codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 10

CX/FH 06/38/10
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-eighth Session

The Intercontinental Hotel, Houston, United States of America

PROPOSALS FOR NEW WORK AND/OR REVISION OF EXISTING STANDARDS

Prepared by Australia

Governments and interested international organizations are invited to submit comments on the document below, especially on Section containing recommendations, and should do so in writing **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2006.**

Introduction

CCFH is formalising its approach to identifying, prioritising and efficiently carrying out its work. At the 37th Session the Committee agreed to use its newly established process by which CCFH will consider possible future work on matters included for discussion at the 37th Session.[1] Specific countries were asked to prepare written proposals for these matters for consideration by an *ad hoc* Working Group for the Establishment of CCFH Work Priorities which would meet immediately prior to the 38th Session with a view to forwarding its recommendations to the Committee.

Four proposals for new work have been received and have been considered against the criteria described in the process for managing the work of the Committee. This paper includes the criteria and the assessment.

The a*d hoc* Working Group has also been asked to prioritise new work in light of work done in 2000 by CCFH to prioritise the revision of existing Codes of Hygienic Practice. This paper includes a review of the status of the codes prioritised at that time.

The paper also includes a proposed agenda for the *ad hoc* Working Group meeting immediately prior to the 38th Session.

[1] Report on the 37th Session of the Codex Committee on Food Hygiene – ALINORM 05/28/13

Comments are sought on the criteria used for assessment, the assessment of new work proposals received and the proposed agenda for the *ad hoc* Working Group meeting. Where possible, these comments will be circulated prior to the meeting.

Background

At the 37th Session the CCFH considered a discussion paper on the 'Management of the Work of the Committee - Proposed Process by which the CCFH will undertake its Work'[2] and agreed to a process, to be used on an interim basis, for the management of its work. The Committee had before it discussion papers on the following matters and countries, as indicated, agreed to prepare written proposals to enable the work to be considered for inclusion in the future work of the Committee.

Sweden: *Guidelines for the Application of the General Principles of Food Hygiene to the Risk-based Control of Salmonella spp. in Broiler Chickens*

United States: *Guidelines for the Application of the General Principles of Food Hygiene to the Risk-based Control of Enterohemorrhagic E Coli in Ground Beef and Fermented Sausages*

New Zealand: *Guidelines for Risk Management Options for Campylobacter in Broiler Chickens*

United States: *Vibrio spp. in seafood*

The Netherlands: *Viruses in Food*

The Committee established an a*d hoc* Working Group for the Establishment of CCFH Work Priorities which would meet immediately prior to the next Session of the CCFH. The objective of the *ad hoc* Working Group is to provide recommendations to the CCFH on the priority of new work proposals to assist the Committee to develop a more manageable work program and thereby providing the opportunity to reduce the length of the meeting to a maximum of five days. Australia agreed to chair the first meeting of Working Group.

The Committee also forwarded the 'Proposed Process by which the CCFH will undertake its Work'[3] to the Codex Committee on General Principles (CCGP) for its advice on its consistency with procedures established by the Codex Alimentarius Commission. CCGP, at its 22nd Session (April 2005) agreed to request such legal advice from the Legal Counsels of FAO and WHO and consider the matter again at its next Session. At its 23rd Session (April 2006) the CCGP[4] considered amended text which was intended to remove repetition of general requirements that already existed in the procedural manual and to ensure consistency with the general texts (such as the Working Principles on Risk Analysis). The CCGP agreed to return the document, as amended, to the CCFH for further consideration and noted that there was no impediment for CCFH to start implementing an appropriate process for prioritisation of new work proposals as far as such process was consistent with the Codex procedures in place[5].

The text of the 'Proposed Process by which the CCFH will undertake its Work' as amended by CCGP is attached. (Attachment 1)

In accordance with the 'Proposed Process by which the CCFH will undertake its Work', member governments and countries were requested to propose new work in accordance with the proposed process[6]. Reponses to this request are considered below. The request also recalled the previous work of the Committee in prioritising Codes of Hygienic Practice at the 33rd Session of CCFH[7].

[2] Management of the work of the Codex Committee on Food Hygiene ALINORM 05/28/13 – Appendix V
[3] ALINORM 06/29/33 Appendix V
[4] ALINORM 06/29/33 paragraph 46
[5] ALINORM 06/29/33 Appendix V
[6] CL 2005.40 – FH August 2005
[7] ALINORM 01/13A

Responses to the request for new work

Four proposals for new work have been received and these are listed in Table 1. In addition, the USA responded that a proposal for new work on Guidelines for the Application of the General Principles of Food Hygiene to Risk Based Control of Enterohemorrhagic *E Coli* in Ground Beef and Fermented Sausages be delayed for one year and signalled its intent to submit a proposal for such work for the 39th Session. The rational for the United States response is provided in the paper submitted in response to the circular letter request at Attachment 2.

Proposals for new work

Table 1: Proposals for new work

Title	Country preparing the proposal
Proposal to develop a risk-based standard for *Campylobacter* in poultry	New Zealand
Proposal for new work on guidelines for the application of Codex General Principles of Food Hygiene to the risk based control of *Salmonella* in broiler chickens	Sweden
Discussion paper on risk management strategies for *Vibrio* spp. in seafood	United States of America
Risk profile of norovirus in bivalve molluscan shellfish	The Netherlands

The proposals are provided in Attachments 3-6. Two of the proposals relate to risk management of pathogens in poultry and two to risk management of pathogens in seafood.

Summary of each proposal

Proposal to develop a risk-based standard for Campylobacter in poultry (New Zealand) Attachment 3**.**

The purpose of the proposed work is to develop a genuinely risk-based 'production to consumption' standard for C*ampylobacter* in broiler chickens to serve risk management needs at the international and the national level. Although no risk profile is included, reference is made to a previous CCFH discussion document and New Zealand risk profiling work. A fairly detailed work plan is included.

The proposal document also suggests criteria for accepting proposals for development of risk-based standards for microbial hazards as new work.

Proposal for new work on guidelines for the application of Codex General Principles of Food Hygiene to the risk based control of Salmonella in broiler chickens (Sweden)

Attachment 4.

The purpose of the proposed work is to provide advice supplemental to the Recommended Code of Practice: General Principles of Food Hygiene on management options for the control of *Salmonella* spp. at primary production, processing and further steps in the production of broiler chickens and broiler products. It is targeted at governments, industry, consumers and other interested parties.

The proposal briefly addresses the criteria for work priorities and includes a risk profile.

Discussion paper on risk management strategies for Vibio spp. in seafood (United States)

Attachment 5

The paper is drafted as a discussion document, developed by a working group led by the United States in 2002, which includes recommendations for new work. The Working Group recommends that the CCFH review existing Codex guidance in codes of hygienic practice to determine whether the guidance for the control of *Vibrio* parahaemolyticus in finfish and shellfish is sufficient and to develop risk management guidance if such information is insufficient.

The paper also proposes that the FAO/WHO Joint Expert Group on Microbiological Risk Assessment use existing risk assessments to assess the impact of specified practices on the risk of *V*. parahaemolyticus to human health and review the areas where information is needed to fill the gaps to inform risk management practices.

The paper includes a risk profile of *V*. parahaemolyticus .

Risk profile of norovirus in bivalve molluscan shellfish (Netherlands)

Attachment 6

Netherlands noted that the proposed new work on viruses in food is too diverse to be addressed as a single topic. Instead the Netherlands proposes that CCFH focus on viral agent/product combinations such as noroviruses in seafood and in particular in bivalve molluscan shellfish because contaminated bivalve molluscs play a major role in food borne transmission. The paper notes that this approach is in accordance with the recommendation of the *ad hoc* Working Group on Matters Referred from the Codex Committee on Fish and Fishery Products (CCFFP) to the 37th Session of CCFH to pursue work on a risk profile on viruses in food and focus early work on viruses in seafood in general with emphasis on bivalve molluscs[8].

The paper is essentially a risk profile and does not address criteria for proposals for new work. However, it concludes that risk management strategies should be developed to address the presence of viral contamination in these shellfish and recommends that CCFH undertake specific management activities to control hazards and manage the risk.

Criteria for considering proposals for new work

The criteria for considering proposals for new work have been established using the guidance provided in the Codex procedural manual[9] and from the document; 'Management of the work of the Codex Committee on Food Hygiene – the Proposed Process by which the Codex Committee on Food Hygiene will undertake its work', as amended by the CCGP[10].

The criteria against which the CCFH should assess proposals for new work are listed in Table 2 below.

Table 2 – Criteria for new work

Criteria	Reference
Include a risk profile Indicate specific nature or outcome of the new work being proposed	CCGP 29th Session report - ALINORM 06/29/33 Appendix V Page 47 – 50 Management of the Work of the Codex

[8] Para 192 report of 37th Session CCFH and CRD 56 to 37th Session
[9] Codex procedural manual 15th edition
[10] ALINORM 06/29/33 Appendix V

	Committee on Food Hygiene Paragraph 6
Typically address a food hygiene issue of public health significance Describe in as much detail as possible the scope and impact of the issue Describe the extent to which it impacts on international trade	CCGP 29th Session report - ALINORM 06/29/33 Appendix V Page 47 – 50 Management of the Work of the Codex Committee on Food Hygiene Paragraph 7
Where appropriate: Address an issue that affects progress within CCFH or by another committees, provided it is consistent with the mandate of CCFH Facilitate risk analysis activities Establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/ or improve consistency with the *Recommended International Code of Practice: General Principles of Food Hygiene*	CCGP 29th Session report - ALINORM 06/29/33 Appendix V Page 47 – 50 Management of the Work of the Codex Committee on Food Hygiene Paragraph 8
Proposal to be presented in project document and include: Purpose and scope of the proposed standard (work); Relevance and timeliness; Main aspects to be covered; Assessment against the criteria for the establishment of work priorities; Relevance to Codex strategic objectives; information on the relation between the proposal and other existing Codex documents Identification of any requirement for and availability of expert scientific advice; identification of any need for technical input to the standard from external bodies so that this can be planned for; and The proposed timeline for completion (not normally to exceed 5 years).	Codex Procedural Manual 15th Edition, p. 21

Additional proposed criteria for considering proposals for new work

The proposal for new work received from New Zealand suggests that an additional set of 'screening criteria' should apply if the intent of a work proposal is to develop a risk-based standard in a timely manner. The additional screening criteria proposed by New Zealand are listed in Attachment 7.

Preliminary assessment of new work proposals against criteria

A brief preliminary assessment of each new work proposal against the criteria is provided in Attachment 8.

The main issues arising from the preliminary assessment of proposals against criteria for new work are:

- Only one of the proposals (*Salmonella* in broiler chickens) includes both a risk profile and has been presented as a project document addressing all the criteria. It is therefore not possible to directly compare the proposals.
- The four proposals intend to address specific pathogens / commodity combinations by developing guidance in addition to the 'General Principles of Food Hygiene' However, further consideration is necessary as to the focus of this additional guidance as well as it's relationship to the 'General Principles of Food Hygiene'
- The two proposals about pathogens of poultry will also need to consider the Draft Code of Hygienic Practice for Meat[11]. Similarly the two proposals relating to shellfish will need to consider the Draft Code of Practice for Fish and Fishery Products[12].
- It is noted that proposals relate to managing the risks of pathogens in poultry and in seafood It may therefore be appropriate to consider undertaking work on poultry and consider both pathogens proposed, or undertake work on seafood and consider both pathogens proposed.

Sponsors of the proposals have been requested to provide additional information on the proposals prior to the *ad hoc* Working Group meeting and to summarise their proposals at the *ad hoc* Working Group meeting.

Previous priorities

At the 33nd Session of CCFH (2000) the Committee considered priorities for revision of Codes of Hygienic Practice including identifying which Codes were superseded and which could be combined. The Committee agreed on the Codes that could be combined and revised on a commodity basis as indicated in the agenda paper[13]. These are listed in Table 1 of Attachment 9 (updated on the 2000 paper).

The agenda paper to the 33rd Session also included suggestions for combining some Codes and these are listed in Table 2 of Attachment 9.

In regard to prioritising the work on the Codes in Attachment 9, the agenda paper to the 33rd Session proposed a priority listing arrived at on the basis of the combination of:

- Known potential public health risk;
- Impact on sensitive populations; and
- Date since last revision.

[11] ALINORM 05/28/16 Appendix II Codex Committee on Meat Hygiene Meeting
[12] ALINORM 05/28/18 Appendix III Codex Committee on Fish and Fishery products Meeting
[13] CX/FH 00/14

The Committee did not agree to the priority listing as such, but recognised the need to revise several of the Codes. Work has progressed on The Code of Hygienic Practice for Egg and Egg Products (which is currently at step 7) and the 'Revised Code of Practice for Foods for Infants and Young Children'. This Code of Practice has been renamed 'The Code of Practice for Powdered Infant Formulae for Infants and Young Children' and is currently at step 2. Work is proceeding on a revision of a Code of Practice for the Processing and Handling of Quick Frozen Foods (at step 5). The hygiene / safety provisions of this Code will be forwarded to CCFH for final consideration before adoption at step 8.

The priority as presented to the Committee is Table 3 in Attachment 7.

It is proposed that the CCFH consider the decision made previously and decide if it wants to reaffirm its decision, with a view to preparing project proposals for consideration at the next Session.

Next steps

The *ad hoc* Working Group for the Establishment of CCFH Work Priorities will meet on the Sunday immediately prior to the opening of the 38th Session of the CCFH (3rd December 2006). A proposed agenda for the meeting is at Attachment 10.

The agenda includes:

- Consideration and agreement on criteria for prioritisation of proposals, including the additional criteria proposed by New Zealand in its proposal to develop a risk-based standard for *Campylobacter* in poultry;
- Consideration of the project proposals described in this paper and a review of the list of Codes agreed to previously by CCFH as in need of revision with a view to providing recommendations to CCFH to assist the Committee to develop a more manageable work program; and
- Arrangements for future Chairs of the *ad hoc* Working Group.

In regard to dot point three above, Australia agreed to chair the first meeting of the Working Group noting that the Committee agreed to further discuss arrangements at its next Session in order to provide more time to evaluate a number of issues and ensure the appropriate balance between geographical representation and efficiency of work.

Recommendations

1. That members note the arrangements and agenda for the *ad hoc* Working Group meeting.

2. That members provide comment on the criteria for assessing proposals for new work as described in this paper, including the additional screening criteria proposed by New Zealand for work proposals to develop risk-based standards.

3. That countries that have submitted proposals, note the request to provide additional information and to present their proposals against the criteria at the *ad hoc* Working Group meeting.

4. That members note that two of the proposals relate to risk management of pathogens in poultry and two to risk management in seafood and consider a recommendation to CCFH that one of these two categories be proposed for new work in order to take into account the need to reduce the current work load of the CCFH.

5. That members consider that this work takes precedence over the work provided in the priority list at Attachment 9.

ATTACHMENT 1

MANAGEMENT OF THE WORK OF THE CODEX COMMITTEE ON FOOD HYGIENE, THE PROPOSED PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK, AS AMENDED BY CCGP ALINORM 05/28/33 (APPENDIX V)

Purpose

1. The following guidelines are established to assist the CCFH to:

- Identify, prioritize and efficiently carry out its work, and
- Interact with [other Codex Committees, Task Forces, and] FAO/WHO and their scientific bodies as the need arises.

Scope

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work; criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; [the approach to interaction of CCFH with other Codex Committees and/or Task Forces on items of mutual interest;] and a process by which CCFH will obtain scientific advice from FAO/WHO.

Process for Considering Proposals for New Work

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities ("*ad hoc* Working Group") at each Session, in accordance with the Guidelines on Physical Working Groups.

4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work.

i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.

ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the ad hoc Working Group as well as the CCFH Host government and Codex Secretariats.

iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.

iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

   If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the 'Criteria for the

Establishment of Work Priorities'[14]. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be "denied" or "returned for revision," a justification for this recommendation will be provided.

v. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project document[15], which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work.

Proposals for New Work

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile[16], as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

6. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

7. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- facilitate risk analysis activities; or
- establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).

Prioritization of Proposals for New Work

8. The Committee will prioritize its proposals for new work at each CCFH meeting if required. This will be carried out by the Committee after consideration of the recommendations from the a*d hoc* Working Group. The *ad hoc* Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the "Criteria for the Establishment of Work Priorities" and if necessary, additional criteria to be prepared by the Committee ~~to~~. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

[14] Codex *Procedural Manual*, 1**5**th Edition.

[15] The elements of a project document are described in the Codex *Procedural Manual*, **15**th Edition.

[16] Definition of a risk profile is "the description of the food safety problem and its context" (Codex *Procedural Manual*, 14th Edition). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

Obtaining Scientific Advice

9. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies (e.g. ICMSF). When undertaking such work, the Committee should follow the structured approach given in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development) and the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[17].

10. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

11. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favorably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

12. The Committee recognizes that an iterative process between risk managers and risk assessors is essential throughout the process described above and for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). The iterative process is described in Annex I.

13. The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 020-1999).

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17 Codex *Procedural Manual*, **15th** edition.

ANNEX I

ITERATIVE PROCESS BETWEEN THE CODEX COMMITTEE ON FOOD HYGIENE AND FAO/WHO FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

[The Codex Committee on Food Hygiene recognizes that an iterative process between risk managers and risk assessors is essential for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s). In particular, dialogue between the Committee and FAO/WHO is desirable to thoroughly assess the feasibility of the risk assessment, to assure that risk assessment policy are clear, and to ensure that the risk management questions posed by the Committee are appropriate.**]** If FAO/WHO agrees that the requested risk assessment proposed in the Risk Profile is feasible and will be undertaken, a series of planned interactions between the FAO/WHO JEMRA and the Committee should be scheduled to assure effective interaction. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees or other FAO/WHO risk assessment bodies, these committees should be included into the iterative process.

[It is essential that communications between these entities are timely and effective.**]**

[The Committee is likely to receive questions from FAO/WHO or the designated risk assessment body (e.g., JEMRA) relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the risk management control options to be considered, key assumptions to be made regarding the risk assessment, and the analytical strategy to be employed in the absence of key data needed to perform the risk assessment. Likewise, the Committee may pose questions to FAO/WHO or their designation (JEMRA) to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop and/or understand the risk management control options selected. Timely, appropriate responses are needed for these interactions.**]**

The Committee may elect to discontinue or modify work on a risk assessment if the iterative process demonstrates that: 1) completion of an adequate risk assessment is not feasible; or 2) it is not possible to provide appropriate risk management options. However, FAO/WHO may decide to continue the work if it is considered necessary to meet the needs of their member countries.

ATTACHMENT 2

REPORT TO THE 38TH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE ON THE REQUEST FOR A PROPOSAL FOR NEW WORK ON GUIDELINES FOR THE APPLICATION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK-BASED CONTROL OF ENTEROHEMORRHAGIC ESCHERICHIA COLI (E.COLI) IN GROUND BEEF AND FERMENTED SAUSAGES*

The 37th session of CCFH charged the United States with developing a written proposal for new work entitled "Guidelines for the Application of the General Principles of Food Hygiene to the Risk-Based Control of Enterohemorrhagic E. coli in Ground Beef and Fermented Sausages" (see paragraphs 166-168 of ALINORM 05/28/13)..

There has been a significant amount of activity within Codex on these pathogen and product combinations. In CCFH, the United States prepared a risk profile on this issue for the 36th session, and presented at the 37th session a "Discussion Paper on Draft Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic E. coli in Ground Beef and Fermented Sausages," which included an updated risk profile and suggested terms of reference for a risk assessment that CCFH was considering requesting of FAO/WHO JEMRA. As a result of the adoption of a new procedure for managing its work, CCFH directed the working group, led by the United States, to submit the discussion paper and its appendices as a request for new work.

The Codex Committee on Meat Hygiene (CCMH) completed a Code of Hygienic Practice for Meat (CAC/RCP 58-2005), adopted by the Codex Alimentarius commission at its 28th (2005) Session. The scope of this Code covers raw meat, meat preparations, and manufactured meat from the time of live animal production up to the point of retail sale. Although not covered in-depth, this Code does address the slaughter of cattle, the proper processing of beef, and the manufacturing of sausage products. This Code does contain a brief discussion on food safety objectives and other performance criteria in Annex II (Verification of Process Control of Meat Hygiene by Microbiological Testing" section 2 under Principles for the Establishment of Microbiological Testing Requirements). The process for the development of food safety objectives for raw ground beef or fermented sausages are not addressed in depth. With the completion of this Code, CCMH has adjourned its functional status until such time that relevant work is identified.

