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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REPORT OF THE *AD HOC* EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOOD (JEMRA)

Prepared by FAO and WHO

1. BACKGROUND

1. Microbiological risk assessment (MRA) is an emerging tool for the evaluation of the safety of food and water supplies. FAO and WHO have an important role in developing MRA at an international level and providing advice to risk managers at both the national and international levels. The Codex Alimentarius Commission (CAC), and in particular the Codex Committee on Food Hygiene (CCFH), has requested sound scientific advice as a basis for the development of risk management tools (standards, guidelines and related texts) for microbiological hazards in foods. This request included specific risk management questions (raised at the 33rd[2] and 34th[3] Sessions of the CCFH) on certain pathogen-commodity combinations.

2. FAO and WHO generate the requested risk assessments and scientific advice through the implementation of *ad hoc* Joint Expert Meetings on Microbiological Risk Assessment (JEMRA).

3. In addition FAO and WHO aim to provide national governments with information and risk assessment tools to use in conducting their own assessments.

4. 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 microbiological risk assessment;

d) Guidelines for utilising microbiological risk assessment;

e) Training material and tools for undertaking microbiological risk assessment.

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[2]Report of the thirty third session of the Codex Committee on Food Hygiene, Washington DC, 23 -28 October 2000. ALINORM 01/13A, ftp://ftp.fao.org/codex/alinorm01/Al0113ae.pdf

[3] Report of the thirty-fourth session of the Codex Committee on Food Hygiene, Bangkok, Thailand, 8 - 13 October 2001, ALINORM 03/13, ftp://ftp.fao.org/codex/alinorm03/al03_13e.pdf

2. RISK ASSESSMENT OF SPECIFIC PATHOGEN-COMMODITY COMBINATIONS

5. Four risk assessments are currently in various states of completion. These address *Listeria monocytogenes* in ready-to-eat foods, *Salmonella* in eggs and broiler chickens, *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafoods. These risk assessments aim to meet the needs of CCFH and FAO and WHO member countries with regard to providing assistance for managing the risks posed by these hazards in specific food products.

2.1. Risk assessment of *Listeria monocytogenes* in ready-to-eat foods (RTE):

6. The objective of this work was to determine how previously developed risk assessments, undertaken at the national level, could be adapted or expanded to address concerns related to *L. monocytogenes* in RTE foods at an international level, and to provide answers to three specific questions posed by the 33rd session of the CCFH. Considering the resources available and time constraints placed on the risk assessors, the work was limited to a finite range of RTE foods, selected to represent various classes of product characteristics, and the risk of these foods serving as a vehicle for human food-borne listeriosis was estimated. The foods selected were pasteurized milk, ice cream, cold-smoked fish and fermented meats. The risk assessment considered several post – process factors that could influence the risk to the consumer of acquiring food-borne listeriosis.

The questions posed by the CCFH were:

Question 1: Estimate the risk from *L. monocytogenes* in food when the number of organisms ranges from absence in 25 g to 1000 colony forming units (CFU) per gram or millilitre or does not exceed specific levels at the point of consumption.

7. Answering this question is dependant on the ability to articulate and interpret dose-response relationships for *L. monocytogenes*, however, there are a number of confounding factors that could influence the approach taken and the complexity of the answer provided. Considering the generic nature of the question and the fact that this is one of the first microbiological risk assessments undertaken for CCFH it was decided to focus the response on communication of key risk assessment concepts and a series of comparisons based on relative risks rather than absolute risk. Therefore, consideration of potential confounding factors was limited and uncertainty and variability were not addressed.

8. Two approaches were taken; a) the predicted risk per serving and predicted number of cases of listeriosis annually were estimated for a "worst-case" scenario by assuming that all servings had the maximum level being considered (0.04, 0.1. 1, 10, 100 and 1000 CFU/g); b) a more realistic but also more complex approach was to use a distribution of the levels of *L. monocytogenes* in foods when consumed rather than an absolute value to estimate the risk per serving and the predicted number of cases of listeriosis annually.

9. Comparisons between these two approaches indicated that there were vast differences in the estimated number of cases when one considers the worst-case scenario as opposed to a scenario that attempts to also consider the frequency and extent of contamination actually encountered in RTE foods. These two scenarios demonstrated that as either the frequency of contamination or the level of contamination increases, the risk and the predicted number of cases also increase. These scenarios assume that ingestion of a single cell has the possibility to cause illness. Thus, if all RTE foods went from having 1 CFU/serving to 1000 CFU/serving, the risk of listeriosis would increase 1 000-fold (under the assumption of a fixed serving size). Conversely, the effect of introducing into the food supply 10 000 servings contaminated with *L. monocytogenes* at a level of 1 000 CFU/g would, in theory, be compensated by removing from the food supply a single serving contaminated at a level of 10^7 CFU/g.

