CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 4 **CX/MAS 19/40/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

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GUIDANCE ON ENDORSEMENT

(Prepared by the EWG led by the United States of America)

Introduction

At its 38th session, CCMAS (CCMAS38) agreed to continue efforts on the workable packages for the review and update of CODEX STAN 234-1999 (CXS 234-1999) as described in CX/MAS 17/38/6. The Committee also agreed to pilot this effort through an update of all methods related to milk and milk products with the assistance of IDF, ISO and AOAC (REP 17/MAS, paras 58-59).

At CCMAS39, IDF presented to the Physical Working Group (PWG) on Endorsement and to the Committee the outcome of the AOAC, IDF, ISO review. The review identified several potential issues with CXS 234, such as, methods listed even when no provision existed in the commodity standard, methods which had not been validated on the matrix listed, and numerous formatting (editorial) inconsistencies and errors. Additionally, AOAC, IDF and ISO identified a number of items that required clarification to expedite future reviews and allow for a consistent approach in the update of CXS 234 (CX/MAS 18/39/4 Add.1).

Many of the items were discussed during the PWG and CCMAS39 (REP18 MAS, paras 24 – 33), and this discussion along with the on-going review and update of CXS 234 raised additional points needing clarification.

Based on those discussions the Committee agreed to establish an electronic working group (EWG) chaired by USA, working in English, to develop a discussion paper for CCMAS40 which would address and recommend guidance for:

- the endorsement and designation of empirical methods as Type I and/or Type IV
- issues around two Type II methods for the same provision and commodity.

It was agreed that the discussion paper will address among others the following questions:

- When there are two empirical (i.e. defining) methods (from different organizations) and the degree of validation differs (i.e. one method has been subjected to an international collaborative study, whereas the other method has not), should one method be Type I and the other method Type IV, or should only one (the best validated) method be endorsed and be listed as Type I?
- Can 2 different empirical methods be endorsed as Type IV for the same commodity and provision?
- Clarify when two different reference methods endorsed as Type II for the same commodity and provision are identical.

EWG and Guidance Document

The electronic working group was initiated and operated through the on-line Codex forum.

The Procedural Manual describes the Terms of Reference and general responsibilities for Codex Committees, including CCMAS, and the broad description of method characteristics. However, deciding the specific details on method review and endorsement have been largely left to the Committee and the Chairs/Participants of the Physical Working Group on Endorsement. This Guidance Document aims to clarify the method review and endorsement process, limit *ad hoc* decisions with the goal of improving

understanding, consistency and transparency. The Guidance Document used the questions raised by AOAC, IDF, ISO and the discussions surrounding updating CXS 234, as a starting point. Using the Procedural Manual as a framework, the guidance document intends to capture and clarify the current CCMAS overall process and provide guidance on the outcome of definitions/decisions based on past CCMAS practices. For example, in addition to stating the definition for a Type I method, it clarifies that only 1 Type I, can be listed in CXS 234, unless Identical methods exist. As stated in the Introduction of the Guidance Document, it is intended to be used in combination with the Procedural Manual and does not supersede any requirements responsibilities stated therein.

The initial drafts of the guidance document as well as all the comments received are accessible on the Codex Forum. **Appendix III** contains the list of participants who registered for the EWG via the Codex Forum. **Appendix I** is the proposed Guidance Document. Where there is still a lack of consensus, the type has been placed between square brackets []. **Appendix II** captures the comments on the second draft circulated in the EWG, that require additional focused discussion before consensus can be reached. Each comment is followed by what action was taken and often by additional "discussion" text, which was added by the EWG chair in an attempt to provide additional information that seems relevant to the comment and future discussions. A number of the more critical comments that are captured in Appendix II are also captured in **Outstanding Questions Section** (below). In both Appendix I and II, any text taken directly from the Procedural Manual is surrounded by a double lined-border.

Outstanding Questions

1. The Definition of Identical

In general, the expanded definition of Identical was accepted by the reviewers, however complete consensus was not reached and further discussion and implications on formatting of CXS 234 are required.

There is still some confusion on how the available validation data influences whether two methods can be defined as identical. Clarity around the use of validation data is necessary, when it exists. For example, if 2 methods from different SDOs have the same steps but have been validated on different matrices, can they be considered identical?

