CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **CX/FH 19/51/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Fifty-first Session

Cleveland, Ohio, United States of America, 4 – 8 November 2019

MATTERS ARISING FROM THE WORK OF FAO AND WHO (including 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 51st Session of the Codex Committee on Food Hygiene (CCFH).

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

A.1 Microbiological risk assessment methodologies

2. Risk assessment of microbiological hazards in foods, commonly referred to as Microbiological Risk Assessment (MRA) was identified as a priority area of work by the Codex Alimentarius Commission (CAC) in the late 1990's. Following the work of CCFH, CAC adopted *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999). Subsequently, at its 32nd session, the CCFH identified a number of areas in which it required expert risk assessment advice[1].

3. In response to the needs of member countries and Codex, FAO and WHO launched a programme of work in the early 2000's with the objective of providing expert advice on risk assessment of microbiological hazards in foods. FAO and WHO undertook development of guideline documents for the hazard characterization (MRA 3[2]), exposure assessment (MRA 7[3]), and risk characterization (MRA 17[4]) steps of risk assessment. The need for such guidelines was highlighted in the work being undertaken by FAO and WHO on risk assessment of specific commodity-hazard combinations and it was recognized that reliable and consistent estimates of risk in the risk characterization step were critical to risk assessment.

4. Over the years, since the guidelines were first developed, much experience has been gained in risk assessment. By 2017, FAO and WHO recognized that a single, updated document on risk assessment was needed, including additional guidance on hazard identification. To this end, FAO and WHO established a group of experts and convened the Expert Meetings in Rome, Italy on 11-15 March 2019. The experts discussed practical guidance and a structured framework for carrying out each of the four components of a microbiological risk assessment.

Scope of the work, approaches and recommendation

5. The Guideline produced by the expert meeting is not intended to be prescriptive, nor do they identify pre-selected compelling options. It will provide descriptive guidance on how to conduct a risk assessment, utilizing a variety of tools and techniques. It has been developed in recognition of the fact that reliable estimation of risk is critical to the overall risk assessment.

6. This document provides guidance on undertaking risk assessment of all microbiological hazards which may adversely affect human health in foods along the food supply chain. This document is also intended to provide practical guidance on a structured framework for carrying out risk assessment of microbiological hazards in foods, focussing on the four components including hazard identification, hazard characterization, exposure assessment and risk characterization. These guidelines therefore represent the best practice at the

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[1] Report of the 32nd 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-712-32%252FAl01_13e.pdf

[2] http://www.fao.org/tempref/docrep/fao/006/y4666E/y4666E00.pdf

[3] http://www.fao.org/3/A0251e/A0251e00.pdf

[4] http://www.fao.org/3/i1134e/i1134e00.pdf

time of their preparation, and it is hoped that they will help stimulate further developments and disseminate the current knowledge.

7. The overarching objectives of these guidelines are to help the audience to identify the key issues and features of a risk; recognize the properties of a best practice risk assessment; avoid some common pitfalls of risk assessment; and perform risk assessments that are responsive to the needs of risk managers.

8. On some issues, an approach is advocated based on a consensus view of experts to provide guidance on the current science in risk assessment. On other issues, the available options are compared and the decision on the approach appropriate to the situation is left to the analyst. In both of these situations, transparency requires that the approach and the supporting rationale be documented.

9. The primary audience for this MRA guideline is the global community of scientists and risk assessors, both experienced and inexperienced, in risk assessment, and the risk managers they serve. Ideally, the reader would begin with the Report of a Joint FAO/WHO Consultation entitled Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts[5]. That report appropriately establishes the purpose of risk assessment as meeting the needs of risk managers. With that report as background the reader would ideally read the current guidelines for risk assessment next. While these guidelines can be read from the beginning to the end, they may equally serve as source of reference and readers may consult specific chapters as needed.

10. Public comments on the updated guidance of Microbiological Risk Assessment Methodologies will be announced in the coming months.

Follow-up action by CCFH

11. The CCFH is invited to provide comments on the revised guidance. Such feedback will be used to refine the ongoing work.

A.2 *Vibrio* spp.

12. In response to the request for scientific advice from CCFH[6], a number of risk assessments on *Vibrio vulnificus*[7], *Vibrio cholerae*[8], *Vibrio parahaemolyticus*[9] and guidance on methods for the detection on *Vibrio* spp.[10] with seafood have been conducted and published by JEMRA since 2001. The existing risk assessment models and tools for *V. parahaemolyticus* and *V. vulnificus* are based on limited data from the Americas, mostly the United States of America. The Committee recognized the need to validate predictive risk models with a view to constructing more applicable models for wide use among countries in 2009[11].

