CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **MAS-CRD/14**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Comments of El Salvador and EU

El Salvador

El Salvador agradece el documento remitido por la Secretaría del Codex Alimentarius, preparado por el Grupo de Trabajo Electrónico presidido por Nueva Zelanda y copresidido por los Estados Unidos de América.

El Salvador ha analizado el tema en cuestión en el Comité Espejo del Codex sobre Métodos de Análisis y Toma de Muestras y presenta los siguientes comentarios:

Generales

1. Se apoya el conjunto CXG 50 revisado (el CXG 50 revisado y sus documentos de respaldo).
2. Se apoya adelantar el anteproyecto propuesto de CXG 50 revisado (Apéndice I) al trámite 5. Se considera que se ha cumplido el propósito de simplificarlas y hacerlas más legibles y comprensibles facilitando su uso.
3. Se apoya el que se restablezca el GTE para que finalice el documento CXG50 y siga desarrollando documentos en apoyo de CXG50, teniendo en cuenta los comentarios recibidos en respuesta a la CL 2021/10/OCS-MAS con la intención de que formen parte del conjunto CXG 50.

Específicos

1. Se recomienda realizar las vinculaciones correspondientes en las secciones de las directrices CXG 50 que son citadas en el anexo II para un mejor uso del anexo en cuestión.
2. Así también se ha revisado la numeración del documento y se ha detectado que faltan algunos numerales de las directrices CXG 50 como el caso del numeral 5.1 no obstante es citado el 5.1.1, 5.1.2, así también al mencionarse los numerales en el texto de la norma no corresponden con la nueva numeración asignada de los subtítulos como en 6.4 Lotes no homogéneos se cita la sección 3.1.8 sobre homogeneidad cuando el numeral correcto en la estructura de la norma es 3.1.10.
3. Se sugiere que en los planes 4.4.6 y 4.4.7. se establezca una gama de criterios de poder seleccionar 2 o 3 muestras a analizar según los diferentes parámetros del plan de muestreo.
4. Se sugiere que el cuadro del apéndice II colocar la información en un diagrama que permita mejor visibilidad. El cuadro tiene bastante información que no se logra visualizar el objetivo del mismo y puede generar confusión.
5. Se sugiere acompañar el documento de diferentes ejemplos como anexos que ilustren y ayude a la comprensión del mismo.
6. Se sugiere que se considere en la elaboración del documento otras guías sobre muestreo vigentes en análisis de alimentos como las establecidas por FAO como por ejemplo la estandarización de toma de muestras para matrices líquidas, polvos, granos, aceites etc.

European Union Comments

Mixed Competence

Member State Vote

The European Union and its Member States (EUMS) congratulate the eWG under the lead of New Zealand and the co-lead of the United States of America for the further development of the revision of CXG50-2004. Sampling is an essential element for the verification of provisions in Codex standards and the current version of CXG50 is a useful information source, though sometimes difficult to read and understand for non-specialists. Therefore, a revision o CXG50 with the overall aim to simplify its structure and language to provide effective guidance to all CAC subsidiary bodies and interested parties for designing/selecting sampling plans is highly welcome. The EUMS view this development as an important step that will greatly facilitate the use of acceptance sampling designs, especially since the associated ISO standards (ISO 2859 and ISO 3951) in their current form leave much to be desired, both from a conceptual and didactical point of view. The EUMS are of the opinion that the presented draft succeeded in principle in reaching the goals set out by CCMAS39 and CCMAS40 in providing not only guidance in the main document but also technical solutions in form of an e-book. However, the re-drafted version of CXG 50 poses a few challenges not only in terms of the apps, but also regarding theoretical aspects. These challenges require conceptual and technical discussions, which will also be relevant in connection with the on-going revision of the above-mentioned ISO standards.

The EUMS are aware that the proposed CGX50 text follows a different approach and style compared to the current version, which was the intent of the re-draft. Information provided as tables and figures in the current CGX50 will be moved to an e-book and will be provided in form of software apps, which is an appropriate and smart way of helping users to understand the impact of certain plans. NZ and USA as chair and co-chair are invited to inform CCMAS41 whether the software apps have been validated and how maintenance and access to the software can be ensured in a sustainable manner.

The EUMS invites the Committee to explain the relationship of the re-drafted CXG 50 between the existing Information Document 'Practical Examples of Sampling Plans' and sampling plans of existing Standards, e.g. those of CXS 193.

In general, the presented draft, however, could benefit from:

- avoiding redundancy, e.g. the aspect of 'fair and valid sampling procedures', though of highest relevance, is over emphasised throughout the text and many of the explanations in the e-book repeat what is already explained in the main body of the draft;
- being consistent in the use of terminology, in particular as it relates to PR, CR, PRQ, CRQ and AQL (the currently available version of the apps still refer to AQL and QL) and the relationship among them;
- clarifying the relationship between relevant ISO standards (i.e. ISO 2859 and ISO 3951) and the re-drafted CXG50, in particular as it relates to 6.2;
- focusing the guidance for the primary target audience, i.e. Codex Commodity Committees, on the most common scenarios encountered when developing/selecting sampling plans and providing more detail to help users to select the correct approach related to the provisions of their Standards. The EUMS are aware of the recommendation of CCMAS39 that the revised CXG 50 shall provide guidance to all CAC subsidiary bodies and other stakeholders; however, the GL should primarily consider plans for sampling inspection of isolated lots, whereas background and plans for niche applications could be explained in the e-book;
- explaining the differences regarding procedures for the inspection of *isolated* lots (relevant e.g. for receiver-oriented situations) versus *continuous* lot inspection (relevant e.g. for production process control).

