

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net



World Health
Organization

Agenda Item 3

CX/FH 11/43/3
November 2011

E

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty third Session

Miami, United States of America, 5 - 9 December 2011

MATTERS ARISING FROM THE WORK OF FAO AND WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

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 and related outputs that FAO and WHO have developed relevant to the specific agenda items of the 43rd Session of the Codex Committee on Food Hygiene (CCFH) and provides an update on follow-up activities in relation to the items on the agenda of the Committee.

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

Expert meeting on *Salmonella* in bivalve molluscs (Relevant to Agenda Item 2)

2. The Codex Committee on Fish and Fishery Products have established a criterion for *Salmonella* in bivalves in the Codex Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008). The value of this criterion has been questioned by Delegates and in order to determine whether to retain this criterion the CCFFP requested FAO/WHO to undertake a risk assessment to determine whether there is a significant public health risk from *Salmonella* associated with consumption of bivalves and to evaluate whether criteria for *Salmonella* are meaningful to ensure adequate consumer health protection

3. In January 2011, FAO and WHO established an electronic expert group to address this issue. The expert group noted that the current Code of Practice for Fish and Fishery Products recommends control of harvesting areas by monitoring faecal coliforms and *Escherichia. coli* and does not recommend pathogen testing for routine monitoring of harvesting waters. An interim report of the expert group presented to the 31st of the CCFFP in April 2011, highlighted the issues, uncertainties, data gaps and challenges in addressing the question and presented certain scenarios to illustrate the risk, epidemiological evidence and the performance of sampling plans at different levels of prevalence of *Salmonella* spp. in bivalves. A physical expert meeting was convened on 20–21 October 2011 in Ottawa, Canada, to review any additional data available, finalise the analysis and provide a final response to the question posed by the CCFFP. The expert meeting concluded the following:

1. Is there a significant public health risk associated with *Salmonella* in live bivalve molluscs?

A: While bivalve molluscs are known to concentrate pathogenic microorganisms that may be present in their environments, there is little epidemiological evidence of a strong association between bivalve molluscs and salmonellosis for bivalves harvested from areas that are managed for harvesting for direct human consumption (HDHC) by shellfish sanitation programs.

In regions of the world where live bivalve molluscs are consumed as a ready-to-eat food, approximately 0.5% to 2% of samples from areas managed for HDHC test positive for *Salmonella*. Despite this, there is little evidence of salmonellosis from bivalves harvested from those areas, though a few outbreaks (in the order of one every few years) and usually involving relatively small numbers (<10) of consumers have been reported.

From the available evidence, it is concluded that live bivalve molluscs harvested from HDHC areas, e.g., managed by shellfish sanitation programs, do not cause frequent outbreaks of salmonellosis.

2. Is the existing Codex microbiological criterion and accompanying sampling plan for *Salmonella* in bivalve molluscs meaningful for public health protection?

A: Two approaches were taken to provide an answer to this question. The first was to compare actual data for parallel testing of both *Escherichia coli* and *Salmonella* prevalence in bivalve molluscs. Specifically, for the data evaluated, *Salmonella* testing in addition to *E. coli* testing would have increased the number of unacceptable lots detected from 9 to 9.5%. Thus, routine monitoring for *Salmonella* appears to add little further health protection above that which is currently achieved by shellfish sanitation programs, such as those recommended by the Codex *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). Furthermore, on the assumption that faecal indicator criteria provide public health protection against a range of enteric pathogens, the public health benefit of testing specifically for *Salmonella* in bivalves harvested from areas managed for HDHC, is further limited.

The first approach was based on limited data. A second, theoretical, approach was used to analyze the performance of the sampling plan associated with the current microbiological criterion for *Salmonella*. It can be shown that the $n = 5$, $c = 0$, absence in 25 g, sampling scheme cannot reliably (i.e., 95% confidence) detect contamination levels in a lot that have less than 2 to 5 *Salmonella* cells per 200g serving (depending on credible assumptions about the composition of a lot, the compositing of samples, and the distribution of *Salmonella* within a lot). According to the FAO/WHO dose-response model for *Salmonella*, the probability of illness from ingesting 2 cells of *Salmonella* is predicted to be ~1 in 200¹. Thus, the sampling plan at best only provides assurance that risk of illness **will not be greater than** one in ~200 servings. That probability of salmonellosis is much higher than the frequency that is currently observed from the consumption of live/raw bivalve molluscs. Thus, this second approach also suggests that the existing *Salmonella* criterion provides little or no additional protection from salmonellosis above that which is achieved by current risk management strategies.

