CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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

Prepared by FAO and WHO

INTRODUCTION

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 42nd Session of the Codex Committee on Food Hygiene (CCFH) and provides an update on follow-up activities to previous work of the Committee.

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

1. Control of *Campylobacter* and *Salmonella* spp. in chicken meat *(Relevant to Agenda Item 4)*

i) Development of a web-based decision–support tool for the control of *Campylobacter* and *Salmonella* spp. in chicken meat

In relation to the development of guidelines for the control of *Salmonella* and *Campylobacter* in chicken meat and following the request of the 40th Session of the Codex Committee on Food Hygiene (CCFH), FAO and WHO have developed a decision support tool for the control of *Campylobacter* and *Salmonella* in poultry which aims to provide risk managers with a means of selecting appropriate control measures based on risk and also demonstrating their impact relative to other control measures.

The tool allows the consideration of control measures in three main areas, i) primary production, ii) processing and iii) distribution and preparation. Each of these areas is subsequently broken down into a series of steps and those relevant to the user can be selected for the assessment. The assessment can be undertaken for either one or both pathogens. An input at each of the relevant steps, in terms of prevalence and/or concentration of the pathogen of concern, is at the discretion of the user. This means that if the user has data specific to his/her situation this can be inputted to the model. If not relevant data from the literature can be substituted or assumptions can be made. The output is expressed in terms of relative risk. The tool aims to be user friendly and rapid in terms of its outputs.

A prototype of the tool was presented to a physical working group developing the draft Codex guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat in Brazil in September 2009 and also to the 41st Session of the CCFH in San Diego, USA in December 2009. Feedback received from meeting participants on both these occasions was taken into account in the subsequent work carried out on the tool.

ii) Review of the web-based tool

The web-based tool was reviewed by a group of experts in April (remote review) and May (physical meeting 10-12 May) 2010. The overall outcome of the review was positive; nevertheless it identified areas for improvement from a technical perspective as well as a user-interface perspective. From a technical perspective, some of the proposed modifications related to the addition of consumer cross-contamination as a process and the ability to model parallel pathways, e.g. when more than one pathway is possible for certain parts of the process, and providing the option to add an intervention that changes the parameters of an existing process, among others. With regard to the interface, recommendations were made to simplify navigation of the tool, provide options for review of inputs before running the model, and in general to make use of the tool easier with the availability of improved user guides and technical documentation. The development of case studies on the application was also considered to be an important aspect to facilitating use of the tool. Once the tool is complete FAO/WHO will initiate work on these case studies. The recommendations for further work were prioritized and are now being implemented. The revised version of the tool will be available for the 42nd session of the CCFH and will be presented during a lunchtime session on Monday 29th November 2010.

iii) Development of a database to support the application of the tool

As Codex requested that the tool developed be non-prescriptive and not impose any specific assumptions but rather allow the user to assess a wide range of processes and interventions, all data inputs to the tool must be undertaken by the user. Given that the process from production to consumption, as defined by CCFH, is made up of 30 steps this can be a daunting task for the user of the tool. Therefore, FAO/WHO is investigating the possibility of developing a database which would support the tool. This would consist of information relevant to each step of the process and if the user did not have their own data they could select from this database. It is proposed that this database would be a living database whereby generators of relevant data would be encouraged to input their data to the database as it becomes available.

Follow-up action by CCFH

FAO and WHO continue to welcome feedback on the tool and in particular additional information/guidance countries might need to apply the tool. FAO/WHO are seeking to identify countries that would be interested in pilot testing the tool in national settings and the development of case studies on their application. Any Delegates with an interest in these should follow up directly with the FAO/WHO JEMRA Secretariat.

2. Performance of microbiological sampling plans *(Relevant to Agenda item 7)*

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

The ability to assess the impact of the implementation of sampling plans, their efficacy in terms of risk reduction and the amount of product rejected as a result of their use comprised one of the components of the JEMRA web-based risk assessment tool for *Cronobacter* spp. in powdered infant formula. As the sampling module is fully extensible to other pathogen-commodity combinations for which sampling may be applied and the issue of sampling in relation to food safety is one which continues to present a challenge to FAO/WHO member countries, JEMRA decided to make it available as a stand-alone tool. In doing so the tool has also been expanded and enhanced and includes a generic sampling tool which enables the assessment of both presence/absence sampling plans and concentration-based sampling plans as well as an industry performance tool which address the issue of continuous improvement. The tool has a web-based and user friendly interface to facilitate ease of use. Documentation on the mathematical basis behind the tool has also been developed in order to provide a transparent description of how the tool operates. The tool can be applied in the context of end product testing or ongoing monitoring of performance of a food safety system. Case studies will be developed to illustrate how the tool can be applied in different scenarios.

