



**REPORT OF THE UNITED STATES DELEGATE  
TO THE 50<sup>th</sup> SESSION OF THE  
CODEX COMMITTEE ON FOOD HYGIENE**

**NOVEMBER 12-16, 2018  
Panama City, Panama**

The 50<sup>th</sup> Session of the Codex Committee on Food Hygiene (CCFH50), chaired by Dr. Emilio Esteban, USDA Food Safety and Inspection Service, was attended by participants from 55 member countries, one member organization (the European Union (EU)), and 15 international intergovernmental and non-governmental organizations, including the World Health Organization (WHO) and the UN Food and Agriculture Organization (FAO). The United States was represented by the Delegate, Ms. Jenny Scott, FDA Center for Food Safety and Applied Nutrition; Co-Alternate Delegates Dr. Bill Shaw, USDA Food Safety and Inspection Service, and Dr. Andrew Yeung, FDA Center for Food Safety and Applied Nutrition; 6 government advisors; and 3 non-government advisors.

The session opened with comments from Eduardo Carles, the Minister of Agriculture, Panama; Eric Ulloa, the Vice Minister of Health, Panama; Ms. Anita Katial, Regional Agricultural Counselor of the U.S. Embassy in San Jose, Costa Rica; Ms. Mary Frances Lowe, U.S. Manager for Codex Alimentarius, USDA; and Ms. Sarah Cahill, Senior Food Standards Officer of the Codex Alimentarius Commission. The importance of Codex in protecting the health of consumers and ensuring fair trade practices was emphasized, and speakers expressed appreciation to Panama for co-hosting the meeting, which was the 50<sup>th</sup> session of CCFH.

This year's meeting did not fully meet the United States' objectives for the meeting, as some documents did not progress as had been hoped (the revision of the *General Principles of Food Hygiene* (GPFH) and the sampling plans for histamine in seafood did not move forward). On the positive side, the document on management of food allergens, co-chaired by Australia, the United Kingdom (UK) and the United States, which was only begun following last year's meeting, was sent to the Commission for adoption at Step 5 (there will be another round of comments and committee consideration). The amendments to the Code of Practice for Fish and Fishery Products on histamine control were sent for final adoption at Step 5/8. CCFH also agreed to take up new work proposed by the United State on Shiga toxicogenic *E coli* (STEC), to be co-chaired by the United States and Chile.

**HIGHLIGHTS**

The 50<sup>th</sup> Session of CCFH:

- Agreed to forward the Draft *Code of Practice on Food Allergen Management for Food Business Operators* to the 42<sup>nd</sup> session of the Codex Alimentarius Commission (CAC42) for adoption at Step 5. (There will be another round of comments and committee consideration at this step.)
- Agreed to forward to CAC42 the project document "Development of Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Beef Meat, Leafy Greens, Raw Milk and Cheese Produced from Raw Milk, and Sprouts" for approval as new work.
- Agreed to establish an electronic working group (EWG), led by the UK and co-chaired by France, Ghana, India, Mexico, and the United States, to continue updating the *General Principles of Food Hygiene* (including HACCP) for consideration by the 51<sup>st</sup> session of CCFH (CCFH51) in November 2019.
- Agreed that the newly adopted histamine control guidance should be in a new section of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) and to forward for final adoption by

CAC42 at Step 5/8 the amendments and editorial corrections in CXC 52-2003 that were needed for consistency with the histamine control guidance adopted by CAC41 earlier this year.

- Agreed to postpone work on the sampling guidance in the commodity standards for fish and fishery products (CXC 52-2003) at least until the Codex Committee on Methods of Analysis and Sampling completes its amendments to the *General Guidelines on Sampling* (CXG 50-2004).
- Agreed to establish an EWG to revise the document on management of microbiological foodborne outbreaks/crises (Revised title: Proposed Draft Guidance for the Management of Biological Foodborne Outbreaks), with Denmark, Chile, and the European Union (EU) as co-leads.
- Agreed to establish an EWG chaired by the United States and Chile for development of draft guidelines on control of Shiga toxicogenic *E. coli* (STEC) in beef meat and leafy greens (and subsequently for raw milk and cheese produced from raw milk and for sprouts) for consideration at CCFH51 (pending acceptance of the new work by CAC42).

