

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda item 4.7

CX/CAC 24/47/9 Add.1 Rev<sup>1</sup>

October 2024

ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

Forty-seventh Session

Geneva, Switzerland, CIGC

25-30 November 2024

### COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 55TH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES FOR ADOPTION BY THE 47TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

#### BACKGROUND

1. This document compiles the comments on the draft standards submitted at Step 5/8 and Step 5 of the Procedure and other matters as indicated in the relevant Circular Letter ([CL 2024/78-CAC](#)). The comments are those received through the Codex Online Commenting Systems (OCS)<sup>2</sup>, or via email by the time this document was issued. The comments are as shown in Appendix I.

#### EXPLANATORY NOTES ON APPENDIX I

2. The comments received are presented in a table format, with two columns as follows:
  - **First column** – Presents the comments with the rationale.
  - **Second column** – Presents the provider of the comments (name of member or observer)

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<sup>1</sup> This revised version includes the comments by Burundi.

<sup>2</sup> OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardised way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

**MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOOD AND FEED  
(AT STEP 5/8)**

**COMMENTS IN REPLY TO CL 2024/78-CAC**

*Comments by Canada, Chile, Colombia, Costa Rica, Ecuador, Egypt,  
European Union, Peru, United Arab Emirates and CropLife International*

COMMENT	MEMBER / OBSERVER
<p>Burundi supports adoption of the following:</p> <ul style="list-style-type: none"> <li>• proposed MRLs,</li> <li>• proposed amendment to CXLs for pepper groups/subgroups in regard to Pyrethrin and Permethrin as recommended by CCPR55</li> <li>• guidelines for monitoring the stability and purity of reference materials and related stock solutions of pesticides during prolonged storage: and</li> <li>• the list of pesticide residue for evaluation by JEMPR.</li> </ul> <p>Burundi further supports the revocation of proposed MRLs.</p>	<b>Burundi</b>
<p>Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II</p> <p>Canada supports the adoption by CAC47 of the maximum residue limits for pesticides in food and feed (at Step 5/8), as reported in REP24/PR55, paragraph 222(i)(a), Appendix II</p>	<b>Canada</b>
<p>Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II</p> <p>Chile apoya la adopción de los LMRs de plaguicidas en los alimentos.</p>	<b>Chile</b>
<p>Límites máximos de residuos de plaguicidas en los alimentos y los piensos, REP24/PR55, párrafo 222 i), a), Apéndice II.</p> <p>Propiconazol: Realizamos la evaluación de seguridad del límite, teniendo en cuenta el peso promedio y la mediana (p50) del consumo de alimentos en población general estimados a partir de las bases de datos de la ENSIN 2015. De acuerdo con nuestra evaluación, encontramos que el LMR propuesto para propiconazol en arroz, suscitara preocupación para la población colombiana ya que se superaría la Ingesta Diaria</p>	<b>Colombia</b>
<p>Límites máximos de residuos de plaguicidas en los alimentos y los piensos, REP24/PR55, párrafo 222 i), a), Apéndice II.</p> <p>Costa Rica apoya la adopción en trámite 5/8</p>	<b>Costa Rica</b>
<p>Límites máximos de residuos de plaguicidas en los alimentos y los piensos, REP24/PR55, párrafo 222 i), a), Apéndice II.</p> <p>Ecuador agradece por la oportunidad de comentar sobre los Límites máximos de residuos de plaguicidas en los alimentos y los piensos, REP24/PR55, párrafo 222 i), a), Apéndice II, considera que están listos para su adopción en el trámite 5/8.</p>	<b>Ecuador</b>

