CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8(b) **CX/RVDF 13/21/9**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-first Session

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

PROPOSED "CONCERN FORM" FOR THE CCRVDF (FORMAT AND POLICY PROCEDURE FOR ITS USE)

(Report of the CCRVDF Electronic Working Group on the "Concern Form")

Governments and international organizations wishing to submit comments on the proposed "Concern Form" for the CCRVDF (*see* Annex 1) are invited to do so **no later than 30 June 2013** as follows: 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: CCRVDF-USSEC@fsis.usda.gov , with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy; E-mail: Codex@fao.org).

Please note that only comments submitted by the above deadline will be compiled, translated and made well in advance to the 21st CCRVDF.

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in Annex 2 to this document.

Background

1. The CCRVDF during its Twentieth Session advanced the work done on the revision of the *Risk Analysis Principles applied by the CCRVDF* and, as a result of the Working Group, which agreed on the usefulness of the "concern form", the Committee agreed that further work was needed. An electronic Working Group was established chaired by Australia and Brazil to develop the scope of the "concern form", the procedure policy for its use and its format, for circulation for comments and consideration by the next Session. The Working Group was also requested to take into account the work of CCPR in this regard, while noting that the scope of the concern form for CCRVDF should not be limited to the scope of the concern form agreed in CCPR.

2. The CCRVDF further noted that the Codex Committee on General Principles, in relation to its discussions on standards held at Step 8, had agreed to establish a facilitated discussion group that would identify and consider root causes of holding standards at Step 8 and that a summary report of their discussions would be made available (ref. REP12/GP, para. 19 and 25-29). The Committee noted that this summary report could be useful in discussions on the "concern form" in CCRVDF.

Proceedings of the Electronic Working Group

3. The electronic Working Group worked through email and two drafts were circulated for comments.

4. The Working Group received comments from Argentina, Australia, Brazil, Chile, Costa Rica, Europe, Japan, Norway, the United States of America and IFAH. The proposal reflects consideration of the comments received to improve the scope, procedure and format of the "concern form".

Discussion

5. While mainly the comments received within the Working Group were in favor of the adoption of a "concern form" by CCRVDF, some countries expressed that there would be no need for "concern forms" at this Committee because of the low numbers of MRLs to deal with at each Session and also because of the ample opportunities that countries have to bring forward their concerns during the risk analysis procedure and the Codex step procedure. Significant comments on the improvement of the scope, procedure and format of the "concern form" were received in response to the circulated documents.

Recommendation

6. The electronic Working Group recommends that the present proposal of the scope, procedure and format of the concern form (see Annex 1) is considered at the specific physical Working Group prior to the 21st Session of CCRVDF, in order to facilitate the discussion and progress of the document.

7. After the adoption of the concern form by the Committee, the agreed procedure should be added to the *Risk Analysis Principles Applied by the CCRVDF* in the Codex Procedural Manual and the format for the concern form should be shared within an appendix to the CCRVDF Report.

Annex 1

PROPOSED "CONCERN FORM" FOR THE CCRVDF (FORMAT AND POLICY PROCEDURE FOR ITS USE)

(for comments)

SCOPE

1. A concern form, as already used by the Codex Committee on Pesticide Residues - CCPR since 2006, is intended to be a tool for Member States to put forward concerns and requests for clarification, accompanied where appropriate with scientific data and information, to the attention of JECFA concerning its risk assessment. It is important because it will assist in making CCRVDF decisions more transparent and can help to advance the proposed draft MRLs.

2. The use of a concern form will facilitate the progress of Codex standards as it ensures that concerns raised at CCRVDF are clearly articulated and, where appropriate, have supporting scientific information for JECFA to evaluate. It provides formality and transparency to the way scientific concerns are expressed to the Committee and will ensure that the concerns are accurately captured and efficiently addressed, allowing the standards (MRLs) to move forward as supported by the science.

3. The concern form is intended to be used when the draft proposed or proposed MRLs are circulated for comments at Step 3 or Step 6 of the Step Procedure. It should be submitted directly to CCRVDF Secretariat prior to its session in order to be circulated among CCRVDF members. Earlier submission of the concern form to CCRVDF might allow JECFA to prepare clarification in response to some concerns during the plenary session, would facilitate the discussion and lead to more rapid consensus.

4. The concern form procedure should be added to the *Risk Analysis Principles Applied by the CCRVDF* in the Codex Procedural Manual when adopted by the CCRVDF. The format for the concern form should be shared within an appendix to the CCRVDF Report to allow for rapid revision if necessary.

PROCEDURE

5. The Working Group proposes the following procedures for the use of concern forms:

- Concern forms should be submitted on the proposed draft or draft MRLs circulated for comments at Step 3 or Step 6 of the Step Procedure, according to the deadline set by the Codex Secretariat;
- Concerns described in the concern form must have sound supporting data or scientific based information that should be made available for a JECFA review. Scientific data should be complete and not a summary statement or synopsis;
- Requests for clarification related to interpretation of the existing supporting data (e.g. review of the ADI) can be submitted without the need for any additional data;
- When necessary, concern supporting data should be made available to the appropriate JECFA Secretariat within one month after the CCRVDF Session for which the concern form was provided, and the Chair and members of the CCRVDF should be informed of the submission to the JECFA Secretariat;
- If the concern is entered at Step 3, the specific MRLs will not advance beyond Step 5, but the rest of the MRLs may be advanced to Step 5/8. If the concern is entered at Step 6, the specific MRLs will not advance beyond Step 7;
- The JECFA Secretariat should schedule the concern for a JECFA review by an appropriate mechanism to allow JECFA to respond by the next CCRVDF Session;
- If the data/information is not provided to the JECFA Secretariat by the one month deadline for submission or the JECFA recommended MRLs remain unchanged, the relevant draft MRLs will follow the normal Step procedure, consistent with the decisions of the most recent CCRVDF Session;
- If necessary, a physical Working Group should be conveyed immediately before the CCRVDF Session in order to discuss and organize the concern forms received.

FORMAT

CONCERN FORM OR REQUEST FOR CLARIFICATION ON THE ADVANCEMENT OF DRAFT MRLs

- *Submitted by:*
- *Date:*
- *Veterinary drugs concerned:*
- *Commodity (species and tissues):*
- *MRL (mg/kg):*
- *Present Step:*
- *Is this a Request for Clarification?*
- *Is this a new Concern?*
- *Concern (Specific statement of reason for concern to the advancement of the proposed MRL):*
- *Request for Clarification (Specific statement of clarification requested):*
- *-Types of data or analysis that will be submitted to JECFA concerning (i.e. toxicology, residue, microbiology, diet):*
- *Proposed solution (consistent with Codex Principles)*
- *Do you wish this Concern to be noted in the CCRVDF Report?*
- *Background materials attached (e.g., outline of data to be submitted to JECFA)?*

Annex 2

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.