

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 2

CX/GP 04/20/2

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON GENERAL PRINCIPLES  
Twentieth Session  
Paris, France, 3 - 7 May 2004**

**MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX  
COMMITTEES**

Matters referred by the 26<sup>th</sup> Session of the Codex Alimentarius Commission were considered by the 19<sup>th</sup> (Extraordinary) Session of the Committee on General Principles.

**A. MATTERS ARISING FROM THE EXECUTIVE COMMITTEE <sup>1</sup>**

The 53<sup>rd</sup> Session of the Executive Committee considered the Implementation the Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards. The Committee discussed in particular the following matters of relevance to the Committee on General Principles.

**REVIEW OF THE MANDATE OF CODEX COMMITTEES AND TASK FORCES**

The Executive Committee endorsed the terms of reference for the review set out in paragraph 6(a) of the document CX/EXEC 04/53/2. The Executive Committee agreed that the recruitment of consultants be postponed until the 54<sup>th</sup> Session of the Executive Committee and the 27<sup>th</sup> Session of the Commission (June-July 2004) so that the final decision to start the review process would be taken by the Commission in the light of the budget available in the Codex Secretariat. The Executive Committee expressed its hope that by expediting the work of consultants, the final proposals coming out as the result of the review could still be presented to the Commission in 2005. It was noted that an informal meeting of Codex chairs to be organized during the next session of the Commission could provide preliminary input to the Secretariat .

**STANDARDS MANAGEMENT**

The Secretariat informed the Executive Committee that it should officially start assuming its standards management function, namely the Critical Review and monitoring of progress of standards development, after the Commission had adopted the amendments to the Rules of Procedure<sup>2</sup> and to the Procedures for the Elaboration of Codex Standards and Related Texts<sup>3</sup>.

The Member for North America stated that the process by which project documents for new work would be developed and reviewed by Codex Committees and be presented to the Executive Committee for the Critical Review needed to be streamlined under a uniform format/approach. This could require further work to be done by the Committee on General Principles, in addition to the proposed amendment to the Procedures for the Elaboration of Codex Standards and Related Texts, already submitted to the Commission.

While recognising the importance of the point raised by the Member for North America, the Executive Committee agreed that this matter could be looked at by the Committee on General Principles in future,

<sup>1</sup> 53<sup>rd</sup> Session, WHO Headquarters, Geneva, Switzerland, ALINORM 04/27/3

<sup>2</sup> ALINORM 04/27/33 Appendix II

<sup>3</sup> ALINORM 04/27/33 Appendix III

given the current heavy workload of that Committee, in light of the experience to be gained under the new procedure.

The Executive Committee recommended that all Committees proposing new work should prepare a project document following the format proposed by the Committee on General Principles (ALINORM 04/27/33, Appendix III).

#### **ACTION PLAN FOR CODEX-WIDE DEVELOPMENT AND APPLICATION OF RISK ANALYSIS PRINCIPLES AND GUIDELINES**

The Executive Committee decided to:

- request each relevant Codex Committee, when developing or completing specific guidelines on risk analysis, to review and document the mechanism it uses to identify and prioritise proposals for new work, particularly in the light of needs for and availability of scientific advice;
- request the Committee on General Principle, when examining specific guidelines submitted by other Committees, to ensure as much consistency as possible between the guideline texts;
- request the Committee on General Principles to continue the revision of the Criteria for the Establishment of Work Priorities, especially from the viewpoint of the need for clear prioritisation of requests for scientific advice; and
- monitor the progress of all the work mentioned above and take into account its outcome in the development of the next Strategic Plan.

#### **CLARIFICATION OF THE SECOND SENTENCE OF RULE IV.1 OF THE RULES OF PROCEDURE**

The second sentence of Rule IV.1 reads: “Not more than one delegate from any one country shall be a member of the Executive Committee”. The Chairperson recalled that the question of whether the Chairperson and Vice-Chairpersons of the Commission should be considered as “delegates” in the sense of this Rule had been raised in the 19<sup>th</sup> (extraordinary) session of the Committee on General Principles<sup>4</sup>, particularly in relation to the special situation of the North America region consisting of two countries only. He indicated that better understanding of the matter from a legal point of view would contribute to clarify, for instance, whether a national of the country currently serving as a Member of the Executive Committee elected on a geographic basis could stand as a candidate in the elections of the Chairperson and Vice-Chairpersons of the Commission. The proposed amendment to the Rules of Procedure implying that Coordinators would become Members of the Executive Committee should also be taken into account.

