

codex alimentarius commission E



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 3

ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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COMMENTS ON PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

(Argentina, Brazil, Malaysia)

ARGENTINA (versión en español)

El uso de resultados analíticos: los planes de muestreo, la relación entre los resultados analíticos, la incertidumbre de medición, el factor de recuperación y su consideración en las normas Codex (ALINORM 06/29/33, APPENDIX IV)

(Para ser incluido en el Manual de Procedimientos CODEX al final de las secciones de Métodos de Análisis y Muestreo pautas para la inclusión en Normas específicas y Textos Relacionados)

Las modificaciones de texto propuestas por Argentina se encuentran en subrayado y negrita.

RECOMENDACIONES

Se recomienda que cuando un Comité de Productos del CODEX discuta y esté de acuerdo con una especificación del producto y los métodos analíticos involucrados, declare la siguiente información en la Norma CODEX:

1. Planes de Muestreo

El plan de muestreo apropiado, como se indica en las Guías de Muestreo (CAC/GL 50-2004), Sección 2.1.2 Guías de muestreo para controlar conformidad de los productos con la especificación.

Esta debe declarar:

Si la especificación se aplica a todos los artículos en el lote, al promedio en el lote, o a la proporción de no conformes.

Al apropiado nivel de calidad aceptable a ser usado;

Las condiciones de aceptación del lote controlado, respecto a la característica cualitativa/cuantitativa a determinar en la muestra.

2. Incertidumbre de la medición

Al decidir si un resultado analítico se cae o no dentro de la especificación se hace una concesión a la incertidumbre de medición. Este requisito no se puede aplicar en las situaciones en que existe un riesgo directo para la salud, como la presencia de patógenos en alimentos. **En el caso de métodos químicos la evaluación de la incertidumbre debe realizarse en acuerdo a los criterios postulados en ILAC G8 96**

ANEXO A

3. Recuperación

Cuando sea apropiado y pertinente los resultados analíticos serán expresados en base a la corrección por recuperación.

En todos los casos tiene que ser declarado cuando el resultado se corrige por recuperación.

Si un resultado se ha corregido por recuperación, debe declararse el método por el cual se obtuvo la recuperación. Cuando sea posible debe determinarse el porcentaje de recuperación.

Cuando se establecen provisiones para las normas, será necesario declarar si el resultado obtuvo por un método de análisis usado para el análisis dentro de los controles de conformidad se expresará en una base recuperación-correcta o no.

4. Cifras significativas

Las unidades **Internacionales** y el número de cifras significativas en que se expresarán los resultados informados.

ARGENTINA (English version)

The Use of Analytical Results: Sampling Plans, Relationship Between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards

(To be included in the Codex Procedural Manual at the end of the sections on methods of analysis and sampling in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts*)

The amendments proposed by Argentina are in bold or underlined

ISSUES INVOLVED

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards. In particular, different approaches may be taken regarding sampling procedures, the use of measurement uncertainty and recovery corrections.

At present there is no official guidance on how to interpret analytical results in the framework of Codex. Significantly different decisions may be taken after analysis of the "same sample". For example some countries use an "every-item-must-comply" sampling regime, others use an "average of a lot" regime, some deduct the measurement uncertainty associated with the result, others do not, some countries correct analytical results for recovery, others do not. This interpretation may also be affected by the number of significant figures included in any commodity specification.

It is essential that analytical results be ~~are~~ interpreted in the same way if there is to be harmonization in the framework of Codex.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results and various Guides prepared dealing with Measurement Uncertainty.

RECOMMENDATIONS

It is recommended that when a Codex Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Codex Standard:

1. Sampling Plans

The appropriate sampling plan, as outlined in the Guidelines for Sampling (CAC/GL 50-2004), Section 2.1.2 Guidelines on Sampling to control conformity of products with the specification. This should state:

- whether the specification applies to every item in a lot; or to the average in a lot, or the proportion non-conforming;
- the appropriate acceptable quality level to be used;
- the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

2. Measurement Uncertainty

An allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens. **In the case of chemical methods the uncertainty should be assessed in conformity with the criteria specified in ILAC G8 96 ANEX A**

3. Recovery

Analytical results are to be expressed on a recovery corrected basis where appropriate and relevant, and when corrected it has to be so stated.

If a result has been corrected for recovery, the method by which the recovery was taken into account should be stated. The recovery rate is to be quoted wherever possible.

When laying down provisions for standards, it will be necessary to state whether the result obtained by a method used for analysis within conformity checks shall be expressed on an recovery-corrected basis or not..

4. Significant Figures

The **international** units in which the results are to be expressed and the number of significant figures to be included in the reported result.

BRAZIL

1. Draft Terms of Reference of the Committee on Food Additives and the Committee on Contaminants in Foods (para 29, Appendix II - Alinorm 06/29/33)

Terms of Reference of the Codex Committee on Contaminants in Food

Considering the decision of the 23rd Meeting of CCGP to add in point (a) of these Terms of Reference a reference to **naturally occurring toxicants** Brazil proposes to include the same reference in points (b), (c), and (e).

In point (d) Brazil proposes to use the same wording used in point (f) of the Terms of Reference of the Codex Committee on Food Additives.

