CODEX ALIMENTARIUS COMMISSION





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

CL 2015/18-RVDF June 2015

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: 15 August 2016

COMMENTS:

U.S. Codex Office,

Food Safety and Inspection Service US Department of Agriculture Secretariat

Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA

E-mail: CCRVDF-USSEC@fsis.usda.gov

To: Copies to:

Secretariat

Codex Alimentarius Commission Joint FAO/WHO Food Standards

Programme

Viale delle Terme di Caracalla

00153 Rome, Italy E-mail: codex@fao.org

BACKGROUND

1. The 22nd Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF22) (27 April -1 May 2015) agreed to forward the Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA to the 38th Session of the Commission Alimentarius Commission for approval.

2. CCRVDF22 agreed to add the explanatory notes "This should include product labels or other evidence of official use authorisation" to point 9 "Veterinary use pattern, including information on approved uses if available" and "This should include a list of the data available with the full study titles" to Point 14 "List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods)" in the "Template for Information necessary for Prioritization by CCRVDF" attached to the Circular Letter requesting comments and information of the Priority List to clarify the type of information available (REP15/RVDF paras 111-112 and Appendix VIII).

REQUEST FOR COMMENTS/INFORMATION

- 3. <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.
- 4. 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.
- 5. Governments and international organizations wishing to provide comments should do so in sending their comments by e-mail to the above addresses before 15 August 2016.

CL 2015/18-RVDF 2

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 (this should include product labels or other evidence of official use authorization)
- 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 (this should include a list of the data available with the full study titles)

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.