



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

54th Session

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DISCUSSION PAPER ON THE MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW

*Prepared by the Electronic Working Group chaired by Chile
and co-chaired by Australia, India and Kenya*

This CRD should be read in conjunction with CX/PR 23/54/11¹; CX/PR 23/54/11-Add.1
and CRDs presented by Codex Members and Observers

INTRODUCTION

1. The electronic working group (eWG) developed the “Discussion paper on the Proposal for the management of unsupported compounds without public health concern scheduled for periodic review”.
2. By means of the CL 2023/37-PR, Codex Members and Observers were invited to provide comments on the work management proposal (CX/PR 23/54/11 - Appendix I, Section 1 and 2) with deadline 31st May.

COMMENTS RECEIVED TO THE CIRCULAR LETTER CL 2023/37-PR

3. The document CX/PR 23/54/11-Add.1, compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/37-PR issued in June 2023.
4. Comments were received from Brazil, Canada, Chile, Egypt, European Union (EU), Iraq, Peru, Uruguay, United States of America (USA).
5. Overall, the comments are in support of the proposal presented in the Section 1 and the options for data support presented in Section 2 of document CX/PR 23/54/11; and support the establishment of an eWG to refine the proposal for consideration by CCR54.
6. Some specific comments were made about some points of the Appendix I. Among other, those comments focused on clarifying some paragraphs.

PRE-MEETING CCPR54

7. The item 9 of the agenda was included in the program of the pre-meeting with the objective to provide Members and Observers with an opportunity to make progress on the development of these proposals based on the information provided in the working documents and comments received in reply to CL 2023/37-PR. The meeting will be held in English and the programme has been published on the Codex website.
8. To facilitate the discussion of the pre-meeting the Co-Chairs of the EWG have prepared a revised proposal (see Appendix I) that considers the comments received in reply to CL 2023/37-PR.

¹ [CX/PR 22/54/11](#); CX/PR 23/54/11-Add.1

RECOMMENDATIONS PRE-MEETING CCPR54

9. Codex members are invited to consider:

- (i) The proposal for the management of unsupported compounds without public health concern scheduled for periodic review described as presented in Section 1 of Appendix I, and, if agreeable, to consider its adoption by CCPR54 (2023).
- (ii) The different options for data support that could be addressed by Codex, FAO/WHO, JMPR, governments and industry to further assist countries in implementing the proposed management approach as presented in Section 2 of Appendix I, and, if necessary, provide comments to further enhance the options given in the paper or additional options as appropriate.

**SECTION 1. MANAGEMENT OF UNSUPPORTED COMPOUNDS
WITHOUT PUBLIC HEALTH² CONCERN SCHEDULED FOR PERIODIC REVIEW**

1. Unsupported compounds without public health concerns (PHCs) due for periodic review will be managed according to the periodic review procedures described in the Codex Procedurales Manual, according to Section IV: Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, especially Chapter ~~5~~Risk management, Role of CCPR, paragraphs 208 – 224²5³.
2. At each Session, the Codex Committee on Pesticide Residues (CCPR) will consider the establishment of an Electronic Working Group (EWG) for Unsupported Compounds.
3. Consistent with current practice, the Chair of the EWG on Priorities will continue to provide the following information regarding compounds listed in Tables 2A, 2B and 3 distributed to members and observers each year:
 - i. Status of health concerns, currently presented in the “Table 2B PHC only” tab of the Scheduling and Priority Lists of Pesticides for Evaluation by the JMPR spreadsheet.
 - ii. Situation of support of the compounds and their respective CXLs
 - iii. Record and details of previous periodic evaluations (Table 3)
4. As soon as a compound is put on Table 2B (periodic review list: compounds listed under 15-year rule but not yet scheduled or listed) CCPR Members and Observers should have a close look to the compounds to see which are supported and which are unsupported.
5. Member states that notice that the Codex maximum residue limits (CXLs) for a compound are not supported and the country itself is not in a position to generate the data, should communicate such concern to the Chair EWG on Unsupported Compounds in response to the Circular Letter that the Chair of the EWG on priorities issues in September each year, which includes, among others, Tables 2A and 2B.
6. In said communication, the member state must provide detailed information about which CXLs it is interested in supporting, as well as information on national register status, the surface (ha) of the crop treated with the pesticide, international trade data or others (e.g., availability of the alternatives etc.) that justify the efforts to generate data⁴.
7. The Chair of the EWG on Unsupported Compounds should ask the JMPR Secretariat, which kind of data are required to conduct the reevaluations (toxicology and/or residue studies and where necessary methods of analysis). The engagement of JMPR at this early stage of the procedure is essential, both to avoid that the dossier to be prepared will be found incomplete, and to avoid unnecessary repetition of studies.
8. The Chair of the EWG on Unsupported Compounds will report for consideration by the CCPR plenary the list of pesticides and CXLs for which some member states have expressed concern about the possible revocation of CXLs due to the lack of support, a qualification of whether there is a ~~reasonable~~ justification to advance in the search for possible supports. CCPR shall ratify the initiation of the process of seeking support within the EWG on Unsupported compounds.
9. Within the EWG on Unsupported Compound, opportunities should be discussed by the stakeholders’ group, including especially from those members having evaluated the compounds and/or authorized uses and those members and observers having an interest in keeping the substance in the Codex system. ~~If there is a national registration supporting current CXL, it should be considered.~~
10. For those compounds for which support is obtained, the member (s) should inform both the Chair of the EWG on Priorities and the Chair of the EWG on Unsupported Compounds whether all or some of the CXLs will be supported and should specify each supported and unsupported CXL and the timeframe for provision of relevant data to JMPR. The timeframe proposed for generating and providing data, should not exceed four-years (four-year rule as specified in the Codex Procedures Manual).
11. For substances where support for one or more CXL for an unsupported substance is announced and support can be realized as described before, the remaining unsupported CXL will be revoked after renewal of the compound.

