

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 13

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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 proposed Guidelines should do so as instructed in CL 2021/44/OCS-PR available on the Codex webpage/Circular Letters¹ or CCPR/Related Circular Letters²

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 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 or member country has committed to submit the data required for evaluation by JMPR. Unsupported compounds are identified in prioritization Tables 2A and 2B³.
 - 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 agreed 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 CCPR51.⁴

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

² <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR>

³ See CX/PR 21/52/19 (Tables 2A and 2B and other tables providing a record of all periodic reviews (past, present and future) and records of chemical-commodity combinations for which specific GAP is no longer supported)

⁴ REP18/PR, paras. 147-151 & 153

CCPR51 (2019)

6. CCPR51 considered the discussion paper⁵ which presented 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. An excerpt of the options presented at CCPR50 is reproduced in Appendix III for information. The full details of these options can be found in the working paper⁶ 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 agreed 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 with the following Terms of Reference (TORs):⁷
 - (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) Based on the above considerations, present a proposal for consideration by CCPR52.

WORK PROCESS

10. The EWG was joined by several member countries, observer organizations and a Member Organization. The list of participants is in Appendix IV.

2019-2020

11. The EWG prepared two drafts for comments within the EWG. The initial document was developed by Chile, Australia, India and Kenya.

First round of comments

12. In order to address TORs (i) and (ii), some questions were presented to the EWG participants. For TOR (iii), the EWG participants were requested to provide advantages and challenges from Options 2b and 3.
13. Comments from Chile, Costa Rica, Germany, European Union (EU), Uruguay, and the United States of America (USA) were received.

Second round of comments

14. Based on the answers received in the first round of comments, summary conclusions were prepared under each TOR.
15. Additionally, EWG participants were asked to propose alternative solutions for the management of Options 2(b) and 3.
16. For the second round, comments from Chile, Uruguay and THIE were received.
17. Comments received during the first and second round of comments were consolidated in CX/PR 20/52/17, Appendix II.

⁵ CX/PR 19/51/17

⁶ CX/PR 19/51/17

⁷ REP19/PR, paras. 207-215

2020-2021

18. In view of the rescheduling of CCPR52 from 2020 to 2021 due to the COVID19 pandemic, the EWG submitted an interim report summarizing the work done between 2019-2020 on TOR given by CCPR51. Codex members and Observers were invited to submit comments through CL 2020/40-PR, on the findings under points (i)-(iv) of the TORs, as presented in CX/PR 20/52/12, Appendix I. Responses received in reply to this circular letter were compiled in CX/PR 20/52/17-Add.1. Working documents issued during 2020, which has been revised or updated in 2021 for consideration by CCPR52, can be found on the Codex website⁸.
19. The comments received in reply CL 2020/40-PR were considered by the EWG Chairs to prepare an improved discussion paper for further discussion by the EWG.
20. The EWG continued to work during 2020 – 2021 to provide an updated analysis of points (i)-(iv) of the TOR for consideration by CCPR52. This stage included one round of comments within the EWG and a total of 3 member countries⁹ provided observations.

Conclusions

21. Appendix I, Section 1 presents the conclusions reached in respect of TORs (i), (ii) and (iii).
22. Appendix I, Section 2 presents the conclusions reached in respect of TOR (iv).
23. Appendix II, contains an excerpt of CX/PR 19/51/17 on management options for unsupported compounds scheduled for periodic review without a public health concern which provide further details of the different options to address this matter presented for consideration at CCPR51.

Recommendations

24. CCPR is invited to decide on an approach for the management of unsupported compounds without public health concern scheduled for periodic review based on the proposals presented in Appendix I, Section II, TOR (iv), taking into account the advantages and challenges arising from Options 2b and 3 as described in Section I, TOR (iii).
25. CCPR is also invited to consider the different options for data support that may assist in the implementation of either Options in paragraph 24 that could be recommended for action by CCPR, FAO, WHO, etc. as described in Appendix I, Section I, TOR (ii).

⁸ <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCPR&session=52>

⁹ Chile, EU and Germany

APPENDIX I

SECTION 1. Conclusions for the TOR (i), (ii) and (iii).

