

ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 26th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF26)

13 to 17 February 2023

Portland, Oregon, United States of America

Agenda item 9.1: Matters of interest arising from the Joint CCPR/CCRVDF Working Group

Agenda item 9.2: Work in parallel on issues pertaining to harmonization of edible offal i.e. Classification of Food and Feed (CXA 4-1989) and Food descriptors – Coordination between JECFA/JMPR

Objective

This document offers a review and analysis of the agenda items planned for discussion at the 26th session of the **Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)**, scheduled to take place face to face from 13 to 17 February 2023. This document is intended for possible use by the Codex communities of practice, promoted by <u>GFORSS</u> and <u>PARERA</u>, as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of select agenda items, their background, and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above (PARERA and GFORSS), their membership, or their management. It provides a synthesis and analysis of the work currently under discussion by the CCFA, which may be useful for delegations from Codex delegations, part of the GFORSS Network Community, to prepare their positions considering the needs and specificity of the region and the potential impact of the proposed food standards.

This analysis is prepared as part of the <u>Codex Initiative for South West Pacific</u>: <u>South West Pacific Codex</u>, implemented by <u>GFoRSS</u> and Venture 37, in Partnership with the Governments of Australia and New-Zealand and funded by the US Codex Office, US Department of Agriculture.

Agenda item 9.1: Matters of interest arising from the Joint CCPR/CCRVDF Working Group

Document

CX/RVDF 23/26/9

Background

CCEXEC73 (2017) noted that the work of CCRVDF included compounds used as both veterinary drugs and pesticides and encouraged closer collaboration between CCRVDF and CCPR when considering MRLs for compounds used as both veterinary drugs and pesticides. CCEXEC73 invited the two Committees to explore innovative ways to foster such collaboration.

CCEXEC77 (2019) called upon CCPR and CCRVDF to collaborate and synchronize work on issues of common interest to both committees to the extent possible to facilitate the establishment of MRLs for pesticides/veterinary drugs for compounds with dual uses.

CCEXEC78 (2020), in performing the regular review of Codex Work Management 2018-2019 (Critical Review Process), noted that cross-committee cooperation including joint EWGs was important and should be encouraged and taken into account in future work planning.

The 81st Session of CCEXEC (2021), the committee recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues between CCRVDF and CCPR to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.

CCRVDF25 (2021) sought advice from the Executive Committee (CCEXEC) on a mechanism for cooperation between CCPR and CCRVDF on the establishment of harmonized Maximum Residue Limits (MRLs) for compounds with dual use.

CCPR52 (2021) encouraged ways to facilitate and promote cooperation on cross-sectional issues between CCRVDF and CCPR.

CCPR53 (2022) noted the information provided by the Chair of the Joint CCPR/CCRVDF EWG on the status of work under their mandate, supported the activities of the Joint EWG and encouraged members and observers to actively participate in the work of the Joint EWG.

CAC44 (2021) agreed to establish a Joint CCPR/CCRVDF EWG chaired by the United States of America, open to all Members and observers working with the support of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Codex Secretariat to address procedural and technical issues related to the establishment of harmonized MRLs for compounds with dual use as described in the Terms of Reference (ToRs):

- The Joint EWG will review work already done cooperatively between CCPR and CCRVDF and will identify, and if possible, prioritize areas of possible further collaboration between CCPR and CCRVDF and how this could be carried out (e.g., jointly, in parallel, etc.) so as to facilitate the consideration of compounds with dual uses by both committees and the possible harmonization of MRLs.
- This may include reflections on improved synchronization of work between CCPR and CCRVDF as well as collaboration between CCPR/CCRVDF and JMPR/JECFA.
- The Joint EWG will provide an update on their preliminary findings to CCPR53 (2022) and CCRVDF26 (2023).

During the CCRVDF26, the Committee will consider the proposal on the work of the electronic working group between CCPR and CCRVDF.

Analysis

The Joint EWG will not replace the ongoing parallel cooperation between the established EWGs under CCRVDF (edible offal) and CCPR (revision of the Classification).

Proceedings of the Electronic Working Group

Two rounds of questions were posted to the Joint EWG, and members were asked to provide comments:

- What work has been done cooperatively between CCRVDF and CCPR?
- What are areas where CCRVDF and CCPR could collaborate in the future?
- ❖ What mechanisms could be used to collaborate between CCRVDF and CCPR?
- What mechanisms could be recommended to JMPR and JECFA to facilitate data sharing between the two risk assessments groups?
- What are ways in which a new Joint EWG could identify and recommend adoption of single, harmonized MRLs for dual-use compounds that have different MRLs for the same edible commodity of animal origin?
- Are there any additional topics affecting both CCPR and CCRVDF that have not been considered by either the draft discussion paper or questions?

The following recommendations to CCPR and CCRVDF were derived from the comments submitted to the EWG.