The CCFH briefly discussed at the 37th session the development of a more detailed code for the management of risks associated with enterohemorrhagic E. coli (EHEC) in ground beef and fermented sausages, however, it was realized that proceeding with the draft code is dependent on the development of practical guidance on establishment of risk management metrics (e.g., FSO, PO). As such, CCFH requested its 37th session that the FAO/WHO consultation, "Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs," which has been scheduled to take place in Kiel, Germany in April, 2006. One of the seven FAO/WHO working documents that are being considered by this consultation is E. coli in ground beef. The discussion paper presented by the United States at the 37th session does not include a thorough discussion on the process for the development of food safety objectives and related performance metrics for raw ground beef or fermented sausages. The issuance of guidance on the application of these metrics to the control of EHEC in ground beef and fermented sausages would be premature before receiving and reviewing the report of the consultation.

In light of the dependency of this work on the acquisition of scientific advice, the United States recommends that a proposal for new work related to the development of a hygienic code for EHEC in ground beef and fermented sausages be delayed for one year, but does want to signal its intent to submit a proposal for such work for the 39th session.

ATTACHMENT 3

PROPOSAL TO DEVELOP A RISK-BASED STANDARD FOR CAMPYLOBACTER IN POULTRY (NEW ZEALAND)

1. INTRODUCTION

1.1. Background

The CAC's strategic framework for 2003 -2007 attaches high priority to promoting science and risk analysis as the basis for Codex standards and other texts. The CCFH has been exploring the use of risk analysis in development of Codex standards for several years. As part of this work, CCFH have identified a number of food-borne microbial pathogens of world-wide concern and have worked with FAO and WHO to commission "global" risk assessments that would form the basis of Codex standards and/or other texts for specific pathogen / commodity pairs. While JEMRA has now completed a large body of risk assessment work, there has been limited progress by CCFH in development of specific "risk-based" Codex standards and/or other texts. This may be due to several reasons:

- Inadequate formulation of questions that the risk managers (CCFH) want to be answered by the risk assessors
- Limited technical resources within JEMRA to complete production-to-consumption risk assessments, especially in terms of variation in regional food chains
- Unavailability of data to complete globally-representative risk assessments, especially in regard to developing countries
- Limited ability of the CCFH to work effectively between sessions to progress discussion papers / draft standards
- Lack of understanding in CCFH of what is actually required in developing a "risk-based" standard, including what form a Codex standard should take.

1.2. Development of standards based on risk assessment

There is no explanation in the Codex system of what is expected when developing a "risk-based" standard. However, there is a general understanding that such standards should be outcome-focused i.e. address actual risks to human health. In this context, a "risk-based" standard can be described as:

> *"A standard that is based on specific knowledge of risks and has the objective of achieving an established level of health protection"*

Further, there is no description in the Codex system of the form in which a risk-based standard should be presented. There are a number of options (see following text) and questions also arise as to the extent of GHP and HACCP provisions that should be included.

1.3. Criteria for acceptance of new work

Generic criteria need to be applied when accepting new proposals for the CCFH work programme e.g. issue is representative of an important human health problem and /or there is a significant impact on international trade, the work will facilitate risk analysis activities etc.[18]

[18] Refer CL2005/40 - FH

It is suggested that an additional set of screening criteria need to be applied if the intent of a work proposal is to develop a risk-based standard in a timely manner (Annex I). The CCFH as the risk manager must recognise the high level of technical input that is required and the need for effective inter-session administration.

2. Proposal for development of a risk-based standard for *Campylobacter* in broiler chickens

2.1. Application of suggested criteria

Priority food / pathogen combination, and importance in international trade

Campylobacteriosis is one of the most commonly reported food-borne diseases on a global scale (refer to Risk Profile).

A number of countries are investing heavily in reducing foodborne disease due to enteric zoonoses and this is likely to result in very different levels of hazard control at the national level. Development of risk-based Codex standards that enable trade on the basis of equivalent levels of consumer protection is essential.

Purpose and scope

The purpose of the proposed work would be to develop a genuinely risk-based "production-to-consumption" standard for Campylobacter in broiler chickens. This standard should serve risk management needs at the international and the national level and should include:

- GHP and HACCP provisions specifically for Campylobacter in broilers, as a platform for the risk-based provisions in the standard
- Modelling of different risk management interventions in a globally representative, production-to-consumption risk assessment model to demonstrate the relative impact of different food safety controls on levels of consumer protection, and provide recommendations for a risk-based standard on that basis
- Utilisation of the risk model to provide a "menu" of risk estimates resulting from different levels of hazard control at relevant points in the production-to-consumption food chain. (Subsets of the risk assessment may be needed to model regional variations in food chains).

Member countries could:

- Choose their sovereign level of protection from the menu of food controls / risk estimates and implement associated controls accordingly, knowing that these are scientifically justified by an international risk assessment methodology
- Discuss the usefulness of a benchmark Codex standard incorporating a globally-representative performance objective(s)
- Use the risk assessment in the standard as a scientifically justified methodology to judge the equivalence of controls applied in exporting countries.

"Champion" Member government

New Zealand offers to act in an administration and co-ordination role through the life cycle of the standard development process. New Zealand would be responsible for completion of the work programme between sessions of the CCFH as outlined below, including co-ordination of technical inputs, management of working groups and facilitating timely interaction with JEMRA.

Risk profile

An earlier discussion document developed by CCFH (CX/FH 03/5-Add.2) provides an international resource for a risk profile. A NZFSA risk profile adds to this by providing more detailed information on various transmission pathways and current regulatory approaches[19].

Risk assessment

The global "production-to-consumption" risk assessment model would be built up from available resources, as in the work plan below. Separately, all currently available risk models are incomplete and suffer from significant data gaps. These disadvantages could be largely overcome by a dedicated CCFH intersession programme to integrate current scientific knowledge into a framework risk assessment model using:

- The JEMRA "international" risk assessment, which is acknowledged as being highly uncertain
- Several national risk assessments that have recently become available and that are subject to a VetProMed initiative to combine the best features of each
- Source attribution campylobacteriosis models that determine the relative proportion of human disease transmitted by particular food pathways, as well as other transmission pathways
- New microbial genotyping studies using techniques such as MLST to inform the risk model.

Risk management instructions

The risk management questions to be answered would flow from the agreed purpose and scope. It is suggested that key instructions could be:

- Describe specific, science-based GHP and HACCP provisions that should be incorporated in food safety programmes for Campylobacter in broilers
- Quantify the relative impacts of different food safety controls for Campylobacter in chickens, either alone or in combination, on levels of risk
- Quantify the influence of different levels of hazard control at different steps in the food chain (including prevalence at the farm level) on risk estimates, and create a "menu" of such controls and the resulting risk estimates
- Repeat simulations for regional food chains that are significantly different to the framework risk assessment
- Quantify the likely proportions of human campylobacteriosis transmitted by broilers compared with other transmission pathways
- Provide the scientific information necessary to discuss the usefulness of a benchmark Codex standard incorporating a globally-representative level of protection

Form of the proposed standard

The form of the final standard could be as follows:

[19] www.nzfsa.govt.nz /science/ risk profiles/campylobacter

1. Introduction

2. Inclusion of a risk profile as an Annex

3. Reference only to prerequisite food hygiene requirements that are not risk-based and which are described generically in existing Codex texts e.g. General Principles of Food Hygiene, Code of Hygienic Practice for Meat

4. Description of specific GHP and HACCP requirements for Campylobacter in broilers that are based on good science

5. Description of risk-based components of the standard:

    - Summary description of the risk assessment model and link to web site

    - Quantification of the relative impacts of different food safety controls for Campylobacter in chickens, either alone or in combination, on levels of risk

    - Quantification of the influence of different levels of hazard control at different steps in the food chain (including at the farm level) on risk estimates, and presentation of a "menu" of such controls and the resulting risk estimates for the use of national risk managers

    - Modelling of scenarios and outcomes where regional food chains are significantly different

    - If appropriate and agreed by CCFH, a benchmark Codex standard that delivers a globally-representative level of protection

6. Quantification of the likely proportions of human campylobacteriosis transmitted by Campylobacter in broilers compared with other transmission pathways

Note that the standard would include a web-based link to a generic, user-friendly PC-based model that Member countries can use to independently develop risk-based controls according to country-specific inputs.

2.2. Work plan

A work plan that is achievable with a high level of input from the "Champion Member government" could be as follows:

December 2006	38th Session CCFH	Agree proposal
		Agree purpose and scope
		Preliminary agreement on risk management instructions
		Agree form of standard

Intersession 06 /07	New Zealand	Complete risk profile[20] Call for scientific data from national governments and assemble "global" production-to-consumption risk assessment model Complete GHP and HACCP components of standard Draft standard, without risk-based outputs, circulated for government comments
December 2007	39th Session CCFH	Draft standard accepted at Step 3
Intersession 07/08	New Zealand	Convene working group to peer review model, and develop risk-based components of the standard
December 2008	40th Session of CCFH	Present draft standard for advancement to Step 5
Intersession 08/09	New Zealand	Continue technical work
December 2009	41st Session CCFH	Present draft standard for advancement to Step 5/8
June 2010	CAC	Adoption

3. Recommendations

It is recommended that CCFH:

1. Accept a proposal to develop a risk-based standard for Campylobacter in broiler chickens
2. Consider the above discussion on components of a risk-based standard and agree the purpose, scope and form of the standard
3. Agree a work plan for development of the standard

[20] Standard format so as to contribute to a library of Codex international risk profiles?

ATTACHMENT 4

PROPOSAL FOR NEW WORK ON GUIDELINES FOR THE APPLICATION OF CODEX GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK BASED CONTROL OF SALMONELLA IN BROILER CHICKENS

(SWEDEN)

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON GUIDELINES FOR THE APPLICATION OF CODEX *GENERAL PRINCIPLES OF FOOD HYGIENE* (CAC/RCP 1-1969, *Rev.4 (2003)*) TO THE RISK BASED CONTROL OF *SALMONELLA* IN BROILER CHICKENS

PREPARED BY: Sweden

PURPOSE AND SCOPE OF THE PROPOSED STANDARD[21]

To provide advice supplemental to the *Recommended Code of Practice-General Principles of Food Hygiene*, CAC/RCP 1- 1969, Rev. 4 2003 on management options for the control of *Salmonella* spp. in broiler chickens.

ITS RELEVANCE AND TIMELINESS

Salmonellosis is one of the most frequently reported foodborne diseases worldwide. Broilers and broiler products are common food vehicles of the disease in many countries.

At its 36th session in Washington the Codex Committee of Food Hygiene noted that the significance of *Salmonella* in broilers in terms of food safety is considerable.

The document is intended to give advice to governments, industry, consumers and other interested parties on management options at primary production, processing and further steps in the food chain, for the control of *Salmonella* spp. in broilers and broiler products.

THE MAIN ASPECTS TO BE COVERED

Risk management options that are applicable at the different steps in the food chain and supplemental to the *General Principles of Food Hygiene.*

AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

The proposed new work is relevant to the following *Criteria for the Establishment of New Work, criteria applicable to commodities:*

Consumer protection from the point of view of health and fraudulent practices;

Volume of production and consumption in individual countries and volume and pattern of trade between countries;

Diversification of national legislations and apparent or potential impediments to international trade;

Coverage of the main consumer protection and trade issues by existing or proposed general standards;

[21] For the purpose of this document the word ”standard” in meant to include any of the recommendations of the Commission intended to be submitted to Goverments for acceptance

Work already undertaken by other international organizations in this field.

RELEVANCE TO CODEX STRATEGIC OBJECTIVES

This new work proposal is consistent with:

Objective 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.

INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The proposed new document is supplemental to and should be used in conjunction with the *Recommended International Code of Practice – General Principles of Food Hygiene,* CAC/RCP 1 – 1969, *Rev. 4* , 2003. It is also supplemental to the *Code of Hygienic Practice for Meat*, CAC/RCP 58 – 2005.

IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

There is a need for scientific data concerning the effect of various risk management interventions at primary production and at processing. However, at present such data seems to be limited.

IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None identified.

THE PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK,

It is expected that the work can be completed within a five-year timeframe.

WORK TO BE LEAD BY:

Sweden.

Risk Profile for *Salmonella* spp. in Broiler Chickens

Pathogen of concern

Salmonella spp. (non-typhoidal).

Commodities of concern

Broiler chicken is the commodity of interest.

Description of the pathogen

The genus *Salmonella* belongs to the family *Enterobacteriaceae* and consists of two species, *Salmonella* enterica and *Salmonella* bongori. S. enterica is further divided into six subspecies: S. enterica subsp. enterica, S. enterica subsp. salamae, S. enterica subsp. arizonae, S. enterica subsp. diarizonae, S. enterica subsp. houtenae and S. enterica subsp. indica (Grimont *et al*., 2000). More than 2400 *Salmonella* serovars have been identified. A few of these are human –host-adapted serotypes, e.g S. Typhi and S. Paratyphi. These serotypes are referred to as typhoidal salmonellae. This risk profile will discuss only non-typhoidal *Salmonella* belonging to the species enterica.

Salmonellae are gram-negative, oxidase negative, rod shaped, facultative anaerobic bacteria. They are motile (a few exceptions exist) due to the presence of flagella. Growth occurs in the range 5°C – 46°C with an optimum between 35°C and 43°C. The pH for optimum growth is between 6.6 and 8.2 with values greater than 9 or lower than 4 inhibiting growth. Depending on the acid used, minimum pH for growth may be as high as 5.5. Minimum water activity for growth is 0.94 in media with a neutral pH but higher values are required as pH decreases towards growth minimum (SCVPH, 2000).

Heat resistance of salmonellae varies considerably between strains. The type of food involved and growth conditions such as pH and water activity also affect the heat resistance as well as other environmental factors. D-values (the time in minutes at a given temperature to get a 90% reduction in the number of viable bacteria) at 60°C usually vary between 2-6 minutes. At 70°C the D-value is usually 1 minute or less. (ICMSF, 1996; Doyle and Mazottta, 2000).

Virulence Characteristics

After oral uptake *Salmonella* is successively exposed to low pH in the stomach, to the strong antimicrobial effect of bile, to decreasing oxygen supply, to the normal gut-flora and it´s metabolites, to intestinal peristalsis and cationic antimicrobial peptides present on the surface of epithelial cells (Rychlik and Barrow, 2005). The encounter with these stressful environments induces expression of a number of genes whose products are essential for *Salmonella* to invade the intestinal epithelium and infect the host.

The ability to cause disease relies on several virulence determinants. Some of these may be considered virulence determinants in the broad sense. Genes involved in nutrient biosynthesis/uptake, stress response (both in and outside the host) and repair of cell damage are among those. These genes may be considered housekeeping genes and are present in other closely related bacteria, such as E. coli (Bäumler *et al*., 2000).

Another group of virulence genes specific for the genus *Salmonella* encode adaptations to overcome host defence mechanisms and may therefore be called true virulence determinants.

The expression of both groups of virulence genes is regulated in response to environmental signals in the host. The regulatory genes mediating this control may also be considered virulence determinants (Bäumler *et al*., 2000).

The genetic control of *Salmonella* virulence is not fully elucidated. However both plasmid and chromosomal genes are involved.

Many of the virulence genes of S. enterica are chromosomal genes located on pathogenicity islands referred to as *Salmonella* Pathogenicity Islands (SPI). These genes are believed to have been acquired by *Salmonella* from other bacterial species through horizontal gene transfer (van Asten & van Dijk, 2005). This includes functions such as host cell invasion and intracellular pathogenesis. At present 12 different SPI have been described. The role in pathogenesis of some SPI is well described but the function in virulence of many genes within SPI is yet not understood (Hensel, 2004).

At least six serotypes of *Salmonella* (Abortusovis, Choleraesuis, Dublin, Enteritidis, Gallinarum/Pullorum and Typhimurium) harbour a virulence plasmid (although not all isolates of these serotypes). These plasmids vary in size between the serotypes. All these plasmids contain the salmonella plasmid virulence (spv) locus. This locus harbours five genes designated spvRABCD (van Asten & van Dijk, 2005). The first gene spvR encodes an activator of spvABCD, but the exact function of the encoded proteins is not fully known. These genes are induced by growth restriction, reduced nutrient supply or lowered pH and are involved in intra-macrophage survival of *Salmonella* (Rychlik *et al*., 2005). Other virulence factors of *Salmonella* include production of endotoxins and exotoxins, and presence of fimbrie and flagella. The role of these factors in the pathogenesis of *Salmonella* spp. is not fully established (van Asten & van Dijk, 2005).

Susceptibility to antimicrobial agents

Antimicrobial- resistant strains of *Salmonella* spp. are now widespread all over the world and are causing great concern not least due to the spread of multi-drug-resistant strains. In developed countries it is becoming more and more accepted that a majority of resistant strains are of zoonotic origin and have acquired their resistance in an animal host before being transmitted to humans through the food chain (Mølbak *et al*., 2002; Threlfall, 2002; WHO 2004).

In animal production antimicrobial drugs are used for therapy, prophylaxis and growth promotion. The use of such drugs causes a selective pressure to be imposed on bacterial populations and antimicrobial resistances are selected. The pool of resistance genes is thus spread in the environment (WHO, 2004).

Antibiotic resistance determinants are usually encoded on plasmids but can also be present on the *Salmonella* chromosome. Resistance can be achieved through mutations and acquisition of resistance encoding genes. Cointegrates of resistance and virulence plasmids in *Salmonella* have been observed. This means that antibiotic pressure may select for these plasmids and that both resistance and virulence traits are obtained simultaneously. This may lead to more antibiotic-resistant and virulent *Salmonella* trains. The outcome of such a scenario is to a large extent dependent on the use of antibiotics (Fluit, 2005). Data suggesting that disease caused by resistant strains can be more severe than disease caused by susceptible strains have been published (Lee *et al*., 1994; Helms *et al*., 2004; Helms *et al*., 2002)

The prevalence of resistant isolates in different countries where intensive animal production is common is between 10 -30 %. When concentrating on strains isolated from food-producing animals that are held under strong antibiotic selective pressures and are important to human health the prevalence of resistant strains can be very high, up to 60-90% (Helmuth, 2000).

Table 1

Antimicrobial	**Percent Sensitive**
Amikacin	>99.9
Amoxicillin/clavulanic acid	88.4
Ampicillin	81.9
Apramycin	98.9
Ceftiofur	96
Ceftriaxone	97.7
Cephalothin	92.3
Chloramphenicol	90.1
Ciprofloxacin	100
Gentamicin	90.8
Kanamycin	87.7
Nalidixic Acid	98.8
Streptomycin	69
Sulfamethoxazole	71.1
Tetracycline	64.8
Trimethoprim/sulfa	96.6

In 1999, 8,508 *Salmonella* isolates of animal origin were tested against 17 antimicrobial drugs in the USA. The results are shown in Table 1 and indicate that many *Salmonella* serotypes are resistant to some of the antibiotics commonly used in human and animal health, and as growth promoters in the animal production industry (Headrick and Cray, 2001).

In 2004 in the EU, human isolates of the two dominating serovars S. Typhimurium and S. Enteritidis, showed a considerable variation in the prevalence of resistant isolates between reporting countries. For S. Enteritidis the prevalence of resistant isolates was generally low but for S. Typhimurium resistance to commonly used antimicrobials was high in some countries. S. Typhimurium strains resistant to 2 or more antimicrobials varied from 7.8 to 56.4%. In the Netherlands 21% of human isolates of S. Typhimurium were resistant to more than 4 antimicrobials. In broiler meat the prevalence of resistant isolates of *Salmonella* spp. also showed great variation with a relatively high level of resistance to several antimicrobials reported from some countries. The percentage of strains resistant to 4 or more of the 11 tested antimicrobials varied between 0 and 36 % among reporting countries (EFSA, 2005).

Salmonellosis in humans

Susceptible populations

Epidemiologic information indicates that susceptibility is highest in infants, elderly people and immuno-compromised hosts (WHO, 2002).

The greatest incidence of salmonellosis in the EU in 2004 was in children aged 0-4 years. This age group represented 26% of all reported cases. A secondary peak was reported for adults aged 25-44 years. The incidence in the age group 65 years and older was the lowest reported of all age groups (EFSA, 2005).

However, it should be pointed out that association with age may be spurious. Diseased children are more likely to be given medical attention and are more likely to be tested than adults. Elderly people with diarrhoea may also be expected to be more frequently cultured than other age groups (Banatvala et al., 1999). Moreover, age association may reflect behavioural characteristics. For example, in Norway an association between eating snow, sand, or soil (most likely a childish behaviour) and infection with S. typhimurium O:4-12 has been demonstrated (Kapperud et al., 1998a). Eating and cooking habits may also be confounding factors.

