codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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REPORTS OF THE *AD HOC* FAO/WHO EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOOD AND RELATED MATTERS:

Prepared by FAO and WHO

1. BACKGROUND

1. As microbiological risk assessment (MRA) emerges as a tool for the evaluation of the safety of food and water supplies, FAO and WHO are developing this tool at the international level as a means to provide science based advice to risk managers at the national and international levels i.e. the Codex Alimentarius Commission (CAC). FAO and WHO generate the risk assessments and scientific advice through the implementation of *ad hoc* Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) and also aim to provide national governments with information and tools to use in conducting their own assessments.

2. The main outputs of JEMRA are: a) Risk Assessments of specific pathogen-commodity combinations; b) Interpretative summaries of the risk assessments; c) Guidelines for undertaking MRA; d) Guidelines for utilising MRA; e) Training material and tools for undertaking MRA.

3. FAO and WHO undertake microbiological risk assessments and related activities primarily at the request of the Codex Committee on Food hygiene depending on available resources and the priorities of both organizations. The purpose of undertaking such work is to facilitate the establishment of standards and related texts by the committee.

2. RISK ASSESSMENT OF SPECIFIC PATHOGEN-COMMODITY COMBINATIONS

4. The risk assessments address different pathogen-commodity combinations of concern. As previously reported the risk assessments of *Salmonella* in eggs and broiler chickens have been published and are available on the FAO (www.fao.org/es/ESN/food/risk_mra_riskassessment_salmonella_en.stm) and WHO (www) webpages. The risk assessment on *Listeria monocytogenes* in ready-to-eat foods has also been completed and is currently in print. A brief summary of the assessment is included below. Since the last session of the CCFH additional works has been carried out on the risk assessments of *Campylobacter* spp. in broiler chickens and *Vibrio* spp in seafood. These are summarized below.

2.1 Risk assessment of *Listeria monocytogenes* in ready-to-eat foods

5. This risk assessment considered four ready-to-eat foods, milk, ice cream, fermented meats and cold smoked fish. Steps from the end of processing to consumption including several post – process factors that could influence the risk to the consumer of acquiring food-borne listeriosis were considered.

6. The risk assessment as a whole indicates that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen. Control measures that prevent the occurrences of high levels of contamination in foods at the point of consumption would be expected to have the greatest impact on reducing the rates of listeriosis. In general a reduction in the frequencies of contamination will lead to a proportional reduction in the rates of illness, provided the level of contamination is similarly reduced. Although high levels of contamination at retail are relatively rare, reducing these occurrences at manufacture/retail in foods that do not permit growth would reduce the public health risk. In foods that permit growth, control measures, such as better temperature control or limiting the length of storage periods, which minimise the potential for growth of *L. monocytogenes* will also minimise the risk. The vast majority of cases of listeriosis are associated with the consumption of foods that do not meet current standards for *L. monocytogenes* in foods, whether the standard is zero tolerance or 100 cfu/g. The risk assessment highlights that in establishing any microbiological specifications the level of compliance which can be achieved is critical to the success of the specification.

7. This risk assessment reflects the current state of knowledge on listeriosis and contamination of foods with *L. monocytogenes* and provides an insight into some of the issues to be addressed in order to control the problems posed by *L. monocytogenes.* For example, if a limit is being established the technical feasibility of achievable levels of compliance must also be considered. While the available data were considered adequate for the current purposes, the risk assessment could be improved with additional data. The gaps in the database have been identified and could be used as a basis for establishing priorities for research programmes. The complete risk assessment will be shortly available on the FAO (www.fao.org/es/ESN/food/risk_mra_riskassessment_en.stm) and WHO webpages (www.who.int/foodsafety/publications/micro/listeria/en/).

2.2 Risk Assessment of *Campylobacter* spp. in broiler chickens:

8. Although work is ongoing to complete this risk assessment the key findings can be presented. The assessment considered interventions at various points in the overall process rather to the investigation of any specific mitigation strategy. This approach provides a flexible tool for risk managers and it may be used to estimate the risk to public health and investigate the impacts of potential interventions. The model framework is modular in nature and each stage of the supply chain is described by a distinct mathematical model.

