CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

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

**CL 2022/72-RVDF**
**October 2022**

**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:** **10 January 2023**

**BACKGROUND**

1. The 25th Session of the Codex Committee on Veterinary Drugs[1] (CCRVDF25) (2021) agreed[2] 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 44th Session of the Codex Alimentarius Commission[3] (CAC44) (2021) for approval. CAC44 approved[4] the Priority List as submitted by CCRVDF25.

2. CCRVDF23 (2016) agreed[5] 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.

3. CCRVDF25 (2021) further agreed[6] to recommend that the database on countries' needs for MRLs for veterinary drugs in foods be made available as a reference document at every session of CCRVDF; and should be available to the Codex Secretariat to accompany the distribution of the circular letter (CL) requesting comments on the priority list of veterinary drugs for evaluation by JECFA. CCRVDF therefore encouraged:

   (i) Codex member countries and observer organizations to submit relevant data/information to allow the evaluation of those compound/commodity combinations identified as high priority needs and as feasible starting points for establishment of relevant MRLs; and

   (ii) Codex member countries and observer organizations to submit relevant data/information to allow the evaluation of other compound/commodity combinations identified in the database on countries' needs for MRLs for veterinary drugs.

4. The database on countries' needs for MRLs for veterinary drugs in foods can be downloaded from: https://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CCRVDF26DBcountriesneedsMRLsvetdrugsE.xlsx

**REQUEST FOR COMMENTS/INFORMATION**

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

5. 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, including compounds listed in the database on countries' needs for MRLs for veterinary drugs in foods as appropriate (see paragraphs 3-4), and to provide the information according to the template in the Annex to this document.

---

1 CCRVDF reports and working documents are available online at: http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCRVDF
2 REP21/RVDF25, para. 116 and App. VI, Parts I and V
3 CAC reports and working documents are available online at: http://www.fao.org/fao-who-codexalimentarius/committees/cac/meetings/en/
4 REP21/CAC44, App. VI
5 REP17/RVDF23, para. 27
6 REP21/RVDF25, paras. 126-128

6. 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[7]), 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 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 regarding the compound.
- The compound has the potential to cause public health and/or international trade problems.
- The compound is available as a commercial product.
- There is a commitment that a dossier will be made available.

**Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF26**

Amoxicillin, Ethoxyquin and Norfloxacin

7. CCRVDF25 agreed[8] to retain Amoxicillin, Ethoxyquin (feed additive use) and Norfloxacin on the Priority List subject to confirmation of the availability of data by CCRVDF26 (2023).

8. Codex members and observers wishing to support the evaluation of these compounds are kindly invited to confirm availability of relevant data/information for consideration at CCRVDF26.

**Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation**
**Part IV. Parallel review - Evaluation of a new compound**

Ethion, Flumethrin and Fosfomycin

9. JECFA88 (2019) could not recommend MRLs for these compounds with the available data.

10. CCRVDF25 noted[9] the continuing JECFA evaluations for these compounds.

11. Codex members and observers who supported the evaluation of these compounds at CCRVDF25 are kindly invited to update on or reconfirm availability of relevant data/information for consideration at CCRVDF26 as indicated in REP21/RVDF25, Appendix VI, Part III.

12. Other Codex members and observers wishing to support the evaluation of these compounds are kindly invited to confirm availability of relevant data/information for consideration at CCRVDF26.

Imidacloprid and Selamectin

13. JECFA94 (2022) evaluated 4 veterinary drugs i.e., Imidacloprid, Ivermectin, Nicarbazin and Selamectin but could not recommend MRLs for the following compounds:

- Imidacloprid: JECFA could not establish an acceptable daily intake (ADI) or an acute reference dose (ARfD), therefore an MRL could not be recommended for this compound.
- Selamectin: JECFA could not recommend MRLs due to a lack of established good veterinary practice (GVP).

*Parallel review discussion in CCRVDF*

CCRVDF24 (2018) 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.[10] JECFA88 could not complete the evaluation of the new compound Selamectin and therefore could not recommend MRLs for consideration by CCRVDF25.

CCRVDF25 (2021) considered this compound in light of the findings of the pilot parallel review carried out by JECFA88[11], the consideration of the parallel review of a new veterinary drug by JECFA and national regulatory agencies and the priority list of veterinary drugs for evaluation or re-evaluation by JECFA. The Committee further noted the continuing parallel review of Selamectin by JECFA.

14. 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 CCRVDF26.

---

7 https://www.fao.org/fao-who-codexalimentarius/publications/en/
8 REP21/RVDF25, para. 147, App. VI, Part II
9 REP21/RVDF25, para. 148, App. VI, Part III
10 REP18/RVDF24, paras. 98-103
11 REP21/RVDF25, paras. 117-122, 129, 149, App. VI, Part IV

**Background documents for consultation**

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

- The Priority List as agreed at CCRVDF25[12]
- The Summary and Conclusions of JECFA88[13] and JECFA94[14]
- The full report of JECFA88[15] and JECFA94[16]
- Other relevant JECFA documents such as toxicological/residue monographs as available on the FAO and WHO websites[17]

**REQUEST FOR COMMENTS**

16. Codex member countries and observer organizations are invited to provide comments on the matters raised in Parts I, II, III and IV.

**GUIDANCE ON THE PROVISION OF COMMENTS**

17. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.

18. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting "Enter" in the "My reviews" page, available after login to the system.

19. Contact Points of Codex members and observers' organizations are requested to provide proposed changes and relevant comments/justifications on a specific paragraph (under the categories: editorial, substantive, technical and translation) and/or at the document level (general comments or summary comments). Additional guidance on the OCS comment categories and types can be found in the OCS Frequently Asked Questions (FAQs).

20. Other OCS resources, including the user manual and short guide, can be found at the following link: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

21. For questions on the OCS, please contact Codex-OCS@fao.org.

12 REP21/RVDF25, paras. 129-150, App. VI (Parts II, III and IV)
13 https://www.fao.org/3/ca7030en/ca7030en.pdf
14 https://www.fao.org/3/cc0433en/cc0433en.pdf
Ninety-fourth meeting - Joint FAO/WHO Expert Committee of Food Additives (JECFA)
15 https://www.who.int/publications/i/item/9789241210324
16 https://www.who.int/publications/i/item/9789240057586
17 FAO: https://www.fao.org/food-safety/resources/publications/en/
WHO: https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)

**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 INFORMATION[1]

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.

### ADDITIONAL INFORMATION

16. Please provide additional information as appropriate by:

- Including links under this section and/or
- Sending attachments to the following addresses: CCRVDF-USSEC@usda.gov with a copy to codex@fao.org.

**Note**: Codex members interested in proposing MRLs for compounds listed in the database on countries' needs for MRLs for veterinary drugs can download the list of compounds/tissues from: https://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CCRVDF26DBcountriesneedsMRLsvetdrugsE.xlsx

[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.