More specific remarks relate to:

Section/Paragraph	**Comment**
General	We fully agree that statistical standards have to be adapted in appearance and contents to the digital world – and in this respect there is a long way to go for ISO 3951 and ISO 2859. Notwithstanding, we are critical of the proposed app in its current form, as the user is not given sufficient guidance to balance sample size, acceptance limit, PR, CR, PRQ and CRQ against each other in an

	appropriate, reproducible and transparent manner. This is exactly where the ISO standards can help: while not designed to always guarantee uniform PRQ and CRQ values, they make possible workable compromises. We think it would be very helpful to review sections 3.1.4 and 6.2 accordingly and to explain the rationale of the standards to the user, adapt it if necessary, and integrate it into the app.
General	Given recent developments in the application of Bayesian approaches in conformity assessment (e.g. JCGM 106), we suggest that some of the implications regarding lot inspection should be discussed in CXG50.
3.1.3	This section suggests CR and PR should both be taken into account in developing sampling plans for lot inspection. While this unquestionably corresponds to the ideal situation, in practice sample sizes which will result from such an approach may be impracticably high.
3.1.3.1 (Figure 2)	This figure (and more generally the app) may give the impression that PR and CR can be specified as low as desired. However, for risk values below the standard 5 % and 10 % values, the required sample size may become impracticably high. We suggest emphasizing the standard 5 % and 10 % values both in the app and in CXG50.
3.1.6	In the table, what is the rationale for letting CR only vary from 1% - 5%? Note: We assume that “Consumer's risk (allowable probability of acceptance)“ corresponds to CR. Especially at the lower stringency levels (to the right of the table), we would have expected 10 % for CR. In general, we also suggest that stringency should only apply to CRQ, and that CR should be set to 10 % across the different CRQ levels. If it is desired to introduce a new CR level for critical situations, then this should be discussed and criteria for deciding whether such a new CR level should be applied should be clearly put forward.
3.1.7	The term “specification” is used in this section and throughout the current draft of CXG 50 in different meanings (often to mean the act of determining a requirement). This may lead to confusion if the term “specification” is also used to refer to a “specification limit” in connection with the conformity assessment of an individual item. We suggest using the complete term “specification limit” for the question of the conformity of individual items. As far as the question of the conformity assessment or acceptance of a lot is concerned, we suggest using the term “quality level” (i.e. percentage of items nonconforming) throughout CXG 50. It should also be clarified that the “quality level” is not the level of risk (see the second bullet point in 3.1.7).

	Similarly, the term “provision” in A.1 in the “Guide to the selection and design of sampling plans” can be misleading as it can be confused with the term provision as applied in connection with analytical methods in the PROCEDURAL MANUAL of Codex Alimentarius. We suggest replacing this term for example by “quality requirement.”
3.1.10	The definition of lot homogeneity should be revised. In particular, neither the concept of “sublot” nor the notion of “all sublots” are clear to us. (For instance: is a “sublot” always spatially connected, or can a sublot also be a random sample from the lot?) In addition, it would be useful to explain that the question of lot homogeneity is only relevant to lot inspection when sampling from the lot is not random..
5.1.2	We disagree that measurement error and measurement uncertainty are “often used interchangeably.” The difference in meaning between these two concepts is clear in all the relevant JCGM documents and ISO standards. We also disagree that one of these two terms is “more conceptual” than the other. Moreover, we disagree with the statement that the “key difference between the two concepts lies in their treatment of systematic error that contributed to bias.” We suggest that there is no need to explain the difference between these two concepts in CXG50. In the third and fifth paragraphs, it is suggested that the term *conformity assessment* should be reserved to the case that a single item is inspected, and should not be applied in the case that a lot is inspected. We disagree with this interpretation of the meaning of the term *conformity assessment*. We suggest removing all mention of Type A and Type B uncertainty evaluations, as this distinction is not relevant to the distinction between random and systematic error.
6.2.2	The first paragraph of Section 6.2.2 states that lot size does not have an important role in determining PR or CR, from a statistical point of view. It seems to us this statement is only true if acceptance probabilities are calculated via the binomial distribution. If the hypergeometric distribution is used, then lot size does play a role. In a section whose main points concern the relationship between lot size and sample size, it is confusing that the probability of rejection values provided in

	the table (presumably for the purpose of illustration) are calculated via the binomial distribution (where lot size plays no role). We suggest having an example from ISO 2859-2 instead. If there are reasons why the probability of rejection values must come from ISO 2859-1, then we suggest that the fact that lot size play no role in these probability values should at least be mentioned – at which point it may be necessary to modify the tenor of the entire section 6.2.2. In the last paragraph of 6.2.2, it is stated that the fact that, in the ISO standards, PRQ-indexing is performed for a continuing series of lots and CRQ-indexing is performed for an isolated lot is "a consequence of employing the sample size versus lot size relationship." This is not clear and requires further explanation. In addition, it would be helpful to elucidate the relationship between the statement discussed in the previous paragraph and the fact that the binomial distribution is used for the acceptance probabilities in connection with the inspection of a continuing series of lots in ISO 2859-1, whereas the hypergeometric distribution is used for isolated lots in ISO 2859-2.
First paragraph of Introduction of "Information Document: e-book"	The sentence "Acceptance sampling depends on the results of the inspection of samples" is incorrect. (Acceptance sampling is a procedure for determining sample size and acceptance rules. It does not depend on the results of the inspection; rather, it provides rules for performing the inspection.)