Mr Tom Topping, the Legal Counsel of WHO, informed the Committee that the view he would express should be considered as provisional, since mutual consultation between the Legal Counsels of FAO and WHO on this matter was still in progress. The Legal Counsel of WHO referred to the precedence that a Member elected on a geographic basis actually resigned following the election of one of its nationals as the Vice-Chairperson and stated that the Commission’s standing practice indicated that the term “delegate” had always been interpreted to include the Chairperson and Vice-Chairpersons of the Commission.

On the other hand, the Legal Counsel of WHO stated that when looking at the roles of the Chairperson and Vice-Chairpersons, they were supposed to represent the interest of the whole membership of the Commission rather than that of his or her country of origin and that it was also possible to differentiate between the Chairperson/Vice-Chairpersons and other Members of the Executive Committee. He was of the opinion that the degree of stringency of the language as it appeared in the Rule in question was not such that would prevent the second interpretation, according to which the Chairperson and Vice-Chairpersons were not considered as “delegates”.

The Legal Counsel of WHO stated that in the future the Commission could choose to adopt an interpretational statement to change the way the term “delegate” was understood, or even to revise the Rule and make the provision less ambiguous. He further indicated that the inclusion of Coordinators as Members of the Executive Committee consequential to the amendment of the Rules of Procedure would not directly affect the interpretation of the term “delegate”.

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<sup>4</sup> ALINORM 04/27/33 paras.15-22

The Executive Committee thanked the Legal Counsel of WHO for providing his advice and hoped to receive legal advice from FAO and WHO whenever the need arose.

## **RELATIONS BETWEEN CODEX AND THE OFFICE INTERNATIONAL DES ÉPIZOOTIES (OIE)**

The Chairperson recalled that the Director-General of OIE had informed the 26<sup>th</sup> Session of the Commission that an OIE Working Group on Animal Production Food Safety had been established in 2002, including experts from Codex, with a mandate to elaborate international standards on microbiological and chemical hazards existing in the animal production chain, to identify gaps and duplication in OIE and Codex texts and to ensure their harmonization and to strengthen the collaboration between the two organizations<sup>5</sup>. The Working Group had held two meetings and a third meeting was to take place in April 2004.

The Executive Committee noted that there were a number of areas for potential collaboration between Codex and OIE, including animal feeding, veterinary drugs, BSE and fish farming, and that there was pressing need to avoid duplication and gaps in the work undertaken by Codex and OIE.

The Executive Committee further noted that cooperation agreements existed between FAO and OIE, and between WHO and OIE, but not between Codex and OIE. It further noted that any future collaboration in which Codex might wish to engage with OIE would need to be appropriately handled by the parent organizations in accordance with the statute of the Commission and the relevant rules of the parent organizations.

The Executive Committee agreed to request FAO and WHO to initiate discussion with OIE as to how to foster and oversee the relations between Codex and OIE, and that the Executive Committee and the Commission should be consulted by the parent organizations before concrete steps be taken to develop such relations. The Committee also noted that cooperation with OIE would be considered in the framework of cooperation with international governmental organizations being developed by the Committee on General Principles.

## **B. MATTERS ARISING FROM FAO AND WHO**

### **Provision of scientific advice**

The FAO/WHO Workshop on the Provision of Scientific Advice (WHO headquarters, 27 - 29 January 2004) considered the proposals to improve the current procedures and to achieve better coordination in the provision of scientific advice. The Workshop also considered the issues related to the selection of experts and the specific problems of developing countries, and identified the gaps where further work was needed.

The recommendations of the Workshop have been circulated for comments to member countries of FAO and WHO. These comments will be collated by FAO and WHO for consideration by the expert consultation, which should be convened towards the end of 2004 to finalize the recommendations on the provisions of scientific advice, if funding is available. A progress report on the consultative process will be presented to the 27<sup>th</sup> Session of the Commission for discussion.

### **Non-human Use of Antimicrobials and Antimicrobial Resistance**

*Note: This information is provided to supplement the information on cooperation with OIE, as the issue of antimicrobial resistance is not for discussion in the Committee on General Principles*

At its 53<sup>rd</sup> session in 2001, the Codex Executive Committee requested FAO and WHO, in collaboration with OIE, to give advice to Codex on non-human antimicrobial use and antimicrobial resistance. It was suggested that issues related to antimicrobials require a more general, multidisciplinary and multi-agency response.

