Overseas Travel Report

41st Meeting of the Codex Committee on Food Hygiene

and

Development of Scientific, Trade and Market Access Linkages

United States of America
November 2009

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Executive Summary

This travel was supported by funding from the Australian Seafood Cooperative Research Centre (CRC) and is clear recognition of SARDI's expertise in the technical seafood safety and market access area. The travel has enabled SARDI to directly support the development of the Australian seafood industry through:

- Negotiation of more favourable international seafood safety standards and guidelines
- Gaining information of direct relevance to current seafood industry sponsored research projects; and
- Improving expertise in the technical seafood safety and market access area.

Direct outcomes of the travel are:

- Improvement of the labelling requirements for the Australian seafood industry contained in the draft Codex *Vibrio* standards i.e. negotiated the removal of proposed across the board requirements for all seafood to be labelled to alert “at risk” consumers to avoid or cook those products.
- Identifying potential new areas of international scientific synergy and collaboration between Australia and the United States, with an immediate outcome of a collaborative scientific review being undertaken on the effectiveness of shellfish processing methods on reducing pathogenic viruses by the USDA and SARDI staff. This collaboration is likely to expand in the future.
- Determining future European shellfish food safety regulation with particular regards to proposed regulatory limits for marine biotoxins and marine biotoxin methods in shellfish.
- Identification of future technical changes in United States regulation (e.g. implementation of new marine biotoxin regulations and limits) of key relevance to the oyster and mussel sectors wishing to export to the US.
- Raising the international profile of the Australian seafood sector through disseminating information on current SARDI/Seafood CRC led research at the Codex Committee on Food Hygiene meeting and to key United States Food and Drug Administration and Department of Agriculture staff.

Travel Objectives

The purpose of this travel was to:

- Provide specialist technical support to the Australian delegation at the Codex *Vibrio* spp. Working Group Meeting, November 2009, San Diego.
- Give technical support to the Australian delegation at the 41st Codex Committee on Food Hygiene plenary meeting.
- Provide technical input into the development of the ‘Code of Hygienic Practice for Control of Viruses in Food’ and the Proposed Code and associated Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Seafood and Molluscan Shellfish – these items are of key interest to the Australian seafood sector and have been rated as high priority issues by the Australian Seafood Access Forum.
- Ascertaining potential technical market access issues related to the Australian shellfish industries' desire to export oysters and mussels to the USA (facilitated through meetings with senior US Food and Drug Administration officials).
- Establish the state of the art in the USA with respect to knowledge on human food borne viruses and *vibrios* in seafood and scope potential for collaboration on future research and risk assessment work.
Overview

Codex standards and guidelines drive seafood safety legislation domestically and internationally. The Codex process is also a key mechanism for the utilisation and adoption of Seafood CRC and SARDI trade and market access research. Because of this it is critical that Australian Seafood CRC participants are involved in the Codex process and, where appropriate, are technically represented. In September 2008 SARDI employed a post doctoral scientist (Seafood Safety) to ensure adequate technical representation via funding provided by the Australian Seafood CRC. Key deliverables of the post doctoral scientist are to:

(a) Provide expert scientific advice to industry and government on international working groups, e.g. Codex.

(b) Provide research outputs that inform food safety and market access policy development of government and industry in accordance with international risk assessment guidelines.

(c) Improve overseas market access for Australian shellfish by resolving current, on-going and future food safety related technical barriers to trade.

Two issues relevant to the seafood industry were placed on the agenda for debate at the 41st meeting of the Codex Committee on Food Hygiene (November 2009):

(1) A Proposed Code and Draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Seafood and Molluscan Shellfish.

(2) A draft ‘Code of Hygienic Practice for Control of Viruses in Food’.

Both issues have potential to seriously impact the Australian seafood industry financially, through proposed mandated testing of *Vibrios* and viruses in seafood, and suggested requirements that seafood be routinely labelled as ‘requiring further processing’ e.g. heating. Therefore, the Seafood Access Forum ranked both issues as a ‘high priority’ for the Australian seafood sector and endorsed technical support by SARDI to the Australian delegation at the 2009 meeting.

Key outcomes of relevance to the seafood sector resulting from SARDI participation in the Codex meeting (detailed meeting notes are included in Appendix Three) were:

- The Australian delegation was successful in having all industry points taken into consideration for the revision of the draft ‘Code of Hygienic Practice for Control of Viruses in Food’. This Code was returned to Step 2 for revision and the next iteration is to be discussed at a Working Group meeting in March 2010. It is recommended that Australia be involved in the re-drafting process.

