CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CRD08**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

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(Comments of AAFCO, AOAC, C&G (AACC), ICC, IDF, IFU, ISO, MoniQA, NMKL and USP)[1]

Agenda Item 10: Listing of Type IV methods in CXS 234 when a Type I method is listed for the same commodity and provision

IAM comments on the e-WG findings concerning the adoption of Type IV methods in CXS 234 when a Type I method is listed for the same commodity and provision.

IAM would like to thank Uruguay and Brazil, co-chairs of the EWG, and its members for the work they have conducted on the difficult topic of adopting Type IV methods while an existing Type I method has been listed.

Comments on the first recommendation of the EWG:

"To continue with the selection of Type IV methods on a case-by-case basis when 'justifiable and motivating reason' is provided until appropriate selection criteria are developed."

IAM wishes to draw the attention of the committee to the following:

In CCMAS40, the committee agreed on the following introduction of the new CXS 234, stating:

> *This Standard contains definitions, lists of methods of analysis, method performance criteria, descriptions of some methods and a list of methods of sampling. The methods of analysis and sampling contained in this Standard are the recommended ones to be used to assess compliance for a specific provision described in Codex standards and can be used for reference, in calibration of methods in use or introduced for routine examination and control purposes. It is recommended that this Standard should be read in conjunction with the related Codex Standards, guidelines and other documents[1].*
>
> *In case of disputes of analytical results, guidance is given in the Guidelines for Settling Disputes over Analytical (Test) Results (CXG 70-2009), including guidance on the use of methods of analysis.*

CXG 70-2009 states,

> *laboratories use specific methods of analysis, which have been endorsed by the Codex Alimentarius Commission (CAC) or use methods of analysis which comply with performance parameters which have been endorsed by the CAC when they are available. Otherwise, methods must have been validated according to the requirements of the CAC.*

According to the Codex Alimentarius Procedural Manual, Type IV methods are, by definition, not fully validated and CCMAS has consistently concluded that methods should ideally be fully validated prior to their adoption within the Codex system. IAM considers this is a central premise of Codex which should be upheld by CCMAS.

Type IV methods should only be adopted when they provide critical data that cannot be produced using any other validated approach and are required to control a particular provision within the Codex system. In contrast, a Type I method is generally fully validated and 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 measurand. Furthermore, only validated methods are applicable in disputes as emphasized by CXG 70-2009. For these reasons, it is inappropriate to list Type IV methods next to a Type I for a specific commodity and provision.

[1] Referred to as the Interagency Meeting (IAM) for the purpose of this CRD

CXS 234 is not intended to be a comprehensive list of all globally available test methods, rather it is a collection of methods of analysis endorsed by the Codex Alimentarius Commission to meet accepted performance criteria for the determination of individual provisions. Outside of dispute situations, laboratories may use any analytical method they prefer. These include, for example, methods highlighted by the EWG. Namely, those used in proficiency testing schemes or one of the multiple routine or alternative methods available from SDOs. Additionally, commercial contracts between sellers and buyers often require the use of specific methods without regard to their Codex Typing.

Considering the evidence above, IAM is of the opinion that adopting a Type IV method when there is already a Type I method in place for a certain commodity and provision shall be considered an exception and not dealt with on a case-by-case basis. As such, selection criteria for these exceptional situations are unnecessary and should not be considered further.

Comments the second recommendation of the EWG:

"To re-establish the EWG to develop co-existence or equivalence criteria for Type I and IV methods."

IAM wishes to direct the Committee's attention to discussions held at CCMAS36 and CCMAS37 related to the equivalence of methods. The US delegation presented a statistical approach for establishing equivalence between two analyte-defining methods (Type I), although the approach may be used for any two methods, regardless of type. Ultimately, CCMAS37 did not reach consensus on the use and scope of the equivalency approach. Additionally, CCMAS37 did include the following statement in its report:

> *"The Committee noted that most of the work in determining equivalence falls on the Standards Development Organizations (SDOs), and noted the offer of the SDOs, through the Inter-Agency Meeting (IAM), to look into this matter and provide recommendations to a future session of CCMAS."*

IAM would like to encourage CCMAS participants to consult with member SDOs when the need arises to validate new methods, or to determine the bias between any two methods. This type of experimental determination of method performance is fundamental to the SDOs' mission and is a routine function of many IAM members. The consensus view of IAM is that it would be redundant and unnecessary to organize a parallel function as part of CCMAS.

Having expertise in this area, SDOs fully understand the enormity of the task of determining method equivalence. Considerations include: recruitment of experts; agreement from subject matter experts on equivalency criteria (all based on knowledge of methods, commodities, analytes); management of experimental design; recruitment of sufficient laboratories; production of test materials; writing instructions to collaborators; review and statistical analysis of data; final review by expert panel; publication of results. The SDOs are keenly aware of the amount of time and resources (needed by both volunteers and staff) required to perform this type of review.

In addition, acceptance criteria need to be developed on a provision/commodity/purpose basis. For example, provisions for highly toxic components might have tighter tolerances for equivalency than compositional provisions. And even within a provision, there may be commodity interactions which will necessitate having different criteria for different commodity groups. It may be possible to reduce the number of criteria by having some groupings of similar commodities, but all criteria will need to be reviewed by experts. Adding further complication to any proposed system is the fact that the purpose and use of a Type IV method may be different than the purpose of a Type I method. Having a generic, one-size-fits-all set of criteria would likely create unmanageable and inappropriate costs for data collection and analysis.

In summary, IAM does not support the recommendations by the EWG:

- to continue with the selection of Type IV methods on a case-by-case basis when 'justifiable and motivating reason' is provided until appropriate selection criteria are developed.
- to re-establish the EWG to develop co-existence or equivalence criteria for Type I and Type IV.

This is for the following reasons:

- It is inappropriate to list a Type IV method next to a Type I for a specific commodity and provision because Type I is, by definition, the only method for establishing an accepted value of the measurand and applicable in disputes.
- In disputes situations, methods must have been validated according to the requirements of the CAC.
- Type IV methods should only be adopted when they provide critical data that cannot be produced using any other validated approach and are required to control a particular provision within the Codex system.
- CXS 234 is not intended to be a comprehensive list of all globally available test methods.

- CCMAS37 did not reach consensus on the use and scope of the equivalency approach and noted that most of the work in determining equivalence falls on the SDOs (IAM members). Considering the highlighted immensity and complexity of the task of determining method equivalence, IAM considers the development of criteria for this to be outside the scope and expertise of CCMAS.