10. In interpreting these results and the actual effect of a change in the regulatory limits for *L. monocytogenes* in RTE foods, one also has to take into account the extent to which non-compliance with established limits occur. Based on data available for the United States of America, where the current limit for *L. monocytogenes* in RTE foods is 0.04 CFU/g, the estimated number of cases for listeriosis for that population was 2130. If a level of 0.04 CFU/g was consistently achieved one could expect less than 1 case of listeriosis per year. This, in combination with available exposure data, suggests that a portion of RTE food contains a substantially greater number of the pathogen than the current limit and that the public health impact of *L. monocytogenes* is almost exclusively a function of the foods that greatly exceed the current limit.

11. The risk assessment indicates that increasing the level of *L. monocytogenes* in RTE foods from 0.04 to 1000 CFU/g would increase the risk of foodborne listeriosis provided that the current rate of non-compliance with the established limit remained proportionally the same. However, it is possible that public health could be improved if an increase in the regulatory limit in RTE foods resulted in a substantial decrease in the number of servings that greatly exceeded the established limit i.e. the rate of non-compliance decreased.

12. To summarise, it would seem that the vast majority of cases of listeriosis result from the consumption of high numbers of *Listeria*, and foods where the level of the pathogen does not meet the current criteria, whatever they may be (0.04 or 100 CFU/g). The model also predicts that the consumption of low numbers of *L. monocytogenes* has a low probability of causing illness. Eliminating higher levels of *L. monocytogenes* at the time of consumption has a large impact on the number of predicted cases of illness.

Question 2: Estimate the risk for consumers in different susceptible population groups

13. The risk assessment showed that the probability of becoming ill from ingesting *L. monocytogenes* was higher for susceptible populations (immunocompromised, elderly, and perinatal) than the general population. The probability of becoming ill was also shown to vary between the sub-groups of the susceptible population. Old age and pregnancy increase susceptibility and the risk of acquiring listeriosis from exposure.

Question 3: Estimate the risk from *L. monocytogenes* in foods that support growth and foods that do not support growth at specific storage and shelf-life conditions.

14. The risk assessment provides three approaches for answering the question: a) the general consideration of the impact of the ingested dose on the risk of listeriosis; b) a comparison of four foods that were selected, in part, to evaluate the effect of *L. monocytogenes* growth on risk, and c) the ability to conduct "what-if-scenarios" for the evaluated foods that support growth of *L. monocytogenes*.

15. The results of the risk assessment show that the potential for growth of *L. monocytogenes* strongly influence risk, though the extend to which growth occurs is dependant on the characteristics of the food and the conditions and duration of refrigerated storage. Using the selected RTE foods, their ability to support the growth of *L. monocytogenes* appears to increase the risk of listeriosis on a per serving basis by 100- to 1 000-fold. While it is not possible to present a single value for the increased risk for all RTE foods, because of the divergent properties of the foods, the ranges of values estimated in the risk assessment provide some insight into the magnitude of the increase in risk that may be associated with the ability of food to support the growth of *L. monocytogenes.* Control measures that focus on reduction of both frequency and levels of contamination have an impact on reducing rates of listeriosis. Controlling growth post-processing is one of these measures.

16. The draft document entitled "Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: Interpretative summary" is being circulated to Codex contact points. More detailed information on the above can be found in that document. The final version of the risk assessment and its interpretative summary will be available on the FAO and WHO webpages in mid 2003.

17. The 34th CCFH recommended that the risk assessment on *L. monocytogenes* in RTE foods be utilized in the development of the work on the "Guidelines for the control of *Listeria monocytogenes* in foods".

2.3: **Risk assessments of *Salmonella* in eggs and broiler chickens and eggs.**

18. The risk assessments had several objectives: a) to consider the efficacy of some risk management interventions to address the problems associated with *Salmonella* in eggs and broiler chickens; b) to develop an example risk assessment framework and model for world-wide application; c) to identify the current gaps in the data that need to be filled in order to more completely address this issue.

