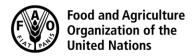
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CODEX ALIMENTARIUS COMMISSION





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

Agenda item 11

CX/PR 24/55/10 April 2024

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Fifty-fifth Session
Chengdu, Sichuan province, People's Republic of China
3-8 June 2024

DISCUSSION PAPER ON ENHANCEMENT OF THE OPERATIONAL PROCEDURES OF CCPR AND JMPR

(Prepared by the Electronic Working Group chaired by the United States of America and co-chaired by Costa Rica and Uganda)

Codex members and observers wishing to submit comments on the recommendations in paragraph 26 and Appendix I should do so as instructed in CL 2024/48-PR available on the Codex webpage¹

1. OVERVIEW

- 1. The 54th Session of the Codex Committee on Pesticide Residues (CCPR55, 2023) re-established the Electronic Working Group (EWG), chaired by the United States of America (USA) and co-chaired by Costa Rica and Uganda, to explore potential approaches to: (1) identify priorities for CCPR and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) enhancement; and (2) develop an implementation roadmap and timeline. The purpose of this discussion paper is to fulfill the EWG's current terms of reference and make recommendations to CCPR55 (2024) on potential approaches to enhance the operational procedures of CCPR and JMPR. The discussion paper is organized into the following sections:
 - **Section 2** provides background on the EWG and other efforts to enhance CCPR and JMPR, this includes amongst others, a summary of key points made by previous sessions of CCPR, the Terms of Reference (ToR) of the EWG and the work progress followed by the EWG in considering its ToR. .
 - **Section 3** summarizes JMPR's deliberation on the EWG discussion paper, recommendations on initial priorities, and additional considerations that require guidance from CCPR.
 - **Section 4** explores potential approaches that may be adopted by CCPR to identify priorities and develop an implementation roadmap and timeline.
 - **Section 5** provides conclusions and recommendations based on the information provided in sections 3 and 4 on which advice from Codex members and observers are requested in order to make progress in the discussion of this matter at CCPR55.

2. BACKGROUND

2.1. EWG Timeline and Terms of Reference

2. Concerns were raised at CCPR53 (2022) that the current CCPR/JMPR system is unable to meet the global demand for the evaluation of new compounds, uses, and periodic reviews. Following discussion of these concerns, Codex Members and observer organizations expressed support of efforts to strengthen the current evaluation system, but recognized that implementing improvements will require a multidisciplinary approach and engagement with a range of stakeholders.

http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

Codex webpage/CCPR/Circular Letters:

https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/tr/?committee=CCPR

² CX/PR 22/53/20

Codex webpage/Circular Letters:

3. As a first step, CCPR53 established an EWG to collect information on the need to enhance the operational procedures of CCPR/JMPR and the associated opportunities and challenges. Based on the work of the EWG, Circular Letter (CL) 2022/75-PR was issued to collect information on the following topics:³

- 4. The need to enhance the operational procedures of CCPR/JMPR:
 - Opportunities for enhancement (e.g., improvements to existing processes) and major reform (e.g., governance and structural changes);
 - Anticipated challenges in implementing proposed enhancements and major reform;
 - Recommendations on key topics and themes for potential stakeholder workshop; and
 - Any addition proposals and recommendations that are relevant to CCPR's discussion of enhancements to CCPR/JMPR.
- 5. A total of 15 (fifteen) Member countries and 3 (three) observer organizations submitted information in response to CL 2022/75-PR. This information was incorporated into an EWG discussion paper that highlighted areas of consensus and divergent opinions on enhancements to the operational procedures of CCPR/JMPR. ⁴ The discussion paper also included a detailed summary table of information on opportunities for enhancement and associated challenges. This summary table is provided in Appendix II of this document and organized into the following themes:

Opportunities for Enhancement (e.g., Improvements to Existing Processes)

- Data Sponsor Dossier and Electronic Data Submission
 - Data Standardization, Digital Templates, and Information Technology (IT)
 - o Timely Data Submission
 - o Current Data Submission Issues
- CCPR Processes and Procedures
 - Development of Efficient Dossiers
 - Schedule and Priority List
 - Coordination on Risk Management Issues
 - o Criteria for Periodic Reviews
 - o CCPR Plenary Discussion on MRLs and Appropriate Scope of Interventions
 - Timely Maintenance of the Codex Pesticide MRL Database
 - CCPR Support for Extra Meetings
- JMPR Evaluation Process and Procedures
 - Required Scope and Level of Detail in Data Sponsor Dossiers and JMPR Monographs
 - Working Procedures
 - Quality Control Check in Data Submission
 - Efficiency in Virtual Collaboration
- JMPR Organizational Structure, Staffing and Resources
 - Funding
 - JMPR Experts
 - Staffing

Opportunities for Major Reform (e.g., Governance and Structural Changes),

- Use of National Reviews and Data
 - Use and Evaluation of National Reviews by JMPR
- Alternative Peer Review Models
 - Scope of Current Approach and Whether Alternatives are consistent with the Codex Risk Analysis Principals
 - o Engagement on National Reviews
- Other Areas of Reform
 - o Scope of Evaluations and Default MRLs
 - o Developing a Continuous JMPR Review Program

^{3 &}lt;u>CL 2022/75-PR</u>

^{4 &}lt;u>CX/PR 23/54/15</u>

6. At CCPR54 (2023), the EWG organized an In-Session Working to discuss its findings with Codex Members and observer organizations and how to further advance work to enhance the operational procedures of CCPR and JMPR.⁵ CCPR54 then agreed to the following actions:

First Step: 2023-2024

(i) CCPR54 requested JMPR, through the JMPR

a) consider the discussion paper prepared by the EWG (Appendix XVI) at its regular mee

ng in September 2023. The discussion paper should be accompanied with the summary of the discussion that took place in plenary as contained in the CCPR54 report as well as comments received in reply to CL 2023/39-PR and

Secretariat, to:

 to provide guidance on the following: (1) General feedback on discussion paper (and particularly Table 1 comments on opportunities for enhancement); (2) Recommendations on initial priorities; (3) Additional considerations that require guidance from CCPR.

