

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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**Agenda Item 7.2**

**CX/MAS 26/45/11 Add.1**

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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

Forty-fifth Session

Budapest, Hungary

9 – 13 March 2026

### **SAMPLING PLANS FOR BULK MATERIALS/HETEROGENOUS LOTS INCLUDING MYCOTOXINS**

#### **Comments in reply to CL 2026/6-MAS**

Submitted by:

*Australia, Brazil, Chile, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Peru, Türkiye,  
United Arab Emirates and the International Commission for Uniform Methods of Sugar Analysis (ICUMSA)*

#### **Background**

This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2026/6-MAS issued in February 2026. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### **Explanatory notes on the Annex**

The comments submitted through the OCS are hereby annexed and presented in tabulated format.

## GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
<p>Brazil appreciates and thanks New Zealand and Germany for their effective coordination of the EWG. The document provides an important technical basis for the ongoing discussion.</p> <p>Brazil acknowledges that the document presents concepts that may be technically relevant to the discussion on sampling plans. However, Brazil notes that the document under consideration goes beyond the mere consolidation of existing information and appears to question methodological approaches previously endorsed within the framework of CCCF.</p> <p>In this context, Brazil supports the continuation of the discussion and recommends that the initiation of new work be conditional upon prior consideration by CCCF and the clear presentation of the technical rationale underpinning the proposed revision of the current approach.</p> <p>Brazil further emphasizes that any concerns regarding the currently applied approach should be clearly and explicitly articulated.</p>	Brazil
<p>Egypt appreciates the efforts made in reviewing the sampling plans in CXS 234, including for bulk materials and heterogeneous lots with mycotoxins, and provides below its responses to the questions raised.</p>	Egypt
<p>The European Union (EU) thank New Zealand and Germany for preparing this document and would like to submit the following comments.</p> <p>The main intent of the discussion paper is to assess the appropriateness of existing mycotoxin sampling plans in CXS 193 by taking the following four distributions into consideration to correctly calculate the producer's and consumer's risks</p> <ul style="list-style-type: none"> <li>• proportion of contaminated increments</li> <li>• variation among contaminated increments</li> <li>• proportion of contaminated kernels within a contaminated increment, and the variation of this proportion among contaminated increments</li> <li>• variation among contaminated kernels</li> </ul> <p>This proposal can indeed improve the existing science around sampling of inhomogeneous bulk lots, but it will encounter complications as:</p> <ul style="list-style-type: none"> <li>• it is unclear who will provide the experimental data needed to improve the existing plans. Thomas Whitaker and his colleagues at USDA spent more than 50 years to produce the data and the statistics behind the sampling plans in CXS 193 and the FAO tool;</li> <li>• it is unclear how the data pool presented in Annex B could assist in deriving the necessary data distributions as required for risk and utility calculations. In particular, as no increment-level data, which seems to be essential, are available;</li> <li>• the proposed utility approach, requires prior and credible information regarding the proportion of contaminated increments, variation of concentration of mycotoxin in increments, etc. This information is usually not available for the sampling of isolated lots when enforcing maximum levels;</li> <li>• it is within the terms of reference of CCCF to propose sampling plans for contaminants in food. Moreover, no problems have been raised in CCCF for the application of the sampling plans in CXS 193.</li> </ul>	European Union

COMMENT	MEMBER / OBSERVER
Additionally, if the project indeed goes ahead and is published as an annex to CXG 50, it may create a discrepancy with the sampling plans in CXS 193 leading to regulatory uncertainty.	
Establishing standardized guidelines for acceptance sampling schemes for heterogeneous bulk materials, particularly with regard to mycotoxins, is a technical and regulatory necessity to ensure fair and reliable acceptance and rejection decisions, reduce health and commercial risks, and enhance regulatory defense against appeals.	Iraq

