



WORLD CUSTOMS ORGANIZATION
ORGANISATION MONDIALE DES DOUANES

Established in 1952 as the Customs Co-operation Council
Créée en 1952 sous le nom de Conseil de coopération douanière

SCIENTIFIC SUB-COMMITTEE

41.670 E

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13th Session

O. Eng.

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H3-1

Brussels, 26 November 1997.

CLASSIFICATION OF PREMIXES CONTAINING ANTIBIOTICS

(Item II.10 on Agenda)

Reference documents :

40.552 (HSC/18)
40.600, Annex IJ/14 (HSC/18 - Report)
41.128 (HSC/19)
41.100, Annex H/5 (HSC/19 - Report)

I. BACKGROUND

1. At its 19th Session, the Harmonized System Committee examined the classification of three “premixes” containing a coccidiostat or antibiotics and intended to be used with animal feeding stuff. The “premixes” at issue were : “Clinacox Premix 0.5”, “Linco-Spectin Premix” and “Lincomix 110”. Details about the composition, use, etc., of these premixes are set out in Doc. 40.552 (see also Annex II to this document).
2. The Committee, unanimously, agreed to classify the “Clinacox Premix 0.5” (containing 0.5 % diclazuril (a coccidiostat)) in heading 23.09.
3. With regard to the two other products at issue, “Linco-Spectin Premix” and “Lincomix 110”, classification in heading 23.09 was also contemplated by some delegates. However, since these products were indicated to have prophylactic and therapeutic properties, it was suggested that the Scientific Sub-Committee be asked to study the nature and extent of antibiotics that could be allowed in the premixes of heading 23.09 in order to distinguish them from veterinary medicaments of Chapter 30.
4. In this connection, one delegate stated that a classification based on the amount of active ingredients in the compound feed to which the products were added, would be misleading since the product had to be classified as presented in its concentrated form.

File No. 2633

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5. The Committee, while noting that it might be very difficult to decide on a common threshold, agreed that the Scientific Sub-Committee be asked to study (i) what kind of antibiotics could be allowed in the premixes of heading 23.09; (ii) the amount (threshold) of such substances which would transform premixes into medicinal preparations with therapeutic or prophylactic properties within the scope of Chapter 30 and; if necessary (iii) whether such threshold or other criteria should be established by also having regard to the final form of animal feeding.
6. The study should also take into consideration the following comments by the Argentine Administration (set out in Doc. 41.128 - HSC/19) :
 - 6.1. "The National Customs Administration of the Republic of Argentina would like to obtain information concerning the classification of "premixes" containing antibiotics or vitamins.
 - 6.2. This request arises from the difficulty in determining when this type of merchandise corresponds to heading 23.09 or to heading 30.03/30.04, in view of the fact that the composition of products in these headings are similar (for example, antibiotics or vitamins on a substrate of silicic anhydride or lactose, etc.).
 - 6.3. In view of the foregoing, this Administration considers that, in order to facilitate the identification of these products, it would be necessary to specify parameters in terms of concentration, activity, etc., to distinguish products for preventing certain illnesses in animals (in which case, the product should fall in heading 23.09) from those used in the treatment of human illnesses (heading 30.03 or 30.04).
 - 6.4. On the other hand, the creation of a list of antibiotics permitted in the premixes of heading 23.09 would be very useful. Not all antibiotics should be included in that heading; after being consumed by animals, some antibiotics passed on to humans through the food chain could be harmful to humans. Such is the case when broad-spectrum antibiotics used in animals could lead to resistance to antibiotics in human beings."
7. Administrations were also requested to submit necessary information to the Secretariat in order for it to become able to prepare a working document for the Scientific Sub-Committee.

II. SECRETARIAT COMMENTS

8. So far, the Secretariat has not received any additional information from administrations.
9. In the present exclusion in the Explanatory Note to heading 23.09 (see page 188) for "preparations for veterinary uses", it is indicated that such preparations "are generally identifiable by the medicinal nature and much higher concentration of the active substance, and are often put up in a different way". Further guidelines are, however, not provided.
10. The technical literature available at the Secretariat does also not provide any reference to the amount of active substances ("feed additives"), such as antibiotics and coccidiostats,

normally present in “medicated“ premixes or to the dosage recommended. The “Kirk Othmer Encyclopedia of Chemical Technology - Fourth Edition/Volume 10”, however, contains a list of approved (by the United States Food and Drug Administration in 1992) “feed additives” (active substances), used for chicken, turkey and swine. For information, this list is set out in Annex I to this document.

