

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 9.1

CX/RVDF 23/26/9-Add.1

January 2023

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26th Session
13-17 February 2023

Portland, Oregon, United States of America

MATTERS OF INTEREST ARISING FROM THE JOINT CCPR/CCRVDF WORKING GROUP

Comments in reply to CL 2022/78-RVDF

submitted by

*Brazil, Canada, Chile, Egypt, European Union (EU), Kenya, Peru,
Saudi Arabia, Thailand, Uganda and African Union (AU)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to circular letter CL 2022/78-RVDF¹ issued in December 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections. For this CL, comments comprise general and specific comments.

Explanatory notes on the annexes

2. Comments submitted through the OCS are hereby annexed and presented in tabulated format.

¹ <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

GENERAL AND SPECIFIC COMMENTS

COMMENT	MEMBER/OBSERVER
<p><u>Whether the recommendations are agreeable as proposed by the Joint EWG</u></p> <p>Brazil congratulates the EWG on its work and supports recommendations 2 and 3 under section 26 as proposed by the Joint EWG.</p> <p>Regarding the recommendation that CCPR and CCRVDF develop a database of dual-use compounds, Brazil suggests the inclusion, in the database, of all dual use compounds registered in Member States (with MRLs established by both Committees, by one Committee only, or no MRLs established) and that, afterwards, a priority list is derived from this database for a joint JECFA/ JMPR risk assessment.</p> <p>Regarding the other recommendations, Brazil agrees that JECFA and JMPR should continue working towards harmonizing their risk assessment methodologies to establish a single, harmonized acceptable daily intake (ADI) for dual use compounds.</p> <p>As for establishing single/ harmonized MRLs for these compounds, Brazil agrees that having a single harmonized MRL is important from the perspective of monitoring the presence of the compound in food of animal origin.</p> <p>However, if a single, harmonized MRL is to be established for a certain animal tissue, the two Committees will need to find ways to determine how much of the residues could derive from the use of the compound as a veterinary drug and how much could come from animal feed (use as pesticide), to allow veterinary drug manufacturers and pesticide manufacturers to calculate a withdrawal period when registering their products.</p> <p>Brazil supports a full risk assessment being carried out jointly for dual use compounds.</p> <p><u>Whether the recommendations can be improved for completeness (please provide technical/substantive revisions only) based on the background information provided in paragraphs 8-25 of CX/RVDF 23/26/9. If so, please provide a revised recommendation in track change mode</u></p> <p>Brazil does not have any considerations as to improving the recommendations for completeness.</p> <p><u>Whether there is room for additional recommendations based on the issues discussed in the Joint EWG as described in paragraphs 8-25 of CX/RVDF 23/26/9. If so, please provide additional recommendation(s)</u></p> <p>Brazil suggests the database should include all dual use compounds registered in Member States, and, based on this database, a priority list should be established for joint JECFA/ JMPR risk assessment purposes.</p>	Brazil
<ul style="list-style-type: none"> • Canada supports the work of the Joint EWG in accordance with the ToRs as agreed by CAC. • Canada has no objections to the first four recommendations listed in this CL. However, for the last recommendation, for dual use compounds that have diverging MRLs for the same edible commodity of animal origin, Canada is concerned with selecting the higher MRL value as the harmonized value without a thorough assessment of each JECFA/JMPR evaluation. <p>O The higher value may be due to older evaluations that considered outdated information or that were based on standards that no longer reflect current standards.</p> <p>O Canada recommends that the underlying JECFA/JMPR evaluations and risk assessments for each MRL be reviewed in greater detail and that harmonization be considered on a case-by-case, based on the most contemporary information.</p> <ul style="list-style-type: none"> • Canada has no additional recommendations to propose. 	Canada

COMMENT	MEMBER/OBSERVER
<p><u>Whether the recommendations are agreeable as proposed by the Joint EWG</u></p> <p>Chile agrees with the recommendations in the document, both those requesting that JECFA/JMPR continue working jointly to find alternatives that can harmonize risk assessment for dual-use compounds and those regarding joint work to find alternatives for data sharing with the authorization of sponsors.</p> <p>Chile also agrees with maintaining an EWG, which addresses the creation of a list of products for harmonized MRL proposals for identical matrices.</p> <p><u>Whether the recommendations can be improved for completeness (please provide technical/substantive revisions only) based on the background information provided in paragraphs 8-25 of CX/RVDF 23/26/9. If so, please provide a revised recommendation in track change mode</u></p> <p>Regarding the second recommendation “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.”</p> <p>Chile proposes that there could be an evaluation regarding including in the process of identifying priorities for evaluation or reevaluation of substances the incorporation of a point that identifies whether the substance requiring evaluation or reevaluation can be of dual use and that indicates whether the sponsor can make a future evaluation available.</p> <p><u>Whether there is room for additional recommendations based on the issues discussed in the Joint EWG as described in paragraphs 8-25 of CX/RVDF 23/26/9. If so, please provide additional recommendation(s)</u></p> <p>There are situations where information is needed, for example, to reevaluate an old molecule, and it could be that in addition to the original information, updated information is required that takes into account the development or update of new reference guidelines for these objectives. In this regard, it may prove interesting to evaluate the possibility of including a list of necessary information, so that international bodies can offer support to the countries involved, so that they can develop and contribute the necessary information.</p>	Chile
Egypt agrees with the recommendations as proposed by the joint EWG	Egypt
<p>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 recommend, where appropriate, a single, harmonized MRL(s) for the compound(s) and affected commodity(ies). The working group might consider selecting the higher MRL value-CCPR and recommending that CCRVDF may then consult JMPR/JECFA conduct a risk assessment using the higher value to determine its acceptability. the acceptability of the recommended MRL(s).</p> <p><u>Whether the recommendations can be improved for completeness (please provide technical/substantive revisions only) based on the background information provided in paragraphs 8-25 of CX/RVDF 23/26/9. If so, please provide a revised recommendation in track change mode</u></p> <p>The EUMS support the recommendations in paragraph 26 of document CX/RVDF 23/26/9 with the following revision of the last bullet point:</p> <p>“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, where appropriate, a single, harmonized MRL(s) for the compound(s) and affected commodity(ies). CCPR and CCRVDF may then consult JMPR/JECFA to determine the acceptability of the recommended MRL(s).”</p> <p><u>Whether the recommendations are agreeable as proposed by the Joint EWG</u></p> <p>The EUMS welcome the establishment of the EWG recognising the importance of its potential role in facilitating and promoting the cooperation on cross-sectional issues between CCRVDF and CCPR.</p>	EU