4. The conclusions of the expert meeting are included in Annex 1. A technical report which provides a full analysis of the information behind these conclusions is currently under preparation.

Parasites in food and their impact on public health and trade (Relevant to Agenda Item 6)

5. The 42nd Session of the CCFH (December 2010) requested FAO and WHO to review the current status of knowledge of parasites in food to better assess the global problem associated with these, the commodities involved and the related public health and socio-economic/trade issues to identify parasite/commodity groups of greatest concern. A Call for Data and Experts has been issued (April 2011) on foodborne parasitic diseases, monitoring and inspection systems, risk ranking, control and management measures adopted. Applications from potential experts are being reviewed and selected qualified experts will be invited to participate in future work of FAO and WHO in the area of foodborne parasitic diseases. The Call is available at: ftp://ftp.fao.org/ag/agn/jemra/JEMRA_Call_for_data_experts_parasites.pdf and www.who.int/foodsafety/micro/jemra/data/en/index.html.

6. To date, 25 countries have sent information. The prioritization of parasite-commodity combinations requested will be based on this data and other information available in public domain, which will also

¹ The value 1 in 200 should not be understood as a risk estimate for *Salmonella* in bivalves. It only describes the upper bound estimate of risk for a serving from a lot where the ONLY information available on the lot is that it is deemed acceptable by the n=5 (no compositing), absence in 25g test.

facilitate identification of data gaps and limitations. FAO and WHO continue to encourage the countries to respond to the call, as this will improve the database for the initial screening exercise. To ensure the most comprehensive response possible, this work will also link with that underway in the WHO Global Burden of Foodborne Diseases Initiative to estimate the burden of disease associated with food borne parasites.

7. FAO and WHO would like to thank the countries and experts for their responses to date.

Follow-up action by CCFH

8. As this is a work in progress there is no specific follow-up required by the Committee at this point in time. However, FAO and WHO would like to request, in particular, those countries who have not submitted data to date to bring the call for data, which is available in 3 languages, to the attention of those working in the area of parasites in their country and encourage them to respond.

Microbiological hazards associated with melons (Relevant to Agenda Item 7)

9. The 42nd Session of the CCFH requested FAO and WHO to issue a call for data and to evaluate the pathogen-specific hazards associated with various types of melons and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards in melons. In response to that request, a Call for Data (February 2011) was issued to collect information on the identification and control of microbial hazards associated with melons to support the development of an Annex. This data was reviewed by FAO and WHO, a report was prepared by an individual expert and made available to the members of the physical working group prior to the meeting in Canada (June 2011). This report is also available at http://www.fao.org/ag/agn/agns/jemra_index_en.asp.

Follow-up action by CCFH

10. FAO and WHO will consider further assessment of the data provided if required and specified by the Committee to complete their work on this Annex.

B) FOLLOW-UP ACTIVITIES TO PREVIOUS WORK OF THE COMMITTEE

Expert meeting on methodology for detection and enumeration of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seafood

11. The 42nd Session of the CCFH requested FAO/WHO to continue the work on *Vibrio* in four steps: recommend test methods for quantification of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seawater and bivalves; develop data collection strategies, encourage data collection in different regions, and modify/develop risk assessment models. It will take several years to fully address this request, and progress will also be dependent on available resources. A workplan has been developed and the work initiated with an expert meeting convened in Ottawa, Canada, 17–19 October 2011. This meeting focused on recommended *V. parahaemolyticus* and *V. vulnificus* testing methodologies for various purposes, performance criteria of various methods used in different regions, and data collection enhancement strategies. Documentation on recommended performance criteria of methods and utility for different user groups as well as data collection strategies are currently under preparation. These documents will be posted on the JEMRA websites of FAO (www.fao.org/ag/agn/agns/jemra_index_en.asp) and WHO (www.who.int/foodsafety/micro/jemra/en/index.html) as soon as they are available and the Committee will be updated on further progress at its next session. JEMRA would like to express their appreciation to Canada and Japan who provided the resources that enabled this work to be initiated and also welcome further support from these and other countries to move forward with this activity.