TOR (i). Investigate the circumstances that lead to unsupported compounds and obstacles that prevent providing support

Circumstances that leads to unsupported compounds

1. Many of the “old” compounds do not receive data support for periodic reviews due to technical and economic reasons. Economic reasons include (but are not limited to) the fact that “old” compounds are no longer protected by patents and can be produced by multiple generic companies, with no economic incentives for the original sponsoring companies to develop the required data to support JMPR periodic reviews. They may also be unwilling to support the generic (“old”) pesticides as they have developed newer compounds that are less toxic, more effective in pest management or offer other advantages from a market perspective.
2. Patented pesticides and some generic compounds are produced now by small manufacturers. Original manufacturers of patented pesticides are not interested in supporting such products. Small manufacturers may lack the technical capacity and the financial resources to generate additional data and/or to have the ownership rights of the existing data (risk assessment and residue data).
3. On the other hand, the parties that might be interested in presenting data do not always have the resources to generate all the required data. The countries that nationally register the unsupported compounds are certain members and observers (mainly developing countries) that do not have the resources, financially and technically to support these compounds.
4. Finally, some Codex member countries and observer organizations lack detailed knowledge regarding the Codex procedures for the scheduling of compounds for periodic reviews and the generation and submission of the required data to enable the JMPR to conduct a periodic review.

Obstacles that prevent providing support to these compounds

5. Lack of technical and economic capacity of some Codex members and observers to generate and submit the data required by JMPR to conduct the periodic review.
6. The possible low demand for these compounds and market competition, where the original sponsoring companies prefer to prioritize new compounds and not support the periodic review.
7. Another obstacle is the absence of members and observers (developing countries) from the Codex meetings.
8. Not all Codex Members are clear about the costs and benefits of generating the required data, in terms of public health and trade and subsequent capacity strengthening.

Information and data that are required to support a periodic review of a pesticide and corresponding CXLs¹⁰

9. While there is a general understanding of the data requirements to conduct a periodic review, not all Codex members and observers participating in CCPR are sufficiently informed and trained to understand, generate and submit the required data to support a periodic review of a pesticide. The cost of generating the required data also limits the capacity of some members.
10. It is noted that those who have the best knowledge are the JMPR experts and the countries that carry out a risk assessment, so that the challenge still persists for FAO and WHO and other international organizations to strengthen and adequately support those countries with less experience.

Consequences that follow from lack of data support for certain compounds/uses

11. While there is a general understanding that the issue is important to CCPR, not all Codex members and observers participating in CCPR are sufficiently aware of the consequences of the lack of data support, which may include the revocation of existing CXLs or the complete removal of the compound from the Codex list of pesticides. This group includes members that still use or market “old” compounds for all or some of their uses.
12. Not all Members are sufficiently aware of the consequences of non-support for the periodic review process; loss of CXLs/MRLs of some compounds/uses and unavailability of important uses to farmers. Losing uses or MRL's of pesticides might create problems for certain exporting countries.

¹⁰ CXLs (= Codex maximum residue limits for pesticides as adopted by the Codex Alimentarius Commission)

TOR (ii). Explore options for efficient data support

13. 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.
14. However, greater efforts are needed to clarify the work namely: define the scope of the problem with respect to the number of 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 be carried out efficiently.
16. Information on the CODEX system and the JMPR periodic review process, data package and dossier, should be transferred to the generic manufacturers as well as to members and observers having unsupported products. This would be the role of Codex and International Organizations involved.

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.
18. In order to carry out this collaboration, the scope of the problem with respect to unsupported compounds without public health concern scheduled for periodic review and the number of CXLs in question must be clearly defined. It is necessary to identify if there is a common interest in specific compounds, what are the existing and missing data, and how the collection of such data would be carried out.

Following collaborative activities can efficiently be developed within the framework of Codex, FAO, WHO, others international organizations, government agencies, industry, etc.:**(a) Codex**

19. Codex or Codex/FAO can provide a collaboration portal/platform/forum for the exchange of views, information and data between all interested parties, would be helpful to bring parties together. Within CODEX, linkage between the National Registration Database and Tables 2A and 2B of Priorities is key for identifying which compounds should be the focus of activity.
20. Through the JMPR and the Codex Secretariat, coordinate and carry out workshops on periodic re-evaluations, including in detail each stage of the procedure, requirements, and data to be submitted by the industry or country interested in supporting the re-evaluation, and they 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. The chairing should be rotated between the interested Codex Members.