- The Australian delegation negotiated the removal of proposed across the board requirements in the *Vibrio* draft guidelines for all seafood to be labelled to alert at risk consumers to avoid or cook those products.

Following the Codex plenary, several meetings were arranged between SARDI and key seafood safety regulators and scientists at the USFDA and the USDA. Several technical issues of mutual interest were discussed with the USDA (details included in Appendix 3); including potential collaborative research in the future. As a result, a joint USDA/SARDI scientific literature review is being undertaken on the ‘effectiveness of shellfish processing methods to reduce pathogenic viruses’. It is expected that this collaboration will expand in the future.

USFDA officials provided valuable information on a range of topics relevant to Australian and SARDI research efforts:

1) Information was provided on the management of sewage treatment plants in shellfish growing areas, which is of high interest to industry in impacted areas in Australia. This information may improve risk management practices that determine the impact of sewage discharges on shellfish in Australia.

2) In September 2009 several oyster and mussel farmers in SA indicated a desire to export shellfish to the USA and they arranged a pre-audit of their food safety programme against USFDA requirements by overseas experts. Informal discussions were undertaken between SARDI and the FDA regarding the potential export of Australia shellfish to the USA. The FDA was positive about the possibility of Australia gaining market access to the US and they identified a clear process for industry and AQIS to undertake (Appendix 3).
3) The USFDA informed that the US marine biotoxin regulatory limits for shellfish are currently being revised. The Australian shellfish industry should maintain a watching brief on this to get early information on potential technical barriers to trade if market access is gained.

4) It is of high interest that the FDA are currently in discussion with the EC regarding the potential ‘equivalence’ of the US and EU shellfish programmes. While it does not seem hopeful that an agreement will be reached in the foreseeable future, it is encouraging that these discussions are taking place, as a mutually recognised system would assist Australia in meeting the export requirements of both markets (see Appendix 3 for details).

Summaries of the travel itinerary (Appendix One), key contacts made (Appendix Two), meeting notes (Appendix Three), and a copy of the 41st Codex Committee on Food Hygiene agenda (Appendix Four) are included. Copies of the official record of the CCFH meeting (draft Alinorm 10/33/13) are available on request.
Benefits from Travel

The following sections detail the benefits from this international travel.

Benefits to Seafood Safety Science in Australia

This travel has assisted Australia to maintain a high level of recognition for its capability in seafood safety risk assessment and research, both nationally and internationally. Specific outcomes of the travel were:

- Promotion of Seafood CRC funded research projects (especially projects focussed on viruses and *Vibrios* in shellfish). This was facilitated through technical advice being provided by Dr McLeod to the Australian delegation on viruses and *Vibrios* (using hard data generated through literature review and projects) at the 41st meeting of the Codex Committee on Food Hygiene and at subsequent meetings.

- Information exchange with key international regulators (EC, USDA and USFDA) and researchers to assist in current Food Safety research projects (e.g. Human Enteric Viruses in Shellfish: Seafood CRC Project 2008/741.1).

- Identification of potential areas of collaborative research between US researchers and Seafood CRC participants. The USDA and SARDI both have research interests in improving methodologies for *Vibrios* and viruses in seafood. Different technologies are employed by each party for the detection of these pathogens. Potential collaborative efforts could involve exchanging method protocols and mutual assessment of procedures. Other potential areas of joint research include the use of high pressure processing to inactivate pathogens in seafood and fundamental research to investigate the specific cells involved in virus uptake by oysters. An initial collaborative effort has commenced involving the preparation of a joint scientific review of literature on the efficiency of seafood processing techniques in inactivating human viruses.

- Delivering technical advice at an advanced international Codex meeting and facilitating subsequent high level meetings requires considerable skill, due to linguistic, social and political differences. Undertaking this travel has improved Dr McLeod’s negotiation and facilitation skills and improved her cultural and political awareness.

Benefits to Australian Seafood Industry

Specific outcomes from this travel that directly benefit the Australian seafood industries include:

- Enhancing export potential of Australian shellfish to the USA through determination of potential future technical barriers to trade (revised marine biotoxin regulations) and by ascertaining key points needing resolution for Australia to gain US market access.

