

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 2

CX/MAS 04/2

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-fifth Session

Budapest, Hungary, 8 – 12 March 2004

#### MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

##### A. DECISIONS OF THE COMMISSION CONCERNING THE WORK OF THE COMMITTEE

###### Amendments to the Procedural Manual

###### Principles for the Establishment of Methods of Analysis

The Commission adopted the amendment to the *General Criteria for the Selection of Methods of Analysis using the Criteria Approach*. The Commission adopted the amendment to the *Principles for the Establishment of Methods of Analysis* with the insertion of a new section addressing *Working Instructions for the Implementation of the Criteria Approach in Codex*.

###### Harmonized IUPAC Guidelines for Single-Laboratory Validation.

The Commission endorsed the position of the Committee and agreed that the preferred approach should always be collaborative studies and only where it was not possible suggested to use single-laboratory validation. The Commission adopted the IUPAC Guidelines by reference for the purpose of Codex. The Commission noted that they became Codex Guidelines and would be included in the Codex Alimentarius as they provided guidance to governments.

###### General Methods for the Detection of Irradiated Foods

###### General Methods for Additives and Contaminants

The Commission adopted the methods as proposed by the Committee.

###### Proposed Draft General Guidelines on Sampling

###### Proposed Draft Guidelines on Measurement Uncertainty

The Commission adopted both Proposed Draft Guidelines at Step 5 as proposed. The Guidelines will be considered respectively under **Agenda Items 3 and 4**.

###### Approval of New Work

The Commission approved as new work the development of Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results and the Review of the *Analytical Terminology for Codex Use* in the Procedural Manual. They will be considered respectively under **Agenda Items 6a) and 7**.

## **B. MATTERS REFERRED BY OTHER COMMITTEES**

### **1. Committee on Fats and Oils (18th Session, 3-7 February 2003)**

#### *Use of Analytical Results*

The Committee considered the document forwarded by CCMAS on “The use of Analytical Results: Sampling, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and the Provisions in Codex standards” (CX/MAS 02/13). The Committee agreed that the concepts described in the paper should be addressed in order to ensure a uniform approach to the development and application of Codex standards. It therefore recommended that instructions with respect to analytical compliance be developed for all Commodity Committees by the Codex Alimentarius Commission or another appropriate horizontal Codex Committee (ALINORM 03/17, para. 24).

#### *Other matters*

The Committee noted the proposal of the Working Group to delete the reference to the year in ISO methods. The Delegation of the United Kingdom pointed out that in application of ISO/IEC 17025:1999, analysts were required to use the latest version of methods of analysis and drew the attention of the Committee to the problems resulting from reference to methods that were no longer available. The Observer from ISO indicated that when ISO methods were updated, the earlier version was no longer available as a publication. However, the Delegation of New Zealand, supported by other, pointed out that the year of publication was an important element in the identification of the method and that it was considered in the endorsement process.

The Committee recognised that it was not possible at this stage to amend the current reference system in the standards for fats and oils and that this issue should be addressed from a general perspective. The Committee therefore asked the Committee on Methods of Analysis and Sampling to consider the problems related to method references in order to provide advice to Codex Committees and to ensure consistency throughout Codex in the identification of methods. The Committee agreed to follow the current identification system for the methods under consideration and to re-introduce the year in the ISO methods (paras. 27-28).

### **2. Committee on Fish and Fishery Products (26<sup>th</sup> Session, 13-17 October 2003)**

#### *Use of Analytical Results*

The Committee considered the document on “The Use of the Analytical Result: Sampling, Relationship between the Analytical Result, the Measurement Uncertainty, Recovery Factors and the Provisions in Codex Standards” that highlighted the need to consider all these related factors in the development of specific provisions in Codex standards and the selection of methods of analysis.

The Delegation of the United Kingdom pointed out that uncertainty should always be considered and taken into account when establishing specific provisions in Codex standards. The Committee agreed that the concepts put forward in the document should be taken into account in future work on standards under consideration, such as bivalve molluscs that included biotoxin and microbiological limits. It also agreed that the Committee on Methods of Analysis and Sampling should continue its work to provide guidance for Commodity Committees in this area.

#### *Other matters*

The Committee noted that the Committee on Methods of Analysis and Sampling had not endorsed the methods for water activity (AOAC 978.18) and acid insoluble ash in the Standard for Dried Salted Anchovies. As no additional information was available at the present session, the Committee invited member countries to provide the clarification required for consideration by the next session of the CCMAS (March 2004) (ALINORM 04/27/18, paras. 14-16).

