CODEX ALIMENTARIUS COMMISSION **E**





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

CX 4/60

CL 2012/30-RVDF October2012

TO: Codex Contact Points

Interested International Organisations

FROM: Secretariat, Joint FAO/WHO Food Standards Programme,

Codex Alimentarius Commission Viale delle Terme di Caracalla

00153 Rome, Italy

SUBJECT: REQUEST FOR COMMENTS/INFORMATION ON PRIORITY LIST OF VETERINARY

DRUGS FOR EVALUATION OR REEVALUATION BY JECFA

DEADLINE: 30 May 2013

COMMENTS: To: Copies to:

U.S. Codex Office, Secretariat

Food Safety and Inspection Service Codex Alimentarius Commission US Department of Agriculture Secretariat Joint FAO/WHO Food Standards

Room 4861, South Building, Programme

14th Independence Avenue, S.W., Viale delle Terme di Caracalla

Washington DC 20250, USA 00153 Rome, Italy E-mail: CCRVDF-USSEC@fsis.usda.gov E-mail: codex@fao.org

BACKGROUND

- 1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) at its 20th Session (May 2012) agreed to forward the Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA to the 35th Session of the Commission.
- 2. The Committee also agreed to establish a physical Working Group, chaired by Australia, open to all Members and Observers and working in English, French and Spanish, which would meet immediately before its next Session, 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 (Ref. REP12/RVDF paras 117-120 and Appendix IX).
- 3. The 35th Session of the Commission approved the list of veterinary drugs requiring evaluation or reevaluation by JECFA with the inclusion of zilpaterol hydrochloride (REP12/CAC para. 177 and Appendix IV).

REQUEST FOR COMMENTS/INFORMATION

- 4. <u>Governments and interested organizations are invited to make</u> proposals for veterinary drugs to be included to the priority list for subsequent recommendation to JECFA for evaluation or re-evaluation and to provide the information according to the template in the Annex to this document.
- 5. 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;

CL 2012/30-RVDF 2

- 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.

6. Governments and international organizations wishing to provide comments should do so in sending their comments **by e-mail** to the above addresses before <u>30 May 2013</u>.

CL 2012/30-RVDF 3

ANNEX

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

ADMINISTRATIVE INFORMATION

- 1. Member(s) submitting the request for inclusion
- 2. Veterinary drug names
- 3. Trade names
- 4. Chemical names and CAS registry number
- 5. Names and addresses of basic producers

PURPOSE, SCOPE AND RATIONALE

- 6. Identification of the food safety issue (residue hazard)
- 7. Assessment against the criteria for the inclusion on the priority list

RISK PROFILE ELEMENTS

- 8. Justification for use
- 9. Veterinary use pattern, including information on approved uses if available
- 10. Commodities for which Codex MRLs are required

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

11. Specific request to risk assessors

AVAILABLE INFORMATION¹

- 12. Countries where the veterinary drugs are registered
- 13. National/Regional MRLs or any other applicable tolerances
- 14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

TIMETABLE

15. Date when data could be submitted to JECFA

¹ When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.