<p>Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II</p> <p>Egypt has concern about the Maximum Residue Limit (MRL) for propiconazole (160) in rice due to its substantial rice consumption. Although exact numbers might vary, it is usually assumed that the average Egyptian consumes 45–50 kg of rice per year per capita. Rice is a staple meal, especially in rural regions. This puts Egypt's consumption of rice among the highest in the world.</p> <p>The possible causes of this concern as follows:</p> <ol style="list-style-type: none"> <li>1- Health Concerns: We can use a less harmful fungicide for rice that is not classified as a carcinogen and has a shorter breakdown time in conformity with registered pesticides in each country. Propiconazole is a fungicide that is frequently used in agriculture, but there may be concerns about its long-term effects on human health, especially when consumed in high quantities.</li> <li>2- Food Safety: Egypt enforces legislation that protect the population from harmful residues.</li> <li>3- Potential Impacts on the Environment: Propiconazole may have an effect on the quality of the soil and water. Egypt might be cautious about residues that could be hazardous on ecosystems.</li> <li>4- The EPA Report: The EPA identified propiconazole as a potential carcinogen in its 2022 report. It is categorized as a Group C possible human carcinogen.</li> <li>5- Rapid risk assessment: We concluded that the expected short-term exposure to propiconazole is higher than the toxicological reference value based on a preliminary risk assessment.</li> </ol> <p>Accordingly, Egypt recommends postponing the adoption of this limit.</p>	<b>Egypt</b>
<p>Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II</p> <p>The European Union (EU) would like to provide a specific comment on 326 Broflanilide (see below).</p> <p>As for previous sessions of the Codex Alimentarius Commission, the EU will, at a later stage, submit a CRD summarizing all EU reservations on MRLs for pesticide residues. 326 Broflanilide</p> <p>The code in “VL 0467 Chinese cabbage (type pe-tsai)” should be changed to “VB 0467 Chinese cabbage (type pe-tsai)”.</p> <p>This is in line with the recommendation of the 55th Session of the Codex Committee on Pesticide Residues (see Report REP24/PR55 (206/207), p. 18, Appendix II (here wrong code)) and the current Codex Classification for vegetables, Group 10 Brassica Vegetables (Except Brassica Leafy Vegetables).</p>	<b>European Union</b>
<p>La Comisión Técnica Nacional de Residuos de Plaguicidas agradece al Comité del Codex sobre Residuos de plaguicidas por él envió de la carta circular CL 2024/78-CAC Solicitud de observaciones sobre las normas y textos afines presentados por el Comité del Codex sobre Residuos de Plaguicidas, en su 55.<sup>a</sup> reunión, con miras a su adopción por la Comisión del Codex Alimentarius en su 47.<sup>o</sup> período de sesiones.</p> <p>La Comisión NO tiene observaciones o comentarios sobre las normas y textos afines presentados por el Comité del Codex sobre Residuos de Plaguicidas, en su 55.<sup>a</sup> reunión, con miras a su adopción por la Comisión del Codex Alimentarius en su 47.<sup>o</sup> período de sesiones.</p>	<b>Peru</b>

<p>Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II</p> <p>With reference to CRD 7 raised by United Arab Emirates to CCPR55, UAE agrees with the Adoption at Step 5/8: Maximum residue limits for pesticides in food and feed, REP24/PR55, paragraph 222(i)(a), Appendix II. It is to mention that a reservation was raised about advancing the proposed MRL for rice polished (CM 1205) due to health concerns based on the risk assessment with its national data. The MRL for polished rice was indeed retained which will give opportunity for further assessment to set adequate MRL in the future.</p>	<p><b>United Arab Emirates</b></p>
<p>Comments should address <b><u>whether the MRLs and Guidelines are ready for adoption.</u></b> If not, provide the rationale and proposals to facilitate adoption. Comments should be provided in compliance with the Procedure for the Elaboration of Codex Standards and Related Texts (Part 3—<i>Uniform Procedure for the Elaboration of Codex Standards and Related Texts</i>), Procedural Manual of the Codex Alimentarius Commission.</p> <p>CropLife International finds the proposed MRLs ready for adoption as they were advanced by CCPR55. CropLife International therefore recommends that the CAC adopts these MRLs at step 5/8.</p> <p>We would like to thank the JMPR, CCPR and CAC for the continuous efforts on Codex standards.</p>	<p><b>CropLife International</b></p>

**GUIDELINES FOR MONITORING THE STABILITY AND PURITY OF REFERENCE MATERIALS AND RELATED STOCK SOLUTIONS OF PESTICIDES DURING PROLONGED STORAGE**

**(AT STEP 5)**

**COMMENTS IN REPLY TO CL 2024/78-CAC**

*Comments by Canada, Chile, Colombia, Costa Rica, Ecuador, Egypt, Guatemala, Peru, United Arab Emirates and CropLife International*

