

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6

MAS/38 CRD/9

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-eighth Session

Budapest, Hungary, 8 – 12 May 2017

REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999: PROPOSED PREAMBLE AND STRUCTURE OF CODEX STAN 234-1999 (replies to CL 2017/4-MAS)

(Comment submitted by European Union, Kenya, Peru, Mexico, Ghana, Egypt)

EUROPEAN UNION

The European Union and its Member States (EUMS) congratulate the eWG lead by Brazil and Uruguay for the excellent work done which advanced the project started in 2013 to a stage which would allow CCMAS to agree on concrete actions to review and update STAN 234-1999. Workable packages have been compiled in Appendix III for consideration by the Physical Working Group on endorsement of methods of analysis, which will have to consider drawing a road map how to dealing with considerable amount of work.

Regarding the use of the term "Codex general methods" the EUMS are of the opinion that this expression does not convey additional and useful information to the potential users of the standard as the new format of STAN 234 will anyway provide the necessary information on which commodity is included in the scope of the method. However, the requirements of the Procedural Manual, i.e. that methods of a horizontal nature with a wide applicability shall be given preference, should be considered at selection and endorsement stage.

The initiative to harmonise the description of commodities, provisions and principles of methods is certainly useful and special considerations have to be given as to how to match the provisions mentioned in Codex commodity standards with the provisions in STAN 234. Harmonising the provisions terminology in STAN 234 without making the necessary changes to the concerned commodity standards will otherwise create inconsistencies and confusion. STAN 234 will undoubtedly benefit from a harmonisation of the description of the principles of methods; therefore, the EUMS are very supportive of this particular aspect of the initiative.

The proposed layout of the revised STAN 234 would profit from taking better into account the structure already proposed by the Codex Secretariat (viz. CX/MAS 16/37/7-Add.2), e.g. by keeping an explanation of the Codex method typology.

KENYA

Kenya appreciates the work done by the EWG led by Brazil and Uruguay in preparation of the discussion paper for members to comment on. Kenya notes the recommendations by the EWG. We do support this discussion paper on the review of CODEX STAN 234-1999 and support Codex to undertake this new work and progression into the next stage. This work would enable quick access of information within the standard once presented in the format presented.

On clause 2.3 which the EWG did not agree, we propose deletion and adoption of the second definition as demonstrated below.

[2.3 Principle- Phenomenon serving as a basis of a measurement OR 2.3 Method of analysis – Principle: The scientific basis of the method of analysis, described concisely, focusing on the technique]

PERU**Observaciones generales:**

Perú en el marco del Codex Alimentarius no tiene comentarios al documento CL 2017/4-MAS.

MEXICO**Comentarios**

Sobre el PROYECTO DE NORMA GENERAL SOBRE MÉTODOS DE ANÁLISIS Y MUESTREO RECOMENDADOS (CODEX STAN 234-1999), se hacen las siguientes consideraciones:

Parte I Preambulo. :

Se debería ser más específico sobre el significado del **MÉTODOS DE ANÁLISIS RECOMENDADOS.**, debe detallarse en esta sección.

Las definiciones de cada una de las tipificaciones y el alcance de cada uno de los tipos debe ser aclarado en esta sección.

Parte II MÉTODOS DE ANÁLISIS RECOMENDADOS.

Se sugiere: This part contains 3 sections depending on how the methodologies are proposed, endorsed and approved by CAC:

Debería decir: This part contains 5 sections depending on how the methodologies are proposed, endorsed and approved by CAC:

Para ofrecer una mejor lectura del texto, México sugiere el siguiente cambio editorial.

1. Standardized methods. This section contains:

- a. The name of the **commodity**, an harmonized list of the principles is listed in annex 1.
 - b. The **provision** to which the methods apply, an harmonized list of the principles is listed in annex 2.
 - c. **Codex Standard** to which the method is directed,
 - d. Identification of the **method**
 - e. **Principle** of analysis method, an harmonized list of the principles is listed in annex 3.
 - f. **Type** of analytical method,
 - g. The **year of endorsement** by CCMAS and the
 - h. **Codex Committee** responsible for the Standard and/or provision.
- When there is no standardized method, the file identification of the method sends to section 2 (codex general methods), section 3 (Method performance criteria) or section 4 (Complete description of the method of analysis)

2. Codex General Methods: this section contains:

- a. The **provision** to which the methods apply,
- b. **Codex Standards** to which the method is directed,
- c. Identification of the **method**,
- d. **Principle** of analysis method,
- e. **Type** of analytical method,
- f. The **year of endorsement** by CCMAS,
- g. The **Codex Committee** responsible for the Standard and/or provision
- h. List of **commodities** that the method presents performance figures fitted for purpose.