- Identification of potential new areas of international scientific synergy and collaboration between Australia and the USA.

- Raising the international profile of the Australian seafood sector through: (a) dissemination of high level technical advice at an international seafood safety standard setting meeting; and (b) through promotion of the Australian shellfish safety programme and high quality of Australian shellfish to US regulatory authorities.

- Ascertaining the future direction of European shellfish food safety regulation with respect to marine biotoxin regulatory limits and methods. Assists in minimising technical barriers to trade and allowing ease of export of shellfish to Europe.
Recommendations and Actions

- Australian seafood interests are critically impacted by the development of international food safety standards, it is therefore imperative to strengthen Australia’s representation at high level strategic multilateral (e.g. Codex) and bilateral (e.g. US-Australia) meetings.

- SARDI to collaborate with the USDA in the preparation of a joint scientific review of literature on the efficiency of seafood processing techniques in inactivating human viruses. A further exchange of specific ideas regarding potential collaboration on norovirus and *Vibrio* related projects should also be undertaken.

- Ensure that a technical representative from Australia is present at the Codex Physical Working Group Meeting on Viruses in Food (2010) and the FAO/WHO Expert Meeting on *Vibrios* in Seafood (2010) to make sure that significant public health and industry issues are addressed.

- Encourage the seafood industry to consider funding industry representatives to attend CCFH and CCFFP where matters of critical interest are discussed to ensure that practical application of Codex standards is achievable by industry.

- The Australian Shellfish Quality Advisory Assurance Committee to review the current toxins and limits applied to marine biotoxins in Australia (with respect to proposed US and EU changes).

- Obtain meeting notes of the scientific workshop (WHO/FAO/OIE) on Nipah and Hendra viruses in Brisbane September 2009 (and other relevant info on Ebola virus detected in swine in the Philippines); assess relevance of the findings to the Australian seafood and potential need for food safety work in this area.

- USFDA information on the impact of sewage discharges on shellfish to be provided to the New South Wales Food Authority and the Kalang River Working Group for use in designing dye studies to estimate the impact of sewage treatment plants on oyster leases in the river.

- Dissemination of information on:
  - *Vibrio tubiashii* to Mark Gluis (SARDI representative assisting SA industry determine cause of oyster mortalities).
  - High pressure processing studies undertaken by USDA to Tom Madigan, SARDI Food Safety.
  - Virus/shellfish method development being undertaken by the USDA to Felicity Brake, SARDI Food Safety.
  - Peer reviews on EFSA opinions on OA and STX to the US FDA for their information and potential follow up with the EC.
## Appendix One – Travel Itinerary

<table>
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<tr>
<th>Dates</th>
<th>FROM</th>
<th>TO</th>
<th>No. of Days</th>
<th>Brief Purpose</th>
<th>Location / Destination</th>
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<tr>
<td>Sun 15 Nov</td>
<td></td>
<td>1</td>
<td>Participation in: (a) The meeting of Codex Committee on Food Hygiene Working Group on Vibrio spp. (1300h – 1900h).</td>
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<td>Mon 16 Nov 2009</td>
<td>Fri 20 Nov 2009 (incl)</td>
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<td>Plenary meeting of the Codex Committee on Food Hygiene</td>
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<td>Write briefing on Codex and Working Group meetings</td>
<td>Washington DC</td>
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<td>Visit US Department of Agriculture Research laboratory</td>
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<td>Visit US FDA (CFSAN) staff (College Park)</td>
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<tr>
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<td>Fri 27 Nov</td>
<td>2</td>
<td>Travel from Washington DC to Adelaide (day lost in transit)</td>
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## Appendix Two – Key Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Organization</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
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<tr>
<td>Name</td>
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Appendix Three - Meeting Notes

The following is an account of the major meetings held. Outcomes requiring follow up action are detailed in the ‘Recommendations and Actions’ section of this report.