2. Type III Method when no Type II exists (Table 2.2):

Regarding the statement in Table 2.2 for Type III, which states "*Cannot exist without a Type II*" there was a mixed support for the two options listed below.

During the first draft of the Guidance Document, the Australian Delegations, raised the point that in the past, the Committee has endorsed a method as Type III, where no Type II existed. In that situation, the Committee could not reach consensus on listing as a Type II. Therefore, in a situation where there is no Type II method and the Committee would endorse a method as a Type III, but have reservations about Type II, what should be the procedure? Should the Committee

- Endorse as a Type III, but only for a limited amount of time (1-2 years) while additional data can be collected about the Type III method, or
- Endorse as Type IV, which would be changed to the Type II, when additional data is presented.

3. Section 3.2i: Methods without Specification in a Codex Standard

A reviewer proposed that the Committee discuss if it is necessary to endorse / maintain methods with no related specification or Codex standard (as we identify in eWG for milk products standards). Based on that discussion some clarification or further description may be necessary in this document.

This comment is also brought up in the review of Dairy Methods for the update of CXS 234. For consideration: Generally, past discussions at CCMAS have focused on the idea that there must be a "provision" in the standard or related standard (General Food Contaminants) in order to have a method listed in CXS 234. In review of the Procedural Manual the wording in the "General Criteria for the Selection of Methods of Analysis", is not specific to "provision" but is more wide-ranging, stating

All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.

4. Section 3.2 iiia

The statement in the Guidance Document; "*It is not the role of CCMAS delegates to research the methods and determine if the method is fit for purpose, since this is the role of the SDOs.*" generated numerous comments and clearly identified different perspectives on the roles of the Committee and the SDOs. Further discussion and clarity is needed.

5. Section 3.2 Designation of Multiple Type III methods

There was a question if the Committee should provide some guidance on determining/listing multiple Type III methods and if some form of equivalency data, Proficiency Testing data, etc. would be required. Currently there is no requirement, so it was not captured in the Guidance Document. The Committee could consider such data necessary, but this would be a change/addition to the Procedural Manual and need to be reflected in the Manual prior to being added to the Guidance Document.

6. Section 3.8 Changing Type I methods to Type IV

A reviewer suggested that Type I methods without validation data could be changed to Type IV. While this is within the purview of the Committee, it would be a dramatic change from current practices and have wide reaching impact across Codex Committees and international trade. Based on the large impact of such a decision, further discussion and clear consensus by the Committee is required.

7. Not addressed in Guidance Document

When there is an active Codex Committee, can a method (any Type) be submitted for review and endorsement at CCMAS or must it come as a Matters Referred from the active committee? If it can be submitted at CCMAS and endorsed, must the endorsement decision of CCMAS be returned to the active committee prior to adoption by the CAC?

Recommendations

The Committee is invited to:

- Consider the proposed Guidance Document (Appendix I);
- consider the above questions and incorporate changes into the Guidance Document where necessary.
- determine the most useful and appropriate location for the Guidance Document, either by capturing the information in the Procedural Manual or keeping the document as a CCMAS internal Guidance Document.

Appendix I

Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS234

1. Preamble/Intro

This document provides integrated guidance on submission to and review of methods of analysis by CCMAS prior to inclusion in CXS234. These guidelines are intended to assist countries and SDOs in the submission and review of methods of analysis for inclusion in CXS234. The methods are primarily intended as international methods for the verification of provisions in Codex standards[1]. This guidance is intended to supplement, and does not replace or supersede, the information found in the *Codex Alimentarius Commission Procedure Manual*[2]. The *Codex Alimentarius Commission Procedure Manual* should be utilized to capture all of the requirements associated with the submission and review of methods.

2. Definitions

Definitions used in the description of methods and their performance characteristics should conform to The *Guidelines on Analytical Terminology* (CXG 72-2009) and the relevant source (e.g. ISO, VIM, Eurachem, etc.) Other descriptors have been used in Codex discussions such as Identical, Complementary, and Mutually Exclusive are defined below:

- Identical (Applies to all types of Codex methods[3])
  - A single method published jointly by two or more SDOs as a single document, or;
  - separate documents containing identical text, or;
  - two or more methods which have the same principle, the same chemicals in the same concentrations, in the same procedure/sequence and the same measuring equipment but are published by different SDOs and written in differing styles.
- Complementary
  - Two or more methods which are all required to determine the desired result.
- Mutually Exclusive
  - Two or more methods required to cover the full range of values

[1] Codex Alimentarius Commission Procedure Manual: *Principles for the establishment of Codex methods of analysis: Purpose of Codex Methods of Analysis*

[2] Where appropriate and important for context excerpts from the *Codex Alimentarius Commission Procedure Manual* are included within this Guidance.