11. The establishment of a common threshold (e.g., a fixed percentage) for the amount of active ingredients allowed in the premixes of heading 23.09 might be a solution. However, the Secretariat is somewhat concerned that it might not be possible to establish such a threshold considering that the activity of various active ingredients differs substantially depending on the nature of the substances and/or the nature of the animals. To illustrate this, the Secretariat has listed some examples of premixes in Annex II to this document. As can be seen from the list, the amount of active ingredients in these premixes varies from 0.5 % to 11 %. The Secretariat has also noted that the same premix can be used for different purposes (i.e., medical treatment or maintenance of desired physical conditions) depending on the level of dilution.
12. Alternatively, it could be considered to establish a common threshold, in terms of content of active ingredients in the final mixture to be fed to the animal. According to the examples set out in Annex II, the recommended dosage varies from 9 g (0.0009 %) to 220 g (0.022 %) per ton of the compound (final) feed, except in the case of “Tylan 40” which can be added in a quantity up to 1 kg (i.e., 0.1 %). It seems to be rather difficult to find a satisfactory threshold. Even if such thresholds could be found for certain antibiotics, the Secretariat wonders how Customs could ascertain, at the time of Customs clearance, the actual level of dilution. The Secretariat is therefore wondering whether it is necessary to explore other possibilities.

III. CONCLUSIONS

13. Taking the above information into consideration, the Sub-Committee is invited to study :
 - (i) what kind of antibiotics could be allowed in the premixes of heading 23.09;
 - (ii) the minimum amount (threshold %) of antibiotics allowed in premixes which would not make them preparations with therapeutic or prophylactic properties within the scope of Chapter 30;
 - (iii) whether thresholds should be established by having regard to the concentration in the final form of animal feeding;
 - (iv) whether any other criteria could be established for distinguishing between premixes of heading 23.09 and medicinal preparations of Chapter 30.

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x x

**“Medicated” feed additives for chicken, turkey, and swine,
grouped according to their usage**

(Extract from “Kirk Othmer - Fourth Edition/Volume 10)

Nutritional Feed Additives :

*Food efficiency/growth promotion
in chicken, turkey, and swine*
arsanilic acid
bacitracin methylene disalicylate
bacitracin zinc
bambermycins
chlortetracycline
oxytetracycline
penicillin
roxarsone
virginiamycin

*Food efficiency/growth promotion
in chicken and swine*
tylosin
lincomycin

*Food efficiency/growth promotion
in swine*
carbadox
tiamulin
tylosin/sulfamethazine

Pigmentation in chicken and turkey
arsanilic acid
roxarsone

*Egg hatchability/production in
chicken and turkey*
oxytetracycline

Egg hatchability/production in chicken
chlortetracycline

Egg hatchability in chicken
bacitracin zinc

Egg production in chicken
bacitracin methylene disalicylate

Eggshell texture and quality in chicken
oxytetracycline

Medicinal feed additives for Turkey :

Medicinal Feed Additives for Chicken
and Turkey :

Blackhead
nitarsons

Blue comb (non-specific enteritis)
chlortetracycline
oxytetracycline
penicillin

Breast blisters
novobiocin

Cholera, fowl
novobiocin
sulfadimethoxine and ormetoprim

Chronic respiratory disease
erythromycin
penicillin

Coccidiosis
amprolium
halofuginone hydrobromide
monensin
sulfadimethoxine and ormetoprim
zoalene

Mycosis, crop
nystatin

Mycotic diarrhoea
nystatin

Stress
chlortetracycline
oxytetracycline

Synovitis
chlortetracycline
novobiocin
oxytetracycline

Airsacculites
oxytetracycline

Hexamatiasis
chlortetracycline
oxytetracycline

Leucocytozoonosis
clopidol

Paratyphoid
chlortetracycline

Sinusitis, infectious
chlortetracycline
oxytetracycline

Transmissible enteritis
bacitracin methylene disalicylate

Medicinal Feed Additives for Chicken :

Cholera, fowl
oxytetracycline

Chronic respiratory disease
chlortetracycline
oxytetracycline
tylosin

Coccidiosis
chlortetracycline
clopidol
decoquinate
lasalocid
maduramycin ammonia
naracin
naracin/nicarbazin
nicarbazin
oxytetracycline
robenidine hydrochloride
salinomycin

Colibacillosis
sulfadimethoxine and ormetoprim

Coryza, infectious
erythromycin
sulfadimethoxine and ormetoprim

Fly control
rabon

Fly control
larvadex

Hepatitis, infectious
oxytetracycline

Necrotic enteritis
bacitracin methylene disalicylate
lincomycin
virginiamycin

Worms
coumaphos
hygromycin B

Medicinal Feed Additives for Swine :

