



Report of the U.S. Delegate, 49th Session, Codex Committee on Food Hygiene

November 13-17, 2017
Chicago, IL, USA

The 49th Session of the Codex Committee on Food Hygiene (CCFH49), chaired by Dr. Emilio Esteban, USDA Food Safety and Inspection Service, was attended by participants from 63 member countries, one member organization (the European Union (EU)), and 15 international intergovernmental and non-governmental organizations, including WHO and 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; six government advisors; and eight non-government advisors.

The session was opened by Ms. Mary Frances Lowe, U.S. Manager for Codex Alimentarius, USDA; she introduced Mr. Ted McKinney, the Under Secretary for Trade and Foreign Agricultural Affairs (TFAA), who welcomed the delegates and emphasized the United States' commitment to science-based decision making in Codex. He noted the connection between food safety and global trade, and that for trade to be successful, we first need to be sure that the commodities traded are safe for consumers. The Under Secretary emphasized that CCFH would not see a change in the United States' dedication to science as the basis for Codex standards. Following Under Secretary McKinney's remarks, Ms. Lowe introduced Dr. Bob Brackett, Vice President, Illinois Institute of Technology and Director of the Institute for Food Safety and Health. Dr. Brackett addressed how food safety impacts both public health and trade in food and agricultural products, and the unique challenges for small and developing economies in addressing food safety.

This year's meeting again took on a different format from previous years, since the Committee focused its work primarily on only two agenda items: the revision of the *General Principles of Food Hygiene* (GPFH) and the new work on histamine directed to CCFH by the Codex Alimentarius Commission (CAC) last year. The United States' objectives for the meeting were met or exceeded, and groundwork was laid for successful progression of the GPFH, as well as future work on Shiga toxicogenic *E coli* (STEC), management of food allergens, and management of microbiological foodborne outbreaks/crises.

HIGHLIGHTS

The 49th Session of CCFH:

- Completed work on histamine control guidance for the *Code of Practice for Fish and Fishery Products* and forwarded the document for final adoption by the 41st Session of the CAC in July 2018 (CAC41).



- Agreed to establish an electronic working group (EWG), led by the United Kingdom 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 50th session of CCFH in November 2018.
- Agreed to establish an EWG, led by the United States and Japan, to address sampling and testing in accordance with terms of reference specified in the final report of CCFH48 and to make changes in the fish code (CXC[1] 52-2003) where needed for consistency with the histamine control guidance.
- Agreed to start new work on management of food allergens, with Australia, the United Kingdom (UK) and the United States as co-leads.
- Agreed to start new work on management of microbiological foodborne outbreaks/crises, with Denmark, Chile, and the European Union (EU) as co-leads.
- Agreed to the United States, Uruguay and Chile as co-leads for development of a discussion paper on Shiga toxigenic *E.coli* (STEC).

The 49th Session of CCFH continued the successful approach of CCFH47 (2015) and CCFH48 (2016) in holding two “Side Events,” including a session on Management of Microbiological Foodborne Outbreaks/Crises and another one on Food Allergens. Both sessions were very well attended and contributed to the understanding of the new work being proposed for the Committee.

The side event on Management of Microbiological Foodborne Outbreaks/Crises was organized and facilitated by the EU. Kris de Smet (DG Sante, EC) provided background for why it would be useful to have Codex guidance on managing foodborne outbreaks/crises. The document is to provide guidance for food safety authorities, in close collaboration with public health authorities, to build a common reference network and approach to ensure preparedness and efficient management of foodborne outbreaks. De Smet provided a preliminary draft of the structure of the document, which would include outbreak detection and investigation tools, alert networks, structures for information exchange, outbreak management, and tracing. Zanne Dittlau (Ministry of Environment and Food, Denmark) emphasized the need to have guidance, using examples of two outbreaks of listeriosis, one in 2014 from lamb rolls and one in 2017 from cold-smoked salmon, to illustrate what could have been done better in the 2014 outbreak and the improved response in the 2017 outbreak. She indicated that there was no single Codex standard covering all aspects of handling a foodborne outbreak. Bob Baker (Mars) concluded the session with an industry perspective on food safety and incident management.