The United States organized this year's side event to celebrate the 50<sup>th</sup> session of CCFH, a panel discussion titled "Fifty Years of CCFH: The evolution from a hazard-based to risk-based approach and beyond." Panelists included Karen Hulebak, past chair of CCFH (2003 – 2007); Emilio Esteban, current, and longest serving, chair of CCFH (2008-present); Wayne Anderson, Ireland; Kimutai Maratim, Kenya; Gabriel A. Conte G, Panama; Jenny Scott, United States delegate; and Jeffrey LeJeune, FAO. The panel was moderated by Hajime Toyofuku, Japan. The panel included discussions on the challenges the Committee encountered in adopting a risk-based approach in its work and the relevance of JEMRA (the Joint Expert Meetings on Microbiological Risk Assessment) to the Committee's work. Representatives from different countries discussed how risk analysis is used in their countries and there was a brief discussion on where we expect the Committee's work to take us in the next 50 years. The panel members presented personal experiences with CCFH and how it had changed during their years of involvement with the Committee.

A summary of the meeting of the 50<sup>th</sup> Session of CCFH is given below. The final report of CCFH50 will be posted on the Codex Website, <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFH&session=50>.

### MEETING SUMMARY

#### **PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969) AND ITS HACCP ANNEX**

The *General Principles of Food Hygiene* (GPFH) is the foundational document of CCFH, begun at the first session of CCFH in 1964 (with the United Kingdom and the United States leading the effort); because of the 50<sup>th</sup> anniversary, CCFH49 (2017) had expressed a desire to accelerate the timetable for the document in order to deliver a final draft at CCFH50. Alas, that was not to be, despite the UK chair preparing a Conference Room Document (CRD) to address country comments received prior to CCFH50, a physical working group (PWG) chaired by the UK the Sunday prior to the session, and several meetings by the EWG chairs during the session to resolve issues.

The PWG focused on several areas related to the eight questions in the draft GPFH circulated for country comments; (1) the issue of food business operators (FBOs) having to review hazards/ conduct a hazard analysis; (2) the use of the term "sanitation;" (3) where to address validation (Principle 3 on critical limits or Principle 6 on verification); (4) definitions, in particular those for water types (e.g., potable, clean); (5) hand washing; and (6) retention of the GHP/HACCP comparison table and decision tree.

The UK presented the report of the PWG, found in CRD2, to plenary.



Hazard analysis. Some countries and the EU supported specifying the need for all FBOs to conduct a hazard analysis and not introducing the term “review of hazards,” since a hazard analysis could be carried out “in a simple way.” Other countries indicated that the term “hazard analysis” implies the same hazard analysis as conducted in developing a HACCP plan, which would not be needed by all FBOs. CCFH49 had agreed that all FBOs should “be aware of hazards associated with their businesses and the control measures required to manage these hazards.” This did not require conducting a hazard analysis or a “review of hazards” (which was a new term that would need further explanation if used). The Committee supported the PWG recommendation to not introduce the term “review of hazards” and to clarify in the text how FBOs become aware of hazards. CCFH50 reaffirmed the previous position that effective implementation of GHPs will be sufficient for some businesses to address food safety, and that HACCP was not always needed.

Sanitation. Because the term “sanitation” presents issues when translated, the Committee agreed to the PWG recommendation to substitute “cleaning and disinfection” in places where the term “sanitation” is used in the document.

Validation. There was a strong desire to not change the wording of the principles. The consensus was that Principle 3 should read “establish critical limits” and not “determine and validate critical limits,” but the explanatory text for that principle could discuss validation of the critical limits. The general view was that Principle 6 should be kept as straightforward as possible, so it was suggested to retain the current text in the Principle, i.e., “establish procedures for verification to confirm that the HACCP system is working effectively,” but to discuss the need for validation at the appropriate section of the text.

Water. FAO provided the PWG with a brief overview of an expert consultation on water, which was currently coming to completion, in which the concept of water as having to be “fit for purpose” has been developed. The PWG agreed in principle to accept this overarching approach for water, which meant that the different types of water would not have to be defined within the text. The Committee agreed to define water as “water, including ice and steam, which is fit for purpose and that does not compromise safety and/or suitability of the food.” According to FAO, “purpose” relates to “intended use” and “fitness” is determined by a risk assessment for each specific purpose. The paragraphs on water in the draft document will be re-considered at CCFH51 (2020) after the report of the FAO/WHO Expert Meeting on the “Safety and Quality of Water Used in Food Production and Processing” becomes available.

