



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26<sup>th</sup> Session

13-17 February 2023

Portland, Oregon, United States of America

#### COORDINATION OF WORK BETWEEN THE CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR) AND THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF) MATTERS OF INTEREST ARISING FROM THE JOINT CCPR/CCRVDF WORKING GROUP

Codex members and observers wishing to submit comments the proposed recommendations as presented in paragraph 26 should do so as instructed in CL 2022/78-RVDF available on the Codex webpage/Circular Letters<sup>1</sup> or CCRVDF/Related Circular Letters<sup>2</sup>

#### DISCUSSION PAPER ON THE WORK OF THE ELECTRONIC WORKING GROUP BETWEEN CCPR AND CCRVDF

##### Background

1. The 25<sup>th</sup> session of the Codex Committee on Residues of Veterinary Drugs in Foods (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.<sup>3</sup> The 52<sup>nd</sup> Session of CCPR (CCPR52, 2021) also encouraged ways to facilitate and promote cooperation on cross-sectional issues between CCRVDF and CCPR.<sup>4</sup> The 53<sup>rd</sup> Session of 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.<sup>5</sup>
2. The 81<sup>st</sup> Session of 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 between CCRVDF and CCPR to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.
3. Following the recommendation<sup>6</sup> of CCEXEC81, the 44<sup>th</sup> Session of the Codex Alimentarius Commission (CAC44, 2021) agreed<sup>7</sup> 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) agreed by CAC44:
  - 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.

<sup>1</sup> <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

<sup>2</sup> <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

<sup>3</sup> REP21/RVDF25, para. 146

<sup>4</sup> REP21/PR52, para. 12

<sup>5</sup> REP22/PR53, paras. 189-190<sup>6</sup> REP21/EXEC81, paras. 33-34

<sup>6</sup> REP21/EXEC81, paras. 33-34

<sup>7</sup> REP21/CAC44, para. 64-66

- 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).
4. Regarding the timeframe, the Joint EWG will continue its work as long as both CCRVDF and CCPR consider it useful.
  5. The Joint EWG will not replace the ongoing parallel cooperation between the established EWGs under CCRVDF (edible offal) and CCPR (revision of the Classification) within their respective ToRs.
  6. Further background on the establishment of single MRLs for edible animal tissues for compounds with dual use can be found in CRD34<sup>8</sup> presented at CAC44.

#### **Proceedings of the Electronic Working Group**

7. Two rounds of questions were posted to the Joint EWG, and members were asked to provide comments.
  - 1. What work has been done cooperatively between CCRVDF and CCPR?**
8. Several members noted the previous work on harmonizing definitions for edible commodities of animal origin. This included a Joint Working Group comprised of experts from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Joint FAO/WHO Meeting on Pesticide Residues (JMPR) that met on 3-7 December 2018. The Joint Working Group determined that the CCRVDF definition for muscle and CCPR definition for meat essentially are equivalent and that the CCRVDF definition for fat and CCPR definition for fat essentially are equivalent. The Joint Working Group also recommended that CCPR consider adopting the CCRVDF definitions for meat, muscle, and fat<sup>9</sup>. Examples of previous work on harmonizing definitions also included the collaboration between the CCPR EWG on the Revision and Classification Food and Feed and the CCRVDF EWG on Edible Offal, which resulted in a definition for edible offal being agreed to by CCRVDF25 (2021), adopted by CAC44 (2021), and forwarded to CCPR53 (2022) for consideration<sup>10</sup>.
9. One member noted the previous efforts to harmonize the risk assessment performed by JECFA and JMPR for dual-use compounds. This included the following:
  - Discussions between JECFA and JMPR on specific areas where the two expert committees differ and areas to continue working together<sup>11</sup>
  - The joint JECFA/JMPR Residue Definition Working Group<sup>12</sup>
  - A published report on a harmonized methodology to assess dietary exposure to residues from dual-use compounds<sup>13</sup>
  - A pilot approach for the risk assessment of combined exposures to multiple chemicals developed by an FAO/WHO Expert Working Group for use by JECFA and JMPR<sup>14</sup>.
10. Another member recalled that the revisions to the *Principles and method for the risk assessment of chemicals in food (Environmental health criteria 240), Chapter 6: Dietary Exposure Assessment of Chemicals in Food* partially was based on the published report on a harmonized methodology to assess dietary exposure to residues from dual-use compounds<sup>13</sup>.

#### **2. What are areas where CCRVDF and CCPR could collaborate in the future?**

11. Several members suggested that CCRVDF and CCPR continue working towards harmonizing definitions for edible commodities of animal origin.

