

The 2012-13 paralytic shellfish toxin event in  
Tasmania associated with the dinoflagellate alga  
*Alexandrium tamarense*

Tactical Research Fund: A SafeFish Review

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## Non Technical Summary

<b>2012/060</b>	Tactical Research Fund: Review of the 2012 paralytic shellfish toxin event in Tasmania associated with the dinoflagellate alga, <i>Alexandrium tamarense</i>
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### OBJECTIVES:

The Review (see Appendix 3) aimed to determine:

1. The factors that led to non-compliance.
2. The key improvements that can be made to the Biotoxin Management Plan for the Tasmanian Shellfish Quality Assurance Program (TSQAP) to reduce the impact (likelihood and severity) of future non-compliance events.
3. The impacts of the non-compliance on the Tasmanian shellfish industry and its stakeholders.
4. What lessons can other bivalve producing states learn from this experience?
5. Is there a need to strengthen the ASQAP manual of operations around biotoxins?
6. The similarities with other non-compliance events domestically or internationally.
7. The lessons other fishery sectors can learn from the bivalve experience to reduce the impact of algal bloom events.
8. What can be done to improve communication and event response for future events with nation-wide impacts?

### NON TECHNICAL SUMMARY:

With adoption of the recommendations the key outcomes of the review are:

1. **Increased safety of Australian shellfish.** Key factors that led to Paralytic Shellfish Toxin (PST) contaminated shellfish being sold were identified and measures proposed to prevent contaminated product reaching the marketplace. Some of these measures are currently being implemented and discussions on implementation of recommendations are underway. Consequently fewer domestic and international consumers will most likely be exposed to PST in Australian seafood and public health risk reduced.
2. **Increased revenue from shellfish produced in Australia.** This will be achieved through the implementation of measures recommended in the review, which aim to prevent non-compliance events occurring in Tasmania and the greater Australian region. This will reduce the need and cost to recall and dump contaminated products, minimise revenue loss through lack of product sales and expenditure to grow unsaleable products.

3. **Decreased cost to the wider seafood industry stakeholders during non-compliance events.** The review includes recommendations on how to improve communication between all stakeholders and how to streamline the emergency response process during an event. Decreased cost to wider stakeholders will be achieved through reducing time inputs of stakeholders and time out of market for potentially impacted fisheries (e.g. rock lobster, abalone) if these recommendations are adopted.
4. **Decreased potential for loss of market access.** This will be accomplished through strengthening the shellfish quality assurance program in Tasmania and in other states through implementing a strategy that aims to decrease the potential for contaminated products to be traded. This will reduce the possibility of trading partners detecting biotoxins in Australian products and consequent trading restrictions. Discussions have commenced regarding strengthening state programs in conjunction with the underpinning national regulatory framework and associated policies.
5. **Reduced overseas compliance testing requirements.** This will be achieved through demonstrating to overseas markets that shellfish quality assurance programs in Australia are commensurate with the risk and thereby produce safe food. The review will be able to be used to demonstrate the responsible approach of the industry and competent authorities to ensure the biotoxin management program is appropriate.

## Background

During October 2012 a shipment of blue mussels (*Mytilus galloprovincialis*) derived from the east coast of Tasmania was tested by the Japanese import authorities (Ministry of Health Labour and Welfare; MHLW) and found to be contaminated with unacceptable levels of paralytic shellfish toxins (PST).

On the evening of 30 October 2012, the Japanese MHLW contacted the Australian Department of Agriculture Fisheries and Forestry (DAFF) in relation to a 'non-compliance' event.

Mussel samples were collected and tested from the implicated consignment and harvest area to confirm the presence of PST. Follow up investigations confirmed that the mussels had bioaccumulated PST through feeding on a bloom of the dinoflagellate alga *Alexandrium tamarense*.

After the presence of PST in mussels was identified, additional seawater and bivalve sampling of sites spanning most of the east coast of Tasmania confirmed the presence of *A. tamarense* cells and PST in bivalve shellfish (oysters and mussels) at several sites between Eddystone Point and Marion Bay (Appendix 3).

During early November 2012, it was confirmed that scallops, clams and rock lobsters also had bioaccumulated significant levels of PST. Other fishery products (including abalone, periwinkles, sea urchins, banded morwong, calamari, flathead and giant crabs) were tested and found to comply (i.e. below) with the maximum limit for PST.

## Public health and economic impacts

The impacts of the harmful algal bloom (HAB) along the east coast of Tasmania during October–November 2012 were estimated for four stakeholder groups:

1. Public health,
2. Commercial fishery,
3. Recreation and tourism, and
4. Regulators.

The direct economic impacts resulting from the non-compliance event and HAB primarily relate directly to stakeholders who require access to the affected harvest areas and include commercial fishery and marine farming operators, and recreational and indigenous fishers.

In addition to the direct effects there are flow-on impacts for value chain participants who derive value from the activities of commercial and recreational fishers including goods and service providers, wholesalers, processors, and restaurants and tourism operators.

There were no confirmed public health cases directly attributable to either the initial non-compliance event or the HAB (two reports were considered to be possible cases of Paralytic Shellfish Toxins not associated with the recalled product). The Review team (Appendix 3) noted that the Tasmanian Department of Health and Human Services (DHHS) public investigation focused on mussels harvested at the decline of the HAB.

A critical aspect of the economic impact analysis of commercial and marine farming fisheries is that the closures coincided with the period of peak demand for shellfish and crustacean supply into markets such as the spring thoroughbred racing carnival, Christmas–New Year festive season and Chinese New Year. The mussel sector was further impaired as it coincided with the entry of new products into supermarket chains in Australia and Japan.

- On a direct economic basis the cost of the HAB event was estimated at \$8,620,000, representing both revenue and expenditure impacts across all stakeholders.
- From a revenue perspective, the marine farming sector losses based on reductions in landed catch equated to an estimated \$6,308,700.
- By contrast the recreational fishery sector was impacted in the order of \$1,992,600.
- When an economic value chain multiplier is applied to the revenue loss of the commercial fishery sector, the economic impact of the algal bloom event increases to an estimated \$23,279,000 (Appendix 3).

## Key contributing factors

Investigations into the circumstances surrounding the non-compliance event have revealed the cause was complex but essentially resulted from a breakdown of the Biotxin Management Plan for the Tasmanian Shellfish Quality Assurance Program (TSQAP) (2012). The breakdown can be attributed to inadequate policies and procedures within the Program to detect and manage a HAB.

- A delay in the seasonal changeover to fortnightly phytoplankton testing by Spring Bay Seafoods (SBS) may have contributed to the toxic bloom of *A. tamarensis* remaining undetected in Spring Bay — the primary harvest area from which

mussels were supplied to domestic and export markets.

- A delay in timely water sample analysis and reporting of the presence of harmful algae by Analytical Services Tasmania (AST) resulted in the bloom remaining undetected during ongoing harvest and supply to domestic and export markets.
- In the absence of a phytoplankton result TSQAP Manager did not follow up with the laboratory and the marine farms remained open when trigger levels for closure had been exceeded.

The combination of systemic weaknesses in the TSQAP led to the failure to detect the HAB and therefore PST being detected in harvested mussels. The HAB remained undetected for an unacceptable period and during this time product was harvested and reached both the domestic and export markets.

These investigations have identified and highlighted issues surrounding the management of marine biotoxins and the HAB that led to the non-compliance event in relation to both the Tasmanian bivalve shellfish industry and other impacted fisheries.

Discussion and analysis of these issues, together with direct and indirect economic impacts and the resulting recommendations to improve the management of HAB events and to minimise their impact on stakeholders, are presented in the appended review (Appendix 3).

### Review recommendations

As a result of this review, the overarching recommendation, which has national implications for biotoxin risk management, is the critical need to reform the national regulatory framework, and associated policies that ensure the Australian Shellfish Quality Assurance Program (ASQAP) provides the foundation for internationally acceptable public health protection.

Given the high-risk status of bivalve molluscan shellfish the Review team strongly recommends any revised national regulatory framework incorporates some prescriptive elements common to appropriate international shellfish programs. This recommendation will provide the underpinning to support implementation of changes needed in each Australian jurisdiction as appropriate, including TSQAP as outlined in the attached review (Appendix 3).