FAO, WHO and OIE considered 1) that the advice needed by Codex would include risk assessment issues as well as risk management implications and 2) that the outcome would have implications not only for Codex work, but also for other standard setting work in OIE, FAO and WHO. It was decided to separate the considerations in two workshops, i.e. a first workshop on scientific issues and a second workshop on management options. The first Workshop (Geneva, December 2003) conducted a preliminary scientific assessment considering all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance. The second Workshop (Oslo, March 2004) considered the broad range of possible risk management options.

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<sup>5</sup> ALINORM 03/41, para.191

The workshop process has resulted in suggestions for a recommended way forward in this area, for Codex, as well as for OIE, WHO and FAO. One of the conclusions was that a Codex/OIE Task Force should be established to develop broad risk management options for antimicrobial resistance related to non-human use of antimicrobials.

The outcome of the consultative process described will be discussed in detail at the 27<sup>th</sup> Session of the Commission, on the basis of the full publication and distribution of both reports to all Member States.

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

### **1. Committee on Methods of Analysis and Sampling<sup>6</sup>**

#### Single laboratory validated methods of analysis

The Committee on Methods of Analysis and Sampling considered criteria for the selection of single-laboratory validated methods of analysis, on the basis of a proposal from the Committee on Pesticide Residues, in order to recognize that inter-laboratory validation of methods of analysis was not always available and applicable for multi-residue analysis purposes. The Committee made some amendments in order to make the criteria generally applicable and agreed to forward the proposed *General Criteria for Selection of Single-Laboratory Validated Methods of Analysis* to the Committee on General Principles for endorsement and to the Commission for adoption. The proposed *Criteria* should be included in the Codex Procedural Manual after the section on *General Criteria* (ALINORM 04/27/23, para 18, Appendix II).

#### Analytical Terminology

The Committee agreed on some amendments to the definitions in the *Analytical Terminology for Codex Use* in the Procedural Manual in order to update and harmonise them with the terminology used by other international organizations such as ISO and IUPAC (ALINORM 04/27/23, paras. 66-72).

The texts proposed for endorsement are presented in the **Annex**.

### **2. Committee on Food Import and Export Inspection and Certification Systems<sup>7</sup>**

#### *Traceability/Product Tracing*

The Committee agreed to continue its discussion on traceability/product tracing in the context of food inspection and certification systems at its next meeting. It was agreed that the Australian Secretariat would prepare a document containing a preliminary set of “principles on traceability/product tracing”, based on the discussion that has occurred over the past two years in the Regional Coordinating Committees, and this document will be circulated for comment through a Circular Letter to all Member countries and international organizations with observer status in Codex. Furthermore, the Committee agreed that the Australian Secretariat would prepare a discussion paper, based on the above document, together with the comments received, the outputs and recommendations from seminars and workshops (as appropriate), discussions in the Codex Committee on General Principles and other relevant Codex Committees and Regional Coordinating Committees, and other relevant documents, for circulation and discussion at its next meeting (ALINORM 04/27/30, paras. 72-74).

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<sup>6</sup> 25<sup>th</sup> Session, 8-12 March 2004, ALINORM 04/27/23

<sup>7</sup> 12<sup>th</sup> Session, 1-5 December 2003, ALINORM 04/27/30

## PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

### 1. 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. those referenced in the harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis)
- ii. the use of the method is embedded in a quality system in compliance with the ISO/IEC 17025:1999 Standard or the OECD 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 where available

### 2. GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS AND RELATED TEXTS PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS

#### AMENDMENTS TO ANALYTICAL TERMINOLOGY FOR CODEX USE

*Specificity: deleted*

**Selectivity:** Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components of similar behaviour.

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence of interferences from other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.

**Accuracy (as a concept) and Accuracy (as a statistic) to be replaced with the following definition:**

**Accuracy:** The closeness of agreement between a test result and the accepted reference value.

Note:

The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

**Trueness:** The closeness of agreement between the average value obtained from a series of test results and an accepted reference value.

Notes:

- 1 The measure of trueness is usually expressed in terms of bias.
- 2 Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.

#### TERMS TO BE USED IN THE CRITERIA APPROACH

**Selectivity:** Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components of similar behaviour.

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence of interferences from other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.