U.S. DRAFT POSITIONS
for the
Codex Committee on
Methods of Analysis
and Sampling
(CCMAS)

37th Session
Budapest, Hungary
22-26 February 2016

These positions may be revised or updated prior
to the Committee meeting.
January 19, 2016
Agenda Item 1
CX/MAS 16/37/1
Adoption of the Agenda

Background:
The CCMAS will review the Provisional Agenda and consider its adoption.

U.S. Position:
The United States supports adoption of the Provisional Agenda as proposed.

Agenda Item 2
CX/MAS 16/37/2
Matters Referred to the Committee by the Codex Alimentarius Commission and Other Subsidiary Bodies

A. DECISIONS OF THE 37TH SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

MATTERS FOR ACTION
Conversion factor

The Commission asked CCMAS to assess the appropriateness of the use of the conversion factor of 5.71 to determine protein content in soybean products in general (while recognizing 5.71 had been endorsed by CCMAS34 for the determination of protein content in the Regional Standard for Tempe, as proposed by CCASIA).

Additionally, Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to request CCMAS to provide advice on the accuracy and appropriateness of 5.71 as the nitrogen factor for soy protein isolates used in formula for infants and young children and to take into account the amino acid profile of the isolate.

Background:
CCMAS March 2013

In March 2013 at the 34th Session of CCMAS the Endorsement Working Group (EWG) reviewed a Standard for Tempeh.

The EWG and the Committee discussed the conversion factor of 5.71 listed for the determination of protein content. Some delegations pointed out that in trade of soybean products a conversion factor of 6.25 was used. Other delegations referred to scientific literature referred to a factor of 5.71 for soybean products. It was also noted that for infant formula the factor used was 5.71 for soy based products. The Committee agreed to ask the CCASIA to review the use of the factor of 5.71.
CCAsia November 2014

Regional Standard for Tempe
The Coordinating Committee noted recommendations of the 34th Session of the Committee on Methods of Analysis and Sampling (CCMAS) and of the 45th Session of the Committee on Food Additives (CCFA) and agreed to:

Retain the conversion factor of 5.71 for the determination of protein content noting that scientific literature (e.g. Food energy – methods of analysis and conversion factors. Report of a technical workshop Rome, 3–6 December 2002. FAO, 2003. Comprehensive review of scientific literature pertaining to nitrogen protein conversion factor) indicated that this factor was appropriate for soybean, which is the main ingredient of tempe; and

The Coordinating Committee agreed to forward the amendments to the Regional Standard for Tempe to CAC38 for adoption (Appendix II) and to inform CCMAS regarding its decision on the conversion factor for the determination of protein content in Tempe.

CAC38 June 2015
FAO/WHO Coordinating Committee for Asia (CCASIA)
Regional Standard for Non-Fermented Soybean Products
One delegation proposed to refer the method of analysis for the determination of protein content to CCMAS for clarification as to the appropriateness of a conversion factor of 5.71, noting that a factor of 6.25 was used in food trade and in some other Codex texts. The Secretariat clarified that the section on methods of analysis had been endorsed by CCMAS34, as proposed by CCASIA. The Secretariat further noted that CCASIA in response to a request from CCMAS to review the use of the factor of 5.71 for the determination of protein content in the Regional Standard for Tempe, had agreed to retain the conversion factor noting that scientific literature indicated that this factor was appropriate for soybean.

Several delegations supported the proposal of the Secretariat to ask CCMAS to consider the appropriateness of the use of the conversion factor of 5.71 to determine protein content in soybean products in general.

CCNFSDU37 November 2015
At the 37th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) the Committee reviewed the Standard for Follow-Up Formula (CODEX STAN 156-1987), Essential Composition and Quality Factors (for older infants 6-12 months) (Section 3).

US Positions:
The United States recognizes the complexity of the issues related to nitrogen conversion factors and believes that the Codex Committee on Methods of Analysis and Sampling may not be able to resolve the matter/determine the “correct” conversion factor for protein content in soybean products in general without further expert review and consideration. Although the delegates and participants at CCMAS have extensive technical expertise in analytical chemistry and method development and validation, specialized expertise is required to evaluate this complex topic and complete a thorough evaluation.

COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU37)
Examination of “ELISA G12” as a potential additional method for inclusion in Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979).
The Committee noted the reply from CCMAS in particular with respect to validation of the R5 and G12 methods, based on the two matrices, maize and rice, but questioned: which method to adopt for mixed matrices; the comparability of the two methods (if different results emerge); and the implications for “gluten-free” labelling.

The Committee decided to seek further clarification from CCMAS with the following request as outlined below.

Taking into account that the thresholds in CODEX STAN 118-1979 were established on the basis of the results given by the ELISA R5 Method, can CCMAS confirm that the results of the two methods (R5 and G12) are fully comparable for all products covered by the standard, in particular:
- products manufactured from ingredients naturally free of gluten (e.g. buckwheat, millet, amaranth, quinoa, etc.);
- products manufactured from gluten-containing ingredients (e.g. partially hydrolysed wheat protein, wheat starch, malt extract, glucose syrups, etc.);
- products based on oats; and
- liquid matrices.

U.S Position:
Currently the United States is unaware of any multi-laboratory studies which have been performed which establish that the methods are “fully comparable” for all of the products covered in the standard. Additionally, even with such studies, both methods could not be endorsed without a change to the current Commodity (Gluten Free Foods) or Type (Type I) of the R5 immunoassay. Furthermore, if neither method has been multi-laboratory validated for mixed matrices then endorsement of either (or both), based on industry use, or single laboratory validation could occur, but only allowing both to be endorsed as Type IV methods.

Agenda 3
CX/MAS 16/37/3
Endorsement of Methods of Analysis Provisions and Sampling Plans in Codex Standards

Background:
The EWG has been asked to review sampling plans from the Committee on Contaminants in Foods (sampling plans for fumonisins and deoxynivalenol). At the 36th Session, the Committee had recommended a number of edits to these plans, which appear to have been incorporated.

The EWG has also been asked to endorse methods of analysis for the following Committees:
Committee on Spices and Culinary Herbs
Committee on Fish and Fishery Products
Committee on Nutrition and Foods for Special Dietary Uses

U.S. Position:
The United States will co-chair the EWG and participate in the discussion of the proposed methods and their Typing. On initial review, the United States has not identified any issues with the proposed methods.
Agenda Item 4
CX/MAS 16/37/4
Development of procedures/guidelines for determining equivalency to Type I methods

Background:
At its 35th session, the CCMAS considered the “Discussion Paper on Considering Procedures for Establishing Criteria for Multianalyte and Type I Methods”.

As part of those discussions, CCMAS agreed that numerical criteria for Type I methods should not be established, however that it might be useful to consider and discuss procedures for establishing equivalency to Type I methods (Para 59 of REP14/MAS).

Based on that decision an eWG, chaired by the United States and working in English only, was established to develop a discussion paper which would consider different procedures/guidelines for determining equivalency to Type I methods (Para 61 of REP14/MAS).

There was considerable interest in the eWG with 20 participants. The discussion paper was presented as a first draft, with request for comment and further discussion to proceed during the 36th Session of CCMAS.

There was general agreement by the Committee that work should continue, but with caution, since equivalency could have unintended consequences. A number of general recommendations were suggested, including
  1) clearly define the concept of equivalent methods and how such equivalency would apply to Type I–IV methods
  2) clarify the role an equivalent method would have in dispute resolution
  3) review other procedures or national protocols for establishing equivalency

A second draft of the discussion paper, prepared by the United States has been submitted to CCMAS for comment and further discussion at the 37th session.

