



## Report Of The United States Delegate 33rd Session of the Codex Alimentarius Commission

Delegates to the 33rd Session (2010) of the Codex Alimentarius Commission (CAC) held July 5-9, 2010, in Geneva, Switzerland, had substantive discussions on all the agenda items. This was a shortened session, with only three days of plenary scheduled, and as a result, two evening sessions were necessary.

The results of the meeting were mixed from the perspective of the United States. The Commission made key decisions on the adoption of Codex standards, approval of new work, and operating policies and procedures that were consistent with U.S. positions. Discussions occurred on strategic issues including the participation of developing countries in the work of Codex, the future of the Codex Trust Fund, and the operation of the Codex Secretariat.

However, for the third consecutive year, the Commission failed to adopt a maximum residue level (MRL) for the animal drug ractopamine. The European Union and China led the opposition, while the United States was a proponent for adoption of the MRL on the basis of the extensive scientific reviews demonstrating its safety. The U.S. was supported by a number of countries representing all regions of the world.

The Commission also established a time-limited Ad Hoc Task Force on Animal Feeding, although the United States went into the meeting favoring the assignment of animal feed work to existing Codex Committees.

The Commission was attended by 471 delegates from 120 Member countries, 1 member organization (the European Union), and 37 international intergovernmental or non-governmental observer organizations. The United States was represented by the U.S. Delegate, Ms. Karen Stuck, Manager, U.S. Codex Office; the U.S. Alternate Delegate, Dr. Michael Wehr, Codex Coordinator for the FDA Center for Food Safety and Applied Nutrition; and 13 government and 8 non-government advisors.

The full report of the 2010 Session can be found in ALINORM 10/33/REP on the Codex Web site, [www.codexalimentarius.net](http://www.codexalimentarius.net).

### Election of Officers and Members of the Executive Committee

Dr. Karen Hulebak of the United States was re-elected as Chair of the Codex Alimentarius Commission. Three Vice-Chairs were also re-elected: Mr. Sanjay Dave, India; Mr. Ben Manyindo, Uganda; and Mr. Knud Ostergaard, Denmark.

### Decisions on Standards

#### Additives

The Commission adopted approximately 120 provisions for the use of various food additives. Several countries, including the European Union, filed reservations on several of the additive provisions. The United States noted that cyclamates and Ponceau 4R are not approved for use in this country, but did not object to adoption of the Codex standards in respect of the Codex process, which includes scientific evaluation of the safety of the compounds. The Commission decided to delay adoption of Ponceau 4R pending completing of additional scientific studies that are underway.

The delegation of Korea, supported by the United States, objected to the frequent use of "Note 161" in Codex Additives provisions. The note ("in accordance with the legislation of the country of retail sale") accompanies a number of the Codex standards for food additives and has raised concern because it appears to permit countries to ignore the standard without presenting a scientific rationale. The Codex Committee on Food Additives has established a working group to prepare proposals for criteria and conditions for use of Note 161.

#### Pesticides

The Commission adopted 217 MRLs for 21 pesticides used on various food commodities. Also approved was a U.S. proposal for a pilot project aimed at encouraging global harmonization of MRLs for pesticides. Under the pilot, the Joint Meeting on Pesticide Residues (JMPR), which provides scientific advice to Codex, would conduct an independent, parallel review in conjunction with a global joint review team and would recommend MRLs before national governments set their MRLs. This would provide a reference for countries to use in setting MRLs. Sulfoxaflor was designated as the pilot project chemical to be reviewed by JMPR in 2011.

#### Apples

After 10 years of work, the Commission completed work on a Standard for Apples. The United States led a work group in 2009 that facilitated approval of the standard by the Committee on Fresh Fruits and Vegetables. Several



countries, including India, Colombia, Egypt, Malaysia, and Thailand expressed reservation to the decision of the Commission to adopt the standard.

#### Processed Cheese

The Codex Committee on Milk and Milk Products (CCMMP) has been working on a general standard for processed cheese to replace a number of existing out-dated standards (*General Standard for Processed Cheese and Spreadable Cheese*, *General Standard for Processed Cheese Preparations*, *General Standard for Variety Processed Cheese and Spreadable Processed Cheese*) dating back to 1978. In spite of lengthy discussions in CCMMP over the past five sessions of the Committee, no consensus could be found regarding the proposed new general standard due to the wide variety of processed cheeses produced globally and significantly different national norms for these products. CCMMP concluded at its last Session (2010) that progress could not be made and recommended discontinuation of work on the standard. It was also recommended that, due to their old and out-dated nature, that the original standards adopted in 1978 be revoked.