Second Step: 2024 and beyond

(ii) Re-established the EWG chaired by USA and cochaired by Costa Rica and Uganda, working in English and Spanish, with the following terms of reference:

- a) Taking into account the feedback of JMPR (point (i) (b)), explore potential approaches, which could include recommending the commissioning of an independent third-party organization to conduct an assessment or working through an existing Codex advisory body or committee, to: (1) identify priorities for CCPR and JMPR enhancement; and (2) develop an implementation roadmap and timeline.
- b) Based on points (i) and (ii), prepare a summary of recommendations for consideration by CCPR55.
- 7. The remainder of this discussion paper addresses the EWG terms of reference summarized in bullets (ii)(a-b) above and proposes potential approaches that may be adopted by CCPR to balance the shorter-term needs of stakeholders to reduce the backlog of scheduled evaluations with longer-term strategic efforts to increase JMPR's review capacity.

2.2 Additional Information Sources on CCPR and JMPR Enhancement

2002 FAO/WHO Report on the Review of the Working Procedures of JMPR

8. While the most recent deliberation at CCPR53 was prompted by the cancellation of JMPR meetings following the Covid 19 pandemic, the growing demands on JMPR and its implications has been an important topic of discussion at several previous sessions of CCPR. Most notably, FAO/WHO commissioned a 2002 review of the working procedures of JMPR that was reviewed at CCPR34 and the JMPR 2002 Regular Meeting. ⁶ Key findings from the 2002 FAO/WHO report are summarized below and remain relevant today:

"Whereas in the 1960s the JMPR monographs, which summarise the scientific data following a critical evaluation, were extremely brief in accordance with the standards of the time, the modern monographs are very detailed and extend to over one thousand pages for a particular Meeting."

"There has been a huge increase in the quantity of scientific data submitted for evaluation, and yet the JMPR only exists for two weeks of the year, in contrast to the situation at a national regulatory authority level."

"Financial resources available for this work have not increased proportionally leading to the generation of a backlog of pesticides waiting for review."

"The current JMPR system is also very vulnerable in that it relies on the goodwill of a limited number of individuals who work on a voluntary basis. These individuals, despite being internationally recognised in their fields, have to prepare the monographs without any financial reward and usually in their own personal time."

"Typically, the Temporary Advisers of the WHO Core Assessment Group and Members of the FAO Panel have to spend the equivalent of 2-4 months full-time prior to the meeting preparing the monographs. The availability of suitable experts that are prepared to work on this basis is very limited."

Presentation on In-Session Working Group on CCPR/JMPR Enhancements

^{2002,} Report on the Review of the Working Procedures of JMPR. Available at: https://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/crit_review.pdf.

9. In its review of the 2002 FAO/WHO report, CCPR34 confirmed that "JMPR was essential to the continued independent international evaluation of pesticide residues" but raised similar concerns that the increased demands on JMPR has resulted in a process that "had become unsustainable and without additional resources the system would fail sooner, rather than later." JMPR re-iterated these concerns at its 2002 regular meeting, but also cautioned that making changes to the operational procedures of JMPR "requires considerable resources and the implementation could become counter-productive if it is no more than the introduction of one suggested change after another without an overall strategic direction."8 JMPR-2002 then concluded by recommending that FAO, WHO, and the Codex Alimentarius Commission prepare a strategic plan that can serve as a framework for future changes.

10. There have been continued discussions on the increased demands on JMPR since FAO/WHO's 2002 report was published, but a strategic plan was never developed to guide future changes to JMPR. CCPR is now revisiting whether there is a need to enhance the operational procedures of CCPR and JMPR and what associated opportunities and challenges may arise from these changes. This information will be used by CCPR and JMPR to further explore approaches to improve the existing system to meet current and future demand for JMPR evaluations.

CCPR Observer Organizations

- 11. CropLife International has called attention to the importance of taking in account information from a range of stakeholders, including Codex members, CCPR and JMPR secretariats, and observer organizations. CropLife International also prepared a discussion paper at CCPR53 (2022) that outlined concerns about the backlog of JMPR evaluations and recommendations on how to enhance the operational procedures of CCPR and JMPR.9
- 12. In the development of this discussion paper, CropLife International convened a 2022 virtual workshop with a range of stakeholders that collected feedback on issues related to data submission, JMPR evaluation, processes, and resources. 10 CropLife International then convened a follow-up virtual workshop in 2023 to gather additional information from stakeholders on opportunities to enhance CCPR/JMPR. The results of this virtual workshop were presented during an in-session working group at CCPR54.¹¹
- 3. 2023 JMPR REGULAR MEETING SUMMARY OF DELIBERATIONS OF ENHANCEMENT WORK
- 13. CCPR54 requested JMPR, through the JMPR Secretariat, consider the discussion paper prepared by the EWG at its regular meeting in September 2023. Summary information on JMPR's input is provided in Section 2.7 of the 2023 JMPR Regular Meeting and summarized in the reminder of this section. 12
- 14. JMPR-(2023) considered some of the opportunities to enhance the operational procedures of CCPR and JMPR and commented issues raised by the EWG. These included, among others, long-standing issues such as the enhancement of electronic quality of data, improved file naming and timely submission of full dossiers by the sponsors.

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CropLife International (2022). Summary of the global virtual workshop on Codex CCPR/JMPR enhancement organized by CropLife International. March 31, 2022. Available at: https://croplife.org/wp-content/uploads/2022/04/Summary-of-<u>CropLife-International-Codex-Enhancement-Workshop.pdf.</u>

^{2002,} Report of the 34th Session of CCPR, Review of the Working Procedures of JMPR, Paragraphs 181-200. Available at: https://www.fao.org/fao-who-codexalimentarius/sh- $\underline{proxy/en/?lnk=1\&url=https\%253A\%252F\%252Fworkspace.fao.org\%252Fsites\%252Fcodex\%252FMeetings\%252FCX-718-proxy/en/?lnk=1\&url=https\%253A\%252F\%252Fworkspace.fao.org\%252Fsites\%252Fcodex\%252FMeetings\%252FCX-718-proxy/en/?lnk=1\&url=https\%253A\%252F\%252Fworkspace.fao.org\%252Fsites\%252Fcodex\%252FMeetings\%252FCX-718-proxy/en/?lnk=1\&url=https\%253A\%252F\%252Fworkspace.fao.org\%252Fsites\%252Fworkspace.fao.org\%252Fsites\%252Fworkspace.fao.org\%252Fsites\%252Fworkspace.fao.org\%252Fsites\%252Fworkspace.fao.org\%252Fsites\%252Fworkspace.fao.org\%$ 34%252FAlO3 24e.pdf.

^{2002,} JMPR Report, General Considerations, Section 2.1: Needs of JMPR. Available at: https://www.fao.org/fileadmin/templates/agphome/documents/Pests Pesticides/JMPR/Reports 1991-2006/Report 2002.pdf.