3. Method performance criteria required for provision determination: this section contains

- a. The name of the **commodity**,
- b. The **provision** to which the methods apply,
- c. **Codex Standard** to which the method is directed,
- d. **Minimum applicable range**,
- e. limit of detection (**LOD**),
- f. limit of quantification (**LOQ**),

- g. **RSDR** (Relative Standard Deviation of Reproducibility),
- h. **% Recovery**,
- i. **Year of endorsement** by CCMAS and the
- j. Codex **Committee** responsible for the Standard and/or provision.

Suggested methods that meet the criteria and their principles also can be mentioned. However, any method which complies with the established performance criteria can be used.

4. Complete description of the method of analysis: this section contains

- a. the name of the **commodity**,
- b. the **provision** to which the methods apply,
- c. **Codex Standard** to which the method is directed,
- d. **year of endorsement** by CAC,
- e. The Codex **Committee** responsible for the Standard and/or provision and a description of the method.

La adición de un punto 5 que describa el listar como:

5. METHODS OF SAMPLING BY COMMODITY CATEGORIES AND NAMES

El **anexo 2**, nos parece una muy adecuada forma de armonizar las provisiones del codex, sin embargo algún texto introductorio, debería redactarse a fin de precisar la diferencia entre los nombres propuestos y los descritos en las normas de producto publicadas por los Comités.

CODEX GENERAL METHODS

En nuestro mejor entender un método general debería considerar a los métodos horizontales aplicables a diferentes matrices. sin embargo un estudio más detallado sobre la clasificación en diferentes provisiones debería ser analizado. Podría considerarse a aquellos que por ejemplo apliquen a un número determinado de provisiones. Sin embargo la definición de CODEX General Method o sus acepciones podría ser un término usado coloquialmente pero que en general se refiere a aquellos métodos citados en la sección I del la versión actualizada del CODEX STAN 234. Nosotros consideramos que los términos “para todas las matrices” o “métodos horizontales” usados en otros contextos, no es idealmente aplicable para los métodos descritos en el sistema de clasificación del CODEX. Es decir los métodos del codex son seleccionados los métodos horizontales o aplicables a diferentes matrices, y luego son clasificados o tipificados de acuerdo a los lineamientos del CODEX. Por lo que creemos que los **CODEX GENERAL METHODS son un sinónimo de Standardized methods.**

Sobre el **METHODS OF ANALYSIS WORKABLE PACKAGES**, nos parece que la agrupación es bastante manejable, sin embargo difícil de realizar ya que no todos los métodos están disponibles o a la manos de los subcomités nacionales, por lo que se hace un exhorto a las organizaciones que generan estos métodos para que en medida de su posibilidades aporten respuestas al análisis requiere.

GHANA

Ghana recommends the endorsement of the methods listed. Methods are workable and user-friendly.

EGYPT

Comment:

Egypt concludes that the importance to leave the column with name maximum level (ML) for performance of test method made (to the table mentioned in page no. 33 from the above mentioned document). As we recommend to add clarifying text for the test method adapted LOQ level for a certain analyze with maximum limit are applicable range during the start-up of developing methods, which are useful to compare between the ML and LOQ level. As mentioned in CODEX-STAN-234-1999-Recommended-Methods-of-Analysis-and-Sampling page no.43.

Example:**Criteria applicable to health-related substances in the Standard for Natural Mineral Waters**

Provision	ML (mg/L)	Min. applicable range (mg/L)	LOD (mg/L)	LOQ (mg/L)	Precision RSDR (%) No more than	Recover y (%)	Suggested methods meeting the criteria	Principle
Antimony	0.005	0.0028	0.001	0.002	44	80-110	ISO 17294-2:2003 ISO 15586:2003 EPA 200.8	ICP-MS GF-AAS ICP-MS
Arsenic	0.01	0.0056	0.002	0.004	44	90-107	ISO 17294-2:2003 ISO 15586:2003 ISO 11969:1996 EPA 200.8	ICP-MS GF-AAS AAS (Hydride) ICP-MS
Barium	0.7	0.35	0.07	0.14	34	95-105	ISO 11885:2007 ISO 17294-2:2003 EPA 200.8	ICP-OES ICP-MS ICP-MS
Borate	5	3.1	0.5	1	25	97-103	ISO 9390:1990 ISO 11885:2007	Spectrophotometry ICP-OES ²¹