The recommendations outlined in the review (Appendix 3) have been developed with the aim of ensuring production of seafood in a manner that protects public health. Without rectification, potential for serious public health risk exists with ensuing loss of market access, business viability and access for recreational and indigenous fishers.

The recommendations are targeted for consideration by government, seafood industry, and recreational and indigenous stakeholders and are directed at providing improvements in:

- the Biotoxin Management Plan for the TSQAP (2012), and
- wider industry and government agency response and management of any future HAB-related non-compliance events.

**KEYWORDS:** Paralytic shellfish toxins, Harmful algal bloom, bivalve shellfish, rock lobsters

## Acknowledgements

This Review was funded by the Fisheries Research and Development Corporation (FRDC), the Tasmanian Department of Primary Industries, Parks, Water and Environment (DPIPWE), the Tasmanian Department of Health and Human Services, Spring Bay Seafoods, the Tasmanian Rock Lobster Fisherman's Association (TRLFA), the Tasmanian Seafood Industry Council (TSIC), the Tasmanian Scallop Fishermens Association (TScallopFA), Oysters Australia, Southern Rocklobster Ltd and the Australian Seafood Cooperative Research Centre.

The Review team would like to thank the steering committee for their guidance and support during the course of the project. The Tasmanian seafood industry, through stakeholder interviews and individual contacts, provided valuable feedback and data on which to base the recommendations within the following pages. The staff of the State and government regulatory agencies, including FRDC, DPIPWE, DHHS and DAFF were always helpful with any questions or inquiries throughout the project. In particular, the project team would like to thank SafeFish for developing the Terms of Reference (ToR), chairing the steering committee, project management, coordination and facilitation of meetings.



## Background

During October 2012, a shipment of blue mussels (*Mytilus galloprovincialis*) derived from the east coast of Tasmania was tested by the Japanese import authorities (Ministry of Health Labour and Welfare; MHLW) and found to be contaminated with unacceptable levels (0.8mg/kg) of paralytic shellfish toxins (PST). Through investigation by regulators and industry it was confirmed that mussels had bioaccumulated PST through feeding on a bloom of the dinoflagellate alga *Alexandrium tamarense*.

After the presence of PST in mussels was identified, additional seawater and bivalve sampling of sites spanning most of the east coast of Tasmania confirmed the presence of *A. tamarense* cells and PST in shellfish (oysters and mussels) at several sites between Eddystone Point and Marion Bay (Appendix 3).

During early November 2012, it was confirmed that scallops, clams and rock lobsters also had bioaccumulated significant levels of PST. Other fishery products (including abalone, periwinkles, sea urchins, banded morwong, calamari, flathead and giant crabs) were tested and found to comply (i.e. below) with the maximum limit for PST.

This project was initiated in response to a request from key industry and government stakeholders for an external review of the non-compliance event. To facilitate the scoping of the Review, SafeFish undertook a series of stakeholder consultations in November 2012 to discuss the terms of reference (ToR) with the following industry and regulatory agency stakeholders:

- Alison Turnbull (Manager, TSQAP, DHHS)
- Phil Lamb (Managing Director, Spring Bay Mussels)
- Hayden Dyke and Tom Lewis (Oysters Tasmania)
- Mark Webster, Dean Lisson and Tony Johnston (Tasmanian Abalone Council)
- Rodney Treløggen (Tasmanian Rock lobster Fishermen's Association) and Julian Harrington (Tasmanian Seafood Industry Council)
- Mark Nikolai (Chief Executive, TARFish)
- Rob Gott, Hilary Revill and Grant Pullen (DPIPWE)
- Lynda Feazey (DAFF)
- Bob Lister (Scallops)

SafeFish developed the Review's Terms of Reference (ToR) and the methodology (see Methods section), together with the proposed outputs and outcomes of the Review in alignment with the feedback from the initial round of consultations.

Stakeholders agreed that the aim of the ToR is to review the process and framework applied by the shellfish industry and regulators to manage this non-compliance event. From this Review and analysis the team have provided recommendations that focus on principles on which management plans and operational strategies can either be established or re-addressed for implementation.

It is the role of industry and government stakeholders to consider the recommendations of the Review and where appropriate either collaboratively or individually formulate and invest in implementing actions relating to above-mentioned management plans and operational strategies for bivalves and/or other fishery stakeholders. Discussions at a State and National level are underway to consider the implementation of the Review recommendations. Several companies have also instigated measures recommended in the Review to reduce likelihood and impact of future non-compliance events.

## Need

The presence of PST at amounts exceeding the maximum permissible level by a factor of 12.5 in the shipment of mussels represented a major breakdown (i.e. a non-compliance event) in the TSQAP management plan for biotoxins in bivalve shellfish. It has also raised concerns for fisheries and health personnel regarding the potential need for marine biotoxin management plans for other fisheries products, such as rock lobsters, scallops and crabs.

On a direct economic basis the cost of the HAB event was estimated at \$8,620,000 representing both revenue and expenditure impacts across all stakeholders. From a revenue perspective the marine farming sector losses based on reductions in landed catch equated to an estimated \$6,308,700. By contrast the recreational fishery sector was impacted in the order of \$1,992,600. When an economic value chain multiplier is applied to the revenue loss of the commercial fishery sector, the economic impact of the algal bloom event increases to an estimated \$23,279,000 (Appendix 3).

Given the loss of revenue, costs of rehabilitation and damage to the industry's reputation as a safe producer of seafood, a review was required to determine the key factors that led to the non-compliance event, and to learn from this event so as to assist in the development of strategies to reduce the probability of future events occurring and impact.

## Objectives

As a result of the PST event, the key stakeholders proposed to undertake an external review with the aim of identifying:

- What factors (e.g. biological, monitoring faults) led to the non-compliance event?
- What have been the impacts of the non-compliance event on the Tasmanian shellfish industry and its stakeholders?
- What similarities can be drawn from other non-compliance events domestically or internationally?
- What are the key improvements that can be made to the TSQAP Biotxin Management Plan to reduce the impact (likelihood and severity) of future non-compliance events?
- What lessons can other bivalve producing states learn from this experience?
- Is there a need to strengthen the ASQAP manual of operations around biotoxins?
- What can the other fishery sectors (e.g. rocklobster and abalone) learn from the bivalve experience to reduce the impact of algal bloom incidents?
- What can be done to improve communication and incident response for future events with nation-wide impacts?

## Methods

The following Terms of Reference (ToR) were developed and agreed to prior to the review commencing.

### Terms of Reference (ToR)

#### 1. ToR One: Non-compliance event evaluation

- Undertake an evaluation of the sequence of events that lead to the detection of PSTs by the Japanese import authority, with a focus on compliance to the TSQAP biotoxin management plan.
- Identify the key factors that contributed to the non-compliance event, in particular identifying how the bloom remained undetected for long enough to produce unacceptable PST levels and if/why the TSQAP biotoxin management plan protocols were breached.
- Undertake a review of the respective response and management of the non-compliance event, including:
  - Monitoring (effectiveness, efficiency, resources)
    - Response time
    - Strategy
    - Laboratory testing and turn-around times
    - Results reporting.
  - Communication (frequency, content, communications channels, effectiveness)
    - Customers/public
    - Industry
    - Government agencies
    - Review of the national Seafood Incidence Response Plan
    - Review of incident notification process, including key regulatory agencies.
- Undertake a quantitative and qualitative evaluation of the economic impacts of the non-compliance event along the shellfish supply chain as a result of the shellfish recall, including impacts on:
  - supply chain stakeholders
  - Tasmanian and Australian shellfish industry, and
  - Tasmanian government agencies.

#### 2. ToR Two: Biotoxin monitoring and management plans

Within the context of the non-compliance event the review will:

- undertake an appraisal of the effectiveness of the current TSQAP management plan for addressing the biotoxin risk and non-compliance events in Tasmanian shellfish growing areas.
- undertake a review of the TSQAP management plan and its capacity to prevent future biotoxin incidents and/or manage future non-compliance events, incorporating:
  - Identifying if the current management plan has sufficient capacity and resources to deal with such an event.