## SPECIFIC COMMENTS

COMMENT	MEMBER / OBSERVER
<b>Question a: the appropriateness and timeliness of developing general guidance on acceptance sampling plans for bulk materials from inhomogeneous lots, with particular emphasis on mycotoxins</b>	
<p>Australia agrees with initiation of new work, believing this item was worth the discussion and if the data is available a 'Utility approach' is worth development as a 'Quantitative assessment', appended to guidance in CXG 50 and additional information /explanations, if necessary, in INF_CCMAS_CXG50. Then consider preparing a proposal for CCCF to assess on how the approach could supplement the various existing Mycotoxin sampling plans provided in CXS 193.</p> <p>Australia suggests that with progression of the new work, CCMAS continue to inform CCCF of its progress. Noting as per REP25/CF18 paragraph 11-13, CCCF 'was informed that CCMAS44 had agreed to develop a discussion paper on sampling plans for bulk materials/heterogeneous lots, including for mycotoxins, and that CCCF would be kept informed of this work and consulted as necessary'. Along with the Codex Secretariat explanation of the rationale for CCMAS decision and providing 'further reassurance that CCMAS would only look at approaches for sampling plans and that it remained the remit of CCCF to develop sampling plans'</p>	Australia
We believe it is appropriate to incorporate this into CXG 50–2004 and, subsequently, for CCMAS to continue working on improving the existing plans in CCCF CXS-193. We also believe that, since both documents will be formally reviewed by CCCF at a later date, there would be no problem in moving forward in this direction.	Chile
El País sugiere la conformación de un EWG que se encargue del desarrollo metodológico de planes de muestreo que incorporen enfoques alternativos (no solo basados en lotes contaminados o en muestras no representativas), sino que, el enfoque de la selección de lotes debe determinarse por su utilidad o la caracterización explícita de la no homogeneidad que permita un mejor análisis.	Ecuador
<p>We consider the development of general guidance on acceptance sampling plans for bulk materials from inhomogeneous lots, with particular emphasis on mycotoxins, to be both appropriate and timely.</p> <p>Inhomogeneity, especially in relation to mycotoxin contamination, presents significant sampling challenges and variability. Harmonized guidance would enhance consistency, scientific robustness, and risk-based decision-making across Codex standards and national control systems.</p>	Egypt

COMMENT	MEMBER / OBSERVER
<p>The development of practical guidance on the evaluation and/or the refinement of existing sampling plans for bulk materials is certainly warranted.</p> <p>The European Union (EU) supports therefore the proposed aspect of exploring available data to better characterize inhomogeneity of bulk lots and to evaluate the existing sampling plans in CXS 193 with respect to consumer's and producer's risks and to identify the aspects which could be considered for change to achieve the desired balance of consumer's and producer's risks.</p>	<p><b>European Union</b></p>
<p>Indonesia supports initiating new work to develop general guidance on acceptance sampling plans for bulk materials in inhomogeneous lots. This work should include a special focus on mycotoxins because contamination levels in the sample matrix are often very low. Consequently, the existing scheme in CXS 193-1995 for "homogeneous" sample lots increases the potential for bias due to population inhomogeneity and the inability of the tested samples to accurately represent the entire lot</p>	<p><b>Indonesia</b></p>
<p>The Procedural Manual indicates that the development of the sampling plans for mycotoxins is under the remit of CCCF. CCMAS, as the committee in charge of general topics on sampling, may consider guidance, but the intension of such guidance should provide the appropriate committee with scientific information from more general point of view. Japan can agree to work on bulk materials in general but does not agree with the particular emphasis on mycotoxins.</p> <p>Furthermore, as indicated in paragraph 101 of REP 25/MAS, the ToR of this EWG is to prepare a discussion paper on sampling plans for bulk material lots. Bulk material lots include both homogeneous and inhomogeneous lots. However, this discussion paper appears to focus only on sampling plans for inhomogeneous lots, with particular emphasis on mycotoxin. Therefore, this work should also include discussion on sampling plans for homogeneous bulk lots, with clear distinction between these two parts.</p>	<p><b>Japan</b></p>
<p>Tomando nota de lo manifestado por el GTE respecto que los planes actuales que presenta la norma(CXS 193) aparentemente muestran inconsistencias conceptuales y metodológicas, lo que puede subestimar riesgos para consumidores o producir costes indebidos para productores; La Comisión Técnica Nacional sobre Métodos de análisis y toma de muestras, apoya iniciar trabajos para elaborar una guía general sobre planes de muestreo de aceptación para materiales a granel/lotas no homogéneos con énfasis en micotoxinas.</p> <p>Se podría Considerar trabajo paralelo para mejorar la herramienta FAO (<a href="https://tools.fstools.org/mycotoxins/">https://tools.fstools.org/mycotoxins/</a>) para permitir ingresar número de incrementos y parámetros de heterogeneidad; y realizar estudios de validación con datos reales.</p>	<p><b>Peru</b></p>
<p>Türkiye supports the systematic assessment and periodic review of sampling plans for inhomogeneous lots, particularly with regard to consumer's and producer's risks. Türkiye also supports the development of guidance that clearly explains the approach and methodology related to such reviews within an appropriate Codex framework.</p> <p>The discussion paper emphasizes the potential inclusion of a utility-based approach grounded in prior information. Under this approach, it is suggested that sampling plans could be optimized in terms of the number of increments, potentially reducing costs and such a framework may allow for a more quantitative evaluation of consumer's and producer's risks.</p> <p>Türkiye note that the proposed utility-based approach require calibration using representative and sufficiently large data sets; therefore utility-based approaches may face practical challenges in implementation, particularly in the absence of robust prior data at national level</p>	<p><b>Türkiye</b></p>

