REPORT OF THE UNITED STATES DELEGATE ON THE 52nd SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

February 28 - March 4 and March 9, 2022 Virtual

The 52nd Session of the Codex Committee on Food Hygiene (CCFH52), chaired by Dr. Emilio Esteban, Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), had over 600 registered participants from 106 Member countries, one Member Organization (the European Union (EU)), 22 Observer Organizations and Palestine. The United States was represented by the Delegate, Ms. Jenny Scott, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration (FDA); Co-Alternate Delegates Dr. Bill Shaw, Food Safety and Inspection Service, U.S. Department of Agriculture, and Dr. Andrew Yeung, CFSAN-FDA; 4 government advisors; and 6 non-government advisors.

The session opened with comments from Mr. Steve Wearne, the Chairperson of the Codex Alimentarius Commission (CAC); Mr. Tom Heilandt, Codex Secretary, also provided a welcome. Mr. Wearne noted that adaptation to a virtual working environment had facilitated the work of Codex and allowed for increased participation and increased transparency and collaboration; these benefits should be retained as Codex looks forward and renews in-person meetings that foster closer relationships. He recognized the outstanding service of the CCFH Chair, Dr. Emilio Esteban, who has fostered a collaborative and positive spirit that has led to the advancement of consensus-driven and science-based standards. Mr. Wearne's remarks can be found in Conference Room Document (CRD) 27 on the meeting webpage.

The United States' objectives for the meeting were realized, as two key documents were advanced to the 45th Session of the Codex Alimentarius Commission (CAC45) for final adoption (one at Step 8 and one at Step 5/8); the documents are in line with the U.S. commitment to science-based decision making. The "Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts" and the "Draft Guidelines for the Safe Use and Re-Use of Water in Food Production" were both returned for redrafting and further discussion by Electronic Working Groups (EWGs), consistent with the U.S. desired outcome for these documents.

HIGHLIGHTS

The 52nd Session of CCFH:

- Agreed to forward the draft *Guidelines for the Management of Biological Foodborne Outbreaks* to CAC45 for final adoption at Step 8.
- Agreed to forward the draft Decision Tree to the *General Principles of Food Hygiene* (CXC 1-1969) to CAC45 for final adoption at Step 5/8 and subsequent inclusion as Annex 2 to CXC 1-1969.
- Agreed to establish an EWG, chaired by Chile and co-chaired by France, New Zealand, and the United States to revise the draft "Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts."

• Agreed to establish an EWG, chaired by the Honduras and co-chaired by Chile and the EU, to continue developing the draft "Guidelines for the Safe Use and Re-Use of Water in Food Production," for consideration at CCFH53.

A summary of the meeting of the 52nd Session of CCFH is given below. The final report of CCFH52 will be posted on the Codex Website at https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFH&session=52.

NEXT SESSION OF CCFH

The 53rd Session of CCFH is tentatively scheduled for November 28-December 2, 2022, in San Diego, CA.

MEETING SUMMARY

PROPOSED DRAFT GUIDELINES FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

To Be Presented for Adoption at Next CAC? Yes Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? No

United States Objective

The United States objective was to finalize this document at CCFH52 and forward it to CAC45 for final adoption at Step 8.

Discussion in Relation to United States' Objectives

Most of the suggested revisions were for clarification that warranted little discussion of the changes. However, not unusual, there was discussion on several of the definitions, in particular the definition of a "lot" of food. A sentence had been added in CRD2 to the definition for "lot" that indicated the need in an outbreak situation to separate a lot using procedures that avoided the risk of contamination; the United States considered this inappropriate for a definition but had a proposal for where to include the statement later in the document. New Zealand proposed a lengthy addition to the definition to address having a separation between lots by a process, such as cleaning, that prevents contamination from raw materials or the processing environment. This generated discussion and ultimately placing the definition in square brackets temporarily. Ultimately, the last sentence of the definition was captured as a new paragraph in the part of the document that addresses the handling of contaminated food (as suggested by the United States), and the remaining part of the definition was retained without the New Zealand addition.

There was discussion on proposed changes to the definitions of "risk communication" (i.e., the Philippines proposed using the definition in the Codex *Procedural Manual* instead) and "metadata" (i.e., to expand the description, including how metadata are used) but no changes were made, since the proposed definitions were considered appropriate in the context of the document. A proposal to consider a definition of "risk assessor" was not accepted, since the term is widely understood.

In the section on identifying and investigating a foodborne outbreak, India recommended adding "and intoxication" after "infection." This generated significant discussion to clarify that this related to microbial toxins (since chemical toxins are out of scope) and suggestions for consequential changes in other areas. Eventually it was agreed that such specificity was not

needed, as the document was focused on investigating foodborne outbreaks.

