CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6.2 **CX/RVDF 16/23/6 Add.1**

September 2016

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

PROPOSED DRAFT MRLs FOR IVERMECTIN (CATTLE FAT, KIDNEY, MUSCLE), TUFLUBENZURON (SALMON FILLET, MUSCLE) AND ZILPATEROL HYDROCHLORIDE (CATTLE FAT, KIDNEY, LIVER, MUSCLE) AT STEP 3

Comments at Step 3 submitted by:

Brazil, Cuba, Philippines, Health for Animals

BRAZIL

Brazil congratulates JECFA for its work and supports the recommendations of the 81st Meeting of the Joint FAO/WHO Expert Committee on Food Additives for the veterinary drugs ivermectin, teflubenzuron and zilpaterol hydrochloride.

CUBA

Cuba agrees with document CX/RVDF 16/23/6 proposed draft MRLs for ivermectin (cattle fat, kidney, liver, muscle), teflubenzuron (salmon fillet, muscle) and zilpaterol hydrochloride (cattle kidney, liver, muscle).

PHILIPPINES

Ivermectin (cattle fat, kidney, muscle)

The Philippines is proposing for the elevation of Ivermectin at Step 5 taking into account the following points:

1) JECFA's new assessment and recommendation on the following revised MRLs of Ivermectin

Cattle fat	400ug/kg
Kidney	100ug/kg
Liver	800ug/kg
Muscle	30ug/kg

2) Ivermectin residues has no adverse effects in human

Zilpaterol hydrochloride (cattle fat, kidney, liver, muscle)

Considering that Philippines is importing a large volume of beef from other countries now using Zilpaterol (e.g. US, Canada etc) develop MRLs for Zilpaterol hydrochloride is very important to ensure consumer health protection and trade and therefore, Philippines supports the following:

1. The JECFA as the risk assessment body to provide the scientific basis for Codex MRLs still need data from the sponsor to establish MRLs for lungs and edible offals.
2. Further, the Philippines supports JECFA's recommended MRLs for Zilpaterol Hydrochloride in cattle: 3.3 ug/kg in kidney, 3.5ug/kg in liver and 0.5ug/kg in muscle hence, proposing for its elevation on Step 5/8.
3. Further, edible offals may be defined as:

   ~~a. by products of food animal carcasses that are edible and fit for human consumption~~

b. in relation to slaughtered animal means offals that have been inspected and passed as fit for human consumption or internal organs and other parts other than carcass capable of use as human food.

HEALTH FOR ANIMALS

Zilpaterol hydrochloride

HealthforAnimals congratulates JECFA for its work and appreciates the recommendations of the 81st Meeting of the Joint FAO/WHO Expert Committee on Food Additives to establish maximum residue limits (MRLs) for the veterinary drug zilpaterol hydrochloride. The sponsor had submitted a comprehensive data package and provided additional data upon the request of JECFA to its 81st meeting. As a result, JECFA proposed draft MRLs for zilpaterol hydrochloride of 3.3 µg/kg in cattle kidney, 3.5 µg/kg in cattle liver and 0.5 µg/kg in cattle muscle, which were derived from an acute reference dose of 0.04 µg/kg bw.

The sponsor had also made the argument that the pharmacological effects of zilpaterol hydrochloride, which are the basis for the acute reference dose, are considerably influenced by the release of the residue from the tissue and organs considered in the exposure assessment. JECFA acknowledged this approach, which was considered in a previous risk assessment for the compound triclabendazole. However, the available data for zilpaterol hydrochloride were not conclusive enough to consider this in the calculation of the MRLs. JECFA clearly outlined what data would be required and the sponsor will generate such new data for a new assessment by JECFA.

Therefore, HealthforAnimals recommends that the proposed draft MRLs for zilpaterol hydrochloride are held at Step 3 of the Procedure until JECFA has reviewed new data which the sponsor commits to provide to the next JECFA meeting.

HealthforAnimals thanks the 23rd CCRVDF for its consideration of this proposal.