Report of the U.S. Delegate on the 37th Session of the Codex Committee on Methods of Analysis and Sampling

February 22-26 2016
Budapest, Hungary

The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its 37thSession from February 22-26, 2016, in Budapest, Hungary. The United States was represented by Dr. Gregory Noonan, U.S. Food and Drug Administration (Delegate); Dr. Timothy Norden, Grain Inspection, Packers and Stockyards Administration, U.S. Department of Agriculture (Alternate Delegate); Dr. Patrick Gray, U.S. Food and Drug Administration; and Ms. Marie Maratos, U.S. Codex Office, Food Safety and Inspection Service, U.S. Department of Agriculture. The session was attended by representatives of 47 Codex member countries, 1 member organization (the European Union) and 17 observer organizations.

The Committee concluded a productive session addressing a number of issues associated with facilitating trade, food analysis and sampling. Specifically, the Committee discussed an appropriate nitrogen conversion factor for soy products in general. Although no consensus was reached, the Committee did agree that conversion factors are not the remit of CCMAS and recommended the consideration of an expert panel to take a science- based approach to establish nitrogen conversion factors.

CCMAS continued work on a number of topics and established five intersessional electronic Working Groups (eWGs), all working in English, as follows:

- A new eWG, chaired by New Zealand, will review the *General Guidelines on Sampling* (CAC/GL 50-2004) and evaluate the need for revision and how such work should proceed if necessary.
- Germany will continue to chair the eWG on developing specific examples of sampling and testing as a supporting document to the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013).
- A third eWG, chaired by Brazil, with the assistance of Uruguay, will continue on the updating of methods in the *Recommended Methods of Analysis and Sampling* (Codex Standard 234-1999).
- The United Kingdom will again chair an eWG to develop procedures for developing numeric criteria for sum of components.
- The final eWG will again be chaired by Chile, co-chaired by France, to develop criteria for biological methods.

The United States will participate in all of the eWGs. The Terms of Reference (TOR), information on the scope for each of the eWGs and related discussion papers can be found in the final report of the 37TH Session of the CCMAS (REP 16/MAS) available at: http://www.fao.org/fao-who-codexalimentarius/meetings-reports/en/.

More detailed summaries on several agenda items from the recent session of CCMAS are provided below.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER COMMITTEES (Agenda Item 2)

Codex Alimentarius Commission (CAC) and Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

Protein conversion factors

Much of the discussion occurred during the physical Working Group (pWG) on Endorsement on Sunday preceding the plenary. During the plenary, the Committee agreed that it was not in a position to reply to the questions posed by CAC (38th Session, 2015) and CCNFSDU (37th session, 2015) as the determination of conversion factors was in the remit of commodity committees and to inform the CAC and CCNFSDU accordingly. Additionally, the Committee noted that it might be timely for the Food and Agriculture Organization and World Health Organization to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors. The United States was satisfied with this conclusion on the protein conversion factors as this is a multi-faceted issue that is not in the remit of the CCMAS.

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, in line with the U.S. position on the matter, agreed to inform CCNFSDU that the two methods (R5 and G12) for the determination of gluten are not comparable; that comparable data for the two methods were not available; and mixed matrices are not included in the scope of either of the methods based on the data obtained during their validation. The developers of these proprietary methods might be able to provide further information on the applicability of the methods.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 3)

Committee on Contaminants in Foods (CCCF)

Sampling plans for fumonisins in maize and maize products

The Committee endorsed the sampling plans for fumonisins and DON with minor recommendations for changes to the title to indicate that the plan also includes numeric values for performance criteria.

Committee on Spices and Culinary Herbs (CCSCH)

Proposed draft Standards for Cumin and Thyme

The Committee endorsed a number of the methods referred by CCSCH, but did have questions regarding the determination of moisture, which were referred back to CCSCH for further clarification.

Committee on Fish and Fishery Products (CCFFP)

Amendments to the methods of analysis for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets – Breaded or in Batter

The Committee endorsed the method of analysis as presented by CCFFP. The Committee noted the concerns with having the nitrogen factors linked to two different websites and proposed that the nitrogen factors be made available on a single website.

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

Methods of analysis in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

The Committee endorsed the methods for the determination of Vitamin A, Vitamin B12, total nucleotides, iodine, fatty acids and pantothenic acid as Type II. The methods for myo-inositol and Vitamin E were also endorsed as Type II, but with questions for the CCNFSDU. The methods for chromium, selenium and molybdenum were endorsed as Type III with additional questions regarding performance referred to CCNFSDU.

DEVELOPMENT OF PROCEDURES/GUIDELINES FOR DETERMINING EQUIVALENCY TO TYPE I METHODS (Agenda Item 4)

The United States introduced the discussion paper and recalled the decisions of the last session of the committee, pointing out that while the procedure was intended to establish a statistical approach for establishing equivalence to existing Type I methods, the recommended procedures could be applicable to establishing equivalence between any two methods, regardless of type (Type I – IV). Moreover, the United States pointed out that the most suitable approach was the Two-One Sided T-test, better known as the TOST procedure, and that before the procedures could be further developed, the Committee should provide guidance on the questions raised in the discussion paper (CX/MAS 16/37/4, paragraph 27).