- The EWG recommends that CCPR and CCRVDF ask JECFA and JMPR to continue working towards harmonizing their risk assessment methodologies, including ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds. This might include exploring the feasibility of a joint evaluation of dual-use compounds and the formation of Joint JMPR/JECFA EWG.
- The EWG recommends that CCPR and CCRVDF ask JECFA and JMPR to consider ways in which data can be shared between the two expert committees. This might include JECFA/JMPR asking sponsors to consent to data sharing upon submission of the data packages.
- The EWG recommends that CCPR and CCRVDF continue to support the current joint EWG to identify and prioritize issues affecting both committees and recommend ways to address the issues and to inform CAC accordingly.
- ❖ The EWG recommends that CCPR and CCRVDF develop a database of dual-use compounds that can be shared between committees to facilitate the development of a single, harmonized MRL. Member countries will provide the entries to the database.
- The EWG recommends that CCPR and CCRVDF form a Joint EWG that will identify dual-use compounds that have different MRLs for the same edible commodity of animal origin and recommend a single, harmonized MRL(s) for the compound(s) and affected commodity (ies). The working group might consider selecting the higher MRL value and recommending that JMPR/JECFA conduct a risk assessment using the higher value to determine its acceptability.

Main Comments from Other Codex Delegations

Areas where CCRVDF and CCPR could collaborate in the future:

- Continue working towards harmonizing definitions for edible commodities of animal origin.
- Harmonizing the risk assessment methodologies used by JECFA and JMPR and possibly conduct a joint evaluation of dual-use compounds.
- Establishing a harmonized acceptable daily intake (ADI) for dual-use compounds, if possible.
- Developing an approach to harmonize MRLs after JECFA and JMPR have recommended MRLs.

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- Developing a database for dual-use compounds to facilitate the development of harmonized MRLs between CCPR and CCRVDF.
- Reviewing how to cooperate on antimicrobial compounds with dual use and whether any restrictions should apply.

Possible mechanisms of collaboration between CCRVDF and CCPR

- One or more joint EWGs to address cross-sectional issues as a way to continue collaboration between CCPR and CCRVDF.
- ❖ A joint EWG to discuss and prioritize the JMPR/JECFA evaluation of dual-use compounds and a joint EWG to evaluate and determine how to harmonize MRLs for dual-use compounds that have different MRLs for the same edible commodity.
- ❖ Increased communication and/or data and information sharing between JECFA and JMPR could help harmonize MRLs for dual-use compounds.
- Ask sponsors to allow both JECFA and JMPR access to their data on dual-use compounds.
- Increased coordination at both the risk assessment and risk management level.

Possible mechanisms which could be recommended to JMPR and JECFA to facilitate data sharing between the two risk assessments groups

- Continue support for the efforts taken by JMPR and JECFA to harmonize the risk assessment methodologies and communicate on cross-cutting issues.
- Ask sponsors to allow both committees (JMPR and JECFA) access to the data packages used to establish MRLs.
- Checkbox on the data submission form that a sponsor could check to signal their agreement with sharing the data between JMPR and JECFA.
- ❖ Encourage sponsors to allow the data to be shared between JMPR and JECFA.

General conclusion and recommendations

SWP delegations may support all proposed recommendations that were derived from other codex delegations to CCPR and CCRVDF.

Agenda item 9.2: Work in parallel on issues pertaining to harmonization of edible offal i.e. Classification of Food and Feed (CXA 4-1989) and Food descriptors – Coordination between JECFA/JMPR

Background

CCPR52 agreed to re-establish the EWG on the revision of the Classification, to continue working on the revision of the Classification as well as matters related to edible animal tissues (including edible offal) in collaboration with the CCRVDF/EWG on Edible Offal.

CCRVDF25 (2021) was informed that the current definition was developed in the framework of cooperation between CCPR and CCRVDF through the parallel work between the CCRVDFEWG on edible offal and the CCPR EWG on the revision of the Classification of Food and Feed (CXA 4-1989) for the purpose of harmonization and to facilitate the establishment of single MRLs for compounds with dual uses.

CCRVDF 25 noted that Recommendations related to the Classification and extrapolation of MRLs were inter-related and was part of the further collaborative work between CCRVDF and CCPR that could be carried out in parallel between the CCRVDF/EWG on edible offal and the CCPR/EWG on the revision of the Classification.

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CCRVDF25 agreed to (i) forward the definition of edible offal as amended by the Committee for inclusion in the Glossary of Terms and Definitions (CXA 5-1993) to CAC44 (2021) for adoption; (ii) recommend CCPR to adopt the same definition for consistency and facilitation of establishment of MRLs for compounds with dual purposes; and (iii) re-establish the EWG, chaired by Kenya, and co-chaired by New Zealand, to work in parallel with the CCPR/EWG-Classification on issues pertaining to harmonization of edible offal (Recommendations 3 to 7).

CCPR53 (2022) agreed to:

- ❖ Harmonize its definition for edible offal with that of CCRVDF as adopted by CAC44.
- Forward the definitions for edible offal, meat, muscle and fat, including definitions for the portion of the commodity to which MRLs apply and which is analyzed for fat and muscle, to CAC for adoption and to inform JMPR accordingly.

CAC44 (2021) agreed to establish a Joint CCPR/CCRVDF on issues of common interest to both Committees.

