Agenda Item 3 **CX/FH 18/50/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Fiftieth Session

Panama, 12 - 16 November 2018

MATTERS ARISING FROM THE WORK OF FAO AND WHO (including JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA))

Prepared by FAO and WHO

Introduction

1. This paper describes the scientific advice as well as related information and resources that the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) have developed relevant to the specific agenda items of the 50th Session of the Codex Committee on Food Hygiene (CCFH).

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

A.1 Water quality (Relevant to Agenda Item 5)

2. At its 48th session[1] in November 2016, the Codex Committee on Food Hygiene (CCFH) noted the importance of water quality in food production and processing and requested FAO and WHO to provide guidance for those scenarios where the use of "clean water" was indicated in Codex texts, in particular, for irrigation water, clean seawater, and on the safe reuse of processing water. In addition, guidance was sought on where it is appropriate to use "clean water".

3. To facilitate this work, FAO and WHO established a core group of experts and convened two Expert Meetings (21-23 June 2017, Bilthoven, the Netherlands; 14-18 May 2018, Rome, Italy). The summary report of the first meeting[2] was presented to CCFH49. An overview of the deliberations and outputs of the second meeting are provided below. A report of the work is under finalization and will be shared in November 2018.

Scope of the work, approaches and recommendations

4. Reviews were prepared on current guidance and knowledge on water use and safety for 1) fresh produce (pre- and post-harvest), 2) fishery products (post-harvest) and, 3) water reuse in establishments, and on risk management approaches to ensure the safety of water and food supplies. These reviews provided background information for the experts to consider in development of a fit-for-purpose concept and decision support systems approach to safe water use within these sectors.

5. Experts emphasized the importance of sustainable management of global water resources that are under stress with population growth and environmental challenges. Not all food producers and processors have access to safe water, while for others safe water access and waste discharge are incurring increasing financial and environmental costs such that minimization of water use and waste, and water reuse are highly desirable. Currently guidance on water safety during food production and processing from Codex, international agencies and competent authorities, is inconsistent and not readily operationalized by food businesses.

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[1] Report of the 48th session of the CCFH available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-48%252FReport%252FFinal%252FREP17_FHe.pdf

[2] Progress Report on the join FAO/WHO Expert Meeting on Microbiological Risk Assessment (JERMA) and Related Matters available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-49%252FWD%252Ffh49_03e.pdf

6. The experts' consensus recommendation was that for Codex documents there needs to be greater emphasis on a risk-based approach to safe water use and reuse in primary production and minimal processing of fresh produce, fishery sectors, and in processing. In Codex texts, rather than specifying use of potable water, or in some instances other water quality types, a risk-based approach and assessment of the fitness of the water for the purpose intended should be articulated. The water should be of sufficient microbiological quality such that following contact with food, the microbiological quality of the food does not decrease.

7. An over-arching framework for developing decision-making algorithms was established to aid in determining the required quality (i.e. "fitness", e.g. potable water or other suitable quality) for use and reuse purposes at various steps in food production and processing. Given the extreme diversity of products that contact water during production and processing, the myriad of microbial hazards, their interactions, and the multiple water contact steps in the food chain, it is not possible to have one decision tree fit for all foods. Each food product must be assessed in a context-specific manner. Model decision trees were constructed for fresh produce, fishery product and water reuse scenarios, acknowledging that an assessment of the health risks of the food at consumption was critically important in the process.

8. The fresh produce decision tree framework is structured around the questions regarding the production process and available resources and guides the user with regard to 1) the implementation of a microbial kill or removal step for product before consumption; 2) the degree of contact between water and the fresh produce; 3) the availability of national or local guidelines or regulations; and 4) the availability of data and resources to conduct a quantitative risk assessment. It then groups the production process into one of three categories: 1) potentially high risk, where little data is available on water quality; 2) potentially medium risk, where data are lacking, yet evidence is available that the available water source is likely to pose medium risk; and 3) potentially low risk, where either some data is available that indicates low or no microbial contamination in the available water source(s). These three risk categories are then entry points to the subsequent "risk mitigation choice" decision tree resulting in a choice of actions that can be suitable to mitigate risks to an acceptable level or at least a lower risk level.