Annual incidence in humans

Each year, approximately 40,000 *Salmonella* infections are culture-confirmed, serotyped, and reported to the United States Centers for Disease Control and Prevention (CDC), which estimates an annual rate of 1.4 million cases, 16,430 hospitalizations, and 582 deaths in the United States alone (Mead *et al*., 1999). Of total cases, 95% are estimated to be caused by foods. International data summarized by Thorns (2000) provides estimated incidences of salmonellosis per 100,000 people for the year 1997: 14 in the USA, 38 in Australia, and 73 in Japan. In the European Union 192,703 cases of salmonellosis were reported in 2004 which represents an incidence of 42.2 per 100,000 people. Incidence ranged from 6.6/100,000 people in Portugal to 300.9/100,000 in the Czech Republic (EFSA, 2005).

Seasonal variations

CDC data (1996) demonstrates that the foodborne disease outbreaks caused by *Salmonella* in the United States occur more frequently in the summer as compared to the winter months. This has also been shown in other parts of the world,e.g. in the EU and in New Zealand (Lake *et al*., 2002; EFSA, 2005). Temperature may be a major factor impacting the survival and proliferation of *Salmonella*, i.e, warm temperatures provide an environment in which *Salmonella* can grow during the processes of production, transport, and storage (Guthrie, 1992; Latimer, 1999).

Outcome of exposure

Exposure to *Salmonella* can cause symptoms from mild diarrhoea up to severe sepsis and death. Symptomless carriers are common.

Severity of clinical manifestation

Non-typhoidal salmonellosis generally manifests as a self-limiting episode of enterocolitis characterised by diarrhea, abdominal pain, mild fever, chills, nausea and vomiting; prostration, anorexia,headaches and malaise may also occur. The incubation period is 5-72 hours. In general the course of disease is benign and clinical recovery takes place in 2-5 days. Occasionally, systemic infections can occur, particularly with *Salmonella* Dublin and *Salmonella* Cholerasuis, infections which exhibit a predilection toward septicaemia (D'Aoust, 1997).

Outcome data for salmonellosis

In the USA it is estimated that in general, 93% of individuals with symptoms of salmonellosis recover fully without visiting a physician, 5% see a physician and recover fully, 1.1% of patients require hospital treatment and 0.04 –0.1% of patients will die (Buzby *et al*., 1996; Mead *et al*., 1999). A summary of data of cases with a known outcome from New Zealand in the years 1997-2001 shows a hospitalisation rate of 8.9 – 14.4% and a fatality rate of 0.05 – 0.4% (Lake *et al.*, 2002).

Nature and frequency of long-term complications

Salmonella has been implicated as a triggering organism for reactive arthritis (ReA) and Reiter's syndrome. Reactive arthritis is characterized by the development of synovitis (joint swelling and tenderness) within a few weeks after the occurrence of gastroenteritic symptoms. An incidence of reactive arthritis of 1.2- 7.3% (mean 3.5%) was estimated in a review of several outbreaks affecting 5525 patients with salmonellosis (Maki-Ikola and Granfors, 1992). Reiter's syndrome is defined as the occurrence of arthritis with one or more extra-articular symptoms typical of the disease such as conjunctivitis, iritis, urethritis and balanitis. The prognosis for ReA is usually favourable with symptoms lasting for <1 year in most persons, although 5 to 18% may have symptoms that last more than 1 year and 15 to 48% may experience multiple episodes of arthritis (WHO/FAO 2002).

Treatment

For uncomplicated enterocolitis in an otherwise healthy adult, no specific treatment other than rehydration and electolyte replacement is usually prescribed. Antibiotic therapy is not routinely recommended (Hohmann, 2001).

Medical, hospital costs

The actual cost of salmonellosis in various countries is difficult to calculate because of the existence of unreported cases. In USA it is estimated that for every verified human isolation there are approximately 50 unreported cases (Todd, 1993). In Sweden the number of unreported cases of human salmonellosis is believed to be low (Engvall *et al*., 1993). Estimates in other European countries usually indicate a frequency of unreported cases lying between the US and Swedish estimates.

Todd (1993) estimated the number of human cases of salmonellosis in USA to be 2 million annually. The cost for this was US$ 927 per case adding up to a total of 1.8 billion. In the Netherlands the cost per case in 1992 was estimated to be US$ 1700 for reported cases and US$ 343 for unreported cases (Notermans *et al*., 1992). In Sweden the corresponding costs in 1992 were US$ 2000 and US$ 600 respectively (Engvall *et al*., 1993). In 1998 the costs of foodborne salmonellosis for the United States population were estimated to be US $2,329 million annually for medical care and lost productivity (Frenzen *et al*., 1999). Normally 1-3 working days are lost due to illness.

Percentage of annual cases attributable to foodborne transmission

Although occasionally associated with exposure to pets, reptiles, and contaminated water, non-typhoidal salmonellosis is primarily a foodborne disease. Mead *et al*. (1999) estimated that 95% of non-typhoidal salmonellosis cases are foodborne in the US.

Poultry and poultry products are often implicated in sporadic cases and in outbreaks of human salmonellosis (Bryan and Doyle, 1995; Humphrey, 2000).

In the US between 1993 and 1997, there were a total of 655 foodborne disease outbreaks involving 43,821 illnesses, attributable to bacterial pathogens. A total of 357 (54.5%) outbreaks involving 32,610 (74.4%) illnesses were due to *Salmonella* spp. (Mead *et al*., 1999). In New Zealand the annual percentage of outbreaks that was caused by *Salmonella* varied between 10.0 and 15.0% during the years 1997 to 2001 (Lake *et al*., 2002).

In outbreaks in Europe between 1993 to 1998 *Salmonella* spp. were involved in 54.6 % of cases. The most important foods where salmonellae caused the outbreak were: eggs and egg products 35 %, cakes and ice-cream 28 %, meat and meat products 8%, meat and eggs 7 %, poultry and poultry products 4%, salads, dressings and mayonnaise 4% (WHO, 2001). The food vehicles implicated in outbreaks from *Salmonella* spp., in the United States between 1993 and 1997 include eggs, beef, ice cream, chicken and pork (CDC, 2000).

It can be concluded that non-typhoid *Salmonella* spp. are a major cause of foodborne infections and that amongst these chicken and chicken products are common vehicles in many countries.

***Salmonella* in broilers and broiler products**

S. Enteritidis and S. Typhimurium are by far the two dominating serotypes isolated from poultry and poultry products (Poppe, 2000; EFSA, 2004) and these two serotypes are also the most frequently isolated serotypes in humans (Herikstad *et al*., 2002).In the EU in 2004 *Salmonella* was detected in 0,1 – 26,8 % in broiler samples taken at slaughter (8 member states), in 0,1 – 26,3 % in fresh broiler meat taken at processing/cutting plant (10 member states) and in 2,0 - 18,5 % in fresh broiler meat at retail level (12 member states). In samples of broiler meat products *Salmonella* was found in 0,1 – 6.9 % .The proportion of *Salmonella*- infected broiler flocks in the member states ranged from 0.1 to 23.4 % (EFSA,2005).

D´Aoust (2000) reported the prevalence of *Salmonella* spp. in retail poultry: chicken 6.9 – 81.5 % (13 reports from Denmark, France, Germany, India, Italy, Japan, Malaysia, Mexico, Northern Ireland, Thailand, the Netherlands, Turkey and the UK); minced chicken 42 % (1 report from the USA); chicken liver 11.1 – 90.2 % (3 reports, Malaysia, Mexico and Thailand) and chicken gizzards 44-88 % (2 reports, Malaysia and Thailand).

In New Zealand 1.2 % of 1318 samples taken on chicken carcasses after chilling and draining dripping were positive for *Salmonella* (Lake *et al*., 2002). In Vietnam 24 (7.9%) of 302 fecal or intestinal samples from chicken were positive for *Salmonella* (Tran *et al*., 2004).

Lake et al. (2002) compiled studies of the prevalence for *Salmonella* in poultry and raw poultry products from 12 countries worldwide showing a variation from 0 to > 50 %.

International trade

Many countries have trade restrictions for *Salmonella* and poultry trade between countries have been interrupted by *Salmonella* contaminated consignments (Mathews *et al*., 2003).

Primary Production

The primary production is the most important reservoir of *Salmonella* spp. entering the food chain (EFSA, 2004). Due to lack of data the effect of different on-farm interventions could not be evaluated in the WHO/FAO risk assessment (WHO, 2002). Nevertheless the importance of reducing *Salmonella* infections in the various levels in primary production is obvious. The efficient control of *Salmonella* spp. in all parent flocks reduces the prevalence at the broiler production stage (SCVPH, 2000). This has been well illustrated in Denmark where a control programme based on top–down eradication, has reduced the proportion of *Salmonella*-infected broiler flocks from >65% in 1989 to < 5% in 2000 (Wegener *et al*., 2003). This reduction has also been shown to have a reducing effect on human salmonellosis (Hald *et al.*, 2004).

In Finland, Sweden and Norway control programmes have documented that the prevalence of *Salmonella* spp. in broiler flocks since 1996 has been < 1% (EFSA 2004). The situation in the broiler flocks is reflected in the prevalence in broiler meat (EFSA 2005).

The sources of salmonella infection for domestic fowls are numerous. Infection can occur via horizontal transmission by litter, faeces, feed, water, fluff, dust, shavings, straw, insects, equipment and other fomites contaminated with S*almonella* and by contact with other chicks or poults, rodents, pets, wild birds, other domestic and wild animals and personnel contaminated with S*almonella* (Poppe, 2000).

Controlling Salmonella spp. in the primary production relies heavily on biosecurity measures including supply of Salmonella-free feed and water. The use of competitive exclusion and pro- and prebiotics are examples of complementary interventions (Wierup *et al*., 1992; Fuller, 1989; Bailey *et al*., 1991).

Due to lack of quantitative data on the efficacy it is impossible to prioritise between different intervention strategies. A combination of different interventions is no doubt beneficent in achieving substantial reductions in the frequency of *Salmonella*-contaminated broilers sent to slaughter.

Transport

During tranport transmission of microorganisms is common. Birds will be contaminated by droppings from birds stored above them and by walking and falling on droppings in the crates. Furthermore, commonly used methods for washing and disinfecting crates are inefficient and washed crates have been found to be contaminated by *Salmonella* (Bailey *et al.*, 2001); Corry *et al*., 2002; Humprey and Allen, 2002).

Improved hygiene management during transport of broilers can reduce the risk of Salmonella-contamination of poultry meat (Heyndrickx *et al*., 2002).

Processing

Poultry processing does not reduce carcass contamination, the proportion of contaminated carcasses may even increase during slaughter. Cross-contamination occurs especially at scalding, defeathering, evisceration and giblet operations (Bryan and Doyle, 1995). At present no effective barriers that might control *Salmonella* during processing exist (Fries, 2002) However, differences in hygiene practices between slaughterhouses with resulting differences in carcass contamination have been demonstrated indicating that improved hygiene management could significantly reduce the risk of *Salmonella* contamination of broiler meat (Heyndrickx et al., 2002).

Specific strategies to reduce the risk of contaminated poultry meat include slaughter of positive flocks at the end of the week or at the end of the day followed by intensified cleaning and disinfection and channelling of meat from infected flocks to heat-treatment or other bactericidal treatments,.

Chemical decontamination of the carcasses, mainly by using chlorinated water for washing and chilling have been widely used. The effect is a matter of discussion. Some studies have shown a reduction of 1-2 [10] logs while other have found a reduction of cross-contamination between carcasses but no effect on bacteria entrapped or otherwise attached to skin and muscle surfaces (Lillard 1989; Yang et al., 2001). In UK the Food Standards Agency (FSA) concluded that the use of chlorine offers only limited public health benefits (FSA, 2001).

Decontamination with irradiation and ionisation are very effective methods, however, public resistance against these methods has hindered their application in many countries even though scientific experts agree on the safety of these techniques.

During further processing contamination of equipment and workers will occur from positive carcasses and the final cut-up products will be contaminated to a greater extent than the carcasses from which they were prepared (Bryan and Doyle, 1995).

Consumer handling

During normal cooking (roasting, frying, grilling) surfaces of poultry will reach temperatures at which Salmonella are killed. A risk for the consumer to be infected exists when eating

undercooked products.

Cross-contamination from raw products to cooked or to ready-to-eat products via contaminated cutting-boards, kitchen utensils, dishcloths, hands etc are also well known.

Educating and informing the consumer about basic food hygiene and about the correct handling and cooking of broilers are means to reduce the incidence of human salmonellosis caused by contaminated broilers and broiler products.

Control Programmes

In many countries *Salmonella* control programmes have been or will be implemented. In the EU, all memberstates will have to implement control programmes and a Community target for the prevalence of *Salmonella* serotypes with public health significance in broiler flocks will be set according to regulation EC No 2160/2003.

In USA the Pathogen Reduction/HACCP Programme for broiler establishments was launched in 1988. In 2002 this programme could demonstrate a reduction of contaminated broilers from a baseline of 20% to 10.2 % and from a baseline of 44.6% in ground chicken to 14.4% (FDA, 2002).

In Finland, Norway and Sweden national *Salmonella* control programmes have been effectuated for many years. These programmes include all steps from breeder production to final processing and are based on a zero-tolerance strategy including all *Salmonella* serotypes. Whenever *Salmonella* is found immediate actions are taken. The prevalence of *Salmonella* contaminated flocks has consistently been very low for the last ten years and positive samples found after slaughter and in cutting plants have been very few, if any (e.g. EFSA, 2005). The effects of these programmes on public health have been elucidated and found to be very good (Engvall *et al*.,1993; Maijala *et al*., 2005).

Available Information and Major knowledge gaps

The risk assessment of *Salmonella* in broiler chickens (WHO 2002) contained limited information concerning the effects of various risk reduction options. However, the outcome of the document is that the risk for *Salmonella* infection is related to the prevalence of *Salmonella* contaminated carcasses.

It was acknowledged that destruction of *Salmonella* positive flocks will have a public health effect but due to lack of specific information on how this would translate to fewer infected birds or fewer

Salmonella cells per infected bird at the completion of processing, the magnitude of risk reduction was not estimated.

Nevertheless it was estimated that a reduction in the concentration of *Salmonella* cells on carcasses leaving processing would reduce the risk of illness per serving at least proportionally.

The expert group found the available data on the importance of various routes for introduction of *Salmonella* spp. into flocks to be inconclusive. It was therefore not possible to evaluate the importance of on-farm routes of introduction of *Salmonella* spp.

Main data gaps for primary production are:

- *Salmonella* prevalence information is available for some countries world – wide, however many of these studies give limited details of study design.
- Data are limited or missing from most countries in Africa, Asia and Latin America.
- There are very limited data on the concentration of *Salmonella* on positive birds.
- The effect on *Salmonella* prevalence of specific risk reduction interventions.

Main data gaps for processing are:

- Quantitative data are limited for several steps of processing.
- There is limited information on processing practices used in different countries.
- Many studies are old, more recent information on changes in prevalence and numbers would be beneficial.

Recommendation

Many interventions aimed at reducing the prevalence of infected broilers and broiler products reaching the consumer have been described. In experimental as well as under natural circumstances these interventions have been shown to be more or less effective.

Even though there is a lack of quantitative data on the effects of these interventions on the prevalence of *Salmonella* contaminated carcasses and the concentration of *Salmonella* on contaminated broilers under full-scale broiler production, the results from various control programmes show that well focused strategies based on combinations of risk management interventions, implemented along the “stable to table”- continuum, can be very effective.

Codex Committee on Food Hygiene is therefore recommended to decide on the development of a risk management document: Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of Salmonella in Broiler Chickens.

References

Bailey J.S., Blankenship L.C. and Cox N.A. (1991) Effect of fructooligosaccharide on *Salmonella* colonization of the chicken intestine. *Poult. Sci*., 70, 2433-2438.

Bailey J.S., Stern N.J., Fedorka-Cray P., Craven S.E. Cox N.A., Cosby D.E., Ladely S. and Musgrove M.T. (2001) Sources and movement of *Salmonella* through integrated poultry operations: A multistate epidemiological investigation. *J. Food Prot*., 64, 1690-1697.

Baird-Parker A.C. (1990) Foodborne salmonellosis. *The Lancet*, 336, 1231-1235.

Banatvala N., Cramp A., Jones I.R. and Feldman R.A (1999) Salmonellosis in North Thames (East), UK: associated risk factors. *Epidemiol. Infect*., 122, 201-207.

Bryan F.L. and Doyle M.P. (1995) Health risks and consequences of *Salmonella* and *Campylobacter jejuni* in raw poultry. *J. Food Prot*., 58, 326-344

Buzby J.C., Roberts T., Lin J. C.-T. and MacDonald J.M. (1996) Bacterial Foodborne Disease, Medical Costs and Productivity Losses. *USDA-ERS Report*, No 741.

Bäumler A.J., Tsolis R.M. and Heffron F. (2000) Virulence Mechanisms of *Salmonella* and their Genetic Basis. In: *Salmonella in Domestic Animals* (C. Wray and A. Wray eds), CABI Publishing, 57-72.

Centers for Disease Control and Prevention. (1996) Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs- United States, 1994-1995. *MMWR*, 45, 737-747.

Centers for Disease Control and Prevention. (2000) Surveillance for Foodborne-Disease Outbreaks-United States, 1993-1997. *MMRW*, 49,1-63.

Corry J.E.L., Allen V.M., Hudson W.R., Breslin M.F. and Davies R.H. (2002) Sources of *Salmonella* on broiler carcasses during transportation and processing: modes of contamination and methods of control. *J. Appl. Microbiol*., 92, 424-432.

D'Aoust J.Y. (1997) *Salmonella* Species. In: *Food microbiology: Fundamentals and frontiers.* (Doyle M.P., Beuchat L.R., Montville T.J., eds), American Society for Microbiology Press, Washington, DC.

D´Aoust J.Y. (2000) *Salmonella*. In: *The Microbiological safety and quality of food* (Lund B.M., Baird-Parker A.C. and Gould G.W. eds.) Vol II, pp. 1233-1299.

Doyle M.E. and Mazzotta A.J. (2000) Review of Studies on the Thermal Resistance of Salmonellae. *J. Food Prot*., 63 (6), 779-795.

Engvall A,. Andersson Y and Cerenius F. (1993) The economics of the Swedish *Salmonella* control. A cost/benefit analysis. In: *NVI/WHO International course on Salmonella control in animal production and animal products* (National Veterinary Institute eds), Uppsala, pp 221-237.

EFSA (European Food Safety Agency) (2004) Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the use of antimicrobials for the control of *Salmonella* in poultry. *The EFSA Journal,* 115, 1-76.

EFSA. (European Food Safety Agency) (2005) EFSA´s 1st Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the European Union, 2004.

http://www.efsa.int/science/monitoring_zoonoses/reports/1277_en.html

FDA (Food and Drug Administration) (2002) FSIS Pathogen Reduction/HACCP.

http://www.fda.gov/ohrms/dockets/ac/02/slides/3816s2_07_Masters.ppt

Fluit A.C. (2005) Towards more virulent and antibiotic-resistant *Salmonella*? *FEMS Immunol. Med. Microbiol*., 43, 1-11.

Food Standards Agency (2001) Achieving the agency´s *Salmonella* in chicken target. Paper FSA 01/03/02b.

Frenzen P.D., Riggs T.L., Buzby J.C., Breuer T., Roberts T., Voetsch D., Reddy S. and FoodNet Working Group. (1999) *Salmonella* cost estimate updated using FoodNet data. *Food Review*, 22,10-15.

Fries R. (2002) Reducing *Salmonella* transfer during industrial poultry meat production. *World´s Poultry Sci.J*., 58, 527-540.

Fuller R. (1989) Probiotics in man and animals. *J. Appl. Bact*., 66; 365-378.

Guthrie R.K. (1992) *Salmonella*. CRC Press, Boca Raton, Ann Arbor, London.

Hald T., Vose D., Wegener H.C. and Koupeev T. (2004) A Bayesian Approach to Quantify the Contribution of Animal-food Sources To Human Salmonellosis. *Risk Analysis*, 24, 255-269.

Headrick M. and Cray P. (2001) Antimicrobial Susceptibility Patterns for *Salmonella* Isolates of Animal Origin, NARMS 1999. From a poster presented at the American Society of Microbiologists (ASM) Meeting held May 20 – 24, 2001 , in Orlando, FL.

Helms M., Vastrup P., Gerner-Smidt P. and Mølbak K. (2002) Excess mortality associated with antimicrobial drug-resistant *Salmonella* Typhimurium. *Emerg. Infect. Dis*., 5, 490 – 495.

Helms M., Simonsen J. and Mølbak K. (2004) Quinolone resistance is associated with increased risk of invasive illness or death during infection with *Salmonella* serotype Typhimurium. *J. Infect. Dis*., 190, 1652 – 1654.

