

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 5

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ORIGINAL LANGUAGE ONLY

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

Forty-third Session

Budapest, Hungary

13 – 18 May 2024

INFORMATION DOCUMENT: THE GENERAL GUIDELINES ON SAMPLING (CXG 50-2004)

Comments in reply to CL 2024/16-MAS

submitted by

Australia, Canada, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Peru, Philippines, Sierra Leone

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/16-MAS issued in February 2024. Under the OCS, comments are compiled in alphabetical order.
2. The Annex includes comments proposing different methods of analysis and/or proposals only.

Explanatory notes on the appendix

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

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
<p>The document introduction states a split into two parts, Part 1; and Part 2 (but not specifically titled as ‘parts’ in the document). However as some sampling plans are discussed in both parts, the reader sometimes feels they are cycling back on similar material in places. There is a paragraph on sampling for multiple characteristics 2.2.2 (second last para.) but basically saying ‘the producer’s risk of inappropriate rejection will increase with the number of characteristics inspected, so should be applied only among ‘similar’ characteristics. So eliminating the singular sampling plans for a commodity as previous used before the CXG 50 (2004) and a simplicity some users may be seeking from this guidance.</p> <p>We appreciate that there is an increased number of case studies with practical applications. But unsure of the linkage with the existing ‘Information document on Practical Examples of Sampling Plans’ and the CXG 50-Revised in 2023 Section ‘4.1-Selection of sampling plans’ and the ‘Appendix I-Guide to the Selection and Design of Sampling Plans’.</p> <p>In Section 5.4, we see the statement ‘For instance, if the measurand is defined in terms of the laboratory sample, then only analytical sources are relevant.’ We find this problematic and potentially providing a ‘definition’ to ‘eliminate sampling uncertainty’ and consequently makes the statistical treatment easier, but ignores the practical situation that there is a level of ‘heterogeneity’ at the lot, particle, and sub-particle level, and so while sampling uncertainty may be considered as ‘not significant’, it will be forever present despite the theoretical model utilised.</p> <p>We are concerned the guidance describes what a complex system sampling can be to balance producer/consumers risks, testing being representative but cost effective, assessments that are comprehensive but timely; however by simply providing numerous sampling options with the expectation that users will elucidate the ‘best’ option for their specific situation, we may have introduced a level of complication that needs to be simplified by removing unnecessary elements or reducing the system to its essential components. We would normally do this by a default sampling plan option which can be refined (if desired) or offering a decision tree to achieve the ‘best’ option, which has been done in part by practical case studies in this info document, the existing ‘Information document on Practical Examples of Sampling Plans’, the CXG 50-Revised in 2023 Section ‘4.1-Selection of sampling plans’, and the ‘Appendix I-Guide to the Selection and Design of Sampling Plans’; but not necessarily linked to give a specific coordinated approach.</p>	Australia
<p>Inspection for Foreign Matter</p> <p>Inspection for Foreign Matter, paragraph 3 & 4 , refers to ‘section 2.5.1’, this reference doesn’t appear correct.</p>	
<p>In this section, two models, first described in Uhlig (2024), will be discussed. These two models can be used to analyze the relationship between within- and between-item variability, and thus allow an estimate of the lot standard deviation which is corrected for any between-item variability.</p> <p>What appears to be a reference with the text ‘Uhlig (2024)’, is not included in ‘Section 5.7 References’.</p>	
<p>This formula allows for only a single component of measurement uncertainty; there is no allowance for bias when multiple tests are performed. The tool allows users to select whether “within lab” or “between lab” between laboratory variation is used, assuming that the between laboratory variation is twice the within laboratory figure (a common assumption). The tables below show the within laboratory variance.</p>	