The new text would read as follows:

(a) to establish or endorse permitted maximum levels or guidelines levels for contaminants and for naturally occurring toxicants in food and feed;

(b) to prepare priority lists of contaminants and **naturally occurring toxicants** for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives;

(c) to consider methods of analysis and sampling for the determination of contaminants and **naturally occurring toxicants** in food and feed;

(d) to ~~develop~~ **consider and elaborate** standards or codes of practice for related subjects; and

(e) to consider other matters assigned to it by the Commission in relation to contaminants and **naturally occurring toxicants** in food and feed.

2. Draft Revised Criteria for Prioritisation Process of Compounds for Evaluation by JMPR (para 39, Appendix III - Alinorm 06/29/33)

Brazil supports the adoption of this amendment to the Procedural Manual.

3. The Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, The Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards (para 44, Appendix IV - Alinorm 06/29/33)

Brazil supports the adoption of this amendment to the Procedural Manual.

4. Proposed Amendments to the Rules of Procedure: Duration of the Term of Office of the Members of the Executive Committee (para 96, Appendix VI - Alinorm 06/29/33)

Brazil supports the adoption of this amendment to the Procedural Manual.

5. Proposed Amendments to the Procedures for the Elaboration of Codex Standards and Related Texts and to the Guidelines on the Conduct of Meetings of Codex Committee and *Ad Hoc* Intergovernmental Task Forces (para 129, Appendix VII - Alinorm 06/29/33)

Brazil supports the adoption of this amendment to the Procedural Manual.

6. Proposed Amendments to the General Principles of the Codex Alimentarius (para 136, Appendix VIII - Alinorm 06/29/33)

Brazil supports the adoption of this amendment to the Procedural Manual.

MALAYSIA

B. PROPOSALS TO AMEND OTHER SECTIONS OF THE PROCEDURAL MANUAL

Amendments to the General Principles of the Codex Alimentarius (Appendix III)

Malaysia recalls the decision of the 28th session of the Commission to delete all sections of the Procedural Manual related to acceptance and to request the Codex Committee on General Principles to review the General Principles to consider how the principles reflected in paragraph 4 of the section on *Codex Alimentarius: Not a Substitute for or Alternative to, Referring to National Legislation of the Guidelines for the Acceptance Procedure for Codex Standards* could be integrated into the General Principles of Codex.

The 23rd session Codex Committee on General Principles agreed to insert as the new first paragraph under the section “Nature of Codex Standards”, the text to reflect the concepts in the deleted paragraph 4 from the Acceptance Procedure as follows: “Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country’s laws and administrative procedures contain provisions with which it is essential to comply.” In addition to this amendment, the Committee also considered some consequential and amendments in view of the abolition of the Acceptance Procedure and the developments of Codex work. This includes the following amendments on the General Principles of the Codex Alimentarius:

- Deletion of the sentence “The Codex Alimentarius also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures intended to assist in achieving the purposes of the Codex Alimentarius” in paragraph 1 on Purpose of the Codex Alimentarius
- Deletion of the sentence “It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures in paragraph 2 on Scope of the Codex Alimentarius

Codex codes of practice and guidelines are advisory instruments and provides guidance to governments. The status of codes of practice as advisory text is clearly demonstrated through the footnote that appears in many existing codes of practice such as Recommended International Code of Practice General Principles on Food Hygiene, Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food, General Guidelines on Claims, etc. which reads “The Code has been sent to all member Nations and Associate members of FAO and WHO as an advisory text, and it is for individual governments to decide what use that wish to make of the Guidelines.”

Malaysia strongly believes that the advisory status of codes of practice and guidelines should be maintained to provide guidance to governments in food control. **The consequence of the deletion of the texts is a major change which will have serious economic implications on the trade of the developing countries, and may be used as a technical barrier to trade.**

Malaysia is fully aware of the reply by the SPS Committee to Codex on the status of the Codex standards, guidelines and recommendations, but this is only in cases of dispute within WTO, whilst Codex is an independent organization and develops international food standards, codes of practice and guidelines to meet the needs of its Members.

Hence, Malaysia supports the adoption at Step 8 of the amendments to the General Principles of the Codex Alimentarius Commission as in Appendix III of the document ALINORM 06/29/4 with minor amendments as follows:

- i. In paragraph 1 on Purpose of the Codex Alimentarius, Malaysia proposes to retain the third sentence and to amend it to read “The **related texts are** ~~Codex Alimentarius also includes provisions of an advisory nature in the form of~~ codes of practice, guidelines and other recommended measures **which are advisory in nature and are** intended to assist in achieving the purposes of the Codex Alimentarius.”; and
- ii. In paragraph 2, on Scope of the Codex Alimentarius, Malaysia proposes to retain the last sentence and amend it to read “It also includes **related texts** ~~provisions of an advisory nature in the form of~~ codes of practice, guidelines and other recommended measures **which are advisory in nature.**”

Hence, paragraphs 1 and 2 will read as follows:

“Purpose of the Codex Alimentarius

1. The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers’ health and ensuring fair practices in the food trade. The **related texts are** ~~Codex Alimentarius also includes provisions of an advisory nature in the form of~~ codes of practice, guidelines and other recommended measures **which are advisory in nature and are** intended to assist in achieving the purposes of the Codex Alimentarius. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so facilitate international trade.”

Scope of the Codex Alimentarius.

2. The Codex Alimentarius includes standards for all principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions with respect of food hygiene, food additives, ~~pesticides~~ residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification. It also includes **related texts** ~~provisions of an advisory nature~~ in the form of codes of practice, guidelines and other recommended measures **which are advisory in nature.**”