In the section on risk communication, Japan expressed concern about a bullet on establishing procedures to identify and address rumors and false information and the practicality of being able to do this. The United States supported inclusion of the bullet – following social media is an important way of finding out what false information is being spread, and social media can be used to counter this. To add flexibility, "where possible" was included in the bullet.

Outcome/ Conclusion

The Committee agreed to forward the *Guidelines for the Management of Biological Foodborne Outbreaks* to CAC45 for final adoption at Step 8.

Other Comments

In discussion on whether to change the definition of "risk communication" to the one in the Codex *Procedural Manual*, the Codex Secretariat indicated (surprisingly) that a definition different from that in the *Procedural Manual* can be used to reflect an understanding of what is in the document, as long as it does not contradict what is in the *Procedural Manual*. This is likely to lead to other definitions that differ from definitions in the *Procedural Manual*.

PROPOSED DRAFT PROPOSED DRAFT DECISION TREE (REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE (CXC 1-1969))

To Be Presented for Adoption at Next CAC? Yes Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? No

United States Objective

The United States objective was to finalize this document at CCFH52 and forward it to CAC45 for final adoption at Step 5/8.

Discussion in Relation to United States' Objectives

The United States had been co-chair of the working group that finalized the revision of the *General Principles of Food Hygiene* (CXC 1-1969) at CCFH51 (2019) that was adopted by CAC43 (2020) at Step 5/8. Although CCFH51 had been unable to agree on a decision tree for determination of critical control points (CCPs) at that time, the Committee agreed to establish an EWG led by Brazil to attempt to find an acceptable decision tree. The United States participated in the EWG that developed the approach presented in CRD3 Rev.1 and, although we had expressed a number of concerns in our comments, decided to support advancement of both the decision tree and the CCP determination worksheet in that CRD given revisions to the specific questions and the chapeau indicating these are examples and that other tools can be used.

There was broad support (especially from delegates of countries with developing economies) to include both the decision tree and the CCP determination worksheet as annexes to CXC 1-1969. Some minor revisions were made for clarification. The delegate from the International Organization for Standardization (ISO) expressed concern about Question 1, which asks about whether the hazard can be controlled to an acceptable level by prerequisite programs such as Good Hygienic Practices (GHPs). Specifically, within GHPs, there are some control measures that are typically seen as CCPs (e.g., adjusting pH or a_W, control measures such as chilling,

cooking, and metal detection) within a Hazard Analysis Critical Control Point (HACCP) approach. ISO felt that by asking Question 1, these control measures will be extracted from a HACCP approach and no longer seen as CCPs. The International Dairy Federation (IDF) also indicated that the use of the term "significant hazard" at this step is not appropriate because, if a hazard is significant, a HACCP approach is needed, not just GHPs; therefore, IDF proposed deletion of the word "significant." The United States responded to ISO's point about certain steps being mentioned in the GHPs by indicating that this does not rule them out as being eligible to being controlled by CCPs; and to IDF's point, the United States does not agree that a significant hazard is necessarily one that needs to be addressed by a CCP (e.g., *L. monocytogenes* is a significant hazard that can be controlled by a "GHP requiring extra attention"). Most countries supported retaining Question 1.

There were concerns expressed by ISO that Question 2 and Question 4 were asking the same thing and that the two questions were in conflict; the delegate proposed deletion of Question 2. There were various proposals to reword questions, change the order of questions (e.g., Questions 3 and 4), and add examples to the decision tree. The United States intervened at several points to explain how the questions worked together to arrive at a determination of whether a step was a CCP. Text was modified in several places to help clarify the approach. Corresponding changes were made to the CCP determination worksheet. There is also a consequential amendment needed to CXC 1-1969 to incorporate the new annex.

Outcome/ Conclusion

The Committee agreed to forward the tools for determination of CCPs to CAC45 for final adoption at Step 5/8 and inclusion as an annex to the *General Principles of Food Hygiene* (CXC 1-1969), along with a consequential amendment in CXC 1-1969 to reference the annex.

Other Comments

The United States, in written comments, had expressed concern about Question 1 in the decision tree (about whether the hazard could be controlled to an acceptable level by prerequisite programs such as GHPs) based on concern that some food business operators could say all hazards are controlled by prerequisite programs such as GHPs and avoid applying a needed CCP (similar to ISO's concern); however, this unlikely to be common if a business is following the guidance in the *General Principles of Food Hygiene;* thus, the United States decided to support the decision tree with the inclusion of Question 1.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC) IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS

To Be Presented for Adoption at Next CAC? No Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? N/A

United States Objective

The United States objective, as one of the co-chairs for this document, was to obtain sufficient input from the Committee to allow an EWG to revise the General Section and the annexes on Raw Beef, Fresh Leafy Vegetables, and Raw Milk and Raw Milk Cheeses following CCFH52 such that they can move forward in the Codex step process at CCFH53 (November 2022).

