

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
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World Health  
Organization

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

Agenda Items 5(a), 6, 8

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

54th Session

Beijing, P.R. China

26 June - 1 July 2023

*Comments submitted by CropLife International*

#### Agenda Item 5(a)

#### Section 2 of the 2022 JMPR Report

#### Report on items of general consideration arising from the 2022 JMPR meeting

##### Background

At JMPR 2022 the meeting recommended that the joint secretariat convene a microbiome expert working group to consider the possible impact of pesticide residues on the human intestinal microbiome with a view to developing draft guidance for discussion and eventual adoption by JMPR.

In addition, in May, most manufacturers who have a new compound under JMPR evaluation this year or a compound under re-evaluation received a request from the WHO secretariat requesting data on the impact of pesticide residues of the compound on the human intestinal microbiome.

##### Comment

CropLife International has followed the discussion by the Joint Meeting of Pesticide Residues (JMPR) on the potential effects of pesticides on the human gut microbiome and supports the recommendation of the 2022 JMPR report<sup>1</sup> i.e. to convene an expert working group that would consider this topic. CropLife International believes the expert group should also be expanded to include risk managers from CCPR and experts from industry. If this expert working group concludes that the science indicates a potential impact of pesticide residues on the human gut microbiome and subsequent health effects, then the matter should be referred to the OECD Working Party on Pesticides and the OECD Working Group of National Coordinators of Test Guidelines (the WNT) to investigate further and potentially develop internationally accepted guidelines and guidance. CropLife International believes that the JMPR working group should not be tasked with developing draft guidance.

CropLife International agrees with the FAO Food Safety Foresight Report (2022)<sup>2</sup> that the science relating to the human gut microbiome and its influence on human health is still evolving. Some of the key points in this report are:

- One of the essential scientific needs is to reach consensus on the definition of a healthy microbiome and to be able to distinguish normal fluctuations in the microbial composition and function from alterations of concern.
- To connect the microbiome with health and disease, it is critical to demonstrate causality and characterize biologically relevant microbiome disturbances. This will require the identification and validation of suitable microbiome-related biomarkers and endpoints.
- For chemical risk assessment, there is a need to define fit-for-purpose experimental models, including the use of appropriate low doses of test compounds (e.g., food additives, residues of veterinary drugs and pesticides) and exposure periods.

<sup>1</sup> Pesticide Residues in Food – 2022 Joint FAO/WHO Meeting on Pesticide Residues Report

<https://www.fao.org/3/cc4115en/cc4115en.pdf>

<sup>2</sup> FAO. 2022. Thinking about the future of food safety – A foresight report. <https://doi.org/10.4060/cb8667en>

As there are currently no regulatory data requirements or guidance on this topic for crop protection products globally, data sponsors likely have not generated these specific data.

In addition, CropLife International would like to highlight that extensive mammalian toxicology data are available for all crop protection pesticides. The vast majority of these data are generated using oral dosing, including chronic oral toxicity studies in animals with intact gut microbiota. Therefore, meaningful apical adverse health outcomes mediated by the gut microbiota have been assessed and incorporated into the comprehensive human health safety evaluation.

In conclusion, CropLife International believes it is currently premature to create new human-gut microbiome data requirements. The need for new data requirements in this area should be agreed upon by the risk managers at CCPR after the science mentioned above has been further developed and outcomes of the expert work are available. If this expert working group believes the science indicates that pesticide residues may have an impact on the human gut microbiome which leads to health effects, then the matter should be referred to the OECD Working Party on Pesticides and the OECD Working Group of National Coordinators of Test Guidelines (the WNT) to investigate further and potentially develop internationally accepted guidelines and guidance.

#### Agenda Item 8

CX/PR 23/54/10

#### Coordination of work between CCPR and CCRVDF: Joint CCPR/CCRVDF working group on compounds for dual use

##### Background

In CX/PR 23/54/10 under the heading Recommendations to CCPR and CCRVDF, paragraph 26.2 states “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.”

##### Comment

The ownership of data for a compound can be very complex. Often ownership of data can vary by country, market segment (crop protection or veterinary), and even the type of use within a market segment (crop protection foliar versus seed treatment).

CropLife International supports the recommendations in paragraph 26 bullets points 1, 3, 4 and 5. It is suggested that bullet point 2 be modified from:

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.

To:

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 **must** include JECFA/JMPR asking sponsors to consent to data sharing upon submission of the data packages.

#### Agenda Item 13

CX/PR 23/54/15

#### Enhancement of the operational procedures of CCPR and JMPR

##### Background

1. At the 53<sup>rd</sup> Codex Committee on Pesticide Residues meeting (CCPR53), concerns have been raised that the current CCPR/JMPR system is unable to keep up with global demand for the evaluation of new compounds, new uses, and periodic reviews. Increased demand for evaluation and increased work required to evaluate a dossier have been identified to be major challenges for resolving the current and future anticipated backlogs. CropLife International has estimated that to meet the future demand for new active ingredients, new uses, and periodic reviews the output from the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) needs to increase by a factor of three [[CropLife International Conference Room Document to CCPR53](#)].

