CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 8.1 **CX/PR 25/56/9**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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08-13 September 2025

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, Ecuador, and Kenya)

Codex members and observers wishing to submit comments on the recommendations in paragraph 26 should do so as instructed in CL 2025/39-PR available on the Codex webpage[1]

BACKGROUND

1. The 55th Session of the Codex Committee on Pesticide Residues (CCPR55, 2024) considered the recommendations on the management of several compounds as follows: to revoke the Codex maximum residue limits (CXLs) for fenthion (39), parathion-methyl (59), amitraz (122), and bitertanol (144), dinocap (87) (except those commodities for which CXLs were set for meptyldinocap (244) until the periodic review of meptyldinocap) and methamidophos (100) (except those commodities for which CXLs were set due to residues of methamidophos arising from acephate use).

2. Chile, as Chair of the Electronic Working Group, speaking also on behalf of its co-Chairs Ecuador, India, and Kenya, recalled that most Codex members who submitted comments in reply to circular letter CL 2024/46-PR[1] supported the above recommendations. However, during the virtual meeting of the working group (VWG) held before the Session, some countries expressed concern over the revocation of the CXLs associated with these compounds and indicated that more time was needed to examine them in line with the *Management of unsupported compounds without public health concerns scheduled for periodic review* agreed by CCPR54 (2023) as described in REP23/PR54[2], Appendix XII, paragraph 10, for internal use by CCPR. Because of this, the VWG recommended that CCPR delay the decision to revoke these compounds for one year to allow countries to gather relevant data to support the periodic review of these compounds.

3. The EWG Chair further clarified that the EWG could not generate data to support the periodic review of compounds that have not received support from the manufacturer. Still, it could assist countries concerned with the potential revocation of the CXLs in seeking assistance from other stakeholders who may be interested in supporting the CXLs/compounds. In that case, the four-year rule could be applied to facilitate data gathering. However, he noted that these compounds underwent periodic review more than 25 years ago; hence, they should be considered for revocation if no commitment to submitting the relevant data package can be confirmed at CCPR56 (2025).

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1 Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.
Codex webpage/CCPR/Circular Letters: https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR

2 Working documents, including reports of CCPR's sessions, are available on the Codex webpage: https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-meetings/en/?committee=CCPR

4. CCPR noted the general support for the recommendations of the VWG and took note of the following comments:

   - It was necessary to generate data, especially toxicological data, to support the periodic review of these compounds to maintain them in the Codex list of pesticides.
   - Revoking the CXLs due to periodic review of compounds should not lead to trade disruption.
   - Presenting the results of the EWG's work at CCPR56 would give Members another year to consider these compounds further and seek assistance from sponsors or other stakeholders who might be able to provide the required data to support the periodic review.
   - The management approach for internal use by CCPR indicates that if no support is obtained according to paragraphs 5-10 of the approach, the Committee will ask again for support. If there is no support, revocation will occur at the next session of the Committee.

5. Regarding dinocap (87) and methamidophos (100), CCPR55 noted the following comments:

   - While recognizing the high toxicity of methamidophos and the need to phase out its use as a pesticide globally, revocation of its CXLs required more careful deliberation since its residue also arises from the use of acephate. The same would apply to the revocation of CXLs for any compound whose metabolite is contained in the residue definition of another compound or which itself is the metabolite of another compound. In the case of methamidophos, other crops besides those mentioned in paragraph 21 of the working document submitted to CCPR55 (CX/PR 24/55/7) seem to have been established based on residues arising from acephate uses. Revocation of methamidophos CXLs should be considered in conjunction with the periodic review of acephate.
   - The residue definitions of meptyldinocap and acephate could be redefined by factoring in the more toxic metabolites dinocap and methamidophos, respectively. This could be done by following the precedence of the pesticide pairs of dimethoate and omethoate, as well as carbosulfan and carbofuran, when omethoate and carbofuran were delisted.

6. In conclusion, CCPR55:

   - noted that most members who responded to CL 2024/46-PR[1] supported the preliminary recommendations from the EWG to revoke the CXLs for fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144).
   - agreed that, under the management approach for internal use by CCPR, if no support is obtained according to paragraphs 5-10 of the approach (REP23/PR54, Appendix XII), the Committee will ask again for support and submission of the suitable data package for the JMPR periodic review of fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144). If there is no support by submitting a suitable data package, CCPR56 (2025) will recommend revocation of the CXLs by CAC48 (2025).

