CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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CL 2021/43-PR
May 2021

TO: Codex Contact Points
Contact Points of international organizations having observer status with Codex

FROM: Secretariat, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme

SUBJECT: **Request for comments on the procedures and principles for the engagement of JMPR in parallel reviews of new compounds**

DEADLINE: **5 July 2021**

BACKGROUND

1. For background information, please refer to CX/PR 21/52/16.

REQUEST FOR COMMENTS

2. Codex members and observers are invited to provide comments on the recommendations for the engagement of JMPR in parallel reviews of new compounds (CX/PR 21/52/16, paragraph 28) based on the conclusion and information provided in Sections 2-7 of the discussion paper as per the Annex to this Circular Letter.

3. General Comments on the (i) overall content and timeframes of the proposed approach (principles and procedures) to enable JMPR to engage in parallel reviews of new compounds as described in Sections 2-7 and (ii) whether the principles and procedures are robust enough to support the implementation of a pilot project on the understanding that the proposed process remains flexible for further improvements based on the experience gained with the pilot project (iii) the recommendation made in this regard (CX/PR 21/52/16, paragraph 28)

4. Specific comments for further improvements may be provided, such as inclusion or removal of provisions, refinement of the current text, timelines, etc.

5. CL 2021/43-PR, Annex is uploaded to the Codex Online Commenting System (OCS): https://ocs.codexalimentarius.org/, as per the guidance below.

GUIDANCE ON THE PROVISION OF COMMENTS

6. Comments should be submitted through the Codex Contact Points of Codex members and observers using the OCS.

7. Contact Points of Codex members and observers may login to the OCS and access the document open for comments by selecting “Enter” in the “My reviews” page, available after login to the system.

8. Contact Points of Codex members and observers organizations are requested to provide proposed changes and relevant comments/justifications on a specific paragraph (under the categories: editorial, substantive, technical and translation) and/or at the document level (general comments or summary comments). Additional guidance on the OCS comment categories and types can be found in the OCS Frequently Asked Questions (FAQs).

9. Other OCS resources, including the user manual and short guide, can be found at the following link: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

10. For questions on the OCS, please contact Codex-OCS@fao.org

ANNEX

PART I: General comments (see CL 2021/43-PR, paragraph 3)

a. To consider the proposed principles and procedures for parallel reviews of new compounds as described in Sections 2-7 and determine whether they are robust enough to provide the basis for the implementation of a pilot project; if so,

b. To encourage data sponsors considering product registration in more than one country in the near-future to nominate compounds for the parallel review pilot in coordination with the Chair of the EWG/Priorities and the FAO/WHO JMPR Secretariats for consideration by CCPR53 (2022).

c. To test the procedure through a pilot project in order to refine the proposed process to reflect practical, real-world considerations, and ensure that JMPR resources continue to be used efficiently.

d. To agree that the proposed process will document the actual outcomes to accelerate the establishment of Codex MRLs and harmonization with international MRLs.

PART II: Specific comments on the proposed approach, if necessary, based on the replies provided to Part I (see CL 2021/43-PR, paragraph 4)

2 – SELECTION OF PESTICIDES FOR JMPR EVALUATION

2.1 – Nomination process - timelines

- The current timelines for the nomination of new compounds would also apply to those part of a parallel review process.
    - September - November 30 – EWG on Priorities' request for nominations: Codex Committee on Pesticide Residues (CCPR) members/observers submit nominations for a new compound, indicating if they would like JMPR to engage in a parallel review, which countries have agreed to engage in the review, and when data packages, including the proposed GAP, will be available. (*Note: Should the process be officially adopted, the nomination form would need to be amended accordingly*).
    - January – EWG on Priorities circulates proposed Schedule and Priority List for Comments
    - April – CCPR agrees to forward the JMPR Evaluation Schedule for the following year to the Codex Alimentarius Committee (CAC) for approval.
    - July – CAC approves the proposed JMPR Evaluation Schedule for the following year.

2.2 – Nomination requirements and criteria for the prioritization and scheduling pesticides for evaluation by JMPR[1]

- **Nomination requirements – new pesticides[2]**

  The current nomination requirements of new pesticides would also apply to those part of a parallel review process:

    - An intention[3] to register the pesticide for use in a member country, or more than one member country for pesticides that will undergo a JMPR parallel review.
    - The foods or feeds proposed for consideration should be traded internationally.
    - There is a commitment by the member/observer of the pesticide to provide supporting data for review in response to the JMPR "data call-in".
    - The use of the pesticide is expected to give rise to residues in or on a food or feed moving in international trade.
    - The pesticide has not been already accepted for consideration.
    - The nomination form has been completed.

- **Prioritization criteria[4]**

  The current prioritization criteria of new pesticides would also apply to those part of a parallel review process, such as:

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1 The Risk Analysis Principles applied by CCPR can be found in the Procedural Manual of the Codex Alimentarius Commission (CAC) available on the Codex website at: http://www.fao.org/fao-who-codexalimentarius/publications/en/

2 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 61

3 A complete data package may have been submitted to participating countries – or – countries have agreed to participate in a parallel review.

