



Report of the U.S. Delegate, 30th Session of the Codex Committee on Methods of Analysis and Sampling

The [Codex Committee on Methods of Analysis and Sampling \(CCMAS\)](#) held its 30th Session from March 9-13, 2009 in Balatonalmadi, Hungary. The 30th Session was attended by 140 delegates and observers representing 48 Member Countries, one Member Organization (EC), and 9 international organizations. The United States was represented by the Delegate, Dr. Gregory Diachenko, Dr. Michael Wehr and Dr. Gregory Noonan, U.S. Food and Drug Administration; Mr. Larry Freese, Grain Inspection, Packers and Stockyards Administration, USDA; Mr. Jack Bobo, U.S. State Department; Dr. Michael Sussman, Agricultural Marketing Service, USDA and Ms. Shannon Cole, Grocery Manufacturers Association.

The United States fully participated on all agenda items and was successful in achieving many of its objectives and goals during this Session. The Committee, recognizing that substantial progress had been made by the U.S. led efforts on the revision of the analytical definitions, agreed to advance the *Proposed Draft Guidelines on Analytical Terminology* for final adoption at Step 8 by the 32nd Session of the Codex Alimentarius Commission. Significant U.S. input was also provided on revising the text of the *Draft Guidelines for Settling Disputes on Analytical (Test) Results* and moving them forward to final adoption at Step 8. These Codex texts may have significant impact on international trade and the work of CCMAS.

The U.S. was partially successful in convincing the Committee to change the title and broaden the scope of the *Proposed Draft Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived From Biotechnology*. The Committee agreed to somewhat broaden the scope and change the title. The Committee also returned the document to Step 2 and established an electronic working group, co-chaired by Argentina, Germany and the United Kingdom, to revise the proposed draft guidelines, taking into account comments previously submitted and those raised at the present session. The revised text will be circulated for comments at Step 3 and consideration at the next CCMAS session.

More detailed summaries on several Agenda items are provided below.

Proposed Draft Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived From Biotechnology

As a result of the U.S. intervention at the last meeting of the Codex Commission and the current CCMAS session, the Committee agreed to a significant revision of the *Proposed Draft Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived From Biotechnology* and the following broadening of the scope for these guidelines:



These guidelines provide information for the validation of methods for the detection, identification, and quantification of specific DNA sequences and specific proteins in foods derived from modern biotechnology. These Guidelines may also provide information on the validation of methods for other specific DNA sequences and proteins of interest in other foods. Information relating to general considerations for the validation of methods for the analysis of specific DNA sequences and specific protein in foods is given in the first part of these Guidelines. Specific annexes are provided that contain information on definitions, validation of quantitative PCR methods, validation of qualitative PCR methods, validation of protein-based methods, and proficiency testing.

The Committee considered two options of the proposed title and agreed to replace the current title with the following: "Proposed draft guidelines on criteria for methods for detection, identification and quantification of specific DNA sequences and specific proteins, in particular in foods derived from modern biotechnology". The Delegation of Australia reserved its position to the decision on the amendments to the title as it did not support any extension of the scope and particularly did not want mention of allergens or pathogens in the scope, which were removed at the request of their delegate and Canada's delegate. The Delegation of the United States expressed its reservation regarding the inclusion of the term "modern biotechnology" in the title. The United States preferred the second title option, which included biotechnology and several other applications in a footnote to the title in order to clarify the broadened scope of the document and the many applications of these method criteria.

After much discussion and several interventions by the U.S., the Committee agreed to return the text to Step 2 and to establish an electronic working group, co-chaired by Argentina, Germany and the United Kingdom, to revise the proposed draft guidelines, taking into account comments submitted on the previous document and discussions at the present session. The revised text will be circulated for comments at Step 3 and consideration at the next CCMAS session.

Proposed Draft Guidelines for Settling Disputes over Analytical (Test) Results

An in-session working group was formed and made revisions in the Draft Guidelines for Settling Disputes over Analytical (Test) Results based on the comments received when it was circulated at Step 6 of the Codex process. The Committee considered the document and made a number of additional revisions in each section. The Guidelines address how to deal with disputes related to test results, but do not address questions of sampling and the text was amended to allow flexibility in solving disputes. These guidelines can only be applied in the situation where both importing and exporting countries are in agreement to use them.



The Committee finalized the document and agreed to send the Draft Guidelines, as amended at the present session, to Step 8 for approval by the next session of the Codex Commission.

Proposed Draft Guidelines on Analytical Terminology

The U.S. Delegation presented a document entitled *Proposed Draft Guidelines on Analytical Terminology* that had been circulated for comments at Step 6 of the Codex process. The Committee considered the document section by section and made a number of amendments and comments. What was originally developed as updated analytical terminology for inclusion in the Codex Procedural Manual will be removed from the Procedural Manual and placed in a guideline for governments in order to facilitate future changes and reduce expansion of the Procedural Manual. The Committee, recognizing that substantial progress had been made by the U.S. led efforts on the revision of the definitions, agreed to advance the *Proposed Draft Guidelines on Analytical Terminology* for final adoption at Step 8 by the 32nd Session of the Codex Alimentarius Commission.

Endorsement of Methods of Analysis for Provisions in Codex Standards

A report of the *ad hoc* Working Group on endorsement of methods was presented by the Chair, Dr. Roger Wood (United Kingdom). The Committee endorsed several methods of analysis in Codex Standards at different steps of the Procedure as proposed by the *ad hoc* Working Group, but with a few minor amendments and comments (para 46-82 and Appendix IV of Alinorm 09/32/23).

Proposed Amendment to the Working Instructions for the Implementation of the Criteria Approach in Codex The criteria approach allows analysts flexibility in selecting validated methods of analysis that meet Codex requirements. CCMAS proposed to amend the section in the Procedural Manual on the working instructions for the implementation of the criteria approach to add a new section on guidelines for establishing numeric values for method criteria and/or assessing methods for compliance with the criteria. This added section includes prescribed acceptance requirements for establishment of numerical values; criteria for applicability associated with concentration values; levels and minimum applicable ranges; criteria for precision and included an example of assessing methods for compliance. The Committee agreed to send the amendment to the General Principles Committee for its endorsement. (ALINORM 09/32/23, para. 92, Appendix V)