



Report of the United States Delegate, 41st Session, Codex Alimentarius Commission

July 2-6, 2018

Rome, Italy

The 41st Session of the Codex Alimentarius Commission (CAC) met in Rome, Italy, July 2 – 6, 2018. The Commission is the governing body of the joint World Health Organization (WHO) and UN Food and Agriculture Organization (FAO) international food standards program, and is recognized in international trade agreements as the international standards setting organization for food safety.

Delegates from 121 member countries and 1 member organization (the European Union/EU) attended the session, as well as observers from 84 intergovernmental and nongovernmental organizations. The United States was represented by Under Secretary for Trade and Foreign Agricultural Affairs, Ted McKinney; Mary Frances Lowe, U.S. Manager for Codex Alimentarius; and 9 additional governmental and 6 non-governmental advisors. The CAC approved the recommendations of its subsidiary bodies, which were generally consistent with U.S. positions on major issues before the CAC.

The United States had hoped that the CAC would also issue clear guidance to its committees to base decisions on science, consistent with the principles in the Codex Procedural Manual. While many countries did support reaffirmation of the scientific basis of Codex standard-setting work, there was no conclusion on guidance to committees. Consideration of the issue will continue based on a document the Codex Secretariat will prepare for the next Codex Executive Committee (CCEXEC77) in July 2019.

Highlights

The Commission:

- Reaffirmed the value of Codex as the preeminent international science-based and rules-based food standard-setting body, underscored its commitment to both science and consensus, and endorsed the Executive Committee's conclusion that the Secretariat prepare a report for further discussion at CCEXEC77.
- Amended the Procedural Manual to clarify how the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) could approach its proposed work to develop extrapolation of Maximum Residue Limits (MRLs) as a risk management body. The purpose of this amendment is to allow for the development of MRLs for additional species without imposing costly, unnecessary additional data requirements.
- Approved several hundred new provisions for food additives and MRLs for pesticides and veterinary drugs.
- Clarified that the Committee on Food Additives had recommended provisions for steviol glycosides consistent with its standard practice, and adopted those provisions as recommended.
- Adopted maximum levels (MLs) for cadmium in certain chocolate products, as prepared for wholesale or retail distribution, for lead in a number of commodities, and for methyl mercury in certain fish species.
- Adopted a Revision of the General Standard for the Labelling of Prepackaged Foods governing date marking.
- Adopted a commodity standard for aubergines with specific provisions for decay in "Extra" class.
- Adopted revisions of the Code of Practice for Fish and Fishery Products for histamine control.
- Adopted a commodity standard for quinoa, subject to further consideration of two issues (described below).
- Agreed to the recommendations and work plan prepared by the Chair of the Committee on Processed Fruits and Vegetables (CCPFV) and created electronic working groups to begin developing standards as described in the work plan. The United States, as host country, will schedule a physical meeting of CCPFV at an appropriate time, based on the progress of the work by correspondence.
- Agreed to continue work by correspondence for another year on the standard for non-centrifuged dehydrated sugar cane juice/panela, despite CCEXEC recommendations that work be discontinued.
- Noted that the Committee on Food Additives (CCFA) had established an electronic working group to develop a solution to replace Note 161 (national legislation) in the General Standard for Food Additives.
- Generally endorsed the recommendations of the 75th Session of the Codex Executive Committee (CCEXEC75, June 26-29, 2018), including recommendations for coordination between the Codex Committee on Pesticide Residues (CCPR) and CCRVDF and guidance to the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on referencing WHO documents in Codex standards.



- Approved new work as recommended by committees, including work on front-of-pack labeling by the Codex Committee on Food Labelling (CCFL).
The official report of the session and related documents can be found on the Codex Alimentarius website at <http://www.fao.org/fao-who-codexalimentarius/meetings/en/>.

MEETING SUMMARY

Following is a summary of the CAC's discussion of matters that were debated in some detail during the plenary session and/or not highlighted above.