1. **Working Group Meeting on the Draft Code of Practise for *Vibrio* in Seafood, 1300 – 1900h, 15 November 2009, San Diego, United States of America.**

   **Present:** Country Members of the Codex Committee on Food Hygiene

   **Meeting Objective:** To discuss the draft *Vibrio* Code of Practise for seafood and annex for bivalve molluscan shellfish and potential changes to the text

   **Meeting Notes:**
   - Many minor aspects related to wording changes and definitions were raised and discussed.
   - Australia raised issues with the guidance given on temperature control of *Vibrio* in seafood being confusing in the draft standard and noted that the guide should be consistent with CCFFP standards. Norway and New Zealand supported this contention. As a result additional text was proposed to be added to the paragraph for clarification purposes.
   - Australia recommended including a footnote to describe parameters that could be used to ‘kill’ *Vibrios* (vibriocidal treatment) (or cross reference documents where information can be found). It was agreed to include this in the standard.
   - Australia raised the issue of a lack of standard microbiological methods to determine pathogenic *Vibrios* and that risk models would need to be validated in the future using data obtained using standard methods. It was agreed that the WHO/FAO would consider convening an expert consultation on methods and risk models. This was supported by Australia, Japan and New Zealand.
   - The US raised that responsibility should be placed firmly on the manufacturer to produce safe seafood products. In this respect the consumer should not be relied on to inactivate or remove *vibrios*. They proposed removal of labelling molluscs as ‘requiring further treatment’. Australia vocally supported this point. As a result it was agreed to remove requirements for bivalve molluscs to be labelled as requiring further treatment.
   - The points raised and discussed at the Working Group meeting on *Vibrios* were then tabled at the 41st Plenary Session of CCFH (see items 2g and 2h below).

2. **Plenary Session of the 41st Codex Committee Meeting on Food Hygiene, 16th – 20th November, 2009, San Diego, United States of America.**

   **Present:** Country Members of the Codex Committee on Food Hygiene (see draft Alinorm 10/33/13 for comprehensive list of attendees)

   **Meeting Notes:** NB: These notes do not represent a comprehensive minute of the meeting (see draft Alinorm 10/33/13 for this), but include salient points identified by the author for consideration by Australian industry, regulators and scientists.

   **(a) Opening of the 41st Session (agenda item 1)**
   - Dr Margaret Hamburg (US FDA Commissioner) noted new USFDA areas of emphasis including: increasing inspection procedures for products imported into the USA; placement of USFDA officers within countries to assist overseas competent authorities and producers to improve the safety of seafood for domestic and export purposes and comply with FDA regulations e.g. Bangladesh, China and India; and a new focus within FDA on prevention of food borne illness issues.
   - Dr Robert Patterson (FAO) noted that at the recent world summit on food security in Rome that it was highlighted that 1/6th of the worlds population suffers from hunger. In relation to this food supply is critical, but so too is safety of that food. Dr Patterson commented that development of
standards and guidelines by Codex is not enough to guarantee food safety and that it is critical that the standards are implemented within individual countries.

- Frank Yiannas (Vice President, Walmart), noted that from an industry perspective that there are a ‘raft’ of standards imposed by various agencies that industry needs to comply with and that at times this can lead to confusion. However Codex standards should be the ‘gold standard’ and they need to be able to be practically applied by industry.

- Following Dr Yiannas’s intervention several meeting attendees queried the appropriateness of industry input into CCFH – suggesting that it should be a meeting only for regulators to set high level policy. While regulators may query the appropriateness of industry input, the guidelines developed by Codex are worthless if they are not able to be implemented by industry. In relation to this it is recommended that the seafood industry consider funding representatives to attend CCFH and CCFFP where matters of critical interest to the industries’ future are discussed to ensure practical application of standards is relevant and achievable.

(b) Matters Referred by the Codex Alimentarius Commission and/or other Codex Committees to the Food Hygiene Committee (agenda item 2)

- Of relevance to the Australian seafood industry, the European Commission (on behalf of 14 EU Member States) suggested that regarding the Draft Standard for Smoked Fish that the standard be altered as follows: “As sampling plans and their accompanying evaluation criteria for histamine may vary between countries it is acknowledged that the actual application of the histamine criterion may also vary among countries”.

- This request, and a request for methods of analysis for histamine to be included in the draft standard, will be reconsidered at the next CCFH meeting in 2010.

(c) Progress on Joint FAO/WHO Expert Meetings (JEMRA) (agenda item 3)

- Of key interest to the Australian food producing sector, the representative from WHO informed the committee that Nipah viruses have now been clearly identified as being spread via food borne transmission (this was confirmed in a FAO/WHO/OIE scientific workshop on Nipah and Hendra viruses, Sept 2009). Reston Ebola virus has also for the 1st time (one year ago) been identified in swine in the Philippines.