19. The risk assessments use a common hazard characterization for *Salmonella* while separate exposure assessments and risk characterizations were developed for each of *Salmonella* in broiler chickens and *Salmonella* Enteritidis in eggs. The hazard characterization could potentially be used in a risk assessment of *Salmonella* in other commodities.

20. For *Salmonella* Enteritidis in eggs a farm-to-table model was developed while for *Salmonella* in broiler chickens the model was developed from the end of processing to the point of consumption.

21. The risk assessment addressed to the extent possible the questions posed by the CCFH as outlined below.

Question 1.1 & 2.1 Estimate the risk from *Salmonella* in eggs and broiler chickens in the various susceptible populations (e.g. elderly, children or immunocompromised patients).

22. The dose of *Salmonella* ingested and the attack rates for children under five years of age were compared with the rest of the population exposed in order to compare susceptible and normal populations. The database did not reveal an increased risk of illness in children under five years of age compared with the rest of the population exposed to *Salmonella*. However, the database may lack sufficient power to reveal the existence of true differences.

Question 1.2: Estimate the risk from *S.* Enteritidis in eggs in the general population at various prevalence and concentration levels of S. Enteritidis in contaminated eggs

23. There seems to be a linear relationship between prevalence and the estimated risk of illness. For example, the risk assessment shows that the risk of illness per serving changes in direct proportion to changes in the within-flock prevalence. Consequently, risk per serving from a flock whose within-flock prevalence is 10% (i.e. 10 in every 100 hens is infected) poses 100 times the risk to humans compared to a flock whose within-flock prevalence is 0.1% (i.e. one in every 1000 hens is infected).

24. For a flock prevalence of 5%, the risk per serving was about 2 per 10 million, regardless of whether the initial number of *S.* Enteritidis per egg was 1, 10 or 100. For a flock prevalence level of 25% the risk increases from 8 illnesses per 10 million servings to 10 per 10 million servings as the number of *S.* Enteritidis in eggs at lay increases from 1 to 100. Nevertheless, for one-log changes in the initial numbers of *S.* Enteritidis, the resulting change in probability of illness is much less than one log.

25. The model predicts that contaminated eggs are produced at a frequency of about 1 in 20 000 when flock prevalence is 25%. If all contaminated eggs contained just one organism and there was no growth or decline before consumption, the model predicts the risk to be 1 illness per 10 million servings. Similarly, the risk if all eggs were contaminated with 10 and 100 organisms is 1 illness per 1 million servings and about 7 illnesses per 1 million servings, respectively.

26. Allowing growth inside eggs would elevate the risk while cooking of egg meals substantially reduces the risk. It would seem that the combined effect of growth and cooking is to stabilize the risk per serving to nearly one per million.

Questions 1.3: Estimate the change in risk likely to occur from on-farm interventions (reduce prevalence of positive flocks e.g. destroy positive breeding and/or laying flocks; use competitive exclusion; vaccinate egg-laying flocks; reduce the prevalence of *S.* Enteriditis-positive eggs e.g. test and divert eggs from positive flocks to pasteurization), including their efficacy.

27. The risk of illness per serving decreases as the percentage of infected flocks (i.e. flock prevalence) decreases. Because the model includes uncertain inputs, risk per serving is also uncertain. The results from this part of the risk assessment can be used to predict the reduction in risk for a country or region that decides to control infected flocks. For example, if a country, with 5% of its flocks containing one or more infected hens, were to institute a programme with 98% effectiveness in reducing flock prevalence, then, successful implementation of the programme would result in a flock prevalence of about 0.1%. The model predicts, in this case, that the mean risk of illness per egg serving would decrease from 2 per 10 million to 5 per 1000 million.

28. The effects of competitive exclusion treatment are difficult to quantify from the available field evidence and given the limited available data it was not possible to evaluate the efficacy of this intervention.

29. To evaluate the effectiveness of vaccination against *S.* Enteritidis a single test, or two tests four months apart, with 90 faecal samples per test, was considered. The vaccine was assumed to be capable of reducing the frequency of contaminated eggs by approximately 75%.

30. Assuming 25% flock prevalence and the baseline egg storage time and temperature scenario, the probability of illness per serving for a single test and vaccination protocol is about 70% of a non-vaccination protocol. Risk is reduced to 60% of the non-vaccination protocol if two tests are applied. Given the efficacy of vaccination, based on field evidence, one could assume that universal vaccination might reduce baseline risk to 25% of the risk resulting from a non-vaccinated population. However, the cost of vaccinating the

entire population of laying hens could be high and the cost of testing all flocks must be weighed against the cost of vaccination.

