

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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CL 2020/18-RVDF (Rev 1)

December 2020

TO: Codex Contact Points
Contact Points of international organizations having observer status with Codex

FROM: Secretariat,
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme

SUBJECT: **REQUEST FOR COMMENTS / INFORMATION ON THE PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA**

DEADLINE: **28 February 2021**

COMMENTS: **To:** CCRVDF Secretariat
U.S. Codex Office
Trade and Foreign Agricultural Affairs
US Department of Agriculture
E-mail: CCRVDf-USSEC@usda.gov

Copy to: Codex Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
E-mail: codex@fao.org

BACKGROUND

- The 24th Session of the Codex Committee on Veterinary Drugs¹ (CCRVDF24) (April 2018) agreed² to forward the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to the 41st Session of the Codex Alimentarius Commission³ (CAC41) (July 2018) for approval. The Commission approved⁴ the Priority List as submitted by the Committee.
- CCRVDF23 agreed⁵ to add information on the registration of the compound as a pesticide and, where applicable, information on the evaluation of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to the form requesting information on compounds for evaluation by JECFA, attached to the Circular Letter (CL) requesting proposals for inclusion in the Priority List.

REQUEST FOR COMMENTS/INFORMATION

Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

- Codex members and observers 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 the Annex 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 Maximum Residue Limit (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.

¹ CCRVDF meetings reports and working documents are available online at:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCRVDF>

² REP18/RVDF, paragraph 116 and Appendix VI, Parts A and D

³ CAC reports and working documents are available online at:

<http://www.fao.org/fao-who-codexalimentarius/committees/cac/meetings/en/>

⁴ REP18/CAC, Appendix VI

⁵ REP17/RVDF paragraph 27

Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF25

5. CCRVDF24 agreed⁶ to retain Ethoxyquin (feed additive use) on the Priority List subject to confirmation of the availability of data by the next session of CCRVDF.
6. Codex members and observers wishing to support the evaluation of this compound are kindly invited to confirm availability of relevant data / information for consideration at CCRVDF25.

Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation

7. JECFA88 (October 2019) was specifically convened to consider residues of veterinary drugs. JECFA evaluated in total eight veterinary drugs but could not recommend MRLs for the following compounds⁷: Ethion, Flumethrin, Fosfomycin and Sisapronil.
8. Codex members and observers wishing to support the completion of the evaluation of these compounds are kindly invited to confirm availability of the required data / information for consideration at CCRVDF25.

Part IV. Parallel review – Evaluation of a new compound

9. CCRVDF24 suggested that JECFA conduct a pilot parallel review on a new compound, including establishing an Acceptable Daily Intake (ADI) and recommending maximum residue limits (MRLs) while the same compound is still under review by a national authority for registration.⁸ JECFA88 could not complete the evaluation of the new compound Selamectin and therefore could not recommend MRLs for consideration by CCRVDF25.
10. This compound will be considered in light of the findings of the pilot parallel review carried out by JECFA88 (Agenda Item 3.1)⁹ and the consideration of the advantages and disadvantages of a parallel approach to a compound evaluation (Agenda Item 9)⁹. Confirmation or commitment of submission of the required data / information to enable JECFA to complete the evaluation would assist to inform the discussion on parallel review at CCRVDF25.
11. Codex members and observers wishing to support the parallel review exercise are kindly invited to provide relevant information that could inform the consideration of this matter / compound at CCRVDF25.

Background documents for consultation

12. Please check the following documents to inform your replies to this Circular Letter.

The Priority List as agreed at CCRVDF24 and contained in REP18/RVDF, Appendix VI (Parts A, B and C) available at: <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=24>

The Summary and Conclusions of JECFA88 (in particular Annex 3) available at:

<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/summary-reports/en/>

The full report of JECFA88 available at: <https://www.who.int/foodsafety/publications/jecfa-reports/en/>

REQUEST FOR COMMENTS

13. In view of the relocation of CCRVDF25 to 12-16 July 2021, the deadline for comments has been extended to give further opportunity to Codex members and observers to provide their comments in advance to CCRVDF25. Kindly note that, in view of the possibility that CCRVDF25 will be held in virtual mode, it is of utmost importance to submit proposals well in advance to the plenary session, i.e. to reduce the number of conference room documents (CRDs) to the minimum possible, in order to facilitate their consideration and inclusion in the Priority List by CCRVDF25 for approval by CAC44.
14. Codex member countries and observer organizations are invited to provide comments on the matters raised in Parts I, II, III and IV.
15. In particular for Part I, please submit proposals and relevant data / information by completing the template in the Annex. In addition, please consider the opportunity to submit proposals for compounds as shown in the Database¹⁰ on Countries' Needs for MRLs and High Priority Veterinary Drugs in Need of Codex MRLs.
16. Codex members and observers wishing to provide comments on the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA should send their proposals **by email, in word file**, to the above addresses and by the **deadline** indicated above.

⁶ REP18/RVDF, paragraph 113 and Appendix VI, Part B

⁷ REP18/RVDF, paras. 112 and 144, Appendix VI, Parts A and C respectively.

⁸ REP18/RVDF, paras. 98-103

⁹ CCRVDF25 working documents are available at:

<http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCRVDF&session=25>

¹⁰ CX/RVDF 20/25/11, paras. 11-13 and Appendix:

http://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CCRVDF25_Database_Country_Need_MRLs_veterinary_drugs_Appendix_E.xlsx

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 INFORMATION¹¹

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 and whether the compound is also registered as pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re-evaluation by JMPR*)

TIMETABLE

15. Date when data could be submitted to JECFA.

¹¹ 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.