4 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 62

- Timing of data availability.
- Commitment by the member/observer to provide supporting data for review with a firm date for data submission.
- The provision of information on the foods or feeds for which CXL are sought and the number of trials for each food or feed.

- **Scheduling criteria**[5]

1. The current scheduling criteria requires a pesticide to be registered for use in a country and formulation labels available to allow the scheduling of a compound for JMPR evaluation in the following year.

2. Considering that a parallel review implies the JMPR assessment of a pesticide prior to its registration in a country, a new sub-paragraph would be needed to acknowledge this new sub-category as follows:

   Only pesticides nominated for a parallel review will be exempted from the requirement for a national registration at the time of scheduling. In order for CCPR to agree to having a pesticide evaluated by the JMPR as part of a parallel review, the complete data package as required by JMPR (see data categories in section 4.2.) must be made available at, or shortly after the CCPR meeting. This will allow JMPR to initiate the parallel review process as soon as the product nominations are approved by CAC in July of each year.

3 – JMPR CALL FOR DATA

3. The JMPR Secretariat typically develops the JMPR assignment list, and assigns compounds for review by FAO/WHO experts in the last quarter of the calendar year. The JMPR call for data is typically undertaken in November with a submission deadline of late-December. It is suggested that the JMPR Secretariat consider early planning for parallel reviews (i.e. early identification of evaluators and early data-intake).

4 – PARALLEL REVIEW

4.1 – Project management

4. It is suggested to identify a global project manager to oversee the parallel review, in close collaboration with the WHO/FAO JMPR Secretariat/JMPR reviewers and national points of contact (governments). The global project manager would liaise with all parties including the sponsors and ensure that the identified timelines and milestones are met throughout the process which includes the conduct of the data completeness check.

4.2 - Interaction between national and JMPR reviewers

5. The nature of parallel reviews implies that it is conducted concurrently with national reviews and that the interaction between reviewers may occur to discuss scientific matters related to the data packages.

6. To optimize the participation of the JMPR in the parallel review process, the JMPR reviewers would be assigned following the endorsement of the schedule by CAC in July, and submission of the JMPR dossier could also occur shortly thereafter (prior to the regular data call-in). The JMPR Secretariat will carefully select the JMPR reviewers to ensure they are not the same experts as the ones involved in the national registration process.

7. To support information-sharing and the engagement of the JMPR reviewers in the parallel review, the contact information of the JMPR reviewer would be provided to the global project manager responsible for coordinating the joint review.

8. The concept of parallel reviews also requires that the exact same data package for toxicology, product chemistry, residue chemistry, including metabolism and environmental fate, be provided to national regulatory agencies and JMPR.

9. In the event that additional toxicology or residue chemistry information is provided to one party, sponsors must ensure that it is provided to all other parties, including JMPR, such that data packages under review remain identical.

4.3 - Parallel review timelines

10. Other than an earlier review start by national authorities, it is possible that the parallel review will take place over two JMPR Meetings (see table 1). Should that be the case, there would be an opportunity for the JMPR reviewer engaged in the parallel review to discuss metabolites /residue definition for MRL enforcement during the JMPR meeting of the first cycle (about a year following the beginning of the parallel review).

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5 CAC Procedural Manual, Section IV – Risk Analysis, Risk Analysis Principles applied by CCPR, sub-section 5.2.2, paragraph 63