2. Despite these challenges, Codex delegations and observers continue to recognize the value of the CCPR and JMPR especially given the global nature of food and feed supply chains. To address this issue, an Electronic Working Group Enhancement of work management of CCPR and JMPR (eWG) has been established to collect information on the need to enhance the operational procedures of CCPR/JMPR and the associated opportunities and challenges [more information [here](#)].
3. In early 2023, the leadership of the eWG prepared a circular letter CL 2022/75-PR to request comments from Codex Members and observer organizations in support of the work of the eWG. A compilation of all submitted comments is provided [here](#).
4. In virtual events organized in 2022, CropLife International began a dialog with many Codex members, CCPR delegations, JMPR experts, Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO) and CODEX, CCPR and JMPR Secretariats to share these capacity concerns. In those virtual events options and ideas to enhance the CCPR/JMPR system to better meet the current and future demands whilst maintaining the independence, scientific rigor, and reputation of JMPR, CCPR and CODEX were explored. Given the success of these virtual events, CropLife International was approached by the leadership of the eWG to consider holding similar events in 2023 to further ideate on how best to enhance Codex. CropLife International responded to this request from eWG leadership by organizing two three-hour virtual workshops on 23<sup>rd</sup> of February and 7<sup>th</sup> of March; the February workshop was intended to attract attendees from the Americas and Pacific Rim, while the March workshop was intended to attract attendees from Europe, Africa, and Asia. These workshops were well attended, as over 150 non-industry participants were noted. The results of the workshop are available [here](#).
5. Proposed improvements arising from the 2022 CropLife International virtual events included: data submitters need to do more/better, resolve JMPR capacity constraints, resolve JMPR procedural limitations, increased and sustainable funds to Codex CCPR/JMPR. It is important to note that the attendees to the 2022 virtual events considered resolving JMPR resource and resourcing limitations as the most important priority.
6. The February and March 2023 CropLife International workshops revisited these proposed improvements for current validity, and to spur the identification of new recommendations that have not been previously suggested. The slide deck utilized to facilitate these workshops can be found [here](#).

#### Outcome

7. Attendees to the Feb. and Mar. 2023 workshops that responded to Mentimeter surveys held during the workshops demonstrated the diversity of participants: out of 68 respondents 8% were representatives of CCPR/JMPR Secretariat, 33% were Codex member country representatives, 27% were representatives of governments or government regulatory organization, and 14% were Codex observers (e.g., grower/commodity groups).
8. Overall, the consensus between the eWG Circular Letter responses and the discussions at the virtual workshops confirmed that the ideas brought forward in the CropLife International March 2022 virtual events are the leading candidates for Codex Enhancement.
9. The top priorities identified by the 2023 workshops were:
  - Resolve JMPR capacity constraints/improve JMPR resources.
  - Use of national reviews as a starting point for JMPR review.
  - Secure increased and sustainable funds to Codex CCPR/JMPR.
  - Data submitters need to do more/better.
  - The 2023 workshops also identified that government attendees supported investigation of a

'fee system' concept for JMPR submissions; of those who responded 92.5 % supported further investigation of a fee system similar to those established in many countries by responding 'yes' or 'may be' when questioned (47.5%, 45% and 7.5% responded respectively 'yes', 'maybe', or 'no'; total of 50 responses were gathered).

- Attendees to the workshops also supported initiating an exercise to compare and contrast JMPR/CCPR with similar Codex expert groups and committees; 89% of respondents considered this a worthwhile exercise (63%, 26%, and 11% from a total of 35 responses responded respectively 'yes', 'maybe', or 'no').
- Finally, attendees who responded, overwhelmingly supported the continuation of the Codex Enhancement eWG with a revised Terms of Reference; 97% of respondents supporting continuing efforts within the CCPR to work toward improving JMPR resources and resourcing and the processes currently utilized by JMPR/CCPR (71%, 26%, & 3% responded respectively 'yes', 'maybe', or 'no'; a total of 34 responses was gathered).
- Also discussed was the option to split the expert panels and create two panels for FAO and WHO each (I and II). These Panels I and II take over full responsibility for the review of 50% of compound reviews, taking decisions at the JMPR in parallel sessions.

10. New ideas that have been presented include:

- Introducing e-submission tools and standardized templates (such as OECD submission tools for pesticides), and regular maintenance of the Codex MRL database.
- Introducing virtual JMPR expert panel meetings and pre-discussions prior to virtual/in-person JMPR expert panel meetings.
- Additional considerations were discussed in relationship to the Toxicology Monographs.
- Identifying and implementing a process for training experts for JMPR work.
- Considering participation of JMPR reviews in joint or parallel reviews.
- Considering supporting permanent staffing to support JMPR expert panels.