ii) Review of the web-based tool

The web-based tool was reviewed by a group of experts in April (remote review) and May (physical meeting 12-14 May) 2010. The outcome of the review was positive and no major calculation errors were identified. The review addressed some specific questions from the developers about the approach to take in certain parts of the tool and a consensus was agreed on how to proceed in these situations. There were

numerous recommendations for improvements particularly in relation to clarity and transparency. The development of case studies was considered to be important in illustrating how the tool can be applied and the review meeting identified a list of 10 case studies to be developed. The recommendations for further work were prioritized and are now being implemented. The tool was presented to the physical working group established to revise the *Principles for the establishment and application of microbiological criteria in foods* which met in Japan on 25-28 May 2010. The revised tool will be available for the 42nd session of the CCFH and will be presented during a lunchtime session on Tuesday 30th November 2010.

Follow-up action by CCFH

FAO and WHO continue to welcome feedback on the tool and in particular additional information/guidance countries might need to apply the tool. FAO/WHO are also seeking to identify countries that would be interested in pilot testing the tool. Any Delegates with an interest in these should follow up directly with the FAO/WHO JEMRA Secretariat.

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

3. Request of the Codex Committee on Food Hygiene related to *Vibrio* spp. in seafoods

The 41st Session of the CCFH requested FAO/WHO to undertake an expert meeting to address a number of issues relating to *Vibrio parahaemolyticus* and *Vibrio vulnificus.* Such a meeting was implemented on 13-17 September 2010. The response to the questions posed by the committee is summarized below. A full report of the meeting will be made available on the FAO and WHO websites in November 2010.

- *Conduct validation of the predictive risk models developed by the United States of America based on FAO/WHO risk assessments, with a view to constructing more applicable models for wide use among member countries, including adjustments for strain virulence variations and ecological factors;*

Rather than undertake a validation exercise the meeting considered it more appropriate to undertake an evaluation of the existing risk calculators with a view to determining the context to which they are applicable and potential modifications that would need to be made to extend their application beyond that context.

The *Vibrio parahaemolyticus* calculator tool may be used to estimate *relative risk* reductions, primarily because of the linear dose-response, associated with temperature controls (post-harvest refrigeration) in areas in which the strain virulence, initial concentration and growth rates of *V. parahaemolyticus* in the bivalve spp. of concern are similar to that indicated in data from the United States.

The *Vibrio vulnificus* calculator tool is less likely than is the *V. parahaemolyticus* calculator to be applicable to a broader region than the United States of America because of uncertainty about the dose-response relationship.

To develop a tool that is applicable to particular regions and/or other products, or to answer other risk management questions, other than post-harvest refrigeration, it would be preferable to first modify the existing JEMRA risk assessment models, or develop a new model, that considers and evaluates the influence of other factors including salinity, strain differences, temperatures etc. A simplified calculator tool could then be developed to answer these other specific question routinely. This is dependent on the availability of the appropriate data and effort must be directed towards this.

Thus for a specific purpose in specific circumstances, a simplified model derived from a complex model works well. However, any modifications to the purpose or circumstances require a return to the full pre-harvest to consumption model.

- *Review the available information on testing methodology and recommend microbiological methods for Vibrio spp. in order to monitor the levels of pathogenic Vibrio spp. in seafood and/or water;*

The development of methods, particularly molecular methods for *V. parahaemolyticus* and *V. vulnificus* is evolving rapidly. This means the identification of any single method for the purposes of monitoring these pathogens is challenging and also of limited value as the method is likely to be surpassed within a few years. Therefore, rather than making any single recommendation the meeting considered it more appropriate to indicate a few of the options available while the final decision on the method selected will depend to a great extent on the specific purpose of the monitoring activity, the cost, the speed with which results are required and the technical capacity of the laboratory.

With regard to seawater the meeting considered that monitoring water had a limited value in terms of indicating the presence of the pathogen in bivalves. There is not a linear relationship between levels in seawater and bivalves and whatever relationship does exist can vary between region, species etc. Also the levels in seawater tend to be very low which presents a further challenge as the method used would need to have a good level of sensitivity. Nevertheless this does not preclude the testing of seawater in certain situations, for example to get an understanding of the aquatic microflora. With regard to monitoring of the seafood this is considered the most appropriate way to get insight into the levels in these commodities at the time of harvest. Monitoring on an ongoing basis could be expensive so consideration could be given to undertaking a study over the course of a year and using this as a means to establish a relationship between total and pathogenic *V. parahaemolyticus* and *V. vulnificus* in the seafood and abiotic factors such as water temperature and salinity. Once such a relationship is established for the harvest area of interest measuring these abiotic factors may be a more cost effective way of monitoring.

