

codex alimentarius commission

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FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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June 2009

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: REQUEST FOR COMMENTS/INFORMATION ON:

- I) VETERINARY DRUGS USED IN DEVELOPING COUNTRIES**
- II) PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION**

BACKGROUND

1. The Codex Committee on Residues of Veterinary Drugs in Foods at its 18th Session (May 2009) agreed to request the Codex Secretariat to prepare a Circular Letter requesting members and observers to provide comments and information on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA.

2. The Committee agreed to establish an electronic working group, led by Australia and open to all interested members and observers and working in English only, to prepare, based on the replies to the Circular Letter, a proposal for a priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA with a view to reaching a decision on the safety of residues in food by developing maximum residue limits (MRLs); or informing risk managers on the safety of residues in food if it is likely that an ADI or MRL cannot be set. The Committee agreed that the report of the electronic working group should be made available in a timely manner in order to allow consideration and comments by all members and observers.

3. The Committee also agreed to establish a physical working group, which would meet immediately before its next session, under the chairmanship of Australia, to consider the report of the electronic working group and comments submitted in order to facilitate the discussion in the Plenary.

4. The Committee noted the offer of the United States of America to assist developing countries in the submission of substances for inclusion in the Priority List in order that these nominations satisfy certain criteria in accordance with the "*Risk Analysis Principles Applied by the CCRVDF*"; and in particular, to assist developing countries in identifying data gaps and facilitating commitment by a sponsor to the provision of dossiers. It was agreed that the Circular Letter on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA would also request developing countries to indicate those priority compounds for which this assistance would be required and provide other relevant information. In view of this development, the Committee noted that at this time no further work was necessary on those compounds listed in the "Starting Point for a Priority List of Veterinary Drugs" for which not enough information was available (ALINORM 09/32/31 paras 138-142 and Appendix VI).

REQUEST FOR COMMENTS/INFORMATION**Part I - VETERINARY DRUGS USED IN DEVELOPING COUNTRIES**

Governments and interested organizations are invited to provide information on veterinary drugs essential for specific species raised in developing countries and for which no Codex MRLs exist at present. Information should include the name of the veterinary drugs, the country in which the MRLs are needed, the species of animal in which the veterinary drug is used and the tissues of interest, the dosage regimen including route of administration used, available product labels, existing data in support of the ADI and MRL, the source (or sponsor) of the data and manufacturer of the veterinary drug.

Governments and interested international organizations wishing to submit the above information should do so in writing, preferably by e-mail, to the U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (E-mail: uscodex@usda.gov, telefax: +1 202 720 3157) with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org, telefax : +39 06 5705 4593) **before 15 October 2009.**

Part II - PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION

Governments and interested organizations are invited to make 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 Annex 1 to this document.

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 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;
- It is available as a commercial products; and

There is a commitment that a dossier will be made available. Governments and interested international organizations wishing to submit the above should do so in writing, preferably by e-mail, to the U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (E-mail: uscodex@usda.gov, telefax: +1 202 720 3157) with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org, telefax : +39 06 5705 4593) **before 15 March 2010.**

**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
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
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework
12. Specific request to risk assessors

Available information¹

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

Timetable

16. 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.