CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

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

CL 2021/5/OCS-RVDF
January 2021

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 on the principles and procedure for the parallel review of a new veterinary drug by JECFA and national regulatory agencies**

DEADLINE: **30 April 2021**

BACKGROUND

1. For background information, please refer to document CX/RVDF 20/25/10[1].

2. In view of the postponement of 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF25) to 12-16 July 2021, and the possible holding of this Session in virtual mode, Codex members and observers are encouraged to submit comments in reply to this CL in order to facilitate the consideration of this matter at the upcoming CCRVDF.

REQUEST FOR COMMENTS

3. Codex members and observers are invited to submit comments on the (i) principles and (ii) proposed process for the parallel review of a new veterinary drug by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and national regulatory agencies while taking into account the advantages and challenges of the proposed process including other considerations raised in CX/RVDF 20/25/10, paragraphs 13 – 18 and findings of the pilot on a parallel review of a new compound (i.e. selamectin) by the 88th Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA88) as provided in CX/RVDF 20/25/3.

4. In submitting comments, please indicate:

   a. General Comments: Whether your country / organization support the parallel review of a new veterinary drug as an alternative / complement to the current[2] process to assess new compounds by JECFA for the establishment of Codex MRLs by CCRVDF and if so, whether the overall format and content of the proposed procedure is agreeable to you.

   b. Specific comments:

      (i) Principles: Whether there additional principles that could/should be taken into account and whether the text for the current principles could be further enhanced.

      (ii) Procedure: Whether there are missing points that need to be included (e.g. additional provisions under each phase, additional phases, etc.) and whether the text for the current provisions could be further enhanced.

   c. Other comments / consideration besides those described in points (a) and (b).

5. For convenience, the principles and process are reproduced in the Annex to this circular letter and uploaded onto the Codex Online Commenting System[3] (OCS), as per the guidance below.

---

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

2 The procedure for the establishment of Codex MRLs for veterinary drugs is described in the Risk Analysis Principles applied by CCRVDF (Procedural Manual, 27th Edition: http://www.fao.org/fao-who-codexalimentarius/publications/en/).
See also CX/RVDF 20/25/10, figure representing the current vs proposed procedure)

3 https://ocs.codexalimentarius.org/

GUIDANCE ON THE PROVISION OF COMMENTS

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

7. 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.

8. 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)[4].

9. Other OCS resources, including the user manual and short guide, can also be found on the Codex website[5].

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

[4] http://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/OCS/Codex_OCS_FAQs_2017-11-06.pdf
[5] http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

PRINCIPLES AND PROCEDURE FOR THE PARALLEL APPROACH TO THE EVALUATION OF A NEW VETERINARY DRUG BY JECFA AND NATIONAL REGULATORY AUTHORITIES[6]

PRINCIPLES

The following principles, as is the case during any scientific review by JECFA, should be observed:

1. **Transparency**. Nominating member country and drug sponsor should identify if a veterinary drug is intended for a parallel process and be open about dossier submission timeframes.
2. **Confidentiality**. Much of the data submitted to JECFA or national regulator(s) is confidential and there is a good precedent to respect the confidentiality of the data.
3. **Independence**. The national authorization process and JECFA process are two separate independent processes and subject to their own independent decisions and therefore are not contingent on one another.

PROCEDURE

The proposed phases of the process are:

Phase 1: Identification of a candidate

1. A product is identified by a drug sponsor and during bilateral discussions with a member country(ies), the product is identified as a candidate. The current Priority List nomination requirements of a veterinary drug would also apply to a JECFA parallel review process. The Risk Analysis Principles Applied by the CCRVDF lists criteria required for a veterinary drug to appear on the Priority List. A 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."

Phase 2: Submission

2. A product is submitted (or is expected to be submitted) to a national regulatory authority, most likely in one of the larger markets (in practice, most veterinary products are first submitted for review in the U.S. or in Europe). At the following CCRVDF meeting, the product would be submitted (by the Codex Member who received the product application or is expected to receive the application by a certain date) for inclusion on the priority list at CCRVDF (Step 1).

Phase 3: Assessment

3. JECFA and the national assessor follow their normal processes of assessing the product. (Step 2).

Phase 4:

4. Draft ADI and MRLs proposed by JECFA and circulated for comment (Step 3).
5. The remainder of the uniform procedures for the elaboration of Codex standards and related texts would be followed, consistent with the current process.

[6] The footnote provides relevant background documents to inform comments on the principles and the procedure: CX/RVDF 20/25/10: http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=25 The procedure for the establishent of Codex MRLs for veterinary drugs is described in the Risk Analysis Principles applied by CCRVDF (Procedural Manual, 27th Edition: http://www.fao.org/fao-who-codexalimentarius/publications/en/). See also CX/RVDF 20/25/10, figure representing the current vs proposed procedure.