31. The efficacy of interventions aimed at reducing the prevalence of *S.* Enteriditis-positive eggs was considered in the risk assessment by evaluating the effect of a "test and divert" programme. Two protocols were assumed, with either one (at the beginning of egg production) or three (beginning of egg production, four months later & just before flock depopulation) tests administered to the entire population of egg production flocks and their effectiveness was estimated over a four-year period. Testing three times per year for four years reduced the risk of human illness from shell eggs by more than 90%. Testing once a year for four years reduced the risk by over 70%. At the end of the fourth year, the flock prevalence for the one-test and three-test protocols were 7% and 2%, respectively.

32. While egg diversion from positive flocks reduces the public health risk from shell eggs, it might be expected that there is some increased risk from egg products. Mandatory diversion causes more contaminated eggs to be sent to pasteurization and this was also considered in the risk assessment. The results suggest that the risk from egg products decreases as flocks are detected and diverted. However, this effect is conditional on nest run eggs (eggs which are stored for less than two days) being substantially less contaminated than restricted or graded eggs. Alternative scenarios to the one considered here may result in some increase in risk from diversion.

Questions 1.4: Estimate the change in risk likely to occur by reducing the number of *S*. Enteritidis in eggs, e.g. by requiring refrigeration of eggs after lay and during distribution, or requiring a specific shelf-life for eggs stored at ambient temperatures.

33. The effects of time and temperature restrictions were evaluated assuming a flock prevalence of 25%. Restricting shelf-life to less than 14 days reduced the predicted risk of illness per serving by a negligible amount (~1%). However, keeping retail storage temperature at no more than 7.7°C reduced risk of illness per serving by about 60%. Were shelf-life to be reduced to 7 days, risk per serving would also be reduced by about 60%.

Questions 2.2: Estimate the change in risk likely to occur from the implementation of on-farm interventions aimed at reducing the prevalence of *Salmonella* positive broiler chicken, and evaluate the importance of various routes for introduction of pathogenic *Salmonella* into flocks

34. The questions concerning on-farm interventions and the importance of on-farm routes of introduction of *Salmonella* could not be evaluated due to the lack of representative data to develop the model for farm practices. For example, the data available concerning the importance of the various routes by which pathogenic *Salmonella* are introduced into flocks were inconclusive and interpretations of existing studies and results are confounded because of the number of different sampling protocols, specimen types and laboratory methods, as well as the nature of poultry-rearing operations. However, the model allows the effects of on-farm or process interventions on risk to be evaluated provided their effect on *Salmonella* prevalence and numbers at the end of processing can be estimated.

Question 2.3: Estimate the change in risk likely to occur by a reduction in the prevalence of *Salmonella*-positive birds at the end of slaughter and processing.

35. If the prevalence of contaminated chickens leaving processing is altered, through some management practice either at the farm level or at the processing level, the expected risk per serving is altered. A reduction of 50% in the number of cases of salmonellosis was estimated if a 20% contamination rate at the retail level was reduced to 10% contamination. The relationship between percentage prevalence and expected risk is largely a linear one. Thus, assuming everything else remains constant, a percentage change in prevalence of contaminated chickens can be expected to reduce the expected risk by the same percentage.

36. The effectiveness of specific mitigation interventions or treatments during processing, were not evaluated in the present risk model because lack of representative data precluded analysis of changes in either or both prevalence and level of contamination that might be attributable to a specific intervention. A review of the literature was undertaken regarding the use of chlorine. There is little evidence that the addition of chlorine at levels of 50 ppm or less actually decreases the numbers of the pathogen attached to the skin of poultry carcasses. However, available data suggest that chlorine prevents an increase in the prevalence of contaminated carcasses, i.e. a reduction in cross-contamination, while one study observed a substantial reduction in prevalence.

37. Unlike a change in prevalence, a change in concentration of the pathogen does not necessarily have a linear relationship with the risk outcome. The expected risk per serving, which incorporates the prevalence of contaminated servings and the probability of undercooking, was estimated to be 1.13 illnesses per one million servings in the original case and 4.28 per one million servings in the situation when the level of contamination is reduced. The expected risk per serving is therefore reduced by approximately 62%.