COMMENT	MEMBER / OBSERVER
An application of the utility-based approach using real datasets for which prior information is already available would facilitate a more informed assessment of its effectiveness and practical feasibility. Such an evidence-based evaluation would help clarify the potential benefits and limitations of the proposed framework.	
<p>1. The UAE considers this work both appropriate and timely, given the increasing volume of international trade in bulk cereals, oilseeds, nuts, and related commodities.</p> <p>2. The UAE supports the development of general guidance on acceptance sampling plans for bulk materials, particularly for contaminants such as mycotoxins that exhibit highly heterogeneous and clustered distribution patterns. In practice, variability arising from sampling often exceeds analytical variability, leading to regulatory uncertainty and potential trade disputes.</p> <p>3. Harmonized Codex guidance would strengthen risk-based enforcement decisions, improve consistency across jurisdictions, and enhance transparency in border control measures.</p> <p>The UAE considers this work both appropriate and timely, given the increasing volume of international trade in bulk cereals, oilseeds, nuts, and related commodities.</p> <p>2.</p> <p>The UAE supports the development of general guidance on acceptance sampling plans for bulk materials, particularly for contaminants such as mycotoxins that exhibit highly heterogeneous and clustered distribution patterns. In practice, variability arising from sampling often exceeds analytical variability, leading to regulatory uncertainty and potential trade disputes.</p> <p>3. Harmonized Codex guidance would strengthen risk-based enforcement decisions, improve consistency across jurisdictions, and enhance transparency in border control measures.</p>	<b>United Arab Emirates</b>
Question a response - yes a document needs to be defined and validated for sampling of non-homogeneous materials but it is questionable if mycotoxins should be the focus. It is likely sampling for pathogens or toxins may required a different approach to other compounds or species of interest.	<b>ICUMSA</b>
<b>Question b: where such guidance should appropriately reside</b>	
Ecuador considera que el documento que pueda obtenerse del EWG con la orientación de la selección metodológica recomendada, se apruebe por la Comisión del Codex para ser incorporado como anexo a las Directrices Generales sobre Muestreo (CXG 50-2004). Se considera fundamental que este proceso sea coordinado con el Comité del Codex sobre Contaminantes de los Alimentos (CCCF) dada su competencia en el tema de micotoxinas.	<b>Ecuador</b>
<p>We consider that such guidance should reside under CCMAS as general guidance, potentially as a Codex Guideline linked to CXS 234-1999 and the General Guidelines on Sampling (CXG 50-2004).</p> <p>Placement under CCMAS would ensure methodological consistency across commodity committees while allowing commodity-specific standards to reference the guidance as appropriate.</p>	<b>Egypt</b>
<p>The EU supports the proposed recommendation that CCMAS<sup>45</sup> requests CCCF of their views on the need for additional guidance for acceptance sampling plans for bulk materials for inhomogeneous lots with a special focus on mycotoxins.</p> <p>In case there would be in CCMAS no agreement on further work, the EU suggests forwarding the discussion paper to CCCF and request their opinion on the raised issues and proposed actions.</p>	<b>European Union</b>