² In the context of this document “unsupported compounds without public health concern” describes compounds, for which no public health concern form has been lodged by a Member or where JMPR has not indicated any public health concern. These compounds are waiting for a periodic review after 15 years without a sponsor stating support for the compound.

³ Codex Alimentarius, Commission, ~~Procedural~~ Manual in its latest version. ~~World Health Organization-Food and Agricultural Organization of the United Nations, Rome, 2019.~~

⁴ Useful information on the data expected and to be evaluated by the JMPR can be found in ‘Submission and evaluation of pesticide residue data for the estimation of maximum residues in food and feed. Third edition. FAO Plant Production and Protection Paper 225, Food and Agricultural Organization Rome 2016.’ the so-called FAO Manual as well as in ‘Principles and Methods for the Risk Assessment of Chemicals in Food (Environmental Health Criteria 240), World Health Organization, 2009’.

12. For compounds and their CXLs for which there is no support obtained according to points 5–~~9~~10, CCPR ~~in its next session~~ should once again ask for support. If no support is given, the withdrawal of CXLs should be endorsed in the following CCPR meeting.

SECTION 2. OPTIONS FOR EFFICIENT DATA SUPPORT THAT COULD BE ADDRESSED BY CODEX, FAO/WHO, JMPR, GOVERNMENTS AND INDUSTRY TO FURTHER ASSIST COUNTRIES IN IMPLEMENTING THE PROPOSED MANAGEMENT APPROACH

13. It is generally agreed that Codex members and observers participating in CCPR can collaborate efficiently with other members which currently lack the ability to independently support important uses/compounds for their production systems.
14. However, greater efforts are needed to clarify the work as described in paragraphs 5 to ~~9~~10 namely: define the scope of the problem with respect to the number of maximum residue limits (MRLs), identify members and observers who are interested in specific compounds, and describe the data required for JMPR to conduct the periodic review.
15. To carry out the above, it is key to prioritize the different cases to ensure that collaboration can be carried out efficiently.
16. Information on the Codex system and the JMPR periodic review process, generation of the required data package and accompanying dossier, should be shared with the generic manufacturers as well as to members and observers having unsupported compounds. This would be the one of the roles of EWG on Unsupported Compounds.

Kind of collaboration activities

17. Collaboration activities focusing on specific projects, courses and training amongst Codex members, between members and observers with the support of the JMPR Secretariat or with other international organizations such as FAO and WHO.

Collaborative activities that can be efficiently developed within the framework of Codex, FAO, WHO, others international organizations, government agencies, industry, etc.:

a) Codex

18. Through the JMPR and the Codex Secretariats, coordinate and carry out workshops on periodic re-evaluations, providing details of each stage of the procedure, requirements, and data to be submitted by the industry or country interested in supporting the re-evaluation. These workshops could be virtual to facilitate participation and reduce costs.

b) FAO, WHO and other international organizations

19. FAO and WHO can provide information on what data is available and more important on what data is missing. This is necessary to define the workload for those who will provide the missing data.
20. Financial support to carry out the workshops indicated in letter a), along with providing experts, if necessary.

c) Relevant government agencies (i.e., twinning activities between Codex members)

21. Relevant government agencies can provide their latest evaluation as far as available.
22. Interested countries could finance translation into native languages, in order to carry out the trainings proposed in letter a)

d) Industry/trading companies

23. Concerned members should strengthen their efforts to bring interested small and medium enterprises (SME) together that produce substances and/or formulations, to facilitate shared data generation, through financial support/sponsorship.
24. The industry/sponsor that initially registered the compound could provide, upon request, the toxicological and residues background for the pesticides to be re-evaluated.

e) Other relevant parties (if any) to assist Codex members, currently lacking the capacity to independently support pesticides/uses important to their production systems, to provide the required data package for the JMPR periodic review

25. Other international agencies may provide projects for capacity building, while research institutes may be willing to conduct some studies.
26. Other relevant parties are trading companies, trading associations, food associations and agricultural organizations to ensure the flow of information between farmers, national agencies and main exporting countries.

27. Work together to conduct necessary field trials to support revised GAPs: Codex /FAO could act to facilitate collaboration amongst interested member countries (national trade bodies/Industrial groups/crop research bodies) via “collaboration fund” to make best use of resources/prevent duplication of effort.

f) Capacity building activities to strengthen capabilities of Codex members to satisfy requirements for JMPR evaluations

28. Provide capacity building activities to promote the improvement of human resources for those Codex members with difficulties in carrying out the necessary technical studies. These would include technical support to meet the requirements of studies and to meet formal procedures for the data submission. Ideally, these activities could be directed towards experts from different sectors within government and/or research institutes. Some activities proposed to carry out capacity building on:

i. Field trials (residues)

ii. Toxicological studies

iii. Data submission within periodic review procedures

iii-iv. Methods of analysis where necessary