- Identifying potential “gaps” in the current management plan.
  - Identifying potential strategies and/or policies to address ‘gaps’ within the management plan.
  - Identifying and assessing if additional risk management communication strategies are required relating to public health protection (domestic and export) with respect to the occurrence of marine biotoxins in Tasmania.
  - Undertaking a cost/benefit analysis for the adoption of additional strategies within the current TSQAP management plan for marine biotoxins in Tasmanian shellfish industry.
- Provide recommendations to stakeholders for enhancing the current non-compliance response management plan for biotoxins in the Tasmanian shellfish industry.

### **3. ToR Three: Impacts and implications for other Tasmanian fishery stakeholders**

At an industry peak body level, identify and evaluate quantitative and qualitative stakeholder impacts (i.e. economic, market, social) of the biotoxin non-compliance event in shellfish on other Tasmanian fisheries (i.e. abalone, southern rocklobster and potentially periwinkles and sea urchins) and recreational fishers, including industry and government agency co-ordination and response.

### **4. General considerations for the ToR**

The review should be undertaken with the aim of ensuring the TSQAP management plan continues to deliver the sustainable and safe production of Tasmanian shellfish in a manner that ensures public health and market access.

Recommendations should be targeted at providing improvements in:

- the current Tasmania TSQAP management plan, and
- industry and government agency response and management of any future non-compliance events.

### **Review Approach**

Based on the ToR above, the overall approach taken was to address each of the ToR within the following assessment framework:

- **Technical Assessment:** identify the cause, impacts and implications of the non-compliance event on the TSQAP, other Tasmanian fisheries and national stakeholders (regulatory and industry).
- **Economic Assessment:** relating to the micro and macro impacts and implications of the non-compliance event on the Tasmanian bivalve industry, other Tasmanian fisheries and national stakeholders.
- **Communication Assessment:** identify the flow and effectiveness of communication within and between key stakeholders (private and public sector) in the Tasmanian bivalve industry, other Tasmanian fisheries and national stakeholders.

Throughout this process the Review Team comprised of shellfish safety, food safety, economic and communication experts (Appendix 3) has compared TSQAP policies and procedures and underpinning legislation in place at the time of the non-compliance event

with internationally acceptable practice for determining what failed and why, and how it might be prevented from recurring.

### Consultation

The methodology involved working collaboratively with industry and regulatory stakeholders to generate information that will lead to a thorough assessment and evaluation. To support achieving the above ToR, the Review Team undertook the following:

- Held an initial meeting of the project Steering Committee of industry and government stakeholders in Tasmania to re-affirm ToR and discuss review process (May 2013).
- Prepared series of questions for interviews with Tasmanian fishery stakeholders (Public and private sector) based on ToR 1, ToR 2 and ToR3.
- Identified and contacted key Tasmanian marine farming and fishery stakeholder representatives (public and private sector), and federal regulatory stakeholders for interviews. One to one interviews were held with the following parties:
  - Mussel sector
  - Oyster sector
  - Scallop sector
  - Rock lobster sector
  - Abalone sector
  - Periwinkles and sea urchins (through commercial divers)
  - Recreational fishing sector
  - Tasmanian Dept. Primary Industries Parks Water and Environment
  - Tasmanian Dept. of Health and Human Services
  - Analytical Services Tasmania
  - DAFF
  - Food Standards Australia New Zealand
- Two case studies were undertaken to evaluate economic impact – one on oysters and one on the tourism sector. This involved visiting oyster farmers at their businesses and conducting ½ day interviews. Surveys were also undertaken to elicit information needed; for the oyster sector 17 of 31 oyster businesses completed the survey, for the tourism sector 48 of 60 operators in the region completed the survey.
- Impacted mussel farmers and commercial divers were also visited at their businesses to more fully evaluate economic impacts.
- Two rounds of written feedback on the review drafts were considered by the Review Team and changes made accordingly.
- Two face-face meetings of the Steering Committee were held to discuss feedback on the review. The review draft was accepted by the Steering Committee at the 6 August 2013 meeting.

- A meeting of State and federal regulators and industry representatives was held in June to discuss key findings of the review and adoption.

## Results/Discussion

The full Review can be found in Appendix 3.

In summary the Review found weaknesses in the underpinning standards for shellfish safety leading to TSQAP not adopting internationally accepted practices for monitoring and compliance. This coupled with a complex combination of procedural failures and testing delays led to the non-compliance event. Recommendations to prevent a recurrence are provided (Appendix 3).

### Benefits

Industry sectors that will benefit from this review include bivalve industries (e.g. mussels, oysters, clams and scallops) and fishery industries such as rocklobsters, crabs and abalone. The recreational fishing sector will also benefit from adoption of the review recommendations.

On a direct economic basis the cost of the HAB event was estimated at \$8,620,000 representing both revenue and expenditure impacts across all stakeholders. From a revenue perspective, the marine farming sector losses based on reductions in landed catch equated to an estimated \$6,308,700. By contrast the recreational fishery sector was impacted in the order of \$1,992,600. When an economic value chain multiplier is applied to the revenue loss of the commercial fishery sector, the economic impact of the algal bloom event increases to an estimated \$23,279,000.

While HAB events will occur again, the establishment of an appropriate QA program for bivalves and high-risk fisheries products (e.g. lobsters, scallops and crabs) would significantly reduce the economic impact of future blooms. Improving the QA program will also reduce the potential for future HAB events to impact public health.



## Further Development

The Steering Committee meeting (6 August 2013) discussed and agreed the following steps for the finalisation, approval and public release of the project final report:

- Review Team to submit the two documents required by the FRDC (including the project final report) by 16 August 2013.
- FRDC will provide embargoed copies of the project final report to Chair of Australian Shellfish Quality Assurance Advisory Committee, DAFF and FSANZ.
- FRDC will email Steering Committee members on 26 August 2013 confirming release on 28 August 2013 and attaching a copy of the report to be publicly released.
- FRDC will load final report as a PDF document on its website on 28 August 2013. FRDC to circulate copies of the report by email to key fishery bodies (NSIA, Rec Fish Aust, SRL, ACA, etc) on 28 August 2013.

The Steering Committee discussed the need for communication plans (containing key messages /positive speaking points / suggested responses to difficult questions) to assist fishery bodies in responding to any media enquiries that (1) may arise as a result of the report being loaded on the FRDC website and (2) may be received prior to the report being loaded onto the FRDC website.

The communication strategy will need to recognise the different needs of different parties (industry bodies, government agencies, trading partners) and will therefore require consistency of messages tailored for the specific requirements of each group.

FRDC (Peter Horvat) has agreed to develop a draft communication strategy that will be provided to the project Steering Committee Chair on 7 August 2013. The Steering Committee Chair (Rob Gott) will circulate it to Steering Committee members. Steering Committee members to provide comments / input directly back to Peter Horvat to enable finalisation of strategy.

## Planned outcomes

The major planned output for this project was the Review of the 2012 PST event in Tasmania associated with the dinoflagellate alga, *Alexandrium tamarense*.

With adoption of the recommendations the key outcomes of the review are:

1. **Increased safety of Australian shellfish.** Key factors that led to PST contaminated shellfish being sold were identified and measures proposed to prevent contaminated product reaching the marketplace. Some of these measures are currently being implemented and discussions on implementation of recommendations are underway. Consequently, fewer domestic and international consumers will be exposed to PST in Australian shellfish and public health risk will be reduced.
2. **Increased revenue from shellfish produced in Australia.** This will be achieved through the implementation of measures recommended in the review, which aim to prevent non-compliance events occurring in Tasmania and the greater Australian region. This will reduce the need and cost to recall and dump contaminated products, minimise revenue loss through lack of product sales and expenditure to grow unsaleable products.
3. **Decreased cost to the wider seafood industry stakeholders during non-compliance events.** The review includes recommendations on how to improve communication between all stakeholders and how to streamline the emergency response process during an event. Decreased cost to wider stakeholders will be achieved through reducing time inputs of stakeholders and time out of market for potentially impacted fisheries (e.g. rock lobster, abalone) if these recommendations are adopted.
4. **Decreased potential for loss of market access.** This will be accomplished through strengthening the shellfish quality assurance program in Tasmania and in other States through implementing a strategy that aims to decrease the potential for contaminated products to be traded. This will reduce the possibility of trading partners detecting biotoxins in Australian products and consequent trading restrictions. Discussions have commenced regarding strengthening State programs in conjunction with the underpinning national regulatory framework and associated policies.
5. **Reduced overseas compliance testing requirements.** This will be achieved through demonstrating to overseas markets that shellfish quality assurance programs in Australia are commensurate with the risk and thereby produce safe food. The review will be able to be used to demonstrate the responsible approach of the industry and competent authorities to ensure the biotoxin management program is appropriate.