Helmuth R. (2000) Antibiotic Resistance in *Salmonella*. In: *Salmonella in Domestic Animals* (C. Wray and A. Wray eds). CABI Publishing, 89 – 106.

Hensel M. (2004) Evolution of pathogenicity islands of *Salmonella* enterica. *Int. J. Med. Microbiol*., 294, 95-102.

Herikstad H., Motarjemi Y. and Tauxe R.V. (2002) *Salmonella* surveillance: a global survey of public health serotyping. *Epidemiol. Infect*., 129, 1-8.

Heyndrickx M., Vandekerchove D., Herman L. Rollier I., Grijspeert K. and De Zutter L. (2002) Routes for *Salmonella* contamination of poultry meat: epidemiological study from hatchery to slaughterhouse. *Epidemiol. Infect*., 129,253-265.

Hohmann E.L. (2001) Nontyphoidal salmonellosis. *Clin. Infect. Dis*., 32, 263-269.

Humphrey T. (2000) Public health aspects of *Salmonella* infection. In: *Salmonella in Domestic Animals* (C. Wray and A. Wray, eds.), CABI Publishing, 245-262.

Humphrey T and Allen V. (2002) Poultry transport crate hygiene. Food Standards Agency Project ZB 00033.

ICMSF (International Commission on Microbiological Specifications for Foods), (1996) Microorganisms in Foods 5: Characteristics of Microbial Pathogens. Blackie Academic & Professional, London; Kluwers Academic/Plenum Publishers, New York.

Kapperud G., Stenwig H. and Lassen J. (1998) Epidemiology of *Salmonella* typhimurium O:4-12 infection in Norway: evidence of transmission from an avian wildlife reservoir. *Am. J. Epidemiol*., 147, 774-782.

Lake R., Hudson A. and Cressey P. (2002) Risk Profile: *Salmonella* (non typhoid) in Poultry (whole and pieces). Inst. Environ. Sci. Res. Ltd, Christchurch Science Centre, Christchurch, New Zealand.

Latimer, H.K. (1999) Quantitative Microbial Risk Assessment for Human Salmonellosis Associated with the Consumption of Raw Shell Eggs. PhD Dissertation. Chapel Hill, NC.

Lee L.A., Puhr N.D., Maloney E.K., Bean N.H. and Tauxe R.V. (1994) Increase in antimicrobial-resistant *Salmonella* infections in the United States, 1989-1990. *J. Infect. Dis*.,170, 128-134.

Lillard H.S. (1989) Factors affecting the persistence of *Salmonella* during the processing of poultry. *J. Food Prot*., 52,829-832.

Maijala R., Ranta J., Seuna E., Pelkonen S. and Johansson T. (2005) A quatitative risk assesssment of the public health impact of the Finnish *Salmonella* control program for broilers. *Int. J. Food Microbiol*., 102, 21-35

Maki-Ikola O. and Granfors K. (1992) *Salmonella*-triggered reactive arthritis. *Scand. J. Rheumatol*., 21, 265-270.

Mathews Jr. K.H., Bernstein J. and Buzby J.C. (2003) International Trade and Food safety. Agricultural Economic Report Number 828 (J. Buzby ed). USDA, 48-74.

Mead P.S., Slutsker L., Dietz V., McCraig L.F., Bresee J.S., Shapiro C., Griffin P.M. and Tauxe R.V. (1999) Food-related illness and death in the United States. *Emerg. Infect. Dis*., 5, 607-625.

Mølbak M., Gerner-Smidt P.and Wegener H.C. (2002) Increasing quinolone resistance in *Salmonella* enterica serotype Enteritidis. *Emerg. Infect. Dis*., 8, 514-515.

Noterman S.H.W., Van De Giessen A.W. and Oosterom J. (1992) Aspects of intervention measures to reduce human infections with *Salmonella*. In: *Proc. Symp. Salmonella and salmonellosis.* Ploufragan, Saint-Brieuc, France, pp 235-244.

Poppe C. (2000) *Salmonella* infections in the Domestic Fowl. In: *Salmonella in Domestic Animals* (C. Wray and A. Wray, eds) CABI Publishing, 107-132.

Rychlik I. and Barrow P.A. (2005) *Salmonella* stress management and its relevance to behaviour during intestinal colonisation and infection. *FEMS Microbiol. Rev*., 29, 1021-1040.

Rychlik I., Gregorova D. and Hradecka H. (2005) Distribution and function of plasmids in *Salmonella enterica*. *Vet. Microb*., (in press).

SCVPH (Scientific Committee on Veterinary Measures relating to Public Health) (2000) EU/SANCO. Opinion on foodborne zoonoses.

Thorns C.J. (2000) Bacterial food-borne zoonoses. *Rev. Sci. Tech. Off. Int. Epiz*., 19. 226-239.

Threlfall E.J. (2002) Antimicrobial drug resistance in *Salmonella*: problems and perspectives in food- and water-borne infections. *FEMS Microbiol. Rev*., 26, 141-148.

Todd E.C.D. (1993) Cost-benefit aspects of food irradiation processing. In: *Proc. Symp. Cost-benefit aspects of food irradiation processing* (organized by IAEA, FAO & WHO), 19-49.

Van Asten A.J.A.M.and van Dijk J.E. (2005) Distribution of classic virulence factors among *Salmonella* spp. *FEMS Immunol. Med. Micribiol*.,44, 251-259.

Wegener H.C., Hald T., Wong D.L.F., Madsen M., Korsgaard H., Bager F., Gerner-Smidt P. and Mølbak K. (2003) *Salmonella* control programs in Denmark. *Emerg. Infect. Dis*., 9, 774-780.

WHO Expert Committee. (1988) Salmonellosis control: the role of animal and product hygiene. *Tech Rep. Ser*. No. 774, World Health Organization, Geneva.,

WHO (2001) *WHO Surveillance Programme for Control of Foodborne Infecctions and Intoxications in Europe, Seventh Report 1993-1998* (K. Schmidt and C. Tirado eds), Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV), Berlin.

WHO (2002) Risk assessments of *Salmonella* in eggs and broiler chickens.*WHO/FAO Microbiological Risk Assessment Series*, 2, World Health Organisation, Geneva.

WHO (2004) *1st Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment,* Geneva, 1 – 5 Dec. 2003. http://www.who.int/foodsafety/publications/micro/nov2003/en/

Wierup M., Wahlström H. and Engström B. (1992) Experience of a 10-year use of competitive exclusion treatment as part of the *Salmonella* control programme in Sweden. *Int. J. Food. Microbiol*., 5, 287-291.

Wong S.S., Yuen K.Y., Yam W.C., Lee T.Y. and Chau P.Y. (1994) Changing epidemiology of human salmonellosis in Hong Kong, 1982-93. *Epidemiol. Infect*., 113,425-434.

Yang H., Li Y. and Johnson M.G. (2001) Survival and death of *Salmonella* Typhimurium and *Campylobacter jejuni* in processing water and on chicken skin during poultry scalding and chilling. J. Food Prot., 64, 770-776.

ATTACHMENT 5

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR *VIBRIO* SPP. IN SEAFOOD

(Prepared by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand)

BACKGROUND

Over the past several sessions, the Codex Committee on Food Hygiene (CCFH) has increased its commitment to, and the extent of its work in, the field of microbiological risk analysis, particularly with respect to microbiological risk assessment and microbiological risk management. As a component part of this effort, CCFH has identified several pathogen/commodity combinations that present a potential significant public health threat for foods placed into international trade and for which it is appropriate to develop risk management strategies.

At the 34th Session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood.[22] The Committee further suggested that the initial focus would be *Vibrio parahaemolyticus* in fish and shellfish as the risk assessments for this microorganism in these products were the most advanced. The Committee agreed that a drafting group led by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand would develop the risk management strategy paper.

After the 35th Session, the Committee decided to suspend further action on the Discussion Paper until there was dialogue with the Committee on Fish and Fish Products (CCFFP). The paper was therefore not included in the Agenda for the 36th Session of the Committee. After receiving encouragement from the CCFFP that the CCFH should take the lead, the CCFH agreed that the risk profile would be included on the Agenda for the 37th Session for further discussion and development. The United States was the lead country for this document in the past and has continued in this role.

SCOPE AND RATIONALE

Based on the suggestion of CCFH that the initial work on *Vibrio* spp. focus on *V. parahaemolyticus* in fish and shellfish, this paper discusses the food safety problem involving *V. parahaemolyticus* in shellfish and finfish. The Paper presents a risk profile for the occurrence of *V. parahaemolyticus* in these products. Also presented are recommendations for work that CCFH may wish to undertake in relation to the risk management of *V. parahaemolyticus* shellfish and finfish.

As noted in the risk profile presented below, *V. parahaemolyticus* is an important bacterial seafood-borne pathogen worldwide and warrants attention from CCFH to develop international risk management guidance. In sufficient numbers, *V. parahaemolyticus* generally causes acute gastroenteritis that is self-limiting; however, severe cases require hospitalization and, on rare occasions, septicemia may occur. While there is substantial uncertainty concerning infectious doses, it is generally recognized that the general population is susceptible to infection by this microorganism. *V. parahaemolyticus* foodborne illness has been associated with the consumption of crayfish, lobster, shrimp, fish-balls, boiled surf clams, fried mackerel, mussels, tuna, mycids, squid, sea urchins, sardines, seafood salad and steamed/boiled crabmeat. The economic impact on the country or on trade varies according to the extent of contamination of finfish and shellfish, the amount of export, and the number of illnesses. In countries in which *V. parahaemolyticus* is endemic, illnesses due to this microorganism appear to be increasing and therefore there is the potential for a significant impact on the economy and public health of both the exporting and importing countries due to contaminated fishery products. The food safety problems associated with *V. parahaemolyticus* in seafood and their impact on international trade in seafood

[22] ALINORM 03/13, paragraph 78.

warrants the attention of the Committee to consider the need for developing specific risk management guidance information for this pathogen/commodity combination.

VIBRIO PARAHAEMOLYTICUS RISK PROFILE

This risk profile section is a comprehensive description of the food safety problem involving *V. parahaemolyticus*, the commodities and public health impact, including economic impact. It is divided into 6 parts, four risk profile elements, a section on risk assessment needs and questions for the risk assessors, and a section on available information and major knowledge gaps. References are found in Annex 1. Tables and figures are found in Annex 2.

1. Pathogen-food commodity combination(s) of concern

1.1 Pathogen of concern

Vibrio parahaemolyticus

1.2 Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this pathogen have been associated.

Foods associated with illnesses due to consumption of *V. parahaemolyticus* include crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife claims, fried mackerel, mussels, tuna, seafood salad, raw oysters, steamed/boiled crabmeat, scallops, squid, sea urchin, mycids, and sardines (5, 8, 9, 15, 19, 34, 42, 43, 45) (Table 7; Figure 1). These products include both raw and incompletely cooked seafood products and cooked products that have been either substantially recontaminated or where low level recontamination has occurred in combination with conditions that support growth to high numbers.

2. Description of the public health problem

2.1 Description of the pathogen including key attributes that are the focus of its public health impact (e.g., virulence characteristics, thermal resistance, antimicrobial resistance).

Vibrio parahaemolyticus is a Gram-negative, halophilic marine bacterium that occurs naturally in estuaries and is, therefore, commonly found in seafood. It was first identified as a foodborne pathogen in Japan in the 1950s (17). By the late 1960s and early 1970s, *V. parahaemolyticus* was recognized as a cause of diarrheal disease worldwide.

- Virulence Characteristics

  Some strains or types of *V. parahaemolyticus* are pathogenic, and can cause illness in people who eat finfish or shellfish containing these strains in numbers that can cause illness. Several different virulence traits have been associated with the pathogenesis of *V. parahaemolyticus* strains. These include their ability to produce a thermostable direct hemolysin (TDH), once the microorganism has entered the gut and colonized the intestinal cell wall (31); produce a thermostable direct hemolysin related toxin (TRH) (36); invade enterocytes (3); produce an enterotoxin (20); and, d) produce urease(1). Because the latter two characteristics have only recently been investigated, the trait most commonly used to distinguish pathogenic from non-pathogenic strains of *V. parahaemolyticus* is the production of TDH. The vast majority of strains isolated from patients with diarrhea are TDH positive (30, 31, 41). It has therefore been considered that pathogenic strains possess a *tdh* gene and produce TDH, and non-pathogenic strains lack the gene and the trait (31). More recently, the expert consultation for *Vibrio* and *Campylobacter* risk assessments held in Geneva, Switzerland in July 2002 suggested that strains that produce TRH should also be regarded as pathogenic.

- Serotypes

  More than a dozen different serotypes have been associated with outbreaks from different countries. These include: O3:K6, O4:K12, O4:K8, O4:K68, O4:K10, O4:K11, O4:K4, O3:K29, O1:K56, O4:K55, 05:K17, 01:K32, 05:K15, 02:K28. It is worth noting, since 1996, serotype transition from O4:K8 to O3:K6 has been observed in Japan. The transition was observed in both environmental and patient isolates. Serovar O3:K6 isolates detected in the United States, Southeast Asia, and Japan resemble each other and are suspected to have a common source (35). Recent increases in O4:K68-caused infections have been observed in Southeast Asia, India and Japan.

- Thermal Resistance

  Vibrio parahaemolyticus is not thermal resistant. Mild heat treatment (5 min at 50 °C) of oysters, which causes at least a 4.5 log decrease in the number of viable *V. parahaemolyticus* in oysters, practically eliminates the likelihood of illness occurring (47).

- Susceptibility to antimicrobial agents

  Treatment of patients: *Vibrio parahaemolyticus* strains are sensitive to most common antibiotics used for treatment (Tables 2&3) (32, 37). However, like most foodborne pathogens, the treatment of patients with oral antibiotics is generally contraindicated except in cases of septicemia.

  Antimicrobial appropriate for food use: *Vibrio parahaemolyticus* is sensitive to a number of antimicrobials commonly employed in food systems (e.g., benzoic acid, sorbic acid)

  Susceptibility to food preservation conditions

  Vibrio parahaemolyticus strains are sensitive to several common food preservation parameters such as low temperature or acidification.

2.2 Characteristics of the disease, including:

- Susceptible populations

  Epidemiological data indicate that the whole population is susceptible to infection by *V. parahaemolyticus*. However, immunocompromised consumers are at increased risk for septicemia and other more severe sequelae associated with *V. parahaemolyticus* infections.

- Annual incidence rate in humans including, if possible, any differences between age and sex and any differences according to regional and seasonal variations

  As noted above, epidemiological data indicate that all age groups are susceptible to infection by *V. parahaemolyticus*, and males and females are equally susceptible (Table 4) (22). The number of illnesses varies with season (Table 5): illness rates are higher during the warmer months than during the colder months (21). Regional differences exist not only from country to country, but also among different regions within one country (Table 5). In countries in which *V. parahaemolyticus* is endemic, illnesses due to this microorganism peaked in the late 1990s, but are still reported with a high frequency (Table 8).

- Outcome of exposure

  Infection usually causes mild gastroenteritis, with an incubation time ranging from 4-96 hours after exposure (6, 7, 24).

- Severity of clinical manifestation

  Symptoms include explosive watery diarrhea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills (Table 6). Most cases are self-limiting; however, severe cases of gastroenteritis requiring hospitalization have been reported. On rare occasions, septicemia, an illness characterized by fever or hypotension and the isolation of the microorganism from the blood, can occur. In these cases, subsequent symptoms can include swollen, painful extremities with hemorrhagic bullae (19, 24).

- Case fatality rate

  In the United States, the annual incidence of fatal raw oyster-associated infections from any *Vibrio* species was estimated to be 1.6/1,000,000 oyster-consuming adults (95% CI: 1.3-1.9) (19).

- Nature and frequency of long-term complications

  Most persons recover after 3 days and suffer no long-term consequences. However, subsequent symptoms including swollen, painful extremities with hemorrhagic bullae (19, 24), as well as reactive arthritis (44) can last months or longer.

- Availability and nature of treatment

  In most cases of gastroenteritis antibiotic treatment is contraindicated unless symptoms are severe and prolonged. Where treatment is indicated, prompt treatment with antibiotics and oral rehydration solutions (ORS) on IV fluid is available for patients in almost all hospitals.

- Percentage of annual cases attributable to foodborne transmission

  In some countries such as Japan and Thailand, almost 100% of annual cases are considered to be foodborne. In the United States about 65% of *V. parahaemolyticus* cases are estimated to be foodborne.

2.3 Characteristics of the foodborne transmission

- Epidemiology and etiology of foodborne transmission, including characteristics of the food or its use and handling that influence foodborne transmission of the pathogen

  Vibrio parahaemolyticus is naturally present in many types of seafood (Table 1). Worldwide, incidents of illnesses have been traced to caterers, manufacturers, households, cafeterias, food stores, restaurants, and street vendors. Outbreaks have involved incidents of cross contamination by raw seafood or processing equipment, improper hygienic practices, inadequate temperature control, and insufficient heating (23, 45). In Japan, incidents attributable to catering and packed-meal manufacturers and households have been increasing since 1996.

- Foods implicated

  Being an indigenous, aquatic bacterium, the microorganism is commonly isolated from aquatic foods. Sampling studies in the Adriatic Sea demonstrated the presence of *V. parahaemolyticus* in fish, mussels and clams (5). Foods implicated in disease include molluscan shellfish (especially raw oysters), crustaceans (crab, crayfish, lobster, shrimp), scallops, squid, sea urchins, sardines, mycids, and finfish (fish-balls) (Tables 1-2, 7) (5, 8, 8, 15, 19, 34, 42, 43, 45). Studies in the U.S. demonstrated the presence of *V. parahaemolyticus* in oysters at retail, including restaurants or oyster bars, and wholesale and retail seafood markets (14); in this study, although levels did not exceed 100 microorganisms/g in the majority of lots tested, the study demonstrated that levels can exceed 10,000 microorganisms/g in certain regions.

- Frequency and characteristics of foodborne outbreaks The frequencies and characteristics of foodborne outbreaks vary widely from region-to-region. In the United States, the first confirmed outbreak occurred in 1971, and between 1973 and 1998, forty more outbreaks were reported to the Centers for Disease Control and Prevention (CDC) from 15 states and territories ranging from 2 to >100 cases per outbreak (15, 16). All involve either the consumption of raw or undercooked seafood or cross-contamination of cooked seafood; the peak numbers of cases occur during warm weather months. Though sporadic cases caused by *V. parahaemolyticus* are common, outbreaks (see below) occur far less frequently. In Japan, outbreaks caused by *V. parahaemolyticus* usually involve fewer than 10 cases. From 1996-1998, 496 outbreaks were reported, and the peak occurrence for these was August (Figure 2). In Thailand far fewer outbreaks caused by *V. parahaemolyticus* have been reported, no more than 5 per year and most outbreaks affected less than100 patients (32, 40). From the Epidemiological Surveillance Report, during 1995-2001 there were 15 incidents with 1650 patients, and no fatalities (4, 40).

- Frequency and characteristics of foodborne sporadic cases

  Sporadic cases caused by V. *parahaemolyticus* infections are commonly reported. Most cases present clinically as gastroenteritis, and are rarely fatal. Life threatening septicemia can occur, especially in patients with underlying medical conditions. Sporadic cases occur throughout the year, with peak occurrence in September to October. Many published case reports outline clinical presentations and outcomes of patients with *V. parahaemolyticus*. For example, one report describes a 35-year-old woman who sought medical attention for abdominal pain after she had consumed raw fish (44). *V. parahaemolyticus* was isolated from the stool culture. She was diagnosed as having reactive arthritis induced by *V. parahaemolyticus* infection. Another clinical case report describes a 31-year-old female with a history of alcohol abuse, hepatitis C virus infection, and cirrhosis, who ingested raw oysters and steamed shrimp 72 hours prior to admission (18). She presented with diarrhea, weakness, leg pain, and urine retention. She developed cardiac arrest and died six days after presentation. *V. parahaemolyticus* was isolated from blood samples.

- Epidemiological data from outbreak investigations

  In the United States during 1971, 3 outbreaks caused by *V. parahaemolyticus* occurred in Maryland (15). Steamed crabs were implicated in two of the outbreaks after cross- contamination with live crabs. The third outbreak was associated with crabmeat that had become contaminated before and during canning. In 1972, an estimated 600 of 1,200 persons who attended a shrimp feast in Louisiana became ill with *V. parahaemolyticus* gastroenteritis (28). In 1974 and 1975 outbreaks were reported aboard two Caribbean cruise ships, most likely caused by contamination of cooked seafood with seawater from the ships' seawater fire systems (26). In Japan, restaurants account for 48% of outbreaks, hotels 18%, catering and packed-meal sales 12%, and households 12%. Retailers account for only 4%. In some incidents, mass meal preparation facilities and manufacturers also have been implicated as sources (Figure 3). In Thailand, school and college cafeterias account for the highest numbers of outbreaks, and meal preparation manufacturers also have been implicated in some incidents (23, 45).