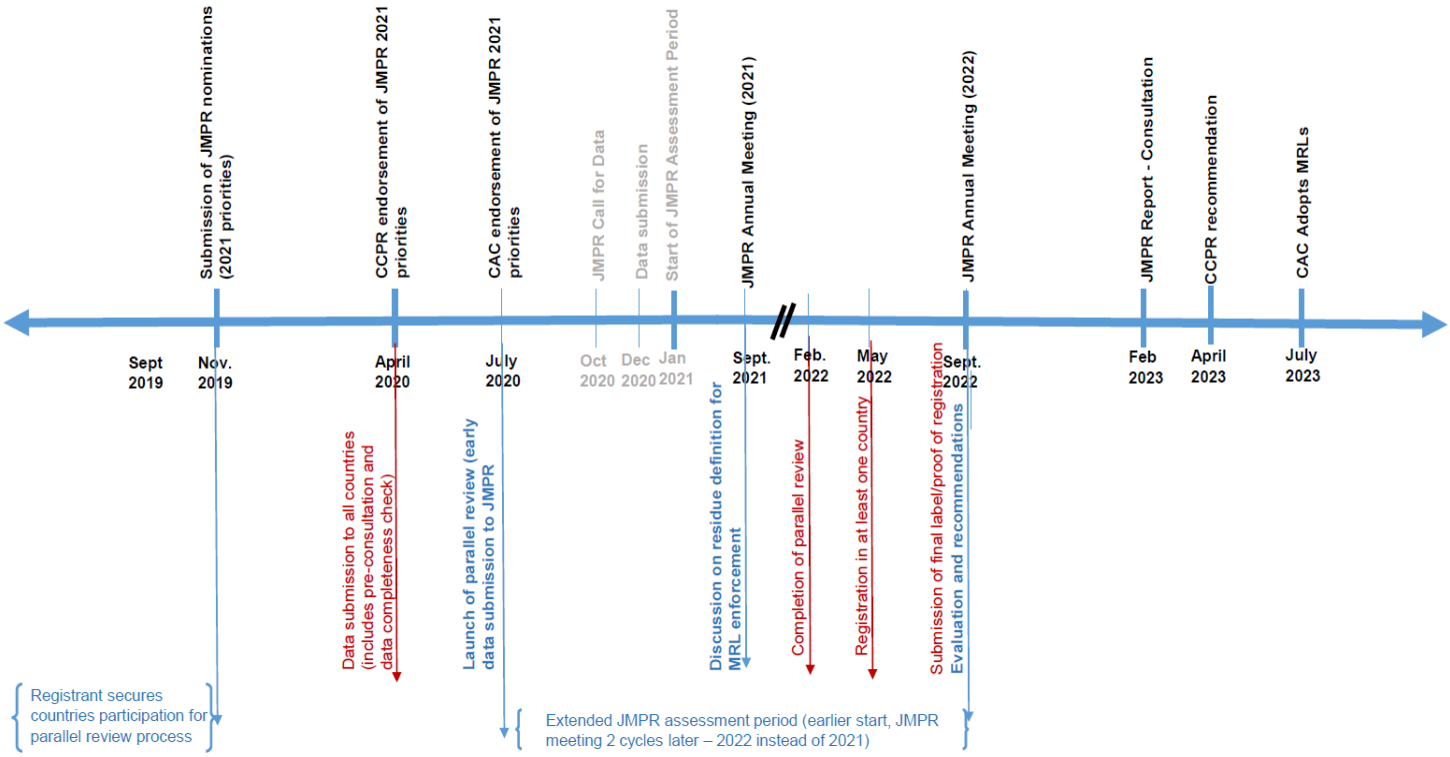
4.4 - Changes to the draft label

11. Should final conditions of registration (i.e., application rate, number of applications, etc) in member countries differ from the GAP reviewed by the JMPR, the expert would apply the FAO 25% variation rules, proportionality or any other applicable approach, to determine whether the recommended maximum residue limits must be recalculated and the dietary risk assessments reviewed.

12. JMPR recommendations to the CCPR occur by consensus. Should changes to the GAP go beyond the principles established by JMPR, and occur following the JMPR annual meeting, the JMPR reviewer would update the evaluation accordingly, consult with participating countries/sponsor and seek endorsement from the JMPR Meeting. The post-review update should be completed prior to the finalization and distribution of the JMPR final report in February, or postponed to the following JMPR Annual Meeting. Considerations should be given to alternative means for decision-making outside of the annual JMPR Meetings, such as teleconferences and email correspondence.

13. The table below is meant to illustrate potential timelines for a parallel review and how they could align with key CCPR/JMPR milestones. Twenty-two months were used as the proxy for national reviews. The timelines for public consultations and product registration would differ per participating countries; the proxy used for public consultation and product registration is three months.

Table 1: Scenario – projected timelines (over 2 JMPR Meetings)



5 - RISK ASSESSMENT METHOLODOGY

14. The JMPR experts engaged in the parallel review would review data packages and provide scientific advice according to the existing evaluation methodologies of the JMPR:

15. FAO Manual on the Submission and evaluation of pesticide residues data for the estimation of MRLs

- JMPR Guidance Document for WHO monographers and reviewers

16. It is also expected that the parallel review will build on the latest OECD guidance on definition of residues[6], which will facilitate alignment of residue definitions for MRL enforcement to the extent possible. It is recommended that alignment of crop categories be discussed between parties.

6 OECD currently working on a revision of its 2009 *Guidance Document on Definition of Residue*, in collaboration with JECFA, FAO and WHO experts.

17. There is recognition that parallel reviews may contribute to alignment of decisions between parties (e.g. MRLs, residue definitions, etc.). However, as all parties will conduct their risk assessment based on their organizational requirements and methodologies, reaching consensus may not be achievable. While differences should be discussed, individual review/registration processes should continue as planned to avoid delays.

6 – SUBMISSION OF FINAL LABEL

18. JMPR's proposed MRLs are typically presented to CCPR in February of each year. At that time, pesticides assessed under the parallel review process should be registered in at least one country, and final label and proof of registration submitted to the JMPR Secretariat. Inability to complete this step of the parallel review would postpone the JMPR MRL recommendation to the following year.

7 – INTERACTION BETWEEN JMPR REVIEWERS AND THIRD PARTIES (NATIONAL REGULATORS, SPONSOR)

19. Evaluators may wish to communicate with the data sponsor throughout the evaluation process to seek clarification or request that additional data be submitted. It is suggested to centralize communications with and from the data sponsor through the global project manager. The objective of centralizing communications would be to streamline communications with the sponsor, promote transparency, and ensure all reviewers receive the same additional data/information or clarifications from the sponsor.