Discussion in Relation to United States' Objectives

A Virtual Working Group (VWG) met the Sunday prior to the meeting to get input on specific issues related to the three annexes; the report of this WG can be found in CRD5. The Committee agreed to the recommendations of the WG, and this information will be used by the EWG to revise the annexes.

The plenary session discussion focused on obtaining input on specific issues related to the General Section of the document (CRD4), starting with several definitions.

The Committee agreed with the definition of "fresh leafy vegetables" presented in CRD4; New Zealand and the EU questioned whether the definition included microgreens. The co-chair from the United States acknowledged that this may need to be addressed after a definition of "sprouts" is developed, since microgreens could be included there. The Committee agreed to the definition of "raw beef" and agreed to include a definition of "tenderized beef" in the Raw Beef Annex to clarify that the scope only included physically tenderized beef and not beef tenderized using brine or other additives. The Committee agreed to the definition of "raw milk" as modified during the VWG to remove reference to heating above 40°C, microfiltration, and bactofugation and instead address this in the scope of the Raw Milk and Raw Milk Cheeses Annex. A proposal to expand the definition of raw milk to indicate it should originate from healthy animals and hygienic milking processes was not accepted, as these aspects were covered in the Annex and are not needed for the definition. In response to a concern that "milk" only applied to cow's milk and the annex would not cover goat's milk, the co-chair from the United States provided the definition from the General Standard for the Use of Dairy Terms (CXS 206-1999) that indicated milk is the normal mammary secretion of milking animals, and the co-chair from France pointed out that the annex referred to milk from animals such as goats in several places. A number of changes were made to the definition of "indicator microorganisms;" no changes were made to the definitions for "raw milk cheese" and "Shiga toxin-producing E. coli."

After discussion, the Committee confirmed that the commodity definitions should appear in both the General Section and in the respective commodity annexes for ease of reading.

The Committee agreed to deletion of "GHP-based" and "hazard-based" before "control measures" because the guidelines do not specify whether specific control measures are "GHP-based" or "hazard-based."

The EU had proposed in comments to include information on how virulence genes can be taken into account in developing corrective actions. The Committee was supportive of this, noting that the concern about specific virulence genes in isolated strains can vary among countries, which impacts how the country would manage STEC, and thus flexibility in the guidance on this would be important.

Several options were proposed for Section 6.1 on Risk-Based Control Measures, including deletion of the section, replacing the paragraphs in the section with a cross reference to the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007), or keeping the section with modification to paragraph 31 (with 3 options on the modification). The Committee agreed to keep the section and use the modification to paragraph 31 recommended by the co-chairs, which referred to the use of risk modelling tools to assess the impact of control measures and that the capability and limitations of the tools needed to be clearly specified and understood by risk managers. The paragraph was modified to make clear that this included specifying the need for quantitative data.

Outcome/ Conclusion

The Committee agreed (1) to return the document to Step 2/3 for redrafting and circulation for comments; (2) to establish an EWG chaired by Chile and co-chaired by France, New Zealand and the United States to update the General Section and the annexes on Raw Beef, Fresh Leafy Vegetables, and Raw Milk and Raw Milk Cheeses based on comments received and the discussions at CCFH52; and (3) to develop an annex on Sprouts. (Chile volunteered to lead the development of the sprouts annex and the United States volunteered to work with Chile.) The Committee also agreed to convene a Physical Working Group (PWG) in conjunction with CCFH53 to prepare a revised document for plenary.

Other Comments

Progress on this document is highly dependent on the timely release of the reports relevant to STEC from the Joint U.N. Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Meeting on Microbiological Risk Assessment (JEMRA) The United States anticipates that the co-chairs will be able to obtain drafts of these reports prior to their release so the relevant information can be included in the Guidelines.

PROPOSED DRAFT GUIDELINES FOR THE SAFE USE AND RE-USE OF WATER IN FOOD PRODUCTION

To Be Presented for Adoption at Next CAC? No Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? N/A

United States Objective

The United States objective was to have these guidelines returned to Step 2 for additional work and to obtain a critical review by JEMRA of information in the examples that assigned risk levels and microbial targets and sampling frequencies for certain aspects of determining that water is fit for purpose.

