CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 (b) **CX/RVDF 12/20/6 Add. 1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

PROPOSED DRAFT MRLS FOR VETERINARY DRUGS

Comments at Step 3 of Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Iran, Kenya, Philippines, IACFO

AUSTRALIA

General Comments

Australia is concerned that the procedure followed by JECFA in estimating dietary exposure may not always be consistent. The particular concern relates to the estimation of the ratio of marker residue to residues of concern (in the absence of information residues of concern = total radioactive residue). It is accepted that the ratio MR/TRR should be established at the time after treatment when the residue 95/95 tolerance declines below the proposed MRL. It is the MR/TRR that is established at this time that is relevant to, and used in, the estimation of dietary exposure.

The detail in the reports of JECFA meetings is not always sufficient to understand the MRL proposals. While in many cases the original data are available as they have also been reviewed by national bodies, this is not always the case.

Specific Comments

Compound	Comment
Amoxicillin	Australia supports advancement of the MRLs to Step 5/8.
Apramycin	Support advancement of the MRLs for cattle and chicken kidney to Step 5/8.
Derquantel	It is not possible to determine from the meeting report some important details such as how the ratio of marker residue to total radioactive residues was calculated. Australia proposes MRLs for derquantel be held at Step 4 until the residue monograph of the meeting is available to allow informed consideration of the proposals.
Monensin	Australia supports advancement of revised the MRL for cattle liver to Step 5/8.
Monepantel	Australia supports advancement of the MRLs to Step 5/8. The report of JECFA lists the EDI as 17% of the upper bound ADI. However when recalculated using the information contained in the JECFA report the EDI is 472 µg/kg or 37% of the upper bound ADI of 20 µg/kg bw.
Narasin	Australia supports advancement of the MRLs to Step 5/8.

BRAZIL

General comments

Brazil congratulates JECFA for its work and supports the recommendations of the 75th JECFA Meeting on numerical Maximum Residues Limits (MRLs) for the veterinary drugs amoxicillin, apramycin, derquantel, monensin, monepantel and narasin.

Specific comments

Brazil asks for the deletion of the term “and production aid” after the name of the veterinary drugs monensin and narasin, limiting it to the pharmacologic class only, to be consistent with the previously recommended MRLs by JECFA and CCRVDF for the same and other antimicrobial agents.

MONENSIN (antimicrobial agent) ~~and production aid)~~

NARASIN (antimicrobial agent) ~~and production aid)~~

CANADA

Canada has no objection to the advancement of the proposed JECFA MRLs for Monensin, Narasin, Amoxicillin, Derquantel , Monepantel and Triclabendazole to the next step.

CHILE

General Comments

We support advancing the Proposed Draft Maximum Residue Limits (MRLs) for Amoxicillin, Apramycin, Derquantel, Monensin and Monepantel.

Rationale

It is important for Codex to advance the study and MRL determination of those active substances normally used in animals for which Codex has not yet established the respective MRL.

COLOMBIA

Through the entire document we will use as reference document CX/RVDF, 12/20/6 Spanish version, attached.

Once we had reviewed the document we would like to submit the following comments for two of the active ingredients, as follows Apramycin and Amoxicillin.

Apramycin

It only suggests MLRs for birds and cattle, but doesn't take pigs in account. We request so include those species.

Amoxicillin

Currently Colombia has approved 13 products to use in birds; the proposed document doesn't take them in account.

COSTA RICA

We agree with advancing the Proposed Draft Maximum Residue Limits for Veterinary Drugs. Narasin in different cattle tissues is already at Step 7 and the following are at Step 3: Amoxicillin in several different tissues of cattle, sheep and pigs; Apramycin in cattle with temporary MRLs; Monensin in cattle and liver tissue (re-evaluation); Derquantel and Monepantel in sheep and all tissues.

Rationale

Costa Rica has registered Narasin, Amoxicillin and Monesin. In the specific case of Apramycin, although it was registered in our country, the registration expired and it was not registered again, therefore we don’t have it right now. Nevertheless, we don't see any issue with continuing the process and waiting until we get improved analytical methods and [residue] depletion studies to change the temporary MLRs into permanent ones.

Regarding antiparasitic agents, Costa Rica does not have Derquantel and Monepantel recommended for sheep registered, but we don’t anticipate an issue since they don’t represent any health risk for the consummer according to the evaluation.

IRAN

1- General comment:

The food basket which is used by JECFA to propose MRLs for veterinary drugs, is very different from the model diet in Iran, So we can not take advantage of these MRLs in our country.

2- Specific comments

- **AMOXICILLIN**

Iran, supports the proposed MRLs for AMOXICILLIN in cattle and sheep.

