codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/RVDF 09/18/8 Add.2**
May 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session

Natal, Brazil, 11-15 May 2009

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OF RE-EVALUATION BY JECFA AND WORKING DOCUMENT LISTING VETERINARY DRUGS OF POTENTIAL INTEREST

(Report of the electronic Working Group on Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation)

Comments Submitted by:

Australia, European Community & the JECFA Secretariat

AUSTRALIA

The drug, Monepantel, in Australia's view, meets the criteria for evaluation by JECFA as set out in the Codex Procedural Manual 17th Edition (Risk Analysis Principles Applied by the CCRVDF, section 3.1.2.13).

- Australia will propose the compound for evaluation.
- The product is registered in New Zealand. There is a product label approved by the Agricultural Compounds and Veterinary Medicines group of the New Zealand Food Safety Authority that provides evidence of the establishment of good veterinary practices.
- Monepantel has the potential to cause international trade problems. It is already registered in New Zealand and is currently being evaluated in Australia where it is expected to be widely used in the Australian sheep industry when registered.
- Monepantel is currently available as the commercial product, Zolvix, in NZ only at present but will be available relatively soon in many other countries.
- Novartis will make an appropriate dossier available.

Recommendations

Australia recommends that Monepantel be included on the priority list of drugs for evaluation by JECFA.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA

Name of the compound	Question(s) to be answered	Data availability	Proposed by	Comments
Monepantel	Request to establish ADI and recommend MRLs in sheep (tissues)	Novartis have committed to provide a dossier	Australia	Australia became aware of this drug after the 29 April 2009 deadline for comment on the draft Priority List had expired.

EUROPEAN COMMUNITY

The European Community and its Member States (ECMS) support the recommendations (point 8 of document CX/RVDF 09/18/8) that the compounds in the draft Priority list, and for which no scientific data were provided, be removed from the priority list and returned to the starting list.

In view of the scientific information presented under agenda point 2, the ECMS request the inclusion of ractopamine in the Priority list of substances for re-evaluation by JECFA.

JECFA SECRETARIAT

In explanatory note some unclear language is used, e.g. for avermectins, benzimidazoles: ..`have been evaluated by Codex`.. what does this mean? Possibly ..`have been evaluated by JECFA and CXLs have been established`….

If this is correct then it should be stated like this.

- The table includes compounds where JECFA evaluation has been completed, however action by CCRVDF is pending. Since this is a priority table for requests for evaluation by JECFA, these compounds should not remain in the table, e.g. carbadox, chloramphenicol, olaquindox, nitrofurans, nitroimidazoles. This would greatly improve transparency of the table.

- The information for olaquindox should be amended, as no ADI has been established and no MRLs proposed. The recommendations from the WG on these substances are strongly supported, i.e. that CCRVDF should confirm that the substances should not be used in food producing animals and agree that Codex does not recommend MRLs or extra-off label use due to concerns for toxicity to the human consumer.

- For many substances it is stated that there is different MRL/residue status between Codex members, so it appears that data do exist that allow registration. However, recommendation to CCRVDF is to not consider for recommendation to JECFA since not enough information is available.

- Similar to the above: what happens to compounds where JECFA identified important data gaps, different MRLs seems to exist in Member States.

- For substances that are prohibited by many Codex Members and there is well documented toxicity, CCRVDF may consider direct action to recommend not to use in food producing animals rather then request an evaluation by JECFA, e.g. Stilbenes (in particular DES).

- Part of the problem with information/data availability appears to be the low response rate to the draft paper. Possibly this requires further discussion at the meeting. Without clear information on support, both positive and negative, and countries information on authorised uses, including label information, no decisions on actions regarding priority listing of the compounds can be taken.