

# 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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 11

CX/PR 22/53/13

May 2022

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

53rd Session

(Virtual)

4-8 July and 13 July 2022

#### 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 proposal in Appendix I to this document should do so as instructed in CL 2022/39-PR available on the Codex webpage<sup>1</sup>

#### 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 or member country has committed to submit the data required for evaluation by JMPR. Unsupported compounds are identified in prioritization Tables 2A and 2B<sup>2</sup>.  
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.<sup>3</sup>

<sup>1</sup> 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/en/?committee=CCPR>

<sup>2</sup> See CX/PR 22/53/15 (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)

<sup>3</sup> REP18/PR50, paras. 147-151 & 153

**CCPR51 (2019)**

6. CCPR51 considered the discussion paper<sup>4</sup> 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 paper<sup>5</sup> 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 to:<sup>6</sup>
  - (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.
10. The EWG was joined by several member countries, observer organizations and a Member Organization.
11. EWG participants were asked to comment on TORs (i), (ii) and (iii) and to propose approaches for options 2(b) and 3 as appropriate.
12. The rescheduling of CCPR52 from 2020 to 2021 due to the COVID19 pandemic, allowed several rounds of comments within the EWG and update/revision of discussion paper prior to CCPR52. Ultimately, the agenda paper presented to the CCPR52 comprised CX/PR 21/52/17-Rev.1 and CX/PR 21/52/17-Add.1. The latter recorded member and observer responses to circular letter CL 2021/44-PR.

**CCPR52 (2021)**

13. At CCPR52, members expressed divergent views<sup>7</sup> in favor of options 2b and 3. Since the Committee did not reach a consensus on any of the options proposals, agreed 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.

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<sup>4</sup> CX/PR 19/51/17

<sup>5</sup> CX/PR 19/51/17

<sup>6</sup> REP19/PR51, paras. 207-215

<sup>7</sup> REP21/PR52, paras 228-235

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

#### **WORK PROCESS**

14. The EWG was joined by several member countries, observer organizations and a Member Organization. The list of participants is in Appendix II.
15. The EWG prepared two drafts for comments within the EWG. The initial document was developed by Chile, Australia, India and Kenya, with the followings considerations for members of the EWG:
  - a. 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.
  - b. In order to advance in this initiative the co-chairs proposed left behind discussing Options 2b and 3 and focused on proposing management alternatives based on the current procedure, which allow, in some justified cases, to explore collaboration possibilities for maintaining certain CXLs.
  - c. The proposal considers the establishment of a *EWG on Unsupported Compounds* whose role is mentioned in the management proposal and which will work in coordination with the EWG on Priorities.
  - d. The proposal emphasizes that member concerned about the possible revocation of CXLs must provide information to justify collaborative efforts for data generation.
  - e. The proposed approach is consistent with current practice but introduces additional measures to improve the presentation of the information of compounds and CXLs at risk of revocation.
  - f. The additional measures may also help to generate or collect the data necessary to maintain CXLs, such as, capacity building activities to strengthen capabilities of codex members to satisfy requirements for JMPR evaluation.
16. In the first round of the EWG, comments were received from Chile, Germany and United Kingdom, and in the second round from Chile, Germany, Thailand and the United States.

#### **RECOMMENDATIONS**

17. CCPR is invited to consider 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.
18. If CCPR agree with the revised proposal, to consider the establishment of an EWG to refine the work management proposal for consideration by CCPR54 (2023).
19. CCPR is also invited to consider 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.

**APPENDIX I****PROPOSAL FOR THE MANAGEMENT OF UNSUPPORTED COMPOUNDS  
WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW****(For comments)****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. 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 the availability of relevant toxicology and/or residue data generated after the last evaluation of the Joint FAO/WHO Meetings on Pesticide Residues (JMPR). 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.
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.:**

**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.

**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.

**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)

**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.

**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.

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

Roxana Vera Muñoz  
 Head of International Agreements Subdepartment, Department of International Affairs  
 Agricultural and Livestock Service, SAG  
 (Chair)

**Co-chairs****Australia**

Mrs. Karina Budd  
 Director  
 Residue Chemistry and Laboratory  
 Performance Evaluation Section,  
 National Residue Survey, Exports  
 Division, Department of Agriculture

**India**

Dr. S.C. Dubey  
 Assistant Director General  
 Plant Protection and Biosafety  
 Indian Council of Agricultural  
 Research

**Kenya**

Mrs. Lucy M. Namu  
 Head Quality Assurance and  
 Laboratory, Accreditation,  
 Kenya Plant Health Inspectorate  
 Service (KEPHIS)

**Argentina**

Carla Serafino  
 Registry of Agrochemicals and Biologics of the  
 National Service of Agrifood Health and Quality  
 (SENASA)

**Canada**

Monique Thomas  
 Pest Management Regulatory Agency, Health

**Chile**

Paulina Chávez  
 Ministerio de Salud

Eduardo Aylwin  
 Agencia Chilena para la Calidad e Inocuidad  
 Alimentaria (ACHIPIA)

Francisco Sánchez  
 Importadores y Productores de Productos  
 Fitosanitarios para la Agricultura (IMPPA).

Patricia Villarreal  
 Asociación Nacional de Fabricantes e Importadores de  
 Productos Fitosanitarios Agrícolas A.G (AFIPA).