The side event on Food Allergens, organized and facilitated by the United States, began with an overview and the public health issues of food allergens and celiac disease by Dr. Steve Taylor (University of Nebraska). He noted that labeling is critical to successful implementation of avoidance diets and that good hygienic practices are needed to prevent allergen cross-contact, but to fully validate allergen cleaning measures we need to know thresholds (how much is too much?) to determine “how clean is clean enough?” This was followed by a presentation by Dr. Lauren Jackson (US FDA) on cleaning



strategies to remove food allergens and tools for determining efficacy. Dr. Jackson noted that many factors influence the effectiveness of cleaning procedures and that validation of these procedures is important to ensure they are effective. Dr. Brent Kobielush (Cargill) completed the session by describing a comprehensive industry approach for managing food allergens, which includes addressing allergen controls at suppliers, as well as at the manufacturing facility.

A summary of the meeting of the 49th Session of CCFH is given below. The final CCFH report of the session will be posted soon on the Codex Website, <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/en/>.

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, so the EWG that worked on revisions the past year was very large and had diverse opinions in several areas. Moreover, there is interest in accelerating the timetable for the document in order to deliver a final draft at the 50th session of CCFH next year. In order to move the revision of the GPFH forward, the Committee decided to hold an in-session physical working group (PWG) chaired by the United Kingdom (UK). The PWG focused on 4 main areas: (1) how to address primary production in the document; (2) clarification of the use of the terms “food hygiene system,” “food safety system,” and “food safety control system;” (3) the need for all food business operators (FBOs) to conduct a hazard analysis; and (4) the types of control measures applied by FBOs.

Primary Production: The existing GPFH has a section on primary production; however, questions had been raised as to whether primary production should simply be addressed throughout the document to better integrate a farm to fork approach. Some comments submitted by countries supported this approach, while others felt that there needed to be a primary production section, in part because several Codex documents follow the structure of the GPFH and refer to the primary production section. Changes in the basic structure of the GPFH will require consequential changes in several other documents. Moreover, there are certain provisions in the primary production section that do not fit elsewhere. The compromise was to retain the primary production section and to include primary production in other sections where applicable.

Food hygiene system/food safety system/food safety control system: The use of these terms in the document has caused confusion, as there may not have been a clear understanding of the distinctions or consistency in how the terms have been used. The PWG decided to use the term “food hygiene system” when referring to measures for both safety and suitability and “food safety control system” (as defined in the *Guidelines for the Validation of Food Safety Control Systems* (CXG 69-2008)) when referring only to food safety aspects.



Hazard analysis: There were many comments submitted on whether all FBOs should conduct a hazard analysis, with a fairly even split of “yes” and “no,” and much discussion in the PWG. Those who were opposed had concerns that all FBOs would need to conduct a hazard analysis in accordance with HACCP Principle 1, and statements that only a “basic” or “simplified” hazard analysis was needed for some businesses raised issues such as confusion with having two “different” types of hazard analyses and how the two hazard analyses would differ. Some delegations indicated that a hazard analysis should be universal, and that every FBO should do an analysis with respect to the risk their products present. Others indicated that GHPs alone would suffice for many FBOs and a hazard analysis would not be needed. Many comments supported the need for a food business to understand and manage hazards associated with the food they produce but noted that the FBO could obtain this information from sources such as industry and government guidance or government regulations. The PWG decided to explain food business responsibilities without using the term “hazard analysis,” but rather indicate that all FBOs should be aware of hazards associated with their businesses and the control measures required to manage these hazards. The PWG acknowledged that GHP-based systems are enough to control hazards in certain cases and that all FBOs should implement GHPs, which may be standalone or prerequisite programs for more specific control systems such as HACCP.

