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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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DISCUSSION PAPER ON OPPORTUNITIES AND CHALLENGES FOR THE JMPR PARTICIPATION IN AN INTERNATIONAL REVIEW OF A NEW COMPOUND

(Prepared by an Electronic Working Group chaired by Canada and co-chaired by Costa Rica and Kenya)

1 BACKGROUND

1. The 50th Session of the Codex Committee on Pesticide Residues (CCPR50, 2018) agreed to establish an electronic working group (EWG), chaired by Canada, and co-chaired by Costa Rica and Kenya, to assess the opportunities and potential challenges that may be associated with the participation of the JMPR in an international joint review of a new compound.

2. It was determined that work of the EWG would be performed according to the following Terms of Reference:

> (i) To identify and assess the benefits, challenges and proposed solutions of the participation of JMPR in an international joint review of a new compound, using previous national and international experience to inform the assessment, such as the sulfoxaflor pilot project;
>
> (ii) This assessment of benefits, challenges and proposed solutions will include but will not be limited to considerations such as resource efficiencies, timelines, enhanced communication and cooperation between competent authorities and the JMPR Secretariat, and science policy issues; and,
>
> (iii) Based on the above considerations, to develop a discussion paper for discussion at CCPR51 (2019).[1]

3. The EWG was established on June 29, 2018, and its membership is comprised of twenty-eight countries / organization and four international groups. The List of Participants is presented in Appendix I.

4. The following EWG members submitted comments which informed the development of the proposed recommendation to CCPR: Argentina, Australia, Canada, Chile, Germany, the European Union, Iran, Japan, the United States of America, and CropLife International.

5. In view of the importance and relevance of this project, the 24th Session of the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF24, 2018) also agreed to undertake a similar study. A discussion paper on the advantages, disadvantages and process, to allow the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to review a product prior to establishment of good veterinary practice for that product (i.e., approval of a marketing authorization by a national regulator) is underway. Considering the similarities and synergies between JECFA and JMPR, this paper will be shared with CCRVDF for considerations.

2 ISSUE

6. The process for establishing Maximum Residue Limits (MRLs) for pesticides varies between countries, with some relying on Codex maximum residue limits (CXLs) to a greater extent than others: to support domestic use of pesticides and/or to enable interregional or international trade of agricultural products. As such, delays in the establishment of a CXL may impact the ability of growers to access the newest products to address agronomic challenges and to sustain safe and viable agricultural production. Delays in the setting of CXLs may also lead to trade implications.

[1] REP18/PR, paras. 167 - 169

7. The concept of early engagement of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in global joint reviews has been raised in many fora as a tool to support the timelier establishment of CXLs to facilitate grower access to pesticides while mitigating trade risks.

3 DEFINING JOINT REVIEWS

8. To support the assessment and the identification of appropriate next steps, some participants underlined the importance of defining the meaning of joint reviews and the objective of involvement of JMPR in such reviews.

9. Given the important role played by the Organization for Economic Co-operation and Development (OECD) Pesticide Program in helping national authorities cooperate on pesticide registration and harmonizing data and methods, the OECD definition of joint reviews will be used for the purpose of this paper:

"A joint review is an evaluation of a pesticide dossier through work-sharing between two or more countries. The participating regulatory authorities review the work of the primary reviewers for each particular science discipline, and the end product (ideally a complete monograph or key components of the monograph) is used by all participating countries (and others) as the basis for regulatory decisions. As a formal process, joint reviews require:

i) a dossier to be submitted to all participating regulatory authorities simultaneously;
ii) a timeline and work allocation to be negotiated in advance;
iii) data reviews and peer-reviews; and
iv) an agreement on both the documentation to be produced and the decision-making target date.[2]"

10. Considering the prescriptive timelines and work-sharing requirements of a global joint review and the importance of maintaining the independence of JMPR, it is suggested that the JMPR review process be done in parallel to a joint review, and include opportunities for information sharing and dialogue between the JMPR and parties involved in the review. It is also understood that the FAO and WHO experts would conduct the toxicological and residue data assessment based on JMPR guidelines.

4 BENEFITS OF ENGAGING JMPR IN A PARALLEL REVIEW

11. The efficiencies and benefits of having JMPR conduct a review at the same time as national authorities was first raised in 2002 in the "Review of the working procedures of the JMPR". It was later reinforced during the first Global Minor Use Summit, in 2007, where countries raised the need for early engagement of the JMPR in international reviews to mitigate trade implications of misaligned MRLs and facilitate grower access to new pesticides. Some of the benefits of engaging JMPR in a parallel review include:

- **Earlier access to new pesticides**

12. Some countries depend on Codex to first establish MRLs before they will consider authorizing the compounds for domestic use. Considering that many countries rely on CXLs to support the domestic registration of pesticides, narrowing the time gap between MRL setting in countries and at Codex would allow a timelier access to newer and safer pesticides for growers across the globe.