Comments' 2nd paragraph, 2nd sentence, suggested removing text 'between laboratory' i.e. 'The tool allows users to select whether "within lab" or "between lab" between laboratory variation is used,...	
In this scenario, the lot standard deviation is known. The same acceptance sampling plan as in Annex 4.1.2 is applied (with). However, the analytical uncertainty is nonnegligible, with (). For a lot with quality the PR is over 11% (instead of 5%) due to the inflated variation of the.	
Scenario 1: known, increase in producer risk', second sentence refers to an Annex, which is not attached.	
Canada appreciates the work, time and care that the Co-Chairs have taken to address the comments related to the information document. Within the CL, countries were requested to identify real-life practical examples based on commodity standards, that were of interest for inclusion. Given this request, Canada suggests that one of the mycotoxin/commodity sampling plans described in CXS 193-1995 (Codex General Standard for Contaminants and Toxins in food and feed) be used as a "real-life practical example" in the information document supporting CXG 50.	Canada
Se considera reestablecer el GTe y continuar desarrollando el documento de información ya que el mismo es muy extenso y complejo. Se debería considerar el nuevo desarrollo de la ciencia para que se aplique y así beneficiarnos en la reducción de costos y de número de muestras.	Ecuador
Egypt appreciates the work which done in the document with the emphasis on addition of Bayesian approaches in this guidelines and other relevant standards	Egypt
The European Union and it Member States acknowledge the good work of the EWG and support the initiative to continue the work of the EWG in 2025.	European Union
Section 4.6 discusses sampling for bulk materials with a particular focus on the plans for mycotoxins described in the <i>General standard for contaminants and toxins in food and feed (CXS 193-1995)</i>.	Indonesia
In the case of mycotoxin acceptance criteria, besides measurement uncertainty, correction for recovery as quality control of the methods might also be considered.	
Agree	Iraq
Japan thanks New Zealand and Germany for their elaboration in preparing the draft information document on the General Guidelines on Sampling (CXG50-2004).	Japan
In this work, we have to keep in mind the purpose of this work, which is to make the Guidelines more user-friendly. This information document is to be elaborated to help readers to understand the Guidelines. On the other hand, if the information document is very long or contains too much information, readers may be fed up with understanding it. Therefore, the information document should contain sufficient information but should be as short and concise as possible. We are of the view that the most important information to be included in the information document should be related to the sampling plans addressed in the CXG50, and we should dare to remove other information from the information document, which increases user-friendliness. According to our analysis of the document, sufficient explanation has already been included in the draft, but some parts are too much for readers of commodity committees and governments, who are busy and are generally not familiar with statistics. Thus, Japan would like to propose the following two points for improvement.	
First, Japan proposes to delete sections from 5.3 to the end. Japan understands that the text in these sections contains important information derived from state-of-arts of science; however, such information is beyond the contents of the Guidelines. We are afraid that	

<p>the sections not directly explaining the Guidelines would hinder users from understanding the Guidelines.</p> <p>Second, Japan proposes to delete Section 4.3. In the section, a new concept of “total measurement uncertainty” is introduced. However, it is neither defined nor discussed in the Guidelines or other CCMAS documents such as “Guidelines on Measurement Uncertainty” (CXG54) and “Guidelines on Analytical Terminology” (CXG 72). Since the information document is elaborated for explanation of the Guidelines, not to introduce new ideas, we should not introduce new concept of “total measurement uncertainty” in the information document.</p>	
<p>El Perú agradece al Grupo de Trabajo Electrónico liderado por Nueva Zelanda y copresidido por Alemania, lo que nos da la oportunidad para presentar los siguientes comentarios.</p> <p>a. Considerar el proyecto de documento informativo (Apéndice I del documento CX/MAS 24/43/7) y las preguntas planteadas en el párr. 7 del documento CX/MAS 24/43/7 :</p> <ul style="list-style-type: none"> • ¿Debería incluirse en el documento informativo nueva ciencia relacionada y relevante que se esté desarrollando en paralelo? Hay debates activos sobre los enfoques bayesianos en otras organizaciones de desarrollo de estándares, dada la forma en que este enfoque puede reducir la cantidad de muestras y, por lo tanto, los costos, y esto es relevante para CXG 50. Respuesta: Se considera que si debiera incluirse en el documento informativo la nueva ciencia relacionada , tal como es el enfoque bayesiano. • Contenido adicional, por ejemplo más centrado en ejemplos prácticos de la vida real basados en normas de productos básicos. Si bien hemos incluido algunos ejemplos en el borrador del documento de información, podemos proporcionar más, pero para hacerlo, necesitamos tener una mejor comprensión de lo que quieren las delegaciones de los países y luego tener tiempo para desarrollar estos ejemplos específicos. Respuesta: De acuerdo en que se incluya contenido adicional con ejemplos prácticos de la vida real basados en normas de productos básicos • Disponer de un documento informativo tanto actual como de futuro. Para ello se tienen en cuenta tanto ejemplos prácticos relevantes como también fundamentos teóricos adicionales. Respuesta: De acuerdo con que el documento tenga un enfoque informativo tanto actual como para el futuro, que incluya tantos ejemplos prácticos relevantes como también fundamentos teóricos. • También hubo comentarios del GTE sobre la necesidad de revisar las referencias del CXS 234 a los planes de muestreo. Respuesta: De acuerdo con la revisión de las referencias del CXS 234. <p>b. Conveniencia de restablecer el GTE para seguir desarrollando el documento informativo para su finalización en la 44.^a reunión del CCMAS(2025). Respuesta: De acuerdo en que se restablezca el GTE para que se continúe desarrollado el documento informativo.</p> <p>c. Considerar una revisión de los planes de muestreo contenidos en CXS 234 como parte del trabajo futuro del GTE que se restablezca Respuesta: De acuerdo con que sea trabajado por el GTE la revisión de los planes de muestreos referenciados en la norma CXS 234</p>	Peru
<p>1. The Philippines expresses appreciation for the work done by the eWG chaired by New Zealand and co-chaired by Germany to continue working on the information document namely the e-book with the sampling plans applications.</p>	Philippines