2.4 Economic impact or burden of the disease

- Medical, hospital costs

  In the U.S. estimated costs per case of *V. parahaemolyticus* by severity (Table 9), and the estimated total cost of *V. parahaemolyticus* by severity (Table 10) demonstrate that the cost increases with severity of the illness (49).

  In Japan, the number of foodborne outbreaks between 1991 and 1997, number of patients involved in each outbreak and the compensation for each case in every incidence that was considered as either bacterial or viral (SRSV) as a causative microorganism was evaluated (2). Table 11 demonstrates the cost of illness due to *V. parahaemolyticus* relative to other foodborne illnesses such as *Salmonella* spp. and pathogenic *E. coli* (2).

- Working days lost due to illness, etc

  Normally 1-3 days are lost due to illness.

- Damage to seafood markets

  The economic effects of illnesses reverberate throughout the seafood supply industry causing loss of consumer confidence and concomitant loss of sales. Consequently, a slowing effect for seafood sales overall occurs, which can represent a short-term serious economic loss. In general, the various reports of seafood related illnesses also appear to combine to affect the entire seafood supply in a cumulative fashion, which can lead to long term depressed sales. There is also the risk of unwarranted trade barriers, i.e., when countries apply a microbial standard if that standard is not based upon sound risk management decision wherein justifying the standard as a public health measure. This may lead to unjustified banning of seafood.

3. Food Production, processing, distribution and consumption

3.1 Characteristics of the commodity (commodities) that are involved and that may impact on risk management

Today, processed products comprise the majority of seafood consumed, and processing with mild heat or by freezing can effectively eliminate or reduce the threat from *V. parahaemolyticus* in raw seafood. Preserving seafoods using acid and preservatives may also reduce or eliminate the risk. Even so, raw oysters and clams continue to be extensively consumed and other raw seafood such as sashimi and sushi, long popular in Japan (12) (Table 7), are becoming increasingly popular in other countries as well. The consumption of raw seafood is an important factor in the transmission of *V. parahaemolyticus* illnesses. However, improper cooking and/or re-contamination after cooking also are important factors (12).

3.2 Description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices).

- Pre-harvest and harvest

  V. parahaemolyticus occurs naturally in estuarine environments and on many types of seafood. Its densities are influenced by water temperature and salinity (33), air temperature (38), tide (25), and plankton (11, 39). The United States *V. parahaemolyticus* risk assessment, found that water and air temperatures at time of harvest are the major factors influencing the initial levels of this pathogen in oysters (47). Temperature control of seafood post-harvest also is important for controlling levels of *V. parahaemolyticus*. Temperature control onboard harvest vessels may be influencing the levels of *V. parahaemolyticus* in seafood if air temperatures are warm and the time between harvest and chilling after landing is extended.

- Post-harvest handling and processing

  Post-harvest handling and processing factors that affect product safety include the following:

  - Quality of water used in washing and processing after harvest;
  - Type and adequacy of sanitation measures;

- o Proper temperatures during processing, distribution and storage including refrigeration temperatures and, as appropriate, hot-holding temperatures.
- o Avoiding cross-contamination. Ensuring all surfaces, baskets, shucking knives, etc., which may have been in contact with raw seafood, are cleaned before use with any additional raw or cooked food/seafood.
- o Appropriate labeling to inform product handlers and users.

Several post-harvest treatments, such as mild heat and freezing, have been shown to be effective in reducing *V. parahaemolyticus* levels in oysters (13).

- What is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects.

Major causes of foodborne *V. parahaemolyticus* infections include:

1) Uptake and concentration of the pathogen by raw fish/shellfish from environmental waters

2) Multiplication of *V. parahaemolyticus* and other bacteria under inadequate temperature control after harvest and during distribution.

3) Improper handling practices after harvest, including:

- o Lack of knowledge by food handlers at restaurants serving raw seafood.
- o Cross contamination and non-sanitary practices by processors, food preparers, and street food vendors.

- Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines).

Factors considered as possible influences on the levels of pathogenic *V. parahaemolyticus* at consumption include:

- o Levels of *V. parahaemolyticus* at harvest.
- o Ambient air temperatures at times of harvest.
- o Length of exposure to ambient temperatures from harvest to refrigeration.
- o Time required to cool raw, product once refrigerated after harvest.
- o For cooked products; recontamination and conditions of time/temperature favoring growth in the interim between recontamination and consumption.
- o Post-harvest treatments, such as mild heat treatment, freezing, hydrostatic pressure, depuration, and relaying[23], to reduce the densities and the risks posed by *V. parahaemolyticus* (47). Irradiation is effective and may be considered where not prohibited by law.
- o Further preservation, e.g. acidification, food preservatives, is likely to inhibit growth and

[23] Process of moving shellfish from contaminated to non-contaminated growing areas for the purpose of removing contaminants.

mitigate risks, even from products with low contamination levels.

Several countries use different strategies and programs to manage the risks associated with various factors. The United States follows the National Shellfish Sanitation Program (NSSP) time/temperature matrix for control of *V. vulnificus* (46), and measures at harvest also have been established to prevent oyster-borne outbreaks caused by pathogenic *V. parahaemolyticus.* In 1999 the Interstate Shellfish Sanitation Conference (ISSC) adopted an Interim Control Plan for *V. parahaemolyticus*, which was then revised in 2001, based on monitoring when and where historical episodes indicate. Detection of pathogenic *V. parahaemolyticus* (*tdh*+) results in closure of waters to harvesting shellfish until monitoring indicates the pathogen is no longer detectable or until environmental temperatures becomes unfavorable for the proliferation of this microorganism. This plan includes monitoring for total *V. parahaemolyticus* levels. When levels greater than 5,000 total *V. parahaemolyticus* cells/g oyster tissue are found, additional oyster samples are promptly examined for pathogenic *V. parahaemolyticus*.

Japan also monitors for total *V. parahaemolyticus* strains, and new standards for seafood consumed raw include the following:

1) Fewer than 100 *V. parahaemolyticus* MPN/g in seafood for raw consumption.

2) For boiled octopus and crabs, *Vibrio parahaemolyticus* should be negative.

3) Temperature of seafood is maintained below 10ºC throughout distribution and storage.

4) After harvest and during food preparation fish/shellfish are washed with disinfected seawater or potable water.

Also in Japan, some local governments release warnings, based on conditions such as water temperature, to make the public more aware of the possible risk associated with eating raw seafood taken from waters during these conditions.

4. Other Risk Profile Elements

4.1 Regional differences in the incidence of foodborne illness due to the pathogen

Differences exist among countries and between different regions within the same country. In Japan, *V. parahaemolyticus* is a major cause of gastroenteritis. Conversely, very few cases are reported in Europe. For example, Denmark reported only two cases of gastroenteritis over a 20-year period. In the United States, as shown in the U.S. risk assessment for *V. parahaemolyticus*, incidence varies from region to region and season to season (47)(Table 5). Different serotypes are found in different countries and in different regions within the same country (47). Although, *V. parahaemolyticus* is found in many seafoods in the different regions of the world, it is predominantly associated with oysters in the United States. In Europe, except for the outbreak in Spain, there does not seem to be any epidemiological evidence that oysters is a significant source of *V. parahaemolyticus* (29, 48).

4.2 The extent of international trade of the food commodity

International trade of seafood for raw consumption is increasing. The FAO statistics on trade of seafood[24] show exports of fish products expanded to approximately $52 billion in 1999. Developed countries accounted for nearly 85 percent of total imports of fishery products. Japan was the largest, accounting for 25% of the global total, followed by the U.S. accounting for about 16%. European countries now account for about 35% of the total value of fishery products imported, but about half of these originate from within the EC. Thailand and Norway are the world's major exporters of fish

[24] http://www.fao.org/DOCREP/003/X9800e/X9800e04.htm#P146_39176

products in value terms, about 15% of total world exports, combined. Thailand exports fresh and cooked frozen shrimp, fresh frozen fish and other kinds of seafood products in considerable amounts each year. Developing countries continue to generate substantial trade surpluses in fish products that are worth between $16-$17 billion annually. This represents a significant source of trade currency earnings. Shrimp accounts for about 20% of the value of exported fishery products over the past 20 years.

Domestic standards for *V. parahaemolyticus* in seafood can affect the ability to import these products and thus impact international trade. Japan's new standard of less than 100 *V. parahaemolyticus* MPN/g will likely affect imports of some raw seafood, particularly during summer months. EU member states do not generally specifically address *V. parahaemolyticus*. However, Denmark exercises some import controls for seafood from non-EU countries, examining about 50% of ready-to-eat seafood for *V. parahaemolyticus* (and other *Vibrio* species), and sporadically testing raw, frozen seafood as well. Denmark allows up to 100 *V. parahaemolyticus*/g whereas some other European countries reject raw seafood if *Vibrio* species are detected.

4.3 Public perceptions of the problem and the risk

The Japanese society recognizes that these infections have become a major social issue and also a serious problem from the viewpoint of health hazards since there is a wide range in age of infected persons including deaths. In the United States, perception of *V. parahaemolyticus* risk appears to be consistent with the level of actual risk. It is believed that the subset of bivalve consumers with knowledge of shellfish as a potential vehicle for foodborne illness could not distinguish *V. parahaemolyticus*, *V. vulnificus*, viruses and pathogenic bacteria as distinct foodborne pathogens, i.e., what agent causes what illness – unless a newspaper article or TV report has just been released in the area. However, the outbreaks in 1997 and 1998 involving several hundred *V. parahaemolyticus* cases have heightened awareness in the United States. This heightened awareness has been most significant among Public Health officials and the shellfish industry.

4.4 Potential public health and economic consequences of establishing Codex risk management guidance

Establishment of Codex risk management guidance based on sound scientific information will help enhance public health by providing "best practices" that can reduce the consumers exposure to pathogenic *V. parahaemolyticus* while simultaneously avoiding decisions based on food safety that are not scientifically defensible, e.g., rejection of certain categories of raw seafood if *V. parahaemolyticus* are detected at low levels that do not posed a significant risk to human health, thereby preventing unwarranted interruption of international trade. The development of consensus risk management guidance based on the national and international risk assessments developed for member countries and Codex Alimentarius would be expected to improve public health by identifying key control measures needed to ensure the safety of the affected foods and provide a scientifically justifiable basis for ensuring the safety of seafood in international trade.

5. Risk Assessment Needs and Questions for the Risk Assessors

Using currently available risk assessments and related scientific evaluation, the impact of the following risk management options on the risk characterization should be developed and compared.

- The effect of keeping the temperature of seafood throughout distribution and storage lower than 4 and 10 ºC, and at other temperatures that may be widely employed.
- The effect of washing fish/shellfish with disinfected seawater or potable water after harvest or at preparation.
- The impact on the number of foodborne outbreaks that would occur with guidance that allows no more than certain levels of *V. parahaemolyticus* in finfish or shellfish meat; suggested are

levels of 100, 1000 and 10,000 microorganisms/gm.

- The effect of different post harvest treatments such as mild heating and high pressure treatment.

6. Available Information and Major Knowledge Gaps

Available information includes the following.

- Quantitative Risk Assessment on the Public Health Impact of *V. parahaemolyticus* in Raw Oysters prepared by the *V. parahaemolyticus* Risk Assessment Team, U.S. Food and Drug Administration (FDA) (47).
- FAO/WHO Risk Assessment on *Vibrio* spp. (work continuing)
- Codex standards and draft codes of practice for fish and fish products.
- Codex Recommended International Code of Practice: General Principles of Food Hygiene and other pertinent Codex commodity codes of hygienic practice.
- Codex codes of practice related to the use of veterinary drugs
- National governmental and/or industry codes of hygienic practice and related information (e.g., microbiological criteria) that could be considered in developing Codex risk management guidance
    - U.S. National Shellfish Sanitation Program (NSSP) (46)
    - U.S. Interstate Shellfish Sanitation Conference (ISSC) Interim Control Plan
    - Danish Food Act
- EU-Commission Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on *Vibrio vulnificus* and *Vibrio parahaemolyticus* (in raw and undercooked seafood), adopted on 19-20 September 2001.
- Report on Preventive Measures for *Vibrio parahaemolyticus* Foodborne Infections by the Committee on Animal Origin Foods under the Food Sanitation Investigation Council (May 2000) (12).

The reports listed above provide a sufficient basis for the development of Codex risk management guidance. However, the development of such guidance could benefit from additional data and related scientific evaluation of the areas listed below (list is not priority order). A circular letter should be forwarded to member nations and interested parties seeking this information.

- Distribution and abundance of pathogenic *V. parahaemolyticus* in finfish and shellfish at harvest, and changes in the levels from pre-harvest through consumption.
- Delineating hygienic control measures for seawater used at fishing ports and fish markets based on microbiological studies.
- Presence/absence of high-risk consumer groups for *V. parahaemolyticus* infection.
- Environmental factors that influence distribution and abundance of pathogenic *V. parahaemolyticus* in the environment for every region and season (i.e. temperature shifts, salinity, animal passage, predation, and introduction of strains from distant areas).

- Rates of hydrographic flushing (water turnover) in shellfish harvest areas based on levels of freshwater flows, tidal changes, winds, and depth of harvesting area.

- Growth and survival of pathogenic *V. parahaemolyticus* in raw oysters and other seafood at various temperatures.

- Industry post harvest handling practices (i.e. time to refrigeration, cool down periods, length of refrigerated storage).

- Industry food processing practices (i.e. acidification, salting, CO2-packaging, food preservatives) and their influence on survival and growth of the bacterium.

- Level of pathogenic *V. parahaemolyticus* at retail.

- Possible changes in the relative abundance of pathogenic *V. parahaemolyticus* during different seasons of the year in the different geographical regions, as well as the identification of associated environmental factors (e.g. temperature or salinity effects).

- Consumption patterns (frequency of raw oyster consumption from different harvest regions or seasons, and consumption by at risk groups).

- Dose-response data: the minimum number of *V. parahaemolyticus* microorganisms required to cause illness, and severity of the illness.

- Possible difference in virulence between pathogenic strains.

- Potential virulence factors other than TDH (i.e. TRH, urease, enterotoxins, acid adaptation, and invasion of intestinal cells).

- Role of the oyster (physiology, immune status) in levels of *V. parahaemolyticus*.

- Consumer handling of oysters prior to consumption.

- Global public health surveillance of *V. parahaemolyticus* to identify epidemic strains as they emerge.

Additionally, information and/or availability of rapid detection methods for the low concentration of total and pathogenic *V. parahaemolyticus* in seafood, such as PCR or nested PCR would be helpful in improving risk management capabilities for this microorganism.

RECOMMENDATIONS

Based on the findings provide above, the Working Group recommends that the Committee:

1. Review existing Codex guidance occurring in codes hygienic practice and codes of practice to determine whether such guidance provides sufficient information for the hygienic control of *Vibrio parahaemolyticus* in finfish and shellfish. If not, specific risk management guidance should be developed by the Committee. Such new work may involve amendments to existing Codex texts or the development of new microbiological risk management guidance. The Committee may wish to consider the benefits of establishing a Drafting Group to develop such guidance. The Committee should consider whether such work should be carried out in conjunction with the Codex Committee on Fish and Fishery Products.

2. Request the FAO/WHO Joint Expert Group on Microbiological Risk Assessment use existing risk assessments to assess the impact of the following on the risk of *V. parahaemolyticus* to human health.

- The effect of keeping the temperature of seafood throughout the distribution and storage lower than 4 and 10ºC, and at other temperatures that may be widely employed.

- The effect of washing fish/shellfish with disinfected seawater or potable water after harvest or at preparation.

- The impact on the number of foodborne outbreaks that would occur with guidance that allows no more than certain levels of *V. parahaemolyticus* in finfish or shellfish meat; suggested are levels of 100, 1000 and 10,000 microorganisms/gm.

- The effect of different post harvest treatments such as mild heating and high pressure treatment.

3. Review the areas where information is needed (see Section 6 above) and encourage WHO, FAO and member countries to the needed data and scientific evaluations.

ANNEX 1

REFERENCES

1. **Abbott, S. L., C. Powers, C. A. Kaysner, Y. Takeda, M. Ishibashi, S. W. Joseph, and J. M. Janda.** 1989. Emergence of a restricted bioserovar of *Vibrio parahaemolyticus* as the predominant cause of *Vibrio*-associated gastroenteritis on the West Coast of the United States and Mexico. J. Clin. Microbiol. **27:**2891-2893.

2. **Abe K., H. Shiratori, K. Uno, and T. Watanabe**. 2000. The Presumption of Clinical Symptoms due to Causative Organisms (Bacteria and SRSV) from Reparation for the Damage by Food Poisoning in Japan. *Miyagiken Hokenkankyou Sentah Nenpou*. **18**: 34-38. (Annual report of the Miyagi Prefectural Health and Environment Center)

3. **Akeda, Y., K. Nagayama, K. Yamamoto, and T. Honda.** 1997. Invasive phenotype of *Vibrio parahaemolyticus*. J. Infect. Dis. **176:**822-824.

4. **Anonymous.** 2001. Annual epidemiological surveillance report. Division of Epidemiology, Office of Permanent Secretary for Public Health, Ministry of Public Health, Nonthaburi, Thailand.

5. **Baffone, W., A. Pianetti, F. Bruscolini, E. Barbieri, and B. Citterio.** 2000. Occurrence and expression of virulence-related properties of *Vibrio* species isolated from widely consumed seafood products. Int. J. Food Microbiol. **54:**9-18.

6. **Barker, W. H.** 1974. *Vibrio parahaemolyticus* outbreaks in the United States. *In* G. S. T. Fujino, R. Sakazaki, and Y. Takeda (ed.), International Symposium on *Vibrio parahaemolyticus*. Saikon Publishing Company, Tokyo.

7. **Barker, W. H., E. J. Gangarosa.** 1974. Food poisoning due to *Vibrio parahaemolyticus*. Ann. Rev. Med **25:**75-81.

8. **Barker, W. H., P. A. Mackowiak, M. Fishbein, G. K. Morris, J. A. D'Alfonso, G. H. Hauser, and O. Felsenfeld.** 1974. *Vibrio parahaemolyticus* gastroenteritis outbreak in Covington, Louisiana, in August 1972. Am. J. Epidemiol. **100:**316-323.

9. **Bean, N. H., E. K. Maloney, M. E. Potter, P. Korazemo, B. Ray, J. P. Taylor, S. Seigler, and J. Snowden.** 1988. Crayfish: a newly recognized vehicle for *Vibrio* infections. Epidemiol. Infect. **121:**269-273.

10. **CDC.** 1999. Outbreak of *Vibrio parahaemolyticus* infection associated with eating raw oysters and clams harvested from Long Island Sound - Connecticut, New Jersey and New York, 1998. MMWR **58:**48-51.

11. **Colwell, R. R. e. a.** 1974. *Vibrio parahaemolyticus*-taxonomy, ecology and pathogenicity, International Symposium on *Vibrio parahaemolyticus*. Saikon Publishing Company, Tokyo.

12. **Committee on Animal Origin Foods Food Sanitation Investigation Council, Japan.** 2000. Report on preventive measures for *Vibrio parahaemolyticus* foodborne infections.

13. **Cook, D. W., and A. D. Ruple.** 1992. Cold storage and mild heat treatment as processing aids to reduce the numbers of *Vibrio vulnificus* in raw oysters. J. Food Protect. **55:**985-989.

14. **Cook, D.W., P.O'Leary, J.C. Hunsucker, E.M. Sloan, J.C. Bowers, R.J. Blodgett, and A. Depaola.** 2002, *Vibrio vulnificus and Vibrio parahaemolyticus* in U.S. shell oysters: A national survey from June 1998 to July 1999. J. Food Prot. **65**: 79-87.

15. **Dadisman, T. A., Jr., R. Nelson, J. R. Molenda, and H. J. Garber.** 1972. *Vibrio parahaemolyticus* gastroenteritis in Maryland. I. Clinical and epidemiologic aspects. Am. J. Epidemiol. **96:**414-418.

16. **Daniels, N. A., L. MacKinnon, R. Bishop, S. Altekruse, B. Ray, R.M. Hammond, S. Thompson, S. Wilson, N. H. Bean, P. M. Griffin, and L. Slutsker.** 2000. *Vibrio parahaemolyticus* infections in the United States, 1973-1998. J. Infect. Dis. **181:**1661-1666.

17. **Fujino, T., Y. Okuno, D. Nakada, A. Aoyoma, K. Fukai, T. Mukai, and T. Ueho.** 1953. On the bacteriological examination of shirasu food poisoning. Med. J. Osaka Univ. **4:**299-304.