*Joint EWG Chair's note: While the work of the Joint EWG was progressing, the 53<sup>rd</sup> Session of CCPR (CCPR53, 2022) agreed to harmonize its definitions of meat, muscle, fat, and edible offal with those of CCRVDF<sup>15</sup>.*

<sup>8</sup> <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=44>

<sup>9</sup> CX/PR 19/51/3-Add. 1

<sup>10</sup> CX/PR 22/51/9

<sup>11</sup> [https://www.fao.org/fileadmin/templates/agphome/documents/Pests\\_Pesticides/JMPR/Reports\\_1991-2006/Report\\_2000.pdf](https://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Reports_1991-2006/Report_2000.pdf)

<sup>12</sup> Summary Report of the JECFA/JMPR Working Group on Residue Definition, 3-7 December 2018. Geneva, Switzerland.

<sup>13</sup> Critical Reviews in Toxicology (2019), 49:1-10, DOI: [10.1080/10408444.2019.1578729](https://doi.org/10.1080/10408444.2019.1578729)

<sup>14</sup> <https://www.who.int/docs/default-source/food-safety/euomix-report-of-expert-consultation-16-18-april-201.pdf>

<sup>15</sup> REP22/PR53 para. 187

12. One member suggested to harmonize the risk assessment methodologies used by JECFA and JMPR and possibly conduct a joint evaluation of dual-use compounds. Another member recommended establishing a harmonized acceptable daily intake (ADI) for dual-use compounds, if possible.
13. Noting that there have been previous attempts at harmonizing risk assessment methodologies, that the differences between a JECFA and JMPR risk assessment are science-based and reflect differences in how the compounds are used, and that the number of dual-use compounds is only a small fraction of the total number of pesticides and veterinary drugs, one member suggested developing an approach to harmonize MRLs after JECFA and JMPR have recommended MRLs. The member suggested that CCPR and CCRVDF select the higher MRL(s) from the JMPR and JECFA evaluations and ask the Codex committee with the corresponding lower MRL(s) to determine if any safety concerns exist if the higher MRL(s) is chosen for the respective edible commodity(ies). It was suggested that the Committee with the lower MRL(s) could ask the corresponding risk assessment body (*i.e.*, JECFA or JMPR) to conduct an exposure assessment using the higher MRL(s) to determine if the higher MRL(s) will result in an exposure that exceeds the health-based guidance value. It was noted that selecting the higher MRL was consistent with a previous FAO recommendation in 1997<sup>16</sup>.
14. Two members expressed interest in developing a database for dual-use compounds to facilitate the development of harmonized MRLs between CCPR and CCRVDF, with the information in the database being supplied by Member countries. A different member suggested that veterinary drug and pesticide databases provide annotations to indicate compounds with dual use. Similarly, another member suggested that CCPR and CCRVDF develop a joint priority list for dual-use compounds.
15. One member expressed interest in CCRVDF and CCPR reviewing how to cooperate on antimicrobial compounds with dual use and whether any restrictions should apply.
16. One member referenced a draft report from their national regulatory authority on a harmonized exposure assessment for residues of veterinary drugs and pesticides in food of animal origin. The member invited the Joint EWG to consider the report once it is finalized to determine whether such an approach could be pursued at the international level.

### ***3. What mechanisms could be used to collaborate between CCRVDF and CCPR?***

17. Several members recommended one or more joint EWGs to address cross-sectional issues as a way to continue collaboration between CCPR and CCRVDF. One member suggested 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. The member referenced the proposed approach in paragraph 16.
18. Two members highlighted that increased communication and/or data and information sharing between JECFA and JMPR could help harmonize MRLs for dual-use compounds, with one member suggesting that JECFA and JMPR ask sponsors to allow both JECFA and JMPR access to their data on dual-use compounds. Similarly, one member suggested joint JMPR/JECFA evaluations of dual-use compounds.
19. One member favored increased coordination at both the risk assessment and risk management level and suggested the formation of a joint JMPR/JECFA EWG for performing the risk assessment of dual-use compounds and a joint CCPR/CCRVDF EWG for risk management considerations.
20. One member stated that the CAC should formalize the work between CCPR and CCRVDF and indicate ways in which collaboration could be achieved.

### ***4. What mechanisms could be recommended to JMPR and JECFA to facilitate data sharing between the two risk assessments groups?***

21. The member that recommended the formation of a joint JMPR/JECFA EWG recognized the importance of sharing data between JMPR and JECFA. The member noted that the precise data sharing mechanism may be detailed in the terms of reference established for the EWG.