Types of control measures: There was discussion about the categories of control measures (GHPs, control measures applied at Critical Control Points (CCPs) and control measures that are essential but not applied at CCPs). In the document circulated before the meeting, these last control measures were provisionally termed “enhanced GHPs,” although some comments preferred to use the ISO term “OPRPs.” There was general agreement that these three types of control measures exist, and that the document does not explain them well. An attempt will be made to explain the concept, but not include a name for the control measures essential for safety but not applied at CCPs. There was discussion as to whether these control measures belong in the GHP section or the HACCP section, with several delegations supporting one or the other. Because these control measures address a specific hazard and are identified by a hazard analysis, many delegations believe they are best addressed in the HACCP section. It was pointed out that those who suggest they belong in the GHP section may be influenced by the provisional term “enhanced GHPs.” Some comments focused on whether the control measure could be monitored in “real-time” and the implications of a deviation, with respect to product for distinguishing essential control measures applied at CCPs, and those not applied at CCPs. One delegation and the Chair reminded the group of the intent to keep the document simple, as it is primarily designed for small and less-developed businesses, which simply need to know what they need to do and not what something is called. One delegation argued for flexibility in the implementation of the non-CCP applied control measures, indicating that they may be measures applied by businesses only using GHPs. Ultimately it will be a decision between the FBO and the competent authority as to what is needed to control hazards and to show that the control measures are effective. It was agreed that examples might help with a way forward.



The United States participated in several meetings of the co-chairs for this work during the breaks to summarize the discussion and outline a way forward. The co-chairs also developed draft Terms of Reference for an EWG.

The UK presented the report of the PWG, found in CRD02, to plenary. The Committee agreed to continue work on the revision of the *General Principles of Food Hygiene* and its HACCP annex and to establish an EWG, chaired by the United Kingdom 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 CCFH50. The Committee agreed to use CRD02 as a basis for further development of the document, taking into account the discussions at CCFH49 and the written comments submitted. The EWG will clarify the relationship of the three types of control measures and how FBOs come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.

The Committee further agreed to establish a PWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico, and the United States, to meet the Sunday before CCFH50 to consider the comments submitted and prepare a revised document for consideration by plenary.

The co-chairs have agreed to have monthly meetings, some virtual and some physical, with one physical meeting to be open to other EWG members (similar to last year's meeting in Canada).

PROPOSED DRAFT GUIDANCE ON HISTAMINE CONTROL

Japan, as co-chair with the United States, introduced this new section on guidance for histamine control for the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), noting the focus on fishing vessels as the key control point for control of histamine formation. The co-chairs had prepared a revised proposal (CRD06) based on the comments submitted, as a starting point for discussions at CCFH49. The revisions make clear that HACCP is not required on fishing vessels, but that applying HACCP and documenting histamine control will provide greater consumer protection.

The Committee agreed to most of the revisions and made a number of additional changes to provide clarity and flexibility. Some of the changes inserted points made in the *FAO/WHO Joint Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products* (FAO/WHO Joint Expert Meeting report). One area of controversy was a statement that freshly harvested scombrototoxin-forming fish typically have histamine levels below 2 mg/kg and that business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg. Brazil and Senegal expressed concern that keeping this bullet would cause confusion and that the 15 mg/kg would be considered the acceptable limit. To address the concerns, Japan inserted a sentence indicating that the receiving establishment should establish the acceptable histamine level for incoming fish and the text with the histamine levels was

moved to a footnote that attributed the statement to the FAO/WHO Expert Meeting Report.

The most contentious issue was whether to include Salmonidae in the list of species at risk for histamine formation. There had been much discussion at CCFH48 with respect to the inclusion of Table 2.3 from the FAO/WHO Joint Expert Meeting report, which had been developed to provide comprehensive information as part of the hazard identification step for risk assessment. CCFH48 had agreed to list species associated with histamine formation but was unable to reach consensus on whether to include Salmonidae, although most delegations supported excluding the family (see the report from CCFH48 for additional discussion on this point). As a compromise, the Committee requested that FAO/WHO conduct a literature review on histamine-related illness in Salmonidae for consideration by the working group, as to whether to include Salmonidae in the list of susceptible species. FAO/WHO prepared a report (the FAO/WHO report on Salmonidae) and concluded that there is not a basis for including Salmonidae in the list for reasons that include: the low frequency of confirmed cases of toxicity (1 confirmed case in 40 years with elevated histamine) in relation to the high volume of production, trade, and consumption; the lack of rejections of Salmonidae traded internationally; the significantly lower levels of histidine in Salmonidae compared to scombroid fish; and evidence that the typical bacterial flora associated with histamine development in fish are not always present. However, the FAO/WHO report on Salmonidae does acknowledge that under certain conditions the development of histamine can occur in Atlantic salmon and rainbow trout. Because the report does not conclude that there is an absence of risk of histamine formation in Salmonidae, Morocco strongly supported including Salmonidae in the list of species at risk for histamine formation. Morocco was supported by several other delegations, including Ghana, Mauritania, and Mali, who argued that no matter how small the risk, it is necessary to include Salmonidae in the list of species subject to this guidance. Norway and Chile argued against inclusion of Salmonidae based on the low risk and the conclusions of the FAO/WHO report on Salmonidae; they were supported by Argentina, Uruguay, Brazil, and Mexico.