13. In 2010, JEMRA convened an expert meeting to update the modelling and tools and the reviews have been continued for following years. Some *Vibrio* studies pointed out that climate, handling practices, resident and emergent *Vibrio* strains and shellfish species may affect the growth and risk of *V. parahaemolyticus* and *V. vulnificus*, hence more representative data from other regions are required, to determine whether it is appropriate to update these models and tools or if indeed new risk assessment are needed.

14. Since then, there have been many developments in this area in the last decade and understanding of these organisms and their management continues to evolve. Taking into account those continuous discussions, another JEMRA expert meeting on *V. parahaemolyticus* and *V. vulnificus* was held at the Centre for Environment Fisheries and Aquaculture Science (Cefas), Weymouth, United Kingdom, 13-15 May 2019. The meeting reviewed and updated the existing risk assessment models/tools of *V. parahaemolyticus* and *V. vulnificus* that could be used to address a range of risk management questions in a number of different regions.

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[5] http://www.fao.org/3/a-y4302e.pdf

[6] 33rd CCFH report: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-33%252Fal0113Ae.pdf

[7] Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological Risk Assessment Series 8, 2005. https://apps.who.int/iris/bitstream/handle/10665/43365/9241563109_eng.pdf?sequence=1

[8] Risk assessment of choleragenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade. Microbiological Risk Assessment Series 9, 2005. http://www.fao.org/tempref/docrep/fao/009/a0253e/a0253e00.pdf

[9] Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological Risk Assessment Series 16, 2011. http://www.fao.org/3/i2225e/i2225e00.pdf

[10] Selection and application of methods for the detection and enumeration of human-pathogenic halophilic *Vibrio* spp. in seafood. Microbiological Risk Assessment Series 22, 2016. http://www.fao.org/3/a-i5982e.pdf

[11] 41st CCFH report: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-41%252Fal33_13e.pdf

Scope of the work, approaches and recommendations

15. Experts reviewed the outcomes of the expert meeting in 2010 on the risk assessment tools for *V. parahaemolyticus* and *V. vulnificus* associated with seafood. Experts agreed that the basic information of pathogenicity (including virulence markers), major factors relevant to the fate of *V. parahaemolyticus* and *V. vulnificus* (water temperature and salinity) and other main contents have not changed; however, there are several models and methods that have become available in the last decade. These include both newly proposed methodologies as well as established approaches that existed a decade ago but have become easily accessible and practicable for widespread application.

Methods

16. Most of the methods for detection of *V. parahaemolyticus* and *V. vulnificus* were outlined and described in MRA Series 22. A multitude of methods for characterization of strains such as improvements in the isolation of these bacteria, serotyping, multi locus sequence typing, genotyping, and more recently whole genome sequencing have been more widely introduced recently which has improved our understanding and characterization of the risks associated with these bacteria. The application of molecular approaches, and in particular the use of whole genome analysis has revolutionized our understanding of these pathogens but has also introduced new questions regarding the importance of strain phylogeny and phylogeography that need to be addressed.

Evaluation of models

17. In addition to the *Vibrio* calculator which can estimate cases based on numbers of servings, the *Vibrio* suitability map, which uses salinity and sea surface temperature as parameter to map visually for environmental suitability for non-cholera *Vibrio* spp., was newly proposed. Experts agreed to develop the table of risk models currently available to compare for their respective applicability and the limitation of the models currently available were also noted.

Post-/Pre-harvest practice

18. Approaches to reduce foodborne risks associated with vibrios include rapid cooling, harvesting restrictions, re-submerging, deep water suspension and relaying are used as good practices to reduce the risk of *Vibrio* spp. In addition, processing controls such as depuration, freezing plus cold storage, high hydrostatic pressure, irradiation, and mild heat treatment have also been applied successfully to reduce and in some instances eliminate foodborne risk. Key information on the applicability of these post and pre-harvest methods was outlined, and provides critical information internationally for practical approaches that can be implemented to reduce human risks associated with these important foodborne pathogens.

