CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3a **CX/FH 16/48/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Forty-eighth Session

Los Angeles, California, United States of America, 7 - 11 November 2016

PROGRESS REPORT ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS

(Prepared by FAO and WHO)

INTRODUCTION

1. As Codex endeavours to provide risk management guidance on a wide range of issues pertinent to the safety and quality of food in international trade in order to protect consumer health, FAO and WHO aim to provide the relevant scientific advice in a timely manner. This paper describes the scientific advice as well as related information and resources that FAO and WHO have developed relevant to the specific agenda items of the 48th Session of the Codex Committee on Food Hygiene (CCFH).

A) RECENT FAO/WHO ACTIVITIES RELEVANT TO THE ONGOING WORK OF CCFH

A.1 Control of Shiga toxin-producing *Escherichia coli* (STEC) (Relevant to agenda Item 8)

2. The 47th session of the Committee requested FAO and WHO to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on the following aspects of STEC: 1) the global burden of disease attribution based on outbreak data, incorporating information from the WHO FERG as appropriate; 2) hazard identification and characterization of STEC, including information on genetic profiles and virulence factors; and 3) current monitoring and assurance programs including the status of the currently available methodology (commercially available and validated for regulatory purposes) for monitoring of STEC in food as a basis for management and control.

3. In response to the request, FAO and WHO convened a Core Expert Meeting in Geneva, Switzerland on 19-22 July 2016. As this pathogenic group of *E. coli* has been referred to using multiple terms and acronyms (e.g. verotoxin-producing and Shiga toxin-producing), the expert group discussed the terminology to be used and agreed to only use the term Shiga toxin-producing *E. coli (*STEC), as it includes enterohemorrhagic *E. coli* and because the interaction between known and putative virulence factors of STEC and the pathogenic potential of individual strains is not fully resolved. Progress made and the next steps to be taken in addressing the three areas identified by the CCFH are highlighted below. A report of the meeting can be found http://www.who.int/foodsafety/areas_work/microbiological-risks/JEMRA-report.pdf?ua=1 and http://www.fao.org/3/a-bq529e.pdf.

The Global burden of foodborne STEC disease and source attribution

4. In its report[1] on the global burden of foodborne disease, WHO estimated that foodborne STEC caused more than 1 million illnesses, 128 deaths, and nearly 13,000 DALYs[2] in 2010. Evidence underpinning these estimates was obtained from a systematic review incorporating all evidence on the incidence of human STEC infections available from 1990 to 2012. While, the incorporation of new data on the incidence of human STEC infections, either from peer-reviewed studies, or via national surveillance, would enhance the precision and global representativeness of the burden estimates, this would also entail additional data collection efforts and given the recent and well recognized endeavours in this area it was not considered a priority for this project. Therefore, it was agreed to focus efforts on source attribution to food categories. However, the work and analysis already undertaken on STEC as part of the WHO Global Burden of Foodborne Diseases project will be collated and presented in a manner that is in line with the information needs of the CCFH. Considering the importance of source attribution of foodborne STEC in guiding the work of Codex, the meeting reviewed the range of source attribution methods to determine the most suitable and feasible approach to take to address the question posed by the Committee. Based on this it was decided to use two approaches to attribute regional and global burden of STEC infections to specific foods: i) analysis of data collected during outbreak investigations and ii) case-control studies of sporadic, laboratory-confirmed infections. This is because the Group considered that data from a

[1] World Health Organization, 2015. WHO estimates of the global burden of foodborne diseases Available at http://www.who.int/foodsafety/areas_work/foodborne-diseases/ferg/en/

[2] Disability adjusted life years

greater number of countries would be available to support these approaches compared with the sub-typing or comparative exposure assessment approaches. Approaches for validation of the outcome were also identified. Additional country level data will be required to complete the source attribution studies.

Hazard Identification and Characterization

5. STEC belonging to serogroup O157 and other serogroups were discussed. Considerable time was devoted to deliberating the evolving complexity of STEC, the scope of illness caused by STEC, and how STEC might be categorized to assist in the interpretation of the public health risk of STEC when detected in food and along the food chain. The Group considered approaches to categorizing *E. coli* on a risk basis and interpretation of the categories, geographical differences in STEC (serotype, virulence), dose-response assessment for STEC virulence types, other factors that affect virulence characterization, and emerging issues such as antimicrobial resistance in STEC. To support hazard identification and characterization by risk managers it was agreed that a set of criteria and/or a decision-tree based on current knowledge of factors known to be required in STEC pathogenesis and phenotypes historically linked with disease should be developed, to provide a harmonized risk-based approach to characterization of STEC isolated from a food or along the food chain. A database of strains and serotypes could be developed to facilitate application of the decision-tree. Such a framework would be subject to peer review by a range of experts in the field to ensure its robustness.