CX/PR 22/53/20

CropLife International (2023). In-Session Working Group on CCPR/JMPR Enhancements: Highlights from the virtual CropLife 11 International workshops 2023 on Codex Enhancement. June 27, 2023. Available at: https://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CropLife_International_Codex_Enhancement.pptx.

¹² 2023, JMPR Summary Report, General Considerations, Section 2.7 - Enhancement Process. Available at: https://cdn.who.int/media/docs/default-source/food-safety/jmpr/jmpr-summary-report-sep-2023.pdf?sfvrsn=fc219dc7 3&download=true.

- 15. Other issues discussed by JMPR included:
 - the challenges of the limited evaluation capacity available, as well as the option to engage full-time paid evaluators, with JMPR serving as peer reviewers;
 - early submission of data, allowing a quality control screen and the early elimination of unsatisfactory dossiers from the assessment process; and
 - the focus on submission of only toxicological studies relevant to dietary exposure as a potential mechanism to reduce workload.
- 16. JMPR also highlighted that meetings are already intensive and long, so any benefits that might result from either lengthening the Meeting or trying to timetable additional meetings were considered unlikely to increase output.
- 17. The issue of adequate, timely submissions of data was also discussed above and further described in Section 2.5 of the 2023 JMPR Summary Report. Specifically, JMPR noted that, "several chemical dossiers submitted for evaluation were subject to multiple progressive updates and submissions over the course of evaluation." When this rolling submission of data occurs, it caused delays and disrupts the evaluation process. As such, JMPR "reemphasized the importance of a complete submission of data on all compounds and their metabolites to enable JMPR to perform a state-of-knowledge risk assessment.

4. APPROACHES TO ENHANCE THE OPERATIONAL PROCEDURES OF CCPR AND JMPR

- 18. Identifying an approach to enhance the operational procedures of CCPR and JMPR will require balancing the shorter-term needs of stakeholders to reduce the backlog of scheduled evaluations with longer-term strategic efforts to increase JMPR's review capacity. Towards this end, it is recommended that CCPR adopt a multiprong approach in which short-term work over the next three years (2024 2026) focuses on:
 - convening an extraordinary meeting of JMPR to reduce the backlog of evaluations; and
 - consulting with JMPR and stakeholders to identify specific projects that will improve its evaluation process.
- 19. JMPR has raised concerns that regular meetings are already time-intensive and long. As such, it may be preferable to convene an extraordinary meeting that focuses on new use evaluations only. This focus on new uses is consistent with the 2019 extraordinary which concluded that, "Extra meetings are currently not suitable for complex evaluations (e.g., new evaluations or periodic reviews) because of the limited availability of experts." If CCPR determines that more than one extraordinary meeting is required, then further deliberation may be required to ensure the appropriate balance between new compounds, new uses, and periodic reviews.
- 20. A range of stakeholders, including Codex members, observer organizations, and JMPR, submitted information on enhancement opportunities related to the theme of "Data Sponsor Dossier and Electronic Data Submission" (See Appendix II, Table 1). This includes several related project ideas that pertain to the development of electronic data submission tools that can improve the data submission process, strengthen data standardization, and reduce the level of effort required to verify that sponsors have submitted complete data packages in a timely manner. This may be a promising area for a targeted project and will directly address stakeholder concerns related to the backlog of evaluations and be responsive to the needs of JMPR. EWG participants have also called attention to work of the OECD Working Party on Pesticides that enables sponsors to make electronic submissions to OECD member countries. Study profile templates, an OECD study list and crosswalk references with national / regional pesticide regulators, and other existing OECD documents and materials should be the starting point for any electronic submission effort within JMPR / CCPR.¹⁴
- 21. If this multiprong approach is adopted, longer-term work over the next three to five years (2026 2028) can also be initiated to address more strategic issues that may relate CCPR/JMPR policy procedures and independent evaluation of JMPR's working procedures. These issues include stakeholder input on a range of strategic enhancements that relate to the themes, "JMPR Organizational Structure, Staffing and Resources," "Use of National Review and Data," and "Alternative Peer review Models (See Table 1 and Table 2 of Appendix II). For example, it has been suggested that employing full-time JMPR evaluators may increase JMPR's expert review capacity. Strategic issues are likely to be more complex and require additional deliberation to reach agreement on priorities and determine if there is support and resources available to conduct a more in-depth organization assessment and review of JMPR's working procedures.

JMPR 2019 Extraordinary Meeting Report, Page 5. Available at: https://www.fao.org/3/ca5711en/ca5711en.pdf.

Additional information on OECD Working Party on Pesticides resources available at: https://www.oecd.org/chemicalsafety/pesticides-biocides/agriculturalpesticides.htm.

22. Additional information on each of these potential short- and long-term approaches are further described in the figure on the following page.

5. CONCLUSIONS AND RECOMMENDATIONS

Conclusion

- 23. The EWG was established to advance efforts to enhance the operational procedures of CCPR and JMPR by exploring approaches to (1) identify priorities for enhancement and (2) develop an implementation roadmap and timeline. The EWG has completed its terms of reference and developed a multiprong approach that balancing the shorter-term needs of stakeholders to reduce the backlog of scheduled evaluations with longer-term strategic efforts to increase JMPR's review capacity.
- 24. As part of this multiprong approach the EWG has proposed short-term work over the next three years (2024 2026) that focuses on:
 - convening an extraordinary meeting of JMPR to reduce the backlog of evaluations; and
 - consulting with JMPR and stakeholders to identify specific projects that will improve its evaluation process.
- 25. While this short-term work advances, longer-term strategic efforts over the next three to five years (2026 2028) can also be initiated as part of the EWG's proposed multiprong approach. Strategic issues are likely to be more complex and require additional deliberation to reach agreement on priorities and determine if there is support and resources available to conduct a more in-depth organization assessment and review of JMPR's working procedures.

Recommendation

26. Based on the information provided in sections 4 and 5, CCPR is invited to consider the proposed short-term and long-term approach presented in Appendix I of this discussion paper to allow for further progress on the enhancement of the operational procedures and capacity of CCPR and JMPR.

<u>APPENDIX I</u>

(For comments)

Potential Short-term Approaches to Enhance the Operational Procedures of CCPR and JMPR, 2024 - 2026

Goal: Address immediate stakeholder concerns related to the backlog of evaluations and be responsive to the needs of JMPR.

Potential <u>Long-Term</u> Approaches to Enhance the Operational Procedures of CCPR and JMPR, 2026 - 2028

Goal: Address strategic issues related to CCPR/JMPR policy/ procedures and independently evaluate JMPR's working procedures.