<b>COMMENT</b>	<b>MEMBER / OBSERVER</b>
<p>Guidelines for monitoring the stability and purity of reference materials and related stock solutions of pesticides during prolonged storage, REP24/PR55, paragraph 230(i), Appendix IX</p> <p>Canada supports the adoption by CAC47 at Step 5 of the Guidelines for Monitoring the Stability and Purity of Reference Materials and Related Stock Solutions of Pesticides during Prolonged Storage (Appendix IX), with the understanding that minor revisions will be required to Approach 2 to provide further clarity on this approach.</p>	<b>Canada</b>
<p>Guidelines for monitoring the stability and purity of reference materials and related stock solutions of pesticides during prolonged storage, REP24/PR55, paragraph 230(i), Appendix IX</p> <p>Chile apoya la adopción de los LMRs de plaguicidas en los alimentos.</p>	<b>Chile</b>
<p>Directrices para realizar un seguimiento de la pureza y la estabilidad del material de referencia y soluciones madre de plaguicidas conexas durante el almacenamiento prolongado, REP24/PR55, párrafo 230 i), Apéndice IX.</p> <p>Las directrices para la vigilancia de la estabilidad y pureza de los materiales de referencia y soluciones madre relacionadas de plaguicidas durante el almacenamiento prolongado, REP24/PR55, párrafo 230(i), Apéndice IX, no está listo para su adopción en trámite 5, de acuerdo a lo descrito en el siguiente cuadro:</p> <p>1. ANALYTICAL PROTOCOL FOR MONITORING THE STABILITY AND PURITY OF PESTICIDE REFERENCE MATERIALS AND INDIVIDUAL STOCK SOLUTIONS. Index 21            Texto original: In Approach 1, the stability of new (or unexpired) and old (or expired) RMs is determined simultaneously, and it is applicable for neat standards and their related stock solutions. The comparisons of peak area or concentration shall be run under repeatable conditions and mitigate other sources of variation in instrument response, such as using internal standards, if applicable. If the deviation (in peak area/purity) after expiration is found within 10%, the analyte in the RM is acceptable and, therefore, can be considered for continued use as an RM. For neat standards and stock solutions, monitoring of stability &amp; purity may be continued regularly up to a maximum of 10 years (SANTE) provided the purity remains acceptable<sup>1,2,6..</sup>. Here, new (or unexpired) RM would be required for comparison.</p> <p>Change: In Approach 1, the stability of new (or unexpired) and old (or expired) RMs is determined simultaneously, and it is applicable for neat standards (induvial or mixed) and their related stock solutions. The comparisons of peak area or concentration shall be run under repeatable conditions and mitigate other sources of variation in instrument response, such as using internal standards, if applicable. If the deviation (in peak area/purity) after expiration is found within 10%, the analyte in the RM is acceptable and, therefore, can be considered for continued use as an RM. For neat standards and stock solutions, monitoring of stability &amp; purity may be continued regularly up to a maximum of 10 years (SANTE) provided the purity remains acceptable<sup>1,2,6..</sup>. Here, new (or unexpired) RM would be required for comparison.</p>	<b>Colombia</b>

