CODEX ALIMENTARIUS COMMISSION E



Food and Agriculture Organization of the United Nations



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

Agenda Item 10

CX/PR 22/53/12 May 2022

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES 53rd Session (Virtual) 4-8 July and 13 July 2022 ENGAGEMENT OF JMPR IN PARALLEL REVIEWS OF NEW COMPOUNDS

CRITERIA FOR SELECTING THE GLOBAL PROJECT MANAGER FOR THE PARALLEL REVIEW PROCESS

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

INTRODUCTION

- Background information on the discussion of this matter can be found in the reports of the CCPR50 (2018)¹, CCPR51 (2019)² and CCPR52 (2021)³.
- 2. At CCPR52 (2021), Canada, as the Chair of the EWG, introduced the agenda item on the "Engagement of JMPR in Parallel Reviews of New Compounds: Procedures and Principles", noting that the parallel reviews of new compounds was initially drafted to grant countries more timely access to new compounds, to harmonize MRLs to facilitate trade and to optimize resources between national agencies and JMPR reviews.
- 3. CCPR52 agreed to proceed with a pilot project to test the parallel review process to refine the proposed approach such that it reflects practical, real-world considerations, and ensures that JMPR resources continue to be used efficiently.
- 4. A number of benefits and challenges, with the parallel review process, were identified by delegations, including the limited capacity of JMPR to effectively participate. It was also identified that a competent global project manager is required to coordinate the parallel review process.
- 5. CCPR52 further agreed to re-establish the electronic working group (EWG), chaired by Canada and co-chaired by Costa Rica and Kenya, working in English and Spanish, with the following terms of reference (<u>REP21/PR</u>):
 - to develop a discussion paper outlining the criteria for selecting a global project manager. The global
 project manager would be responsible for overseeing the parallel review in close collaboration with the
 JMPR reviewers, national authorities involved in the parallel review as well as the manufacturer of the
 nominated pesticide.
- 6. The Codex Secretariat issued an invitation to join the EWG which was conducted through the online platform. A total of 20 Codex members and 3 Codex observers participated. The list of participants is in Appendix II.
- 7. The EWG participants raised concerns pertaining to the possibility that the manager would be required for more than one year, that experience should be considered in place of a high level of formal education, and that lessons to inform this guidance would be gained from a pilot project.

CONCLUSIONS AND RECOMMENDATIONS

- 8. Appendix I reflects the discussions and conclusions from the members of the EWG to establish the criteria for the global project manager.
- 9. A pilot parallel review would better define the role of a global project manager and enable further improvements described in Sections 1 and 2 of Appendix I.

¹ REP18/50, paras. 167 - 169

² REP19/51, paras. 198 - 202

³ REP21/52, paras. 217 - 227

- 10. The global project manager requires significant technical training, experience, and competencies for a voluntary position, which could extend over one year of pesticide evaluations. There is concern that finding and placing a suitable candidate may in fact become a restriction on executing a successful parallel review process.
- 11. CCPR is invited to:
 - a. Consider the proposed role and qualifications of the global project manager as described in Appendix I and determine whether they reflect the needs for managing the parallel review process.
 - b. Consider potential candidates who meet the proposed qualifications and competencies to fulfill the role of the global project manager.
 - c. Assess and modify the proposed qualifications and competencies upon the successful completion of a pilot parallel review.

APPENDIX I

(For comments)

PROPOSED CRITERIA FOR SELECTING THE GLOBAL PROJECT MANAGER FOR THE PARALLEL REVIEW PROCESS

1 – PROJECT MANAGEMENT

1.1 – Role of the global project manager

1. A key component of the parallel review is the role of the global project manager. This individual would oversee the parallel review, in close collaboration with the JMPR Secretariat/JMPR reviewers and reviewers from the national authorities involved in the parallel review. The global project manager would liaise with all parties including the manufacturer to ensure that the identified timelines and milestones are met throughout the review process, including the conduct of the data completeness check.