[3] See footnote 1 and Description of Method Typing (below).

Table 2.1: Clarification and Examples on Method Definitions

Name	Meaning	Example	Relevant Type	Separator in CXS 234
Identical	1. A single method published jointly by two or more SDOs as a single document, **or** 2. separate documents containing identical text **or** 3. two or more methods which have the same principle, the same chemicals in the same concentrations, in the same procedure/sequence and the same measuring equipment but are published by different SDOs and written in differing styles.	ISO 5534 | IDF 4	All Types	**|** ***/*** ***/***
Complementary	Two or more methods required to determine/calculate the required answer	ISO 5534 | IDF 4 and ISO 1735 | IDF 5	All Types	and
[Mutually exclusive*]	Two or more methods required to cover the full range of values	See below	All Types	Separate lines, scope specified under commodity column
	Cottage cheese (for samples containing lactose up to 5%) Milkfat ISO 1735|IDF 5 Gravimetry (Schmid-Bondzynski-Ratzlaff) I Cottage cheese (for samples containing lactose over 5%) Milkfat ISO 8262-3|IDF 124-3 Gravimetry (Weibull-Berntrop) I			

*This will be a proposal to the dairy eWG, in order to harmonize how this case is presented in CXS 234 (currently the difference of scope is written in the principle for this case)

Description of Method Typing from Procedural Manual

Methods of Analysis

Definition of types of methods of analysis

(a) Defining Methods (Type I)

Definition: A method which determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.

Examples: Howard Mould Count, Reichert-Meissl value, loss on drying, salt in brine by density.

b) Reference Methods (Type II)

Definition: A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes.

Example: Potentiometric method for halides.

(c) Alternative Approved Methods (Type III)

Definition: A Type III Method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

Example: Volhard Method or Mohr Method for chlorides

(d) Tentative Method (Type IV)

Definition: A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Committee on Methods of Analysis and Sampling have not yet been determined.

Examples: chlorine by X-ray fluorescence, estimation of synthetic colours in foods.

Table 2.2: Guidance on Method Listing in CXS234

Types	Further explanation	Coexistence with other types	Examples
I	Need validation data.[4]	There can be only one Type I method listed for each commodity and provision (unless complementary or identical). No other Type II or Type III methods can be listed for same commodity and provision.	Determination of nitrogen content by Kjeldahl, determination of fat by Weibull-Berntrop,
II	Need validation data.[4]	There can be only one Type II method listed for each commodity and provision (unless identical or complementary).	Chromatography, spectrophotometry
III	Need validation data.[4]	Multiple Type III methods can be listed for a commodity and provision. [Cannot exist without a Type II.]	Chromatography, spectrophotometry
IV	No or insufficient validation data.	Can be listed as alternative to Type I/II/III if deemed useful by CCMAS. More than 1 Type IV method may be listed for each commodity and provision. May be only method type listed when there are no other methods that meet the general criteria for selection of methods.	

[4] Previously endorsed methods without validation data can remain.

3. Process for the submission of methods of analysis for provisions in Codex Documents

3.1 Steps in the process

i. Signaling and capturing the need for a method when a new or amended provision or reference to the provision is incorporated in a Codex document.

ii. Initiative of one or more SDOs, Codex Members, or other Codex related entities (e.g. Bureau International des Poids et Mesures, International Oil Council, inter-governmental) to identify an existing candidate method or to develop and validate the candidate method.

iii. Submission of the candidate method to the concerned Codex Commodity Committee, Codex General Subject Committee, or directly to CCMAS when the concerned committee has been adjourned. (See Section 3.2 ii)

iv. Review of the method suitability (fitness for purpose) by the concerned Codex Commodity Committee or a Codex General Subject Committee and submission to CCMAS for review.

v. Review, assign typing, endorsement of the method by CCMAS including decision on submission of a proposal to CAC for adoption of the method and inclusion in CXS234, optionally indicating replacement or retyping of already listed method(s) in CXS234. (See Section 3.4)

vi. Decision on adoption by CAC and inclusion in CXS234, optionally replacing or editing already listed method(s) in CXS234.