A number of delegations, including many from Latin America and Africa, expressed concern regarding the revocation, noting the need for a standard for this product type. These delegations also objected to the discontinuation of the old standards if no new standard was to take their place. The Chair of CCMMP suggested that, as a way forward, discussion on the feasibility of a standard for processed cheese be conducted in relevant Codex Regional Coordinating Committees with proposals and recommendations guiding the Commission to decide if and how progress on the development of the new general standard could be made. As an alternative approach, it was proposed that CCMMP continue work by correspondence on the new general standard; however this proposal was not supported because it was considered unrealistic to advance a subject as difficult as this by correspondence when no agreement had been reached in a regular physical meeting.

After significant discussion, and noting the importance to countries of an international standard for processed cheese, the Commission agreed to defer the decision on this matter until its next Session. The Commission further agreed to request pertinent Regional Coordinating Committees (CCAFRICA, CC Latin America and the Caribbean, CC Near East) to discuss the necessity and scope of regional standards for processed cheese and report their findings back to the 34th (2011) Session of the Commission. Based on the findings and recommendations of the coordinating committee, the Commission would decide on discontinuation of work.

#### Ractopamine

The Commission spent several hours addressing the MRL for ractopamine in pork and beef, which had been held at Step 8 of the process at the last session pending a review of new data from China. The result was a decision to continue holding the MRLs at Step 8 while a "Friends of the Chair" group works on a resolution to be presented at the next Commission meeting. The group includes the United States, Canada, European Union, Norway, South Africa, Ghana, Mexico, Brazil, China, Japan, and Tunisia with Consumers International and the International Federation for Animal Health as observers.

This decision followed discussion during the plenary as well as lengthy intra-session meetings in an effort to craft a compromise solution. The Secretariat of the FAO/WHO Joint Expert Committee on Food Additives, which provides scientific advice to Codex, said that three additional studies by China had been reviewed as well as an additional experimental study on ractopamine residues in pig tissues that was submitted by China in May 2010. The Secretariat informed the Commission that the JECFA meeting had concluded that the recommended MRLs were compliant with the Acceptable Dietary Intake (ADI) with regard to pig tissues of muscle, liver, kidney and fat. No additional health concerns were identified by JECFA. It was the opinion of the expert group that the only possible source that that could lead to consumption of residues above the ADI was lung tissue, if considerable amounts of the tissue were consumed on a regular basis. Based in part on this conclusion, China opposed adoption of the other MRLs until further study was completed on lung and other offal, which are consumed in China at a higher rate than in other parts of the world.

The European Union opposed adoption of the ractopamine MRLs because the drug is banned for use in the EU. The EU sought a footnote for the MRLs limiting their scope to countries where marketing had been authorized by the government.

The United States, Canada, Australia, Saudi Arabia, South Africa, Brazil, Mexico, and several other countries supported adoption of the MRLs noting that the scientific reviews demonstrated safety of the drug and that the Codex process had been followed. Furthermore, the United States and others argued that the addition of the footnote as favored by the EU would have the effect of allowing the EU to avoid its obligations under the World Trade Organization's Sanitary and Phyto-Sanitary (SPS) Agreement. The SPS Agreement establishes Codex standards as reference points, and countries that adopt stricter standards must justify them on a scientific basis.



#### Other Standards

The Commission completed, with little or no discussion, final adoption of the following standards:

1. Annex on Fresh Leafy Vegetables including Leafy Herbs (Annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables)
2. Code of Practice for Fish and Fishery Products (sections on lobsters and crabs and relevant definition)
3. Code of Ethics for International Trade in Foods
4. Maximum levels for Melamine in Food and Feed Products
5. Principles and Guidelines for the Conduct of Assessments of Foreign Official Inspection and Certification Systems
6. Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* spp. in Seafood
7. Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish
8. Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Food
9. Methods of Analysis for Natural Mineral Waters
10. Principles and Criteria for legibility of Nutrition Labeling
11. Standard for Bitter Casava
12. Standard for Sturgeon Caviar
13. List of Analytical Methods for Dietary Fiber
14. Maximum levels for total aflatoxins in shelled, ready-to-eat Brazil nuts and shell, destined for further processing Brazil nuts
15. Amendments to the International Numbering System for Food Additives
16. Revision to the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts

#### Approval of New Work

The Commission approved, largely without debate, the following proposals for new work:

1. Standard for Pomegranate
2. Amendment of the General Principles for the Addition of Essential Nutrients to Foods
3. Revision of the Codex Guidelines on Formulated Supplementary foods for Older Infants and Young Children
4. Revision of the International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters
5. Revision of the Principles for Establishment and Application of Microbiological Criteria for Foods
6. Maximum levels for Deoxynivalenol (DON) and its acetylated derivatives in cereals and cereal-based products
7. Maximum levels for aflatoxins in dried figs
8. Establishment of label claims for sugars, salt/sodium, and trans-fatty acids
9. Organic aquaculture
10. Establishing a definition for nutrient reference values

#### **Consideration of the Impact of Private Standards**

Considerable time was allocated to a discussion, in which developing countries were the primary participants, of a paper prepared by FAO, *Consideration of the Impact of Private Standards*. The FAO representative noted that private standards have been around for a long time and are now a major influence on both developed and developing countries. Many of the developing countries questioned the legitimacy of private standards. Among the concerns expressed were that these standards were too prescriptive, and that their proliferation could diminish the role of Codex. They also believed that the standards were not based on science and tended to raise the price of foods. They believed that private standards did not take into account the realities and difficulties faced by developing countries. They noted that the negative effects of private standards were felt most strongly by small producers and urged Codex to find ways to limit the impact of private standards. The Chair reminded the Members Countries that while trade should ideally be based on a public standard, private standards were a reality.

It was universally agreed among Member Countries that private standards should harmonize with the Codex standards and the Codex standards should remain the preeminent food safety standards.

The FAO representative stated that private standards could be compatible with Codex. She acknowledged that in order for private standards to be effective, the standard setters have to work very closely with the producers and when this did not happen there were problems meeting the private standard. She recognized that while private standards did present challenges, there were solutions to the problems and encouraged the delegates to remain vigilant in searching for them. She reminded the delegates that standards weren't static and stressed that no one should read into the report an implication that Codex should be emulating private standards.

#### **Speed of Standard Setting**

In response to a request from the Commission, the Secretariat prepared a paper summarizing the standard setting



activities for each Codex Committee from 1994 - 2008. The Secretariat concluded that, during the period, it took an average of 4.2 years to finalize a Codex text and 3.5 years for texts dealing specifically with food safety issues. This, they maintained indicated that Codex worked more quickly than was generally thought.

In noting the discrepancy between the committees in terms of their efficiency and output, the United States suggested that further analysis could be done to determine the reasons for these differences and whether or not some committees could adopt the good management practices exhibited by other committees to expedite their work. This led to a discussion of issues that hold up committee work, the focus of which became "national legislation issues"; that is, some countries block adoption of a Codex standard because of their own legislation and not because of scientific information. Members expressed concern that because the Commission was not successful in adopting MRLs -- due to national legislation issues -- data owners were reluctant to submit data to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) for review by JECFA, with the eventual result that Codex would no longer be able to set MRLs. Some members suggested that the delegates to CCRVDF be encouraged to adhere to Item IV in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which other Factors Are Taken Into Account*, which suggests that Members can abstain from accepting a standard without necessarily preventing Codex adoption.

#### **Chair's Proposal for Physical Work Groups**

In a follow up to a meeting of the Codex Committee Chairs in April 2010, the Executive Committee discussed concerns that have arisen regarding physical work groups, primarily those relating to the overall number of participants, and, at the same time, the lack of participation by developing countries. It was felt that the large number of participants-sometimes as many as 50 or 60-resulted in the work group being difficult to manage and inefficient. Among the options for resolving these problems was to limit participation in the work groups to two or three experts from each region and the use of facilitators. In response to several questions, including those related to the determination of regional experts and the inclusion of observers, the Codex Chair acknowledged that many issues would have to be worked through before new guidelines could be put into place.

It was emphasized that any new guidelines pertaining to work groups would not replace the existing ones found in Codex Procedural Manual, but rather would provide Chairs with options. Furthermore, it was acknowledged, that the goal of the new guidelines, would be to improve the transparency and inclusiveness of the work group.

The Executive Committee agreed that a survey of the Committee chairs regarding their experiences with physical work groups should be conducted, and the matter would be referred to the regional coordinating committees for discussion. Ordinarily, this matter would be referred to the Codex Committee on General Principles (CCGP), but as the CCGP will not meet until 2012, it was decided that, taking into consideration input from the Chairs and regional coordinating committees, the Codex Chair, Vice Chairs, and other interested parties would prepare a paper for consideration by the 2011 Executive Committee. The recommendations from the 2011 Executive Committee would be presented to the Commission and then referred to the CCGP for consideration at its 2012 meeting.

