Seafood Services Australia: Seafood food safety risk assessment – phase 2

Dr J. Sumner

FISHERIES
RESEARCH &
DEVELOPMENT
CORPORATION

Project No. 2000/245

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ISBN 0 9585825 3 X

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OBJECTIVES:

1. Complete a comprehensive food safety risk assessment for the seafood industry in Australia.
2. Complete a compendium of hazards and controls for each species and process used by the seafood industry in Australia.
3. Communicate the results of the risk assessment in forms appropriate to the needs of the stakeholders (including industry, government and customers).

NON TECHNICAL SUMMARY:

OUTCOMES ACHIEVED

1. The present project has provided the seafood industry with a comprehensive risk profile linking hazards, products and vulnerable consumer groups.
2. The Australian industry is the first to have such a profile, which bestows several potential benefits including:
   - Setting a benchmark for inter-country equivalence negotiations
   - Indicating priorities for improved processing regimes
   - Providing risk assessment data for risk managers in industry and controlling authorities
3. The *Guide to Hazards and their Control in the Seafood Industry* contains a rigorous HACCP validation process which will enhance the safety of seafood products.
4. A series of workshops linked risk assessment and risk management for members of the industry in several States.
5. The project successfully positions the industry in a risk-based environment.

A survey was made of all documented seafood-related illness for the period 1990-2000, when there were at least 2,638 who became ill after consuming seafood during the last decade, mainly after consuming oysters raw or eating fish known to be associated with ciguatera. The 2638 known illnesses represent a likelihood of illness every 6,000,000th meal. Allowing for 1% reporting of illness results in 263,800 illnesses over the decade and a likelihood of seafood causing illness increases in every 60,000th meal.

The prevalence of at-risk consumer groups was identified. Most of us have natural defences against food poisoning micro-organisms which first must survive the stomach acid before they can take up residence in our intestine. Unfortunately, for susceptible groups within the community, their natural defences are less effective and even small doses of bacteria or viruses can cause food

poisoning. Around 20% of the Australian population has at least one at-risk factor, such as age, pregnancy, extreme youth, diabetes or cancer. At-risk consumers are especially vulnerable to certain hazards in seafoods.

Risk assessments were completed for ten hazard:product pairings. Using a risk characterisation tool, a Risk Ranking between 0 and 100 was estimated for each pairing.

Those hazard:product pairs with a low risk ranking (<36) were *Clostridium botulinum* in vacuum packed cold-smoked fish (28); or in canned fish (25); mercury poisoning (24); parasites in sushi/sashimi (31); enteric bacteria in imported cooked shrimp (31); viruses in oysters (31); algal biotoxins from shellfish grown in controlled waters (31).

There have been no documented cases of illness from any of these hazard:product pairings in Australia.

Hazard:product pairs with a medium risk ranking (37-59) were *V. parahaemolyticus* in cooked prawns (37); *V. cholerae in cooked prawns* (37); *L. monocytogenes* in cold smoked seafoods (39); Histamine poisoning (40); *V. vulnificus* in oysters (41); *L. monocytogenes* in cold smoked seafoods consumed by susceptible individuals (45); Ciguatera in the general Australian population (45); *L.* monocytogenes in cold smoked seafoods consumed by highly susceptible individuals (47); enteric bacteria in imported cooked shrimp consumed by susceptible individuals (48).

With the exception of *V. cholerae* in imported prawns these products and hazards have all caused outbreaks of food poisoning in Australia. Hazard:product pairings with a high risk ranking (>60) were ciguatera from recreational fishing in susceptible areas (60; viruses in shellfish from contaminated waters (67); algal biotoxins from uncontrolled waters in an algal event (72).

These products and hazards have caused severe problems. Ciguatera poisoning is said to be higher among coastal Queenslanders than in the general population. Viruses in oysters have been responsible for almost 4,000 cases of illness since 1978, with some deaths. Harvesting of pipis from waters affected by toxic algae caused more than 100 cases in NSW in 1997.

A compendium of hazards (*Guide to Hazards and their Control in the Seafood Industry)* was made and the validity of Critical Control Points associated with certain hazards was assessed.

Three risk management workshops were held and a booklet "*Risk and seafood safety – how to estimate it and manage it*" was published (obtainable from Seafood Services Australia, 19 Hercules St, Hamilton, 4007; Tel: 1300 130 321).

KEYWORDS: Seafood safety, risk assessment, HACCP.