3.2 Acceptance of methods of analysis

In line with the Procedural Manual, methods submitted for endorsement by the CCMAS for adoption by Codex Alimentarius should be proposed by the relevant commodity or other sponsoring committee. Codex specifications for products in commercial trade between countries need to be defined by each committee.

i. Each provision in a specification needs to have a value (limit value, maximum or minimum level) and a suitable method of analysis for use should a dispute arise. Other methods used for purposes of product authenticity may also be referenced.

ii. When a committee works on a specification during the development process and before submission to CCMAS, the commodity experts should:

   a. Consider the criteria approach in place of recommending specific methods;

   b. Determine if a suggested method of analysis is fit for purpose in consultation with relevant trade organizations, referee laboratories, competent authorities and standards development organizations.

   c. Determine if there are validation data available for the method and analyte in the commodity or food.

   d. Determine if the suggested method of analysis has been studied by one or more SDOs.

   e. Consult the appropriate SDOs on the validation and publication status and applicability of the methods.

   f. whenever possible, provide information to the Committee on Methods of Analysis and Sampling for each individual analytical method proposed, relating to specificity, accuracy, precision (repeatability, reproducibility) limit of detection, sensitivity, applicability and practicability, as appropriate[5]

iii. Proposal of methods of analysis to CCMAS for endorsement should be carried out with the knowledge that the methods of analysis meet the above criteria (ii. a-f).

[5] Procedural Manual of the Codex Alimentarius Commission: Relations between Commodity Committee and General Subject committee: Method of Analysis and Sampling, Normal Practice

a. [It is not the role of CCMAS delegates to research the methods and determine if the method is fit for purpose, since this is the role of the SDOs.]

b. [Methods of analysis elaborated by international organizations occupying themselves with a food or group of foods are preferred.]

c. [Methods which have been validated in interlaboratory trials are preferred.]

iv. Committees are encouraged to offer proposals for the Typing of a method and the Principle (definition of the technique) according to the requirements of CXS234. CCMAS will confirm these proposals and also consider the advice of relevant SDOs.

v. Method proposals should be supplied to CCMAS well in advance [(60 days)] of a physical meeting to enable receipt of comments from interested parties.

a. Delegates, SDOs and observers are strongly encouraged to provide written comments in a timely fashion to enable translation.

3.3 Endorsement by CCMAS of a proposed method of analysis is a multi-stage process:

i. Proposed methods are reported to the committee under Agenda Item 2 and Agenda Item 3 of the CCMAS Provisional Agenda.

ii. Methods together with their Typing and Principle are discussed by the Physical Working Group (PWG) on Methods Endorsement, generally held immediately prior to CCMAS.

1. Delegates and observers are encouraged to review the methods and make any recommendations on possible alternative methods or identical methods in writing prior to the PWG and according to CCMAS timelines.

2. If recommendations of alternative methods or identical methods are made during the PWG and not prior to the PWG, discussion and endorsement of these methods may be withheld until the next meeting of the committee to allow for adequate review of the recommendations.

iii. The PWG report recommends endorsement or denial of methods to the committee.

iv. CCMAS discusses the report of the Physical Working on Methods Endorsement in plenary.

v. Methods endorsed by CCMAS are forwarded to CAC for adoption.

3.4 Revocation/removal by CCMAS of a method of analysis listed in CXS234:

CCMAS has agreed (REP16 MAS, Appendix IV) to an on-going periodic (10 years) review of methods. This periodic review is partly intended to capture methods that need to be revoked/removed. Additionally, the following steps are applicable to initiate the revocation/removal of a method outside of the periodic review process:

i. The recognition that a method is obsolete, inappropriate (no longer fit for purpose) or has been withdrawn by the relevant SDO should be brought to the attention of CCMAS by commodity and horizontal committee members, member countries, observers and SDOs.

ii. When a method becomes obsolete the committee originally proposing the method of analysis should be informed and should find a replacement and bring it to the attention of CCMAS

iii. The SDO should bring the information directly to CCMAS if the committee is adjourned or otherwise inactive/unresponsive

iv. Proposals for a replacement are encouraged and will be deliberated by CCMAS.

v. If CCMAS identifies an obsolete or inappropriate method it should alert the committee (if active) of proposed removal from CXS 234, to allow the committee to respond to the revocation.