Development of a web-based decision support tool for the control of *Campylobacter* and *Salmonella* in chicken meat

12. With the development of guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat and following the request of the 40th Session of the CCFH, FAO and WHO have developed a decision support tool (WBT) which allows the consideration of control measures in three main areas: primary production, processing and, distribution and preparation. The WBT allows users to explore risk management options for control of pathogens in poultry, permits flexible characterization of processes and interventions and provides a quantitative basis for estimating the net risk reduction of multiple user-specified

interventions. Final modifications are being made to the tool which will be launched at the beginning of December. It will be accessible through the FAO and WHO JEMRA webpages and specific details will be provided at the meeting. Following the request of the 42nd Session of the CCFH, the bibliography relating to hazard based control measures prepared by the Committee in developing the Guidelines for the control of *Campylobacter* and *Salmonella* in poultry is now available at www.fao.org/ag/agn/agns/jemra_riskmanagement_en.asp, <http://www.who.int/foodsafety/micro/jemra/assessment/campy/en/index.html> and <http://www.who.int/foodsafety/micro/jemra/assessment/salmonella/en/index.html>.

Follow-up action by CCFH

13. FAO and WHO welcome feedback on the tool and any additional information/guidance countries might need to apply the tool. Delegates with an interest in this tool should follow up with the FAO/WHO JEMRA Secretariat. FAO/WHO will continue to develop support materials to facilitate application of the tool in 2012.

Development of a web-based tool to assess the performance of microbiological sampling plans

14. A user friendly web-based tool (WBT) to assess presence/absence sampling plans and concentration-based sampling plans was developed by FAO/WHO. Case studies on its application are currently being finalised and the tool will be launched in December 2011.

Follow-up action by CCFH

15. FAO and WHO welcome feedback on the tool and any additional information/guidance countries might need to apply the tool. Delegates with an interest in this tool should follow up with the FAO/WHO JEMRA Secretariat. FAO/WHO will continue to develop support materials to facilitate application of the tool in 2012.

C) OTHER RELATED ISSUES

FAO Food Safety Expert Roster

16. The FAO Emergency Prevention System for Food Safety (EMPRES Food Safety) has set up a roster of external scientific experts with the aim of delivering timely scientific advice and technical assistance to support the member countries in cases of food safety emergencies and assessing emerging risks. Scientists with relevant expertise are invited to apply. The roster can be found at: www.fao.org/food/empres-food-safety/expert-roster/en/.

JEMRA publications

17. Recent additions to the FAO/WHO Microbiological Risk Assessment Series

Recently published

- **Risk Assessment of *Vibrio parahaemolyticus* in seafood: Interpretative summary and technical report.** Microbiological Risk Assessment Series 16 - FAO/WHO (2011)
- **Enterohaemorrhagic *Escherichia coli* in raw meat and meat products – Approaches for the provision of scientific advice: Meeting report.** Microbiological Risk Assessment Series 18 - FAO/WHO (2011) (*available only electronically at the moment*)

Coming soon

- **Risk Assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood: Meeting report.** Microbiological Risk Assessment Series 20 - FAO/WHO
- ***Salmonella* spp. in bivalve molluscs: Meeting report.** Microbiological Risk Assessment Series 21 - FAO/WHO

18. All the publications in Microbiological Risk Assessment (MRA) Series are available on the FAO (www.fao.org/ag/agn/agns/jemra_index_en.asp) and WHO (<http://www.who.int/foodsafety/publications/micro/en/index.html>) websites.

Other publications

FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies

19. This document was developed to assist countries in understanding essential elements in the application of risk analysis during emergencies, within the framework of their Food Safety Emergency Response (FSER) plan. The principles and procedures may also apply to other food safety events that are not necessarily emergencies but that require action to be taken under time constraints and uncertainty. The guide outlines best practice for the application of risk analysis during food safety emergencies, and suggests practical ways of incorporating such processes into existing systems. The document can be found at: www.fao.org/docrep/014/ba0092e/ba0092e00.pdf and http://www.who.int/foodsafety/publications/fs_management/risk_analysis/en/.