See the 'Methods' section for details on consultation undertaken throughout the review and dissemination of results.

## Conclusion

The objectives of the Review were to identify:

- What factors (e.g. biological, monitoring faults) led to the non-compliance event?
- What have been the impacts of the non-compliance event on the Tasmanian shellfish industry and its stakeholders?
- What similarities can be drawn from other non-compliance events domestically or internationally?
- What are the key improvements that can be made to the TSQAP Biotoxin Management Plan to reduce the impact (likelihood and severity) of future non-compliance events?
- What lessons can other bivalve producing states learn from this experience?
- Is there a need to strengthen the ASQAP manual of operations around biotoxins?
- What can the other fishery sectors (e.g. rocklobster and abalone) learn from the bivalve experience to reduce the impact of algal bloom incidents?
- What can be done to improve communication and incident response for future events with nation-wide impacts?

The Review contained in Appendix 3 considers each of these objectives and comprehensively addresses them.

As a result of this review, the overarching recommendation, which has national implications for biotoxin risk management, is the need to reform the national regulatory framework, and associated policies that ensure the Australian Shellfish Quality Assurance Program (ASQAP) provides the foundation for internationally acceptable public health protection.

Given the high-risk status of bivalve molluscan shellfish, the Review Team strongly recommends any revised national regulatory framework incorporates some prescriptive elements common to appropriate international shellfish programs. This recommendation will provide the underpinning to support implementation of changes needed in each Australian jurisdiction as appropriate, including the TSQAP, as outlined in the attached Review.

The recommendations outlined in the Review (Appendix 3) have been developed with the aim of ensuring production of seafood in a manner that protects public health. Without rectification, potential for serious public health risk exists with ensuing loss of market access, business viability and access for recreational and indigenous fishers.

The recommendations are targeted for consideration by government, seafood industry, and recreational and indigenous stakeholders and are directed at providing improvements in:

- the Biotoxin Management Plan for the TSQAP (2012), and
- wider industry and government agency response and management of any future HAB-related non-compliance events.

The Review Team strongly recommends that a stakeholder group be convened and led by Department Primary Industries, Parks, Water and Environment to develop an action plan which details both short- and long-term strategies to address short-comings identified in the Review and provide this action plan to FRDC and federal regulators by way of response to the Review.

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## Appendix 1: Intellectual Property

N/A

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## Appendix 3: Review





The 2012–13  
**paralytic shellfish toxin**  
event in Tasmania associated  
with the dinoflagellate alga,  
*Alexandrium tamarense*

Tactical Research Fund

A SafeFish Review

June 2013

FRDC Project 2012/060

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### Acronyms and abbreviations

AAA — Advanced Analytical Australia

ASP — Amnesic shellfish poisoning

ASCRC — Australian Seafood Co-operative Research Centre

ASQAP — Australian Shellfish Quality Assurance Program

AST — Analytical Services Tasmania

AZP — Azaspiracid acid poison

DAFF — Australian Government Department of Agriculture Fisheries and Forestry

DHHS — Department of Health and Human Services (Tasmania)

DPIPWE — Department of Primary Industries, Parks, Water and Environment (Tasmania)

DSP — Diarrhetic shellfish poisoning

DST — Diarrhetic shellfish toxins

EU — European Union

FAQ — Frequently asked questions

FRDC — Fisheries Research and Development Corporation

FSANZ — Food Standards Australia New Zealand

HAB — Harmful Algal Bloom

ICMSS — International Conference on Molluscan Shellfish Safety

IOC — Intergovernmental Oceanographic Commission

LC-MS — liquid chromatography – mass spectrometry

NSP — Neurotoxic shellfish poisoning

NST — Neurotoxic shellfish toxins

NZ — New Zealand

PEHS — Public and Environmental Health Services (Tasmania)

PST — Paralytic shellfish toxins

SBS — Spring Bay Seafoods

SIRP — Seafood Incident Response Plan

SIRT — Seafood Incident Response Team

SSA — Seafood Services Australia

TAC — Tasmanian Abalone Council

TARFish — Tasmanian Association for Recreational Fishing

TSFA — Tasmanian Scallop Fishermen's Association

TSIC — Tasmanian Seafood Industry Council

TRLFA — Tasmanian Rock Lobster Fishermen's Association

TSQAP — Tasmanian Shellfish Quality Assurance Program

# Executive summary

## Event overview and key recommendations

### Background

During October 2012 a shipment of blue mussels (*Mytilus galloprovincialis*) derived from the east coast of Tasmania was tested by the Japanese import authorities (Ministry of Health Labour and Welfare (MHLW)) and was found to be contaminated with unacceptable levels of paralytic shellfish toxins (PST).

On the evening of 30 October 2012 the Japanese MHLW contacted the Australian Department of Agriculture Fisheries and Forestry (DAFF) in relation to a 'non-compliance' event.

Mussel samples were collected and tested from the implicated consignment and harvest area to confirm the presence of the PST reported. Through investigation by regulators it was confirmed that mussels had bioaccumulated PST through feeding on a bloom of the dinoflagellate alga *Alexandrium tamarense*.

After the presence of PST in mussels was identified, additional seawater and bivalve sampling of sites spanning most of the east coast of Tasmania confirmed the presence of *A. tamarense* cells and PST in shellfish (oysters and mussels) at several sites between Eddystone Point and Marion Bay.

During early November 2012 it was confirmed that oysters, scallops, clams and rock lobsters also had bioaccumulated unacceptable levels of PST. Other fishery products (including abalone, periwinkles, sea urchins, banded morwong, calamari, flathead and giant crabs) were tested and found to comply with the maximum limit for PST (see Table 4).

### Public health and economic impacts

The impacts of the harmful algal bloom (HAB) along the east coast of Tasmania during October–November 2012 were estimated from the perspectives of:

1. Public health
2. Commercial fisheries and marine farming
3. Recreation and tourism
4. Regulators.

The direct economic impacts resulting from the non-compliance event and the HAB primarily relate directly to stakeholders who require access to the affected harvest areas and include commercial fishery and marine farming operators, recreational and indigenous fishers.

In addition to the direct effects, there are flow-on impacts of consumers eating catch from the closed areas (i.e. public health impacts) and value chain participants who derive value from the activities of commercial and recreational fishers including goods and service providers, wholesalers, processors, restaurants and tourism operators.

There were no confirmed public health cases directly attributable to either the initial non-compliance event or the HAB (two reports were considered to be possible cases of PSP not associated with the recalled product). The Review team noted that the Tasmanian Department of Health and Human Services (DHHS) public investigation focused on mussels harvested at the decline of the HAB.

A critical aspect of the economic impact analysis of commercial fisheries and marine farming industries is that the closures coincided with the period of peak demand for shellfish and crustacean supply into markets such as the spring thoroughbred racing carnival, the Christmas–New Year festive season and the Chinese New Year.

The mussel sector was further impaired as it coincided with the entry of new products into supermarket chains in Australia and Japan.

On a direct economic basis the cost of the HAB event was estimated at \$8,620,000 representing both revenue and expenditure impacts across all stakeholders.

From a revenue perspective the marine farming and wild catch fisheries sector losses based on reductions in production equated to an estimated \$6,308,700.