COMMENT	MEMBER / OBSERVER
Guidelines for sampling schemes for inhomogeneous lots, particularly for determining mycotoxin contamination levels, can be recommended as supplementary guidance to Annex III of document CXS 193-1995	Indonesia
The guidelines were included as a specialized annex to CXG 50-2004 (General Guidelines on Sampling), with the development of a technical text in coordination with the Committee on Contaminants in Food (CCCF).	Iraq
<p>Regarding sampling plans for mycotoxins, Japan would like to remind CCMAS of the explanation provided by the Codex secretariat at CCCF18: "The Secretariat provided further reassurance that CCMAS would only look at approaches for sampling plans and that it remained the remit of CCCF to develop sampling plans. CCMAS would ensure that there was communication with the Committee once the CCMAS discussion paper was more advanced." (REP 25/CF). The explanation clearly states that development of the sampling plans for mycotoxins is under the remit of CCCF, not CCMAS.</p> <p>Taking into account the earlier discussion, Japan proposes that the text, especially the part focusing on mycotoxins, should be included in CCMAS report and forwarded to CCCF for their consideration, since such information may be useful to CCCF.</p>	Japan
<p>La Comisión Técnica Nacional sobre Métodos de análisis y toma de muestras, recomienda incluir la información como anexo técnico a la CXG 50-2004 (Directrices generales sobre muestreo), porque considera que sitúa la orientación en el marco existente sobre muestreo; facilitaría su uso por comités de productos y autoridades competentes; y permitiría un proceso formal de adopción en el sistema Codex.</p> <p>Complementariamente, podría considerarse contar con una base de datos vinculados del CXS 234-1999 que almacene parámetros, estudios y conjuntos de datos representativos; o una aplicación de cálculo accesible públicamente (Por ejemplo una versión mejorada de la herramienta FAO).</p> <p>También nos mostramos a favor que exista coordinación formal y continua con el Comité del Codex sobre Contaminantes de los Alimentos (CCCF) y los comités de producto relevantes durante todo este proceso.</p>	Peru
Türkiye considers that the proposed work could be included as an annex to the General Guidelines on Sampling (CXG 50-2004), subject to further discussion and agreement within the Committee.	Türkiye
<p>Question B – Placement Within Codex Texts 1. The UAE recommends that the guidance be developed as a horizontal annex to the General Guidelines on Sampling (CXG 50-2004) to ensure broad applicability across contaminants and commodities characterized by inhomogeneous distribution. 2 2. The guidance should: a. Clearly articulate its relationship to Maximum Levels (MLs) and compliance decisions. b. Reference relevant statistical principles, including operating characteristic considerations. c. Maintain consistency with Codex risk analysis principles; and d. Ensure alignment with existing Codex sampling terminology and structure.</p> <p>The UAE recommends that the guidance be developed as a horizontal annex to the General Guidelines on Sampling (CXG 50-2004) to ensure broad applicability across contaminants and commodities characterized by inhomogeneous distribution.</p> <p>The guidance should:</p> <p>a. Clearly articulate its relationship to Maximum Levels (MLs) and compliance decisions.</p> <p>b. Reference relevant statistical principles, including operating characteristic considerations.</p> <p>c. Maintain consistency with Codex risk analysis principles; and</p> <p>d. Ensure alignment with existing Codex sampling terminology and structure.</p>	United Arab Emirates