13. Supporting the transition to newer and safer chemicals can only be achieved if growers in all markets can use new chemistries, which requires that MRLs and CXLs be set to support both domestic use and international trade. Growers in exporting countries will typically delay using a new chemical until MRLs are established in foreign markets and/or at Codex. While effective at maintaining the high quality of agricultural exports, this approach limits the ability of growers to access new and innovative products until the issue of MRL gaps has been resolved.

- **Trade facilitation**

14. With population growth and changing food preferences, trade has played an important role in meeting global demands for safe, abundant, diverse, and affordable food choices. Trade has also been critical in improving global food security, particularly in net-importing countries where agronomic conditions limit the potential for increases in agricultural productivity.

15. Growers rely on plant protection products to improve crop quality and yield, and to address agronomic challenges. Given the importance of international trade of agricultural products, and the need to have exported crops meet the requirements of importing markets, growers must ensure that MRLs for the pesticides they use are set in foreign markets, including at Codex (which standards are often used by trading partners to regulate pesticides and facilitate imports).

[2] OECD Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides, May 2011, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2011)11&doclanguage=en

16. While some countries may have a regulatory framework that allows the registration of new pesticides and the establishment of MRLs, growers from these countries are often unable to export their products to countries relying on CXLs, as a CXL may not yet exist.

- **Optimization of resource management**

17. The involvement of the JMPR in parallel reviews is expected to *"accelerate the evaluation of new pesticides by giving the JMPR evaluator access to the relevant joint assessment documents and deliberations of participating national governments and the full data packages. In particular, many of the technical issues involved would be identified by the governments and authorities during the commenting process.[3]"*

18. The initiation of the pre-screening process by national authorities well in advance of the JMPR review is expected to ensure efficient resource management by identifying deficiencies in the toxicology and residue chemistry data packages at the on-set, leading to the submission of additional information prior to the start of the JMPR review or to postponing the review to a later time.

- **Availability of the same data package supporting alignment of MRLs**

19. The submission of the same data package to all participants, including JMPR, is expected to contribute to a more global scientific assessment by allowing the review of the same data by all parties, consideration of the full scope of uses to be registered from the onset.

"Involving Codex in the global review process up-front provides the additional benefit of having all of the globally available scientific expertise applied at the beginning—reducing rework and providing the final link in ensuring that results are globally harmonized ***to the extent possible.****"*[4]

20. Having JMPR engage in a parallel review with national authorities will allow for discussion over the same data package and documentation of diverging science policy elements. This process may promote alignment whenever possible.

5 CHALLENGES - PROCESS

21. The challenges were classified in two categories: process and governance.

22. The discussion related to the process is meant to identify the policies and procedures needed to enable JMPR participation in parallel reviews.

5.1 Evaluation of new chemicals without national registration

23. The engagement of JMPR in parallel reviews would lead to the JMPR reviewing data based on proposed national registration information (proposed label). That approach is inconsistent with the current JMPR requirement for "*registered label information, including good agricultural practice (GAP), for estimation of maximum residue levels*[5]*.* One of the key concerns with this approach is the potential for late changes to GAP by national authorities, and their implications on the JMPR review[6].

24. Concerns relate to the impact late changes to the critical GAP (e.g. application rate, number of treatments, treatment interval, PHI) may have on JMPR resources, should changes occur after the completion of the JMPR assessment and invalidate the review or require that it be redone.

25. Building on some country registration experience, it is generally observed that the GAP on the final label remains the same as the one on the proposed label.

- **Recommendation 1 - Establish parameters to address potential changes to GAP**

26. Procedures on how JMPR could operate using proposed labels, to ensure expert time for evaluations is used efficiently. Using current national approaches, potential considerations include:

  - Determining what changes between the draft proposed label and the final registered label can lead to reconsideration of the supervised trials by JMPR
  - Exploring and defining what constitutes significant changes among Codex members (e.g., variance of greater than 25% to the maximum seasonal rate or pre-harvest interval for a crop/crop group)

[3] CCPR-41, CX/PR 09/41/6
[4] CCPR-41, CX/PR 09/41/6
[5] CCPR-41, CX/PR 09/41/6

- **Recommendation 2 - Establish criteria for the nomination of new compounds that are part of a parallel review**

27. There is currently no process to support the nomination of a new compound that is part of a parallel review. Instead of creating a new category, it was recommended that these products be included on the list of "new compounds" but with the setting of selection criteria, such as :

- Minimum number of participating countries (2),
- Harmonization of use patterns (GAPs) – one critical GAP,
- Inclusion of minor uses.