Several delegations expressed concerns that the proposed statistical approach to test equivalency to Type I would not be feasible in the analytical field due to its difficulty to apply, and that comparable work and many protocols outside of Codex already existed to help analysts in this regard. The Committee could not reach consensus on the use and scope of the equivalency approach and agreed to reconsider this matter in the future when more information became available. The Committee noted that most of the work in determining equivalence falls on the Standards

Development Organizations (SDOs), and welcomed the offer of the SDOs, through the Interagency Meeting (IAM), to look into this matter and provide recommendations to a future session of CCMAS.

CRITERIA APPROACH FOR METHODS WHICH USE A 'SUM OF COMPONENTS' (Agenda Item 5)

The United Kingdom, as lead of both the eWG and pWG, introduced the working group reports, reminding the Committee of the decision at the last session for the work to continue. The pWG looked at examples and concluded that there was no single mechanism for determining numeric method performance criteria for methods and that performance criteria should be addressed on a case-by-case basis.

The Committee agreed to re-establish the eWG, led by the United Kingdom and working in English only, to develop a document in the style of guidance to Codex commodity committees and CCMAS; to concentrate on chemical methods of analysis only; and to use the working group paper prepared for this session (CX/MAS 16/37/5) as a starting point to continue to develop guidance on how maximum levels (MLs) and methods of analysis which involve a sum of components could potentially be converted to method performance criteria. The guidance, to be used on a case-by-case basis, will contain some of the current potential approaches available.

DISCUSSION PAPER ON CRITERIA FOR ENDORSEMENT OF BIOLOGICAL METHODS USED TO DETECT CHEMICALS OF CONCERN (Agenda Item 6)

Chile and France, as chair and co-chair of the eWG, introduced the discussion paper and explained that the eWG only addressed the first point of its terms of reference, viz. classify biological methods according to the nature, principles, characteristics, etc. The eWG first looked at biological methods typed in Codex and noted that most of these were Type II and III, with one Type I method (rat bioassay for determination of the protein efficiency ratio), while the methods for determination of marine biotoxins were Type IV. The vast majority of the methods were for the determination of vitamins. France pointed out that an obstacle was that some of the methods in Codex Standard 234 either need to be removed because there were no longer provisions for them (e.g., methods for minarine and margarine), or needed to be reviewed by the Committee since vitamins were now quantified by chromatographic methods. It was therefore suggested to revise the list and not define criteria for the methods which might be removed from the list. A proposal could then be put to the relevant Codex committee to review the methods and inform CCMAS whether they still wished to retain the biological methods.

The Committee agreed to re-establish the eWG led by Chile and co-chaired by France, working in English only, to identify those methods already adopted by Codex as possible replacements for some of the biological methods for determination of vitamins and to identify clear questions that can be put to the relevant Codex committees in relation to these methods; to continue with the classification of biological methods; and to identify to which classes of methods the criteria approach applies and recommend criteria to endorse each class of biological methods defined.

DISCUSSION PAPER ON ELABORATION OF PROCEDURES FOR REGULAR UPDATING OF METHODS (Agenda Item 7)

Brazil, as Chair of the eWG on the review and updating of Codex Standard 234-1999, introduced the item and drew the attention of the Committee to the recommendations related to the internal procedure to be followed by CCMAS to proceed with the maintenance of the standard and amendments to the *Procedural Manual* aimed at identifying the standard as the single source for methods of analysis and sampling adopted by CAC.

The Committee reaffirmed its earlier decision to have Codex Standard 234-1999 as the single reference for methods of analysis in Codex standards and recalled that the Committee on General Principles (CCGP) had informed the Committee that CCMAS should prepare proposed amendments to the *Procedural Manual* for endorsement by CCGP and adoption by CAC. No amendments were made at the session, but this would be taken up at a future session of the CCMAS.

The Committee agreed to continue to work on the review and updating of Codex Standard 234-1999 by means of an eWG led by Brazil and co-chaired by Uruguay, working in English only, with the possibility to meet in a pWG immediately prior to the next session of CCMAS.

INFORMATION DOCUMENT ON PRACTICAL EXAMPLES ON THE SELECTION OF APPROPRIATE SAMPLING PLANS (Agenda Item 8)

Germany, as lead country of the eWG on the development of practical examples for the selection of appropriate sampling plans, introduced the item and recalled that the practical examples were intended to assist governments to choose appropriate sampling plans to avoid disputes between importing and exporting countries, and as such, they were not of a prescriptive nature, but should assist governments in the implementation of the *Principles for the Use of Sampling and Testing in International Trade* (CAC/GL 83-2013).

The Committee discussed whether the examples should remain as a freestanding document or become an Annex to the *Principles for the Use of Sampling and Testing in International Food Trade: Explanatory Notes* and if specific examples concerning pesticides and veterinary drugs were appropriate. The Committee also agreed to attach the document, as an Appendix, to the report of the session to allow countries to submit additional examples and comments before finalizing the document at the next session of CCMAS.

OTHER BUSINESS

The United States agreed to chair the physical Working Group on Endorsement at the 38th Session of CCMAS, with Australia acting as co-chair.

Chairman Arpad Ambrus, who has led the Committee for eight sessions, reported that he is resigning as Chair and that a replacement should be named prior to the next session. Chairman Ambrus, drawing on his extensive experience and knowledge of testing and sampling, has been a tremendous asset to the Committee. His knowledge and leadership will be missed.

NEXT SESSION

The next Session of the CCMAS will take place in Budapest, Hungary in 2017, but a specific date has yet to be set.