CCEXEC75 Critical Review: Consideration of the outcome of CCRVDF's deliberations on proposed draft MRLs for zilpaterol hydrochloride in cattle fat, kidney, liver and muscle

At the request of the United States, the CAC agreed to consider the results of CCEXEC75's Critical Review under Agenda Item 2, presentation of the CCEXEC75 report. The Commission noted the report's summary of the discussion of the implications of the failure of CCRVDF to advance the MRLs for zilpaterol hydrochloride, even though there was consensus in CCRVDF on the science and the safety of the recommended MRLs. The standard was not advanced by CCRVDF due to objections based on factors that are outside the scope and mandate of Codex, such as animal welfare and a concern that establishing an MRL would encourage use of the drug, which is banned in some countries.

During CCEXEC75, the Legal Offices of FAO/WHO had presented a legal opinion in which they stated that the CCRVDF outcome did not breach any rule of Codex. The Legal Offices went beyond the legal question posed to express the view that recent developments, including the abolition of the Codex Acceptance Procedure and the signing of international trade agreements, had altered the original nature and status of Codex standards. They further observed that this "would seem to warrant a review" of the Codex Procedural Manual's Statements of Principle on the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account. The purpose of the review would be "to better clarify the extent to which 'other legitimate factors relevant for health protection fair trade practices' may be taken into account in the adoption of Codex standards."

The CAC had an extensive discussion on this issue. Over 40 member countries intervened. Many countries from Africa, Latin America and the Caribbean, and Asia joined the United States in stressing the importance of science as the cornerstone of Codex, and that science is fundamental to Codex's credibility and role as the international reference point for food safety standards in trade agreements. These members also noted that CAC and its subsidiary bodies should only consider factors other than science that are within the mandate of Codex, as articulated in the *Procedural Manual*. Some members also said that they did not authorize use of the compound in their countries, but did not object to Codex's setting an MRL for zilpaterol hydrochloride.

Countries that had opposed advancing the zilpaterol MRLs at CCRVDF, primarily from the European region, expressed the view that consensus was also a core value of Codex, supported the review suggested by the FAO/WHO Legal Offices, and stressed their view that science and risk assessment alone should not determine Codex decisions. Some suggested that the Codex Committee on General Principles should undertake work in this area.

In conclusion, the CAC endorsed the work proposed by CCEXEC75 for consideration by CCEXEC 77, i.e., the discussion would continue at the next CCEXEC, facilitated by a report prepared by the Codex Secretariat in conjunction with the CAC Bureau and the Legal Offices of FAO and WHO. The CAC further requested that the Secretariat's report be shared sufficiently in advance to enable regional coordinators to solicit input from member countries in their regions.

ADOPTION OF STANDARDS AT STEP 8 AND 5/8

All committee recommendations were adopted. Many of the adopted standards are important to the United States from the perspectives of food safety, public health, and international trade. Only a few standards triggered discussion at CAC41, as outlined below.

Standard for Auberginèse



In response to concerns over the inclusion of a tolerance for decay in “Extra” class raised by the EU, the United States explained that this tolerance was realistic and reflected existing industry and trade practices, since a zero tolerance for decay was not possible for fresh products shipped in international commerce. The CAC supported the U.S. position and the standard was adopted as recommended by the Committee on Fresh Fruits and Vegetables (CCFFV).

Risk Management Recommendations (RMR) for Gentian Violet (CCRVDF)

The United States was joined by seven other countries in expressing a reservation to the RMR for Gentian Violet. The reservation was specifically directed to the last sentence, which reads, “This can be accomplished by not using gentian violet in food-producing animals.” Countries expressing reservations stated their view that this guidance could be interpreted as overly prescriptive and beyond the scope of Codex when read independently of the CCRVDF report. The CAC noted that the text should be interpreted flexibly, to allow member countries to choose appropriate risk-management approaches to prevent residues of gentian violet in foods, consistent with the conclusions of CCRVDF.

Food Additive Provisions for Steviol Glycosides (CCFA)

The EU requested that CCFA reconsider the additive provisions for steviol glycosides with the possibility of assigning them separate numbers in the International Numbering System (INS), depending on the method of production. The United States, supported by the CCFA Chair, explained that this issue had been discussed thoroughly at the last session of CCFA and that the Committee’s established policies and precedents called for grouping food additives sharing the same Acceptable Daily Intake (ADI) under the same INS number. The CAC adopted the provisions as recommended by CCFA.