Current Monitoring and Assurance Programs (including methodology)

6. A review of a limited number of country programs, based on the response to the call for data, illustrated the variability that exists among approaches to risk-based monitoring and assurance programs for STEC in food, as well as in the laboratory methodologies. In general, regulatory programs are in place to ensure that food safety systems in food manufacturing establishments are functioning as intended. The Group noted differences in specific STEC monitoring approaches between countries, mostly driven by the purposes of the monitoring program e.g. market access. It was generally agreed that the need for STEC monitoring in foods should be developed for a valid purpose and should be commodity specific. Otherwise, other indicators should be used to monitor process hygiene. The Group decided more data are required in order to develop a comprehensive compilation of currently available STEC monitoring programs. A template (annex II of the meeting report) was developed to facilitate collection and review of such data from more countries and will be sent to all member countries by the end of the year. Any input from Codex members on how to facilitate country feedback to this would be welcomed.

7. The group noted some challenges and limitations with laboratory methods that are used in regulatory food testing, specifically their applicability to the variety of foods that are now implicated in STEC infections and the limited number of methods and the variability of methods that are available for non-O157 STEC. It was therefore agreed to develop an overview of currently available methods.

8. The main purpose of this Core Expert Meeting was to agree on the overall approach and develop a work plan. The work will be implemented over 2 to 3 years. Regular updates will be provided to the Committee and replies to the three issues identified by the Committee will be made available as soon as they are completed.

Follow-up action by CCFH

9. The CCFH is invited to consider the aforementioned information and proposed approaches to address the questions posed by the Committee. FAO and WHO would welcome feedback from the Committee on these as well as input on how to optimally access country information, particularly on monitoring and quality assurance programs. It would be appreciated if any other aspects related to STEC which the Committee feels should be considered by JEMRA be identified at this stage in the process.

A.2 Water quality (Relevant to Agenda Item 4)

10. At its 47th Session, in relation to its new work on the revision of the General Principles of Food Hygiene (GPFH) and its HACCP Annex, the Committee requested FAO and WHO to: 1) undertake a review of the existing FAO and WHO guidelines and related texts on water and water quality to determine whether they cover all aspects of water use relevant to food production and processing. This includes water used in primary production (including use of recycled and waste water), water in contact with food or used as an ingredient and water used in enclosed systems in food operations (e.g. heating, cooling); and 2) identify any gaps in the existing FAO and WHO water related guidelines.

11. To address this issue FAO and WHO are taking the following approach

a. A review of available resources at FAO and WHO in relation to water quality and safety - FAO and WHO have initiated this work by collating the currently available FAO and WHO resources relevant to water quality and safety. An overview of the existing resources is available here.

b. A review of other non-FAO/WHO resources available on water quality and safety along the food chain – A preliminary review has been undertaken to understand the level of data available in the public domain. While data for some sectors such as aquaculture and produce for raw consumption is available for a few countries, it has also been noted that much of this information is not readily available in the public domain. FAO and WHO are considering approaches to get a greater understanding of the actual resources available within the food

industry and the approaches that different sectors are using to inform their water safety management programmes.

c. Gap analysis in relation to guidance on the quality and safety of water used in food production systems.

12. As indicated in the list of resources, WHO have developed extensive guidance on drinking water quality and safe water use. These guidelines promote the development of locally relevant standards and regulations using a health-based targets approach. The guidelines describe four distinct types of health-based targets: health outcome, water quality, performance and specified technology targets. Health outcome targets, expressed as loss of disability-adjusted life years (DALYs) or no adverse effect or negligible risk, must then be translated into water quality, performance or specified technology targets in order to be actioned by the water supplier as part of the water safety plan. This approach is similar to that outlined in the Codex Framework for microbiological risk management for food safety. The guidelines are based on the best available evidence and include risk assessment of the various hazards that may be present in drinking water. They describe reasonable minimum requirements of safe practice to protect the health of consumers and contains numerical "guideline values" for constituents of water or indicators of water quality. While the focus of these guidelines is drinking water, the approaches defined there could be widely applied. In addition, the guidelines provide an overview of treatment methods and their performance level which may be particularly relevant to the food sector. In addition, WHO, in collaboration with FAO and the United Nations Environment Programme (UNEP) have developed guidance on the use of waste water and grey water in agriculture and aquaculture. These documents provide a highly technical perspective on the issue, which serves as good basis. To facilitate application of these guidelines, WHO have developed a number of resources such as the Sanitation Safety Planning Manuel (see the list of resources) and FAO has developed a user friendly guidance to facilitate their application at primary production level[3].

13. While risk assessment and management of water safety have been addressed extensively, the primary audience for this work has been the water management community. It does not explicitly address the food safety management community although reference to food production and food processing has been made. Considering this context, a gap that may need to be addressed is translation of this work into a format which is useful and relevant to food safety managers, taking into consideration some of the specific situations in which water is used along the food chain.