<p>2. The Philippines considers the following:</p> <ul style="list-style-type: none">a. The draft information document (Appendix I) and the questions raised in para. 7b. To re-establish the EWG to further develop the information document for finalisation by CCMAS44c. To review of the sampling plans contained in CXS 234 as part of the further work of the EWG <p>Rationale: The draft information document provides specific examples and guidance for creating or modifying and revising sampling plans which is very helpful. However, re-establishment of the EWG is needed to further develop the information document, to provide more detailed examples on measurement uncertainty and to focus on real-life practical examples based on commodity standards.</p> <p>The review of the sampling plans contained in CXS 234 is also necessary to be consistent with the Information Document: General Guidelines on Sampling (CXG 50-2004).</p>	
Sierra Leone endorse the codex texts as there are clarities in the sampling plan.	Sierra Leone

SPECIFIC COMMENTS

Whether related and relevant new science that is happening in parallel should be included in the information document? There are active discussions on Bayesian approaches in other standards development organisations, given the way this approach can reduce the number of samples and therefore costs, and this is relevant to CXG 50.	
Respuesta: Se considera que si debiera incluirse en el documento informativo la nueva ciencia relacionada , tal como es el enfoque bayesiano.	Peru
We have no issue with 'new science' as long as it has 'proven application in practice'.	Australia
Additional content, for example more focus on real-life practical examples based on commodity standards. While we have included some examples in the draft information document, we can provide more, but to do this, we need to have a better understanding of what country delegations want and then time to develop these specific examples.	
Respuesta: De acuerdo en que se incluya contenido adicional con ejemplos prácticos de la vida real basados en normas de productos básicos	Peru
Real-life practical or case studies, are invaluable for complex guidance, but we don't want too many.	Australia
To have both current and a forward-looking information document. This takes into account both relevant practical examples as well as additional theoretical background.	
Respuesta: De acuerdo con que el documento tenga un enfoque informativo tanto actual como para el futuro, que incluya tantos ejemplos prácticos relevantes como también fundamentos teóricos.	Peru
We believe there is a comprehensive combination of both current and a forward-looking information, however this answer doesn't provide a simplified CXG 50 guidance as requested by commodity committees, or reduce the sample numbers to a level which would have conformed to the superseded Codex STAN 233-1969 (replaced by CXG 50 - 2004) but whose guidance continued to be replicated in Sampling plan submissions by commodity committee to CCMAS.	Australia
The need to review CXS 234 references to sampling plans.	
Respuesta: De acuerdo con la revisión de las referencias del CXS 234.	Peru
Australia did suggest and continues to think it is relevant that 'We need to decide how we should document sampling plans when endorsed in CXS-234, as the current table format may not have sufficient detail, especially if the sampling is based on 'provisions' as well as 'commodity categories' or a 'hybrid' which is not specifically stated but we believe alluded to in the CXG 50 Sampling Information Document'.	Australia