

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 9

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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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)

Codex members and observers wishing to submit comments on the recommendations in paragraph 17 should do so as instructed in CL 2023/37-PR available on the Codex webpage¹

BACKGROUND

CCPR50 (2018)

1. At CCPR50, when considering the establishment of Codex schedules and priority lists of pesticides for evaluation by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Chair of the Electronic Working Group (EWG) on Priorities (Australia) reported that several unsupported compounds were listed in the Schedule for periodic review re-evaluations.
2. In the context of the CCPR prioritization process, an unsupported compound is a pesticide that is due for re-evaluation for which neither a manufacturer nor member country has committed to submit the data required for evaluation by JMPR. Unsupported compounds are identified in prioritization Tables 2A and 2B.
Table 2A: Schedules and priority lists of periodic reviews (pesticides scheduled for periodic review)
Table 2B: Periodic review list (pesticides that have been last evaluated 15 years ago or more, but not yet scheduled or listed for periodic review)
3. CCPR50 noted two key situations which arose in the periodic review:
 - (i) unsupported compounds without public health concerns and
 - (ii) unsupported compounds with public health concerns
4. Several members indicated the need for the preparation of a discussion paper to consider strategies for the management of unsupported compounds scheduled for periodic review by JMPR.
5. CCPR50 consequently agreed² that this work would be carried within the framework of the EWG on Priorities chaired by Australia and co-chaired by Canada, Chile, and Kenya, and were tasked to present a discussion paper on the management of unsupported compounds scheduled for periodic review for consideration by CCPR51.

¹ Codex webpage/Circular Letters:
<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

Codex webpage/CCCF/Circular Letters:
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/tr/?committee=CCPR>

² REP18/PR50, paras. 147-151 & 153

CCPR51 (2019)

6. CCPR51 considered the discussion paper³ presenting proposals on how to address the management of unsupported compounds (with and without public health concerns) listed in Tables 2A and 2B.
7. CCPR51 noted that the major concern was on the management of unsupported compounds without public health concern and focused its discussions on the management options provided for these compounds. CCPR noted the preference of delegations for either option 2, in particular Option 2b or Option 3. The full details of these options can be found in the discussion paper presented at CCPR51.
8. CCPR51 noted that it was difficult to reach consensus on the management options in view of the complexity of the issue and agreed to assess options 2 (in particular 2b) and 3 to determine an appropriate way forward suited to those supporting either of the options.
9. CCPR51 therefore agreed⁴ to establish an EWG on unsupported compounds without public health concern scheduled for periodic review chaired by Chile and co-chaired by Australia, India, and Kenya to:
 - (i) Investigate the circumstances that lead to unsupported compounds and obstacles that prevent providing support.
 - (ii) Explore options for efficient data support.
 - (iii) Explore the advantages and challenges that arise from the Options 2b and 3 as recommended by CCPR51:

Option 2b - Only those CXLs for which there are registrations listed in the national registration database (NRD) will be retained

Option 3 - Codex members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs. (i.e., 4-year rule). If members or observers are unable to address the data requirements, all CXLs are to be revoked, and
 - (iv) Present a proposal for consideration by CCPR52 based on the above considerations.

CCPR52 (2021)

10. CCPR52 considered the discussion paper⁵ prepared by the EWG. Members expressed divergent views in favor of options 2b and 3. Since the Committee did not reach a consensus on any of the options proposals, agreed⁶ to re-establish the EWG chaired by Chile and co-chaired by Australia, India, and Kenya with the following terms of reference (ToR):
 - (i) To further develop a management proposal for unsupported compounds without public health concern scheduled for periodic review based on Option 2b and 3:
 - a) Option 2b – Only those CXLs for which there are registrations listed in the national registration database (NRD) will be retained and if so, to outline the amendments required in the Risk Analysis Principles applied by CCPR to operate this option, and
 - b) Option 3 – Codex members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs (i.e., 4-year rule). If members or observers are unable to address the data requirements, all CXLs are to be revoked.
 - (ii) The proposal should take into consideration the discussion paper presented in CX/PR 21/52/17, Appendix I, and the written comments submitted and those made during the plenary session.
 - (iii) To further develop the recommendations under CX/PR 21/52/17, Appendix I, TOR (ii)-explore options for efficient data support that could be addressed by Codex, FAO/WHO, JMPR, governments and the industry to further assist countries in implementing either option.

Based on the above considerations, the EWG was tasked to present a management proposal for consideration by CCPR53.

³ CX/PR 19/51/17

⁴ REP19/PR51, paras. 207-215

⁵ CX/PR 21/52/17

⁶ REP21/PR52, paras 228-235

CCPR53 (2022)

11. CCPR53 noted that the recommendations made in the discussion paper⁷ prepared by the EWG, were considered by a virtual meeting of the working group held prior to the session, which provided revised recommendations for the consideration of unsupported compounds without public health concern scheduled for periodic review as described in a conference room document (CRD09):
 - (i) The revised proposal for the management of unsupported compounds without public health concern scheduled for periodic review described as presented in CRD09, Appendix I, Section 1.
 - (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 CRD09, Appendix I, Section 2.
 - (iii) The establishment of an EWG to further develop and refine the management proposal for consideration by CCPR54.
12. CCPR agreed⁸ to re-establish an EWG on unsupported compounds without public health concern scheduled for periodic review chaired by Chile and co-chaired by Australia, India, and Kenya, working in English with the following ToRs:
 - (i) To further develop and refine the management proposal for unsupported compounds without public health concerns scheduled for periodic review presented in the Section 1 of Appendix I of CRD09.
 - (ii) To further develop the recommendations of Section 2 of Appendix I of CRD09, to explore further options for efficient data support that could be addressed by Codex, FAO/WHO, JMPR, governments and the industry to assist countries in the preparation of data packages required to conduct periodic reviews.
 - (iii) That proposals should take into consideration the information presented in CX/PR 22/53/13, CRD09 and the written comments submitted and those received during the plenary meeting.
 - (iv) Based on the above considerations, to present a management proposal for consideration and adoption by CCPR54.

WORK PROCESS

13. The EWG was joined by several member countries, observer organizations and a Member Organization. The list of participants is in Appendix II.
14. The EWG prepared two drafts for comments within the EWG. The initial document was developed by Chile, Australia, India, and Kenya.
15. The revised proposal is based on the exchange of opinions held prior to and during the CCPR52, where it was not possible to reach a consensus on one of the 2 proposed options.
16. In the first round of the EWG, comments were received from Costa Rica, Germany, Thailand, United States and Uruguay and in the second round from Germany.

RECOMMENDATIONS

17. CCPR is 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.

⁷ CX/PR 22/53/17

⁸ REP22/PR53, paras. 201-206

APPENDIX I**SECTION 1. MANAGEMENT OF UNSUPPORTED COMPOUNDS
WITHOUT PUBLIC HEALTH⁹ 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 Procedures Manual, according to Section IV: Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, especially Chapter 5¹⁰.
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 that justify the efforts to generate data¹¹.
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.
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.
12. For compounds and their CXLs for which there is no support obtained according to points 5–9, 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.

⁹ 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.

¹⁰ Codex Alimentarius Commission. Procedural Manual in its latest version. World Health Organization-Food and Agricultural Organization of the United Nations, Rome, 2019.

¹¹ 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’.

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 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

APPENDIX II**LIST OF PARTICIPANTS****Chair: Chile**

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