ACKNOWLEDGMENTS:

The present work by Seafood Services Australia (SSA) occurred in two stages, the first of which preceded and the second succeeded, a comprehensive risk assessment study commissioned by the Seafood Division of Safe Food Production NSW. Some researchers worked on both sets of assessments and, to an extent, the Hazard Identification, Hazard Characterisation and Exposure Assessments of both the Seafood Services Australia and Safe Food assessments reflect the cooperative nature of both projects.

The Risk Characterisation element of the present work is based on estimates generated from a risk characterisation tool designed primarily by Tom Ross of the University of Tasmania. The risk estimates benefit greatly from this tool, which has undergone continued development thanks to comment from a large number of individuals.

During the course of the assessment, Dr Leigh Lehane, then of the National Office of Animal Plant Health, Canberra, produced comprehensive reviews on histamine (in cooperation with Dr June Olley of the University of Tasmania), ciguatera (in cooperation with Dr Richard Lewis of Queensland Department of Primary Industries) and paralytic shellfish poisons. These reviews were an invaluable source of information and informed discussion.

Peter Ben Embarek of Fisheries Industries Division, FAO, Rome provided a number of up-to-date publications on seafood risk assessments and Nick Ruello of Ruello and Associates, Sydney provided material on seafood consumption in Sydney.

The work was commissioned by Seafood Services Australia and the encouragement of Ted Loveday, Jayne Gallagher and the SSA Advisory Panel are gratefully acknowledged.

The assessments were reviewed by Drs Ababouch, Ben Embarek, Lupin and Valdimarsson of the Fisheries Industries Division of the Food and Agriculture Organisation in Rome.

I express my gratitude to all these people for their help and encouragement.

John Sumner
June, 2001

Background

Phase 1 of the project, which was undertaken in 1999, completed the hazard identification and exposure assessment phases of risk assessment and identified issues which required attention on a State-by-State basis.

Phase 2 of the project ran from June-December, 2000 and focused on hazard characterisation and risk characterisation of the hazards and products identified in Phase 1.

In addition, a validation review was undertaken of Critical Control Points (CCPs) which are the nexus of HACCP plans.

Need

Risk analysis is becoming the tool of first choice for regulatory authorities in all of the countries with which Australia trades seafoods. The United States is particularly active in risk analysis and it is commonly accepted that the tool will be used as a basis for food safety equivalence between trading nations.

On an intra-country basis, risk analysis is an integral part of HACCP plans, where the HACCP first principle is to assess the hazards *and risks*.

On a State basis, risk analysis is being been used by SafeFood production, NSW as the basis for regulation of its meat, dairy and seafood industries.

The need for risk analysis therefore pervades modern food regulation and it is doubtful whether a due diligence defence would be sustainable in the absence of a risk analysis.

Objectives

The project had three main objectives to:

1. Complete a comprehensive food safety risk assessment for the national industry.
2. Complete a compendium of hazards and controls for each seafood species and process used by the seafood trade in Australia.
3. Communicate the results of the risk assessment in forms appropriate to the needs of the stakeholders (including industry, government and customers).

Methods

The work was carried out by the Principal Investigator (PI) who:

- Identified hazards which have caused seafood-based illness in Australia.
- Quantified the consumption patterns of products with which the hazards are associated.
- Determined the prevalence of at-risk consumers within the total Australian population.
- Developed, in conjunction with Dr Tom Ross, a novel risk characterisation tool.
- Undertook risk analysis of ten hazard:product pairs according to the methodology stipulated by the Codex Alimentarius (*Principles and guidelines for the conduct of microbiological risk assessment – CAC/GL-30-1999*).
- Undertook various "what if" scenarios for specific hazard:product pairs to illustrate the increased risk by specific sub-populations.
- Completed an inventory of hazards associated with species in the Australian seafood trade.
- Analysed the validity of certain critical control points.
- Prepared an easy-to-read text on risk analysis of seafoods *"Risk and seafood safety – how to estimate it and manage it"*.
- Prepared and presented the findings of the project in risk management workshops.

Results/discussion

The results are presented in three publications.

1 Seafood food safety risk assessment

The risk assessment comprised two sections, Part 1, which contained the basic information for Part 2, the risk assessments.