Question 2.4: Estimate the impact on risk of a change in consumer behaviour

38. The effectiveness of strategies aimed at changing consumer behaviour is difficult to anticipate, and to measure. However, the potential impact on risk resulting from modifying food preparation practices was investigated by running a simulation that assumed implementation of a strategy to reduce the probability of the consumer not adequately cooking the food. For those that do tend to undercook, it was assumed that the degree of undercooking was less. Using this scenario the expected risk is reduced from 1.13 illnesses per 100 000 servings, to 2.26 illnesses per 1,000 000 servings. Thus, the changes in consumer practices reduce the expected risk per serving by almost 80%.

39. It is important to note that the mitigation strategy to alter cooking practices does not address the risk associated with cross-contamination. In the baseline scenario, the expected risk per cross-contamination event was shown to be the larger risk. As a result, strategies to change the consumers cooking practices need to be tempered by the fact that cross-contamination may in fact be the predominant source of risk, although the nature of cross-contamination in the home is still a highly uncertain phenomenon.

40. While it was possible to develop some examples, in general more information is needed to evaluate the efficacy of some of the more specific management interventions to reduce the risk associated with *Salmonella* in broiler chickens.

41. The results obtained from the risk assessment of *Salmonella* Enteritidis in eggs could be taken into consideration in the proposed draft revision of the "Code of Hygienic practice for Egg Products". The results of the MRA work on *Salmonella* in poultry could be useful in the review of the "Discussion Paper on Risk Management Strategies for *Salmonella* spp. in poultry" as recommended by the 34th Session of the CCFH.

42. The "Risk assessments of *Salmonella* in eggs and broiler chickens" and its Interpretative Summary are being distributed to all Codex Contact Points.

2.4: **Risk assessment of *Vibrio* spp. in seafood:**

43. The work involves undertaking a risk assessment of *Vibrio* spp. in seafood products that have the most impact in public health and/or international trade. It covers *Vibrio parahaemolyticus* on raw oysters, *Vibrio vulnificus* in raw oysters, *Vibrio parahaemolyticus* in finfish consumed raw, *Vibrio parahaemolyticus* in bloody clams and *Vibrio cholerae* in shrimp from developing countries for export. This work was discussed at an expert consultation in Geneva, 23 – 27 July 2001,[4] and the progress made since then was reviewed at an expert consultation held in Bangkok, Thailand, 5 – 9 August 2002.[5]

44. The approach taken was to adapt a risk assessment model developed in one country for different scenarios and data from other countries. The different assessments are in various states of completion and the risk assessment of *V. parahaemolyticus* in raw oysters and *V. vulnificus* in oysters are most suited for risk managers to help them to make informed risk management decisions.

45. In the case of the risk assessment of *V. parahaemolyticus* in oysters the results of the application of the models showed the differences in the relative effectiveness of various mitigation strategies (control of temperature/salinity) in relation to reducing the prevalence and number of these micro-organisms in oysters and reducing the number of cases of food-borne diseases. The risk assessment of *V. parahaemolyticus* already addresses some of the questions included in the "Discussion Paper on risk management strategies for *Vibrio* spp. in seafood" prepared by a Codex drafting group but still needs further development to be

[4]Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, Geneva, Switzerland, 23 – 27 July 2001, Hazard identification, exposure assessment and hazard characterization of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood. WHO/SDE/PHE/FAO/01.4 http://www.fao.org/es/ESN/pagerisk/announce.htm ; http://www.who.int/fsf/Micro/index.htm

[5]Joint FAO/WHO Expert Consultation on Risk Characterization of *Campylobacter* spp. in broilers chickens and *Vibrio* spp. in seafood, Bangkok, Thailand, 5 – 9 August 2002.

applicable in different situations. The risk assessment on *V. vulnificus* in oysters is in a similar state of development.

46. The qualitative (descriptive) risk assessment of Choleragenic *Vibrio choleare* 01 and 0139 in shrimps shows that there is not a public health problem associated with the consumption of imported warm-water shrimp.

47. The small-scale risk assessment of *V. parahaemolyticus* in clams is an example of how to undertake a risk assessment using available data when resources and time are limited.

48. A qualitative (descriptive) exposure assessment of *V. parahaemolyticus* in finfish eaten raw was prepared but the lack of data prevented its further development. However, it still includes information that may be important for many countries and so will be included in the final risk assessment document. If the necessary quantitative data become available, it will be incorporated and the assessment updated.