By contrast the recreational fishery sector was impacted in the order of \$1,992,600.

When an economic value chain multiplier is applied to the revenue loss of the commercial fishery and marine farming sector, the economic impact of the algal bloom event increases to an estimated \$23,279,000.

## Key contributing factors

Investigations into the circumstances surrounding the non-compliance event have revealed the cause was complex but essentially resulted from a breakdown of the *Biotoxin Management Plan for the Tasmanian Shellfish Quality Assurance Program (TSQAP)* (2012). The breakdown can be attributed to inadequate policies and procedures within the Program to detect and manage a HAB.

- A delay in the seasonal changeover to fortnightly phytoplankton testing by Spring Bay Seafoods (SBS) may have contributed to the toxic bloom of *A tamarensis* remaining undetected in Spring Bay — the primary harvest area from which mussels were supplied to domestic and export markets.
- A delay in timely water sample analysis and reporting of the presence of harmful algae by Analytical Services Tasmania (AST), resulted in the bloom remaining undetected during ongoing harvest and supply to domestic and export markets.
- In the absence of a phytoplankton result the TSQAP Manager did not follow up with the laboratory (until the day of the notification of the violative results from Japan) and the marine farms remained open when trigger levels for closure had been exceeded.

The combination of systemic weaknesses in the TSQAP, led to the failure to detect the HAB and therefore PST being detected in harvested mussels. The HAB remained undetected for an unacceptable period and during this time product was harvested and reached both the domestic and export markets.

These investigations have identified and highlighted issues surrounding the management of marine biotoxins and the HAB that led to the non-compliance event, in relation to both the Tasmanian bivalve shellfish industry and other impacted fisheries.

Discussion and analysis of these issues, together with the direct and indirect economic impacts and the resulting recommendations to improve the management of HAB events and to minimise their impact on stakeholders, are presented in the following report.

# Review recommendations

As a result of this review, the overarching recommendation, which has national implications for biotoxin risk management, is the critical need to reform the national regulatory framework and associated policies that ensure the Australian Shellfish Quality Assurance Program (ASQAP) provides the foundation for internationally acceptable public health protection and ongoing market access.

Given the high-risk status of bivalve molluscan shellfish the Review team strongly recommends any revised national regulatory framework incorporates some prescriptive elements common to appropriate international shellfish programs. This recommendation will provide the underpinning to support implementation of changes needed in each Australian jurisdiction as appropriate, including the TSQAP, as outlined in the following review.

The recommendations outlined have been developed with the express aim of ensuring production of seafood in a manner that protects public health. Without rectification, potential for serious public health risk exists with ensuing loss of market access, business viability and access for recreational and indigenous fishers.

The recommendations are targeted for consideration by government, regulators and seafood industry, recreational and indigenous stakeholders and are directed at providing improvements in:

- the *Biotoxin Management Plan for the TSQAP* (2012), and
- wider industry and government agency response and management of any future HAB-related non-compliance events.

## Short-term priorities (0–6 months)

### The TSQAP

In the short term ensure the TSQAP is adequately resourced to:

- Design and implement an interim *Management Plan* that will deal with the current year, incorporating recommendations arising from this report where possible.
- Deliver services to the bivalve shellfish sectors currently covered by TSQAP to a level that adequately protects public health at all times.
- Provide a service level to the bivalve shellfish sectors currently covered by TSQAP based on currently-recognised global best practice.
- Minimise the impact of non-compliance events on market access.

### The Biotoxin Management Plan for the TSQAP (*Plan*)

- Review the recommendations outlined in the FRDC project 1999/332 (*Cawthron Report No. 646*, 2001) and where appropriate adopt and implement recommendations within the *Plan*.
- Incorporate within the *Plan* an event response protocol for non-compliance events, which identifies a structured response process.
- Replace phytoplankton testing as the primary risk management tool with shellfish flesh testing, retaining phytoplankton testing as a predictive early warning tool.
- Increase the frequency of sampling (and testing) in medium-risk and high-risk areas in line with policies and interventions considered commensurate with risk and food safety regulations internationally.
- Review and revise current ambiguous guidelines relating to the closure of marine farms covered by the *Plan* to provide clarity around implementing regulatory responses where samples or test results are not forthcoming within expected time frames.
- Replace existing agreements with laboratory testing service providers with a performance-based contract that encompasses capability and key performance indicators (KPIs).



- Review current protocols and communication channels for the delivery of laboratory test results to ensure continuity and consistency in communicating results to regulators and industry stakeholders. Consider a web-based pathway, or mobile phone technology, for direct delivery of results to all relevant stakeholders.

## Other fisheries management

To inform the development of appropriate risk management plans for fisheries products, the Review team recommends the following work is prioritised for action by regulators and industry:

1. A risk ranking exercise for fisheries species to ascertain which ones should be included in the management plan and any relevant associated framework or regulation.
2. Concurrent sampling of potential bivalve sentinel species (for example, mussels) alongside higher-risk fisheries species (for example, lobster, abalone) during algal blooms to ascertain usefulness of sentinel species in predicting the risk of contamination of fisheries products.

## Communications

- Create and implement an interim communications response protocol, across all sectors, for the coming season, which covers the immediate event response and ongoing HAB management, together with a database of key contacts within each target audience (for example, industry stakeholders, government, tourism operators and public).
- Ensure the event response protocol clearly articulates communication responsibilities and processes for all lead agencies, including communication around fishery closures.
- Review and evaluate the adoption of modern social networking channels (facebook, twitter, SMS messages) in addition to existing channels (media releases, radio, television, newspapers).
- Implement a media training program for key industry leaders to ensure cohesive leadership and consistent media communication in the event of a future non-compliance event.

## Longer-term priorities (6+ months)

In the longer term the Review team recommends a state-wide cross-sector biotoxin management approach that incorporates a strategic inter-agency and industry stakeholder event response protocol with a structured process to address events, together with roles and responsibilities (regulatory and industry) and a built-in post-event review process.

## State-wide biotoxin management

In the medium to long term:

- Review current legislation governing cross-sector management of marine biotoxin events and ensure lead agencies are critically aware of the legislative framework that underpins applicable regulations and levels of authority, together with the roles and responsibilities of the agencies during an event.
- Use data gathered from monitoring fisheries products to inform comprehensive risk assessments and to ascertain the potential impact that PSTs could have on public health.
- Evaluate the opportunity to use routine TSQAP data to inform management of other fisheries.
- Integrate risk management protocols for higher-risk fisheries species (e.g. potentially scallops, rock lobsters, abalone and crabs) into the *Plan*, which currently covers bivalves. The fisheries species to be included in the plan should be based on the recommended risk ranking exercise (to be undertaken in the short-term).'
- Prepare a risk-based plan that identifies how to manage algal blooms and associated biotoxins not seen before in Tasmania. Identify the agency responsible for managing the event response protocol and the appropriate division of resources. Ensure the plan outlines a strategy for determining appropriate risk management responses.
- As part of the management plan, consider developing and implementing a 'library system', which provides storage of in-house fishery samples from successive harvests for retrospective analysis to inform product recall in the event of a marine biotoxin event.
- Ensure proposed changes to any aspect of the *Plan* (for example, fishery closure trigger levels) are rigorously peer reviewed to ensure the approach is scientifically justified with technical and/or public health rationale.

# Review recommendations (cont.)

- Develop a succession plan for the on-going delivery of the TSQAP with a focus on decision making and resources.
- Prepare and file for future use a library of broad-based factsheet templates, on all identified potential marine biotoxins, which can be quickly adapted for individual event response and delivery to industry stakeholders.

## Lessons for other states and DAFF

As stated previously, in light of the issues being raised, the Review team recommends all states take this opportunity to review their current biotoxin management programs and the underpinning regulatory framework to protect public health and ensure sustained market access.

In particular all states should review their respective current biotoxin programs against the Cawthron Report 2001 recommendations.

DAFF annually audits the TSQAP to ensure compliance with the ASQAP Export Standards 2004 (and export legislation). During the review it was highlighted that the ASQAP Export Standards are outcome based and the auditor requires an understanding of public health risk management.