- Subsequent discussions between Dr McLeod and Dr Peter Ben Embarek (WHO) revealed that recent testing has been undertaken of swine and people that work closely with swine in the Philippines. The testing showed that both humans and swine had antibodies to Reston Ebola virus and suggests the transmission of the virus between humans and swine (and raises the possibility of immunisation). These findings could have serious ramifications for swine production. In relation to this it is recommended that SARDI Food Safety obtain meeting notes of the scientific workshop (WHO/FAO/OIE) on Nipah and Hendra viruses in Brisbane September 2009 (and other relevant info on Ebola virus), assess relevance of the findings to the Australian seafood industries and potential need for food safety work in this area.

- The delegation from Japan suggested that Nipah and Ebola viruses should be addressed in the draft code of practise for viruses in food.

(d) Viruses in Food

- The proposed Draft Code of Hygienic Practice for Control of Viruses in Food was discussed by the Committee. Australia provided extensive comments on the draft code, particularly on aspects of key importance to the seafood industry including: the recommendation that labelling of bivalve molluscs as requiring cooking be removed and that testing for viruses following rainfall should not be uniformly adopted in the standard.

- Other countries also submitted a number of comments on the draft Code.
The delegation of the Netherlands (lead country for working group) emphasised that the comments received made it evident that more work was needed to improve the current document and outlined 12 key areas where that work would focus. These areas encompassed all of Australia’s key issues with the draft Code, including:

- The definition of viruses in the Code requires clarification
- The structure of the document needs to be revised
- Further guidance is required on hand washing procedures
- The cleaning and disinfection procedures require more detail
- Criteria for returning of food handlers to the work place after infection needs further elucidation
- The labelling requirements for bivalve molluscs need revising
- Better guidance is required for the management of bivalve molluscs following virus contamination events, including more information on re-opening procedures, monitoring of bivalves and water, and methodological considerations.

In subsequent discussions the Netherlands delegation thanked Australia for its extensive comments and noted that the comments were constructive and would be ranked highly in considerations for revisions.

The Committee agreed to establish a physical working group, led by The Netherlands, to revise the proposed draft Guidelines taking into accounts comments received at the meeting. The working group meeting was tentatively scheduled to be held in The Netherlands, 23 – 25 March 2010. **Recommendation:** A technical expert from Australia should participate in the Physical Working Group meeting to revise the draft Code to ensure that key points of significance to industry are encompassed in the revised Code.

(e) **Vibrio in Seafood and Vibrio in Bivalve Molluscs**

**Draft Seafood Guidelines**

- A key issue discussed was the labelling section and Australia’s intervention for paragraph 100 to be amended to indicate that seafood at high risk of being contaminated with pathogenic *Vibrio* spp. (rather than all seafood irrespective of risk) should be labelled to alert at-risk consumers were agreed. Australia’s suggested text was incorporated.

- CCFH agreed to forward the renamed Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* Species in Seafood to the 33rd Session of the Commission for adoption at Step 5/8.

**Draft Bivalve Mollusc Annex**

- There was discussion on the inclusion of Table 1, which included information on growth rates of *V. parahaemolyticus* and *V. vulnificus* populations in raw oysters (*Crassostrea virginica*) in specific environmental conditions, with ICMSF stating the table was specific for countries and not validated information. Australia shared similar concerns and supported a recommendation for an expert consultation to conduct validation of predictive models. The Committee agreed to delete Table 1. CCFH endorsed the recommendation to convene an Expert meeting with the following terms of reference:
  - Conduct validation of the predictive risk models developed by the USA, based on the FAO/WHO risk assessments, with a view to constructing more applicable models for wide use among member countries, including adjustment of strain virulence variations and ecological factors
  - Review the available information on testing methodology, and recommend microbiological methods for *Vibrio* spp. in order to monitor the levels of pathogenic *Vibrio* spp. in seafood and/or water, and
  - Conduct validation of the growth rates and doubling times for *V. parahaemolyticus* and *V. vulnificus* in *Crassostrea virginica* provided in Table 1 of the proposed draft Annex with a view of including more strains isolated from different parts of world, and different bivalve molluscs species.
• Recommendation: Ensure that a technical representative from Australia is present at the FAO/WHO Expert Meeting on Vibrios in Seafood (2010) to make sure that significant public health and industry issues are addressed.