<p>Note: Approach 1 it's also applicable to mixture of standards as the comparison between old and new standard is made by peak area.</p> <p>2. ANALYTICAL PROTOCOL FOR MONITORING THE STABILITY AND PURITY OF PESTICIDE REFERENCE MATERIALS AND INDIVIDUAL STOCK SOLUTIONS. Index 22. Texto original:As per Approach 2, whenever a new (or unexpired) RM is procured by any laboratory, its purity is monitored periodically before and after expiry using the same analytical conditions as mentioned in the reference material document. Here, new (or unexpired) RM need not be procured. An unexpired internal standard is to be used to account for any change in the response of the equipment. This approach applies only to neat RMs accompanied by reference material documents</p> <p>Change: As per Approach 2, whenever a new (or unexpired) RM is procured by any laboratory, its purity is monitored periodically before and after expiry using the same analytical conditions as mentioned in the reference material document. Here, new (or unexpired) RM need not be procured. An unexpired internal standard is to be used to account for any change in the response of the equipment. As for mixture of standards the concentration or peak area of each component should be monitored periodically before and after expiry using the same analytical conditions as the initial measurement.</p> <p>Note: Approach 2 is also applicable to a mixture of standards. Furthermore, the term "neat" may not apply to mixture of standards as by definition they are not pure or contain only one individual component</p> <p>Approach 1: Comparing the stability of old (or expired) and new (or unexpired) pesticide reference standards; applicable to neat standards of reference materials and related stock solutions. Index 22 - 23. Texto original:Approach 1: Comparing the stability of old (or expired) and new (or unexpired) pesticide reference standards; applicable to neat standards of reference materials and related stock solutions.</p> <p>Change: Approach 1: Comparing the stability of old (or expired) and new (or unexpired) pesticide reference standards; applicable to neat standards (indivial or mixed) of reference materials and related stock solutions. Note: ¿Do the name "reference materials" apply for mixture of standards?</p> <p>Example:</p> <p>Reference Material: "Material sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034)".</p> <p>In this case the term RM would apply to neat and mixture standards</p> <p>Index 30. Texto original: To monitor the stability of the RM over time, a plot of the measured purity/concentration vs. time of monitoring may be made, which would help identify the deviation in stability with time. Change: To monitor the stability of the RM over time, a plot of the measured purity/concentration/Peak Area/%deviation vs. time of monitoring may be made, which would help identify the deviation in stability with time.</p> <p>Tittle. Texto original: Approach 2: Verification of purity of neat standards of pesticide reference materials during prolonged storage (not suitable for verification of stock solutions). Change:Approach 2: Verification of purity of neat (indivial or mixed) standards of pesticide reference materials during prolonged storage.</p> <p>Comments</p> <ul style="list-style-type: none"> <li>• Since the document in its current state does not cover laboratories that use mixture-type analytical standards (RM), we believe it is not yet ready for implementation.</li> <li>• We suggest including a new Approach for the extension of the shelf life of mixture-type standards with the aim of covering the reference materials currently used by</li> </ul>	
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<p>laboratories.</p> <ul style="list-style-type: none"> <li>Mixture-type standards are widely used by pesticide residue analysis laboratories and are an approach to the rapid implementation of methodologies, which facilitates development and validation processes. Additionally, since these are already prepared by a reference material provider, they allow for easy traceability of measurements, which helps facilitate laboratory audit and accreditation processes.</li> </ul> <p>Suggestions</p> <p>To cover the previously mentioned points, we present here a third approach to allow the extension of the validity of mixture-type analytical standards.</p> <p>Approach 3: Verification of stability of standards of pesticide reference materials during prolonged storage.</p> <p>43. To extend the shelf life of a mixture type RM, a chromatographic assay shall be performed, preferably as per the analytical conditions mentioned in the reference material document by the RMP. This approach is based on the assessment and monitoring of stability by ISO 33405.</p> <p>44. Prepare a fresh stock solution of the unexpired standard of RMs and internal standard (a different unexpired RM) of appropriate concentration in a suitable solvent. For proper concentration, which will depend on the response of the RM in the detector, paragraph 22 of Approach I may be referred.</p> <p>45. The standard solution of the RM prepared at an appropriate concentration from the stock solution is analyzed by the instrument (HPLC-DAD, HPLC-UV, GC-FID, LC-MS, GC-MS (full scan mode, SRM or MRM) or qNMR) as per the analytical conditions mentioned in the reference material document. A minimum of five replicate measurements shall be performed to obtain a mean value of the ratio of the RM area to the internal standard for each individual component. To verify the reproducibility of the measurement the %RSD of the replicates should be <math>\leq 10\%</math>.</p> <p>46. Repeat the same procedure at regular intervals of at least once a year using a new stock solution of the RM, particularly before and after the RM's expiry, to monitor its stability and purity during prolonged storage.</p> <p>47. After the expiry of the RM, repeat the procedure as described in paragraph 45 and create a graph of the area ratio of each component against time.</p> <p>No fue posible pegar la figura.</p> <p>Figure 1. Example plot of storage time vs Area ratio response.</p> <p>48. Perform a linear regression analysis and determine if the model fits the data correctly. Example Below.</p>	
<p>Directrices para realizar un seguimiento de la pureza y la estabilidad del material de referencia y soluciones madre de plaguicidas conexas durante el almacenamiento prolongado, REP24/PR55, párrafo 230 i), Apéndice IX.</p> <p>Costa Rica apoya la adopción en trámite</p>	<b>Costa Rica</b>
<p>Directrices para realizar un seguimiento de la pureza y la estabilidad del material de referencia y soluciones madre de plaguicidas conexas durante el almacenamiento prolongado, REP24/PR55, párrafo 230 i), Apéndice IX.</p> <p>Ecuador agradece por la oportunidad de comentar sobre el documento de Directrices para realizar un seguimiento de la pureza y la estabilidad del material de referencia y soluciones madre de plaguicidas conexas durante el almacenamiento prolongado, REP24/PR55, párrafo 230 i), Apéndice IX; considera que está listo para su adopción en el trámite 5.</p>	<b>Ecuador</b>