Discussion in Relation to United States' Objectives

There was very little discussion about specific aspects of these guidelines, which consist of a General Section and annexes on Fresh Produce and Fishery Products (with an annex on the Dairy Sector to come). The Committee supported use of the term "potable" water instead of "drinking water" throughout the document.

In the Fresh Produce annex, several paragraphs were derived from the *Code of Hygienic Practice* for Fresh Fruits and Vegetables (CXC 53-2003); in response to a question about whether to replace the paragraphs with a cross-reference to CXC 53-2003, most members supported retaining the paragraphs, as the document would be more user friendly. This was the position of the United States, given that these paragraphs have been adapted and thus are not exactly the same as those in CXC 53-2003. In addition, CXC 53-2003 is likely to be updated based on relevant information being developed by JEMRA.

The Fresh Produce Annex contains examples and decision trees, and most delegates supported their inclusion. While the examples are useful in helping assess whether water is fit for purpose, the United States has concerns about risk levels and specific microbiological targets and sampling frequencies in the examples and supported further input from FAO/WHO and JEMRA on these.

A request was made for FAO/WHO to critically review the examples and how they could be adapted by different countries/regions in a flexible manner, particularly in countries where water is scarce, without compromising food safety.

For the Fishery Products Annex, discussion focused on definitions, and the Committee agreed to reduce their number. In addition, the EWG co-chairs intend to work with FAO/WHO JEMRA on the examples.

The Dairy Sector Annex has not been developed, and the co-chair from India was not able to commit to leading this effort. The International Dairy Federation indicated they have a lot of relevant information and would like to help develop the annex. Since a lead country has not yet been identified, it is likely that this annex will progress at a different rate from the rest of the document, an approach that has been used frequently with CCFH documents.

Outcome/Conclusion

The Committee agreed (1) to return the document to Step 2/3 for redrafting and circulation for comments; (2) to establish an EWG chaired by Honduras and co-chaired by Chile and the EU to continue developing the guidelines; and (3) that the EWG co-chairs and FAO/WHO would schedule regular communications to obtain the needed advice to address issues such as the critical review of the examples. The Committee also agreed to convene a physical working group (PWG) in conjunction with CCFH53 to prepare a revised document for plenary.

Other Comments

Definitions were not addressed in the discussion, but the United States has commented that some of the terms for water appear to overlap, and the terms as used in the document are not always consistent with their definition. The United States also has significant concerns about the definition of "risk assessment" in the document not being the one used in the *Procedural Manual*. As noted in "Other Comments" to the guidelines on managing foodborne outbreaks, the Codex Secretariat stated during that discussion that definitions can be different for the purposes of a document if it does not contradict what is in the Codex *Procedural Manual*. In this case, the proposed definition of "risk assessment" is not consistent with the one in the Codex *Procedural Manual*. This should be addressed before the document is finalized.

NEW/FUTURE WORK

To Be Presented for Adoption at Next CAC? N/A Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? N/A

United States Objective

The United States objective was to signal the need for FAO/WHO to (1) update the advances in science for control of *Salmonella* in poultry in order decide whether there is a need to update the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011), and (2) conduct a risk assessment for *Listeria monocytogenes* that could be used along with the report from a recent JEMRA meeting on this organism to update the *Guidelines on the Application of General Principles of Food Hygiene in the Control of Listeria monocytogenes in Foods* (CXG 61-2007).

Discussion in Relation to United States' Objectives

The Committee agreed to request that JEMRA compile the available information on both *Campylobacter* and *Salmonella* in chicken meat. The representative from FAO had previously noted that FAO/WHO would convene a meeting on a farm to table risk assessment for *Listeria monocytogenes*.

Outcome/ Conclusion

FAO/WHO will develop updated information on *Campylobacter* and *Salmonella* in poultry and a risk assessment for *Listeria monocytogenes* so CCFH can determine whether to undertake new work to update existing documents. The United States agreed to continue to Chair the working group on CCFH work priorities at CCFH53.

Other Comments

The Global Alliance for Improved Nutrition (GAIN) had prepared CRD26 on the need for international guidelines on food safety for traditional food markets. The United States indicated that it was not in a position to sponsor new work in this area but encouraged countries to take to take a look at the CRD and determine if they would be interested in sponsoring the work; Indonesia, Peru, Bolivia, Kenya, and Nigeria expressed an interest.

At CCFH51 Japan (with support of New Zealand) offered to review the JEMRA report on *Vibrio* and prepare a discussion paper on the possible revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010). Canada (with support of The Netherlands) offered to prepare a discussion paper on the possible revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012). Both Japan and Canada confirmed that these discussion papers would be forthcoming for CCFH53.

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