Preventing E. coli in food

20. In response to ongoing concerns regarding *E. coli* in Food, the FAO Food Chain Crisis Management Framework presented a short leaflet on this subject. The Food Chain Crisis Management Framework (FCC) is the primary instrument of the FAO to address the risks to the human food chain in an integrated and interdisciplinary manner at all stages, from production to consumption. The leaflet can be found at: www.fao.org/foodchain/fcc-home/news-events/en/.

Annex 1**Conclusions of the Expert meeting on *Salmonella* in bivalve molluscs:**

1. There are many potential sources of *Salmonella* contamination in the growing waters of bivalve molluscs, including commercial growing areas. Measures to completely prevent the sporadic occurrence of *Salmonella* in bivalve molluscs are not currently achievable.
2. Environmental parameters such as temperature and salinity are not predictive of *Salmonella* contamination in a growing or harvest area.
3. There is, however, a relationship between the concentration of *E. coli* in a bivalve mollusc sample and the likelihood that it will be positive for *Salmonella*, although the relationship, and strength of relationship, varies with country and region.
4. In areas that are managed by sanitary surveys and faecal indicator monitoring, the prevalence of *Salmonella* decreases with stringency of classification status. This suggests that HDHC area management based on sanitary surveys and testing for faecal indicator organisms can be an effective means of reducing the risk of salmonellosis associated with consumptions of live/raw bivalve molluscs.
5. Based on available data, the frequency of contamination/detection of *Salmonella* in bivalves sampled from the market and harvested from an area managed for HDHC is 0.5 to 2%.
6. Routine sampling of oysters and large clams usually involves compositing multiple animals into a single sample. As a result, a sample of n=1 may constitute an effective sample of between 10 and 20 animals. Similarly, n=5 may constitute a sample of between 50 and 100 animals. Compositing can dramatically increases the effective sensitivity of the test, depending on:
 - i) the compositing ratio, and
 - ii) the level of contamination of the most contaminated animal in each sample.

As such, the sampling plan will either provide very little information (n=5, no compositing, very few detections), or ambiguous information (n=5, with compositing, unclear separation of lots according to risk).
7. Compliance of a sample of bivalves molluscs with a $n = 5$, $c = 0$, $m = 0/25$ g sampling plan theoretically provides 95% confidence that the concentration is less than 2 to 5 cells per 200 g. Based on the FAO/WHO (2002) dose-response model for human salmonellosis, this contamination level corresponds to an approximately 1 in 200 chance of illness from consumption of a bivalve molluscs meal of 200g. In other words, the current criterion can, at best, only provide assurance that the probability of salmonellosis will not be greater than 1 in 200. This assumes that the test method can reliably detect 1 cell in 25 g. In practice, the performance of available test methods is less than that (perhaps only 5 cells per 25 g), i.e., the actual sensitivity of the sampling plan may be up to five-fold lower than the theoretical level.
8. The conclusion in Pt. 7 will be affected by the potential for growth of *Salmonella* in bivalves after harvest. If growth occurred that led to a 10-fold increase in the level of *Salmonella* at the time of consumption compared to the time of testing, the sampling plan provides 95% assurance only that the risk of salmonellosis per bivalve meal from that batch is less than 1 in 20 servings. Data to quantify the likely extent of *Salmonella* growth in bivalves after harvest are not available currently. Other data for prevalence of *Salmonella* at harvest or at market suggest that growth is uncommon and that *inactivation* of *Salmonella* in harvested bivalve molluscs can occur under some circumstances.
9. As inferred in Pt. 6, the predicted efficacy of the sampling plan will be affected by the variability in contamination levels within and between growing areas. The data currently available do not allow the overall effect on efficacy to be determined.
10. It should be noted that testing for faecal indicator organisms provides broad protection from contamination from a variety of enteric pathogens, including *Salmonella*. The incremental value of testing for other pathogens would need to be similarly considered given the primary screening that is provided by the faecal indicator testing.