3.5 The role of SDOs in Commodity/Horizontal/Regional Committees

To play a positive role in the maintenance of methods of analysis for use in the Codex system, SDOs wishing to maintain ownership and exercise their rights as methods providers (intellectual property and copyright issues) should undertake the following oversight activities:

i. Have Codex Alimentarius observer status

ii. Follow the activities of relevant Codex committees

iii. Contribute timely written comments on relevant issues
iv. Provide relevant information to the CCMAS during method review
v. Contribute oral comments during plenary proceedings
vi. Inform Codex of changes in SDO activities (for instance in a report/brief news item
vii. Bring to the attention of CCMAS actions at a commodity or other committee which may lead to a change in requirements for a method of analysis

viii. Bring to the attention of a commodity or other committee actions by CCMAS which may lead to a change in requirements for a method of analysis

ix. Provide Codex Alimentarius with assistance when deliberations involve technical details or a deeper understanding of analytical issues

x. Encourage horizontal and regional committees to seek the advice of relevant SDOs on analytical issues at all stages of standard development, including contacting those organizations not participating during a discussion.

xi. Ascertain that references in CXS234 to their standards are correct and kept up to date.

3.6 The role of SDOs at CCMAS in the methods endorsement process

SDOs should be:

i. The provider of accurate information regarding the status of an analytical method and its stage within the organization's method evaluation process (e.g. publication status, SLV, full collaborative study or anecdotal or PT data collection) and its fitness for purpose.

ii. In agreement when methods are "Identical" or have sufficient differences to affect the analytical outcome. SDOs are to provide this assurance to CCMAS.

iii. Able to consider scope and scope extension vs "Codex general methods".

iv. Able to provide advice on method typing as these criteria are specific to Codex, and not generally used by SDOs outside of CCMAS.

3.7 Replacement of Type I methods

This sub-section is applicable to the replacement of a Type I method with a new Type I or with Type II/III method(s).

i. Commodity committee, either through members or consultation with SDO, proposes to replace an existing Type I method

ii. The new method may be an empirical or rational method

iii. The new method is referred, reviewed and endorsed as outlined in sub-section 3.1

iv. As part of the endorsement a time frame to complete the change is established

v. If adopted by the Commission, the new method would replace the older method in CXS 234 at designated date.

3.8 Type IV methods and their transitioning to other method types

i. New candidate methods may only be typed as Type I, II or III when submitted with a full set of validation data, e.g. precision data obtained in conformity with internationally accepted standards. With the submission of other lesser validation data these methods will be listed as Type IV.

ii. Existing Type I methods without a full set of validation data are to be considered on a case-by-case basis by the relevant SDO(s) on:

a. the feasibility of collecting and submitting the missing validation data to Codex

b. the availability of an alternative candidate-method to become the Type I method

c. the rationale for keeping the existing Type I method in place as is

d. the rationale for retyping the method or revocation of the method.

iv. A method typed as Type IV may transition to another type after the submission of acceptable validation data to the SDO and its adoption. Submission to and endorsement by CCMAS is required. A method should not remain as Type IV indefinitely.

v. Where two methods are proposed as Type I for a particular provision, the relevant SDOs shall determine if the methods are Identical (in which case they can both be listed) or if, based on the performance data or other information, one better meets the required criterion than another. In cases where there is a regional preference for one method over another, the relevant commodity committees and/or regional committees should decide which method to put forward to CCMAS.