9. A decision tree with a binary structure (Yes/No) has been developed to assess the critical control points (CCPs) with regard to water quality for fish eaten raw or undercooked. Two scenarios have been elaborated; one for fresh-water and one for pond water fish. Consideration has been given to foodborne pathogens with most relevance to fish and fishery products. The decision tree is based on a multi-barrier approach and aims to 1) identify all points where the load of pathogens could be potentially increased through the use of water of poor quality (meaning of lesser quality than at the previous step); and, 2) identify CCPs for the use of water in the production of safe fish and crustaceans eaten raw. The experts concluded that a multi-barrier approach is possible with regard to water quality management in the processing of fish and crustaceans consumed raw and identified the most critical control points to be: 1) washing of the fish with (running) potable water after point of degutting; 2) control of temperature to avoid further pathogen growth; 3) avoidance of cross-contamination by using good hygiene measures; 4) protection of pond from external faecal contamination of animal or human origin.

10. A risk-based framework for fit-for-purpose water reuse considered the application of different types of reuse water in a food operation, in particular: 1) water as a food ingredient; 2) water for intentional food contact applications (contact with food or surfaces); 3) water for unintentional food contact applications (contact with food or surfaces); and 4) water for not-for-food contact applications. When evaluating the fit-for purpose status of water, the experts recommended using a risk assessment approach incorporating all steps along the food chain from processing to consumption; the intended consumer and consumer use of the food; the impact of the recovery, storage, transport, reconditioning and recycling of reuse water on its microbiological status (quality); and the day-to-day food operation management and verification of control of water reuse applications.

11. The proposed risk-based framework guides the user to the selection of a suitable treatment technology that can recover fit-for-purpose water quality or that can eliminate or inactivate microorganisms or reduce them to acceptable levels of reuse water. Examples discussed include: 1) pasteurization or boiling by heating; 2) use of chlorine, chlorine dioxide, ozone; 3) UV light disinfection and 4) membrane filtration (to physically remove microorganisms from water). All these approaches may be used to bring the reuse water up to the quality level that allows for its use as an ingredient or else for a direct or indirect food contact application, keeping in mind that a case by case risk evaluation and matching of water sources with fit-for-purpose applications is required. Validation is a key pre-operationalization requirement and verification is crucial as a post-operationalization requirement.

Cross-cutting issues

12. Cross cutting challenges remain in applying a risk based approach particularly in following areas:

a) Criteria for the microbiological quality of safe water used in food production and processing; for example there is a lack of guidance for the various types of water used in the food industry along the value chain for verification, operational and surveillance monitoring, and, where they are recommended, there are inconsistencies in the criteria among competent authorities in different countries. Microbial indicators are most commonly enumerated as an alternative to pathogen (bacteria, viruses, parasites) detection in water; however, there is no universal agreement on the most appropriate microbial indicator species or groups for the range of hazards and the science rationale for this is controversial. Levels of *E. coli* alone are not appropriate measure of water quality when assessing safe water use in the food safety as it is not considered an appropriate surrogate for the diversity of bacteria, viruses and parasites that may be present.

b) Understanding the behaviour and the persistence of microbial hazards introduced via water, the interaction of water with the diverse range of products and in different environments at different steps along the supply chain, the effectiveness of risk reduction measures at these steps to improve water quality, and concerns of unforeseen contaminations in water reuse

c) Availability of qualitative and quantitative data for use in risk assessments which are very limited and, in some regions, non-existent.

d) The value in this approach for food production operations and the need for effective risk management of safe water use in food chains.

e) Terminology, particularly with regard to communicating safe water recycling activities in food production and processing to customers

13. The full report is expected to be available in November 2018.

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. In particular, FAO and WHO would welcome feedback from the Committee on the nature and priorities of those tools that are considered most benefical to the committee's work. This feedback will inform further evaluation and refinement through pilot testing.