> PART 1: Background information
>
> Summary
>
> - Consumption of seafood in Australia
> - Risk characterisation - vulnerable groups
> - Characterisation of risk

For example, the causes of seafood illness for 1990-2000 were:

Causes of seafood-borne outbreaks in Australia, 1990-2000

Category	Cases	Outbreaks	Cases/outbreak
Ciguatera	612	9*	12
Histamine	28	10	3
Viruses	1737	3	579
Bacterial pathogens	159	6	27
Biotoxins	102	3	34
Total	2638	32	82

* Includes an annual estimate of 48 cases per annum in coastal Queensland

> PART 2: Risk assessment of pathogen: product pairings
> Summary
> - Seafood safety
> - Ciguatera poisoning
> - Scombrotoxicosis (histamine poisoning)
> - Algal toxins in molluscs
> - Mercury in seafood
> - Viral contamination of shellfish
> - Vibrios in molluscs and crustaceans
> - *Listeria monocytogenes* in ready-to-eat seafood
> - *Clostridium botulinum* in canned and vacuum-packed ready-to-eat fish products
> - Parasites in raw fish for sushi/sashimi
> - Contamination of cooked crustaceans with enteric (non-*Vibrio*) organisms

Risk rankings of hazard:product seafood pairings

Hazard:product pairing	Selected population	Risk ranking
Ciguatera in reef fish	General Australian population	45
Ciguatera in reef fish	Recreational fishers, Queensland	60
Scombrotoxicosis	General Australian population	40
Algal biotoxin in shellfish-controlled waters	General Australian population	31
Algal biotoxin – during an algal bloom	Recreational gatherers	72
Mercury in predaceous fish	General Australian population	24
Viruses in oysters - contaminated waters	General Australian population	67
Viruses in oysters - uncontaminated waters	General Australian population	31
V. parahaemolyticus in cooked prawns	General Australian population	37
V. cholerae in cooked prawns	General Australian population	37
V. vulnificus in oysters	General Australian population	41
L. monocytogenes in cold smoked seafoods	General Australian population	39
L. monocytogenes in cold smoked seafoods	Susceptible (aged, pregnant, etc)	45
L. monocytogenes in cold smoked seafoods	Extremely susceptible (AIDS, cancer)	47
C. botulinum in canned fish	General Australian population	25
C. botulinum in vacuum packed smoked fish	General Australian population	28
Parasites in sushi/sashimi	General Australian population	31
Enteric bacteria in imported cooked shrimp	General Australian population	31
Enteric bacteria in imported cooked shrimp	Susceptible (aged, pregnant etc)	48

2 Guide to seafood hazards and controls

This is the first edition of the Seafood Services Australia (SSA) *Guide to Hazards and their Control in the Seafood Industry*. It is intended as a companion work to the National Seafood Risk Assessment. Its purpose is to assist the industry (fishers, aquaculturists, processors, marketers, retailers, regulators and academics) in the development of HACCP plans. Not by publishing generic HACCP plans since these are already available in a series of SeaQual Food Safety Guidelines but by defining Critical Control Points (CCPs) for those processes most commonly used in the Australian seafood industry. As such, it is intended that the Guide will act as a forum for the industry to ask, and answer, key questions, such as "Is there a CCP for viruses in oysters eaten raw, or for *Listeria monocytogenes* in cold-smoked seafood?" Based on expert opinion, SSA intends to revise and improve the Guide from time to time, as our state of knowledge alters on a particular subject and as informed comment is gained.

3 Risk and seafood safety – how to estimate it and manage it

This booklet was written to help present the concepts of Risk Management and Risk Communication to the industry. Hazards which occur in the Australian seafood trade are ranked and the task of managing risk and communicating it to all stakeholders is described.

Benefits of the project

The project has the following benefits:

1. Provides statistical analysis of the causes of seafood-borne illness for the decade 1990-2000.

2. Constitutes a benchmark in the year 2000 of the risks of seafood products in Australia.
3. Provides a basis for food safety equivalence based on risk.
4. Comprises a tool which risk managers at the company, regulatory or industry association level can use for their specific issues.
5. Provides a validation review of CCPs in ten HAACP systems
6. Brings risk analysis to a level where it can be easily understood by the lay person.

Further development

Risk analysis is a dynamic discipline and it is hoped that States and commercial operations will use the basic assessments as a starting point to make their own assessments as a prelude to managing food safety risks in their jurisdiction.

The compendium of hazards and their control comprises a starting point for the expert panel process by which gaps between regulators and businesses can be reduced.

Planned outcomes

The outputs of the project were: a series of risk assessments, a *Guide to Hazards and their Control in the Seafood Industry* and a workshop series supported by the booklet *"Risk and seafood safety – how to estimate it and manage it"*. These outputs were pivotal to the planned outcomes of the project and were specified in the project plan.