3.9. Presentation of methods for incorporation into CXS234

CXS234 is a summary document that contains all the methods of analysis that cover provisions contained in Codex Commodity standards but excludes methods for

pesticides and veterinary drugs in food, the assessment of micro biological quality and safety in food, and the assessment of specifications for food additives

In time this will be the sole reference for these methods. [Insert reference to eWG on CXS234 for introduction]

i. Information required:

a. A provision in a Codex standard with a limit/range of values

b. A suitable method for the analysis, preferably from an accepted SDO

c. Principle

d. Codex Typing

e. Assurance that sufficient testing has been carried out to generate precision data

f. [Validation data that prove] Fitness for purpose[6]

ii. Correct use of separators between methods presented in CXS 234 (as per Table 2.1).

iii. [If separator is not applicable (e.g. not Identical), methods should be listed in separate rows]

[6] Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose. *Guidelines on Analytical Terminology (CXG 72-2009)*

Apppendix II

SUMMARY OF COMMENTS AND ACTIONS TAKEN TO PRODUCE THE GUIDANCE DOCUMENT IN APPENDIX I (FOR INFORMATION)

Definitions and Table 2.1

Comment: A number of comments related to the definitions and to Table 2.1, regarding when 2 methods could be considered "Identical" were received, these included:

- Requested text added to Identical "Or 2 methods with identical method performance criteria for the same analyte".
- When methods are identical that they also have the same validation data
- Another reviewer stated that methods are sharing (partly) the same validation data.
- Another reviewer suggested the text "and validation data which meet the same criteria for accepting." Be added to the end of definition for identical.

Response: No change was made to the table.

The Table reflects past inclusion of methods in the same line and more importantly on recent discussion at CCMAS regarding Identical Methods and comparing method performance. For Type I methods the Committee has consistently agreed to not address method performance comparison (i.e. equivalency). For Type II methods the Procedural Manual states that a Type II will be chosen from the Type III methods. When performance is used with Type II methods, numeric criteria are established and the formatting of how methods are listed is not appropriate.

Comment: Reviewer would prefer to keep the "Technically Identical" classification because Identical means two SDO's jointly publishing the exact same text, to be indicated with a | (example: IDF and ISO).

Technically identical means the same method, same principle, same chemicals, same concentrations, same performance etc., but separately published. Technically identical does not rule out that one method has a wider scope than the other. Technically identical methods may be published by different SDOs (example: ISO|IDF and AOAC). Keeping both terms would allow the ability to effectively distinguish between the possible situations (updates, withdrawal, revisions, etc).

Response: No change was made to the table.

During comments on DRAFT 1 it was clear that the term Technically Identical was causing significant confusion. The DRAFT 2 approach, to expand the definition of identical, addresses the method procedure aspect, but also allows for punctuation differences (| and /) which had been agreed in the revision of CXS 234 to be assigned during endorsement. There are still outstanding questions regarding if two identical methods (same exact steps but published by different SDO) have been validated on different matrices, how are they listed. That determination is independent of the punctuation used to list them.

Table 2.2

Comment: With respect to the "need validation data" listed for Type I and the accompanying footnote which reads "Previously endorsed methods without validation data can remain".

One reviewer observed: Many Type I methods are not fully validated and will not become fully validated because of the length of time that they have been in use and their general acceptance by trade organizations and SDOs. This issue is identified in Section 3.8 bullet ii.

Another reviewer pointed out that older Type I methods are not likely to be validated because of the years they have been used and general acceptance.

Another reviewer noted that the CCMAS already decided to revise the endorsement every 10 years. The Process to Update Methods of Analysis in CXS 234-1999 (for internal use by CCMAS) was agreed in 2016 (APPENDIX IV of the REP16/MAS).

Response: No change was made to the table.

The table indicates what is preferred moving forward when Type I methods referred for endorsement, while the footnote captures the current situation with some Type I methods currently listed in CXS 234. The reviewer comment about review of methods is accurate and can be captured in another portion of the document. It is outside the scope of this particular section.

Comment: Reviewer noted that for coexistence of methods, for Type I: The committee should consider if there are defining methods that can be equivalent to more modern ones and are largely used currently, such as: Kjeldahl and Dumas; Pycnometry and Densitometry.

Response: No change was made to the Table.

There seems to be general agreement that replacement of empirical methods with rational methods would be beneficial. No change was made because there is nothing in the Procedural Manual or captured in this Guidance which prevents the Committee from replacing a Type I method with a different method (Type I, II/IIII). Additionally, Section 3.7 of this Guidance Document does address replacement of Type I methods. What is not currently allowed is the listing of multiple different methods for the same commodity and provision if a Type I methods is listed.

Comment: Regarding the statement for Type III, which states "Cannot exist without a Type II" there was a mixed response, with some reviewers preferring a Type IV status and other open to the concept of a Type III for a limited amount of time 1-2 years while additional data can be collected.

