

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4a)

CX/MAS 01/4-Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-Third Session

Budapest, Hungary, 26 February – 2 March 2001

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES

PROPOSED DRAFT GUIDELINES FOR THE APPLICATION OF THE CRITERIA APPROACH BY THE COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING GOVERNMENT COMMENTS AT STEP 3

IRELAND

Ireland concurs with the general thrust of the document and the objective that it aims to achieve.

However considering that this document is intended for global application.

Considering the role of Codex in world trade and considering the universal application of ISO/IEC 17025 as the basis for the assessment of the quality of analytical data.

It is essential that the document adheres to international terms and definitions where it is possible, particularly these enumerated by ISO.

Specific comments

Page 3, Appendix I

Present System

Add an additional bullet point "limit of quantitation or quantification" after the bullet point "*limit of detection*"

Top of page 4.

Bullet 11 "*all proposed methods of analysis...directed*" add to the end of this bullet "and be fit for the purpose of that standard".

Page 4, **Type II and Type III reference methods**

Type II: reference methods

On line 3 insert the word "method" between for and calibration.

Reason, the international definition of calibration (International Vocabulary of Basic and General Terms in Metrology, ISO, Geneva) covers many possibilities and the paper should leave no ambiguity.

Page 5

5th paragraph commencing "*The minimum approved...*" 1st indent "*precision*". The statement in parenthesis is incorrect. As will be seen from paper CX/MAS 01/8, page 4, it is possible to conduct a collaborative trial and to obtain a full uncertainty budget. In addition this indent is not equivalent with what is stated in the 5th bullet point, page 3, heading "PRESENT SYSTEM".

It should either be replaced by the definition on page 3 or amended to read (within and between laboratories, generated from collaborative trial data, in accordance with ISO 5725)

Same comment applies to 5th bullet on page 6.

5th indent on page 5,

Replace “*determination*” by “quantitation or quantification”, as it has greater international usage. Same comment applies throughout the document, eg 4th bullet page 6 again on page 7.

UNITED STATES

GENERAL COMMENTS

Appendix I of document CX/MAS 01/4 has been prepared from the point of view that “after the generation of the criteria it will not be necessary to distinguish between Type II and Type III methods“ since “all procedures conforming to the criteria will be equally valid.” Despite the disclaimer, we maintain that either CCMAS must choose the single method (Type II) that must be used in cases of a dispute based upon compliance with a specification or the judicial system will choose it. In legal proceedings, unless the method of analysis is specified, different results by different methods, particularly if the result is a difference in acceptability, are interpreted by the legal profession as real disagreements, even in cases that lack statistical significance. These differences result in focusing on which method of analysis is more correct rather than on the real problem of product acceptability.

We support the criteria approach described in this document for Type III methods, but suggest that a method choice for dispute situations (Type II) should be made by the technical experts of the Commodity Committee and CCMAS, not by the legal or administrative experts. It is our position that either a Type II method must be endorsed by CCMAS for dispute situations or that an alternative dispute resolution procedure must be adopted that will ensure the use of a single method meeting Codex criteria. An acceptable alternative dispute resolution procedure would probably contain a provision that would require the disputing parties to use the CCMAS endorsed Type II method if they could not come to agreement on the use of a Type III method meeting Codex criteria. By continuing to endorse Type II methods, CCMAS will be providing expert method guidance for those laboratories seeking direction on specific suitable methods or methodology for calibrating purposes while also eliminating method selection bias in dispute situations, when needed.

SPECIFIC COMMENTS ON APPENDIX I: PROPOSED DRAFT GUIDELINES AND WORKING INSTRUCTIONS TO AID IN THE IMPLIMENTATION OF THE CRITERIA APPROACH TO THE SELECION OF METHODS OF ANALYSIS FOR CODEX PURPOSES

Type II and III Methods

Paragraph 3, sentence 2: Commodity Committees often have neglected to furnish methods for compliance with the specifications in the standard. Implying that CCMAS will assume the responsibility for conversion of methods to criteria will undoubtedly encourage further avoidance of responsibility. CCMAS or its *ad hoc* endorsement Working Group may not have the expertise or timely access to literature to suggest methods of analysis or criteria utilized by commodity or discipline specialists. The wording and Secretariats to the Commodity Committees should make clear that the primary responsibility for supplying methods of analysis and criteria resides with the Commodity Committees.

Paragraph 3, sentence 3: We hope that criteria will not replace at least references to recommended methods of analysis. Otherwise the expertise that CCMAS provides in reviewing methods for compliance with criteria will be lost. If individual suppliers of methods are permitted to conclude that their methods comply with the Codex criteria, we will revert to a situation that existed prior to the imposition of the Codex classification scheme. The continued endorsement of compliance with criteria by CCMAS is critical to the success of the criteria approach.

Paragraph 8, sentence 4: We disagree with the statement that “After generation of the criteria it will not be necessary to distinguish between Type II and III methods. . .” Despite the disclaimer, we maintain that either CCMAS must choose the single method that must be used in cases of a dispute or the judicial system will choose it. Unless the dispute resolution situation is acceptably resolved without the need for a Type II method, we suggest replacing the above sentence with the following:

“CCMAS will also select from the Type III methods, a method designated as Type II that must be used by all parties in case of dispute involving compliance with the corresponding Codex specification unless the disputing parties agree on a Type III method meeting the method criteria in the standard.”

ANNEX I: ANALYTICAL TERMINOLOGY FOR CODEX USE AND INFORMATION OF ACCEPTABLE NUMERIC VALUES

Assessment of the Acceptability of the Precision Characteristics of a Method of Analysis

Paragraph 2, we suggest using the simpler version of the equation as formulated by Thompson:

$$RSD_R = 2C^{(-0.1505)}.$$

The number in the parentheses below the Table is now “(~10 000).”

ANNEX II: EXAMPLES

Our understanding of the criteria approach was that the criteria were to be derived from method performance studies of the capabilities of the method, not from external considerations. Pesticide residue methods, for example, cannot meet the recovery value stated for Trace Elements, although they are in the same concentration range. It is not clear why the precision requirements for lead, cadmium, and arsenic are different from the generalized criteria for trace elements.

We suggest substitution of the simpler version of the Horwitz equation given above for that used in the text.