<p>Guidelines for monitoring the stability and purity of reference materials and related stock solutions of pesticides during prolonged storage, REP24/PR55, paragraph 230(i), Appendix IX</p> <p>Egypt appreciates the work which is done in the guidelines and agrees on the adoption of it at step 5</p>	<p><b>Egypt</b></p>
<p>Directrices para realizar un seguimiento de la pureza y la estabilidad del material de referencia y soluciones madre de plaguicidas conexas durante el almacenamiento prolongado, REP24/PR55, párrafo 230 i), Apéndice IX.</p> <p>Con respecto al procedimiento sobre la extensión de vida de estándares y soluciones para análisis, los resultados son adecuados y satisfactorios para reducir los costos en los procedimientos</p> <p>Las observaciones deben abordar <b><u>si los LMR y las directrices están listos para su adopción</u></b>; y, en caso negativo, proporcionar la justificación y propuestas para facilitar su adopción. Las observaciones deberán presentarse de acuerdo con los <i>Procedimientos para la elaboración de las normas del Codex y textos afines (Parte 3: Procedimiento uniforme para la elaboración de las normas del Codex y textos afines) del Manual de procedimiento de la Comisión del Codex Alimentarius</i><sup>1</sup>.</p> <p>Todos los LMR están listos para su adopción</p>	<p><b>Guatemala</b></p>
<p>La Comisión Técnica Nacional de Residuos de Plaguicidas agradece al Comité del Codex sobre Residuos de plaguicidas por él envió de la carta circular CL 2024/78-CAC Solicitud de observaciones sobre las normas y textos afines presentados por el Comité del Codex sobre Residuos de Plaguicidas, en su 55.<sup>a</sup> reunión, con miras a su adopción por la Comisión del Codex Alimentarius en su 47.<sup>o</sup> período de sesiones.</p> <p>La Comisión NO tiene observaciones o comentarios sobre las normas y textos afines presentados por el Comité del Codex sobre Residuos de Plaguicidas, en su 55.<sup>a</sup> reunión, con miras a su adopción por la Comisión del Codex Alimentarius en su 47.<sup>o</sup> período de sesiones.</p>	<p><b>Peru</b></p>
<p>United Arab Emirates has few remarks to enhance the draft guidelines (attached within the report REP24/PR55, paragraph 230(i), Appendix IX).</p> <p>Comments should address <b><u>whether the MRLs and Guidelines are ready for adoption</u></b>. If not, provide the rationale and proposals to facilitate adoption. Comments should be provided in compliance with the Procedure for the Elaboration of Codex Standards and Related Texts (Part 3—<i>Uniform Procedure for the Elaboration of Codex Standards and Related Texts</i>), Procedural Manual of the Codex Alimentarius Commission.<sup>1</sup></p> <p>Comments should address whether the MRLs and Guidelines are ready for adoption. If not, provide the rationale and proposals to facilitate adoption. Comments should be provided in compliance with the Procedure for the Elaboration of Codex Standards and Related Texts (Part 3—<i>Uniform Procedure for the Elaboration of Codex Standards and Related Texts</i>), Procedural Manual of the Codex Alimentarius Commission.</p>	<p><b>United Arab Emirates</b></p>



<p>Comments should address <b><u>whether the MRLs and Guidelines are ready for adoption</u></b>. If not, provide the rationale and proposals to facilitate adoption. Comments should be provided in compliance with the Procedure for the Elaboration of Codex Standards and Related Texts (Part 3—<i>Uniform Procedure for the Elaboration of Codex Standards and Related Texts</i>), Procedural Manual of the Codex Alimentarius Commission.</p> <p>CropLife International finds the proposed MRLs ready for adoption as they were advanced by CCPR55. CropLife International therefore recommends that the CAC adopts these MRLs at step 5/8.</p> <p>We would like to thank the JMPR, CCPR and CAC for the continuous efforts on Codex standards.</p>	<b>CropLife International</b>
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