It was noted that staffing changes during the past five years have seen a reduction in relevant expertise on assessing the ability of state-managed programs to meet the ASQAP Export Standards.

In conclusion, the Review team recommends that given the impacts on export-bound product and the findings of the Review, DAFF assesses its role and responsibilities within the auditing and certification process.

## Seafood Incident Response Plan (SIRP)

- Clarify and communicate to regulators and industry stakeholders the triggers that determine when the SIRP is enacted regarding a non-compliance event.
- Clarify within the SIRP how the Plan will operate alongside existing response and risk management plans.
- Evaluate and confirm the future role of SIRP including resources (infrastructure and finance) available for responding to similar future events.

# Introduction

## An overview of the project

This project was initiated in response to a request from key industry and government stakeholders for an external review of the non-compliance event.

The Review aimed to determine:

- The factors that led to the non-compliance event.
- The key improvements that can be made to the *Biotxin Management Plan for the TSQAP* to reduce the impact (likelihood and severity) of future non-compliance events.
- The impacts of the non-compliance event on the Tasmanian shellfish industry and its stakeholders.
- The similarities with other non-compliance events domestically or internationally.
- The lessons fishery sectors (for example, rock lobster and abalone) can learn from the bivalve experience to reduce the impact of algal bloom events.
- What can be done to improve communication and event response for future events with nation-wide impacts.

To facilitate the scoping of the Review, SafeFish undertook a series of stakeholder consultations to discuss the terms of reference (ToR) with the following industry and regulatory agency stakeholders:

- Alison Turnbull (Manager, TSQAP, DHHS)
- Phil Lamb (Managing Director, Spring Bay Seafoods Pty Ltd)
- Hayden Dyke and Tom Lewis (Oysters Tasmania)

- Mark Webster, Dean Lisson and Tony Johnston (Tasmanian Abalone Council)
- Rodney Treloggen (TRLFA) and Julian Harrington (TSIC)
- Mark Nikolai (Chief Executive, TARFish)
- Rob Gott, Hilary Revill and Grant Pullen (DPIPWE)
- Lynda Feazey (DAFF)
- Bob Lister (TSFA)

SafeFish developed the Review's Terms of Reference (see Appendix 1, page 68) and the methodology (see Table 1), together with the proposed outputs and outcomes of the Review in alignment with the feedback from the initial round of consultations.

Stakeholders agreed that the aim of the ToR is to review the process and framework applied by the shellfish industry and regulators to manage this non-compliance event. From this Review and analysis the team has provided recommendations that focus on offensive and defensive principles on which management plans and operational strategies can either be established or re-addressed for implementation.

It is the role of industry and government stakeholders to consider the recommendations of the Review and where appropriate either collaboratively or individually formulate and invest in implementing actions relating to above-mentioned management plans and operational strategies for the shellfish, marine farming and wider seafood sectors.

## SafeFish – a snapshot

SafeFish, a partnership of seafood safety and market access experts, was formed to help the Australian seafood industry resolve technical trade impediments, especially in relation to issues that arise associated with the safety and hygiene of their products. SafeFish acts as a facilitator between industry, regulatory bodies and scientists, as well as a technical entity for the provision of evidence-based science advice to assist decision-making processes.

SafeFish provides technical advice to support the resolution of issues and challenges relating to the export, import and domestic trade of Australian seafood products.

SafeFish undertakes the following key functions:

1. Development of technical advice for trade negotiations to assist in the resolution of market access and food safety issues.
2. Development of technical briefs on high priority Codex issues.
3. Facilitation of technical attendance at high priority Codex meetings and specific working groups.
4. Identification of emerging market access issues.

**Table 1. Summary of the project methodology for the *Review of the 2012-13 paralytic shellfish toxin event in Tasmania***

Terms of Reference (ToR)	Technical assessment	Economic assessment	Communication assessment	Methodology
Non-compliance event evaluation <sup>(ToR one)</sup>	<ul style="list-style-type: none"> <li>Interview key stakeholders including individual business operators (micro), Tasmanian fishery industry representatives and government agencies (macro)</li> <li>Interview and record detailed operational information on supply chain process (pre, during and post non-compliance event) from two nominated case study participants</li> <li>Collate information and prepare initial impact assessment and outcomes for detailed analysis, recommendations and reporting</li> </ul>			<ul style="list-style-type: none"> <li>Personal interviews</li> </ul>
Biotoxin monitoring and management plans <sup>(ToR two)</sup>	<ul style="list-style-type: none"> <li>Review current the <i>Biotoxin Management Plan for the TSQAP</i></li> <li>Based on completed interviews undertake a GAP analysis to identify potential opportunities for modifying the <i>Biotoxin Management Plan for the TSQAP</i></li> <li>Based on completed interviews undertake a GAP analysis to identify micro and macro costs of non-compliance event (pre, during and post) to Tasmanian bivalve shellfish marine farming industry</li> <li>Identify and compare non-compliance events and outcomes within the seafood and broader food supply chain (for example, beef, fruit, vegetables) which may provide comparative information (domestic/global)</li> <li>Collate information and prepare initial impact assessment and outcomes for detailed analysis, recommendations and reporting</li> </ul>			<ul style="list-style-type: none"> <li>Personal interviews</li> <li>GAP analysis</li> <li>Desktop research</li> </ul>
Impacts and implications for other Tasmanian fishery stakeholders <sup>(ToR three)</sup>	<ul style="list-style-type: none"> <li>Based on completed interviews undertake GAP analysis to identify the impacts and implications for management of non-compliance events in other Tasmanian fisheries</li> <li>Based on completed interviews undertake a GAP analysis to identify macro costs of non-compliance event (pre, during and post) to other Tasmanian fisheries</li> <li>Collate information and prepare initial impact assessment and outcomes for detailed analysis, recommendations and reporting</li> </ul>			<ul style="list-style-type: none"> <li>GAP analysis</li> <li>Desktop research</li> </ul>

## The Tasmanian context

As a relatively small island state, seafood is an intrinsic part of the Tasmanian culture. And from an economic perspective, commercial and recreational fishing have long been an important source of direct and indirect revenue for the state. On a national scale, the Tasmanian seafood industry is the most valuable seafood industry in Australia (Skirtun et al 2012).

During 2010–11 the gross value of Tasmanian seafood production increased by 5% (\$28.7 million) relative to 2009–10, to \$596.7 million.

The total volume of production also increased, by 1419 tonnes, to 43 545 tonnes during 2010–11.

In value terms, the wild catch sector accounted for 28% (\$164.9 million) of the state's total production and the marine farming sector accounted for the remaining 72% (\$431.8 million). Rock lobster accounted for 31% (\$59.5 million) of the total value of Tasmanian seafood species of interest harvested in 2010–11.

## The Tasmanian Shellfish Quality Assurance Program (TSQAP)

The value of abalone production was \$102 million during 2010–11, with the volume of production (2874 tonnes).

Edible oysters accounted for around 10% of the state's marine farming production volume during 2010–11 and contributed \$23.5 million towards Tasmania's gross value of production. Mussel production continued to expand with production during 2010–11 of 717 tonnes, valued at \$2.5 million.

### Harmful algal bloom (HAB) events

In most marine and freshwater environments, microscopic organisms, referred to as phytoplankton or microalgae, form the base of the food chain upon which nearly all other marine organisms depend.

An algal bloom occurs when there is a rapid increase in concentration of phytoplankton. This can occur for several reasons. Most often, an increase in the nutrients the algae feed on, or some environmental condition, such as a change in water temperature or patterns in water circulation, are the cause of the population explosion.

Some blooms can have considerable negative impacts on the affected area. The extent of the impacts can vary depending on a number of factors, including the length and size of the bloom. Larger blooms have been known to last for more than a year and stretch along several miles of coastline.

Some species of algae produce toxins, which can be released into the water and air. Shellfish can bioaccumulate these toxins and if humans consume these shellfish (and toxins) in sufficient quantities they can become ill.

The negative impacts from HABs not only affect the environment and human health, but also impact the local economies of the affected areas through the flow-on effects of economic losses to commercial shellfish operators, goods and service providers to the industry, recreational and indigenous fishers and tourism operators (Lucas et al 2010).