Convene an extraordinary meeting of JMPR to reduce the backlog of new use evaluations.

While JMPR has raised concerns that additional meetings are resource intensive and may not increase the long-term output of JMPR, a targeted extraordinary meeting that focuses on new uses may help reduce the backlog of evaluations. Convening an extraordinary meeting will require coordination with stakeholders to:

- determine the appropriate review capacity,
- identify candidate compounds, and
- confirm that there are resources, staffing, and experts available to support the meeting.

Complete a targeted project that improves JMPR's evaluation process.

The aim of the targeted project is to improve a specific issue in JMPR's current evaluation process. One promising area for a targeted project is electronic data submission and data quality standards. Completing a targeted project will require coordination with stakeholders to:

- consult with JMPR to identify candidate projects and requirements,
- detailed the scope of work and impact on JMPR's evaluation process, and
- confirm that there are available resources and expertise to complete the project.

Request recommendations from JMPR and data sponsors on enhancements to policy and procedural Issues.

The EWG has previously gathered information from a range of Codex members and observer organizations on opportunities to either enhance or reform the operational procedures of CCPR and JMPR. Building off this information, CCPR could identify specific policy and procedural issues that can be addressed to increase review capacity. This will require coordination with stakeholders to:

- reach consensus on policies and procedural issues that can be changed to increase the review capacity of JMPR,
- develop a process to implement changes, and
- update the Codex policy and procedural manual as appropriate.

Request that FAO/WHO conduct an organizational assessment and review the working procedures of CCPR and JMPR.

There may be advantages to consulting with a third-party organization to build upon the 2002 Review of the Working Procedures of JMPR and conduct an independent organizational assessment of CCPR and JMPR. The aim of such an effort could be identify priorities and develop and strategic roadmap and timeline to address long-standing issues related to JMPR's review capacity, staffing, resources, and JMPR's operational model. This will require coordination with stakeholders to:

- consult with JMPR on the overall goals and objectives of an independent organizational assessment, and
- confirm that there are available resources and expertise to complete the project.

APPENDIX II

Summary of comments in response to CL 2022/75-PR Request for Comments on the Need to Enhance CCPR/JMPR and the associated opportunities and challenges (For information)

Charge Question 2 and 3

Please comment on opportunities to enhance the operational procedures of CCPR/JMPR to improve the efficiency of the evaluation process and increase JMPR's evaluation capacity. Please consider both opportunities for enhancement (e.g., improvements to existing processes) and major reform (e.g., governance and structural changes) in your comments. If possible, please organize your response using the suggested categories below.

• Opportunities for Enhancement

- o Data Sponsor Dossier and Electronic Data Submission
- CCPR Processes and Procedures
- JMPR Evaluation Process and Procedures
- JMPR Organizational Structure, Staffing and Resources
- Other Areas of Enhancement

Opportunities for Major Reform

- Use of National Reviews and Data
- Alternative Peer Review Models
- Other Areas of Reform

For the opportunities you have identified, please comment on the anticipated challenges, and propose possible solutions that may be implemented by CCPR and JMPR. This may include challenges related to resources, process and procedures, and governance.

Responses to Charge Questions 2 and 3 are excerpted in *Table 1* and *Table 2* below which provide information on opportunities for enhancement (e.g., improvements to existing processes) and major reform (e.g., governance and structural changes), respectively. The summary information presented in the tables was excerpted directly from submitted comments and organized based on common themes.

Table 1: Summary of Comments on Opportunities for Enhancement to CCPR/JMPR and Associated Challenges.

Theme	Excerpted Comments on Challenges and Opportunities
Data Sponsor Doss	sier and Electronic Data Submission
Data Standardization, Digital Templates, and Information Technology (IT)	 JMPR has developed extensive guidance documents on the preparation of dossiers and supporting data for evaluation by the FAO and WHO panels of JMPR. While the guidance documents outline requirements related to data formatting and organization of pesticide residue and toxicological information, there may be further opportunity to standardize the submission of data files that are submitted to JMPR for evaluation. For example, are there data submission software tools and data reporting standards that can be used to harmonize data across different sponsors? Harmonization of data submission across sponsors could potentially improve the efficiency of the evaluation process because JMPR reviewers could evaluate supporting data in a single format when performing analysis and summarizing relevant information. A potential area of interest that could be explored further is whether a standardized submission format could be developed for field residue trial data. Other areas of interest could be identified by JMPR and discussed with sponsors to determine the feasibility of developing tools to further standardize the reporting and submission of data.

Theme	Excerpted Comments on Challenges and Opportunities
	 Data sponsors have made progress to provide quality dossiers. Data sponsors seek yearly feedback on how they can further improve the dossiers to facilitate the work for the experts at JMPR. Periodic workshops to develop and implement improved digital templates and tools will be welcomed going forward.
	 Furthermore, IT tools need to be modernized to accept full dossiers as electronic submissions and study data in structured form. For example, FAO requested in its manual for the submission of residue data from 2016 the submission of residue data on spreadsheets.
	 Several templates have been developed and presented by Sponsors, but to date there is no agreed solution. As a major step forward FAO/WHO should establish relational databases with interfaces for upload of (structured) information provided by sponsors; utilizing electronic submissions by adopting OECD recommended formatting and naming conventions for study reports would also add efficiencies to the process.
	 As a first step it is suggested to explore and map all the possible non costly ways to enhance the operational procedures like improving templates and forms to enable expedited reviews and evaluation reports. The feedback could be also collected from the JMPR experts and industry to see which parts can be improved. It is also important for industry to be more proactive and send complete data packages to ensure that assessments are carried out without delay. For periodic reviews, the industry already knows the schedule many years in advance and can commit themselves to prepare the data packages well in advance.
	 There is need to develop a quality criterion to be used by the Data Sponsor Dossier and Electronic Data Submission to enhance credibility and verifiability of the JMPR global monographs. In addition, the sponsors should provide sufficient and current data within a specified time frame for efficient evaluation of pesticides to completion.
	 There is an opportunity to use electronic database as a tool for evaluation or screening process. For example, data sponsor dossier and electronic data submission, the national registration database to consider the re-evaluation of pesticides, particularly those unsupported compounds without public health concern, can be digitalized.
	 Data submitters should ensure to submit the same data as that submitted to all national authorities.
	 Data submitters are strongly encouraged to use a similar format to that which is in the JMPR Evaluations to generate the dossiers, especially the residue tables, as experts spend a considerable amount of time reformatting the dossier to meet the JMPR formatting requirements.
Timely Data Submission	It is considered that if data submissions could be made available to JMPR reviewers in a timely and consistent format which reduces the need for data entry, clearly identifies all food and feed metabolites and addresses all data requirements, then this should increase JMPR's efficiency. Ensuring that data submissions clearly address identified issues, and the avoidance of submissions which do not provide for the updating of relevant end points would assist in focusing work and avoid committing evaluator time without a concrete outcome from the JMPR process. The submission of incomplete data packages for new compounds and periodic re-evaluations can result in a significant waste of time and resources. Contemporary templates or electronic formats which ensure the onus on the sponsor to provide "user friendly" dossiers could provide substantial productivity improvements. Additional training through workshops on JMPR requirements for data packages could also be helpful.
Current Data Submission Issues	 When crop field trial data do not reflect the critical GAP, FAO experts spend a considerable amount of time trying to be flexible, attempting to "fit" the data to the critical GAP.