9. The risk characterization estimates the probability of illness per serving of chicken associated with the presence of thermophilic *Campylobacter* spp. on fresh and frozen whole broiler chicken carcasses with the skin intact and which are cooked in the domestic kitchen for immediate consumption. Results are presented as relative rather than absolute risk and do not represent any one geographic location but rather provide a generic evaluation of the situation.

10. Several scenarios were constructed; “general” scenarios provide insight into potential approaches that might be used to reduce the risk, without defining and testing out a specific strategy while “specific” scenarios evaluate the potential performance of a particular strategy, or determine whether there are any complications, caveats, or issues that need to be considered when implementing the strategy.

SCENARIO 1: CHANGE IN PREVALENCE OF CHICKENS GOING TO RETAIL

11. A linear relationship was found to exist between prevalence of contaminated chickens at the retail level and risk of illness from consumption of chicken. Thus, a percentage reduction in retail level prevalence is estimated to correspond with a comparable percentage reduction in the mean risk of illness for example a 50% reduction in prevalence of chicken at retail is estimated to result in a 50% reduction in expected risk of human illness.

SCENARIO 2: CHANGE IN LEVEL OF CONTAMINATION

12. This general scenario shows that although chicken may be contaminated, if the level of *Campylobacter* on the chicken is reduced the risk of illness will also be reduced. The level of risk reduction varies according to the initial level of *Campylobacter* on the chickens. For example, if the initial level of contamination is approximately 6 log CFU, and this is reduced by 44%, the risk is reduced by approximately 11%. However if the level of contamination on the chickens is lower to start with, a further reduction in contamination will result in a greater decrease in risk. For example, if the initial level of contamination is approximately 2 log CFU, and this is reduced by 44%, the risk is reduced by approximately 82%.

SCENARIO 3: CHANGING "BETWEEN FLOCK" AND "WITHIN FLOCK" PREVALENCE

13. The third scenario investigated the effect of altering the "between flock"(prevalence of contaminated flocks at the farm) and "within flock" prevalence (prevalence of contaminated chickens within a contaminated flock). Three scenarios were investigated and compared to a baseline level and the percentage risk reduction is shown in the table below.

	Between flock prevalence	**Within flock prevalence**	**Relative risk reduction**
Baseline	80%	100%	-
Strategy1	40%	100%	54%
Strategy 2	80%	50%	21%
Strategy 3	40%	50%	63%

14. The results while not extremely surprising, do lead to some interesting observations Specifically, when the "between flock" prevalence is reduced, not only is the probability of a bird from a contaminated flock reaching the consumer reduced (strategy 1), but the probability of a contaminated flock being processed prior to the current one is also reduced, thereby reducing the probability of cross contamination from the previous flock carrying through to the next batch either during transport or processing. Strategy 2 is somewhat less effective due to the fact that the birds from these flocks are in fact being processed in an environment in which they are surrounded by positive birds and thus subject to high cross contamination probabilities. Strategy 3 indicated that a reduction in both "within flock" and "between flock" prevalence translates to a greater effect than either of the other two individually. The performance of any one strategy needs to be weighed in conjunction with other parameters such as cost, efficiency, time or feasibility. When these are factored in, it may be the case that "within flock" prevalence reductions could be achieved very easily, cheaply or quickly, and as such the resulting 21% risk reduction could be a very good investment and in fact turn out to be the preferred option.

SCENARIO 4: CHANGING INTERNAL AND SURFACE CONTAMINATION LEVELS BEFORE AND THROUGH PROCESSING

15. This scenario considered four alternative strategies as a means of investigating the impact of changes in the level of contamination before and through processing and compared them to a baseline. The results, given in the table below, show that the impact of altering the contamination level can be quite varied.