Follow-up action by CCFH

14. The CCFH is invited to consider the information provided to date and provide FAO and WHO with additional guidance on what would optimally serve the needs of the Committee. Such feedback will be used to refine the work-plan and development of a report on this issue in the coming months.

A3 Histamine in fish and fishery products (relevant to Agenda Item 6)

15. FAO/WHO convened a Joint Expert Meeting on the Public Health Risks of Histamine and other Biogenic Amines from Fish and Fishery Products in Rome on 23-27 July, 2012, following the discussion of this issue in the 31st session of CCFFP. Currently, Codex standards include histamine criteria under two sections (a) decomposition and (b) hygiene and handling. The session concluded that while sensory evaluation remains a highly useful tool for quality control programs, acceptable sensory quality cannot be taken as final assurance of low histamine, nor can low histamine be taken as final assurance that fish is not decomposed. In view of this, the expert meeting focussed their advice on histamine limits and related sampling plans to those focused on consumer protection.

16. The expert meeting concluded that a dose of 50 mg histamine is the no-observed-adverse-effect level (NOAEL) that could be used as the appropriate hazard level and based on a serving size of 250g, calculated the maximum concentration of histamine in a serving that would not cause adverse effect to be 200 mg/kg. Based on data made available by industry, the meeting noted that when food business operators apply good hygienic practices (GHP) and HACCP, an achievable level of histamine in fish products was lower than 15 mg/kg. Since the problem is related to only fish with high histidine levels and the information on the fish species likely to be involved would be important for risk management, the expert meeting developed the most comprehensive list to date of fish associated with scombrotoxin fish poisoning (SFP) based on data from different parts of the world.

17. The expert meeting concluded that the risk from SFP is best mitigated by applying basic GHPs and where feasible, a HACCP system. Appropriate sampling plans and testing for histamine should be used to validate the HACCP systems, verify the effectiveness of control measures, and detect failures in the system. In order to provide more explicit guidance on sampling approaches, the meeting analysed a range of sampling plans implemented under different scenarios of histamine levels as defined by mean and standard deviation and presented examples of attributes sampling plans appropriate to different levels of tolerance for samples above 200 mg/kg, and for different assumptions about the standard deviation of histamine concentration within lots. The spread of contamination levels in the batch (i.e., standard deviation of contamination levels) has a strong effect on the tolerable average contamination level and, thus, on the number of samples that must be tested to 'accept'

[3] *FAO On farm practices for the safe use of water in urban and peri-urban horticulture Available at:* http://www.fao.org/3/a-i3041e.pdf

the batch. Appropriate selection of the criterion against which test units comprising the sample will be assessed for compliance (m value), can considerably improve the time- and cost-effectiveness of sampling – requiring the least number of samples to be tested to achieve the same level of confidence about the disposition of the lot being assessed. The meeting report is available at http://www.fao.org/3/a-i3390e.pdf.

18. Based on one of the recommendations of the expert meeting, FAO and WHO developed a tool to support decision-making related to the establishment and use of sampling plans for detection of histamine. The tool provides support in two main areas related to sampling for histamine:

- Designing a Sampling Plan: This tool function attempts to find sampling plans which meet user-defined objectives, by searching for combinations of the number of samples (n) and a concentration threshold (m).
- Analyzing the performance of a Sampling Plan: This tool function estimates the probability of accepting lots of product tested according to a user defined sampling plan. The histamine sampling plan tool is a free resource tool and is available at www.fstools.org/histamine.

19. FAO and WHO welcome feedback on the tool and comments to date has resulted in a number of updates to the tool over the past year.

Follow-up action by CCFH

20. The CCFH is invited to consider the aforementioned expert meeting report and sampling tool in their work in histamine and highlight any aspects for further clarification or possible improvements to the sampling tool.

B) OTHER RELATED ISSUES

B.1 Antimicrobial resistance

21. An update of the FAO and WHO activities on AMR was presented to the39th session of the Codex Alimentarius Commission in June 2016 and the relevant information is available in CX/CAC 16/39/12. Since then FAO and WHO remain highly active in the area of AMR

- On 21st September the Director-Generals of FAO and WHO together with the Director General of OIE participated in a high level meeting of the UN General Assembly which addressed the issue of AMR, where Member States agreed upon a strong Political declaration that provides a good basis for the international community to move forward in addressing the issue of AMR.
- FAO published its action plan on AMR in support of the implementation of the WHO Global Action Plan on Antimicrobial Resistance. The FAO action plan is available at http://www.fao.org/3/a-i5996e.pdf.
- FAO and WHO are working together with OIE to support the implementation of a One Health approach to AMR and have received project funding to support in particular low and lower-middle income countries in development and implementation of their national action plans on AMR.
- WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) will have its 7th annual meeting in mid-October in North Carolina, USA. During this meeting, AGISAR expects to finalize the revised WHO AGISAR guidance document on integrated surveillance on AMR and update the list of WHO critically important antimicrobials for human medicine. In addition, the guideline development group members will formulate recommendations on which the future WHO guideline, for use in food producing animals of the critically important antimicrobials for human medicine, will be based on.

