 - Préparations chimiques contraceptives à base d’hormones, d’autres produits du n° 29.37 ou de spermicides”.

B. PROJET DE MODIFICATIONS DES NOTES EXPLICATIVES

CHAPITRE 30.

Page 468. N° 3004.32.

Nouvelle rédaction :

“3004.32 -- **Contenant des hormones corticostéroïdes, leurs dérivés et analogues structurels**”.

Page 471. N° 3006.60.

Nouvelle rédaction :

“3006.60 - **Préparations chimiques contraceptives à base d’hormones, d’autres produits du n° 29.37 ou de spermicides**”.

Page 473. N° 30.06. Alinéa 8).

Nouvelle rédaction :

“8) **Les préparations chimiques contraceptives à base d’hormones, d’autres produits du n° 29.37 ou de spermicides**, même conditionnées en emballage pour la vente au détail.”.

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ARTICLE 16 PROCEDURE

A. PROPOSED AMENDMENTS TO THE NOMENCLATURE

CHAPTER 30

Subheading 3004.32.

Delete and substitute :

“3004.32 -- Containing corticosteroid hormones, their derivatives and structural analogues”.

Subheading 3006.60.

Delete and substitute :

“3006.60 - Chemical contraceptive preparations based on hormones, other products of heading 29.37 or spermicides”.

B. PROPOSED AMENDMENTS TO THE EXPLANATORY NOTES

CHAPTER 30

Page 468. Subheading 3004.32.

Delete and substitute :

“3004.32 -- **Containing corticosteroid hormones, their derivatives and structural analogues**”.

Page 471. Subheading 3006.60.

Delete and substitute :

“3006.60 - **Chemical contraceptive preparations based on hormones, other products of heading 29.37 or spermicides**”

Page 473. Heading 30.06. Item (8).

Delete and substitute :

“(8) **Chemical contraceptive preparations base on hormones, other products of heading 29.37 or spermicides, whether or not put up in packings for retail sale.**”.

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