



WORLD CUSTOMS ORGANIZATION
ORGANISATION MONDIALE DES DOUANES

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HARMONIZED SYSTEM
COMMITTEE

NC0131E1

-
24th Session

O. Eng.

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Brussels, 1 October 1999.

STUDY OF POSSIBLE CRITERIA FOR DISTINGUISHING BETWEEN MEDICAMENTS
AND PREMIXES CONTAINING ANTIBIOTICS

(Item VII.12 on Agenda)

Reference documents :

40.522 (HSC/18)
40.600 Annexes IJ/14 (HSC/18 - Report)
41.128 (HSC/19)
41.100, Annex H/5 (HSC/19 - Report)
41.670 (SSC/13)
41.690, Annex A/10 (SSC/13 - Report)
42.850, Annex A/5 (SSC/14 - Report)
NC0016E1 (HSC/23)
NC0090E2, Annex E/1 (HSC/23 - Report)

I. BACKGROUND

1. On the basis of Doc. 42.195, the Scientific Sub-Committee at its 14th Session examined criteria for distinguishing between medicaments and premixes containing antibiotics.
2. Many delegates agreed that the criteria cited below could be a good basis for deciding classification on a case by case basis and that more precise criteria for distinguishing between products of heading 23.09 and medicaments of Chapter 30 were difficult to establish.
 - (i) The manner of presentation of such preparations.
 - (ii) Packing.
 - (iii) Concentration of active ingredients.
 - (iv) Type of carriers used in the preparation.
 - (v) Indications of use and dosage.

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- (vi) Limitations as to the period of use.
 - (vii) Whether the preparation could be used for regulating growth of animals or for treatment purposes only.
 - (viii) Whether supervision of a veterinarian was required for use.
3. The following suggestions were also put forward to improve or clarify the above mentioned criteria.
- (i) Incorporate control of infestation as one of the criteria for inclusion in Chapter 23.
 - (ii) Indications regarding methods of administration should also be specified.
 - (iii) It would be useful to check whether a product was made for an entire herd of animals or for a particular animal or group of animals to treat a specific problem, in order to understand whether the product was intended for use as a medicament or animal feeding stuff.
4. It was further suggested that the Explanatory Note to heading 23.09 be modified to incorporate the criteria cited above as general guidance for distinguishing between medicaments and premixes containing antibiotics.
5. The Sub-Committee finally agreed to report to the Harmonized System Committee that no general criteria could be established for distinguishing between medicaments and premixes containing antibiotics. However, the criteria mentioned in paragraph 2 above and the modifications indicated in paragraph 3 above could be adopted for guidance to classify products on a case by case basis, and that these could be incorporated in the Explanatory Notes.
6. The Harmonized System Committee at its 23rd Session took note of the above observations of the Scientific Sub-Committee and requested the Secretariat to study this matter further.

II. SECRETARIAT COMMENTS

7. As requested by the Harmonized System Committee, the Secretariat has prepared a draft text to incorporate the criteria suggested in paragraphs 2 and 3 above in the Explanatory Note to heading 23.09. The draft text is set out in the Annex to this document.

III. CONCLUSIONS

8. The Committee is invited to examine the proposed amendments to the Explanatory Notes as set out in the Annex to this document.
9. The Committee is also requested to decide whether it is still necessary to examine the classification of "Linco-Spectin Premix" and "Lincomix 110" forwarded by the Polish Customs Administration (see Doc. 40.552 and Annex H/5 to Doc. 41.100) in view of its decision regarding the classification of premixes in general and its decision concerning the proposed Explanatory Note in the Annex to this document.

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Annexe au Doc. NC0131B1
Annex to

(CSH/24/oct. 99)
(HSC/24/Oct. 99)

ANNEXE

MODIFICATIONS A APPORTER EVENTUELLEMENT

AUX NOTES EXPLICATIVES DU N° 23.09

(Point VII.12 de l'ordre du jour)

ANNEX

POSSIBLE AMENDMENT TO THE EXPLANATORY NOTE

TO HEADING 23.09

(Item VII.12 on Agenda)

MODIFICATIONS DES NOTES EXPLICATIVES
A EFFECTUER PAR VOIE DE CORRIGENDUM

Page 188. N° 23.09 Partie II C). Dernier paragraphe.

Nouvelle rédaction :

"Les préparations relevant de cette catégorie ne doivent, toutefois, pas être confondues avec certaines préparations à usage vétérinaire. Même si aucun critère de portée générale ne permet de distinguer ces deux groupes de produits, les critères suivants doivent être pris en considération pour déterminer leur classement : mode de présentation, conditionnement, teneur en ingrédients actifs, type de substrat utilisé, posologie et dosage, date de péremption, emploi éventuel de la préparation pour la régulation de l'engraissement des animaux ou uniquement pour le traitement de ces derniers, supervision éventuellement requise d'un vétérinaire pour les administrer, lutte contre la contagion, indications quant aux différents modes d'administration et conception éventuelle du produit pour un troupeau entier d'animaux ou pour un animal ou un groupe d'animaux en particulier, afin de traiter un problème spécifique".

AMENDMENT TO THE EXPLANATORY NOTES
TO BE MADE BY CORRIGENDUM

Page 188. Heading 23.09. Part (II) (C). Last paragraph.

Delete and substitute :

“The preparations of this group should not, however, be confused with certain preparations for veterinary uses. While no general criteria exist to distinguish between these two groups of products the following factors should be taken into consideration in determining classification : manner of presentation, packing, concentration of active ingredients, type of carrier, indication of use and dosage, limitation as to the period of use, whether the preparation could be used for regulating growth of animals or for treatment purposes only, whether supervision of a veterinarian is required for use, control of infestation, indication regarding methods of administration and whether the product is made for an entire herd of animals or for a particular animal or group of animals to treat a specific problem.”