Hand washing. The UK Chair noted at the PWG that the paragraph on hand washing was far more prescriptive than the rest of the document. It was agreed that the principle of ensuring that hands should be washed and dried in a manner that would not cause recontamination should be simply stated.

Comparison table and decision tree. The Committee agreed to move the comparison table and the decision tree into annexes. They will be updated for CCFH51 to reflect the text. If necessary, annexes can move forward separately from the main text.

The Committee agreed to use the term “greater focus” for Good Hygiene Practices (GHPs) that warrant “greater attention” with respect to monitoring and verification because the GHPs have a greater impact on food safety. The Committee also agreed to retain the definitions of “contaminant,” “contamination,” and “food suitability” and agreed to revised definitions for “disinfection” and “food hygiene system.” Other definitions, such as “acceptable level,” “food business operator,” and “Good Hygiene Practices (GHPs)” need further discussion.

The Committee agreed to return the draft *General Principles of Food Hygiene* to Step 2 for redrafting and to establish an EWG, chaired by the UK and co-chaired by France, Ghana, India, Mexico, and the United States, working in English, Spanish and French, to prepare the proposed draft revision of the GPFH for



circulation for comments and consideration at CCFH51. The Committee agreed to use the text in Appendix 1 of CRD2 as a basis for further development of the document, taking into account the discussions at CCFH50, and to exclude text agreed to by CCFH50 from the request for comments.

The Committee further agreed to establish a PWG, chaired by the UK and co-chaired by France, Ghana, India, Mexico, and the United States, to meet immediately before CCFH51 to consider the comments submitted and prepare a revised document for consideration by plenary.

### **PROPOSED ALIGNMENT OF THE CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS WITH THE NEW CHAPTER ON HISTAMINE CONTROL**

The Committee reviewed the revised *Code of Practice for Fish and Fishery Products* (CXC 52-2003) histamine alignment in CRD7 that the United States and Japan (EWG co-leads) had prepared. The alignment inserted references to the newly adopted chapter on histamine control, added the scombrototoxin histamine hazard at several production steps for different products, and provided additional histamine control guidance for different products where needed. The Committee agreed with the proposed alignment with minor editorial changes, and a change proposed by Norway in a salt fish step. Following adoption, FAO/WHO will publish the Code with the new chapter on histamine control on the Codex website.

### **PROPOSED HISTAMINE SAMPLING GUIDANCE FOR CODEX COMMODITY STANDARDS FOR FISH AND FISHERY PRODUCTS**

The United States and Japan revised the draft sampling guidance (CRD6) before the meeting based on comments received. The Chair noted the Terms of Reference for this work were to develop sampling plans for different purposes that would be practical and feasible while ensuring food safety using a risk-based approach. Morocco strongly opposed the EWG sampling proposal, noting their view that the plan was impractical, costly and unnecessary to ensure safety. Many African countries and some Latin American and Asian countries supported Morocco with prepared statements. The breaking point for the EWG proposal was strong opposition from the EU, which did not participate in the EWG, but commented that only one sampling plan should be used, and that it should be a 3-class plan, like the EU plan. Exporting countries are affected by the EU requirement for histamine testing and supported the EU plan because of its small sample size.

The United States and Japan explained that there were two plans for different purposes, one for suspect lots (e.g., unknown origin, unreliable controls) and one for firms or countries using Good Manufacturing Practices (GMPs)/HACCP, which allowed the EU plan. The Chair reminded the Committee that developing sampling plans for different purposes was the charge to CCFH. Most countries were not interested in different plans for different purposes and criticized the plan for suspect lots because it specified 59 samples. In their opinion, the plan was too stringent and costly, and it could be inferred based on the number of samples that histamine was a serious hazard when histamine was a moderate hazard that rarely caused illness or death. Countries indicated that the guidance on sampling plans for fish where GMPs/HACCP had been applied was ambiguous and would lead to confusion as to an appropriate sampling plan, so the document should focus on a single sampling plan.