49. Expert advice on the effectiveness of pre-harvest measures in the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs and the effectiveness of post-harvest treatment technologies to eliminate *V. parahaemolyticus* and *V. vulnificus* in these products has been provided by the expert consultation[5] for the Codex Committee on Fish and Fish Products.

50. Further information is available in the interpretative summary of the work carried out to date which is being distributed to all Codex contact points.

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

51. This risk assessment was discussed at an expert consultation in July 2001[4], and subsequently was reviewed and at an expert consultation in Bangkok, Thailand on 5 – 9 August 2002[5]. In the elaboration of this risk assessment there has been some interaction with the Codex drafting group on Risk Management Strategies for *Campylobacter* in poultry.

52. Priority was given to the consideration of interventions at various points in the overall process (e.g. effect of chilling method, freezing, chlorinated water etc.) rather than 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.

53. The model developed attempts to understand how the incidence of human campylobacteriosis is influenced by various factors during chicken rearing, processing, distribution, retail storage, consumer handling, meal preparation and finally consumption. The model framework is modular in nature and each stage of the supply chain is described by a distinct mathematical model.

54. 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 skin intact and which are cooked in the domestic kitchen for immediate consumption.

55. Although not yet complete some of the key findings to date include:

- Overall campylobacter concentration on chicken carcasses decreases through processing, with temporary increases occurring during transport and evisceration.
- There was very little uncertainty that reduction of the between-flock prevalence of campylobacter would reduce any associated public health risk. A linear relationship was found to exist between flock prevalence and probability of illness, i.e. a two-fold reduction in flock prevalence would result in a corresponding two-fold reduction in the probability of illness.
- The prevalence of campylobacter-positive carcasses from negative flocks increases up to and including evisceration and decreases at later stages. This decrease after evisceration was also found for positive flocks, depending upon the method of chilling.
- Assuming that cooking performance is independent of the chicken being fresh or frozen, frozen chicken posed a lower risk via consumption than fresh chicken.
- The washing-off effect associated with water chilling translated to water-chilled chickens posing a lower risk than air-chilled chickens. However, there was uncertainty associated with the degree of cross-contamination that occurs in the chill tank during water chilling that would have an impact on this comparison and may be affected by the addition of chlorine to the chill water.

56. There are large uncertainties associated with the risk assessment. For example the current model is unable to provide a central estimate of risk due to virtually unbounded uncertainty on the estimation of the impact of undercooking and the impact on cross-contamination.

57. Further information is available in the interpretative summary of the work carried out to date which is being distributed to all Codex contact points.

3. GENERAL GUIDELINES ON RISK ASSESSMENT

Two sets of draft guidelines are currently undergoing peer review and should be completed in 2003 (http://www.fao.org/es/ESN/food/risk_mra_guidelines_en.stm; http://www.who.int/fsf/Micro/index.htm)

58. FAO/WHO Guidelines on Hazard Characterization of Microbiological Hazards in Food and Water.: These guidelines provide a practical framework and structured approach for the characterization of microbiological hazards, either in the context of a full risk assessment or as stand-alone process. They provide guidance on the issues to be considered and addressed when characterizing a hazard. Data needs and utilization including methodology for incorporating data from different sources and the methodology for dose-response modelling are addressed.

59. FAO/WHO Guidelines on Exposure Assessment of Microbiological Hazards in Food and Water: These guidelines are intended to be used by a multidisciplinary audience involved in developing, reviewing or using microbiological risk assessment documents at the international or national level. They will also be of use to risk managers who use risk assessment to assist decision making and need to be aware of the underlying principles and methodology. These guidelines outline the principles to be adhered to in undertaking exposure assessment, and provide guidance on the modelling approaches, the use of predictive microbiology, data needs, characteristics, and utilization. The document also considers how to deal with variability, uncertainty and sensitivity, and quality assurance of the process as well as communication of the results. In the elaboration of these guidelines and specifically the chapters addressing data, consideration was given to paper CX/FH 01/15 submitted by Brazil at the 34th session of the CCFH.

60. 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). Future work will include the development of guidelines on risk characterization of microbiological hazards in food.

4. GUIDELINES FOR INCORPORATING MICROBIOLOGICAL RISK ASSESSMENT IN THE DEVELOPMENT OF FOOD STANDARDS

61. As the risk analysis framework is an evolving process there is a recognized need to elaborate principles and guidelines to assist risk managers at both national and international levels to optimally use risk assessment in their risk management activities. Interaction between risk assessors and risk managers is important to clearly define the scope of the risk assessment work at the outset, to revise the scope early in the assessment if necessary, and to ensure the development of appropriate guidance by risk managers.

