

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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

Agenda Item 11

CRD06

June 2022

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

53rd Session

(Virtual)

4-8 July and 13 July 2022

MANAGEMENT OF UNSUPPORTED COMPOUNDS

WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW

(Prepared by Chile as EWG Chair)

This CRD should be read in conjunction with CX/PR 22/53/13; CX/PR 22/53/13-Add.1 and CRD 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 2022/39-PR, Codex members and Observers were invited to provide comments on the work management proposal (CX/PR 22/53/13-Appendix I, Section 1) and the Options for data support (CX/PR 22/53/13-Appendix I, Section 2, with a deadline 15th June.

COMMENTS RECEIVED TO THE CIRCULAR LETTER CL 2022/39-PR

3. The document CX/PR 22/53/13-Add.1, compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/39-PR issued in May 2022.
4. Comments were received from Canada, Chile, Egypt, European Union, Ghana, Kenya, Philippines, United Kingdom, United States and IFT.
5. Overall, the comments are in support of the proposal presented in the Section I of document CX/PR 22/53/13 and the options for data support presented in Section 2; 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, the specific comments are focused on clarifying or holding more detailed discussions at the CCPR:
 - To clarify the term “without public health concerns” used in the title of the document
 - How the JMPR could provide information on what data is available and what data is missing, on what basis/at what stage this information would be provided
 - Deepening the discussions on the steps of the proposal (capacity building/data support) that could be adding to the workload of JMPR, the governments, other international organizations and industry
 - further discussion on the specific roles and responsibilities of the EWG and its chair to ensure that they are (i) well defined and (ii) within the scope of CCPR.

PRE-MEETING CCR53

7. The item 11 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 proposal based on the information provided in the working documents and comments received in reply to CL 2021/39-PR. The meeting will be held in English, French and Spanish and the program has been published on the Codex website.
8. To facilitate the discussion of the pre-meeting the cochairs of the EWG have prepared a revised proposal (see Appendix I) that considers the comments received in reply to CL 2022/39-PR.

RECOMMENDATIONS PRE-MEETING CCPR53

9. Codex members and Observers are invited to consider:
- (i) the revised proposal for the management of unsupported compounds without public health concern scheduled for periodic review described as presented in Section 1 of Appendix I.
 - (ii) the establishment of an EWG to refine the work management proposal for consideration by CCPR54 (2023).
 - (iii) 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.
 - (iv) presenting for the consideration of the CCPR53, the conclusions and recommendations that result from the pre-meeting.

APPENDIX I**PROPOSAL FOR THE MANAGEMENT OF UNSUPPORTED COMPOUNDS
WITHOUT PUBLIC HEALTH CONCERN¹ SCHEDULED FOR PERIODIC REVIEW****SECTION 1. MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC RE-EVALUATION**

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.
 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. It should be noted that CCPR has agreed that the data requirements for a JMPR re-evaluation of an unsupported compound without public health concerns will not be reduced from those required for any other compound.
 5. 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) Codex Members should have a close look to the compounds to see which are supported and which are unsupported.
 6. 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.
 7. 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 data.
 8. The Chair of the EWG on Unsupported Compounds should ~~seek ask the availability of relevant toxicology and/or residue data generated after the last evaluation of the the Joint FAO/WHO Meetings on Pesticide Residues (JMPR Secretariat), which kind of data are required to conduct the reevaluations (toxicology and/or residue studies) if necessary, the Chair must engage the JMPR in this process, through the JMPR Joint Secretaries.~~ 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.
 9. The Chair of the EWG on Unsupported Compounds will report to 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 as well as the studies that should be presented according to the JMPR.
 10. Opportunities should be discuss by a stakeholders group including especially from those members having evaluated the active substance and/or authorized uses and those members and observers having an interest in keeping the substance in the Codex system.
 11. 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.
- No support of compound/CXL combinations**
12. 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.

¹ 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.

13. 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.

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

14. 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

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

15. It is generally agreed that it is possible 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.
16. 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.
17. To carry out the above, it is key to prioritize the different cases to ensure that collaboration can be carried out efficiently.
18. 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

19. 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

20. 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.
21. The EWG of unsupported compounds could be functioning permanently as a complement to the EWG on priorities.

b) FAO, WHO and other international organizations

22. 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.
23. 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)

24. Relevant government agencies can provide their latest evaluation as far as available.

25. Interested countries could finance translation into native languages, in order to carry out the trainings proposed in letter a)

d) Industry/trading companies

26. 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.
27. The industry/sponsor that initially registered the compound could provide, upon request, the toxicological and residues background for the pesticides to be re-evaluated.
28. In case all efforts mentioned in paragraph 30 failed, other stakeholders (industry, trading agencies and relevant government agencies) can create common infrastructure and financial support system for capacity building and research facilities to aid in the generation of necessary data to support CXLs.

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

29. Other international agencies may provide projects for capacity building, while research institutes may be willing to conduct some studies.
30. 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.
31. 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.