Strategy	Effect	Relative reduction in risk (compared to baseline)
Strategy 1	90% reduction in surface contamination level after transport	35%
Strategy 2	90% reduction in levels contaminating carcasses at evisceration	25%
Strategy 3	90% reduction in surface contamination post evisceration	63%
Strategy 4	90% reduction in initial internal contamination levels (overall reduction in contamination entering the system)	69%

16. In the first strategy, the impact of reducing the contamination level after transport by 35% is noteworthy. However, it is less significant than some of the others because when simply reducing the contamination level on the surface at this early point in the process, it is possible that the chicken carcasses will be recontaminated at a later stage, for example, as a result of potential viscera damage, thus diminishing its effectiveness. The second strategy, reducing the level of contamination occurring during the evisceration stage, while not the most effective (25%) could be a reasonably easy step to take, both technologically and economically, thus making it more attractive. The effect of reducing surface contamination after evisceration (strategy 3), is estimated to have quite a significant effect. As this reduction occurs after evisceration, with fewer subsequent occasions for contamination or recontamination after that step, there are fewer opportunities to negate the strategy. An overall reduction in both internal and surface contamination (strategy 4) be it through intervention at the farm level or at the end of processing is the most effective in reducing risk.

SCENARIO 5: IMPACT OF FREEZING ON REDUCING RISK.

17. Comparisons were made between fresh product stored refrigerated for up to 9 days, and product held frozen prior to consumption for up to 6 weeks. Freezing has been found to have a killing-off effect on the level of campylobacter contamination. As a result, it is estimated that the chickens that are frozen have a lower risk than those that are sold and stored refrigerated. However consumers' preparation practices could have a dramatic impact on the effectiveness of freezing as a risk reduction strategy. For example, when a product is frozen it is possible that the cooking effectiveness could be reduced due to insufficient thawing, resulting in a lower temperature being attained in parts of the chicken. In considering this scenario it was found that if freezing or rather insufficient thawing reduce the temperature in cooler spots of the chicken by 2^{o}C or more during cooking then the risk reductions brought about by freezing in the first place begin to diminish.

2.3 *Vibrio* spp in seafood

18. The risk assessment on *Vibrio* spp. in seafoods focuses on pathogen-product combinations that have the most impact on public health and/or international trade. Three species, *V. parahaemolyticus, V. vulnificus* and choleragenic *V. cholerae* (toxigenic *V. cholerae* O1 and O139 that may cause cholera) were identified as being responsible for most illnesses caused by *Vibrio* spp.. The approach taken was to quantify those illnesses caused by *Vibrio* spp. in different countries following the consumption of a range of seafoods. Five risk assessments are in various stages of completion. These are summarised below. In addition, as part of this risk assessment, FAO and WHO have addressed specific questions posed by the Codex Committee on Fish and Fish products. The response was provided to the last session of the CCFFP (Alinorm CX/FFP 03/2-Add.1).

***Vibrio parahaemolyticus* in oyster**

19. The approach being taken is to use the United Stated FDA Draft Risk assessment on the Public Health Impacts of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish model (FDA-VPRA) and further develop it to accommodate data inputs from other countries (New Zealand, Australia, Canada and Japan). The FDA-VPRA contains several key linkages between prevalence of V. *parahaemolyticus* in oysters and temperature, most notable being temperature of harvest waters and of oysters throughout the post-harvest-retail – consumption continuum. The objective of the international risk assessment was to take the FDA-VPRA model developed for one particular scenario and extend it to consumers in other countries.

20. This approach was partly successful in that it was possible to make predictions of risk for other countries. The risk estimates were varied between one country and the next which could be due to numerous factors such as water temperature and salinity, harvesting practices and oyster species. Finding the appropriate data to input to the model was difficult as many countries do not collect this data. If countries want to apply such a model then they need to consider the issue of appropriate data. The model can also be used to demonstrate the effect of potential interventions such as reduced time to refrigeration (rapid cooling), heat treatment and freezing or frozen storage.