• CCFH agreed to forward the proposed draft Annex on Control Measures for Vibrio parahaemolyticus and Vibrio vulnificus in Bivalve Molluscs to the 33rd Session of the Commission for adoption at Step 5/8.


Present: Dr Catherine McLeod (SARDI) and Dr Paolo Caricato (DG SANCO, Directorate General for Health and Consumer Affairs), European Commission.

Meeting Objective: To discuss potential new (European Food Safety Authority) marine biotoxin requirements regarding limits and methods for bivalve molluscs.

Meeting Notes:

• Dr Paolo Caricato noted that the European Commission have proposed to the EU member states that the reference method for the lipophilic marine biotoxins be changed from the mouse bioassay to LC-MS. The first technical vote has been undertaken and was widely supported by the EU member states, with the exception of Spain who voted against the replacement of the mouse bioassay and Ireland who abstained.

• Dr Caricato noted that given the wide support for replacement of the mouse bioassay in the technical vote, it was highly likely that the mouse test would be replaced as the reference method by LC-MS. The timeframe for the legislation change is likely to be June-July 2010.

• Dr Caricato noted that when the EC legislation is changed Australia will be able to use LC-MS for the analysis of lipophilic toxins in shellfish, as long as the methods have been adequately validated. No submission of method validation from Australia to the EC will likely be required.

• Regarding the European Food Safety Authority (EFSA) opinions on marine biotoxins and suggested changes to the regulatory limits. Dr Caricato informed that the Commission have sent the SARDI/Seafood CRC review of the EFSA Opinion on marine biotoxins to EFSA and requested EFSA to revise their opinion accordingly. The Commission noted that they were now unlikely to change the regulatory limits for marine biotoxins.


Present: Dr Gary Richards, Dr David Kingsley, Dr Brooke Dancho, Dr Catherine McLeod

Meeting Objective: To discuss mutual areas of research and scope potential for collaboration

Meeting Notes:

• Dr Richards informed on work he is undertaking to determine cause of oyster mortalities in the US. Indications to date suggest that Vibrio tubiashii may be the cause of juvenile oyster deaths. Dr Richards has isolated several phages of Vibrio tubiashii that have been shown to reduce the numbers of the pathogen significantly and may prevent or decrease the number of oyster mortalities occurring. Recommendation: dissemination of information on Vibrio tubiashii to Mark Gluis (SARDI representative assisting SA industry determine cause of oyster mortalities).

• Results of the recent study undertaken by Dr Kingsley on the effects of high pressure processing on norovirus in oysters were discussed. Dr Kingsley explained that oysters were injected with a known quantity of norovirus. Three separate groups of oysters were then subjected to three differing high-pressure treatments. Oysters were then fed to human volunteers. Results indicate that high-pressure treatment may not be as effective for norovirus as other viruses e.g. feline calcivirus, murine norovirus, hepatitis A virus. Oysters that were treated with 600 MPa did not induce illness in volunteers; however it is likely that this pressure
treatment is not achievable in routine industrial practices. **Recommendation: dissemination of information to Tom Madigan, SARDI Food Safety.**

- The US DA informed that they have tried to repeat the work reported by Tim Straub et al on culturing human norovirus in a 3D culture system. They have been unable to get replication of norovirus with the cells and have tried several adaptations of the method.

- Dr Brooke Dancho noted that she is currently working on trying to formulate a faster, cheaper extraction and real time PCR method for norovirus in shellfish; work focuses on testing of various extraction kits at present and may move to the use of fully automated extraction procedures. She expressed a willingness to collaborate with SARDI on method development activities we are currently involved in. **Recommendation: provide Felicity Brake with Brooke Dancho’s contact details for potential discussions on virus/shellfish method development.**

- Discussions were held on potential collaboration in the future and several potential areas of work identified e.g. further method development work on both norovirus and *Vibrios*. **Recommendation: Collaboration to be pursued as funding opportunities arise.**

5. **United States Food and Drug Administration – SARDI (Informal), 24th November, 2009, College Park, Maryland, United States.**

**Present:** Dr Sherwood Hall, Dr Paul Distefano, Dr Bill Watkin, Dr Bill Jones, Dr Catherine McLeod (SARDI)

**Meeting Objective:** To discuss potential future technical changes in US seafood safety policy, US market access for Australian shellfish, and mutual areas of research.