COMMENT	MEMBER / OBSERVER
Question b - where the document should reside within the Codex structure will depend on the decisions made about the testing the sampling is for (see Question a answer). General comment - terminology for anything other than a homogeneous material is difficult and needs to be addressed/clarified before finalising any sampling document related to inhomogeneous/non-homogeneous material	ICUMSA
<b>Question c: the proposed acceptance sampling plans for bulk materials from inhomogeneous lots (e.g. whether the content and structure offer a sound basis for continued development). In particular, input is sought on areas that may require further clarification, expansion, or the inclusion of additional provisions to enhance completeness and coherence (CX/MAS 26/45/11 Appendix 1)</b>	
El País considera que el contenido y la estructura del documento de debate, constituyen una base técnica sólida para continuar con el desarrollo de los planes de muestreo. No obstante, Ecuador recomienda aclarar si el trabajo propuesto complementará o eventualmente reemplazará planes existentes en CXS 193. Se debe evaluar la viabilidad práctica y el impacto operativo con las autoridades competentes de la región y, finalmente se recomienda desarrollar ejemplos prácticos comparativos entre planes actuales y los planes futuros a desarrollarse y ser considerados como óptimos.	Ecuador
We consider that the proposed content and structure provide a sound basis for continued development. However, further clarification may be beneficial in the following areas: <ul style="list-style-type: none"> <li>• Clear definitions of lot structure and degrees of inhomogeneity;</li> <li>• Statistical justification and performance characteristics of the proposed plans;</li> <li>• Practical guidance for implementation in bulk handling scenarios;</li> <li>• Explicit linkage between sampling variability and analytical uncertainty;</li> <li>• Alignment with existing Codex risk-based approaches.</li> </ul> Additional illustrative examples or case studies (e.g., for mycotoxins in bulk cereals) could further enhance clarity and practical applicability.	Egypt
The EU is not in favour of the utility approach for enforcement sampling, as in the example given there is a need for prior information on variation of aflatoxin concentration between lots, on the proportion of contaminated increments in a lot and the variation of aflatoxin concentration between contaminated increments within a lot. This information is not available when sampling is performed for enforcement verifying if the lot is exceeding or not an established maximum level. The EU would be grateful to receive additional information on how the utility approach can be used for enforcement sampling verifying compliance with an established maximum level, not having this prior information available.	European Union
We suggest further clarification on the following aspects to enhance comprehensiveness, consistency, and applicability: Explain the statistical basis for the plan, including the target confidence level and product and consumer risks. Include numerical examples or guidelines linking batch size, degree of heterogeneity, and the proposed number of subsamples. Explain the methodology for classifying batches based on degree of heterogeneity and the practical criteria for doing so. State the rules for decision-making in cases near extreme limits, taking into account measurement uncertainty. Clarify the relationship between the proposed text and existing horizontal guidelines to avoid overlap and ensure consistency. Conclusion	Iraq



COMMENT	MEMBER / OBSERVER
We believe that addressing the above points will enhance the scientific rigor and practical applicability of the text across different control systems and will contribute to providing a balanced framework for managing acceptance and rejection risks in the context of heterogeneous bulk materials.	
Again, establishment of such sampling plans is under the remit of other committees. CCMAS may consider statistical issues around them and inform appropriate committees, but further work is beyond the ToR of CCMAS.	Japan
La Comisión Técnica Nacional sobre Métodos de análisis y toma de muestras, considera que la estructura ofrece una base sólida, para seguir desarrollando el tema; y se sugiere priorizar el incorporar ejemplos para brindar mayor claridad a la información.	Peru
<p>Question C – Comments on the Proposed Acceptance Sampling Plans 1. The UAE considers the proposed sampling plans presented in Appendix 1 of CX/MAS 26/45/11 to be a sound starting point for further development. However, additional clarification and refinement are recommended in the following areas: a. Explicit differentiation between sampling variance and analytical measurement uncertainty. b. Clear decision rules for borderline or near-ML results. c. Operational guidance for bulk marine consignments and containerized shipments. d. Clarification of applicability across different lot sizes and logistical configurations. e. Practical considerations related to inspector safety and feasibility at ports of entry. 2. The UAE emphasizes that final guidance should balance statistical robustness with operational practicality, particularly for implementation in diverse regulatory environments. 3. The UAE appreciates the opportunity to contribute to this important work and looks forward to continued discussion within the Codex Committee on Methods of Analysis and Sampling.</p> <p>The UAE considers the proposed sampling plans presented in Appendix 1 of CX/MAS 26/45/11 to be a sound starting point for further development. However, additional clarification and refinement are recommended in the following areas:</p> <p>a. Explicit differentiation between sampling variance and analytical measurement uncertainty.</p> <p>b. Clear decision rules for borderline or near-ML results.</p> <p>c. Operational guidance for bulk marine consignments and containerized shipments.</p> <p>d. Clarification of applicability across different lot sizes and logistical configurations.</p> <p>e. Practical considerations related to inspector safety and feasibility at ports of entry.</p> <p>2. The UAE emphasizes that final guidance should balance statistical robustness with operational practicality, particularly for implementation in diverse regulatory environments.</p> <p>3. The UAE appreciates the opportunity to contribute to this important work and looks forward to continued discussion within the Codex Committee on Methods of Analysis and Sampling.</p>	United Arab Emirates