A.2 Source attribution of Shiga toxin-producing *Escherichia coli* (STEC) illnesses (Relevant to Agenda Item 9)

15. CCFH47 agreed on the importance of addressing STEC in foods and requested FAO and WHO to develop a report compiling and synthesizing available relevant information on foodborne STEC, using existing reviews where possible. As previously reported, two expert meetings were convened (19- 22 July 2016, Geneva, Switzerland; 25 - 29 September 2017, Rome, Italy). A report describing the outcomes of these meetings was published.[3]

16. Two key conclusions of the STEC report include 1) the consensus that risks of severe STEC infection is best predicted by the constellation of virulence factors the infecting agent encodes, and 2) analysis of outbreak data point to beef, vegetables/fruits, dairy and small ruminant meat as the most important foodborne sources of STEC infections, with differences identifiable between regions.

17. Following to that, the expert subgroup continued further consideration of source attribution by analyses of outbreak data and case-control studies of sporadic infections.

18. STEC outbreak surveillance data received from 27 countries covering the period between 1998 and 2017 in response to call for data from WHO/FAO to national focal points and by direct contact with regional offices. In total, the data set included 957 STEC outbreaks, 345(36%) were caused by a simple food, 80(8%) by a complex food (food contain multiple ingredients), and 532(56%) were caused by an unknown source.

19. Analysis of 21 case control studies describing sporadic STEC infections attributed cases to similar food commodities as identified in the outbreak analysis: Consumption of beef and meat-unspecified were significant risk factors for STEC infection. Some study factors (e.g. sub-region, age of the study population) were sources of heterogeneity. The smaller number of reports describing cases associated with other commodities may have limited the power to identify of food risks.

[3] http://www.fao.org/3/ca0032en/CA0032EN.pdf

20. The expert group noted that these results highlight the food categories to which a large proportion of STEC illnesses at the global level can be attributed. However, it is important to note that these analyses used broad food categories, and that the results do not suggest that all food items within these large categories are frequent sources of STEC.

21. The expert group also noted that, with data-driven approaches, the quality of the outcomes depend on the availability and quality of the data and for both the outbreak data and the case-control studies, the obtained data was limited to certain regions. As outbreak investigation and surveillance capacity across the world increases, source attribution of STEC at global, regional and local levels will improve.

Follow-up action by CCFH

22. The CCFH is invited to consider the information provided and advise on any needs the committee may find still unaddressed.

B) OTHER RELATED ISSUES

B.1 *Vibrio* work

23. Work on Risk Assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood, the pertinent data and tools is ongoing with a particular focus on data from recent outbreaks of vibriosis and any implications it may have on existing risk assessments. The work is focusing on the identification of global data to validate/revise existing risk assessments and identify implications for risk management. Background documents are under preparation and an expert meeting is planned for 2019.

B.2 Risk assessment methodology work

24. In addition to the scientific advice requested directly, the FAO/WHO secretariats have been working to update risk assessment methodologies, taking into account recommendations from experts' comments, meetings, and the latest scientific developments. This project will consolidate and update the existing FAO/WHO guidance on Hazard characterization (MRA 3[4]), Exposure assessment (MRA 7[5]), and Risk characterization (MRA 17[6]) to provide a unique reference document on microbiological risk assessment. Issues for further consideration which have been identified in the review process will be addressed by an expert group in 2019. Regular updates on progress will be provided to the Committee.

B.3 Antimicrobial resistance

25. Responding to the request from the CAC and the Task Force to provide scientific advice on the potential role of crops, environment and biocides in foodborne antimicrobial resistance (AMR),[7] FAO and WHO convened, in collaboration with the World Organisation for Animal Health (OIE), a joint "FAO/WHO expert meeting on foodborne antimicrobial resistance: role of environment, crops and biocides" on 11-15 June 2018 in Rome, Italy.

26. The meeting addressed the following priority areas: the prevalence of antimicrobial-resistant bacteria and ARGs of fruit and vegetables; antimicrobial residues, antimicrobial-resistant bacteria and ARGs in the immediate food production environment, namely in soils, irrigation water, and aquaculture; use of biocides in the food processing environment; evidence implicating the use of frequently approved antimicrobials and copper in horticulture production and the subsequent occurrence of antimicrobial-resistant bacteria and ARGs in food; and crops, aquaculture products, and their production environments in integrated surveillance of AMR. The summary report is available online[8].