Jorge Carvajal  
 Servicio Agrícola y Ganadero (SAG)

**Costa Rica**

Amanda Lasso  
 Codex Advisor

Alejandro Rojas León  
 State Phytosanitary Service (SFE)

Ivania Morera Rodríguez  
 State Phytosanitary Service (SFE)

Tatiana Vasquez Morera  
 State Phytosanitary Service (SFE)

**Ecuador**

Jakeline Arias  
 Coordinadora del Subcomité del Codex sobre residuos  
 de plaguicidas

**European Union**

Siret SURVA  
 European Commission

**Finland**

Tiia Mäkinen-Töykkä  
 Finnish Safety and Chemicals Agency (Tukes)

**France**

Florence Gérard  
 Ministry of Agriculture

Xavier Sarda  
 ANSES

**Germany**

Karsten Hohgardt  
 Federal Office of Consumer Protection and Food  
 Safety (BVL)

Monika Schumacher  
 Federal Ministry of Food and Agriculture

Angela Göbel  
 Federal Ministry of Food and Agriculture

**Guatemala**

Karen Gatica  
 Chemical analyst

Cristián Rossi  
Technical expert

#### **India**

K.K. Sharma  
Network Coordinator, ICAR-IARI

Shri Somnath Das  
Export Inspection Agency

Ruchi Gupta  
Research Associate, ICAR-IARI

Dr. Shobhita Kalra  
Research Associate, ICAR

National Codex Contact Point, NCCP  
Food Safety Standards Authority

#### **Japan**

Hidetaka KOBAYASHI  
Agricultural Chemicals Office, Ministry of Agriculture,  
Forestry and Fisheries

Koutarou TOMITA  
Agricultural and Veterinary Chemical Residue Office,  
Food Safety Standards and Evaluation Division,  
Pharmaceutical and Environmental Health Bureau,  
Ministry of Health, Labour and Welfare

#### **Morocco**

JAAFARI Ahmed  
Head of the Chemical Inputs Division at the National  
Food Safety Office (ONSSA)

MESSAOUDI Bouchra  
Engineer in the service of standardization and the  
Codex Alimentarius at the National Food Safety Office  
(ONSSA)

#### **New Zealand**

Warren Hughes  
New Zealand Food Safety, Ministry for Primary  
Industries

#### **Paraguay**

José Eduardo Giménez Duarte  
Servicio Nacional de Calidad y Sanidad Vegetal y de  
Semillas (SENAVE)

#### **Republic of Korea**

Codex Contact Point  
Quarantine Policy Division, Ministry of Agriculture,  
Food and Rural Affairs (MAFRA)

Kiseon Hwang  
Ministry of Agriculture, Food and Rural Affairs

Hyejin Park  
National Agricultural Products Quality Management  
Service

Eun Young Lee  
Rural Development Administration

Jung Kyunghye  
Ministry of Drug and Food Safety

Park Yumin  
Ministry of Drug and Food Safety

Im Moo-Hyeog  
Daegu University

#### **Kingdom of Saudi Arabia**

Saif M. AL-Mutairi  
Saudi Food and Drug Authority

Nimah Baqadir  
Saudi Food and Drug Authority

#### **Singapore**

WU Yuan Sheng  
Food Safety Monitoring & Forensics Department

#### **South Africa**

Aluwani Madzivhandila  
Food Control

#### **Sweden**

Niklas Montell  
Ministry of Health, Welfare and Sport, National  
Institute for Public

#### **Thailand**

Namaprn Attaviroj  
National Bureau of Agricultural Commodity and Food  
Standards (ACFS), Ministry of Agriculture and  
Cooperatives

Chutima Sornsumrarn  
National Bureau of Agricultural Commodity and Food  
Standards (ACFS), Ministry of Agriculture and  
Cooperatives

#### **The Netherlands**

Karin Mahieu  
Ministry of Health, Welfare and Sport, National  
Institute for Public

#### **Uganda**

Geoffrey Onen  
Assistant Commissioner Directorate of Government  
Analytical Laboratory (DGAL)

Josephine Nyanzi  
Principal Regulatory Officer, Vet Medicine National  
Drug Authority (NDA)

Moses Matovu  
Research Officer National Agricultural Research  
Organization (NARO)

John Wabuzibu Mwanja  
Ministry of Agriculture, Animal Industry and Fisheries

Rose Nakimuli  
Inspection manager Chemiphar (U) Ltd



Joseph Iberet  
Uganda National Bureau of Standards

Arthur Mukanga  
Uganda National Bureau of Standards

Ruth Awio  
Uganda National Bureau of Standards

Hakim Mufumbiro  
Uganda National Bureau of Standards

**United Kingdom**

Paul Brian  
Health and Safety Executive

**United States of America**

Aaron Niman  
Environmental Health Scientist U.S. Environmental  
Protection Agency

David Miller  
Chemistry & Exposure Branch and Acting Chief,  
Toxicology & Epidemiology Branch U.S. Environmental  
Protection Agency

Alexander Domesle  
Senior Advisor for Chemistry, Toxicology and Related  
Sciences U.S. Food Safety and Inspection Service U.S.  
Department of Agriculture

Marie Maratos Bhat  
U.S. Codex Office U.S. Department of Agriculture

**Uruguay**

Susana Franchi  
DAD-DGSA-MGAP

**Observer Organizations**

**CropLife International**

Wibke Meyer  
Director Regulatory Affairs

**International Fruit & Vegetable Juice Association  
(IFU)**

John Collins  
Executive Director