(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 and where the assessment was performed not longer than 5 years ago.
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. Since the individual company is not capable of generating data due to financial and technical constraints, 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 organisations 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.
32. Finally, as another conclusion to the TOR (ii), there is consensus between Members, that the minimum data requirements for a JMPR re-evaluation should not be further reduced.

TOR 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

Advantages

33. There is consensus that this option helps to maintain more CXLs, which helps to facilitate international trade.
34. This option allows to reduce the existing gap between developed and developing countries, regarding the understanding, implementation and usefulness of the standards, recommendations and codes of practice established by Codex.
35. This option also allows simplifying the procedure for the periodic review, reducing the workload and costs, mainly for JMPR but also for CCPR.

Challenges

36. The main points identified are related to the fact that some CXLs may be considered outdated in terms of the underlying risk assessment, because their GAP (= good agricultural practice) could have changed or have obsolete toxicological evaluation and, therefore, lead to possible health problems.
37. On the other hand, it would be essential to keep the NRD up-to-date and improve the coverage outreach of Codex members to send information.
38. The procedures associated with the periodic review should be adapted or modified to incorporate this option.

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

Advantages

39. With this option only CXLs that are periodically re-evaluated under the periodic review are maintained and therefore, the revised CXLs are sufficiently protective for consumers. The 4-year rule grants a sufficient period of time to address the data requirements for periodic review, not implying changes in current Risk Analysis Principles applied by CCPR.

Challenges

40. The main points identified are that, with this option, the loss of CXLs would occur if the necessary data is not generated, reducing the options of pesticides for agriculture and trade. Under this option, CXLs for unsupported compounds which no identified public health problems, would be revoked by the Codex Alimentarius Commission.
41. To find a workable mechanism to generate data and minimizing the data requirements
42. The foremost challenge is to create capacity and collaborative work among Codex members and observers, so as to generate the data required by JMPR within 4 years, and not lose CXLs of unsupported compounds for which no public health concerns have been raised.

SECTION 2. Conclusions for TOR (iv) - Proposed alternatives for the management of unsupported compounds without public health concern scheduled for periodic review

Option 2b. Only those CXLs for which there are registrations listed in the NRD will be retained

Partial revision of the Risk Analysis Principles applied by CCPR

43. To introduce an amendment to the Risk Analysis Principles applied by CCPR under its "Periodic Review" section. Regarding to this amendment, two alternatives (i, iii) are proposed to include in the letter "a." of section 5.4 Revocation of CXLs (paragraph 88), of Codex Alimentarius Commission Procedural Manual:
- i. As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years, **with public health concerns**, and are not supported by any member/observer
 - ii. As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and are not supported by any member/observer **and there are not registrations listed in the National Registration Database (NRD)**

Proper functioning of the national registration database (NRD)

44. To promote the proper functioning of the NRD, which will be presented at CCPR52 (2021) (see Agenda Item 14), CCPR will need to develop suitable mechanisms, for example, sending update reminders to nominated focal points and access from the Codex website, to ensure that the NRD is kept up-to-date.

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

Proper functioning of the national registration database (NRD)

45. To promote the proper functioning of the NRD, which will be presented at CCPR52 (2021) (see Agenda Item 14), CCPR will need to develop suitable mechanisms, for example, sending update reminders to nominated focal points and access from the Codex website, to ensure that the NRD is kept up-to-date.

Enhanced presentation of the information on the schedules and priority lists of pesticides for evaluation by JMPR prepared by the EWG/Priorities relevant to the periodic review

46. For each compound included in the table 2A, the following should be noted:
- i. Status of health concerns presented
 - ii. Commodities and associated CXLs
 - iii. Commitment to submit data for re-evaluation for each of the current CXLs
 - iv. Future status of the CXLs for each commodity, for example, "To be revoked by " or " to be reviewed"
 - v. Additionally, it would be recommended that Table 3 highlights those compounds that are close to be included in the period of periodic review.

Additional practices within CCPR in support of Option 3 [or both options]

47. The following procedure could be considered:
- i. As soon as an active substance reaches the 15-year time limit (para 54 of the Risk Analysis Principles), the Chair of the eWG on Priorities or a Chair of a newly formed, ongoing eWG on Unsupported Compounds asks members and observers (a) to support this active substance, and/or (b) to provide authorised uses, and forwards a timetable when to send such information.
 - ii. If no support is indicated, but authorised uses indicate interest by members, an interest group is established, based on a request by the Chair of the eWG on Priorities, to collect nominations. Interested parties, especially from those members having evaluated the active substance and/or authorised uses during a period not longer than 5 years ago and those members having an interest in keeping the substance in the Codex system, will discuss opportunities.
 - iii. A crucial step is to define what has changed since the last JMPR evaluation covering toxicology and residue behavior, as it will define the amount of work to be done. 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.