18. **Hally, R. J., R. A. Rubin, H. S. Fraimow, and M. L. Hoffman-Terry.** 1995. Fatal *Vibrio parahaemolyticus* septicemia in a patient with cirrhosis: a case report and review of the literature. Dig. Dis. Sci. **40:**1257-1260.

19. **Hlady, W. G.** 1997. *Vibrio* infections associated with raw oyster consumption in Florida, 1981-1994. J. Food Protect. **60:**353-357.

20. **Honda, T., M. Shimizu, Y. Takeda, and T. Miwatani.** 1976. Isolation of a factor causing morphological changes of Chinese hamster ovary cells from the culture filtrate of *Vibrio parahaemolyticus*. Infect. Immun. **14:**1028-1033.

21. **Infectious Disease Surveillance Center (IDSC)**. 1999. *Vibrio parahaemolyticus*, Japan 1996-1998, Infectious Agents Surveillance Report (IASR), **20 (7)**:1-2.

22. **Inaba, Y.** 1978. Presented at the Gastrointestinal infection in Southeast Asia (III). Proceeding of the 5th SEAMIC Seminar, Tokyo Metropolitan Research Laboratory of Public Health, Tokyo.

23. **Khuharat, S.** 1998. Foodborne disease outbreak in a group of students attended at a university for training course, Nonthaburi Province September 1996. **29:**477-493.

24. **Klontz, K. C.** 1990. Fatalities associated with *Vibrio parahaemolyticus* and *Vibrio cholerae* non-O1 infections in Florida (1981-1988). So. Med. J. **83:**500-502.

25. **Kumazawa, e. a.** 1999. Geographical features of estuaries for neritid gastropods including *Clithon retropictus* to preserve thermostable direct hemolysin-producing *Vibrio parahaemolyticus*. J. Vet. Med. Csi. **61:**721-724.

26. **Lawrence, D. N., P. A. Blake, J. C. Yashuk, J. G. Wells, W. B. Creech, and J. H. Hughes.** 1979. *Vibrio parahaemolyticus* gastroenteritis outbreaks aboard two cruise ships. Am. J. Epidemiol. **109:**71-80.

27. **Levine, W. C., P. M. Griffin, and Gulf Coast Vibrio Work Group.** 1993. *Vibrio* infections on the Gulf Coast: results of first year of regional surveillance. J. Infect. Dis. **167:**479-483.

28. **Lowry, P. W., L. M. McFarland, B. H. Peltier, N. C. Roberts, H. B. Bradford, J. L. Herndon, D. F. Stroup, J. B. Mathison, P. A. Blake, and R. A. Gunn.** 1989. *Vibrio* gastroenteritis in Louisiana: A prospective study among attendees of a scientific congress in New Orleans. J. Infect. Dis. **160:**978-984.

29. **Lozano-Leon, A., J. Torres, C. R. Osorio, and J. Martinez-Urtaza.** 2003. Identification of tdh-positive *Vibrio parahaemolyticus* from an outbreak associated with raw oyster consumption in Spain. FEMS Microbiol. Lett. **226:**281-284.

30. **Matsumoto, C., A. Chowdhury, J. Okuda, M. Nishibuchi, M. Ishibashi, M. Iwanaga, J. Albert, P. Garg, T. Ramamurthy, V. Vuddhakul, H.-C. Wong, Y. B. Kim, and A. DePaola.** 1999. Isolation and analysis of *Vibrio parahaemolyticus* strains responsible for a pandemic spread to seven Asian countries and the United States. Presented at the 35th U.S. Japan Cholera and other Bacterial Infections Joint Panel Meeting, Baltimore, MD.

31. **Miyamoto, Y., T. Kato, Y. Obara, S. Akiyama, K. Takizawa, and S. Yamai.** 1969. In vitro hemolytic characteristic of *Vibrio parahaemolyticus*: its close correlation with human pathogenicity. J. Bacteriol. **100:**1147-1149.

32. **Nettip, N., Suthienkul O, Eampokalap, B, et al.** 1992. Antibiotic Susceptibility of 526 *Vibrio parahaemolyticus* Strains Isolated From Diarrheal Patients at the Bamrasnaradura Infectious Diseases Hospital (BIDH), April 1990-March 1991. Presented at the XIIIth International Congress for tropical Medicine and Malaria, Ambassador Hotel, Jomtien, Pattaya, Thailand, 29 November-4 December, 1992.

33. **Ogawa, H., H. Tokunou, T. Kishimoto, S. Fukuda, K. Umemura, and M. Takata.** 1989. Ecology of *Vibrio parahaemolyticus* in Hiroshima Bay. Hiroshima J. Vet. Med. **4:**47-57.

34. **Okabe, S.** 1974. Statistical review of food poisoning in Japan especially that by *Vibrio parahaemolyticus*., p. 5-8. *In* G. S. T. Fujino, R. Sakazaki, and Y. Takeda (ed.), International symposium on *Vibrio parahaemolyticus*. Saikon Publishing Company, Tokyo.

35. **Okuda, J., M. Ishibashi, E. Hayakawa, T. Nishino, Y. Takeda, A. K. Mukhopadhyay, S. Garg, S. K. Bhattacharya, G. B. Nair, and M. Nishibuchi.** 1997. Emergence of a unique O3:K6 clone of *Vibrio parahaemolyticus* in Calcutta, India, and isolation of strains from the same clonal group from Southeast Asian travelers arriving in Japan. J. Clin. Microbiol. **35:**3150-3155.

36. **Okuda, J., M. Ishibashi, S.L. Abbott, J. M. Janda, and M. Nishibuchi**. 1997a. Analysis of the thermostable direct hemolysin (*tdh*) gene and the *tdh*-related hemolysin (*trh*) genes in urease-positive strains of *Vibrio parahaemolyticus* isolated on the west coast of the United States. J.Clin.Microbiol. **35**:1965-1971.

37. **Pumiprapat, J., Suthienkul, O, Siripanichagon, K, et al.** 1993. Antibiotic Susceptibility of 300 *Vibrio parahaemolyticus* Isolated From Raw Seafood, April 1991-August 1991. Presented at the World Congress on Tourist Medicine and Health,, The Mandarin Hotel, Singapore., 10-15 January, 1993.

38. **Sarkar, B. L., G. B. Nair, A. K. Banerjee, and S. C. Pal.** 1985. Seasonal distribution of *Vibrio parahaemolyticus* in freshwater environs and in association with freshwater fishes in Calcutta. Appl. Environ. Microbiol. **49:**132-136.

39. **Sumner, e. a.** 2001. Hazard identification, exposure assessment and hazard characterization of *Vibrio* spp. in seafood. FAO/WHO.

40. **Suthienkul, O.** 2000. Situation of food microbial and public health. Thai J. Epidemiol. **8:**134-151.

41. **Suthienkul, O., Ishibashi, M, Iida, T, et al.** 1995. Urease production correlates with possession of the trh gene in *Vibrio parahaemolyticus* strains isolated in Thailand. J. Infect. Dis. **172:**1405-1408.

42. **Suthienkul, O., Kowcachaporn, P., Kachornchaiyakul, S., et al.** 1998. Detection of enteropathogens in frozen food by DNA hybrization and PCR. Final Report. Mahidol University.

43. **Suthienkul, O., Punchitton, S., Pongrapeeporn, K., et al.** 2001b. Rapid detection of *Vibrio parahaemolyticus* and hemolysin genes in frozen shrimp samples by nested PCR. Final Report. National Research Council of Thailand.

44. **Tamura, N., S. Kobayashi, H. Hashimoto, and S.-I. Hirose.** 1993. Reactive arthritis induced by *Vibrio parahaemolyticus*. J. Rheumatol. **20:**1062-1063.

45. **Tangkranakul, *et al.*** 2000. Food poisoning outbreak from gastroenteritis from contaminated fish-balls. J. Med. Assoc. Thai **83:**1289-1295.

46. **USDHHS Public Health Services.** 1995. National Shellfish Sanitation Program Manual of Operations: Part 1. U.S. Department of Health and Human Services,, Washington, DC.

47. **U.S. Food and Drug Administration.** 2005. Quantitative risk assessment on the public health impact of *Vibrio parahaemolyticus* in raw oysters. http://www.cfsan.fda.gov/~dms/vpra-toc.html

48. **Vuddhakul, V., Chowdhury, A., Laohaprertthisan, V., et al.** 2000. Isolation of a pandemic 03:K6 clone of a *Vibrio parahaemolyticus* strain from environmental and clinical sources in Thailand. Appl Environ Microbiology. **66:**2685-2689.

49. **Zorn, D.** 2002. Economic Burden of Foodborne Illness from *Vibrio parahaemolyticus i*n the United States. FDA/CFSAN.

ANNEX 2

TABLES AND FIGURES

Table 1. Investigation Results of Environment/Food Sources in Japan (1999)

<table>
<tr><th></th><th></th><th>Total no. of samples</th><th>No. of V. parahaemolyticus positives(%)</th><th>No. of O3:K6TDH+ positives(%)</th><th>Notes</th></tr>
<tr><td rowspan="2">Seawater/Sea mud</td><td>7 prefectures</td><td>329</td><td></td><td>10 (3)</td><td>Using beads</td></tr>
<tr><td>5 prefectures</td><td>222</td><td>126 (57)</td><td>1 (0.5)</td><td></td></tr>
<tr><td rowspan="3">Fish</td><td>Coast/Vessels</td><td>23</td><td>12 (52)</td><td>0</td><td rowspan="6">92 samples of a total 189 found

Vibrio parahaemolyticus positive</td></tr>
<tr><td>Production site markets</td><td>68</td><td>36 (53)</td><td>0</td></tr>
<tr><td>Retailers/ Distribution markets</td><td>48</td><td>12 (25)</td><td>0</td></tr>
<tr><td rowspan="3">Shellfish/ Prawns/ Squid/ Octopus</td><td>Coast/vessels</td><td>19</td><td>18 (95)</td><td>0</td></tr>
<tr><td>Production site markets</td><td>14</td><td>7 (52)</td><td>0</td></tr>
<tr><td>Retailers/ Distribution markets</td><td>17</td><td>7 (41)</td><td>0</td></tr>
<tr><td colspan="2">Distribution markets for shucked shellfish</td><td>144</td><td>41 (29)</td><td>0</td><td>19 testing facilities</td></tr>
<tr><td rowspan="2">Imported ready-to-eat shucked shellfish</td><td>Ark shell</td><td>356</td><td>6 (2)</td><td>0</td><td>Investigation by quarantine station</td></tr>
<tr><td>Sea urchin</td><td>587</td><td>14 (2)</td><td>0</td><td></td></tr>
</table>

Source: Japanese Ministry of Health, Labor and Welfare

Table 2. Antibiotic Susceptibility of 526 *Vibrio parahaemolyticus* Strains Isolated From Diarrheal Patients at the Bamrasnaradura Infectious Diseases Hospital (BIDH), April 1990-March 1991

Antimicrobial agents	No.% of isolates		
	Resistant	Intermediate	Sensitive
Ampicillin	514 (97.7)	5 (1.0)	7 (1.3)
Chloramphenicol	1 (0.2)	0(0.0)	525 (99.8)
Colistin	348 (66.2)	119 (22.6)	59 (11.2)
Cotrimoxazole	0 (0.0)	0 (0.0)	526 (100.0)
Gentamicin	0 (0.0)	0 (0.0)	526 (100.0)
Nalidixic acid	0 (0.0)	0 (0.0)	526 (100.0)
Nitrofurantoin	0 (0.0)	0 (0.0)	526 (100.0)
Tetracycline	0 (0.0)	0 (0.0)	526 (100.0)

Source: The Ministry of Public Health, Thailand

Table 3. Antibiotic Susceptibility of 300 *Vibrio parahaemolyticus* Isolated From Raw Seafood, April 1991-August 1991 (Pumiprapat *et al.*, 1993)

Antimicrobial Agents	No. (%) of isolates		
	Resistant	Intermediate	Sensitive
Ampicillin (AM)	272(90.7)	5(1.7)	23(7.7)
Chloramphenicol (C)	3(1.0)	0(0.0)	297(99.0)
Colistin (CL)	244(81.3)	45(15.0)	11(3.7)
Cotrimoxazole (SxT)	10(3.3)	0(0.0)	290(96.7)
Gentamicin (GM)	0(0.0)	0(0.0)	300(100.0)
Nalidixic acid (NA)	4(1.3)	1(0.3)	295(98.3)
Nitrofurantoin (F/M)	6(2.0)	2(0.7)	292(97.3)
Tetracycline (Te)	18(6.0)	0(0.0)	282(94.0)
Norfloxacin (NOR)	0(0.0)	0(0.0)	300(100.0)

Source: The Ministry of Public Health, Thailand

Table 4. Age and Sex Distribution of Diarrheal Patients Infected With *Vibrio parahaemolyticus* at the Bamrasnaradura Infectious Diseases Hospital (BIDH), April 1990-March 1991 (Nettip et al, 1992)

Age-group	**No. (%) *V. parahaemolyticus* positive cases**			
	Male	Female	Total	%
≤ 4	8 (57.1)	6 (42.9)	14	2.7
5-9	13 (86.7)	2 (13.3)	15	2.9
10-14	11 (61.1)	7 (38.9)	18	3.4
15-19	24 (60.0)	16 (40.0)	40	7.6
20-24	46 (49.5)	47 (50.5)	93	17.7
25-29	41 (58.6)	29 (41.4)	70	13.3
30-34	30 (51.7)	28 (48.3)	58	11.0
35-39	21 (50.0)	21 (50.0)	42	8.0
40-44	17 (47.2)	19 (52.8)	36	6.8
45-49	12 (44.4)	15 (55.6)	27	5.1
50-54	10 (40.0)	15 (60.0)	25	4.8
55-59	14 (37.8)	23 (62.2)	37	7.0
60-64	8 (42.1)	11 (57.9)	19	3.6
65-69	3 (27.3)	8 (72.7)	11	2.1
70-74	4 (66.7)	2 (33.3)	6	1.1
75-79	3 (60.0)	2. (40.0)	5	1.0
80-84	1 (12.5)	7 (87.5)	8	1.5
85-89	0 (0.0)	2 (100.0)	2	0.4
Total	266 (50.6)	260 (49.4)	526	100.0

Source: The Ministry of Public Health, Thailand

TABLE 5. ANNUAL PREDICTED NUMBER OF ILLNESSES ASSOCIATED WITH OYSTERS HARVESTED FROM EACH REGION AND SEASON IN THE U.S. (U.S. FDA QUANTITATIVE RISK ASSESSMENT ON *VIBRIO PARAHAEMOLYTICUS* IN RAW OYSTERS, 2005)

Region	Summer (July to September)	Fall (October to December)	Winter (January to March)	Spring (April to June)	Total
Gulf Coast (Louisiana)	1,406	132	7	505	2,050
Gulf Coast (Non-Louisiana)[a]	299	51	3	193	546
Mid-Atlantic	7	4	<1	4	15
Northeast Atlantic	14	2	<1	3	19
Pacific Northwest (Intertidal)[b]	4	<1	<1	<1	4
Pacific Northwest (Dredged)[b]	173	1	<1	18	192
TOTAL	1,903	190	10	723	2,826

[a] Includes oysters harvested from Florida, Mississippi, Texas, and Alabama. The time from harvest to refrigeration in these states is shorter than for Louisiana. [b] Oysters harvested using intertidal methods are exposed for longer times before refrigeration compared with dredge methods.

TABLE 6. CLINICAL SYMPTOMS ASSOCIATED WITH GASTROENTERITIS CAUSED BY *VIBRIO. PARAHAEMOLYTICUS* (BARKER AND GANGAROSA, 1974; LEVINE *ET AL.*, 1993)

Symptoms	Incidence of symptoms	
	Median	Range
Diarrhea	98%	80 to 100%
Abdominal cramps	82%	68 to 100%
Nausea	71%	40 to 100%
Vomiting	52%	17 to 79%
Headache	42%	13 to 56%
Fever	27%	21 to 33%
Chills	24%	4 to 56%

Table 7. Incidents Where the Production Sites Were Identified in the Food Poisoning Source-tracing Investigation in Japan (Committee on Animal Origin Foods Food Sanitation Investigation Council, Japan. 2000)

Location	Type of seafood	Serotype
Pacific Ocean offshore → Miyagi Pref	Tuna	O3:K6
City A, Hokkaido	Scallops	O3:K6 and others
City B, Hokkaido	Scallops	O3:K6
City B or C, Hokkaido	Seafood for sushi	O3:K6
City B, Hokkaido	Sea urchin	
Hokkaido	Boiled crab	O3:K6
Aomori Pref.	Sea urchin	O3:K6
Iwate Pref.	Sea urchin	O3:K6
A, Iwate Pref.	Squid	O3:K6
Iwate Pref.	Sea squirt	O3:K6
B, Iwate Pref.	Sea urchin	O3:K6
Iwate Pref.	Sea squirt	O3:K6
Iwate Pref.	Sea urchin	O3:K6
Fukushima Pref.	Surf clam	O3:K6
Niigata Pref.	Sashimi	O3:K6
Wakayama Pref.	Horse mackerel	Various types
Ishikawa Pref.	Rock oyster	
Tottori Pref.	Turban shell	O3:K6
Tottori Pref.	Fresh fish	O3:K6
A, Nagasaki Pref.	Horse mackerel	
B, Nagasaki Pref.	Olive shell	O3:K6
C, Nagasaki Pref.	Horse mackerel	O4:K55
D, Nagasaki Pref.	Sardines	O3:K6
A, Nagasaki Pref.	Jack-knife clam	O4:K8

Kumamoto Pref.	Mysids	O3:K6, O11K ?
Surrounding Saishu Island	Squid	O3:K6
Republic of Korea	Sashimi	O3:K6 and others
Republic of Korea	Pen shells	O3:K6, O4:K13
China	Sea urchin	O3:K6 and others
North Korea	Pen shells	O3:K6 and others
China	Sea urchin	O3:K6
Chile	Pickled turban shell	O3:K6, OUT:KUT

Table 8. Changes in the Number of *V. parahaemolyticus* Infection Incidents from 1991 to 2004 in Japan.