Theme	Excerpted Comments on Challenges and Opportunities
	 In recent years, metabolites were not consistently named in the WHO and FAO dossiers, making it very difficult to cross-link the metabolites, and ensure the appropriate and correct ones are considered in the residue definition.
	 Additional scientific and robust data on the toxicology of major plant and animal metabolites would assist in refining the residue definitions for risk assessment and limit the frequency of conducting metabolite-specific risk assessments based on Cramer Classes, which are very time consuming.
CCPR Processes an	d Procedures
Development of Efficient Dossiers	There are opportunities for improvement particularly for the resource intensive and data rich dossiers for periodic reviews of Codex MRLs. As a matter of fact, the number of substances that are scheduled for periodic reviews is building up. Since the resources of JMPR are limited, the list of periodic review substances are leading to a growing list of 'reserve compounds' for new substances. That is an unsatisfactory development from a sponsor's point of view. Sponsors need to prioritize the preparation of dossiers which were postponed. For the next JMPR, the dossier for a rescheduled periodic review needs to be updated with new information that has become available, to avoid inconsistencies between data submitted to JMPR and national authorities. Where new data become available, a clear procedure for submission is needed from CCPR to add these data, due to the fact that they no longer show-up on the schedule.
Schedule and Priority List	 To reduce the number of new uses for the same compound being reviewed at different JMPR Meetings, sponsors should consider maximizing the number of uses requested within one petition.
Coordination on Risk Management Issues	 JMPR should clearly describe the principles followed in its scientific risk assessments and ensure that issues that relate to risk assessment policy are referred to the CCPR. The CCPR reports shall explicitly state such policies in sufficient detail to ensure that the national governments and JMPR can apply them in their evaluations. This shall promote effective communication on risk assessment processes and procedures between CCPR and JMPR.
Criteria for Periodic Reviews	 An approach to enhance CCPR process is to extend the duration of periodic review specified in the Codex Procedural Manual, especially for the non-toxic pesticide of which the national registration exists. If GAPs for pesticide uses remain unchanged, CXLs are able to be retained.
	 Determine if it is possible to extend out the period for period evaluations such as 20 years. This will reduce the number of periodic evaluations over time
CCPR Plenary Discussion on MRLs and Appropriate Scope of Interventions	 The CCPR processes and procedures are relatively efficient, especially considering the scheduling of pre-meetings for various eWGs, ahead of the plenary, where several concerns raised by member countries are resolved, allowing a more focused discussion during the plenary.
	 In recent years, the MRL discussions have taken up significantly less time during plenary. However, the delays in reaching a consensus on some compounds appear to be due to the interventions from non-members (observer status) raising concerns that are not always scientifically-based and validated. While the CCPR Chair and secretariat have been very respectful and diplomatic in addressing these interventions, CCPR is encouraged to explore opportunities to limit such interventions from observers, used predominantly to show case their organization.
Timely Maintenance of the Codex	 Extra resources could be put towards updating the pesticide MRL database in a timely manner following adoption by Codex. Countries rely on this database as the source of truth for CXLs, so maintaining its currency should facilitate trade.

Theme	Excerpted Comments on Challenges and Opportunities
Pesticide MRL Database	 In addition, the Codex secretariat is asked to update the online CODEX MRL database shortly after the CAC meeting, ideally within 90 days, to reflect the most recent decisions and allow for practical search for CXLs by food value chain partners and competent authorities.
CCPR Support for Extra Meetings	 CCPR is responsible for establishing the schedule and priority list for JMPR and has more limited ability to improve the efficiency of the evaluation process and increase JMPR's evaluation capacity. In the past, CCPR has also helped support extraordinary meetings of JMPR and 2019 and 2021. Extraordinary meetings can help increase the review capacity of JMPR in short-term instances; however, increasing the frequency of meetings also places additional burden on JMPR evaluators and will not increase JMPR's overall capacity if there is not an increase in the number of trained JMPR experts who are available to participate.
JMPR Evaluation P	Process and Procedures
Required Scope and Level of Detail in Data Sponsor Dossiers and JMPR	 Does JMPR undertake a pre-assessment of the Data Sponsor Dossier before assessment is undertaken. If not, then this could be an opportunity to filter out incomplete dossiers before they enter the assessment process. They then go to the back of the queue. Depending on the process, there could be backup submissions to replace those submissions rejected at the pre-assessment.
Monographs	 Where additional uses are made for existing compounds, when the compound is due for a periodic evaluations, what is JMPR position on assessment of such data eg less than 5 years from when the periodic evaluation commences.
	 JMPR monographs need to be transparent and sufficient for a third party to determine how JMPR reached its conclusions and recommendations. The key challenge is how much is too much and how little is too little.
	 Therefore, is the balance between these two correct for current monographs? Should it be considered they are 'over engineered' then they could be reduced saving time for assessors and allowing them to assess more submissions.
Working Procedures	The main bottle neck are the capacity and limited number of experts rather than the processes and procedures within JMPR.
	CCPR should consider the following concrete proposals:
	a. JMPR should continue to work face-to-face complemented by virtual meetings.
	 Provide the opportunity for pre-submission meetings between the data sponsors and the expert evaluators.
	c. There should be an opportunity for the data sponsor to respond to concerns during the JMPR. This could reduce the number of MRLs that cannot be set because of "missing" data, or misalignment between tox and environment evaluations.
	 Regarding scientific procedures, where data requirements change, following discussions in JMPR or other expert consultations, FAO/WHO are asked to better explain the rationale for this change and invite public comments before implementation. Changes in requirements should be published on-line as amendments to existing guidance, and not requested on an ad hoc basis during evaluations. FAO and WHO should increase their efforts to ensure that all decisions are taken consistently in line with published guidance.
	 Revision of evaluations after the JMPR leads almost unavoidably to a one year delay in progressing a standard. FAO and WHO are asked to implement procedural changes so that, where necessary, JMPR opinions can be revised prior to the next CCPR meeting. In case of concerns, a peer review by different experts as a second opinion is suggested.