COMMENT	MEMBER/OBSERVER
<p>Kenya supports the work of the EWG and makes the following recommendation:</p> <ul style="list-style-type: none"> • CCPR and CCRVDF 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. • JECFA/JMPR ask sponsors to consent to data sharing upon submission of the data packages. • The current joint EWG to identify and prioritize issues affecting both committees and recommend ways to address the issues and to inform CAC accordingly. • Development of a database of dual-use compounds that can be shared between committees to facilitate the development of a single, harmonized MRL, and • Creation of 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) to be transmitted to CCPR and CCRVDF. <p><u>Rationale:</u> Some compounds are used as veterinary medicines and as pesticide. Those compounds can have different MRLs for the same edible commodity of animal origin. To solve that issue, CCEXEC (CCEXEC81, 2021) recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.</p>	Kenya
Peru does not have comments on the Electronic Working Group’s Recommendations to CCPR and CCRVDF; Peru finds them acceptable.	Peru
Saudi Arabia support the recommendations arising from the Joint CCPR/CCRVDF EWG	Saudi Arabia
<p>General comment: A formal terminology of “dual-use compounds” should be clearly developed to give a consensus interpretation for member countries to classify substances into dual-use compounds.</p> <p>In principle, we do not object to continue working towards harmonizing risk assessment methodologies between JECFA and JMPR. In addition, we are of the view that consequence of harmonization of term “meat/muscle” to current MRLs established by CCRVDF and CCPR as well as the establishment of MRLs from this harmonized term/definition of dual-use compounds should be taken into consideration.</p> <p>We are of the view that the priority list of dual-use compounds for evaluation by JECFA and JMPR should be established to promote an ongoing process.</p> <p>It is important that when selecting the higher MRL value, this value must be re-evaluated by JECFA/JMPR to ensure its safety for consumers.</p>	Thailand
<ul style="list-style-type: none"> • Uganda is in support of the recommendations by the EWG that CCPR and CCRVDF continue working together <p><u>Rationale:</u> Some compounds are used as veterinary medicines and as pesticide. Those compounds can have different MRLs for the same edible commodity of animal origin. To solve that issue, CCEXEC (CCEXEC81, 2021) recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.</p> <ul style="list-style-type: none"> • Uganda is in support of the recommendations by the EWG that CCPR and CCRVDF request JECFA/JMPR to ask sponsors to consent to data sharing upon submission of the data packages. • Uganda is in support of the recommendations by the EWG for CCPR and CCRVDF to continue supporting the current joint EWG to identify and prioritize issues affecting both committees and recommend ways to address the issues and to inform CAC accordingly 	Uganda

COMMENT	MEMBER/OBSERVER
<ul style="list-style-type: none"> Uganda is in support of the recommendations by the EWG for CCPR and CCRVDF of developing a database of dual-use compounds that can be shared between committees to facilitate the development of a single, harmonized MRLs. <p><u>Rationale:</u> Some compounds are used as veterinary medicines and as pesticide. Those compounds can have different MRLs for the same edible commodity of animal origin.</p> <p>To solve that issue, CCEXEC (CCEXEC81, 2021) recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.</p> <ul style="list-style-type: none"> Uganda is in support of the recommendations made by the EWG for CCPR and CCRVDF to form a joint EWG. <p><u>Rationale:</u> Some compounds are used as veterinary medicines and as pesticide. Those compounds can have different MRLs for the same edible commodity of animal origin.</p> <p>To solve that issue, CCEXEC (CCEXEC81, 2021) recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.</p>	
<p>African Union notes and supports the recommendations of the joint CCPR/CCRVDF EWG. Some compounds are used as veterinary medicines and as pesticides. These compounds can have different MRLs for the same edible commodity of animal origin. Hence, advancing work on harmonizing risk assessment methodologies, including identifying ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds will facilitate regulatory efforts and predictability in the international food trade.</p>	AU