Fiscal Year	**1991**	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
No. incidents	247	99	110	224	245	292	568	839	641	422	307	229	108	205
No. patients	8,082	2,845	3,124	5,849	5,515	5,241	6,786	12,318	9,147	3,620	3,065	2,714	1,342	2,773

TABLE 9. ESTIMATES OF COST PER CASE OF *VIBRIO PARAHAEMOLYTICUS* BY SEVERITY IN THE UNITED STATES (ZORN, 2002)

	Illness	Hospitalization	Death
Days affected by *V. parahaemolyticus*	6	7	5,110
% Well-being lost/day	42	53	100
Medical costs	$0	$15,927	$0
Total	$1,596	$18,251	$2,746,000

TABLE 10. TOTAL COST OF *V. PARAHAEMOLYTICUS* BY SEVERITY IN THE UNITED STATES (ZORN, 2002)

	Range of Cost	Most Direct Estimate of Cost
Illness	$5,886,000 to $9,606,000	$9,606,000
Hospitalization	$493,000 to $639,000	$493,000
Death	$10,983,000 to $30,203,000	$10,983,000
Total	$17,362,000 to $40,448,000	$21,082,000

Table 11. Economic burden of foodborne illness in Japan (Abe *et al*., 2000)

Organism	**No. Outbreaks**	**No. Cases**	**Cases per Outbreak**	**Total Indemnity (yen)**	**Ave. Compensation per case (yen)**	**Ave. Compensation per outbreak (yen)**
V. parahaemolyticus	299	9560	32	279,147,299	29,200	933,603
Pathogenic *E. coli* (exclude EHEC)	29	5,072	175	72,530,455	14,300	2,501,050
Salmonella spp.	178	11,908	67	583,109,790	48,968	3,275,898

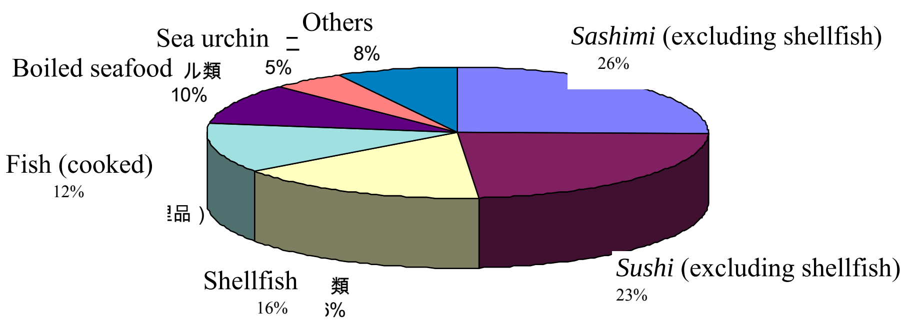

Figure 1. Ratio of occurrence by implicated food group
(Source: The Ministry of Health, Labour and Welfare, Japan)

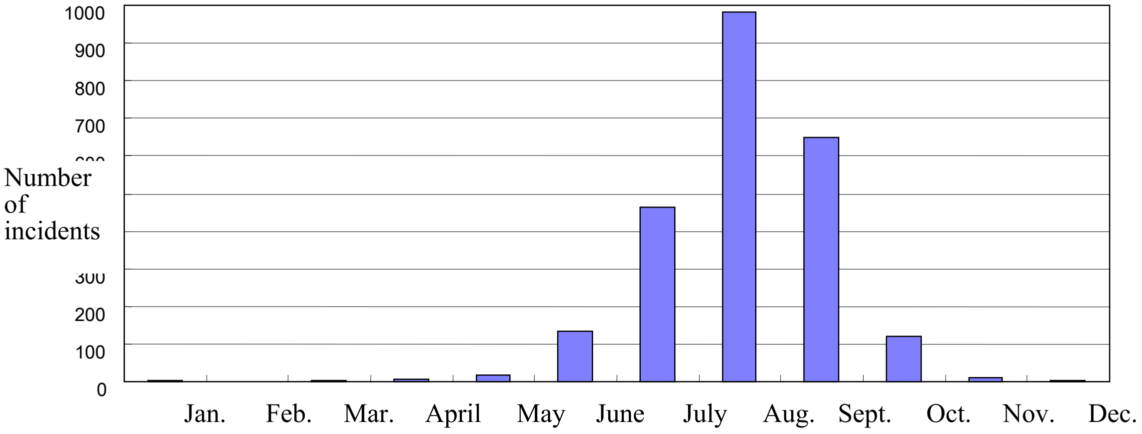

Figure 2. Number of incidents by month

(Source: The Ministry of Health, Labour and Welfare, Japan)

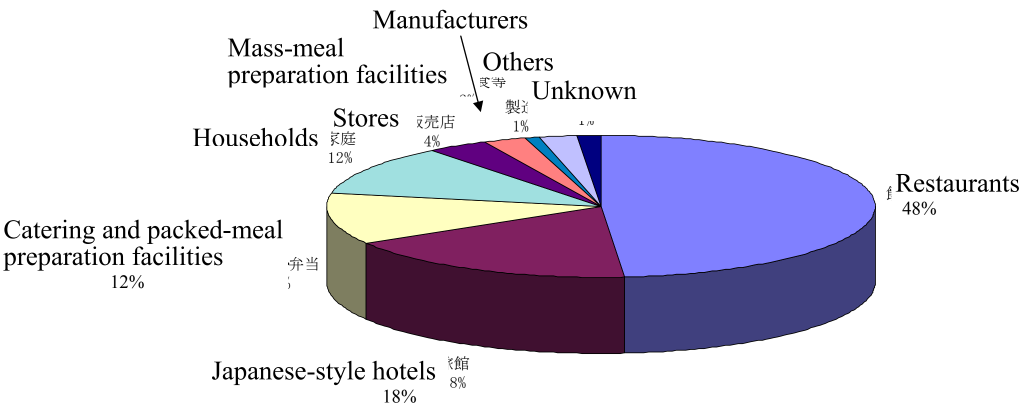

Figure 3. Ratio of occurrence by source facility category in Japan

ATTACHMENT 6

RISK PROFILE OF *NOROVIRUS* IN BIVALVE MOLLUSCAN SHELLFISH (Netherlands)

INTRODUCTION

During the 37th session of the Codex Committee on Food Hygiene (CCFH) it was agreed to place five proposals for new work areas into the Committee's work management system (Report of the 37th Session of CCFH, ALINORM 05/28/13, paragraph 168). The Netherlands was appointed to prepare a written proposal for one of the items, that is, viruses in food.

The ad hoc Working Group for the Establishment of CCFH Work Priorities (ad hoc Working Group) recommended to pursue work on a risk profile on viruses in food and focus early work regarding viruses in food on viruses in seafood in general with emphasis on bivalve molluscs (ALINORM 05/28/13, paragraph 192).

This view is fully adopted by the authors of the present document. More than that, it was deemed necessary to restrict the approach to norovirus in bivalve molluscs at this point, as norovirus infections must be considered an emerging infectious disease with contaminated bivalve molluscs playing a major role in food borne transmission. Other viral infections with regard to bivalve molluscs, particularly hepatitis A, can be addressed in a different stage.

To our opinion the entire issue of food borne viral infections is too diverse to be addressed as a single topic, as transmission routes, product matrices and disorders differ greatly. Because of the complexity of the matter we would strongly suggest to focus on viral agent/product combinations, e.g. noroviruses in shellfish or fresh berries, hepatitis A virus in shellfish or fresh berries, rather than on "viruses in food" in general.

BACKGROUND

Noroviruses (NoV) are formerly known as 'small-round-structured-virus' or 'Norwalk-like virus' (NLV) and belong to the family Caliciviridae. Noroviruses have been associated with gastro-enteritis with an acute onset of nausea, vomiting, abdominal cramps, and diarrhea as prominent symptoms. In adults, projectile vomiting frequently occurs. Constitutional symptoms such as low-grade fever, headache, chills, and myalgia are frequently reported. The illness generally is considered mild and self-limiting, with symptoms lasting on average 12-60 hours *(1,2)*. Besides being the cause of large (institutional) outbreaks, recent data suggest that norovirus are among the most common causes of sporadic gastroenteritis. People from all age groups are affected *(3)*.

Although this highly contagious virus is readily transmitted from person-to-person, noroviruses have also emerged as a food-borne virus that is likely due to an increased awareness combined with improved diagnostic assays. In risk factor analysis, using data collected with questionnaires during a community-based study, it was estimated that 12-17% of the norovirus infections in the Netherlands are likely to be food-related, which estimates the incidence of food-borne norovirus disease in the same range as for *Salmonella* and *Campylobacter (4)*. Virtually any food may be implicated in norovirus transmission, but bivalve molluscan shellfish present a particularly high risk because of their ability to concentrate viruses from contaminated waters.

SCOPE AND RATIONALE

The first linkage of viruses with shellfish-borne gastroenteritis was made in 1976/1977 in the UK *(5, 6)*. Since then enteric viruses causing gastroenteritis have been epidemiologically linked to outbreaks of shellfish-vectored illness on numerous occasions and in numerous countries *(7)*. The rationale to focus on noroviruses in shellfish is based on the following

Shellfish can act as a vehicle for transmission of noroviruses.

Microbiological quality control criteria are not sufficiently validated to indicate presence or absence of viral contamination

Shellfish harvested from contaminated areas may contain a cocktail of viruses and the simultaneous infection of patients may lead to the generation of recombinant norovirus strains. New recombinants may be more virulent than the known ones and may cause a sudden rise in number of outbreaks after introduction into a population as was observed in the winter of 2000/2001 *(4).*

There is a substantial global trade in bivalve molluscan shellfish, which may lead to spreading of new viruses.

Noroviruses serve as a model for other enteric viruses, like hepatitis A virus, hepatitis E virus and the enteroviruses. By filter feeding, bivalve molluscan shellfish may concentrate these enteric viruses as well. Due to the longer incubations periods and high rate of asymptomatic infections, illness caused by these enteric viruses may be more difficult to relate to consumption of shellfish. The detection of norovirus in shellfish may therefore strongly indicate that also other enteric pathogens, that may be less easily detected or diagnosed, are present in food too.

For these reasons appropriate strategies to reduce this documented risks should be developed.

PATHOGEN-FOOD COMMODITY COMBINATIONS OF CONCERN

<u>Pathogen of concern</u>: *Norovirus*

<u>Description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this hazard have been associated</u>

The bivalve molluscan shellfish, not the finfish or non-filter feeding shellfish, feed by filtering small particles from surrounding water. In this process the bivalve mollusks may concentrate and retain human pathogens derived from sewage contamination. The presence of noroviruses in naturally contaminated shellfish from polluted harvesting areas, or in shellfish associated with disease outbreaks, has been documented in varying percentages depending on the sanitation categories of the harvesting areas *(7).* The hazards posed by bioaccumulation are compounded by the traditional consumption of certain shellfish species (such as oysters) raw or only lightly cooked (mussels and clams), and by consumption of the whole animal, including the viscera where the human viruses are trapped.

Data on heat inactivation for noroviruses are scarce, because noroviruses can not be grown in cell culture or in an animal model. By comparative analysis, animal caliciviruses and hepatitis A virus have been proposed as model viruses for studies on infectivity. Noroviruses appear to be inactivated by normal cooking processes but are not always inactivated in shellfish given only (minimal) heat treatment as used for the preparation (grilling, stewing or frying) *(8).* Heating required to open the shells is not necessarily sufficient to inactivate viruses. Norovirus heated to 60 ºC for 30 minutes remained infectious for volunteers *(9).* Raising the internal temperature of the shellfish meat to 90 ºC for 1.5 minutes is likely to be sufficient *(10).* The time required may also depend on the direct environment; for another enteric virus, hepatitis A virus, it was demonstrated that inactivation in mussels was dependent on the recipe applied *(11).* Also freezing does not inactivate hepatitis A or animal caliciviruses, and is unlikely to affect norovirus infectivity. Frozen foods that did not receive further cooking have been implicated in a number of norovirus outbreaks.

DESCRIPTION OF THE PATHOGEN AND PUBLIC HEALTH PROBLEM

THE PATHOGEN

Noroviruses (NoV), formerly known as ‘small-round-structured-virus’ or ‘Norwalk-like virus’ (NLV), belong to the family Caliciviridae. NoV are small, non-enveloped spherical viruses, measuring between 28 and 35 nm in size, that contain a single stranded RNA (ribonucleic) genome of 7.3-7.6 kb. The genome is of positive polarity. It contains coding information for a set of non-structural proteins located at the 5’-end of the genome and for a major structural protein at the 3’-end. Based on sequence data of the capsid and polymerase (POL) areas norovirus found in humans can be divided into three major genetic groups (genogroups). Distinct genotypes have been recognized within each genogroup, of which the number is increasing. Additional noroviruses segregating into a fourth genogroup have been found in cattle.

There is little precise information on the stability, again because no *in vitro* culture systems exist to assess viability. Noroviruses appear to survive on inanimate surfaces and in the environment. Epidemiological evidence from lingering outbreaks that have occurred in hospitals, in residential homes and on cruise ships supports this *(9*). Noroviruses are more resistant to heat, disinfection and pH changes than are most vegetative bacteria *(12).* They retain their infectivity after exposure to pH 2.7 for 3 hours at room temperature, but also after refrigeration and freezing. They survive well on inanimate surfaces. They are considered to be resistant to inactivation in the presence of 3.75-6.25 mg chlorine/L, equivalent to 0.5-1.0 mg/L. Noroviruses are inactivated by 10 mg chlorine/L, which is the concentration used to treat a water supply after a contamination incident *(9*). They may survive for extended periods of time in seawater, especially in the winter months when temperatures are low *(7).*

THE PUBLIC HEALTH PROBLEM

Studies of community acquired infectious intestinal disease have been done in The Netherlands and in the UK and have demonstrated that viral infections account for a large proportion of community-acquired gastro-enteritis, especially the noroviruses. For the Netherlands (population 16.3 million) it is estimated that >500.000 cases of norovirus illness occur in the community during the study period (1999) *(13).* Many smaller surveys in limited populations have confirmed the high burden of illness due to noroviruses *(4).* Data from seroprevalence studies suggest that norovirus infections are found worldwide *(14).*

Only a few particles are needed to produce illness *(15).* In outbreaks, the average attack rate is high- typically 45% or more *(16).* The average incubation period is 12-48 hours after exposure. The illness generally is considered mild and self-limiting, with symptoms lasting on average 12-60 hours *(1-3).* Asymptomatic infections are also common. A total of 5% of healthy controls were found to shed noroviruses in a community study, as compared with 16% of people with gastroenteritis *(13).* Similarly, in outbreaks settings, 75% of people with gastroenteritis were found to shed noroviruses compared to 20% of healthy contacts *(16).*

The incidence of norovirus is highest in young children, but illness also occurs regularly in adults. In addition, the majority of outbreaks of gastroenteritis in institutions such as nursing homes and hospitals is caused by noroviruses *(17).* The high attack rate in both residents and personnel of such institutions often lead to major understaffing problems during outbreaks. The group of individuals who would be at greatest risk of serious illness and mortality includes young children, the elderly, pregnant women and the immunocompromized *(18).* Recently evidence was provided for severe clinical features in patients with several underlying diseases, such as cardiovascular disease, renal transplantation and immunosuppressive therapy *(19).*

Data from a community-based cohort study in the Netherlands were surprising in that 20% of norovirus infected persons reported symptoms for more than two weeks *(3).* Some long term shedders with long term complaints have been described *(20),* although no long term sequelae of norovirus infections have been reported and it remains to be seen if this was a chance observation *(21).* Sometimes hospitalisation and even parenteral fluid therapy due to severe dehydration are required in norovirus infections. During a norovirus outbreak at an international scout summer camp in the Netherlands up to 18% of affected people were admitted to a local hospital for rehydration *(22).*

It is known that after experimental infections in volunteers the infected persons may become protected from reinfection, but only for a short period, and only when the challenge virus is closely related to the genotype of the strain that was used for the infection *(23, 24*). A breakthrough in the field has been the discovery that clear differences in susceptibility have been found between persons with different blood groups and other genetic markers. This is explained by the observation that norovirus particles bind to carbohydrates that are part of the histo-bloodgroup antigens. Further research has shown that the binding properties differ between different genetic variants, thus providing very different patterns of host susceptibility for different norovirus genotypes *(25).*

The first linkage of viruses with shellfish-borne gastroenteritis was made in 1976/1977 in the UK when cooked cockles were epidemiologically linked to 33 incidents affecting nearly 800 people *(5, 6).* Subsequently, norovirus-like particles were detected in about 90 % of the clinical samples of nine separate shellfish vectored gastro-enteritis outbreaks *(6).* Since then enteric viruses causing gastroenteritis have been epidemiologically linked to outbreaks of shellfish-vectored illness on numerous occasions and countries *(7).* The US FDA risk assessments estimate cases of norovirus gastro-enteritis related to seafood consumption at some 100,000 per year *(26).* Such estimates for other countries have not been performed or are not readily available in the scientific literature. Data based on outbreak reporting are clearly underestimating the true extent of foodborne transmission.

Progress with clinical PCR assays for noroviruses and other enteric viruses prompted the exploration of the technology to detection of viruses in food and more specifically in seafood. The detection of virus in shellfish associated with outbreaks by PCR techniques have been described *(7).* Since the year 2000, reports describing the successful linking of cases of viral disease to contaminated food by the demonstration of an identical norovirus sequence in clinical specimens and suspected oysters are becoming available *(27*-29). The complexity of norovirus detection was described by a French outbreak with oysters *(28).* Moreover, when multiple norovirus types are present in suspected shellfish, linking may be hard as the predominating norovirus type in the clinical samples may then not be necessarily the same as the norovirus type detected in the suspected shellfish samples.

The amplification of food-borne infections after consumption of shellfish through person-to-person transmission is an issue that needs further consideration. The initial outbreaks will occur in people who ate e.g. oysters, but secondary and tertiary waves of infection may occur, which then are recognized as person-to-person outbreaks. This is exemplified by the following: In the winter of 2000/2001, several outbreaks of norovirus illness developed in 3 countries, associated with imported shellfish. The viruses clearly stood out, because they were of unusual type that had not been observed in most surveys prior to date. Tracking of this virus learned that over 200 outbreaks occurred in 7 countries, following this initial introduction *(4).*

In addition, in the above example, it was shown that this was a highly unusual virus strain, because it consisted of 4 different recombinant genomes. Recombination can only happen if two viruses infect the same cell at the same time, and mix their genetic material to form a novel virus. It can be postulated that consumption of multiple contaminated oysters constitutes an extra risk for generation of novel norovirus strains (codex 2005*)(4).* Besides recombination, noroviruses evolve by accumulation on of mutations." Epidemic waves" in which new variant noroviruses emerged were noticed in 2002 across Europe *(30)* and in 2004 in a more limited geographic region *(31).* The mechanisms of evolution of these viruses remains unclear, but given the ample evidence for foodborne transmission, food is likely to play a role in the dissemination of such novel variants. In this context, it is important to note that there is an increasing global trade in shellfish, which may enhance such dissemination.

FOOD PRODUCTION, PROCESSING, DISTRIBUTION AND CONSUMPTION

Most countries have enacted sanitary controls on the production of live bivalve molluscan shellfish. In the EU, these are covered by Council Directive 91/492/EEC *(32)* and in the United States, by interstate trading agreements set out in the FDA National Shellfish Sanitation Program Manual of Operation *(33)* The legislation requires that third country imports into EU and US have to be produced to the same standard as domestic products.

A major feature of these controls is the use of traditional indicators of faecal contamination, such as faecal coliforms or *E. coli*, either measured in the shellfish themselves (EU approach) or in the shellfish growing waters (US FDA approach). The microbiological standard of that less that 230 *E. coli* or 300 faecal coliforms in 100 g of shellfish flesh is internationally accepted and is based on a 5-tube 3-dilution most probable number (MPN test) which should be validated for shellfish matrix. It should be noted that viral standards are not currently set in EU or US legislation and that there is little correlation between coliform counts and viral contamination levels. Council Directive 91/492/EEC refers directly to the problem of viral contamination in shellfish and the need to introduce standards when such techniques become available *(9).* Since then, a network of reference laboratories for virus detection in shellfish has been established, but at present methods are not standardised yet.

Shellfish harvesting areas have been classified based on microbiological monitoring outcomes from clean areas (EU 'category A ' and US FDA 'approved'), to contaminated areas (EU 'category B'; US FDA 'restricted') to heavily contaminated areas (EU 'category C') *(9).* Shellfish from clean areas can be taken for direct human consumption without further processing. Shellfish from contaminated areas ('B class') may only be placed on the market following commercial puration (purification) or relaying (transfer to cleaner water for self-puration), or after treatment by heat processing using an approved method. Shellfish from 'heavily contaminated areas ('C class') may only be placed on the market following protracted relaying or following commercial heat treatment by an approved method.

Several commercial heat treatment processes have been officially approved including the UK heat cook parameters of raising the internal temperature of shellfish meats to 90 °C for 1.5 min (Anon, 1993a)(10). This method seems to be effective for inactivating norovirus, but since norovirus cannot be cultivated, was only tested for hepatitis A virus and feline calicivirus, a possible model virus for norovirus. The degree of cooking required to reliably inactivate noroviruses would however probably render oysters unpalatable to consumers. The inability of home or restaurant cooking to provide adequate guarantees of consumer protection against viral contamination for bivalve shellfish emphasis the reliance on harvesting and, for category B areas, depuration (see below)*(9*).

Depuration periods may vary from 1 to 7 days, however around 2 days is probably the widely used mehod (Lees, 2000) *(7).* Council Directive 91/492/EEC details requirements for approval of shellfish purification centers *(9)*. Compliance with *E. coli* (or faecal coliform) end-product standards does however not provide a guarantee of virus absence as was demonstrated with documented outbreaks associated with depurated shellfish *(7, 9).* Viruses are eliminated from bivalve molluscs at a slower rate than faecal coliforms or *E. coli.* Viral removal during depuration seems to be dependent on different parameters, including the critically important temperature of the seawater that affects the activity of shellfish *(9).* Shellfish derived from restricted areas may be placed on the market once they comply with the microbiological standard for shellfish. These shellfish may however still be contaminated with pathogenic viruses, like norovirus, but also other enteric pathogens which may be even more difficult to relate with illness due to shellfish consumption.

The most effective way to tackle shellfish transmitted viral disease is to prevent or reduce sewage pollution of shellfish harvesting areas. Infrequent sanitary control monitoring programs provide however little protection against intermittent spills associated heavy rainfalls or fecal contamination related with water-recreation in production areas.

Limited information is available on consumer behaviour and the way these shellfish are prepared prior to consumption. However, Eurostat gives production and trade information figures, which give an impression of the total consumption in the EU of food products of particular interest. In 1998-1999, the bivalve molluscs production in EU given in tonnes live weight, including the weight of the shells, was about 35000 tonnes for wild caught shellfish and about 86000 tonnes for farmed shellfish. Data on the intra and extra EU imports as well as extra EU exports for 1998-2000, show that international trade is global and substantial *(9)*.