**Meeting Notes:**

- Discussions were held on the recent European Food Safety Authority opinions on marine biotoxins and FDA representatives (Dr Sherwood Hall & Dr Paul Distefano) noted that the FDA did not agree with recommendations to decrease the current regulatory limits for marine biotoxins (particularly saxitoxin and OA). They noted that they have not had an outbreak of illness related to marine biotoxins in shellfish from regulated areas in the US in over 20 years and that current levels seem protective of human health. Dr Hall and Distefano requested copies of the SARDI peer reviews of the EFSA opinions on OA and STX and will consider sending similar information to the EU on this matter.

- US FDA noted that they are currently in discussions with the European Commission on equivalence of the US and EU shellfish programmes. The EU visited the US several months ago to audit the shellfish programme and found several minor deficiencies. As a consequence of this the EU have proposed that exports of US shellfish to the EU be halted if the issues are not rectified within a 6 month period. The USFDA officials noted that their analysis of the US and EU systems show that the US system for assessing sanitary status of growing areas achieves a higher level of public health protection that the EU system (as evidenced by outbreaks of viral illness in the EU).

- Discussions were held regarding the feasibility of shellfish export from Australia to the USA. The FDA were of the view that Australia would be very close to complying with USFDA regulatory standards for shellfish and therefore an MOU between the two countries that recognises the equivalence of the shellfish safety standards would be possible. In order to facilitate an MOU the USFDA would require:
  - a request from the competent authority (AQIS) to re establish the MOU
  - an official FDA physical inspection of shellfish growing areas and laboratories
  - an official FDA review of the paperwork.

The FDA will also require ongoing inspections by US certified Plant Standardisation Officers and Laboratory Evaluation Officers. Unfortunately Australia does not have any US certified officers and the cost of training these individuals in the US may be prohibitive to gaining market access. New Zealand has a certified Plant Standardisation Officer and a Laboratory Evaluation Officer and the FDA indicated that if Australia made a specific request in writing to them that they may allow the use of New Zealand’s certified officers to undertake this work.
• The USFDA officials noted that they are currently revising their marine biotoxin standards, with respect to limits. It is likely that these will include new limits for Azaspiracids. Other limits are likely to remain the same. The USFDA have agreed to notify SARDI when the limits have been reviewed by their legal and policy arms. **Recommendation: ASQAAC review the current toxins and limits applied to marine biotoxins in Australia**

• Discussions were held on methods of assessing the impact of sewage treatment plants on oyster growing areas. FDA officials noted that they have been undertaking dye studies and ascertained that a dilution factor of 1000:1 should be sufficient to ensure inactivation of norovirus. While they have found that this factor can be dropped to 400:1 for sewage treatment plants in which ultra violet sterilisation is used, often the UV sterilisation step may not be being performed optimally and it is best to use the conservative factor of 1000:1. FDA has developed a series of PowerPoint presentations and user guides for local authorities to use in designing dye studies and interpreting data. These are being provided to SARDI for guidance. **Recommendation: The information be provided to the New South Wales Food Authority and the Kalang River Working Group for use in designing dye studies estimating impact of STP on oyster leases in the river.**
Appendix Four – Agenda of 41\textsuperscript{st} Codex Committee on Food Hygiene
Agenda Item 1

To be held at the Loews Coronado Bay Hotel, California, United States of America, from Monday 16
November at 9.30 hours through Friday 20 November 2009

The Working Group on the revision of the Proposed Draft Code of Hygienic Practice for Pathogenic
Vibrio species in Seafood led by Japan will meet in the above Hotel on Sunday, the 15 November 2009
from 13:00 and the Working Group for Establishment of CCFH Work Priorities led by Guatemala will
be held in the above hotel on Sunday, the 15 November 2009, from 9:00 to 12:00 hours

PROVISIONAL AGENDA

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Working documents will be uploaded onto the Codex website:
www.codexalimentarius.net/web/index_en.jsp

Delegates are kindly requested to bring with them to the meeting all documents which have been distributed,
as the number of additional copies which can be made available at the session is limited.
   - Comments at Step 3

   - Comments at Step 3

7. Proposed Draft Annex on Control Measures for Vibrio parahaemolyticus and Vibrio vulnificus in Molluscan Shellfish
   - Comments at Step 3

8. Proposed Draft Code of Hygienic Practice for Control of Viruses in Food at Step 4
   Comments at Step 3

9. Inconsistencies Arising in Documents Elaborated by the CCFH and Adopted by the Commission

10. Other Business and Future Work:
    (a) Discussion of the Report of the Ad Hoc Working Group for Establishment of CCFH Work Priorities
    (b) Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene
        - Comments

11. Date and Place of the Next Session

12. Adoption of the Report

**NOTES ON THE PROVISIONAL AGENDA**

**Opening of the Session:** The Session will be opened by the Host Government.

**Agenda Item 1. Adoption of the Agenda** (Doc. Ref. CX/FH 09/41/1). In accordance with Rule VII.2 of the Rules of Procedure, the first item on the Provisional Agenda shall be the adoption of the Agenda.