Although widely enjoyed by domestic and international consumers alike, filter-feeding bivalve shellfish, such as oysters, mussels, clams and scallops, can pose a public health risk when water quality is compromised. Other species, such as rock lobster and abalone, which are not filter feeders, pose a lesser level of risk, but may still bioaccumulate toxins.

In the absence of proper food safety controls for shellfish harvesting and processing, the risk of illness and deaths linked to shellfish consumption is significant.

The TSQAP establishes a risk management program that aims to protect public health from risks posed by naturally-occurring and anthropogenic hazards. The program is funded by industry and the Tasmanian state government and covers bivalve shellfish marine farming and commercial wild harvest bivalve shellfish fishing activities, excluding the commercial scallop fishery.

The TSQAP has the role of creating, maintaining and implementing the *Biotoxin Management Plan* in all Tasmanian commercial bivalve shellfish growing areas. It has the oversight of the sampling program, and has the responsibility for training samplers and determining the locations and frequencies of sampling.

The TSQAP is responsible for:

- Implementing closures and re-openings of growing areas affected by marine biotoxins, notifying all parties concerned, and maintaining records of these closures.
- Surveillance of harvesting in closed areas to ensure illegal harvesting does not occur.
- Coordinating the analysis of algal and shellfish samples with appropriate laboratories including the arrangement of sample transportation to these laboratories when marine farms are in the open status, or when TSQAP believes the growing area is nearing re-opening conditions.
- Communicating with appropriate agencies and companies and any other body that is collecting algal and/or algal toxicity information around the state (for example, industry, CSIRO, the University of Tasmania).

## TSQAP regulatory framework and operational responsibilities

- The Marine Farming branch of DPIPWE issues marine farming licences to bivalve shellfish farmers and is responsible for ensuring the conditions of the license are met. A standard license condition in a bivalve shellfish marine farming license requires the holder to comply with the TSQAP.
- The TSQAP administers the *Biotoxin Management Plan* under the *Tasmanian Food Act 2003*, and the *Public Health Act 1997*.
- Maximum biotoxin levels in shellfish are set by FSANZ in the *Australia New Zealand Food Standards Code*.
- Standards relating to shellfish harvested for export are given in the *Export Control Orders 2004*.
- The *Biotoxin Management Plan for the TSQAP* follows the requirements of the *Australian Shellfish Quality Assurance Manual of Operations Version 2006-01*.
- The Marine Farming Branch of DPIPWE administers marine farming licenses under the *Living Marine Resources Management Act 1995*.

## The non-compliance event

On the evening of 30 October 2012 the Japanese import authority (MHLW) contacted DAFF in relation to a 'non-compliance' event regarding mussels from SBS on the east coast of Tasmania.

Mussels tested by the Japanese authority had been found to contain levels of paralytic shellfish toxins (PST) approximately 64 mouse units/g (MU/g), which is above the allowable limits of 4MU/g (equivalent to 0.8 mg/kg).

Subsequent investigations in Australia by DHHS and SBS confirmed toxin levels in excess of the limits stipulated in the *Australia New Zealand Food Standards Code* (Standard 1.4.1) in SBS mussels from the same harvest period.

Investigations by the review team into the circumstances surrounding the non-compliance event have revealed the cause of the event was complex. It was caused by a number of systemic weaknesses, which resulted in the failure to detect a HAB of *Alexandrium tamarense* resulting in violative biotoxin levels in the shellfish. These combined factors resulted in an unacceptable period without any food safety verification data, during which time violative product reached Japan.

Including the non-compliant product detected overseas, 50.9 tonnes of mussels were harvested between 14 October 2012 and 29 October 2012, with 44.6 tonnes destined for the domestic market.

Across a similar period of time scallops, clams and oysters were also harvested from the HAB-affected region and sold on the domestic market.

The commercial rock lobster fishery was not open during this period. The *A. tamarense* bloom was active during this period of time, as evidenced by the delayed finding of elevated cell counts from water samples taken from Spring Bay on 14 October (see Table 2, page 18).

Additionally, a research water sample taken by SARDI (analysed after the non-compliance event) between St Helens and Bicheno on the east coast of Tasmania on 4 October (and tested by Microalgal Services Ltd) was confirmed to contain *A. tamarense* cells.

Following notification of violative product reaching Japan, DHHS collected 11 samples of scallops (of which five samples had muscle and roe tested) from the Tasmanian domestic retail market on 2 November 2012. Some scallop samples were found to be above the maximum limit for PST stipulated in the *Australia New Zealand Food Standards Code* (Standard 1.4.1).

Abalone, periwinkles, urchins<sup>1</sup>, giant crab<sup>2</sup>, banded morwong, calamari and flathead were also tested, but were shown to contain levels of PST below the Australia New Zealand Food Standards Code (Standard 1.4.1).

Only mussels and abalone were exported during the period 15 – 30 October 2012, and as previously noted, abalone had levels of PST under the allowable limit stipulated in the *Australia New Zealand Food Standards Code* (Standard 1.4.1).

Discussion and analysis of these issues, together with the direct and indirect economic impacts and resulting recommendations to improve the management of HAB events and minimise their impacts on stakeholders are presented in the following report.

<sup>1</sup> Only three sea urchin samples were tested and results for one sample was supplied.

<sup>2</sup> Giant crabs were only tested late in the event and were found to contain ~0.5mg/kg



# What happened and what was the response?

## The non-compliance event<sup>(TOR One)</sup>

At the end of October 2012 Japanese import authorities (MHLW) recalled a shipment of blue mussels (*Mytilus galloprovincialis*) derived from the east coast of Tasmania due to the presence of unacceptable levels of paralytic shellfish toxins (PST).

The discovery of unacceptable PST levels in blue mussels from SBS caused a national and international recall of SBS product spanning markets from Japan, Hong Kong, Singapore, Thailand and China to New Caledonia and Vietnam.

Between 17 September and 30 October SBS harvested 120 tonnes of mussels for the domestic and export markets. About 30 tonnes were withdrawn or recalled between 21 October and 29 October, of which 10.6 tonnes were recovered through the FSANZ product recall protocol, the balance of which (20.9 tonnes) was either credited to 'not returned', 'consumed', or 'otherwise not accounted for'.

Mussel samples from the implicated consignment and harvest area were collected and dispatched for further testing. Flesh testing for the presence of PST undertaken by Advanced Analytical Australia (AAA) confirmed the mussels had bioaccumulated PST.

Delayed analysis of water samples from Spring Bay taken on 14 October (lodged at AST on 17 October) subsequently indicated the HAB bloom was active during this period of time. This was supported by results obtained from a research water sample taken by SARDI (analysed after the non-compliance event) between St Helens and Bicheno, analysed by Microalgal Services Ltd. that also identified the presence of *A. tamarensis* cells on 4 October 2012 (1200 cells/L).

An early assessment undertaken by the Department of Health and Human Services (DHHS) suggested the consumption of a standard meal of mussels could lead to serious illness (see Section 3 for further discussion on the public health impacts of the event). Consequently risk managers implemented a precautionary approach by closing marine farming areas and issuing public health warnings (Appendix 3).

### The wider impacts

After the presence of PST in mussels was confirmed, additional seawater (phytoplankton) and bivalve (flesh) sampling of sites spanning the east coast of Tasmania revealed the presence of *A. tamarensis* cells and PSTs in



Figure 1 Area of coastline determined to be affected by the 2012 bloom of toxic dinoflagellate algae *Alexandrium tamarensis* (Source: DHHS, 2013)

water samples and bivalve shellfish (oysters, scallops, clams and mussels) at several sites between Eddystone Point and Marion Bay.

In addition to the water sample results, flesh testing results from 11 samples of scallops collected from the domestic retail market on 2 November 2012 revealed some samples had PST levels above the maximum limits stipulated in the *Australia New Zealand Food Standards Code* (Standard 1.4.1).

As investigations continued, over the next three months, it became evident that the initially-undetected harmful algal bloom (HAB) of toxic algae affected more than 200km of coastline along the eastern seaboard of Tasmania, Australia (see Figure 1).