- iv. Starting such work at the 15-year time limit ensures that interested members and observers would have a total of 10 years to take decisions and generate the necessary data.
- v. In case data is provided before the 25-year limit, CCPR can proceed with the normal procedure of scheduling the compound for evaluation by the JMPR.
- vi. At the 25 year limit, the compound should be scheduled for review by JMPR.
- vii. In case no or incomplete data is provided by the 25-year limit and when the compound is scheduled for review by JMPR, all CXLs are withdrawn and the active substance is deleted from the list of Codex substances, at the next CCPR meeting following the year when the 25-year time limit (para 74 of the Risk Analysis Principles) was reached.
- viii. It should be considered to flag active substances in Tables 2A and 2B whose last JMPR evaluation covering toxicology and residue behavior is 20 years old or more, by adding a column indicating the anticipated year of deletion, in case the substance remains unsupported. Moreover, two years before the anticipated year of deletion, a note on the impending deletion should be included in the list of Codex MRLs.

Capacity building activities to strengthen capacities in Codex members to enable them to meet the requirements of Option 3

48. 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 whether within the government, private industry, research institutes or other partner bodies/institutions. Some activities proposed to carry out capacity building on:
 - i. Field trials (residues)
 - ii. Toxicological studies
 - iii. Data submission within periodic review procedures

To create a forum or similar platform to share information

49. To provide a forum or similar platform for allowing different Codex Members have the possibility to provide data or partial studies of compounds in order to help Members with difficulties to gather the data required.

APPENDIX II**EXCERPT OF CX/PR 19/51/17 ON MANAGEMENT OPTIONS FOR UNSUPPORTED COMPOUNDS
SCHEDULED FOR PERIODIC REVIEW WITHOUT A PUBLIC HEALTH CONCERN****III.2 Unsupported compounds without public health concern**

12. The following options are presented for managing unsupported compounds listed in Tables 2A and 2B **without public health concerns**
13. The Codex Secretariat shall issue a circular letter (CL) in early September each year to all Members/observers requesting the submission of toxicology, residue and other relevant data to support the re-evaluation of pesticides listed in Table 2A and submit the same to the Chair of the EWG on Priorities and to the FAO/WHO JMPR Secretariats.
14. The CL should be prepared by JMPR in coordination with the Chair of the EWG on Priorities.
15. If the information requested as above on the listed pesticides is not provided, the following procedure will be adopted:
16. Option 1. Maintain status quo; the pesticide is maintained in Table 2A and all CXLs for the pesticide are retained.
17. Option 2. Options 2a and 2b may be considered for compounds that have one or more registrations as per the "National Registration Database (NRD)" managed by EWG chaired by Germany and co-chaired by Australia (see Agenda Item 13).
 - Option 2a*. All CXLs will be retained if there is a single registered use listed in the NRD; or
 - Option 2b*. Only those CXLs for which there are registrations listed in the NRD will be retained.
18. Under either Option 2a or 2b, CCPR may recommend that Members do not grant new registrations for these compounds. Relevant CXLs will be withdrawn if valid national registration no longer exists.
19. Option 3. Members are granted 4 years to fulfill the data requirements to maintain the CXLs. (i.e., 4-year rule). If Members are unable to address the data requirements, all CXLs are to be withdrawn.
20. After 25 years the toxicological evaluation may be outdated and no longer reliable. Health concerns cannot be excluded in this case. Independent of the options above a re-evaluation of toxicology should take place. Otherwise all CXLs should be revoked. The health concerns should be reported to the CCPR to indicate a need for re-evaluation.
21. If at any stage a member submits a public health concern, supported by the JMPR, for a pesticide being managed under any of the above options, the provisions described under **III.1 Unsupported compounds with public health concern** would apply. Clear guidance should be developed by the JMPR as to when a public health concern would result in Case III.I being applied.

APPENDIX III
LIST OF PARTICIPANTS

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