Atrophic rhinitis
chlortetracycline
oxytetracycline
tylosin
tylosin/sulfamethazine

Bacterial swine enteritis (scours)
apramycin
carbadox
chlortetracycline
oxytetracycline

Cervical abscesses
chlortetracycline

Colibacillosis
apramycin
colimix

Dysentery
arsanilic acid
bacitracin methylene disalicylate
carbadox
lincomycin
roxarsone
tiamulin
virginiamycin

Dysentery, vibronic
carbadox
oxytetracycline
tylosin
tylosin/sulfamethazine

Worms, lungworms
fenbendazole
levamisole hydrochloride

Leptospirosis

chlortetracycline
oxytetracycline

Mycoplasma pneumonia

lincomycin

Necrotic enteritis

carbadox
oxytetracycline

Stress

chlortetracycline

Worms, kidney

fenbendazole

Worms, large roundworms

dichlorvos
fenbendazole
hygromycin B
levamisole hydrochloride
pyrantel tartrate
thiabendazole

Worms, nodular

dichlorvos
fenbendazole
hygromycin B
pyrantel tartrate

Worms, small stomach

fenbendazole

Worms, thick stomach

fenbendazole

Worms, threadworms

levamisole hydrochloride

Worms, whipworms

dichlorvos
fenbendazole
hygromycin B

x

x

x

Composition of various premixes

Product name [active substance] (other ingredients)	Amount of active ingredient in <u>premix</u>	Premix <u>dosage</u> *	Amount of active ingredient in <u>final feed</u> *	<u>Use</u>
“Clinacox Premix 0.5 %” **				
[Diclazuril - coccidiostat]	0.5 %	unknown	unknown	prophylactic anticoccidial, chicken
(polyvinylpyrrolidone - 0.20 %)				
(sodiumhydroxide - 0.05 %)				
(soybean meal - 99.25 %)				
“Linco-Spectin Premix” **				
[Lincomycin - antibiotic]	2.2 %	2.0 kg	88 g	treatment of enteric conditions, pigs;
[Spectinomycin - antibiotic]	2.2 %	1.0-2.0 kg	44-88 g	control of enteric conditions, pigs;
(liquid paraffin - 1.0 %)		1.0-2.0 kg	44-88 g	treatment of mastitis, metritis, agalactia (MMA), pigs;
(soya bean mill feed - 94.6 %)		1.0-2.0 kg	44-88 g	control of mycoplasmal pneumonia, pigs
“Lincomix 110” **				
[Lincomycin - antibiotic]	11.0 %	0.4 kg	44 g	prevention of dysentery; pigs;
(paraffin oil - 1.00 %)		1.0 kg	110 g	treatment of dysentery, pigs;
(micro tracer/colour - 0.75 %)		0.2-0.8 kg	22-88 g	prevention of lung inflammation, pigs;
(soya bean - 87.25%)		2.0 kg	220 g	treatment of lung inflammation, pigs;
		0.2-0.4 kg	22-44 g	treatment of enteritis, poultry

Notes: * Per ton of compound (final) feed.

** Products considered or under consideration by the HS Committee.

Product name [active substance] (other ingredients)	Amount of active ingredient in premix	Premix dosage *	Amount of active ingredient in final feed *	Use
“ Hygromix-8 ” premix/medicated [Hygromycin B - antibiotic] (other ingredients - no information)	1.8 %	0.4-0.7 kg	8-12 g	anthelmintic (i.e., control against worms), chicken; anthelmintic (i.e., control against worms), swine
		0.7 kg	12 g	
“ Coban 45 ” premix/medicated [Monensin - coccidiostat] (other ingredients - no information)	9.7 %	0.9-1.1 kg	90-110 g	prevention of coccidiosis (coccidiostat), chicken
“ Elancoban 100 ” premix/medicated [Monensin - coccidiostat] (other ingredients - no information)	10.0 %	1.0-1.2 kg	100-120 g	prevention of coccidiosis (coccidiostat), chicken
“ Tylan 40 ” premix/medicated [Tylosin - antibiotic] (other ingredients - no information)	9.2 %	1.1 kg	100 g	prevention of dysentery, pigs; reduction of incidence of liver abscesses, beef cattle; weight gain, pigs; weight gain, chicken; improving feed efficiency, laying chicken; aid in the control of chronic respiratory disease, broilers.
		0.1 kg	9 g	
		1.1 kg	100 g	
		0.04-0.6 kg	4-50 g	
		0.2-0.6 kg	20-50 g	
		8.7-10.9 kg	800-1000 g	

Note: * Per ton of compound (final) feed.