U.S. Position:
The United States believes that procedures for establishing the equivalency between 2 analytical methods would be useful, but is concerned that such procedures would then be used to introduce “endorsed” alternatives to Type I methods. CCMAS has consistently and correctly retained the special status of Type I methods (no criteria, only a single Type I) and the United States supports maintaining that status. Therefore, before further work is performed on detailing the procedures for establishing equivalence in CCMAS, it is necessary to reach an understanding and consensus on where the final procedures will reside, for whom they are intended and what status, if any, will equivalent methods have within Codex.
**Agenda Item 5**
**CX/MAS 16/37/5**

Criteria approach for methods which use a “sum of components”

**Background:**
At its 35th session of CCMAS, the Delegation of United States introduced the report of the eWG as presented in CX/MAS 14/35/5 and noted that there was general interest in the concept of developing criteria for Type I methods and/or multi-analyte methods, but that this was a starting point and no attempt was made to reach consensus on this. The Delegation highlighted the recommendations made and pointed out that the Committee would need to consider a number of factors when deciding on development of criteria for either Type I methods or for multi-analyte methods, such as:

(i) when considering criteria for Type I methods, it may be possible to establish procedures for assessing equivalency between methods and not criteria. However, since not all Type I methods were created equal there may be instances where equivalency could not be established;

(ii) in the case of multianalyte methods, how to deal with TEFs, whether these should be left out of the standard as in the approach taken by CCFFP; and,

(iii) whether a general approach was appropriate or whether different approaches would be necessary for multi-analyte methods (there might be differences between different toxins).

In view of the general discussion on the recommendations, the Committee agreed to pursue the work further through the establishment of a separate electronic working group, open to all members and observers and working in English only, as follows:

Development of a criteria approach for methods which use a “sum of components”, led by United Kingdom. The working group would prepare a discussion paper that evaluates and discusses current options; and considers general guidelines and evaluates criteria for use on a case-by-case basis.

The Discussion Paper prepared by the United Kingdom was reviewed at CCMAS36 and the Committee agreed that work should continue and the eWG, led by the United Kingdom and working in English, was re-established.

The Working Group would:

i) Concentrate on chemical methods of analysis only.

ii) Undertake an analysis of CODEX STAN 234-1999 and individual methods in relevant commodity standards, to determine the extent to which methods of analysis that use a sum of components approach are cited and used; and try to identify potential methods that could be considered by the Committee for future conversion to method performance criteria.

iii) Develop potential options for establishing criteria approaches for methods that are sum of components using CX/MAS 14/35/5 and CX/MAS 15/36/6 as a starting point.

iv) Evaluate the options identified within recommendation 3 to ascertain fitness for purpose.
v) Based on the outcome of recommendations 1 – 4, consider the need to either amend the General Criteria for the Selection of Methods of Analysis section of the Procedural Manual and/or for development of a Guideline Document for governments.

**U.S. Position:**
The United States thanks the United Kingdom for their work on this document and will participate fully in the physical working group planned during the 37th Session of CCMAS. The United States supports the recommendation put forward in the working document (CX/MAS 37/16/5) that sum of components be evaluated on a case-by-case basis. The specific examples presented in the paper are an excellent starting point for establishing possible options.

**Agenda Item 6**  
**CX/MAS 16/37/6**  
**Criteria for endorsement of biological methods to detect chemicals of concern**

**Background:**
At the 35th Session of CCMAS (March 2014), the Committee established criteria for the determination of biotoxin analogues and endorsed both the mouse bioassay and the receptor binding assay as Type IV. Based on concerns of a number of delegates, this decision was reviewed at the 36th Session of CCMAS (Feb 2015). This review led to the establishment of an eWG on criteria for endorsement of biological methods to detect chemicals of concern, led by Chile, and co-chaired by France, and working in English only.

It was agreed the eWG would:
- i) classify biological methods according to their nature, principles, characteristics, etc.;
- ii) identify to which classes of the method the criteria approach applies; and
- iii) recommend criteria to endorse each class of biological methods identified in step (ii).

**US Position:**
The United States thanks Chile and co-chair France for their work on this topic and document. The list of methods appears to contain some methods based on microbioassay and some based on mouse/rat bioassays. The United States agrees that these methods, based on different principles, likely need to have different performance criteria.