Conclusions

The project had three milestones, which were also performance indicators:

December, 2000	Completion of draft "Protocol for Risk management"
	Complete risk characterisation
January, 2001	Completion of draft "Australian guide to seafood hazards and controls"
March, 2001	Finalisation of publications and workshops conducted.

Milestone 1 was achieved in December, 2000.
Milestone 2 was achieved in January, 2001.
Milestone 3 was achieved in May, 2001.

Appendix 1: Intellectual property

The intellectual property in the assessments will be shared with the stakeholders via a CD-rom which will allow the development of risk management strategies. The CD-rom will contain:

- The national risk assessments
- The compendium of seafood hazards and their controls

Appendix 2: Staff

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Appendix 3: Publications

Sumner, J. (2001) HACCP and the international seafood trade. 10th Australian Food Microbiology Conference, Melbourne, (March, 2001).

Sumner, J. and Ross, T. (2001) A Semi-Quantitative Seafood Safety Risk Assessment. International Journal of Food Microbiology (submitted for publication)

Appendix 4: Workshops

Workshops were held in Perth, Melbourne and Brisbane with a total of around 100 participants. An evaluation of the workshops indicates a satisfactory outcome (see attached evaluation summaries).

Workshop evaluation

1) What is your occupational background?

Government 41% Industry 47% University/TAFE/training/consultant 12%

2) How do find the overall value of the workshop?

No value at all for me	0%
Little value	0%
Useful	24%
Very useful	76%

3) How do you find the duration of the workshop?

Too long 0% Too short 0% Fine 100%

4) How do find the documents and material distributed?

Poor	0%
Acceptable	0%
Good	65%
Excellent	35%

5) How do you find the technical level of the lectures?

Too easy 0% Appropriate 100% Too high/difficult 0%

6) Has the Workshop contributed for your better understanding of risk analysis?

Yes 100% No 0% Very little 0%

7) Have your expectations been fulfilled by the workshop?

Yes 82% No 0% Partly 18%

8) Do you have any additional comments to the above questions or other comments?

There were numerous comments which reflected participants' responses, above.

Appendix 5: Independent review

Staff of the Fisheries Industries Division, United Nations Food and Agriculture Organisation (FAO) reviewed the risk assessments.

Grimur Valdimarsson, Director
Dr Lahsen Ababouch, Service Chief
Dr Peter Ben Embarek, Fishery Industry Officer
Fishery Industries Division
Food and Agriculture Organisation of the UN

Terms of Reference

- Consider the Codex Alimentarius criteria for risk assessment as summarised on page 175 of International Journal of Food Microbiology (2000) volume 58.
- Comment on the risk estimates generated by our spreadsheet tool
- Comment on the usefulness of the assessments for helping each State controlling authority in Australia to focus on risk management.

Review summary

We have reviewed the Australia seafood Risk Assessment document that you forwarded us. As expressed in earlier correspondence, we have concentrated our efforts on the main general sections and on pairs of hazards/commodities namely Listeria monocytogenes, Histamine and Ciguatera. To our best evaluation, the document complies with the criteria against which you asked us to perform the review. In addition to the positive comments we made on the Listeria and Histamine chapters, we would like to add the following to the Ciguatera chapter. Although it can be argued that Ciguatera being a toxin and not a microorganism, it does fall within the scope of the Codex Guidelines for the conduct of Microbiological Risk Assessment, Codex Alimentarius Commission (CAC/GL-30 (1999)). Therefore this chapter can be evaluated against the same criteria as the other chapters.

One of our reviewers raised some concerns about the approach taken in this chapter but these were clarified by Dr. Sumner in subsequent communications. It would be useful to detail further the rationale behind the approach taken and possibly highlight the main questions posed by the Risk managers as briefly expressed at the end of the summary section of the main document. Quote : "At present, risk managers have difficulty comparing risks from different sources and a risk assessment tool capable of quickly estimating potential mitigation strategies has been developed". This would help avoiding possible misunderstanding on the scope and nature of the risk assessment. Also, the use of the term "semiquantitative" is not at all defined in the Codex document and should therefore be avoided. Despite this we find the Risk Characterisation tool developed in the course of this study excellent and will without doubt provide much needed assistance to Risk Managers.