**Agenda Item 2. Matters Referred by the Codex Alimentarius Commission and/or Other Codex Committees to the Food Hygiene Committee** (Doc. Ref. CX/FH 09/41/2). The document is based on the information prepared by the Codex Secretariat. The Committee is invited to consider matters referred to it by the Codex Alimentarius Commission and/or other Committees and to take actions, if necessary.

**Agenda Item 3. Matters arising from the Work of FAO, WHO and other International Intergovernmental Organizations:**

(a) **Progress Report on the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) and Related Matters** (Doc. Ref. CX/FH 09/41/3). The paper
prepared by the FAO/WHO summarises microbiological risk assessment activities conducted last year in support of the Committee activities;

(b) Information from the World Organisation for Animal Health (OIE) (Doc. Ref. CX/FH 09/41/3-Add.1). Following decisions taken by the 28th Session of the Commission, OIE will present information about their activities relevant to the work of the Committee.

Agenda Item 4. Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat at Step 4 (Doc. Ref. CX/FH 09/41/4). The Committee at its last session had agreed to return the proposed draft Guidelines for further elaboration by a physical Working Group led by New Zealand and Sweden for circulation at Step 3. Comments are presented in CX/FH 09/41/4-Add.1.

Agenda Item 5. Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruits and Vegetables at Step 4 (Doc. Ref. CX/FH 09/41/5). The Committee at its last session had agreed to return the proposed draft Annex for further elaboration by an electronic working group led by the United States of America for circulation for comments at Step 3. Comments are presented in CX/FH 09/41/5-Add.1.

Agenda Item 6. Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood at Step 4 (Doc. Ref. CX/FH 09/41/6). The Committee at its last session had agreed to return the proposed draft Code for comments at Step 3. Comments are presented in CX/FH 09/41/6-Add.1.

Agenda Item 7. Proposed Draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish at Step 4 (Doc. Ref. CX/FH 09/41/7). The Committee at its last Session had agreed that physical Working Group led by Japan would develop the above Annex for circulation at Step 3. Comments are presented in CX/FH 09/41/7-Add.1.

Agenda Item 8. Proposed Draft Code of Hygienic Practice for Control of Viruses in Food at Step 4 (Doc. Ref. 09/41/8). The Committee at its last Session had agreed to start new work on the above proposed draft Code, subject of approval by the 32nd Session of the Commission and that physical Working Group led by The Netherlands would develop the proposed draft Code for circulation at Step 3. Comments are included in CX/FH 09/41/8-Add.1.

Agenda Item 9. Inconsistencies Arising in Documents Elaborated by the CCFH and Adopted by the Commission (Doc Ref. CX/FH 09/41/9). The last Session of the Committee had requested the Secretariat to look at inconsistencies that might have arisen from previous revocations and amendments and to make proposals for consideration by the Committee. Following this request, the document is prepared by the Codex Secretariat.

Agenda Item 10. Other Business and Future Work. In accordance with Rule VII.5 of the Rules of Procedure, any Member of the Commission may propose the inclusion of specific items in the Agenda with respect to matters of an urgent nature.

(a) Discussion of the Report of the Ad Hoc Working Group for Establishment of CCFH Work Priorities. The Committee would be invited to consider the report of the physical Working Group (CRD 1) and comments received in response to document CX/FH 09/41/10, which would contain collated proposals for new work submitted by Member Governments in response to CL 2009/5-FH. The document CX/FH 09/41/10 to be prepared by Guatemala.

Agenda Item 11. Date and Place of the Next Session. The Committee will be advised of the tentative dates and the venue of the next meeting.

Agenda Item 12. Adoption of the Report. In accordance with Rule X of the Rules of Procedure, the Committee shall adopt the report of its 41st Session based on a draft provided by the Secretariat.