Environment and Behavioural risk including trade

19. The interaction between human behaviour, trade and the environment may also play a role in amplifying human health risks associated with vibrios. In particular, an increase in the global trade of seafood, with many products marketed year-round may modulate human health risks. In addition, economic growth may greatly influence food preference in middle class populations increasing the demand of aquaculture production domestically and globally. Experts highlighted the need for social science studies (behavioural) related to food safety. Globally, surveillance systems of associated with these pathogens are weak, and in many countries and regions vibrios are not notifiable infections, limiting the impetus required to gather epidemiological data. Improvements in the reporting, and collating epidemiology data are subsequently required. In particular, the emergence of foodborne *Vibrio* infections, especially in geographical regions lacking long-term epidemiological datasets, represents enormous challenges.

Climate change

20. Changes in sea temperature impact coastal ecosystems worldwide. Non-cholera vibrios such as *V. vulnificus* and *V. parahaemolyticus* grow in warm, low-to-moderate salinity waters and their growth is proportional to ambient environmental temperature. Climate warming is associated with increases in reported vibrio infections in endemic regions. Moreover, infections from these pathogens are now being reported in areas with little or no previous incidence.

Follow-up action by CCFH

21. The CCFH is invited to consider the information provided and advise on any outstanding scientific advice needs the Committee may find still unaddressed on this topic.

A.3 Water (Relevant to Agenda Item 6)

22. At its 48th session of CCFH, the Committee 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".

23. 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 report of the first two meetings was published[12] in 2019. To follow up the cross-cutting issues raised during the meetings, another Expert meeting was convened 23-27 September 2019, Geneva, Switzerland. An overview of the deliberations and outputs of the third meeting are provided below.

24. The purpose of the meeting was to discuss the application of microbiological criteria of water used in production of fresh fruits and vegetables to support decision making when applying the concept of fitness for purpose of water for use during pre- and post-harvest production of fresh produce. Practical interventions that could be applied pre- and post-harvest to mitigate food safety risk when water does not meet the requirement of fit-for-purpose was also considered.

25. Following a farm-to-fork approach from production in the field to food retail and consumer handling, each downstream step (i.e. closer to the consumer) requires higher or at least equal levels of microbiological quality/safety of water, unless there is a subsequent validated pathogen reduction treatment or a pathogen kill step e.g. heating process.

26. Any water, even that which has been conventionally treated and disinfected, may potentially contain human pathogens albeit at low concentrations. A risk assessment appropriate to the national or local production context should be conducted to assess potential risks of using a specific water source or supply and associated risk-reduction needs.

27. The determination of microbiological criteria of water used for the safe production of fresh fruits and vegetables should use on risk-based approaches, taking into account:

- the availability and suitability of the water for its intended purpose and the production stage at which it will be used, including the potential and extent of intentional or non-intentional food-water contact;
- the type of fresh fruits and vegetables and any specific characteristics (e.g. leafy vegetables, netted rind melons), the production system (e.g. contact with soil, grown on trees, hydroponic), whether they are usually eaten raw or cooked, peeled or unpeeled;
- retention level and timing of contact of the water with the product;
- potential for decline or proliferation of pathogens or recontamination of fresh fruits and vegetables after each water contact.

28. Multiple analytical methods are available to assess the degree of microbiological contamination of water involved in the production of fresh fruits and vegetables. The choice of microbiological assessment methods for water quality should be based on validated test methods the capacity and resources available.

29. Risk assessments can make use of a number of qualitative and quantitative water quality input variables in the water being assessed. These include, but not limited to, the direct measurement of presence of pathogens or, more often, indirect measurement of the concentration of microorganisms indicative of the presence faecal contamination, and often referred to as "indicators".

30. In the processing of fresh fruits and vegetables, the presence of indicator microorganisms is used to indicate unhygienic conditions, the presence of faecal pollution or failures in performance of control measures.

31. Sampling plans for microbiological targets used to determine water quality, including pathogen presence or concentration of microbiological indicators, should be based on risk assessment and risk management goals. For instance, baseline water quality assessment, validation monitoring of an abatement technology, and verification monitoring that, as different parameters are most suitable for different goals.

32. Scientific evidence to consider when choosing whether to include microbiological indicators as risk assessment inputs, or when choosing specific microbiological indicators and criteria, include:

- no one water quality indicator is appropriate/useful for all water types, and for some water types there may not even be a single useful indicator.
- at present, there is no reliable microbiological indicator/proxy that can reliably predict pathogen occurrence or numbers because bacterial indicators are typically surrogate measures of faecal pollution, rather than measures of pathogens themselves. It is not possible, with the use of indicators, to predict the presence or concentrations of the specific pathogens in the contaminating faecal material.