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<sup>16</sup> Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Lyons, France 22 September 1 October 1997 (<https://www.fao.org/3/w8141e/w8141e00.htm>)

22. One member recommended continued support for the efforts taken by JMPR and JECFA to harmonize the risk assessment methodologies and communicate on cross-cutting issues. This member suggested that JMPR and JECFA could ask sponsors to allow both committees access to the data packages used to establish MRLs. The member provided the suggestion of a checkbox on the data submission form that a sponsor could check to signal their agreement with sharing the data between JMPR and JECFA. This member also noted that CCPR and CCRVDF could encourage sponsors to allow the data to be shared between JMPR and JECFA. Finally, the member noted that sharing of data would alleviate some burden of sponsors and aid in MRL harmonization.

***5. 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.***

23. One member suggested that a new Joint EWG could identify those dual-use compounds that have differing MRLs for the same edible commodity. The new EWG could recommend that the Committee (CCRVDF or CCPR) with the lower MRL value ask their risk assessment body (JMPR or JECFA) to conduct a risk assessment using the higher MRL value. The Committee with the revised value can then advance the higher MRL in their Step process if the risk assessment determines that the HBGV will not be exceeded. The member highlighted that selecting the higher value is consistent with a previous FAO recommendation on how to address MRLs that differ between two Codex committees<sup>16</sup>. The member also recommended that CCPR and CCRVDF ask JECFA and JMPR to continue considering whether a compound has dual uses and the potential exposure from both sources in an effort to harmonize the MRLs for dual-use compounds during the evaluation.
24. Another member expressed that, where diverging MRLs were established for the same compound in the same edible commodity by CCPR and CCRVDF, selecting the higher MRL value should not become the harmonized value without an evaluation. The member noted that the higher value may be due to older evaluations that considered outdated information. The member suggested harmonization on a case-by-case basis to ensure that the newest information is considered.

***6. Are there any additional topics affecting both CCPR and CCRVDF that have not been considered by either the draft discussion paper or questions?***

25. One member referenced the development of a draft OECD Guidance Document on the definition of residue. The member suggested that JMPR/JECFA could consider the work carried out by the OECD Working Group.

**Recommendations to CCPR and CCRVDF**

26. 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.

**APPENDIX I**  
**LIST OF PARTICIPANTS<sup>1</sup>**

<b>Chair</b>	<b>Name</b>
<i>United States of America</i>	<i>Jonathan Greene (Chair)</i>
<b>Member Country</b>	<b>Name</b>
Argentina	PUNTO FOCAL CODEX
Argentina	Carlos Eugenio Alli
Australia	Dugald MacLachlan
Australia	Karina Budd
Australia	James Oliver Deller
Belgium	Stefano Messori
Canada	Monique Thomas
Chile	Claudio Núñez Contardo
Chile	Roxana Inés Vera Muñoz
Costa Rica	Amanda Lasso Cruz
Costa Rica	Tatiana Vásquez Morera
Costa Rica	Ivania Morera Rodríguez
France	Anne-Marie Jacques
Germany	Dr. Anke Finnah
Germany	Karsten Hohgardt
Germany	David Schumacher
Iran	Ehsan Zayerzadeh
Japan	codexjapan
JAPAN	kei iwata
New Zealand	Warren Hughes
New Zealand	Bill Jolly
Poland	Tomasz Kiljanek
Republic of Korea	Republic of Korea
Republic of Korea	Hwang Kiseon
Republic of Korea	Yejin Min
Republic of Korea	Soyoung Lee
República Dominicana	Luís Martínez Polanco
South Africa	Aluwani Alice Madzivhandila
South korea	Park Yu-min
Sweden	Niklas Montell
Thailand	Chonnipa Pawasut
Thailand	Sakranmanee Krajangwong
Thailand	Namaporn Attaviroj

<sup>1</sup> Please contact the focal point of the Member Country or Observer Organization for the details of the delegates. The list of Codex contact points for members are available from the Codex website at:  
<http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/>  
<http://www.fao.org/fao-who-codexalimentarius/about-codex/observers/observers/obs-list/en/>

<b>Member Country</b>	<b>Name</b>
United States of America	Kenneth Lowery
United States of America	Dong Yan
United States of America	Marie Maratos Bhat
United States of America	Aaron Niman
United States of America	Alexander Domesle
United States of America	Kimon Kanelakis
Uruguay	Susana Franchi
<b>Observer Organization</b>	<b>Name</b>
CropLife International	Wibke Meyer