STANDARDS HELD AT STEP 8 (SHORT OF FINAL ADOPTION)

Recombinant Bovine Somatotropin (rBST)

Since 1995, MRLs for recombinant bovine somatotropin (rBST) have been held at Step 8, which is an extremely rare occurrence in Codex. There was no request to change the status of the draft MRLs at CAC41, so there was no discussion and the MRLs remain at Step 8. No new data have been submitted that would call into question the previous conclusions of the Joint Expert Committee on Food Additives (JECFA) and CCRVDF on the safety of rBST.

ADOPTION OF STANDARDS AT STEP 5

The following standards were adopted at Step 5 for further consideration in the relevant committees:

- Standard for Ware Potatoes (CCFFV)
- Essential Composition Requirements for Older Infants and Young Children in the Standard for Follow-Up Formula (Codex Committee on Nutrition and Foods for Special Dietary Uses). Many countries expressed support for completion of the revision of this standard and the need to update it to reflect current science to ensure safety and nutritional adequacy. An observer group strongly opposed work to update the standard and argued that these products should not be marketed.
- Code of Practice for the Reduction of 3-Monochloropropane-1,2 Diol Esters and Glycidly Esters in Refined Oils and Food Products made with Refined Oils (CCCF)
- Proposed Guidelines for Risk Analysis of Instances of Contaminants in Food Where there is no Regulatory Level or Risk Management Framework Established (CCCF)
- Proposed Draft MRL for flumethrin in honey (CCRVDF)
- Endorsement of Methods of Analysis and Sampling Plans for Provisions in Codex Standards (CCMAS).

PROPOSALS FOR NEW WORK

CAC 41 approved the following proposals for new work recommended by Codex committees:

- Standard for Yams (CCFFV)
- Standard for Onions and Shallots (CCFFV)
- Standard for Berry Fruits (CCFFV)



- Development of Guidance on use of Simplified Nutrition Information on the Front of Pack (CCFL). Consistent with CCFL recommendations, the focus of this work will be on voluntary guidelines that provide clear, transparent, science-based guidance to governments, industry, and consumers. It will not attempt to establish a specific global scheme of front-of-pack nutrition labelling.
- Code of Practice for Food Allergen Management for Food Business Operators (Codex Committee on Food Hygiene/CCFH)
- Code of Practice on Guidance for the Management of (Micro) Biological Foodborne Crises/Outbreaks (CCFH). Representatives from FAO and WHO questioned the added value of the work, which was originally proposed by the EU, but CAC 41 approved the CCFH recommendation to undertake new work, based on broad support from member countries.
- Priority Lists of Substances Proposed for Evaluation (CCFA, CCRVDF, and CCPR)
- Amendment of the Guidelines on Measurement Uncertainty (CCMAS).

CODEX COMMITTEES WORKING BY CORRESPONDENCE

Non-Centrifuged Dehydrated Sugar Cane Juice - Codex Committee on Sugars (CCS) -

Although CCEXEC73 (2017) and CCEXEC75 (2018) had recommended the Codex Committee on Sugars discontinue work on the standard for non-centrifuged dehydrated sugar cane juice/panela, due to lack of consensus on fundamental aspects, the CAC agreed to extend the work by correspondence for another year. This was primarily due to requests from Latin American countries, who indicated that there was high consumer demand for this product. The Chairperson suggested the possibility of a physical meeting to resolve outstanding issues.

Standard for Quinoa - Codex Committee on Cereals, Pulses and Legumes (CCCPL)

The standard was adopted at Step 8 with further work required on moisture content and grain size, as well as testing methods for the determination saponin content. An electronic working group, chaired by Costa Rica and co-chaired by Chile and the United States, will conduct this work. It is noteworthy that this Committee, working by correspondence, was ahead of schedule in completing work on the standard.