7. CCPR55 therefore agreed to re-establish the EWG on the Management of unsupported compounds without public health concerns scheduled for periodic review, chaired by Chile and co-chaired by Australia, Ecuador, Kenya, and India, to implement the internal management approach agreed by CCPR to:

   - examine further fenthion (39), parathion-methyl (59), dinocap (87)/meptyldinocap (244), methamidophos (100)/acephate (95), amitraz (122), and bitertanol (144), according to the internal management approach; and
   - coordinate with the EWG Chair on Priorities in accordance with the internal management approach; and
   - Based on this mandate, the EWG should present the results for consideration by CCPR56[3]

WORK PROCESS

8. The EWG was joined by 24 Member countries, 3 Observer organizations, and a Member organization. The list of participants is in Appendix II.

9. Members and observers were invited to submit comments and/or concerns in accordance with the ***Management of unsupported compounds without public health concerns scheduled for periodic review*** **(REP23/PR54-Appendix XII),** specifically paragraphs 5 and 6:

3 REP24/PR55, paras. 231-238

Paragraph 5: Member countries 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 of the EWG on Unsupported Compounds in response to the circular letter that the Chair of the EWG on Priorities issues each year, which includes, among others, Tables 2A and 2B.

Paragraph 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 alternatives, etc.) that justify the efforts to generate data.

10. The internal management approach agreed by CCPR54 is reproduced in Appendix I for easy reference.

KEY POINTS OF DISCUSSIONS

Review of comments submitted in reply to CL 2024/46-PR

11. As this EWG continued the work presented and discussed at CCPR55, the comments made by Codex members and observers in reply to CL 2024/46-PR were also considered relevant. These comments are available in the comment paper[4] and in the relevant conference room documents (CRDs)[5].

12. Some specific comments are highlighted below as considered relevant for further consideration by CCPR56 when considering the recommendations in paragraph 26:

- **Amitraz (122)**: This compound is still used in many countries. No commitments regarding data were identified, nor were any potential implications for CXLs of other compounds observed.
- **Dinocap (87)**: Concerns over the revocation of dinocap CXLs could impact CXLs of meptyldinocap. Revoking CXLs for dinocap should not affect those for meptyldinocap, as its residue definition remains 'dinocap, sum of isomers'. CCPR could consider requesting that the JMPR consider changing the residue definition for meptyldinocap from 'dinocap, sum of isomers' to 'meptyldinocap' to prevent confusion noting that the current meptyldinocap CXLs were based on the recommendations of the JMPR Meeting in 2010 and the meptyldinocap residue trials assessed in 2010 addressed the meptyldinocap isomer alone.
- **Methamidophos (100)**: Concern over the revocation of methamidophos CXLs could impact acephate CXLs. The application of acephate may result in the presence of methamidophos residues. Since the current residue definition for acephate does not include methamidophos, residues of methamidophos detected in these commodities could present trade problems if there are no CXLs for methamidophos. Therefore, all methamidophos CXLs for which there is a corresponding acephate CXL should be maintained until the JMPR re-evaluates acephate. Acephate is currently listed in Table 2B of the priority list.

Consideration of comments in the EWG

13. The EWG received comments from Brazil, Chile, Germany, India, Thailand, and Uruguay by 31 January 2025.

Concerns received over the possible revocation of CXLs

14. Germany provided complete information about the regulatory status of fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144) in the European Union (EU). The EU has approved none of these compounds.

15. Chile proposed to revoke all CXLs for fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144).

16. India mentioned that bitertanol (144) is registered in India for use on groundnut and wheat and MRLs established by the Food Safety and Standards Authority of India (FSSAI) are available for apple, ground nut, ground nut oil, eggs, meat and meat products, edible offal of (mammalian), milk and milk products, poultry meat, edible offal of (poultry), tea and wheat.

17. Any of these three Member countries submitted any concern about the CXLs revocation of fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144).