- *Conduct validation of growth rates and doubling times for V. parahaemolyticus and V. vulnificus in Crassostrea virginica (Eastern or American oyster) using strains isolated from different parts of the world and different bivalve molluscan species.*

Again in this case the meeting undertook an evaluation exercise rather than attempt to validate the existing growth models. The JEMRA growth model for *V. vulnificus* and the FDA growth model for *V. parahaemolyticus* is appropriate for estimating growth in the American oysters (*Crassostrea virginica*). The JEMRA growth model for *V. vulnificus* is appropriate for estimating growth in at least one other oyster species (*Crassostrea ariakensis*). The FDA model for *V. parahaemolyticus* is also appropriate for estimating growth in at least one other oyster species (*Crassostrea gigas*) but is not appropriate for predicting growth in the Sydney rock oyster (*Saccostrea glomerata)*. There is some evidence that the *V. parahaemolyticus* model currently used over predicts growth at higher temperatures (e.g., > 25°C) in live oysters. This phenomenon requires further investigation. Such studies were primarily undertaken using natural populations of *V. parahaemolyticus* as these are considered to be the most representative. Data are limited and inconsistent with respect to the impact of strain on growth rate although recent studies in live oysters are suggestive of differences between tdh/trh (pathogenic) populations versus total or non-pathogenic populations of *V. parahaemolyticus*. There is no data to evaluate the performance of the growth models in any other oyster species or other filter feeding shellfish or other seafoods and as such its use in these products cannot currently be supported, and if used should be done so with clear understanding of the associated uncertainty. This indicates a data gap which needs to be addressed before the risk assessments could be expanded in a meaningful manner.

Follow-up action by CCFH

This work was carried out in specific response to the questions posed by the 41st session of the CCFH. Based on the output of the meeting the revision of the existing models or the construction of new models would be required to address other products and regions as well as risk management questions other than post-harvest refrigeration. However, an important aspect to be considered in carrying our further work in this area is the lack of data which would clearly have to be addressed. In light of this the committee is asked to consider whether or not it supports/recommends this work to continue, and if so the direction it should take i.e. focus on data collection for a couple of years before further modelling work is attempted or use a modelling approach similar to that for pathogens in poultry, whereby a generic model including all relevant steps is developed but selection and characterization of those steps would be completely reliant on the data inputs of the user. Both approaches would require investment of time and resources by both member countries and FAO/WHO.

C) OTHER RELATED ISSUES

4. Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing *(Relevant to Agenda Item 4)*

Following the requests of the CCFAC and CCFH to address the safety of use of 'active chlorine' in the food industry, a Joint FAO/WHO Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing was held on 27-30 May 2008 in Ann Arbor, Michigan, United States of America. The full report of this meeting in now available in print (on request) and on-line on the WHO (http://whqlibdoc.who.int/publications/2009/9789241598941_eng.pdf) and FAO

(http://www.fao.org/ag/agn/agns/files/Active%20Chlorine%20Report%20Version%20Final%20December%202009.pdf) websites.

5. Improving the safety of poultry products in East Africa *(Relevant to Agenda Item 4)*

FAO is involved in a series of interlinked activities in East Africa aimed at improving the safety of poultry products to minimise the risk to human health and to ensure market opportunities are optimized. A recently concluded project in Uganda contributed to the management of the risks posed by microbial hazards in poultry products through the application of a risk-based approach to the development and implementation of control measures at appropriate steps in the food chain. This has included the development of guidelines on good hygienic practices at appropriate steps of the poultry chain, using as a basis the Codex draft guidelines for the control of *Campylobacter* and *Salmonella* spp. in Chicken Meat. In parallel, FAO, in collaboration with WHO has recently initiated a series of studies in Kenya, that aim to assess and manage in an integrated manner, the public health risks associated with use of antimicrobials, microbiological contamination (*Salmonella* spp, *Campylobacter* spp), and antimicrobial resistance (AMR), along the poultry value chain continuum from production to consumption.