[12] http://www.fao.org/3/ca6062en/CA6062EN.pdf

- it is generally agreed that indicators of faecal contamination, particularly *E. coli* and intestinal enterococci, have been useful and widely adopted for monitoring water quality. It is anticipated that *E. coli* and intestinal enterococci will can also have wide and useful applications as faecal indicator in the context of water for food production.
- bacteriophages, especially male-specific coliphages and *Bacteroides*-specific phages, also have been found to be effective predictors of human faecal contamination. They can be useful for verification and validation of virus-reduction treatments. Although their presence does not correlate with human pathogenic viruses in groundwater, if present, they may be useful indicator of the occurrence of other virus.
- there are currently no meaningful indicators (indirect measures) for parasites in water (e.g. protozoa, nematodes and cestodes).
- correlation between indicator microorganisms and pathogens is stronger in heavily polluted waters, but this correlation is insignificant and biologically uninformative when pollution levels are low.

33. Quantitative Microbiological Risk Assessment (QMRA) is a valuable tool for establishing tailored water quality criteria based on health targets. Existing guidelines provide templates for how to carry out the calculations, based on either established health targets or assumptions. However, appropriate data are needed to conduct a QMRA. A QMRA cannot be based on microbiological indicator concentrations, but only conducted with actual pathogen measurements, or assumptions. Exposure assessments can also be used as a basis to develop water quality standards, where no health targets have been established or no reliable dose-response relationship for a pathogen of concern is available. Exposure assessments based on the association of the concentration of indicator microorganisms with the presence/absence of pathogens is a suitable approach.

34. It is recognized that risk assessment and any microbiological water quality criterion based on such assessments have a higher potential to be effective within a comprehensive whole-system approach that harmonizes risk assessment and risk management actions.

35. Each country has individual characteristics that precludes generalisation of water quality targets in food production and processing compared with drinking water supplies e.g. varying environmental and socio-cultural conditions among countries, both national and local/traditional practices in food production, different supply chain dynamics, individual national regulations and levels of oversight, and diverse exposure levels and pathways of contaminants in the water to food vary among the countries and regions.

36. For application of a fit-for-purpose concept to be successful in producing safe fresh fruit and vegetables, the risk management systems and control measures applied along the value chain pathway must be complementary, stringent and followed at all times. Water quality criteria for use in fresh fruit and vegetable supply chains should be established within the framework of national food and water regulations and guidelines and take into consideration local resources, infrastructure and capability, etc.

Follow-up action by CCFH

37. The CCFH is invited to consider the aforementioned information in determining the next steps to address the safety and quality of water used in food production and processing. FAO and WHO would welcome feedback from the Committee on the report above and also any considerations by the Committee on any other aspects that should be considered by JEMRA in relation to risk management of clean water.

A.4 International Food Safety Authorities Network (INFOSAN) (Relevant to Agenda Item 7)

38. The Secretariat of the joint FAO/WHO International Food Safety Authorities Network (INFOSAN) continues to develop and strengthen this global voluntary Network to facilitate the management of food safety events at the international level. In 2018, the INFOSAN Secretariat responded to 74 food safety emergencies and in 2019, so far, it managed 70 events, facilitating rapid communication and exchange of information among INFOSAN members. The last 2 years have been, by far, the busiest years ever for the network (annual average in past years has been 42 events per year) and included three of the largest events the Network has ever dealt with. During the past year, the Secretariat also organized one regional meeting for members in the Americas (November 2018) and one regional meeting for the members in Asia (December 2018), as well as a national workshop in Tunisia (March 2019). Two upcoming national workshops are planned in Ghana (October 2019) and China (November 2019). Membership has been steadily increasing over recent years, with many new Focal Points registering from the range of different national agencies involved in food safety around the world. The Americas is now the first region with 100% membership in INFOSAN where all Member States have designated an Emergency Contact Point. In January 2019, an in-depth study of INFOSAN has been initiated that will help us to better understand the membership needs and interests and increase active participation in the activities of the Network. The Secretariat is also increasing its public information sharing with regular

quarterly summaries of activities; these summaries are available on the INFOSAN website (https://www.who.int/activities/responding-to-food-safety-emergencies-infosan)

39. The INFOSAN Secretariat has also continued to deliver webinars to further develop the members' knowledge and capabilities and encourage active participation in the Network. This year these have been conducted in English, French, Spanish and Portuguese. Online emergency simulation exercises were run in English, Spanish and Portuguese for countries in Asia, the Americas and Africa, 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.

40. Preparation is well underway for the Second Global Meeting of INFOSAN members to be held in Abu Dhabi, the United Arab Emirates, convened by WHO and FAO in December 2019 in collaboration with and support from the Abu Dhabi Agriculture and Food Safety Authority.