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4 CX/PR 24/55/7-Add.1 (Australia, Canada, Chile, Colombia, Egypt, the European Union (EU), Malawi, Peru, Sierra Leone, the United Arab Emirates (UAE), the United Kingdom, and the United States of America (USA))

5 CRD06 (Burundi); CRD09 (Philippines); CRD11 (United Arab Emirates (UAE)); CRD13 (Thailand); CRD14(Rev) (Uruguay); CRD15 (Indonesia); CRD16 (Japan); CRD17 (Uganda); CRD18 (India); CRD20 (Ghana); CRD22 (Morocco); CRD24 (Agrocare Latinoamerica); CRD26 (Ecuador)

18. Thailand reiterated its comments in reply to CL 2024noted that the CXLs for amitraz (122) should be maintained since the compound has been registered in agricultural products and many countries still use it.

19. Uruguay agreed with the revocation of all CXLs for fenthion (39), parathion-methyl (59), dinocap (87), and methamidophos (100), amitraz (122), and bitertanol (144), except for CXLs for dinocap, in those commodities for which CXLs were set for meptyldinocap (244), and CXLs of methamidophos, in those commodities for which CXLs were set due to residues of methamidophos arising from the use of acephate (95).

20. Brazil's expressed concern regarding the CXLs for the active substances acephate (95) and methamidophos (100) and provided background information, such as an analysis of the CXLs for acephate and methamidophos, crops with authorized uses for acephate in Brazil, export data (value and main destination countries) for these crops, and a list of countries with acephate registrations. It concluded that deleting CXLs for methamidophos may have limited immediate impact on major exports from Brazil related to acephate-treated food commodities. However, it highlighted the importance of a comprehensive approach to MRLs across the Codex Alimentarius system.

21. Brazil further indicated the following: "*As noted in other compounds with similar relationships (i.e., carbosulfan/carbofuran, dimethoate/omethoate), the Codex Alimentarius Commission should consider thoroughly reviewing the MRLs for acephate to account for the presence of methamidophos as its metabolite. This review will ensure that the MRLs accurately reflect the potential for residue formation and facilitate trade*."

22. Neither Thailand nor Uruguay provided information in accordance with paragraphs 5 and 6 of the ***Management of unsupported compounds without public health concerns scheduled for periodic review*** that would justify efforts to seek support for amitraz (122), and the CXLs for methamidophos (100) resulting from the use of acephate and for dinocap (87) resulting from the use of meptyldinocap, respectively.

23. While Brazil provided information regarding the potential effects of revoking the CXLs for methamidophos (100) resulting from the use of acephate (95), it concluded that they would be limited.

24. No Member country, Member organization, or Observer organization committed to submitting an appropriate data package for the periodic review of these compounds conducted by the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR).

Commitment to the submission of data has been received

25. The EWG noted that no Member country, Member Organization, or Observer organization committed to submitting an appropriate data package for the JMPR periodic review of fenthion (39), parathion-methyl (59), dinocap (87), methamidophos (100), amitraz (122), and bitertanol (144) in the European Union (EU).

RECOMENDATIONS

26. CCPR is invited to consider the following recommendations, based on the issues raised at CCPR55 and the key points of discussion in the EWG:

CXLs for fenthion (39), parathion-methyl (59), dinocap (87), amitraz (122), and bitertanol (144)

(i) To revoke all CXLs for fenthion (39), parathion-methyl (59), dinocap (87), amitraz (122), and bitertanol (144).

CXLs for methamidophos (100)

(ii) To revoke CXLs for methamidophos (100) in cottonseed, fodder beet, potato, and sugar as these commodities do not have corresponding CXLs for acephate (95).

(iii) To retain all methamidophos CXLs for which there is a corresponding acephate CXL until the JMPR conducts the periodic review of acephate (95)

(iv) To recommend that JMPR revise the residue definition of acephate (95) to include methamidophos (100) when conducting the periodic review of acephate.

APPENDIX I

MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH[1] CONCERN SCHEDULED FOR PERIODIC REVIEW

(For internal use by CCPR)

(Extract from REP23/PR54, Appendix XII)

(For information)

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 Procedural Manual, according to Section IV: *Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues*, especially Chapter Risk management, Role of CCPR", paragraphs 208 – 224[2].

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 data[3].

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 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.

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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.

2 Procedural Manual (PM) in its latest version.

3 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'.

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.

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

APPENDIX II

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