11. Results from the Circular Letter responses which were made available shortly prior to the workshops, were discussed in limited detail during the workshop, but was agreed also warrant careful consideration:

- Circular Letter response regarding 'critical gap' – proposing an approach of 'a single representative use' already applied as part of the JMPR process. The concept stipulates that as long as one country has a use/GAP that is 'inclusive' of other countries' use/GAP that should be enough to establish a Codex MRL without the need to provide labels from all registration countries.
- Develop one standard template/format, individual national reviews (excluding decisions) or summaries of each scientific study can be relied upon by JMPR, precluding JMPR experts from recreating tables and entering data. The use of national reviews of data was considered in the 2002 review of the working procedures of JMPR. It was suggested that it may be helpful to re-evaluate this approach, based on advancements by the Organization for Economic Cooperation and Development (OECD) and regional approaches and to further leverage it by JMPR.
- Improving the incentives for individuals to become JMPR experts is also an avenue for improvement. The workshop discussions have yielded several potential actionable solutions to tackle this challenge head-on. A significant improvement would be if experts could dedicate time to JMPR review as part of their daily jobs, authorized by their employers. One moderately effective approach is to actively recruit and train a greater number of interested and qualified experts for JMPR work. By expanding the pool of experts, the productivity of the meetings

would increase incrementally without compromising the quality of discussions. It was however recognized, that simply adding more manpower is not a complete solution in and of itself. This, in turn, another proposal is to consider slightly shortening the (in-person) meeting duration, making it more enticing for new experts to participate. Delays in their national regulatory work should be minimized, as it holds significant importance. Additionally, this would prioritize the well-being and welfare of the reviewers. Proactively identifying and reaching out to potential experts who have a keen interest in JMPR work could be a starting point, followed by developing targeted training programs to equip new experts with the necessary skills and knowledge. Streamlining the meeting agenda and ensuring efficient time management to facilitate more focused discussions would aid the duration optimization of the meetings, while cases not requiring discussion be treated by digital means. Actively promoting the benefits and rewards of participating in the JMPR process could attract new experts.

- Providing different resources, methods, and sufficient financial/funding support for the regular convening of the committee through proposing annual fees to be paid by industry.

### Recommendations

12. To tackle current challenges, improve existing systems and meet future demands, CropLife International proposes the Codex Enhancement eWG continue its work using the following terms of reference (ToR):
  - i. *Develop a discussion paper for the consideration at CCPR54 and later meeting report to transmit to JMPR.*
  - ii. *Consider possible solutions for enhancing CCPR/JMPR that were given a priority by attendees at the 2023 workshops such as:*
    - *Develop a framework for converting national/regional reviews into a primary draft review in the initiation of JMPR expert panel evaluations.*
    - *Develop a process to adopt existing OECD tools and approaches (e.g., study profile templates, study summaries, OECD naming conventions for data requirements and study titles) to support electronic submissions and to develop an electronic submission portal for JMPR submissions,*
    - *Conduct a study to compare and contrast processes and procedures utilized by Codex Committees and their allied expert groups working on veterinary drugs and food additives, on one side, with the process and resources utilized by the JMPR/CCPR, on the other.*
  - iii. *Coordinate work with related eWGs such as the eWGs on priority lists, national registration database, and unsupported compounds.*
  - iv. *Facilitate proposals and actions to relevant delegations.*
13. Based on the discussions from the 2022 and 2023 CropLife International workshops, as well as considering the responses to the eWG Circular Letter, CropLife International would like to put forward the following recommendations to improve the functioning of JMPR/CCPR. Please note that CropLife International intends to discuss these recommendations with stakeholders that share our interest in enhancing CCPR/JMPR outside of the CCPR/JMPR process:
  - To improve JMPR resources and resourcing:
    - Establish a pilot project for 3-5 years to create 'permanent' staff to provide support for the JMPR Expert Panels. The primary role of this 'permanent' staff would be the production of initial reviews of new active ingredients, periodic review, or new uses in the JMPR format used to initiate review and consideration by the JMPR expert panels. In addition, the 'permanent' staff would support the execution of the JMPR in-person meetings in September (e.g., providing drafting support for the experts in the making of changes in review documents under

JMPR consideration), and otherwise generally support the WHO/FAO Secretariat in the operation of the JMPR expert panels.

- i. To fill these 'permanent' staff roles in this pilot project, secondments from existing institutions, or recently retired experts from governments could be considered. Consideration should also be given to retirees from the industry as their work would be limited to preparation of the initial review draft (i.e., not involved in the expert panel decisions).
  - ii. To support the pilot project of creating 'permanent' staff, establish a 'fee system' that would allow funding from industry resources to support new active ingredients/new uses. Existing fee systems at a national/regional level should be leveraged to establish such 'fee system' at JMPR.
- Increase the number of experts particularly in regions underrepresented in current and past JMPR expert panels. In addition, it is crucial to identify and implement a process for training experts for JMPR work by leveraging ongoing capacity building efforts (e.g., establishment of Regional Excellence Center National at the University of Colombia in Bogotá).