The EWG continued to work on edible animal tissues, including edible offal, in collaboration with the CCRVDF/EWG on edible offal based on the recommended definition provided by CCRVDF25.

During the CCRVDF26 (2023), the committee will consider the recommendations (3 to7) for edible offal and other animal tissues of relevance for the purpose of harmonization and elaboration of MRLs for compounds with dual uses (either as pesticides or veterinary drugs).

Analysis

CCPR and CCRVDF have taken action within the current available procedures to improve communication through standing common agenda items such as referring matters of concern through the Codex Secretariat or through the identification of specific issues of concern such as harmonization of the definition of edible offal and the establishment of parallel EWGs sharing the mandate of work together on issues pertaining to harmonization of terminology and definitions, including a possible harmonization of the Classification of Food and Feed, that could support the establishment of MRLs for pesticides and veterinary drugs for food of animal origin.

Recommendations for edible offal and other animal tissues of relevance for the purpose of harmonization and elaboration of maximum residue limits for compounds with dual uses.

Definition for edible offal for adoption:

Those parts of an animal, apart from the skeletal muscle and fat, that are considered fit for human consumption

- 1. CCRVDF to adopt the definition for edible offal and to incorporate it in the Glossary of Terms and Definitions (Residues of Veterinary Drugs in Foods) (CXA 5-1993).
- 2. CCRVDF to recommend CCPR to adopt the same definition for consistency and facilitation of MRLs for dual compounds.

Recommendations (1 and 2) are achieved after adoption by CCRVDF25, CAC44 and CCPR53 – the current definition of edible offal was developed based on cooperation between CCPR Electronic Working Group (EWG) on the revision of the Classification of Food and Feed and the CCRVDF/EWG on Edible Offal for the purpose of harmonization and to facilitate the establishment of single MRLs for compounds with dual uses.

CCRVDF26 will consider the following recommendations (3 to7):

- Classification of Food and Feed (CXA 4-1989)
 - 3. CCRVDF and CCPR to explore the possibility to develop a mechanism for consolidation of edible offal hierarchical classification in the Classification of Food and Feed (CXA 4-1989) while considering that different extrapolation rules would apply for residues of pesticides and veterinary drugs for edible animal tissues (including offal) and to other food animal species.
- > Extrapolation of MRLs for edible offal

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- 4. The CCRVDF EWG on extrapolation should continue its work and develop rules applicable to residues of veterinary drugs.
- 5. CCRVDF to develop and apply a suitable approach for the extrapolation of residues of veterinary drugs in edible offal when appropriate.
- 6. CCPR and CCRVDF to consider setting MRLs for edible offal based on extrapolation rules rather than setting MRLs for individual edible offal tissues.
- Other Matters: Food descriptors Coordination between JECFA/JMPR
 - 7. CCRVDF to seek guidance from JECFA on appropriate descriptors, such as "fat", "fat with skin", "fat/skin", "skin", and to recommend JECFA to coordinate with JMPR on this matter.

General comments

Referring to the CL 2021/6/OCS-RVD related to the request for comments on the recommendations for edible offal and other animal tissues of relevance for the purpose of harmonization and elaboration of maximum residue limits for compounds with dual uses.

- Egypt agrees with "the above definition for edible offal and the above recommendations" taking into account the following points:
 - 1) It is necessary to apply the rules of extrapolation of residues of veterinary drugs in edible offal.
 - 2) Applying extrapolation to setting MRLs for edible offal is a temporary process with the necessity to recommend JECFA to confirm MRLs for edible offal tissues.
- ❖ Iran considers that the definition of edible offal as that recommended by CCPR but for classification as edible offal globally may not be appropriate due to the large variety of tissues and textures making each situation regarding residues significantly different. Since it cannot be classified in one group thus, it is recommended to classify them according to the residue survey for certain groups.
- ❖ Peru agrees with the recommendations pertaining to edible offal and other relevant animal tissues with a view towards harmonizing and developing MRLs for dual use compounds and notes that if scientific information existed supporting the extrapolation of MRLs in edible offal, it would be possible to consider applying that rather than establishing an MRL for each edible offal. In addition, Peru agrees with the proposal to seek the advice of JECFA in coordination with JMPR on the appropriate use of terms such as "fat," "fat with skin," "fat/skin," and "skin."
- Australia considers that under the current proposal it appears edible skin could be classified as offal.
- Ecuador consider that the agreement on the recommendation of the 51st meeting of the CCPR, that the advice of JECFA/JMPR be sought regarding appropriate descriptors. It is pertinent that—due to the existence of different circumstances for veterinary drugs whose use or application is essentially direct treatment, unlike the incidental exposure that can occur with pesticides—it would be feasible to request guidance from the risk assessment bodies (JECFA and JMPR) for this type of extrapolation, keeping in mind the difference between veterinary drugs and pesticides, as well as their uses.

Conclusion and recommendation

SWP Codex delegations may support all proposed recommendations for edible offal and other animal tissues of relevance for the purpose of harmonization and elaboration of maximum residue limits for compounds with dual uses.