***Vibrio vulnificus* in oyster**

21. This risk assessment was undertaken using the *V. parahaemolyticus* in oysters risk assessment framework and model parameters as a basis. This greatly facilitated and expedited the risk assessment process. The exposure assessment predictions were validated by their close agreement with retail study data. Due to the lack of feeding trial or outbreak data that could be used to characterize the hazard and determine the dose-response, the dose-response relationship was developed from exposure predictions and the reported frequency of illness.

22. The risk assessment predicted the mean number of illnesses on a seasonal basis and considered in particular the impact of salinity and temperature on risk. As there was only data available from the United States these predictions can only be considered valid for that country. The risk was estimated to be 0.5, 11.7, 12.2 and 8.0 cases of illness in the population per season for the winter, spring, summer and autumn seasons, respectively. The risk assessment also considered the impact on risk of implementing a strategy that would reduce the level of *V. vulnificus* in oysters to 300, 30 and 3 per g. Substantial reductions in risk were found to be associated with target levels of 3/g and 30/g with an approximate 10-fold range of uncertainty as indicated in the table below.

Target	Mean risk per serving (median and 90% interval of uncertainty distribution)	Annual number of cases (median and 90% interval of uncertainty distribution)
3/g	1.09×10^{-7} (4.10×10^{-8}, 2.73×10^{-7})	0.16 (0.06, 0.4)
30/g	8.20×10^{-7} (3.42×10^{-7}, 2.12×10^{-6})	1.2 (0.5, 3.1)
300/g	5.26×10^{-6} (2.60×10^{-6}, 1.05×10^{-6})	7.7 (3.8, 15.3)

23. The risk assessment also illustrated the effect of time unrefrigerated on expected numbers of illness, and the reduction of illness from consumption of raw oysters harvested from growing area with salinities >30ppt in comparison to oysters harvested from moderate salinity growing area, regardless of temperature.

24. This model may be applicable to countries outside the United States of America that wish to pursue risk assessment. These countries need to initiate data collection efforts on *V. vulnificus* numbers in seafoods associated with primary septicaemia, at harvest and the point of consumption and characterize the susceptible population. For seafoods other than raw oysters the model will need to be altered and evaluated but the dose-response data may still be applicable.

***Vibrio parahaemolyticus* in bloody clam**

25. A harvest to consumption risk assessment was conducted using bloody clam, one of the most popular seafood species in a tropical region of the world. Transportation time and temperature distributions of the environment where clams were kept, prevalence and concentration of the pathogen at each stage of the production chain, and consumption patterns were modelled in this case study. This assessment was undertaken in a limited time period and restricted to a single food item, and it is recognised that the sample size and sampling times might not be sufficiently large. Nevertheless, this project serves as a case study for initial data generation and risk assessment modelling in a developing country, with limited time, resources and quantitative data.

26. A new linear dose-response approximation was also developed to consider the fractional change in human illnesses that would occur if measures to control bacterial growth were implemented. The way in which these two models might assist risk managers is addressed.

27. This study estimated that only a few people per 10,000 population acquire V. *parahaemolyticus* infection as a result of consuming boiled bloody clams. Therefore, the present risk estimate does not appear to support the common perception of the population of Hat Yai City that bloody clams are a major cause of diarrhoeal illness, including V. *parahaemolyticus* illnesses. These results are considered with the observations, data limitations and data gaps.

***Vibrio parahaemolyticus* in finfish eaten raw**

28. In order to respond to the risk management question with regards to the effect of washing fish with disinfected seawater or potable water after harvest or at preparation, the expert drafting group focused on one fish species, ”horse mackerel” which is commonly eaten as “Sashimi” (sliced fish fillet) and reported as implicated food in V. *parahaemolyticus* food borne outbreaks in Japan. A quantitative risk assessment model was developed. The risk assessments indicates that preparation techniques including washing the visceral cavity of horse mackerel during preparation of sashimi, has a greater impact on the reduction of risk than the using disinfected water at sea ports. The impact of using disinfected water at the port and for transportation does not show significant risk reductions. However, this may be due to the fact that the data used in the risk assessment was obtained in an experimental setting simulated to represent real practices and might not truly reflect the actual effects of using disinfected water.