28. These selection criteria would be in addition to the current criteria to establish the Codex Schedules and Priority Lists of Pesticides, where the selected food commodities :

(a) form a component of international trade;
(b) represent a significant proportion of the diet; and
(c) contain quantifiable pesticide residues.

5.2 Possible misalignment of review timelines

29. The Codex MRL-setting process typically follows an 18-month cycle. It is based on a strict schedule that starts with the submission of the data package in January, and incorporates fixed milestones:

- JMPR review meeting: September
- CCPR recommendation: April
- Final MRL approval by the Codex Alimentarius Commission: July

30. Similarly, strict and firm timelines are also specified in joint reviews. They are negotiated in advance by all participating countries and may affect the ability to align the joint review timelines with those of the JMPR (18 month-cycle) or result in a shift in the JMPR/Codex review process (multi-year assessment).

31. Careful consideration should be given by registrants and participating countries to aligning the joint review process with the JMPR timelines, to support the narrowest interval between national product registration and the setting of the Codex MRL.

32. Involving JMPR in a parallel review from the start appears to be the best way to engage it in the decision-making process and ensure its participation in critical decision points throughout the review process. While there may be merit for WHO experts to engage at the beginning of the review process, to support the preparation of the monograph, it may be more efficient for FAO experts to join once draft summaries of metabolism studies have become available. Depending on the parallel review timelines, JMPR engagement may be multi-year with the participation from reviewers in pre-defined milestones. There may also be special circumstances that will need to be addressed. For example, JMPR expert volunteer their time to serve as reviewers. Changes in the availability of JMPR reviewers may result in discontinuity in the JMPR engagement in the parallel reviews.

- **Recommendation 3 – Work with JMPR Secretariat to develop parameters to support multi-year engagement in parallel reviews**

33. Parameters would include considerations such as:

- Minimizing impact on JMPR resources to ensure they are not over-utilized
- Identifying critical milestones for participation of JMPR reviewers, with a distinction between WHO and FAO reviewers, if needed.

5.3 Differing interpretation based on differing data packages

34. Differences in science policies and data interpretation between parties, including JMPR, may require more dialogue and opportunity for evaluators to work together. Possible divergence include differences in crop groups, residue definitions, and interpretation of independence of supervised residue trials

35. JMPR reviewers conduct scientific assessments in accordance with the methodology specified in *the FAO Manual on the Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed*, and the *JMPR Guidance Document for WHO monographers and reviewers*.

36. Different outcomes may occur when different data packages are provided to the individual authorities and JMPR (e.g. different MRL based on different number and location of field trials and corresponding critical GAPs, etc.). Nevertheless, there is acknowledgement and recognition that

"*no government or other authority gives up its independent rights and its responsibilities to meet its governing requirements through participation in joint reviews. In the same way, JMPR remains an independent scientific body following its governing requirements and meeting its responsibilities. There would never be any requirement that the expected outcome of any process that is developed is harmonized endpoints/MRLs just as it is not a requirement that the outcome of any particular chemical review is harmonized endpoints/MRLs*.[6]"

- **Recommendation 4- Make available a complete and identical data set**

37. A complete and identical data package should be submitted to all parties involved in the review, including to JMPR reviewers. This approach will help mitigate the risk for delays resulting from data gaps. Consideration should also be given to enabling the participation of JMPR reviewers in pre-meetings with data sponsor and national authorities to discuss scientific matters related to the data packages.

6 CHALLENGES - GOVERNANCE

38. The discussion on governance is intended to explore organizational considerations and policies required to maintain the efficiency and independence of JMPR when participating in international reviews.

6.1 Maintaining independence of JMPR

39. There is acknowledgement and recognition that "*no government or other authority gives up its independent rights and its responsibilities to meet its governing requirements through participation in joint reviews. In the same way, JMPR remains an independent scientific body following its governing requirements and meeting its responsibilities. There would never be any requirement that the expected outcome of any process that is developed is harmonized endpoints/MRLs just as it is not a requirement that the outcome of any particular chemical review is harmonized endpoints/MRLs*.[7]"

40. To ensure international and public trust in CXLs, it will be important to maintain the independence of JMPR reviewers involved in parallel reviews to mitigate the risk for perception of a conflict of interest. That can be done by clearly identifying the role and responsibilities of JMPR reviewers and the scope of their participation in parallel reviews, taking into account that JMPR reviewers will interact with national regulators and registrants, on an as-needed basis.

- **Recommendation 5 - Establish terms of reference**

41. Clearly identify the roles and responsibilities for JMPR reviewers, the scope of their participation in parallel review of new compounds, taking into consideration the current Codex and JMPR guidelines on this topic and the extent to which JMPR may take into account assessments conducted by national authorities.