Response: No change made to the Table. Further discussion and consensus by the Committee is necessary.

Section 3.1 iv

Comment: Reviewers asked for method characteristics which should be reviewed (specify commodity, provision, method and principle together with the proposed typing).

Response: No change made here.

This section is a list of the general steps, greater detail about the method review and endorsement is provided in a later section and reference to this information is captured there.

Section 3.2 i

Comment: Proposed that the committee discuss if it is necessary to endorse / maintain methods with no related specification or Codex standard (as we identify in eWG for milk products standards). Based on that discussion some clarification or further description may be necessary in this document.

Response: No change made to the document. Further discussion is needed to reach a consensus.

This comment is also brought up in the review of Dairy Methods for the update of CXS 234. For consideration: Generally, the discussion at CCMAS has focused on the idea that there must be a "provision" in the standard or related standard (General Food Contaminants) in order to have a method listed in CXS 234. In review of the Procedural Manual the wording in the "General Criteria for the Selection of Methods of Analysis", is not specific to "provision" but is more wide-ranging, stating

> All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.

Section 3.2 ii b

Comment: The method should at least be compatible with the criteria approach.

Response: No change was made.

It was unclear what change would be needed and exactly to what situation this comment was directed.

Section 3.2 11 c

Comment: Preference should be given to data from interlaboratory trials if available.

Response: Bullets added to address this comment. While this is implied in the Procedural Manual it is worthwhile to also capture in the Guidance Document.

Section 3.2 iii a

Comment: Reviewer disagreed with the statement

"It is not the role of CCMAS delegates to research the methods and determine if the method is fit for purpose, since this is the role of the SDOs."

Response: Text has been placed in square brackets.

In reading this comment and some responses it is possible that there is a difference in how this text is being interpreted. For background discussion:

Definition of Fit for Purpose

Fitness for purpose**:** Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.

From the Procedural Manual 26th Ed. (English) pg 54

> The Committee on Methods of Analysis and Sampling will assess the actual analytical performance of the method which has been determined in its validation.

Based on the Procedural Manual, CCMAS reliance on the resources and expertise of the SDOs, there has to be a clear differentiation between evaluation of validation status and applicability to Codex standard. For example, a method can be fully and successfully validated and still not be appropriate for determining a limit set in a Codex Standard (i.e. Fit for Purpose). We have encountered this very recently with the determination of elements in infant formula. Therefore, while the SDOs cannot be expected to supply the method details for every method reviewed, some performance characteristics should be provided to the Committee in order for the Committee to determine if a method is fit for purpose. Subsequently, the Committee should not be requiring a full validation data report but understand that the SDOs have long standing review and evaluation procedures for determining if a method has been successfully validated.

Further discussion around this point and clarification on guidance will be necessary to reach consensus.

Section 3.2

Comment: Is it worth adding text to provide guidance for the committee on how to designate multiple Type III methods: "Should in the future information be collected on 'equivalency' of methods (related to Type III) either by comparison of methods on the same samples, or proficiency tests?

Response: No change made because further discussion and consensus on this approach should be reached before inclusion.

Any requirement for equivalency data, PT data, could potentially change the definition for Type III methods and may require changes to the Procedural Manual.

Section 3.8 ii

Comment: Reviewer in favour of changing Type I methods without validation data to Type IV.

Response: No change made to text. This is a large overarching change and not one that has been in place. This document is intended to capture and clarify the current CCMAS practices. The Committee can consider this proposal, but it is not a current practice, so no changes have been made.

Full Document:

Comment: Recommend the addition of an annex which includes a listing of the information needed to review and endorse a method. This would inform the Codex Product Committee to include the information related, for example scope of the method (matrices), principle and range, validation data and specification or product standard where the method applies. When some information is not provided the Product Committee could justify the reason so CCMAS could consider this technical information during review of the method.

Response: No changes made

All or most of this information is listed in Section 3.2 ii f and complete details of the information is listed in the Procedural Manual.

Comment: For empirical methods the necessity to discuss changes in methods when the specification is set considering another operational conditions (as we found in eWG for milk products standards) and include in this document.

Response: No changes made.

It was not entirely clear where changes should be made to the Guidance Document or to which particular section this comment was directed.

Appendix III

LIST OF PARTICIPANTS

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