CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6.1 **CRD3 rev**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

Houston, Texas, United States of America, 17 – 21 October 2016

Comments on the PROPOSED DRAFT MRLs FOR IVERMECTIN (CATTLE MUSCLE) AND LASALOCID SODIUM (CHICKEN, TURKEY, QUAIL AND PHEASANT KIDNEY, LIVER, MUSCLE, SKIN+FAT) AT STEP 4

Comments of El Salvador, European Union, Philippines

EL SALVADOR

El Salvador supports the draft MRL for ivermectin for cattle muscle of 4 µg/kg, according to the JECFA evaluation at its 78th session.

For lasalocid sodium, we recommend that JECFA continue to evaluate this drug to obtain data that includes more information on the MRL, acceptable daily intake, and the estimated dietary exposure.

EUROPEAN UNION

Lasalocid sodium (step 4)

The EU takes note of the opinion of the 81st meeting of JECFA and appreciates the responses given in relation to the concerns expressed by the EU at the 22nd CCRVDF meeting.

In addition, the EU appreciates that JECFA is working on the development of methodologies for the derivation of a microbial acute reference dose (mARfD) as, in the absence of internationally agreed methodology, the concern previously raised by the EU cannot be addressed in a fully satisfactory manner.

In addition, the EU has concerns about the use of the Estimated Daily Intake (EDI) approach to estimate consumer exposure. By using the EDI approach JECFA estimated the consumer intake to represent approximately 27% of the overall (toxicological) ADI. However, when using the Theoretical Maximum Daily Intake (TMDI) approach to estimate consumer exposure, the proposed draft Codex MRLs lead to a consumer intake of 882.11 µg/person, which represents 294% of the overall (toxicological) ADI and when the EU MRL for eggs is also included, the TDMI amounts to 921.58 µg, representing approximately 303% of the ADI. Therefore, the EU considers that the proposed draft MRLs may represent a risk to consumers.

In light of the above the EU cannot support the proposed draft Codex MRLs for lasalocid sodium.

PHILIPPINES

The Philippines supports the new evaluation and recommendation of the 81st JECFA's on ivermectin on cattle muscle MRL OF 30 µg/kg; and the ADI established and MRLs recommended at the 78th JECFA for lasalocid sodium. JECFA evaluation justifies the establishment of MRLs for which newer studies were accounted and considered to be informative for the evaluation of JECFA on ivermectin and lasalocid sodium.

Ivermectin and Lasalocid

JECFA evaluation justifies the establishment of MRLs for which newer studies were accounted and considered to be informative for the evaluation of ivermectin and lasalocid sodium.

The Philippines supports the recommendation of the 81st JECFA's on ivermectin on cattle muscle **MRL of 30 µg/kg.** Ivermectin residues has no adverse effects in human.

Lasalocid

The Philippines supports the following MRLs as recommended by 78thJECFA:

Species	Skin + fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Chicken	600	600	1200	400

Turkey	600	600	1200	400
Quail	600	600	1200	400
Pheasant	600	600	1200	400

The Philippines supports the advancement of the proposed draft MRLs (78thJECFA) for lasalocid sodium at Step 5 with the following justifications:

1) Since 2005, lasalocid sodium has been a duly registered in-feed anti-coccidial in the Philippines through the Bureau of Animal Industry with 7 days withdrawal period (WDP). Laslocid sodium is also registered elsewhere in over 50 countries.

2) Being a coccidiocidal (vs. a coccidiostat) antiparasitic agent, and being the only divalent polyether ionophore, it had been relied upon by veterinarians for the effective poultry health management programs vs. coccidiosis, particularly without having any concern of incompatibility with tiamulin, another widely used anti-mycoplasmal drug for poultry.

3) Complementing the drug's efficacy and compatibility with other widely-used medicaments in poultry, is its wide margin of safety, with studies and in-field experience showing that lasalocid is non-toxic, producing no adverse effects in poultry when used as directed.

4) Lasalocid produces no violative residues in meat when used as directed.