Evaluation

In general, we consider the work acceptable and very useful to the fish industry in Australia and other parts faced with similar challenges in fish safety. More specifically, in addition to a general review of the first part, we have reviewed the RA for 2 hazards: Listeria and Histamine.

Part 1: Consumption, susceptible groups and characterisation of the risks : These 3 chapters are well presented and give valuable information on the consumption patterns in Australia and in the individual states. In the same manner, there is a thorough description and characterisation of the population and of the different susceptible sub-groups. The chapter on characterisation of the risk

gives a presentation of the new tool developed for the purpose of this study. The strengths and weaknesses of the tool are well described. Some additional details could be provided to better understand the ways the tool works. for example the risk ranking function described on page 3-8 could be presented in greater details. In particular the formula used is not obvious for non specialists.

Paired product/hazards:

1) Listeria monocytogenes in ready-to-eat seafood : Criteria of IJFM (page 175) 2000, vol 58. :
In general, the criteria listed in the IJFM article are met. The following comments can be made.
Criterion 3: The different elements of the Risk assessment are there although not in the same order. However, by reading the Risk assessment on Listeria, this does not seem to be a problem.

The Hazard identification is somewhat short and lacks some justification in evaluating whether the microorganism is a hazard when present in seafood. Iot also fail to link cases of listeriosis to seafood. This information is included in other chapter and could easily be moved or included in the Hazard identification.

The Exposure Assessment could include more detailed information on the effect of processing, distribution and handling on the pathogen.

Hazard characterisation: there is some discussion at international level on how susceptible young children are. The recent US RA on Listeria included neonates up to a month in the at-risk group while children over one month of age are in the general population group. This aspect could perhaps be revised in the present document.

In chapter 7.4, it would be useful to add some consideration on the role/importance of shelf life of refrigerated cold smoked salmons. In most cases, shelf life are determined by commercial parameters/requirements rather than quality or safety related parameters.

It would also be useful to integrate the recent data on the differences in pathogenicity potential of *Listeria monocytogenes* isolates from the smoked fish industry (Norton et al., Applied and Environmental Microbiology Feb 2001, pp646-653).

The Assessments show great promises to help individual States in Australia to focus on Risk management. It contains the right information and the necessary flexibility needed to enable each state to identify the management options having the best potential in reducing the risk associated with the hazard/product pair identified here.

2- Histamine poisoning

Likewise, the paper meets the criteria listed in the IJFM article, although the order of the elements of the Risk assessment can be changed. But, this does not affect the substance of the paper.

In the hazard identification, the role of biogenic amines as toxicity potentiators should be further emphasized. It is more likely that future regulations, especially in Europe, will be built around biogenic amines, not only histamine. Also, cured fish, especially salted anchovies, used in large

volumes by the pizza industry, can be at the origin of histamine poisoning. However, it should be noted that in the case of salted anchovies or other fish products with an enzymatic ripening phase, different bacteria (fermentative bacteria, *Cl. perfringens*) are involved in histidine decarboxylation into histamine.

The exposure assessment should take the above into consideration. Also, it should be highlighted that actually, the maximal levels of histamine authorized by different countries have been drafted to reflect temperature abuse and not safety limits. In fact, the European Union authorizes up to twice more histamine in enzymatically ripened fish by comparison to its levels in fresh/frozen or canned fish of the families *Scombridae, Engraulidae or Clupeidae.*

The hazard characterization step should emphasize the effect of fish thawing frozen raw material (especially for preparing canned tuna) as the major process step where histamine can accumulate.

Given the scarcity of data for Australia, the risk characterization can use the data available for the USA and Europe to make inferences for Australia especially in relation to the consumption canned and cured fish

Critical data gaps

Again, lack of scientific data on the toxicity potentiation effect of other biogenic amines, as well as the different kinetics of histamine accumulation depending upon the fish species, are major gaps that need to be addressed by the scientific community.
The overall paper will be useful in managing the risk of histaminosis in Australia.
Additional sources of value are:
1- Taylor, S.L, 1986. Histamine food poisoning: toxicology and clinical aspects. CRC Critical Reviws in Toxicology, 17:91-117
2- Ababouch, L, 1991. Histamine food poisoning: An update. Fish Tech News, 11(1): 3-5, 9
3- Draisci, R et al., 1999. Biogenic amines in semi-preserved anchovies as affected by processing. Ital, J. Food Sci. 11(4): 347-354.
4- Leigh Lehane and June Olley. 2000. Histamine fish poisoning revisited. Int'l J. Food Microbiol. 58:1-37.