The United States and Japan met with Morocco one evening to discuss Morocco's concerns on several issues in the document, with the hope of addressing their concerns so the document could be finalized at CCFH49. The United States also had many side discussions during breaks with Norway and Chile to develop a strategy to have a risk-based list of fish that did not include Salmonidae. Norway, Chile, the United States, Morocco and several other African delegations met during a break to try to resolve the Salmonidae issue. A suggestion to delete the list was considered as a possible way forward but rejected, since the absence of a list was not sufficiently informative as to which fish would be subject to the controls for histamine. The United States proposed text that recharacterized the list as the finfish species that present the greatest potential of developing hazardous levels of histamine, rather than simply the risk of developing hazardous levels of histamine. This was supported by Norway, Brazil, Chile, and Mexico. The Chair of CCFH made the point that, as risk managers, CCFH should take a risk-based decision, there is no "zero risk," and including in the list fish such as



Salmonidae that present such a low risk would not be a risk management decision commensurate with risk. Norway agreed with the Chair, noting that we had asked for a literature review from FAO/WHO to help us determine whether to include Salmonidae, and based on the information provided in the FAO/WHO report on Salmonidae it was not appropriate to include Salmonidae. Argentina, France, Trinidad and Tobago, Mexico, Chile, and the European Union (EU) supported this position. Morocco and its supporters, primarily delegations from African countries (Mauritania in particular), continued to take the position that, based on the information in the FAO/WHO report on Salmonidae, as risk managers it was necessary to take risk management measures to control histamine in Salmonidae. After additional discussion, which seemed to point to an impasse, the United States suggested that, since some sections of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) referred to six families associated with SFP, the guidance could include these six families instead of the list. Norway, Chile, Paraguay, Peru, Uruguay, and Mexico supported the proposal. The impasse was broken when ECOWAS (the Economic Community of West African States), Ghana, and Senegal agreed, in the spirit of compromise, to support the U.S. intervention. The Committee agreed to forward the document to CAC41 (July 2018) for adoption at Step 5/8, noting reservations of Morocco and Mauritania about not including Salmonidae. Morocco agreed to modify its reservation to remove the erroneous statements about traces of histamine in fish causing an “allergenic reaction.”

The Committee agreed to establish an EWG, led by Japan and the United States, to identify an appropriate place in CXC 52-2003 to place the guidance, to consider whether consequential changes were needed to other sections of that code as a result of this guidance, and to address the charge to the Committee on sampling and testing related to histamine. Note that the guidance will not be published until the consequential changes to the code, if any, are made and adopted by the Commission.

FUTURE WORK

The United States chaired the PWG on CCFH Work Priorities (Proposals for New Work and/or Revision of Existing Standards). The PWG first discussed the revisions to the *Process by Which the Codex Committee on Food Hygiene Will Undertake its Work* (CRD04). Key changes to the prioritization process were the creation of a single criterion for public health impact by combining two questions and the creation of a stepwise approach to apply the criteria. The PWG agreed with the revision with minor modifications.

Australia introduced the project document submitted by Australia and the United States on a Code of Practice on Food Allergen Management for Food Business Operators. This Code of Practice would address good hygienic practice (GHP) in manufacturing and food preparation practices in food service and complement the revised *General Principles of Food Hygiene* (CXC 1-1969), which will include information on the importance of controlling food allergens. Australia noted that the Codex Committee on Food Labeling (CCFL) is considering new work in allergen labeling and proposed to



develop a discussion paper as an option to allow better alignment with CCFL, and noted this could be discussed later.