B) OTHER RELATED ISSUES

B.1 Allergen (Relevant to Agenda Item 5)

41. In response to the request from CCFH and CCFL, FAO and WHO will issue a call for experts and data by the end of 2019. The ad hoc expert meeting is scheduled for September of 2020, to validate and update the list of foods and ingredients in section 4.2.1.4 of the *General Standard for the Labelling of Packaged Foods* (GSLPF) based on the risk assessment, to establish the thresholds of the priority allergens for Food Business Operators (FBOs).

B.2 STEC (Relevant to Agenda Item 8)

42. FAO and WHO have issued a call for experts and data[13] in the area of Shiga toxin-producing *Escherichia coli* (STEC) to support their work to provide scientific advice in line with the request of the CCFH, on the development of guidelines for the control of STEC in beef, raw milk and cheese produced from raw milk, leafy greens and sprouts. The assessment of potential experts started on 31 October 2019. The deadline for submission of data is 31 January 2020. The expert meeting is scheduled for June of 2020. Delegations are encouraged to disseminate these calls to relevant experts, researchers and data generators within their countries. FAO and WHO would welcome feedback from the Committee on this topic that should be considered by JEMRA in relation to risk management of control of STEC.

B.3 *Listeria monocytogenes*

43. In addition to the scientific advice requested directly, the FAO/WHO secretariats have been working to update the existing risk assessment of *L. monocytogenes*[14,15], taking into account recommendations from the latest scientific developments and recent outbreaks. This is mission-critical effort to assure that the scientific advice provided is always based on up-to-date methodology and the latest scientific knowledge. In this context, review and updating of the existing JEMRA guidance documents on risk assessment of *L. monocytogenes* are under way. The work will be implemented over 1 to 3 years. Regular updates will be provided to the Committee.

C) PUBLICATIONS

44. 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.

45. Recent publications:

- Attributing illness caused by Shiga toxin-producing *Escherichia coli* (STEC) to specific foods: Report. Microbiological Risk Assessment Series No. 32. 2019. Available at: http://www.fao.org/3/ca5758en/ca5758en.pdf and https://www.who.int/foodsafety/publications/mra_32/en/
- Safety and Quality of Water Used in Food Production and Processing: Meeting Report. Microbiological Risk Assessment Series No. 33. 2019. Available at: http://www.fao.org/3/ca6062en/CA6062EN.pdf https://www.who.int/foodsafety/publications/mra_33/en/
- Critically important antimicrobials for human medicine, 6th revision. Available at: https://www.who.int/foodsafety/publications/antimicrobials-sixth/en/

[13] http://www.fao.org/3/ca6067en/ca6067en.pdf

[14] Risk assessment of *Listeria monocytogenes* in ready to eat foods: Interpretative summary. Microbiological Risk Assessment Series 4, 2004. http://www.fao.org/fileadmin/templates/agns/pdf/jemra/mra4_en.pdf

[15] Risk assessment of *Listeria monocytogenes* in ready to eat foods: Technical report. Microbiological Risk Assessment Series 5, 2004. http://www.fao.org/3/y5394e/y5394e.pdf

- Risk Communication Applied to Food Safety Handbook (Chinese) Food Safety and Quality Series. 2019. Available at: http://www.fao.org/documents/card/en/c/i5863zh
- Technical guidance principles of risk-based meat inspection and their application. Food Safety and Quality Series No. 6. 2019. Available at: http://www.fao.org/documents/card/en/c/ca5465en
- Food control system assessment tool. Food Safety and Quality Series No. 7/1. 2019. Available at: http://www.fao.org/documents/card/en/c/ca5334en
- INFOSAN Activity Report 2016-2017. Available at: https://www.who.int/foodsafety/publications/infosan_activity2016-17/en/
- INFOSAN Quarterly Summaries. Available at: https://www.who.int/activities/responding-to-food-safety-emergencies-infosan

46. Forthcoming publications include:

- Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of the Environment, Crops and Biocides: Meeting Report. Microbiological Risk Assessment Series No. 34. In press to be released in 2019.
- Guidance of Whole Genome Sequencing as a Tool to Strengthen Foodborne Disease Surveillance and Response. In press to be released in 2019.
- ESBL producing *E coli* protocol, the Tricycle protocol, an AGISAR integrated surveillance on AMR initiative to support the Global Action Plan on AMR in the One health perspective. In press to be released in 2019.
- Risk Assessment Tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* Associated with Seafoods: Meeting Report.