



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-second Session

San José, Costa Rica, 27 April – 1 May 2015

**DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY
JECFA
(Report of the EWG on Priority)**

**Replies to CL 2014/3-RVDF from Algeria, Chile, Costa Rica, Norway, Republic of Korea and the United
States of America**

Background

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) at its 21st Session (August 2013) agreed to establish an Electronic Working Group, chaired by Australia and working in English only, to consider the replies to the Circular Letter requesting comments and information on the Priority List of Veterinary Drugs requiring Evaluation or Re-evaluation by JECFA and report to the 22nd CCRVDF.
2. The Circular letter CL 2014/3-RVDF (*Request for Comments/Information on Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA*) requested nominations for the priority list and was circulated in January 2014 with a closing date for responses of 15 December 2014.
3. That circular letter noted that according to Section 3.1.2 “Establishment of Priority List” of the *Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods* (Procedural Manual of the Codex Alimentarius Commission), in order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:
 - A Member has proposed the compound for evaluation (a template for information recommended for consideration in the priority list by Codex Committee on Residues of Veterinary Drugs in Foods has been completed and be available to the Committee);
 - A Member has established good veterinary practices with regard to the compound;
 - The compound has the potential to cause public health and/or international trade problems;
 - The compound is available as a commercial product; and
 - There is a commitment that a dossier will be made available.
4. Responses were received from Algeria, Chile, Costa Rica, Norway and the Republic of Korea.
5. The responses of Algeria, Chile, Norway and the Republic of Korea are summarised in Annex 1.
6. Costa Rica noted that it was difficult to propose priorities when they needed to be supported by scientific information.
7. An invitation to participate in the electronic Working Group on Priorities was circulated in October 2014 with a closing date for responses of 14 December 2014.
8. The Electronic Working Group consisted of Australia, Belgium, Germany, Iran, Japan, Norway, Peru, the Republic of Korea, the USA, FAO, WHO, Consumers International and the International Federation for Animal Health.
9. The Electronic Working Group considered the nominated veterinary drugs and an additional submissions to the Group from the USA.
10. International Federation for Animal Health members have confirmed data availability for all nominations except ampicillin and nitarstone.

11. The Electronic Working Group recommended that CCRVDF forward the Priority List (Annex 1) to the 38th Session of the Codex Alimentarius Commission for approval.

Recommendations

12. The Electronic Working Group on Priorities recommends that CCRVDF forward the Priority List (Annex 1) to the 38th Session of the Codex Alimentarius Commission for approval.

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

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments
Amoxicillin	Request MRL establishment in fin fish muscle and skin in natural proportions	Nominator notes that relevant MRLs are established in a number of countries. Some data in public domain.	Republic of Korea	JECFA ADI of 0–0.7 µg/kg body weight on the basis of microbiological effects (2011). MRLs established in EU for all food producing species. Classified by WHO as critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as critically important antimicrobial in veterinary medicine (VCIA) with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.
Ampicillin	Request ADI & MRL establishment in fin fish muscle and skin in natural proportions	Nominator notes that relevant MRLs are established in a number of countries. Availability of sponsor data not clear. Some data in public domain. IFAH members unable to provide data.	Republic of Korea	MRLs established in EU for all food producing species. Classified by WHO as critically important antimicrobial in human medicine (CIA). Prudent use in animal husbandry recommended. Classified by OIE as critically important antimicrobial in veterinary medicine (VCIA) with comments including: This class is very important in the treatment of many diseases in a broad range of animal species; Few economical alternatives are available.
Diflubenzuron	Request MRL establishment in fin fish (salmon) <i>muscle and skin in natural proportions</i>	Nominator notes pharmacokinetic, metabolism, residue depletion and method data available on request. Previous FAO-JMPR reports	Norway	ADI of 0-0.02 mg/kg body weight previously established by JMPR (1985). In 2001 JMPR confirmed the ADI established in 1985. MRL established in EU for Salmonidae. Norway notes CVMP is considering toxicological significance of metabolite 4-chloroaniline.
Ivermectin	Request re-evaluation of the current CODEX ADI and reevaluation of MRLs based on the revised ADI and other pertinent information	Toxicity in dogs, human tolerance and other use information in humans. Residue depletion study. Sponsor confirmed data availability	United States of America	JECFA ADI of 0–1 µg/kg body weight (1992). MRLs established by Codex and by many jurisdictions, including for all mammalian food producing species in EU. Cattle muscle MRL to be considered by 22 nd CCRVDF.
Lufenuron	Request ADI and MRL establishment in fin fish (salmon) <i>muscle and skin in natural proportions</i>	Nominator notes data available on request.	Norway and Chile	National registrations not confirmed at time of nomination. Fin fish MRL established in EU. Lufenuron on JMPR schedule for toxicology evaluation in 2015.

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments
Nitarsone	Request ADI & MRL establishment in turkey edible commodities	Pharmacology, toxicology, metabolism, residue depletion, analytical methods. IFAH members unable to provide data.	Algeria	JECFA Provisional Tolerable Weekly Intake (PTWI) for inorganic arsenic withdrawn (2011).
Teflubenzuron	Request MRL establishment in fin fish (salmon) muscle and skin in natural proportions	Nominator notes data exists and that relevant MRLs are established in a number on countries.	Norway	ADI of 0-0.01 mg/kg body weight previously established by JMPR (1994). Proposed for periodic review by JMPR in 2016. MRL established in EU for Salmonidae.