Theme	Excerpted Comments on Challenges and Opportunities
	 For new compounds, periodic reviews, and new uses where new toxicology data is submitted to WHO, consideration should be given to having WHO complete their evaluation one year prior to FAO conducting their evaluation. Having the Health Based Guidance Values (HBGVs) and toxicology assessment of the metabolites well ahead of the FAO evaluation could reduce the amount of time spent during the Meeting conducting the risk assessment. Currently, FAO receives the WHO assessment on the metabolites days before the end of the Meeting, creating significant but unnecessary stress and anxiety.
Quality Control Check in Data Submission	 Quality assurance criteria is set for the data submitted to JMPR for review and evaluation and FAO and WHO explore the practical considerations associated with undertaking some of the work of the JMPR on an inter-sessional basis.
	 Rationale: This will enhance the credibility of the data and the monographs while the inter- sessional meetings are likely to reduce the workload.
	 Typically when a complete data package is submitted and no issues are identified, the JMPR manages to complete assessments of compounds within a 12 month timeframe. Data packages are usually submitted in the 4th quarter of the year prior to the JMPR Meeting. These data packages are assessed and recommendations made and published in the month following, usually in October. That is significantly faster than many national authorities.
	 Ensuring that the JMPR evaluator has a complete dataset, by a set cut off date, may help facilitate a more efficient JMPR evaluation. An effective mechanism for JMPR conducing preliminary checks of submission quality may be beneficial.
	The current approach is for the JMPR toxicology and residue evaluations to be conducted at the same time, but the completion of a draft toxicology monographs the year before the residue's evaluation is undertaken may allow for more efficiencies for the residues evaluation particularly with regard to the residue definition determination and dietary exposure assessments. This however may require clear identification of potential food and feed metabolites to the JMPR toxicology evaluator by the sponsor and a potential need for the toxicology monograph to be revisited when the residues monograph has been drafted.
Efficiency in Virtual Collaboration	 Virtual meetings: Although virtual meetings cannot replace in-person meetings, they could be a mechanism for potentially increasing the number of approvals for smaller and less complex evaluations (e.g. new uses). Virtual meetings cost less to host than in-person meetings and generally require less planning (i.e. no need to book hotels and flights). However, the challenge with virtual meetings is the differing time zones.
	In recent years, FAO has held a few virtual pre-meetings leading up to the September meeting, with members grouped according to time zones, to go through as many identified issues before the Meeting. However, as these pre-meetings do not involve all FAO experts, consensus can only be reached during the Meeting, where occasionally differing scientific opinions are raised and experts are required to revisit/re-assess decisions previously reached in the pre-meetings.
	 JMPR Sharepoint: FAO created a sharepoint to share information, provide updates, exchange reviews, which has been extremely useful.
	All FAO experts have the opportunity to peer-review the reviews on the sharepoint, ahead of the Meeting, which would facilitate and expedite discussions during the Meeting. However, most FAO experts are so busy with their day-to-day jobs, reviewing/completing their own compounds (on their own time), there is very little time for the entire panel to peer-review the reviews available on the sharepoint ahead of the September meeting.
	 The effective use of virtual meetings and more extensive peer review should be continued with the aim of resolving possible issues in advance of the face-to-face meeting.

Theme	Excerpted Comments on Challenges and Opportunities
	 The virtual meetings held during the pandemic shutdowns highlighted the importance of face-to-face meetings to enable full engagement in discussions of complex issues over a number of days. Particularly given the variety of time zones involved. As a result, for anything other than relatively simple decisions, face-to-face meetings are essential.
JMPR Organization	nal Structure, Staffing and Resources
Funding	 Funding is one of the key constraints. If JMPR could employ more staff and pay assessors this would assist.
	 The previous 2002 review of the working procedures of JMPR: https://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/c rit_review.pdf. This report found that "both the FAO and WHO are severely limited in the financial resources that they can make available for the work of the JMPR due to competing demands on their respective budgets."
	 Position: Developing countries have financial limitations and therefore recommends that FAO and WHO explore the possibility of securing additional funds from donors e.g., Crop Life International to allow the better resourcing of the JMPR.
	 Rationale: Additional funding shall improve efficiency and increase output.
	 While increasing the capacity of JMPR may address the workload demand, to do so requires increased sustainable funding from various national authorities. However, in the current financial climate, it is questionable whether national authorities will agree to commit funds to support JMPR/CCPR in light of all other national priorities.
JMPR Experts	 Since the shortage of JMPR experts to carry out the evaluation of toxicological and residues dossiers submitted by the agrochemical industry and member countries has been identified as a key contributing factor behind the built-up of the backlog. It is also suggested that CCPR and JMPR shall jointly explore the possibilities and approaches for enrolling more JMPR expert from Member Countries. Equally important is to recruit and train up promising young officers with good scientific qualification and technical experience in the critical domain areas through capacity building and mentorship programme.
	 One option could be the implementation of additional meetings of the JMPR. However, it seems very unlikely that experts already working for JMPR pro bono will be available for more than one meeting. Instead, a second group of experts and an overarching structure would be needed to keep the two expert groups connected and harmonize procedures and evaluations (otherwise, a lack of consistency is likely to occur).
	Despite the FAO training and recruiting workshops held most recently in 2017 (Ottawa) and 2020 (Chile), these sessions only identified a handful of successful candidates, some of which have joined the JMPR, while others declined due to competing priorities and career opportunities. These last few years, several knowledgeable and experienced experts have retired. While the overall number of FAO experts may not have fluctuated considerably over the last few years, the workload has increased exponentially. As a result, each expert is assigned one new compound or periodic review with up to 3 new uses, which is not sustainable, especially considering that most experts conduct their reviews outside of work hours, on their own time and on a voluntary basis.
	 Recruiting more JMPR experts is very difficult and resource-intensive. Regulatory authorities are not always able to send more than 1-2 experts to JMPR or allocate time during their work hours to conduct JMPR review due to priorities of the national authority. In addition, experts are volunteers and are not compensated for the amount of time spent working on the evaluations. In addition, although the in-person meetings give experts the opportunity to travel, there is very little recreational time for them to enjoy the cities. FAO experts only get one day off (over an almost 3 week meeting) and work late hours. There is a lack of incentive to become an expert.