PROPOSAL FOR A CODEX COMMITTEE ON STANDARDS ADVANCEMENT (CCSA)

A considerable amount of time was devoted to discussing perceived problems encountered by committees working by correspondence (no longer holding physical meetings), and to the Secretariat's proposal for a pilot for a Committee on Standards Advancement (CCSA). The CAC agreed that when work is approved for a committee that is not holding physical meetings, flexibility is needed in determining how best to accomplish the work, and that decisions about the work need to be made on a case-by-case basis. The CAC acknowledged that the rules for working by correspondence should not be any different from those applicable to other committees.

In an effort to assist committees working by correspondence and expedite their work, the CAC requested the Codex Committee on General Principles (CCGP) to formulate guidance for committees working by correspondence based on, and consistent with, the existing guidance in the *Procedural Manual*, and directed the Secretariat to prepare and circulate a paper for discussion well in advance of the planned 2019 CCGP meeting.

With respect to the proposal to pilot a CCSA, CAC agreed that currently there were no candidates for such a pilot program, and to await the outcomes of the CCGP guidance before pursuing this option.

CODEX TRUST FUND

The current Codex Trust Fund focuses on in-country capacity building for more effective participation in Codex, with less emphasis on developing countries' attendance at Codex meetings than the original Trust Fund. Due to time constraints, the Trust Fund administrator limited her remarks to announcements regarding the deadlines for the next round of applications and the need for additional contributions. In response to a question from an observer group, she also emphasized that the Codex Trust Fund does not accept contributions from the private sector.

FAO/WHO SCIENTIFIC SUPPORT TO CODEX (REPORT ON ACTIVITIES)

The importance of scientific advice to Codex work was emphasized by the member countries, who noted that the lack of funding for the expert bodies could negatively impact the work of Codex. Members were in general agreement that sustainable funding should come from the core budgets of FAO and WHO. The WHO representative strongly urged



member countries to speak with their representatives in the WHO governing bodies to highlight the importance of food safety and Codex work.

In an effort to ensure sustainable funding for FAO's work relating to scientific advice for Codex, the 159th Session of the FAO Council (June 2018) agreed that a blind trust fund (BTF) for scientific advice should be established. The BTF would require safeguards for the independence and impartiality of the joint FAO/WHO scientific advice program. The FAO Council also stated that although currently no funds were available from FAO's unspent balances, the recommendations regarding the use of funds from this source to support Codex scientific advice remained valid for future consideration, should unspent balances become available.

ELECTIONS

CAC41 41 re-elected the current officers by acclamation: Mr. Guilherme Antonio da Costa of Brazil as chair and Purwiyatno Hariyadi of Indonesia, Mariam Eid of Lebanon, and Steve Wearne of the United Kingdom as vice chairs.

OTHER BUSINESS

Management of CAC Sessions

There was little time for consideration of "other business" at this CAC session. Cuba in particular complained that topics suggested under "other business" had received little consideration, despite a night session that went until after 10 pm, and suggested that side events had taken time away from the CAC's agenda. The Secretariat responded that more time had been dedicated to plenary discussion than in past CAC sessions, and that side events had not reduced the time available for plenary discussion.

World Food Safety Day

The Commission was informed that the FAO and WHO would convene an International Food Safety Conference in 2019. Member countries were also asked to support the adoption of a resolution before the United Nations General Assembly to establish a World Food Safety Day on June 7, 2019.

Endocrine Disruptors

The delegation from India issued a Conference Room Document (CRD 4) highlighting potentially serious trade issues relating to EU policies on chemicals identified as endocrine disruptors. India requested that the CAC recommend CCPR undertake new work on this issue. Although many countries, including the United States, sympathized with India and agreed that this issue had real potential to result in trade disruptions, they did not support directing CCPR to undertake new work and noted that the issue was currently being discussed in the World Trade Organization Committee on Sanitary and Phytosanitary Measures. The Commission noted that India could resubmit its proposal to CCPR based on the revised paper it had prepared.

NEXT SESSION

The next session of the Codex Alimentarius Commission (CAC42) will take place in approximately one year's time, in Geneva, Switzerland, and will be preceded by a session of the Codex Executive Committee (CCEXEC77).