6.2 Management of resources

42. Concerns have been raised regarding the cost implications of engaging JMPR in parallel reviews, to support effective and timely interaction between reviewers and establish a new process to support such reviews. Drawing a parallel with global joint reviews, the incremental costs of engaging in such a review process is assumed to be minimal for the JMPR evaluators. The difference with the JMPR parallel assessment of the new compound is that it will done concurrently to a joint review, and that interaction with other parties may occur.[8]

43. However, there is a concern that engagement in parallel review activities take resources away from current work tasked to JMPR experts, especially if the review is part of a multi-year project or if late changes are required to the proposed labels/critical GAP.

44. It will be important to identify critical milestones for participation of JMPR reviewers, with a distinction between WHO and FAO reviewers, and to determine how to minimize multi-year engagement on JMPR resources to ensure they are not over utilized. Recommendation 3 (section 5.2.) to develop parameters to support multi-year engagement in parallel reviews, will also help identify how to minimize resource implications of such an approach.

- **Recommendation 6 – Work with JMPR Secretariat to develop parameters to support multi-year engagement in parallel reviews[9]**

[6] CCPR41, CX/PR 09/41/6
[7] CCPR41, CX/PR 09/41/6
[8] There is acknowledgement of the current situation facing JMPR experts who currently conduct JMPR evacluaitons on a pro-bono basis, and in addition to their normal work: two months of preparation to draft reports (evenings, and week-ends), two weeks of full time attendance at the September meeting and several coordinating teleconferences.
[9] This recommendation is identical to Recommendation 3 under section 5.2

45. Parameters would include considerations such as:

- Minimizing impact on JMPR resources to ensure they are not over-utilized
- Identifying critical milestones for participation of JMPR reviewers, with a distinction between WHO and FAO reviewers, if needed.

7 CONCLUSION – Development of options to enable engagement of JMPR in parallel reviews

46. Based on the benefits and challenges relating to the engagement of JMPR in parallel reviews, the EWG considers that options should be drafted for consideration by CCPR52 (2020), with a focus on the development of:

- Proposed terms of reference to clearly identify the roles and responsibilities of JMPR reviewers when participating in parallel reviews, taking into consideration:
  - the current JMPR guidelines to maintain independence of reviewers (Recommendations 4 and 5)

    To ensure international and public trust in CXLs, it will be important to maintain the independence of JMPR reviewers involved in parallel reviews. The terms of reference should clearly identify the roles and responsibilities of JMPR reviewers; the scope of their participation in a parallel review of a new compound, taking into consideration the current JMPR guidelines; the extent to which JMPR reviewers could participate in meetings with data sponsors (prior to the submission of a data package and throughout the review process); and the extent to which JMPR may take into account assessments conducted by national authorities.

- Proposed procedures to support the engagement of the JMPR in parallel reviews, specifically:
  - Parameters to address potential late changes to GAP (Recommendation 1)

    The objective of the parameters is to define what changes between the draft proposed label and the final registered label can lead to reconsideration of the supervised trials by the JMPR. Work to define the parameters will include exploring and defining the notion of significant changes (e.g., 25% variance of the maximum rate or pre-harvest interval for a crop/crop group) and identifying a consistent approach to address variances between the final registered GAP and the suitability of the residue data submitted.

  - Selection criteria for new compounds that would be subject to a parallel review (Recommendation 2)

    The EWG suggested that the current nomination process for new compounds also apply to those that are part of a parallel review. It is recommended that selection criteria be established to ensure that the candidates for a JMPR parallel review support broad use of the pesticide. Criteria for consideration include: minimum number of participating countries, harmonization of use patterns (one critical GAP), inclusion of minor uses.

  - Parameters to support multi-year engagement in parallel reviews (Recommendations 3/6)

    Initiating a JMPR parallel review from the start of a joint review appears to be the best way to ensure its participation in critical decision points throughout the process. Depending on the joint review timelines, JMPR engagement may be multi-year with the participation from reviewers in pre-defined milestones. It will be important to identify critical milestones for participation of JMPR reviewers, with a distinction between WHO and FAO reviewers, and to determine how to minimize multi-year engagement on JMPR resources to ensure they are not over-utilized.

RECOMMENDATIONS

47. CCPR is invited to consider establishing an EWG to develop draft terms of reference and procedures related to the participation of the JMPR in parallel reviews. The draft terms of reference and procedures would further explore the concept and build on the benefits, challenges and solutions identified in the current discussion paper. They would be developed in consultation with the FAO/WHO JMPR Secretariats, and would be submitted for consideration by CCPR 52 (2020).

APPENDIX I

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