**Agenda Item 7**  
**CX/MAS 16/37/7**  
**REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999**

**Background:**
At the 34th CCMAS Session, in 2013, updating the references of methods of analysis and related texts was discussed. The Committee agreed that a general single document or database with all the methods of analysis allows permanent and dynamic revision. The Committee agreed to establish an eWG to prepare a discussion paper with proposals:

- on establishing a format for a single source document (database) to capture all methods in the scope of CCMAS;
At the 35th CCMAS Session, in 2014, the Committee agreed that the list to be compiled with all methods of analysis would be utilized for internal use of the Committee (i.e. for updating the methods) and that the mechanism for this process would first be tried before examining the necessity of having it recommended for inclusion in the Procedural Manual.

Regarding the information in the list, the Committee noted that the information on performance criteria of an analytical method would be required during endorsement by CCMAS, and agreed that such information would not be necessary at the time of identifying the analytical method that needed review, but agreed that this requirement would remain in the Table 1 (as presented in CRD 22), but that the concerns raised related to proprietary information should be taken into account when developing the single source document.

At the 36th Session of CCMAS, there was general agreement that the work should continue, but there was also discussion on the establishment of CODEX STAN 234 as a single reference for the methods of analysis and sampling. A number of delegates expressed the view that while a single reference would have advantages, there might still be a need to retain methods in commodity standards, especially in cases where full descriptions were provided in the commodity standards. The methods of analysis for determination of authenticity of fruits juices, was cited as an example where it might be essential to maintain the methods of analysis in the commodity standard.

Based on the discussion, the Committee agreed to continue the work on the update and review of the endorsed methods of analysis through an eWG led by Brazil, co-chaired by Japan, and working in English only with the following terms of reference:

- Continue working on the identification of inconsistencies in CODEX STAN 234 and other Codex Standards.
- Include methods from CCNFSDU in the workable packages.
- Look over the Codex Committees Standards to identify limits and parameters that don’t have related method of analysis.
- Discuss where and how to make reference to methods completely described in the Commodity Standards.
- Propose to CCMAS a process to update the endorsement of Codex Methods.
- Incorporate the suggestions made by the CCMAS regarding the inclusion of the numerical provisions and identification of the Commodity Standards to which the methods apply in CODEX STAN 234.

**U.S. Position:**
The United States continues to support the review of previously endorsed methods and thanks Brazil and Japan for their efforts in chairing the eWG. They have done a tremendous amount of work in preparing the document and spreadsheets. The United States is in agreement with the procedures for classifying and prioritizing methods, but is still unclear of when and how the assessment (review) of each method will occur. Will this review be part of the Endorsement Working Group or proceed during the plenary? In a more specific comment, the spreadsheet listing “performance criteria” methods contain a
column on date of CCMAS endorsement, but it is our understanding that once criteria are established there is no longer a need for method endorsement.

**Agenda Item 8**
**CX/MAS 16/37/8**
**Information document on Practical Examples on the Selection of Appropriate Sampling Plans**

**Background:**
At its 35th Session of the CCMAS, the Committee agreed to develop practical examples on the selection of appropriate sampling plans (REP13/MAS, paragraph 86), including case-by-case advice of consideration of sampling uncertainty (definition), that fulfill the following criteria:

matrix combinations vs measurand / provision:

- Fruits/vegetables, fats/oils, fish/fishery products, milk/milk products, meat/meat products, natural mineral waters, cereals
- Sensory inspection, food additives, food hygiene, pesticide residues, contaminants, residues of veterinary drugs
- Packages/bulk material/foodstuff for consumption.

**U.S Position:**
The United States agrees that current guideline on sampling is difficult to follow and apply, and that practical examples on the selection of sampling and as an annex to the Principles on sampling and testing in international trade would be beneficial. The United States supports further work and development of this document.

**Agenda Item 9**
**CX/MAS 16/37/9**
**Procedures for determining uncertainty of measurement results**

**Background:**
At its 35th Session of the CCMAS, the Committee agreed to develop procedures for determining uncertainty of measurement results including sub-sampling, sample processing and analysis (REP14/MAS, paragraph 86). This was initially undertaken as a part of the development of the *Principles on Sampling and Testing in International Trade*, but has developed into discussing more practical problems in determining measurement uncertainty.

**U.S. Position:**
The United States has not completed a thorough review of this document, but will fully participate in the plenary discussion associated with the document. We welcome any comments and suggestions on this item.
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