1.2 – Interaction between national and JMPR reviewers

- 2. The nature of parallel reviews implies that it is conducted concurrently with national reviews and that the interaction between reviewers is encouraged to discuss scientific matters related to the data packages.
- 3. 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 occurring shortly thereafter (prior to the regular data call-in).
- 4. To support information-sharing and the engagement of the JMPR reviewers and the reviewers from the national authorities in the parallel review, the contact information of all reviewers would be provided to the global project manager responsible for coordinating the joint review.
- 5. The concept of parallel reviews also requires that the global project manager ensure the same data package for toxicology, product chemistry, residue chemistry, including metabolism and environmental fate, be provided to national regulatory agencies and JMPR.
- 6. 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.
- 7. If 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.

1.3 – Timelines

8. It is possible that the parallel review will take place over two JMPR Meetings which would require the commitment of the global project manager for a minimum of two years.

2 – QUALIFICATIONS

9. The specialized-technical nature of the global project manager's responsibilities will require a broad range of knowledge, experience, and competencies to successfully administer the parallel review. The following are a number of proposed requirements for potential candidates.

2.1 – Education

10. The candidate, at a minimum, should possess a science degree in a related field, with preference for an individual with the technical knowledge required to assess exposure to chemical compounds. A Master's degree or PhD in science is preferred, however a combination of education and experience may be considered. Working knowledge of English is required.

2.2 - Experience (international and technical)

11. Candidates familiar with regulatory sciences (toxicology, exposure), scientific research and/or similar experience at a senior level would be required. An additional asset would be an individual with Codex knowledge or a good understanding of the JMPR process. A proven ability to plan and implement programs related to scientific initiatives and provide advice would be required.

2.3 – Competencies

12. Given the role as a coordinator working with experts within the JMPR, governments, and registrants, candidates should possess the requisite competencies: results focus, communication, partnering and advocating, building effective relationships, engagement, and leadership.

3 – CONSIDERATIONS

13. Although specific qualifications are essential for a successful candidate in the role of global project manager, this is a voluntary, unpaid position. The selection process needs to be relatively informal with the understanding that candidates meeting all proposed criteria may not be available. An informal process in the selection of a global manager means the nomination of a candidate may be made by the JMPR Secretariat as noted in 3.3 and 3.4. In addition, the selection of the global project manager should not become a restriction on the process for parallel reviews.

3.1 – Pilot

14. The selection of a new compound for consideration in the parallel review pilot project has not yet been made. Therefore, the time requirements, list of duties, and responsibilities cannot be clearly articulated until after the end of the pilot project. Essentially this is also a pilot of the global project manager position.

3.2 – Candidate pool

15. Candidates may be selected from national authorities, international organizations, registrants, or academia. As this work is voluntary, candidates must be able to demonstrate that they have the commitment and capacity to complete the parallel review. This may be achieved through a letter of support from their organization.

3.3 - Nomination process

16. Potential applicants may be nominated by the JMPR Secretariat, by a national authority, or other members involved in the pilot project.

3.4 – Candidate selection

17. Successful candidates may be selected through mutual agreement of the JMPR Secretariat and the national authorities participating in the parallel review process.

3.5 - Conflict of Interest

18. To avoid any question of bias, there must be no perceived or actual conflict of interest between the global manager and the review process. An example of conflict of interest is any potential benefit to the global manager upon the successful results of a parallel review.

3.6 - Assessment

19. An assessment as to the position requirements against anticipated needs will occur at the end of the pilot process.

Chile

APPENDIX II¹

LIST OF EWG PARTICIPANTS

Chair: Canada

Co-chairs: Costa Rica and Kenya

<u>Members</u> Argentina Australia Austria Canada

Costa Rica European Union Germany India Iran Japan Kenya Morocco New Zealand Republic of Korea Saudi Arabia South Africa Thailand United Kingdom

Observers

Croplife International Institute of Food Technologists Tea & Herbal Infusion Europe

United States of America

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