#### **Timely Distribution of Documents**

The issue of timely distribution of documents was raised during a discussion of the capacity of the Codex Secretariat. Several Member Countries expressed dissatisfaction over the late receipt of Codex documents in the Spanish language, and described how difficult this made developing a national position and otherwise preparing for Codex meetings. However, it was noted by other Member Countries that this problem was not limited to Spanish language documents and that at several recent Codex meetings, documents were distributed at the very last minute in all languages.

The Secretariat offered several explanations, ranging from translation problems to failure to receive the necessary information to complete the documents. The Representative from FAO expressed concern over the failure to distribute documents in a timely manner. He indicated that FAO, as a parent organization, did not want the Codex Member Countries to suffer from what may be a lack of resources in the Codex Secretariat. He indicated that he would review the situation to see if the Secretariat was adequately staffed.

#### **Future Work on Animal Feeding**

Following adoption in 2004 of the *Codex Recommended Code of Practice on Good Animal Feeding*, developed by an Ad-Hoc Intergovernmental Task Force on Animal Feeding, the Commission has continued to discuss the need for additional work on animal feeding. The discussions have been marked with very little consensus as to how to move forward.

At the 32nd (2009) Session of the Commission, an electronic working group was established to carry out three specific tasks: (i) review existing Codex texts on risk analysis principles as to their applicability to animal feed; (ii) review Codex texts on emergency situations and the exchange of information on rejected food as to their applicability



to animal feed; and (iii) propose suitable mechanisms for addressing three remaining items proposed by a prior electronic working group reporting to the 32nd Session of the Commission. Those items were: (1) development of guidelines for governments on the application of risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients; (2) development of a prioritized list of hazards in feed and feed ingredients for governmental use; (3) establishment of criteria for the global identification and notification of emergency situations affecting feed.

With respect to items (i) and (ii), the working group made several recommendations for changes to existing Codex texts to include feed within the scope of the documents. The working group also recommended including an overarching statement in the Codex Procedural Manual to clarify that Codex texts applied to both feed and feed ingredients as they impact on food safety. The Commission expressed mixed views on these proposals and ultimately agreed to refer the proposals to the relevant committees (CCGP, CCFA, CCCF, CCPR, CCRVDF, CCFICS) for review. The Commission also agreed to request CCGP to ensure consistency of the risk analysis texts after they are reviewed by the relevant committees.

With respect to item (iii), a suitable mechanism to carry out the three remaining work items (see items 1-3 above), the Commission could not reach consensus in the plenary, so used an intra-session working group to attempt to reach a suitable approach both as to the disposition of the three items and the mechanism to carry out the work.

The Commission reached consensus that work item 3 (discussion on establishment of criteria for the global identification and notification of emergency situations affecting feed) should be referred to FAO and WHO, and they agreed to take on this responsibility.

With regard to the two remaining items, the Commission had an extensive discussion on the merits of either having them carried out by a time-limited task force or having them handled by the existing Codex Committee structure. The Commission considered many options; placing the work within CCRVDF, which was proposed by the United States and supported by a number of countries; placing the work within CCCF; or placing the work in various committees including CCRVDF, CCCF, CCPR, CCFH.

Those favoring a task force noted the integrated and holistic nature of this approach, the ability to bring together feed experts, and prior favorable experience with Codex task forces. Those opposed noted resource implications for the Codex Secretariat and Member Countries, difficulties in participating in another Codex body, particularly for developing countries, and the need to have a permanent forum to address feed issues.

After prolonged discussion in the plenary, the United States, in order to move the issue along, proposed a time-limited Task Force with narrow terms of reference, specifically to work on items 1 and 2 above. The proposal was adopted with the Task Force authorized for two sessions beginning in 2011, with an option for a third session. Switzerland agreed to host the Task Force, noting that it was willing to consider co-hosting one session with a developing country.

In line with a U.S. proposal, the Commission also noted that relevant Codex Committees (e.g., CCRVDF, CCCF, CCPR) would continue to be responsible for the specific work assigned to them in the area of animal feeding; that is, work on animal feeding other than the items assigned to the Task Force, both for the present and for long term, would be handled by the pertinent Codex committee.