27. A detailed update on all FAO, WHO and OIE AMR related activities will be made available in advance of coming Codex ad hoc Task force on AMR[9].

B.4 INFOSAN (Relevant to Agenda Item 8)

28. Between 2000 and 2003, The World Health Assembly of WHO and the Codex Alimentarius Commission, realizing the need for the rapid exchange of information between national food safety agencies during international food safety events, have requested the set-up of such a mechanism. In 2004, WHO in

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[4] Available at: http://www.fao.org/docrep/006/y4666e/y4666e00.htm
[5] Available at: http://www.fao.org/docrep/010/a0251e/a0251e00.htm
[6] Available at http://www.fao.org/docrep/012/i1134e/i1134e00.htm
[7] REP18/AMR
[8] Available at http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/FAO_WHO_AMR_Summary_Report_June2018.pdf?ua=1
[9] The relevant papers will be available at http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=6

collaboration with FAO set up the International Food Safety Authority Network (INFOSAN). Today, some 600 members from 188 Member States and Territories use the network to exchange information about foodborne diseases outbreaks or about contaminated foods that have entered international trade in order to facilitate the management of these events and minimize their public health and trade impact.

29. The Secretariat of the joint FAO/WHO INFOSAN, continues to develop and strengthen this global voluntary Network. In December 2017, the INFOSAN Secretariat hosted a two-day meeting with a small group of INFOSAN members at the WHO headquarters in Geneva, Switzerland. Members were selected based on their experience and knowledge of INFOSAN at the operational and technical levels and their shared enthusiasm for strengthening the network. It was envisioned by the INFOSAN Secretariat that these INFOSAN Advocates would meet together to exchange ideas and experiences related to the improvement of INFOSAN, then advocate for such improvements within their respective spheres of influence, subsequently inspiring other INFOSAN members to follow in their paths, leading to a more active, effective and impactful INFOSAN. Outcomes from this meeting are feeding into the development of a new strategic plan for INFOSAN.

30. The INFOSAN Secretariat responded to 45 food safety emergencies in 2017, and already more than 60 events in 2018, facilitating rapid communication among INFOSAN members. One regional meeting for members in the Americas (November 2017), one sub regional workshop in the Caribbean (March 2017), as well as three national workshops in Mexico (June 2017), Bangladesh (August 2017) and Chile (October 2017), were organized in 2017. The number of active members in the Network increased by 5% in 2017, with continued growth in Africa and in the Americas. Efforts to strengthen partnerships with regional authorities and networks continued with the EFSA's Emerging Risks Exchange Network (EREN), the EC's Rapid Alert System for Food and Feed (RASFF), the Community of Portuguese Language Countries (CPLP) and the African Union Food Safety Management Coordination Mechanism (AU-FSMCM).

31. INFOSAN members' knowledge and capabilities to participate actively in the Network has been further developed through the delivery of several webinars, conducted by the INFOSAN Secretariat in English and French. In addition, a 6-part Technical Webinar Series was launched in collaboration with, and presented by, INFOSAN members in the United States of America and was widely attended by INFOSAN members from around the globe. Online emergency simulation exercises were run in English, French and Spanish for countries in Africa and the Americas, targeting INFOSAN Emergency Contact Points and National IHR Focal Points in order to strengthen capacity for food safety emergency response activities and bolster emergency preparedness. The past year was also marked by INFOSAN together with the Global Outbreak Alert and Response Network (GOARN) managing and responding to the largest ever recorded outbreak of listeriosis in South Africa and affecting 15 other countries in Southern Africa.

Follow-up action by CCFH

32. The Committee is invited to note the aforementioned information under the relevant Agenda Items and to determine the next steps for FAO/WHO. FAO and WHO would like to thank all those who supported these activities. FAO and WHO would like to thank in particular the various experts from around the world and the donors who contributed financially and in kind to the programme.

C) PUBLICATIONS

33. 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.

34. Recent publications:

Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring

Histamine in Salmonids

Technical Guidance for the Development of the Growing Area Aspects of Bivalve Mollusc Sanitation Programmes.