62. To assist in this process, FAO/WHO have implemented two Meetings[6] to discuss this interaction and as a result of the last one have prepared draft guidelines for incorporating microbiological risk assessment in the development of food safety standards.

63. The guidelines utilize a generic framework for systematically incorporating MRA in the development of food safety standards, guidelines and related texts. The guidelines includes consideration related to the incorporation and utility of microbiological risk assessment during 4 steps: a) preliminary risk management activities, b) evaluation of risk management options, c) implementation of risk management options and d) monitoring and review.

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[6]WHO Expert Consultation (in cooperation with FAO and the Institute for Hygiene and Food Safety of the Federal Dairy Research Center, Germany) on the Interaction between Assessors and Managers of Microbiological Hazards in Food, Kiel, Germany, 21-23 March 2000; and FAO/WHO Expert Consultation (and the Federal Dairy Research Center and the Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany) on the Elaboration of Principles and Guidelines for the Incorporation of Quantitative Microbiological Risk Assessment in the Development of Food Hygiene Standards, Guidelines and Related Texts, Kiel, Germany 17 – 22 March 2002. http://www.who.int/fsf/Micro/InteractionConsultationinKiel/index.htm; http://www.fao.org/es/ESN/food/risk_mra_guidelines_en.stm

64. The guidelines could assist the CCFH in the discussion of papers CX/FH 03/6 “Proposed Draft Process by which the Committee on Food Hygiene could undertake its work in microbiological risk assessment/management”; paper CX/FH 03/7 “Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management”; and paper CX/FH 03/11 “Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures”.

65. The draft guidelines are available on the FAOand WHO web pages:

(http://www.fao.org/es/esn/food/risk_mra_riskmanagement_en.stm: http://www.who.int/fsf/Micro/index.htm).

5. INFRASTRUCTURE NEEDS FOR RISK ASSESSMENT

5.1 WHO EXPERT CONSULTATION, WITH THE PARTICIPATION OF FAO, ON DEVELOPING A STRATEGY FOR GLOBAL SURVEILLANCE FOR FOOD-BORNE DISEASES AND RISK ANALYSIS. GENEVA, SWITZERLAND, 26-29 NOVEMBER 2001

66. The consultation set the foundations of a global network based on existing national and regional networks involved in the surveillance of food-borne diseases. Such a global network could be used for a rapid outbreak alert system, strengthening surveillance systems in developing countries and rapid exchange of new information and technologies. Partner networks were identified, and a website and a steering committee for the handling of the network will be established to facilitate the consideration of data from food-borne disease surveillance and data from food monitoring systems in the design of public health policies and appropriate food safety measures. The consultation also considered how data from surveillance systems could be better utilized or enhanced for use in risk analysis and in particular risk assessment. The needs in terms of surveillance data for risk analysis were identified, the ways in which the necessary data can be collected and how interaction between risk assessors, managers, communicators and epidemiologists could be enhanced were also considered**.**

5.2 WHO expert consultation on methods of food-borne disease surveillance in selected sites. Leipzig, Germany, 18-21 March 2002

67. The consultation focused on the feasibility to establish sentinel studies (pilot programs) on food-borne diseases in selected countries. It will be possible to generate data, to analyse and potentially to extrapolate to allow a better overview on the burden of these diseases in the different regions. Working plans for establishing pilot programs in the selected regions considering the current situation in the countries were developed. Sentinel sites and specific study designs are currently being developed.

6. SUMMARY OF ISSUES TO BE CONSIDERED BY THE CCFH

68. The Committee is invited to consider the following issues under Agenda Item 5:

- the incorporation of the outcomes of the risk assessments on *Salmonella* and *Listeria* 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 and the Guidelines for the Control of *Listeria monocytogenes* in foods.
- the potential use of the risk assessment on *Campylobacter* in the development of risk management tools in the context of the committees' discussion paper on Risk Management Strategies for *Campylobacter*.
- the adequacy of the scope, approach and preliminary outputs of the five *Vibrio* risk assessments to address the needs of the committee in relation to the "Discussion Paper on risk management strategies for *Vibrio* spp. in seafood", any additional issues on which scientific advice is required and the formulation of appropriate questions to request this advice.
- 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 development 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.

69. 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.