The EU presented the project document on Guidance for the Management of Microbiological Foodborne Crises/Outbreaks, noting that the scope of the new work was to provide guidance to competent authorities on the management of foodborne outbreaks/ crises. This project resulted in much discussion, with European delegations considering there was sufficient information in the project document to start this as new work. Other delegations considered a discussion paper to be necessary to allow for better understanding of the gaps in existing guidance/documents; to allow for further evaluation by their countries' agencies involved in outbreak management; and to expand the scope to include the role of food business operators in a foodborne crisis.

The United States briefly discussed the FAO/WHO expert meeting on STEC and the attribution to four main commodities: beef, fruits and vegetables, certain dairy products made with unpasteurized milk, and meat from small ruminants (see Other Matters). Most delegations agreed that the scope of the discussion paper should cover all commodities associated with illness from STEC. This will allow for full evaluation in subsequent discussion of this project at the next meeting.

The delegations gave both of the proposed new projects the highest ranking. The United States, in presenting the report of the PWG, noted that there had been insufficient time to discuss the allergen project. In light of this, Australia stated that although the PWG agreed to a discussion paper for CCFH50, the proposal submitters were willing to start this as new work, which could still be aligned with the work of CCFL.

The Committee agreed that since both projects had been ranked as high priority and the agenda could accommodate new work, both project documents (pending revisions requested by the Secretariat) would be forwarded to CAC41 for approval as new work. The EWG for allergen management will be chaired by Australia and co-chaired by the UK and the United States (These three countries are also involved in developing a discussion paper on allergen labeling for CCFL.) The EWG for the management of foodborne outbreaks/crises will be chaired by Denmark and co-chaired by Chile and the EU.

The Committee agreed to re-establish the working group on CCFH Work Priorities, which will meet in conjunction with CCFH50 and will be co-chaired by the United States and Panama.

OTHER MATTERS

Spices and Aromatic Herbs

The Committee on Spices and Culinary Herbs recommended that CCFH change the name of the Annex on Spices and Dried Aromatic Herbs in the *Code of Hygienic*



Practice for Low-Moisture Foods to refer to “culinary herbs.” The Committee agreed to the change.

Shiga toxigenic *E.coli* (STEC)

FAO provided a report on the second expert meeting held in September 2017. This expert meeting focused on the public health burden and attribution. The FAO/WHO work was undertaken at the request of CCFH47 in preparation for future work in the area. Key findings of the expert meeting indicated that the most important sources of STEC illnesses included beef, vegetables/fruits, dairy (primarily from unpasteurized products), and the meat of small ruminants. The report also recommends the use of virulence factors rather than serotype to assess strains most likely to cause severe illness. FAO noted that there is very little information from some regions such as Africa, but since the report has not been finalized it is not too late for countries to provide additional data on attribution for the report. The representative of the World Organization for Animal Health (OIE) indicated that OIE would consider taking up relevant work in this area based on the outcome of CCFH decisions about new work on STEC. The Committee confirmed that a discussion paper on new work on STEC will be prepared for CCFH50; the discussion paper, which is to focus on the categories of food identified by FAO/WHO as major sources of human STEC illnesses, will be developed by the US, Uruguay, and Chile.

Water Quality

The issue of “clean water” versus “potable water” has come up in several Codex documents, especially with respect to defining “clean water” and determining when it is acceptable to use clean water and when it is necessary to use potable water. CCFH48 had requested that FAO/WHO provide guidance for scenarios where the use of clean water was indicated in Codex texts, in particular irrigation water, clean seawater and the safe reuse of processing water, as a possible way forward in defining the term “clean water.” The expert meeting considered that the quality of “clean water” required context such as the nature of the food being produced/processed, where in the food chain the water is being used, and the nature of any subsequent processing steps. Thus, to connect water quality and its use, the expert meeting applied the term “fit for purpose” and acknowledged that it is not possible to have a universal definition for “clean water.” It is more appropriate to take a risk-based approach to specify water that is “fit for purpose” for water use in Codex texts. Some delegations supported development of a separate document on how to take a risk-based approach to determining whether water was “fit for purpose” for food production and processing, with examples for specific sectors to illustrate the assessment, rather than explaining the concept in each text that refers to water quality. FAO will continue their work and provide additional information at the next meeting. That information could help the Committee make a determination as to whether separate guidance is needed.



NEXT SESSION OF CCFH

The 50th Session of CCFH is tentatively scheduled for November 12-16, 2018 in Panama City, Panama.