The co-leads presented arguments in support of the EWG proposal, such as:

- 1) Scombrototoxin fish poisoning is the most common fish-borne illness in the United States (in fact, in the world).
- 2) The histamine safety limit is near the level causing illness and has no margin for safety.
- 3) The proposed plan for suspect lots (59 samples) will detect one sample unit over the safety limit (with 95% probability) when 5% of the units in the lot are over the safety limit.



- 4) Allowing one sample in 20 (5%) to exceed the safety limit for suspect lots is barely justifiable for a safety hazard in suspect lots (1:10,000 is more typical).
- 5) The plan used by the EU will detect one sample unit over the safety limit (with 95% probability) when one in 3.4 (26%) of the units in the lot is over the safety limit.
- 6) The level of protection can be improved with fewer samples if the limit (“m”) is lowered.
- 7) Rapid testing methods and compositing samples reduces the cost of testing.
- 8) The frequency of testing affects overall cost more than sample size.

Canada, New Zealand, Australia, and perhaps other countries could have supported the sampling guidance if it included more clarity on when each sampling purpose would apply. However, time was limited for histamine during plenary, and the Chair asked for terms of reference for the next electronic working group on sampling plans before revisions prepared by the co-leads and New Zealand that may have advanced the document could be proposed. Japan commented that it might be best to postpone work for a few years because of continued disagreement. The United States supported Japan, noting that perhaps work could continue after the revision of the *General Guidelines on Sampling* (GL50), and the Committee agreed to suspend work. The outcome of suspending work is more favorable than further work leading to adoption of a plan, such as the EU sampling plan, that is unreliable for detecting histamine in high-risk lots.

### **PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS**

Australia introduced the agenda item on food allergen management, noting that the co-chairs (Australia, UK and United States) had prepared a revised proposal in CRD4 that addressed country comments received prior to CCFH50. The main issues to be addressed related to thresholds for allergens, allergen risk assessment methods, and the use of precautionary allergen labeling (e.g., “may contain”). The Committee agreed to most of the revisions and made additional changes/editorial corrections (such as using “prevent or minimize allergens” throughout the text and replacing “risk” with “likelihood” where appropriate).

The Committee supported the use of precautionary allergen labeling provided that such labeling did not replace implementation of measures to prevent or minimize the presence of undeclared allergens. The Committee agreed to seek input from the Codex Committee on Food Labeling (CCFL) with respect to precautionary allergen labeling, including the definition, and put relevant statements in square brackets pending CCFL input. The Committee also agreed to submit food labeling provisions to CCFL for endorsement. In addition, the Committee agreed to seek scientific advice from FAO/WHO (and developed Terms of Reference) related to thresholds and risk assessment to support decisions for allergen management, such as use of precautionary allergen labeling, and validation of cleaning procedures between foods with different allergen profiles.

The Committee agreed to forward the proposed draft code for adoption by CAC42 at Step 5, which will allow for another round of comment. Countries will be able to comment on the document prior to CAC42.

### **PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISES/OUTBREAKS**

In comments submitted prior to CCFH50 on this document the United States (along with a number of other countries) had indicated the need to clarify the scope of the document in order to address the terminology to be used. The United States also expressed concern about the incorporation of a list of



references (14) that included a large number of FAO/WHO documents. Users of the draft guidance would have to search through those documents for relevant information. Moreover, it was unclear whether the incorporation of the references (which were developed using a process much less inclusive than a Codex document) would give them status with respect to the World Trade Organization (WTO) agreements that would be similar to that of a Codex document.

The co-chairs (Denmark, Chile and the EU) had prepared for discussion a revised proposal in CRD10 based on written comments submitted prior to CCFH50. However, they focused instead on getting input in several key areas in order to prepare a revised document.

With respect to references, the Codex Secretariat indicated that references to external documents should be minimized and that relevant information could be incorporated into the text in order to remove references in the final document. The co-chairs proposed, and the Committee agreed, to incorporate relevant information from the references into the text of a revised document.