Theme	Excerpted Comments on Challenges and Opportunities
	 The 2002 JMPR report found that participation of JMPR experts is done on a voluntary basis and requires the support of national regulatory authorities. National authorities may be resistant to allowing their experts to work on JMPR. Given these constraints in resources and staffing, it may be more promising to consider other opportunities that increase the efficiency of the existing evaluation process or re-evaluate the JMPR evaluation model.
	It is considered that recruiting and training new expertise and retaining existing JMPR expertise is of critical importance. JMPR training sessions for potential new toxicology and residues evaluators may help recruit new experts but additional initiatives to attract and retain experts may be needed. Retaining existing expertise to help train new additions and to complete the more complex evaluations in the short-term is of great importance but care should be taken to not over-burden experienced experts. JMPR experts can spend considerable amounts of their own time preparing JMPR monographs and it has been suggested that a cap on the number of hours JMPR experts can individually spend on monograph preparations prior to the meeting may help attract and retain experts.
	 Another option for increasing the JMPR expert capacity that should be explored is for the FAO and WHO to employ full-time JMPR evaluators, or second staff on a semi-permanent basis, to draft a certain number of monographs per year. This would assist with providing monographs to the meeting, however it should be noted that there still may be challenges within the current format for enough 'face-to-face' time for discussion of issues. A clear process for peer review for these reports would be required, which may still rely on the resources of the JMPR experts.
	 JMPR meetings are typically held in Rome or Geneva, but more flexibility in terms of meeting locations may be attractive to JMPR experts, particularly for those based outside of Europe.
	- More experts are needed to expand the capacity of the JMPR panels.
Staffing	 FAO/WHO joint secretariats need additional staff, but not in a position to quantify that demand.
	 For matters requiring a high degree of specialization, FAO and WHO are asked to add experts to their panels representing multiple geographical regions, including from underrepresented ones.

Table 2: Summary of Comments on Opportunities for Major Reform to CCPR/JMPR and Associated Challenges.

Theme	Comments on Challenges and Opportunities	
Use of National Re	Use of National Reviews and Data	
Use and Evaluation of National Reviews by JMPR	 In principle this is something that should be explored. It assumes there are national reviews completed when JMPR assesses the compound. Another consideration does there need to be criteria on what is considered an acceptable national review. 	
	 Recommens the use of National and/or Regional Scientific Data for Risk Assessment by JMPR. The use of these national or regional summaries of data by the JMPR would result in substantial time savings, while allowing the JMPR to concentrate on international risk assessment. 	
	 We are of the view that there is an opportunity to use the national reviews for JMPR's evaluation. However, the capacity building is also needed to strengthen capabilities of Codex members to fulfil the requirements for JMPR evaluations. Furthermore, the details of each stage of the national review procedure should be thoroughly provided. 	

Theme	Comments on Challenges and Opportunities
	 JMPR experts should consider national reviews in their evaluations. The submission of national reviews to initiate JMPR reviews has been requested by FAO for a long time. These national reviews could be submitted by national authorities in response to the Circular Letters, where all stakeholders are invited to submit relevant information. Therefore, especially the owners/publishers of those reviews should be encouraged to submit this information. Codex could also develop a system of all new national MRL reviews. For periodic reviews of existing MRLs, Codex could refer to private global databases (e.g. Homologa) that can be leveraged as they have tracked global MRL and labels for more than two decades.
	Given that it may be difficult to change the availability of JMPR resources and staffing, one potential area of opportunity is the use of national-level reviews by JMPR. The relates to current work by CCPR to enable the participation of JMPR in the global joint review of new compounds. The use of national reviews of data was considered in the 2002 review of the working procedures of JMPR and may be helpful to re-evaluate based on advancements by the Organization for Economic Cooperation and Development and regional approaches that may be able to be further leveraged by JMPR.
	 It is unclear what is being proposed by use of national reviews and data. The data packages provided to the JMPR often represent data from several countries. Following review of the data and the regulatory approvals in place at the time of the JMPR assessment, the critical GAP is decided upon the supporting data used to make a maximum residue limit recommendation.
	 If the proposal is for JMPR to use national reviews of data and the related risk assessment, it is considered that there are pros and cons associated with the potential use of national reviews. There may be efficiencies in terms of monograph preparation if a national review could be used by the JMPR evaluator, for example to produce tables of residue trial results. The Australian Pesticides and Veterinary medicines Authority has an established process for considering international assessments to inform its regulatory decision, but it does not simply adopt the conclusions of that international assessment. If national reviews were to be used by the JMPR, a process will need to be determined to maintain the independence (both perceived and actual) of the JMPR and ensure that the decisions made by the JMPR are consistent with the JMPRs risk assessment framework. The concept of JMPR joint reviews with a national regulator has been discussed recently, but to date lacks any real drive.
	 JMPR consists of experts from many different regulatory agencies and already takes note of National Review documents and data to support their conclusions. A decision on using National Reviews directly for establishing CXLs would be up to the risk managers. They also would have to define the circumstances under which such an approach would be acceptable for Codex Members.
	 National Reviews often differ from one authority to another due to different science policies and legislative requirements and in many cases because manufacturers often submit different data to each authority. All national reviews have their merits, therefore, it is questionable how JMPR will determine which national review it will rely on. Furthermore, the format and templates used to review toxicology and residue chemistry data are different among the various authorities. If all authorities and JMPR can agree to one standard template/format, perhaps the 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.
	 Use of national reviews and data by JMPR must be balanced with the need to maintain JMPR as an independent, international scientific advisory panel. This is a core element of JMPR so clear working procedures would have to be developed to maintain its ability to independently evaluate pesticides when making MRL recommendations.