B.2 Whole Genome Sequencing and food safety

22. FAO organized a Technical Meeting on the impact of Whole Genome Sequencing (WGS) on food safety management in conjunction with the ninth meeting of Global Microbial Identifier (GMI9), at FAO headquarters, Rome on 23-25 May 2016. The meeting, which targeted food safety managers and assessors around the world, provided an opportunity to exchange information on the potential use and impact of WGS on food safety management, and discuss the opportunities, challenges, concerns and solutions it may present in the context of consumer protection, trade facilitation and food security. Specific considerations were given to the benefits and potential drawbacks of WGS for developing countries, with burgeoning food safety systems and limited resources. The background paper for the meeting was developed in collaboration with WHO and is available at http://www.fao.org/documents/card/en/c/61e44b34-b328-4239-b59c-a9e926e327b4/.

For more information see http://www.fao.org/food/food-safety-quality/a-z-index/wgs/.

23. WHO and PAHO will convene a meeting in 2017 on the application of WGS as a tool to strengthen foodborne disease surveillance in developing countries. During the meeting practical guidance for ministries of health, aimed at supporting countries plan for the implementation of WGS, will be developed. In addition, a landscaping paper looking at the evidence base for the effective use of WGS in public health surveillance, the options for implementation, challenges and benefits of the technology and the future applications within the context of public health surveillance and outbreak response, will be published in early 2017.

B.3. Good Hygiene Practices

24. FAO continues to develop resources to support countries in the application of good hygiene practices and HACCP. Based on its work at country level, FAO is developing an online resource "FAO Good Hygiene Practices (GHP) Toolbox", a practical resource on good hygiene practices along the food chain for food safety trainers of small and medium sized businesses. The full resource will be published at the end of the year. An example of some of the materials to be provided therein can be currently accessed at http://www.slideshare.net/FAOoftheUN/tag/ghp. FAO have recently published "Guidance on hygiene and safety in the food retail sector" which can be accessed at http://www.fao.org/documents/card/en/c/0bd89d7b-a1c9-42d3-9d20-6d36683353ad

Follow up action by CCFH

25. The Committee is invited to note the information above. FAO and WHO would like to thank all those who supported the programme of work to provide the above-mentioned scientific advice and in particular the various experts from around the world and the donors who contributed financially and in kind to the programme either through or outside the Global Initiative for Food-related Scientific Advice (GIFSA).

C) PUBLICATIONS

26. All the publications in Microbiological Risk Assessment (MRA) Series are available on the FAO (http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/) and WHO (http://www.who.int/foodsafety/publications/risk-assessment-series/en/) websites.

27. Recent publications in this series include:

- Selection and application of methods for the detection and enumeration of human pathogenic halophilic *Vibrio* spp. in seafood: Guidance, Microbiological Risk Assessment Series No. 22. 2016. Available at: http://www.fao.org/3/a-i5982e.pdf and http://apps.who.int/iris/bitstream/10665/249530/1/9789241565288-eng.pdf?ua=1

- Statistical aspects of microbiological criteria Related to Foods: A risk managers guide, Microbiological Risk Assessment Series No. 24. 2016. Available at: http://www.fao.org/3/a-i3996e.pdf and http://apps.who.int/iris/bitstream/10665/249531/1/9789241565318-eng.pdf?ua=1

- Microbial Safety of lipid based ready-to-use foods for the management of moderate acute and severe acute malnutrition: First report, Microbiological Risk Assessment Series No. 28. 2016. Available at: http://www.fao.org/3/a-i5347e.pdf and http://apps.who.int/iris/bitstream/10665/249581/1/9789251090626-eng.pdf?ua=1

- Interventions for the Control of Non-typhoidal *Salmonella* spp. in Beef and Pork: Meeting Report and Systematic Review, Microbiological Risk Assessment Series No. 30. 2016. Available at: http://www.fao.org/3/a-i5317e.pdf and http://apps.who.int/iris/bitstream/10665/249529/1/9789241565240-eng.pdf?ua=1

28. Other recent publications of interest include.

- FAO Risk based imported food control guidance. Available at http://www.fao.org/3/a-i5381e.pdf

- FAO/WHO Risk Communication Applied to Food Safety. Available at http://www.fao.org/3/a-i5863e.pdf