The Committee agreed to limit the scope of the document to biological foodborne outbreaks and not include situations where food is contaminated but there are no cases of illness. The co-chairs proposed, and the Committee agreed, to use the term “foodborne outbreak” throughout the document and eliminate terms such as “crisis” and “emergency.” A foodborne outbreak was defined as “the observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.” The Committee also agreed to use “rapid risk assessment” rather than “outbreak assessment” in the document and defined a rapid risk assessment as “a risk assessment, based on the information available on the foodborne outbreak, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain full development of the four steps of a classical risk assessment.”

The Committee returned the document to Step 2 for redrafting and established an EWG co-chaired by Denmark, Chile and the EU to revise the document for CCFH51.

## **FUTURE WORK**

The United States and Panama co-chaired the PWG on CCFH Work Priorities (Proposals for New Work and/or Revision of Existing Standards), which addressed the discussion paper on STEC and the Forward Workplan.

### Shiga toxigenic *E.coli* (STEC)

The United States introduced the discussion paper and project document submitted by the United States, Chile and Uruguay on “Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Beef, Unpasteurized Milk and Cheese produced from Unpasteurized Milk, Leafy Greens, and Sprouts” and proposed to develop new guidance based on the FAO/WHO JEMRA report (“Shiga Toxin-Producing *Escherichia coli* (STEC) and Food: Attribution, Characterization, and Monitoring”) that had been commissioned by CCFH47 (2015). The United States discussed the public health burden of STEC across the world, as well as the risk management challenges associated with STEC and trade. According to the data compiled by JEMRA, the most important sources of STEC estimated globally based on outbreak data are produce (13%), beef (11%), and dairy products (7%); dairy products are largely associated with consuming unpasteurized milk and products made from unpasteurized milk. The United States also described the importance of virulence factors described in the JEMRA report and noted that the proposed guidance document would provide guidance to risk managers on how to apply the set of virulence factor



criteria in the JEMRA report for characterizing the potential risk of severe illness (rather than current risk management approaches that use serotyping).

Chile described the proposal for the structure of the guidance document: a chapter structure where the first chapter would be devoted to the characteristics of STEC and its virulence factors, followed by chapters that describe the validated interventions for each commodity at primary production, processing, and distribution, including laboratory analysis detection criteria for STEC according to the JEMRA virulence factor analysis.

The EU expressed concern about this work, indicating that the main source of STEC was fecal contamination, that controls often were not specific for STEC (e.g., they would be similar to controls for *Salmonella* in meat), and that the value of the work was limited since the controls would be similar to those in existing Codex documents. However, a number of countries, in particular countries from Latin America, spoke up to support the work, which could complement existing guidance.

The PWG suggested that to better manage the workload of the Committee the guideline development could take on one commodity at a time. Several delegations suggested beef as the first commodity because of public health and trade issues. The Committee agreed to the proposed structure and that the guidelines should be developed in a step-wise manner, with beef and leafy greens being the first priorities. The Committee also agreed to refer to “raw milk” rather than “unpasteurized milk” to avoid confusion with milk that may have received a thermal treatment but not pasteurization. The specific types of beef meat to be covered will be decided during the drafting of the document.

The Committee requested that the United States and Chile revise the project document to reflect the step-wise approach, including revising the timeline. The Committee agreed to establish an EWG chaired by Chile and the United States to prepare draft guidelines for consideration at the next session.

### Forward Workplan

Panama presented the Forward Workplan. One delegation suggested that because of the large outbreak of listeriosis in South Africa, there may be a need to revise the CCFH guidelines related to the control of *Listeria monocytogenes*. Panama indicated that interested delegations can prepare a project document for this work. The Committee considered the Forward Workplan and agreed to remove the work on control of STEC since it was being submitted to CAC42 as new work. The work on principles for safe water in food processing was evaluated against the criteria for new work priorities and, as a result of the evaluation, moved to the top of the list. Revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007) was added to the Forward Workplan.

In order to progress the work on principles for safe water in food processing, a discussion paper is needed. Honduras, with the assistance of Chile, the EU, India and Denmark volunteered to prepare a discussion paper for consideration at the next session.

The Committee agreed to re-establish the working group on CCFH Work Priorities, which will meet in conjunction with CCFH51 and will be chaired by the United States.

### **NEXT SESSION OF CCFH**

The 51<sup>st</sup> Session of CCFH is tentatively scheduled for November 4-8, 2019, with a location in the United States to be determined.