***Vibrio cholerae* in warm water shrimp for export**

29. A semi-quantitative risk assessment model was developed to estimate the risk of cholera associated with the consumption of imported warm water shrimp. A production to consumption approach was considered and available information on each of these steps are described in the risk assessment. However, as this information was not sufficient and a lot of assumptions would have to be made in order to carry out the risk assessment an alternative model was developed using the detailed data are available on shrimp imported by mainly developed countries as well as their annual reported number of cholera cases.

30. Based on the available data, the prevalence of choleragenic *V. cholerae* O1 and O139 in exported warm water shrimp is very low at around 0.01%. The risk of getting cholera from imported warm water shrimp on a yearly basis was estimated for each of seven countries for a six year period for which data were available. For all countries the level of risk was estimated to be low, in the region of two to four cases every 100 years. By combining the data from all the countries the risk per serving of imported warm water shrimp for each of the six years analyzed was estimated, for example, in the year 2000 the risk per serving was estimated to be 3.73E-11 – one serving in every 373000 million servings would result in cholera. Even thought the likelihoods are very low it is still possible that someone somewhere sometime could get cholera from the consumption of imported warm water shrimp. The estimates of the number of annual cases is in apparent agreement with the epidemiological data available in the scientific literature i.e., that there are no known cases of cholera associated with the consumption of imported warm water shrimp.

4. FAO/WHO GUIDELINES ON RISK ASSESSMENT

31. The guidelines are intended to complement and expand on the general guidance that has been developed by Codex in their "*Principles and Guidelines for the Conduct of Microbiological Risk Assessment*" [CAC/GL-30 (1999)]. Guidelines on Hazard Characterization of Microbiological Hazards in Food and Water have recently been published and can be downloaded from the FAO (www.fao.org/es/ESN/food/risk_mra_hazard_en.stm) and WHO webpages (www.who.int/foodsafety/publications/micro/pathogen/en/). Guidelines on Exposure Assessment for Microbiological Hazards in Food and Guidelines on Risk Characterization for Microbiological Hazards in Food will be published in 2004.

5. SUMMARY OF ISSUES TO BE CONSIDERED BY THE CCFH

32. The Committee is invited to consider the following issues under Agenda Item 10:

- the incorporation of the outcomes of the risk assessments on *Salmonella, Listeria, Campylobacter and Vibrio* into the development of risk management tools by the committee, for example, their use in the revision of the Code of Hygienic practice for Egg Products; the development of Risk Management Strategies for *Salmonella* spp. in poultry, Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the [Management] of *Listeria monocytogenes* in Foods, Risk Management Strategies for *Campylobacter* in poultry and the "Discussion Paper on risk management strategies for *Vibrio* spp. in seafood",
- the utility of the Draft FAO/WHO Guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts in the discussion of the working procedures between the JEMRA *ad hoc* consultations and the CCFH.
- whether the committee still considers enterohaemorrhagic *E. coli* to be one of its priority concerns on which it requires risk based scientific advice and if so to facilitate the provision of this advice through the provision of a focussed scope for the risk assessment including the specific questions to be addressed by the assessment.
- the identification of other priority areas in which the committee requires scientific advice from FAO/WHO and the elaboration of well defined questions, based on a risk profile to facilitate the provision of an adequate response.

33. FAO and WHO have also provided information to the committee on microorganisms of concern in powdered infant formula (CX/FH04/12-Add.1). The Committee is also invited to consider, under Agenda Item 11, whether work on a risk assessment on *E. sakazakii* in powdered infant, that has been initiated, to evaluate more diverse set of scenarios should be continued with the objective of providing more information to facilitate the work of the committee on this issue.

34. FAO and WHO consider that the outcomes of the risk assessments present CCFH with a very valuable resource for use in the elaboration of risk management tools and represent a significant improvement in the available scientific advice for the management of the risk posed by specific hazards in foods. A thorough consideration of the important issues presented in the risk assessments, which are outcome of CCFH's initiatives to base risk management considerations on risk assessment to the extent practically possible, is suggested.