### **3. Committee on Food Import and Export Inspection and Certification Systems (11<sup>th</sup> and 12<sup>th</sup> Sessions)**

The 11<sup>th</sup> Session of the Committee noted the request of the 24<sup>th</sup> Session (November 2002) of the Committee on Methods of Analysis and Sampling to provide advice insofar as inspection issues were involved in the use of analytical results. The CCFICS agreed to consider this issue in detail at its next Session pending the provision of further clarification and depending on future progress within the Codex Committee on Methods of Analysis and Sampling (ALINORM 03/30A, para. 7)

The 12<sup>th</sup> Session of the Committee (December 2003) acknowledged the request of the 24<sup>th</sup> Session of the CCMAS to provide advice insofar as inspection issues were involved in the use of analytical results. The Committee noted that the paper recommended that when a Codex commodity committee agreed to a commodity specification, it should state information on sampling, measurement of uncertainty and recovery factors.

A number of delegations were of the view that these recommendations should be clearly expressed to be of use to commodity committees and should be clearly related to conformity assessment of product (e.g. sampling plans used for the determination of lot acceptance). In addition, measurement of uncertainty should be allowed in sampling under certain circumstances. Many delegations, however, questioned the practicability of developing such advice on a commodity by commodity basis and noted that it might be useful for CCMAS to provide clear guidance to Codex committees and governments in a more general way. These delegations felt that it would be useful for CCMAS to develop an overarching document to clearly explain the relationship between measurement of uncertainty and other issues that affected the use of analytical results, such as bias, in conformity assessment. Other delegations highlighted the importance of the relationship between sampling methods, analytical results, measurement of uncertainty and recovery factors in accepting/rejecting lots of foods with the subsequent problems in the food trade.

The Committee agreed on the importance of the document in the development of Codex specifications and its relationship with the sampling procedures, interpretation of analytical results, and compliance/rejection of lots of products. It encouraged the CCMAS to continue to work on this issue in a more general way with a view to advising Codex commodity committees and governments about matters related to methods of analysis and sampling and the development and enforcement of Codex commodity standards (ALINORM 04/27/30, para. 10-12).

### **4. Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices (3<sup>rd</sup> Session, 6-10 May 2003)**

#### *Sampling*

The General Guidelines on Sampling elaborated by CCMAS are applicable to fruit juices. In certain cases, for example Brix, the minimum value should be used and applied to every sample representing the lot. In other cases, an average value is used among countries. The Drafting Group agreed that they did not have the expertise required to address this issue and deferred the matter to CCMAS to advise on sampling from the general point of view, in order to ensure consistency throughout Codex.

#### *Measurement Uncertainty*

An allowance for measurement uncertainty should be made when deciding whether an analytical result fell within a specification or not.

#### *Recovery*

Analytical results for quality, composition and authenticity should not be corrected for recovery.

#### *Method Performance*

The Drafting Group agreed to support the performance based approach to Methods of Analysis and in fact used that approach to establish the list of methods for juice commodity standards (ALINORM 03/39A, para. 64-68).

## 5. Committee on Pesticide Residues (35<sup>th</sup> Session, 31 March – 5 April 2003)

The Committee recalled that the 24<sup>th</sup> Committee on Methods of Analysis and Sampling had considered the criteria for the selection of single-laboratory validated methods of analysis and had agreed to inform the CCPR of its discussions. The Committee agreed to propose to the CCMAS to consider the following criteria for inclusion in the Procedural Manual to reflect that single-laboratory validated methods could be selected under certain conditions (ALINORM 03/24A, paras. 146-148).

*General Criteria for the Selection of Single-Laboratory Validated Methods of Analysis (to be included after the General Criteria)*

Inter-laboratory validated methods are not always available or applicable, especially in the case of multi-analyte/multi substrate methods and new analytes. The criteria to be used to select a method are included in the General Criteria for the Selection of Methods of Analysis. In addition the single-laboratory validated methods must fulfill the following criteria:

- i. *the method is validated according to an internationally recognized protocol (e.g. the CCPR-Guideline on Good Laboratory Practice in Residue Analysis or the IUPAC Guideline);*
- ii. *the use of the method is embedded in a quality assurance system in compliance with the ISO 17025 Standard or the principles of Good Laboratory Practice;*

The method should be complemented with information on accuracy demonstrated for instance with:

- *regular participation in proficiency schemes, where available;*
- *calibration using certified reference materials, where applicable;*
- *recovery studies performed at the expected concentration of the analytes;*
- *verification of result with other validated method*