We have no comment on Pig because its consumption is banned in Iran (not Halal).

- **Other Drugs**

IRAN has no comments on other drugs because they are not registered in our country for use in specified species.

KENYA

ISSUES AND OBSERVATIONS

1. AECRVDF notes the proposed draft MRLs for Amoxicilin in cattle, sheep and pigs at Step 3
2. A ECRVDF notes the proposed draft MRLs as recommended by JECFA for Apramycin in cattle and chicken kidneys at step 3 and notes JECFA's inability to recommend MRLs for the other tissues and species due to data limitation
3. The MRL for Derquantel is noted but it is not clear why the ADI was calculated based on LOAEL derived from acute clinical studies on dogs.
4. The proposed MRL for Monensin (antimicrobial/ growth promoter) for cattle live r is acceptable.
5. The proposed MRLs for Monepantel for sheep tissues (liver, kidney, muscle , fat) are on the high side (300-5500 ug/kg)
6. The proposed MRLs for Narasin (an anticoccidial) for cattle tissues (muscle, kidney, liver and fat) are acceptable

COMMENTS

1. AECRVDF recommends the advancement of MRL for Amoxicillin to the next step.

Rationale: Amoxicillin has a low MRLs of 4-50ug/kg in the tissues of these animals.

2. MRLs for Apramycin for cattle and chicken kidneys should remain at step 3 until there is a validated analytical method for conducting depletion studies for other species and tissues.

Besides, the recommended MRL of 5000ug is on the high side.

3. Based on the low MRLs for Derquantel (an antiparasitic agents), we recommend that MRL for be advanced to the next level.

4. The proposed MRL for Monensin for cattle liver should be advanced to the next step.

5. The proposed MRLs for Monepantel (an anthelminthic) for sheep tissues (muscle, liver, kidney and fat) may not be advanced to the next step.

6. The proposed MRLs for narasin for cattle tissues should be advanced to the next step. Besides, the MRLs of (15 -50ug/kg) is low.

PHILIPPINES

Amoxicillin

Philippines supports the proposed MRLs for Amoxicillin in muscle, liver, kidney and fat of cattle, sheep and pigs; and milk of cattle and sheep noted in Annex 1 at Step 4.

Apramycin

Philippines does not support further advancement of the recommended draft MRLs for Apramycin. JECFA's recommendation for kidney is too high. We believe that additional data is needed to justify its advancement.

Derquantel

Philippines supports the proposed MRLs for Derquantel in muscle, liver, kidney and fat of sheep. We support for its advancement at Step 4 .

Monensin

Philippines supports further advancement of the recommended draft standards for Monensin in cattle's liver. We also support advancing these to the next step of the Codex procedure to the forthcoming CCRVDF Session.

Monepantel

Philippines does not support further advancement of the recommended draft MRLs for Monepantel. JECFA's recommendation for liver and fat is too high. We believe that additional data is needed to justify its advancement.

Narasin

Philippines supports the proposed MRLs for Narasin in muscle, liver, kidney and fat of sheep.

IACFO International Association of Consumer Food Organizations

IACFO proposes that information on the classification of drugs by the World Health Organization (WHO) as important antimicrobial (IA), highly important antimicrobial (HIA), or critically important antimicrobial (CIA) to human medicine be included in this agenda item. IACFO offers the following format for including this information (next to the name of the drug, above the ADI, EDI, and Residue Definition, as shown below):

*AMOXICILLIN (antimicrobial agent, **CIA***)

[…]

*APRAMYCIN (antimicrobial agent, **CIA****)*

[…]

WHO has defined antimicrobials as Critically Important (CIA), highly important (HIA) and important (IA) to human medicine.

Rationale: The WHO classifies amoxicillin and aminoglycosides as critically important drugs to human medicine – meaning that these drugs require the most urgent development of risk management strategies in order to preserve their effectiveness in human medicine.[1] This Committee focuses on veterinary drug residues, but the Committee should not overlook additional overlapping scientific issues, including antibiotic resistance (ABR). ABR linked to the use of veterinary drugs is a significant cross-cutting issue for the Committee to consider and it is well within the expertise of the members. When making decisions on the use and allowable levels of veterinary drug residues in food products, issues surrounding the potential to promote the spread and development of ABR pathogens should be noted. Codex has guidance on ABR, but the CCVDRF is the only Committee where the impact of individual drugs is considered. It is also important to note that CCRVDF developed a Code of Practice to Minimize/Contain Antimicrobial Resistance, which was adopted by CAC in 2005.[2]

[1] Critically Important Antimicrobials for Human Medicine: http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf

[2] CCRVDF Related Standards: http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=6