Theme	Comments on Challenges and Opportunities
	 It is considered that the use of national monographs may pose certain challenges with the perception of independence of the evaluation process, as well as requiring permission to be obtained not only from the sponsor but from the national authority for the use of the document.
Alternative Peer R	eview Models
Scope of Current Approach and Whether Alternatives are consistent with the Codex Risk Analysis Principals	 Is the current Peer Review model fit for purpose? Is it too extensive or light, or just right. It is not clear what criteria are used for peer review process or the number of persons involved in the peer review process. These could be reviewed as to whether they are still fit for purpose.
	 Alternative peer review models would certainly alleviate the JMPR workload, however, any organization/authority designated as peer-review would need a sound knowledge of residue chemistry data, the Codex Risk Analysis Principles, the JMPR science policies (FAO Manual) and historical JMPR decisions to ensure consistency and accountability.
Engagement on National Reviews	In order to facilitate the use of national reviews, we encourage the involvement of JMPR experts as observers. Procedurally, JMPR gets involved after a pesticide has been authorized in at least one Codex member state, as a condition for scheduling. For substances that have been nominated, by change of procedures, JMPR experts could be invited as observers to meetings of authorities when decisions are taken on relevant topics, such as the definition of the residue(s), health-based guidance values, and MRLs. This could help to minimize differences between JMPR and national evaluations and to identify data gaps which could be closed prior to information submission to the JMPR. The independency of JMPR Reviewers' conclusions is ensured by the specific JMPR criteria they apply to a dataset summarized by a national review agency.
Other Areas of Rej	form
Scope of Evaluations and Default MRLs	 Should the scope of commodities that can have a MRL established be revisited (for example animal feed commodities). If this is reduced then this would reduce the number of submissions and hence the workload for JMPR assessors.
	 Where a Codex MRL has been established for a new compound, could a default MRL (such as 0.01mg/kg) be also established if there is no dietary exposure concerns. This would assistance by both reducing trade irritants and potentially reducing the number of MRL submissions.
Developing a Continuous JMPR Review Program	 Concerns were raised about whether annual decision making in Codex still meets current demands of Codex members. It was suggested that establishing a permanently existing JMPR working on scheduled submissions as a more appropriate solution to provide scientific advice. In addition, as already mentioned above, providing early advice to the CCPR on the schedule of existing chemistry for periodic re-evaluation could be an important contribution to reduce workload in JMPR and CCPR.
	 In order to move to a continuously working Codex system, a second virtual CCPR meeting could be established in addition to the annual meeting of CCPR. This additional virtual CCPR could exclusively decide CXLs while the face-to-face CCPR meeting manages CXLs and all other CCPR matters (e.g. eWGs). In order to leverage the efficiencies gained at CCPR, the CAC should adopt the proposed CXLs through a written procedure in addition to adopting CXLs at the face-to-face CAC meeting.

APPENDIX III

LIST OF PARTICIPANTS

CHAIR

UNITED STATES OF AMERICA

Aaron Niman
U.S. Environmental Protection Agency

Co-CHAIRS

COSTA RICA

Costa Rica

Amanda Lasso Cruz Ministerio de Economía Industria y Comercio

> Alejandro Rojas Leon Servicio Fitosanitario del Estado

UGANDA

Geoffrey Onen
Assistant Commissioner
Directorate of Government Analytical laboratory

MEMBERS NATIONS AND MEMBER ORGANIZATIONS ÉTATS MEMBRES ET ORGANISATIONS MEMBRES ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS

AUSTRALIA - AUSTRALIE

Karina Budd

Department of Agriculture Water & the Environment

James Oliver Deller

Australian Pesticide and Veterinary Medicines Auth

BELGIUM - BELGIQUE - BÉLGICA

Wim Hooghe

FPS Health, Food Chain Safety and Environment

CHILE - CHILI

Roxana Inés Vera Muñoz Servicio Agrícola y Ganadero

Jorge Elvis Carvajal Vásquez Servicio Agrícola y Ganadero

COSTA RICA

Tatiana Vásquez Morera

Servicio Fitosanitario del Estado-MAG

Ivania Morera Rodríguez Servicio Fitosanitario del Estado

EGYPT - ÉGYPTE - EGIPTO

Mariam Barsoum Onsy

Egyptian Organization for Standardization & Quality

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Siret Surva

European Commission

FRANCE - FRANCIA

Xavier Sarda Member Country

ANSES

GERMANY - ALLEMAGNE - ALEMANIA

Karsten Hohgardt

Bundesministerium für Ernährung und Landwirtschaft

GUATEMALA

Zenia Aguilar Other

Ministerio de Agricultura, Ganadería y Alimentación de

Guatemala

INDIA - INDIE

Dr S C Dubey Member Country

Indian Council of Agricultural Research, New Delhi

Dr VANDANA TRIPATHY Member Country

ICAR-Indian Agricultural Research Institute

Sukesh Narayan Sinha Member Country

ICMR-National Institute of Nutrition

Santhosh J Eapen

ICAR

JAPAN - JAPON - JAPÓN

Codex Japan FAO/WHO

Ministry of Health, Labour, and Welfare

Tomoyuki KAWAI Member Country

Ministry of Agriculture, Forestry and Fisheries

MALAYSIA - MALAISIE - MALASIA

Mohammad Nazrul Fahmi Abdul Rahim Department of Agriculture Malaysia

Nurhayati Kamyon Department of Agriculture

MEXICO - MEXIQUE - MÉXICO

Tania Daniela Fosado Soriano Secretaría de Economía

NEW ZEALAND - NOUVELLE-ZÉLANDE - NUEVA ZELANDIA

Warren Hughes

Ministry for Primary Industries

Sophie Geyrhofer Member Country

Ministry for Primary Industries, Plant Exports

REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA

Park Yoona

Ministry of Food and Drug Safety

Hwang Kiseon MAFRA

SAUDI ARABIA - ARABIE SAOUDITE - ARABIA SAUDITA

Nimah Baqadir

Saudi Food & Drug Authority

Saif Moala AL-Mutairi Member Country

SFDA

SIERRA LEONE - SIERRA LEONA

Raymonde A. B. Johnson Member Country

Ministry of Agriculture and Forestry

SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA

Aluwani Alice Madzivhandila Department of Health

SWEDEN - SUÈDE - SUECIA

Niklas Montell

Swedish Food Agency

THAILAND - THAÏLANDE - TAILANDIA

Chonnipa Pawasut

ACFS

Namaporn Attaviroj

National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives

UGANDA - OUGANDA

Fred Barungi Member Country

Uganda National Bureau of Standards

Ruth Awio Member Country

Uganda National Bureau of Standards

UNITED KINGDOM - ROYAUME-UNI - REINO UNIDO

Julian Cudmore Member Country

Health and Safety Executive, UK

UNITED STATES OF AMERICA - ÉTATS-UNIS D'AMÉRIQUE – ESTADOS UNIDOS DE

AMÉRICA

Marie Maratos Bhat USDA-US Codex Office

OBSERVERS - OBSERVATEURS - OBSERVADORES

International Council of Beverages Associations

Simone SooHoo

CropLife International

Wibke Meyer

CropLife / Bayer Crop Science

Greg Watson

Tea & Herbal Infusions Europe (THIE)

Cordelia Kraft