RISK ASSESSMENT NEEDS AND QUESTIONS

The key needs in relation to the risk posed by the presence of norovirus in bivalve molluscan shellfish are as follows:

- for risk assessment purposes, information is needed on consumer behaviour and food preparation prior to consumption;

- for risk assessment purposes there is also a need for quantitative data on the presence of noroviruses in shellfish;

- information is needed on factors that can inactivate (noro)viruses in shellfish;

- there is a need for a cell culture system that will allow propagation of norovirus;

- given the low infectious dose of norovirus and the possible presence of other pathogenic viruses in shellfish especially from restricted areas, the question arises whether the practice for placing these shellfish on the market after depuration or relaying should be reconsidered;

- there is a need for improved surveillance of (foodborne) viral illness;

- there is a need for harmonized detection and genotyping to allow linking of patients and contaminated products.

AVAILABLE INFORMATION AND MAJOR KNOWLEDGE GAPS

PCR based procedures for the detection of noroviruses in shellfish are technically complex and currently not ready for routine food control laboratories. No standard internationally accepted methods (such as ISO) exist for shellfish extraction or norovirus RT-PCR, although the CEN/TC275/WG6/TAG4 (Microbiology of food and animal feeding stuffs, horizontal method for detection of norovirus and hepatitis A virus in food by RT-PCR) is preparing such protocols. Measuring the presence of RNA molecules by RT-PCR does not provide evidence that positively tested shellfish contain infectious particles. Here a drawback is that there are at present no *in vitro* culture systems for norovirus. On the other hand RNA molecules outside the viral capsid will be very instable. Moreover, positively tested shellfish samples can contain infectious particles as was demonstrated in outbreak studies with norovirus strains detected in the shellfish perfectly matching those detected in the stools of the patients *(27-29)*. Only a few particles will be needed to produce illness.

CONCLUSIONS

Norovirus is an emerging infection that has been clearly linked with the consumption of raw or lightly cooked bivalve molluscan shellfish. Although the illness generally is considered mild and self-limiting, there is evidence that severe clinical features can occur in patients with several underlying diseases. Except for the secondary or tertiary waves of transmission that can be started after consumption of contaminated shellfish, consumption of shellfish containing a cocktail of viruses may even lead to the generation of recombinant norovirus strains which may have far-reaching epidemiological implications. After contact with fecally contaminated water the shellfish may also harbor other pathogenic viruses for which norovirus may act as an indicator. The permission of releasing shellfish derived from restricted areas once they comply with microbiological standards, cause for concern as mentioned in this risk profile on the norovirus-shellfish commodity. Risk management strategies have to be developed in order to address the presence of viral contamination of these shellfish.

RECOMMENDED RISK MANAGEMENT ACTIONS

Considering the current state of knowledge related to this emerging foodborne pathogen, it is recommended that the Codex Committee on Food Hygiene undertake the following management activities.

Reassess the depuration procedure of shellfish from B and C-areas.

Stress the importance of implementing sanitary rules for waste disposal from ships or recreational sailing with all kinds of vessels in the neighbourhood of commercial shellfish areas and install appropriate discharge locations.

Mandatory reporting of viral food-related outbreaks through RASFF alerts.

Develop guidelines on the minimum level of evidence required to act upon suspected viral contamination in the absence of quantitative data on virus detection and viability in the implemented products.

Consequently, mandatory follow-up of viral food-related outbreaks through RASFF alerts.

REFERENCES

1 Kapikian AZ and Chanock RM. Norwalk group of viruses. In: Fields Virology 3rd ed., B.M. Fields, D.M. Knipe Howley P.M. (Eds.), Lippincott-Raven Philadelphia, USA. 1990. Pp. 783-810.

2 Kaplan JE, Feldman R, Campbell DS, Lookabaugh C, Gary GW. The frequency of a Norwalk-like pattern of illness in outbreaks of acute gastro-enteritis. *Am. J. Public Health.* 1982, 72; 1329-1332.

3 Rockx B, De Wit M, Vennema H, Vinjé J, De Bruin E, Van Duynhoven Y, Koopmans M. Natural history of human calicivirus infection: a prospective cohort study. *Clin Infect. Dis*. 2002, 35; 246-253.

4 Codex Committee on Food Hygiene, 37th Session, Discussion paper on the viruses in food, February 2005

5 Appleton H and Pereira MS. A possible virus aetiology in outbreaks of food-poisoning from cockles. *Lancet*. 1977, 1; 780-781.

6 Appleton H, Palmer SR, Gilbert RJ. Foodborne gastroenteritis of unknown aetiology: a virus infection? *Br. Med. J. (Clin Res Ed).* 1981, 282; 1801-1802.

7 Lees D. Viruses and bivalve shellfish. *Int. J. Food Microbiol.* 2000, 59; 81-116.

McDonnell S, Kirkland KB, Hlady WG, Aristeguieta C, Hopkins RS, Monroe SS,Glass RI. 8 Failure of cooking to prevent shellfish-associated viral gastroenteritis. *Arch Intern Med*. 1997, 157; 111-116.

9 Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Norwalk-like Viruses 2002 (adopted on 30-31 January 2002).

10 Council Decision of 11th December 1992 approving certain heat treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods (93/25/EEC). *Off. J. Eur. Communities*. 16, 22-23.

11 Croci L, De Medici D, Di Pasquale S, Toti L. Resistance of hepatitis A virus in mussels subjected to different domestic cookings. *Int. J. Food Microbiol.* 2005, 105; 139-144.

12 Duizer E, Bijkerk P, Rockx B, de Groot A, twisk F, Koopmans M. Inactivation of calicivirus. Appl. Environ. Microbiol. 2004, 70; 4538-4543.

13 de Wit MA, Kortbeek LM, Koopmans MP, de Jager CJ, Wannet WJ, Bartelds AI, van Duynhoven YT. A comparison of gastroenteritis in a general practice-based study and a community-based study. *Epidemiol. Infect*. 2001, 127; 389-397.

14 Koopmans M and Duizer E. Foodborne viruses: an emerging problem. Int J Food Microbiol. 2004, 90; 23-41.

15 Moe C. Studies of the infectivity of Norwalk and Norwalk-like viruses. *http://es.epa.gov/ncer/science/drinkingwater/moe_r826139.pdf*

16 Vinjé, J., Altena, S., and Koopmans, M.. The incidence and genetic variability of small-round-structured viruses (SRSV) in outbreaks of gastroenteritis in The Netherlands. *J. Inf. Dis*. 1997, 176 ; 1374-1378.

17 Codex Committee on Food Hygiene, 32th Session, Discussion paper on the viruses in food, October 1999

18 Gerba CP, Rose JB, Haas CN. Sensitive populations: who is at the greatest risk? *Int. J. Food Microbiol*. 1996, 30; 113-123.

19 Mattner F, Sohr D, Heim A, Gastmeirer P, Vennema H, Koopmans M. Risk groups for clinical complications of norovirus infections: an outbreak investigation. *Clin Microbiol Infect*. 2006, 12; 69-74.

20 Nilsson M, Hedlund K-O, Thorhagen M, Larson G, Johansen K, Ekspong A, Svensson L. Evolution of human calicivirus RNA in vivo: accumulation of mutations in the protroding P2 domain of the capsid leads to structural changes and possibly a new phnotype. *J Virol.* 2003, 77; 13117-13124.

21 Centers for Disease Control and Prevention. 2001. “Norwalk-like- viruses”: public health consequences and outbreak management. *MMWR* 50: RR09, 1-18

22 Duizer E, Timen A, Moory G, de Roda Husman AM. Norovirus outbreak at an international scout jamboree in the Netherlands, July-August 2004: international alert. *Eurosurveillance weekly releases* 2004, vol8, issue 33, nr.1

23 Hale AD, Crawford SE, Ciarlet M, Green J, Gallimore C, Brown DW, Jiang X, Estes MK. Expression and self-assembly of Grimsby virus: antigenic distinction from Norwalk and Mexico viruses. *Clin Diagn Lab Immunol.* 1999, 6; 142-145.

24 Noel JS, Ando T, Leite JP, Green KY, Dingle KE, Estes MK, Seto Y, Monroe SS, Glass RI. Correlation of patient immune responses with genetically characterized small round-structured viruses involved in outbreaks of nonbacterial acute gastroenteritis in the United States, 1990 to 1995. *J. Med. Virol*. 1997, 53; 372-383.

25 Hutson AM, Atmar RL, Estes MK.. Norovirus disease: changing epidemiology and host susceptibility factors. *Trends in Microbiol*., 2004, 12; 279-287.

26 Williams RA and Zorn DJ. Hazard analysis and critical control point systems applied to public health risks: the example of seafood. *Rev. Sci. Tech. Off. Epiz*. 1997, 16; 349-358.

27 Shieh Y, Monroe SS, Fankhauser RL, Langlois GW, Burkhardt 3rd W, Baric RS. Detection of norwalk-like virus in shellfish implicated in illness. *J. Inf. Diseases* 2000, 181; S360–S366.

28 Le Guyader FS, Neill FH, Dubois E, Bon F, Loisy F, Kohli E, Pommepuy M, Atmar RL. A semiquantitative approach to estimate Norwalk-like virus contamination of oysters implicated in an outbreak. *Int. J. Food Microbiol.* 2003, 87; 107-112.

29 Boxman ILA, Tilburg JJHC, te Loeke NAJM, Vennema H, Jonker K, de Boer E, Koopmans M. Detection of noroviruses in shellfish in the Netherlands. *Int. J. Food. Microbiol*. 2006, 108; 391-396.

30 Lopman B, Vennema H, Kohli E, Pothier P, Sanchez A, Negredo A, Buesa J, Schreier E, Reacher M, Brown D, Gray J, Iturriza M, Gallimore C, Bottiger B, Hedlund KO, Torven M, von Bonsdorff CH, Maunula L, Polisak-Prijatelj M, Zimsek J, Reuter G, Szucs G, Melegh B, Svennson L, van Duijnhoven Y, Koopmans M. Increase in viral gastroenteritis outbreaks in Europe and epidemic spread of new norovirus variant. *Lancet*. 2004, 363; 682-688.

31 Kroneman A, Vennema H, van Duijnhoven Y., Duizer E., Koopmans M. High number of norovirus outbreaks associated with a GII.4 variant in the Netherlands and elsewhere: does this herald a worldwide increase? *Eurosurveillance*. 2004, 8, issue 52, http://www.eurosurveillance.org/ew/2004/041223.asp#1.

32 Council Directive of 15th July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs (91/27492/EEC). *Off. J. Eur. Communities*. 1991, 268; 1-14.

33 National Shellfish Sanitation Program, Manual of Operations, 1993 Revision. US Department of Health and Human Services, Public Health Service, Food and Drug Administration.

ATTACHMENT 7

ADDITIONAL 'SCREENING CRITERIA' PROPOSED BY NEW ZEALAND FOR ASSESSING RISK BASED WORK PROPOSALS.

Priority food / pathogen combination, and importance in international trade	Should be an important food safety problem on a global scale Current or future problems in international trade will increase priority
Purpose and scope	Need a clear decision on the purpose and scope of the standard The standard should have risk management utility at both the Codex and the national level
"Champion" Member government	Required to: ▪ Administer development of the standard throughout its life cycle ▪ Manage working groups ▪ Co-ordinate technical inputs (including JEMRA if needed) ▪ Maintain iterative links between risk managers, risk assessors and risk communicators between successive sessions of the CCFH
Risk profile	A risk profile must be available to provide the context for the standard
Risk assessment	A risk assessment of sufficient scope, detail and representativeness must be sourced / assembled in a timely manner A framework risk assessment that caters for regional variation in food chains may be needed
Risk management instructions	CCFH must formulate the risk management questions that need to be answered by the risk assessment
Form of the proposed standard	CCFH should agree a description of the expected final form of the risk-based standard

ATTACHMENT 8

PRELIMINARY ASSESSMENT AGAINST THE CRITERIA

A preliminary assessment of each of the above proposals has been made against the above criteria and elements required in the project document.

Criteria for assessment	**Proposal for new work**			
	Proposal to develop a risk-based standard for Campylobacter in poultry - **New Zealand**	Proposal for new work on guidelines for the application of Codex General Principles of Food Hygiene to the risk based control of Salmonella in broiler chickens – **Sweden**	Discussion paper on risk management strategies for *Vibrio parahaemolyticus*. in seafood **-USA**	Risk profile of norovirus in bivalve mollusc and shellfish- **Netherlands**
• Include a risk profile	Risk profile provided	Risk profile provided	Risk profile provided	Risk profile provided
• Indicate specific nature or outcome of the new work being proposed	The CCFH is requested to develop a risk based standard for Campylobacter in broiler chickens	The CCFH is requested to decide on the development of a risk management document: Guidelines for the Application of the General Principles of Food Hygiene to the Risk based Control of Salmonella in Broiler Chickens	The CCFH is recommended to review the existing Codex guidance material to determine if sufficient information is provided on the hygienic control of *Vibrio parahaemolyticus* in finfish and shellfish. Request FAO/WHO Joint expert group on Microbilogical risk assessment assess the impact of *V. parahaemolyticus* to human health	The proposal recommends the CCFH undertake management activities to address the problem of noroviruses in shellfish
• Typically address a food hygiene issue of public health significance	The proposal addresses Campylobacter in broiler chickens. This is considered	The proposal addresses Salmonella in broiler chickens. This is	This proposal addresses *V. parahaemolyticus* in finfish and shellfish. This is	The proposal addresses Noroviruses in shell fish. This is considered to be a public

	to be a public health issue	considered to be a public health issue	considered to be a public health issue	health problem
• Describe in as much detail as possible the scope and impact of the issue	Proposal describes scope and impact of issue	Proposal describes scope and impact of issue	Proposal describes the scope and impact of issue	Some information provided
• Describe the extent to which it impacts on international trade	Additional information required	Additional information required	Impact on international trade is discussed	Some information provided
The proposal for new work may also: • Address an issue that affects progress within CCFH or by another committees, provided it is consistent with the mandate of CCFH • Facilitate risk analysis activities • Establish or revise general principles or guidance, adding the need to revise existing CCFH texts may be to reflect current knowledge and/ or improve consistency with the Recommended International Code of Practice: General Principles of Food Hygiene	Additional information required	Proposal recommends the establishment of Guidelines for the Application of the General Principles of Food Hygiene		This proposal suggests the development of guidelines and may also affect the work of the Codex Committee on Fish and Fish Products (CFFP)
• Proposal presented in a Project Document	Some additional information is required to addresses all criteria outlined in a project document	A project document is provided and the proposal addresses the criteria for a project document	Some additional information is required to address all the criteria outlined in a project document	A project document is required. For example additional information on how the proposal relates to the work of the CCFFP is required

ATTACHMENT 9

TABLE 1: LIST OF CODES FOR REVISION BY CCFH – (Attachment 1 to CX/FH 00/14)

Title of Code	Date current Code adopted by CAC	Code Category
CAC/RCP 001 -Recommended International Code of Practice General Principles of Food Hygiene Annex: Guidelines for The Application of The Hazard Analysis Critical Control Point (HACCP) System CAC/Gl 021 - Principles for the Establishment and Application of Microbiological Criteria for Foods	1969, revised 1997, 2003	General
CAC/RCP 008-Recommended International Code of Practice for The Processing and Handling of Quick Frozen Foods	1976 Step 5 EXEC/CAC	General -freezing
CAC/RCP 023-Recommended International Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods	1979 revised 1993	General- thermal processing
CAC/RCP 040-Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods	1993	General- thermal processing
CAC/GL 017-Guidelines Procedures for The Visual Inspection of Lots of Canned Foods for Unacceptable Defects	1993	General- thermal processing
CAC/RCP 039-Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering	1993	Food for mass catering
CAC/RCP 043-Code of Hygienic Practice for the Preparation and Sale of Street-vended Foods (Regional Code for Latin America and Caribbean)	1995, revised 2001	Street vended foods
CAC/RCP 021-Recommended International Code of Hygienic Practice for powdered formulae for Infants and young Children (including Microbiological Specifications and Methods for Microbiological Analysis)	1979 At Step 2	Infant Foods
CAC/RCP 003-Recommended International Code of Hygienic Practice for Dried Fruits	1969	Fruit and Vegetables
CAC/RCP 005-Recommended International Code of Hygienic Practice for Dehydrated Fruits and Vegetables Including Edible Fungi	1971	Fruit and Vegetables
CAC/RCP 002-Recommended International Code of Hygienic Practice for Canned Fruit and Vegetable Products	1969	Fruit and Vegetables
CAC/RCP 006-Recommended International Code of Hygienic Practice for Tree Nuts	1972	Nuts
CAC/RCP 004-Recommended International Code of Hygienic for Desiccated Coconut	1971	Nuts or Fruit and Vegetables
CAC/RCP 022-Recommended International Code Of Hygienic Practice For Ground Nuts (Peanuts)	1979	Nuts
CAC/RCP 015-Recommended International Code of Hygienic Practice for Egg Products	1976 At Step 7	Eggs and Egg Products
CAC/RCP 042-Code of Hygienic Practice for Spices and Dried Aromatic Plants	1995	Spices

CAC/RCP 030-Recommended International Code of Hygienic Practice for The Processing of Frog Legs	1983	Frogs legs
CAC/RCP 033-Recommended International Code of Hygienic Practice for The Collecting, Processing and Marketing of Natural Mineral Waters	1985	Water

TABLE 2: CCFH agreed combining of current Codes of Hygienic Practice

Proposed Outcome from Revision	**Incorporating**
Code of Hygienic Practice for Fruits & Vegetable and Products Thereof	CAC/RCP 003 - 1969; CAC/RCP 005 - 1971 CAC/RCP 002 - 1969
Code of Hygienic Practice for Nuts	CAC/RCP 006 - 1972 ; CAC/RCP 022 - 1979
Recommended International Code of Hygienic Practice for Collecting Processing & Marketing Natural Mineral Waters	CAC/RCP 033 - 1985 - consideration should be given as to whether this can be combined with the Draft Code of Hygienic Practice for Bottled/Packaged Drinking waters Other than Natural Mineral waters- (at Step 8)
Recommended International Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods, including Aseptically Packaged Low Acid Canned Foods	CAC/RCP 023 - 1979, revised 1992; CAC/RCP 0401993; CAC/RCP 017 - 1993.

TABLE 3: Priority proposed for Revision of Codes.

Code	**Priority**
Egg Products	1
Foods for Infants and Children	2
Tree nuts and Groundnuts with a view to combining these two codes into a single code of practice for nuts	3
All codes of hygienic practice for fruits and vegetables, with a view to combining all existing codes of hygienic practice for fruit, vegetables and products thereof into a single code of practice for fruits and vegetables	4
Desiccated Coconut, with a view to combining this code with the code for fruits and vegetable **or** the code for nuts if considered to be more appropriate	5
Quick Frozen Foods, ensuring that all general requirements for frozen foods from the fruit and vegetables and fish codes are adequately addressed;	6
Spices and Aromatic Plants	7
Low-Acid and Acidified Low-Acid Canned Foods and Aseptically Processed and Packaged Low-Acid Canned Foods, with consideration being given to whether these codes can be combined and incorporated as appendices to the General Principles of Food Hygiene	8
Natural Mineral Waters	9
Recommended International Code of Hygienic Practice for The Processing of Frog Legs	10
Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering	11
Code of Hygienic Practice for the Preparation and Sale of Street-vended Foods	As required

ATTACHMENT 10

MANAGEMENT OF THE WORK OF THE COMMITTEE ON FOOD HYGIENE

AD HOC WORKING GROUP FOR THE ESTABLISHMENT OF CCFH WORK PRIORITIES

3rd December 2006 10.00 am to 5.00pm

Draft AGENDA

1. Welcome and introduction by Chairperson – Australia

2. Terms of reference of the *ad hoc* Working Group.

3. Criteria for prioritisation of proposals

    3.1. Consideration of Codex Committee General Principles (CCGP) paper 'Management of the Work of the Codex Committee on Food Hygiene, The Proposed Process by which the Codex Committee on Food Hygiene will undertake its Work', as amended by CCGP ALINORM 05/28/13 – Appendix V, (Attachment 1)

    3.2 Consideration of additional criteria proposed by New Zealand in its paper 'Proposal to develop a risk-based standard for *Campylobacter* in poultry.

4. Consideration of project proposals received in response to CL2005/40 – FH Request for proposals for new work and/ or revision of an Existing Standard.

5. Consideration of priorities for the revision of Codes of Hygienic Practice

6. Recommendations to CCFH on new work

7. Arrangements for the Chair of the Working Group

Terms of reference:

1. The objective is to develop recommendations for consideration by the CCFH on the acceptance, revision and / or rejection of proposals for new work[25]

2. The *ad hoc* Working Group will meet for one day prior to the CCFH to complete the work.

[25] ALINORM 05/28/13 paragraph 34