6. *Salmonella* in aquacultured products

During an FAO study of causes of detentions and rejections of exported seafood it was noticed that annually there are over 300 import alerts due to *Salmonella* in fish and fishery products. To get a better understanding of the public health impact of *Salmonella* associated with aquacultured products, FAO organized an Expert Workshop on the **Application of biosecurity measures for the control of *Salmonella* in sustainable aquaculture** in Mangalore, India on 19-21 January, 2010. The Experts concluded that (a) though *Salmonella* is a major foodborne pathogen, products of aquaculture are rarely involved in outbreaks of salmonellosis; (b) serovars of *Salmonella* detected in raw products of aquaculture are rarely detected in human cases of salmonellosis in fish importing countries; (c) very low levels of prevalence are seen in raw products of aquaculture in developed countries, but this has not led to any significant public health problem in these countries; (d) there are a variety of pathways reported as to how *Salmonella* can enter the aquaculture environment ranging from feed stock, wild animals, domestic stock, poor sanitation and inappropriate disposal of human and animal wastes. Control of such pathways pose major challenges, particularly in such cases as land runoff during rains and control of wild animals in the farm environment; (e) Good hygienic practices during aquaculture production and biosecurity measures can minimise but not eliminate *Salmonella* in products of aquaculture; (f) and currently there is insufficient data to carry out a quantitative risk assessment for *Salmonella* in aquaculture.

7. JEMRA celebrates 10 years

It is 10 years since JEMRA was established by FAO and WHO at the request of the Codex Alimentarius Commission to address the need of Codex for good quality scientific advice on microbiological food safety issues in a timely and efficient manner. As a program of work it is now enshrined into the strategic objectives of both organizations and as well as provide scientific advice to support the management and control of microbiological hazards in foods by Codex and member countries, it also aims to provide guidance on doing and using risk assessment and making risk assessment as a tool in food safety, more widely accessible through activities such as training, tool development and provision of access to relevant information. During the past 10 years JEMRA has provided inputs to every session of the CCFH and on a more *ad hoc* basis to other Codex committees e.g., CCFFP. It has published 19 volumes in the FAO/WHO Microbiological Risk Assessment series which includes risk assessments and scientific advice on a range of pathogen product combinations as well as guidelines for doing risk assessment. It has also implemented expert meetings on microbiological risk management, developed training materials on MRA and more recently developed user-friendly risk assessment tools. This work would not have been possible without the many experts, institutions and governments around the world that supported this activity. FAO and WHO would like to take this opportunity to express their appreciation to the hundreds of experts over the past 10 years that have participated in meetings, prepared the assessments and reviewed the work of JEMRA. Grateful appreciation is also extended to the data providers who continue to grow in numbers as the response to JEMRAs *Calls for Data* continue to increase thereby improving the quality of scientific advice provided. More than half of JEMRAs work is funded by extra budgetary resources and therefore would not have been possible without the generous support of numerous donors.

Many people working in food safety have told us how they appreciate and use the work of JEMRA and how the MRA publication series has become an important part of their food safety library. However, elaborating and using good scientific advice remains a challenge for many. After 10 years JEMRA is reflecting on how it can continue to improve the way it works, and develop products to meet the ongoing challenge of providing safe food for all. Your feedback, comments and suggestions would be very welcome at jemra@fao.org and foodsafety@who.int. Finally, your ongoing support is needed and appreciated to ensure the sustainability of JEMRA. Please contact the Secretariat at the email addresses above on how you can get involved. More details can also be found in the FAO Strategy for the Provision of Scientific Advice for Food Safety (http://www.fao.org/ag/agn/agns/files/gifsa/ScienceFor_English_230610_low.pdf)

8. Recent JEMRA Publications

i) Recently published

- **Risk assessment of *Campylobacter* spp. in broiler chickens: Interpretative Summary.** Microbiological Risk Assessment Series 11 - FAO/WHO (2009)
- **Risk assessment of *Campylobacter* spp. in broiler chickens: Technical Report.** Microbiological Risk Assessment Series 12 - FAO/WHO (2009)
- **Risk characterization of assessment of microbiological hazards in foods: Guidelines.** Microbiological Risk Assessment Series 17 - FAO/WHO (2009)
- **FAO/WHO Technical Meeting on Salmonella and Campylobacter in Chicken Meat: Meeting Report.** Microbiological Risk Assessment Series 19 - FAO/WHO (2009)

ii) Coming soon

- **Risk assessment of *Vibrio parahaemolyticus* in seafood: Interpretative summary and Technical Report.** Microbiological Risk Assessment Series 16 - FAO/WHO
- **Enterohaemorragic *Escherichia coli* in meat and meat products: Meeting report.** Microbiological Risk Assessment Series 18 - FAO/WHO

The French and Spanish translations of guidelines for the exposure assessment (MRA 7) and risk characterization (MRA 17) as well as the risk assessments on *Vibrio vulnificus* (MRA 8) and *Vibrio cholerae* (MRA 9) in seafoods will shortly be available on the FAO (http://www.fao.org/ag/agn/agns/jemra_index_en.asp) and WHO (http://www.who.int/foodsafety/micro/en/) websites.