## Other bivalve shellfish products

During the period 15 October to 13 November (prior to harvest area closures) commercial sector representatives confirmed that shellfish products such as scallops, clams and oysters entered the domestic market across a number of states.

As such, scallops, oysters and clams harvested, sold and consumed during this period may have contained elevated levels of PSTs.

No product recall was instigated for scallops, oysters or clams, however scallops held by a commercial fisher were directed to be destroyed. Some product withdrawals (Pacific oysters) did occur from Moulting Bay, where there was evidence of toxic cells.

It is noteworthy that public health authorities were not notified of any cases of illness related to scallops, oysters or clams.

## Other fisheries products

Rock lobsters from the affected zone were found to contain levels of PST above the maximum permissible limit in the hepatopancreas (muscle tissue was not contaminated).

As such, the commercial rock lobster fishery remained closed (seasonal closure extended) over this period.

Other fishery products (including abalone, giant crabs<sup>3</sup>, flat head, periwinkles, sea urchin) were tested by AAA and found not to contain significant levels of PSTs.

This HAB event, as evidenced by increased cell counts (exceeding agreed closure limits as outlined by the *Plan*), triggered closures of associated commercial and recreational bivalve shellfish production/harvest areas.

Details of public health warnings, commercial and non-commercial closures can be viewed in Appendix 3, page 71. Further discussion is presented in Section 2 of this report.

## The event – timeline

A detailed log of the activities leading up to, and immediately following, notification by the Japanese authorities of unacceptable PST levels in imported mussels from SBS is outlined in Table 2 (see pages 18-19).

Further information on the legislative basis for each closure (commercial, non-commercial) and public health warnings is presented in Appendix 3, page 71.

<sup>3</sup> Giant crabs were tested late in the event and found to contain levels of 0.5 mg/kg PST.



## Factors leading to non-compliance (TOR One)

A rigorous investigation by the Review team of the events and time frames outlined in Table 2, and the factors that combined to result in non-compliance, has identified five key issues:

1. Inadequate policies and procedures in the *Plan* led to the presence of PST toxins being identified in shellfish in the market.
2. A delay in the seasonal changeover to fortnightly phytoplankton sampling by SBS may have contributed to the toxic bloom of *A. tamarensis* remaining undetected during ongoing harvest and export.
3. A delay in timely water sample analysis for harmful algae by Analytical Services Tasmania (AST) contributed to the bloom remaining undetected in the lead-up to harvest and export.
4. Failure of the TSQAP Manager to demand timely test results from AST until the day of notification by the Japanese authorities, resulted in marine farms remaining open when trigger levels for closure had been exceeded.
5. The lack of a structured process for addressing non-compliance events together with poor identification of roles and responsibilities (regulatory and industry) of participants and an inadequate review process has contributed to inconsistent closures and risk management approaches.

### The *Biotoxin Management Plan* (TOR Two)

It is the view of the Review team that a key factor contributing to the delivery of contaminated mussels to the Japanese market and the potential delivery of contaminated mussels, oysters, scallops<sup>4</sup> and clams to the domestic market is the lack of rigour in the policies and procedures of the *Plan* in place at the time of the event.

*Note that the Plan is intended to cover molluscan bivalve shellfish species (oysters, mussels, clams, scallops<sup>4</sup>) and does not extend to rock lobsters, giant crab, abalone and other fisheries products.*

Section 4 of this report deals specifically with the *Management Plan* and outlines recommendations for its enhancement in order to minimise the opportunities for an event of this nature in the future.

### Deviation from the *Plan* (TOR One)

As outlined in Appendix 2, SBS operates in a 'medium-risk' classified area under the *Plan*. This 'medium-risk' classification requires the changeover from monthly phytoplankton testing to fortnightly phytoplankton testing during October each year (see Appendix 2, page 70).

In the lead-up to the changeover, a routine reminder about the onset of the 'summer' fortnightly testing was not forthcoming (refer to comment 1 October, Table 2) from the TSQAP staff (refer to page 29 for further details). This situation was further exacerbated due to SBS collecting its first fortnightly water sample on 14 October.

*Note: The previous routine monitoring sample was collected on 17 September 2012.*

### Delayed water sampling results (TOR One)

The SBS water samples (collected on 14 and 21 October) remained untested by AST until 30 October 2012 (the day after SBS received notification from its Japanese customer) and after specific requests from the TSQAP Manager — verbally on 29 October 2012 and by written request after the notification.

This led to a situation where the export and market entry of product was undertaken without supporting data for an unacceptable period, which resulted in the HAB of *A. tamarensis* remaining undetected (see page 20 for more information).

### Missed fishery closure trigger levels (TOR One)

The extended turnaround time for water sample testing results from AST, as outlined above, allowed east coast fisheries to remain open when trigger levels for closure were being exceeded in the harvest areas.

Potentially harmful algae levels, above the TSQAP trigger level, were confirmed by AST on 31 October 2012, correcting a previous false negative report on 30 October 2012 on the same samples.

PST levels at up to 12.5 times the maximum allowable standard (0.8mg/kg) in the *Australia New Zealand Food Standards Code* (Standard 1.4.1) were confirmed (by the Lawrence method) by Advanced Analytical Australia (AAA) on 1 November 2012.

<sup>4</sup>Discussions with the TSQAP Manager and the wild harvest scallop industry confirmed the scallop industry is not currently a participant in the TSQAP.

# Section 1

**Table 2 Timeline of actions leading up to and subsequent to the non-compliance event for mussels**

Date (2012)	June to September	17 September	October	14 October	18 October	21 October	24 October	29 October	
<b>Activity</b>	Routine monthly phytoplankton testing as per <i>Biotoxin Management Plan for Tasmanian Shellfish Quality Assurance Program</i>	SBS submits routine monthly water sample to AST	Change-over to fortnightly phytoplankton sampling for 'medium risk classified area' [SBS classified 'medium risk' under <i>Biotoxin Management Plan for Tasmanian Shellfish Quality Assurance Program</i> ]	SBS sends first pre-export water sample to AST for phytoplankton testing		SBS sends second pre-export Spring Bay water sample for phytoplankton testing  SBS yet to receive first water sample results but harvest regardless	Medium-risk growing area remains open for exporting despite receiving no phytoplankton test results for more than two weeks	SBS mussels harvested 21 October land in Japan	<b>Non-compliance event occurs</b>  Routine testing in Japan detects positive result for PST in mussel flesh  ▼ Retailer notifies SBS of potential non-compliance after business hours  ▼ SBS notifies TSQAP Manager of non-compliance  ▼ TSQAP Manager contacts AST laboratory requesting immediate analysis of water samples submitted by SBS on 14 and 21 October
<b>Contribution to non-compliance event</b>	<b>No paired flesh testing for biotoxins</b>  <i>(major contributing factor)</i>	Results returned 26 September from samples collected 17 September show negative for harmful algae	Delayed start to fortnightly sampling  <i>(potential contributing factor)</i>	Changeover to fortnightly testing by SBS carried out at end of allowable period irrespective of late notification to change sampling frequency.  SBS failed to follow <i>Biotoxin Management Plan for Tasmanian Shellfish Quality Assurance Program</i> irrespective of notification of new sampling frequency	<b>No AST phytoplankton results yet supplied for sample collected 14 October and lodged at AST 17 October</b>  <i>(major contributing factor)</i>		<b>DHHS (under TSQAP) failed to close area when test results unavailable after one and two weeks (no phytoplankton results since 17 September 2012)</b>  <b>No data from previous four weeks to support exports</b>  <b>No paired flesh testing for biotoxins to date</b>  <i>(major contributing factor)</i>		
<b>Comments</b>	Is in line with ASQAP export standard 2004 but not <i>Cawthron Report 2001 #646</i>		Late notification to SBS to commence sampling. Notification given to SBS after 10 October	Extended period without data may have contributed to bloom being missed	SBS has had no phytoplankton results for four weeks, which may have compromised food safety of pre-harvested product		A delay in harvesting would have prevented contaminated product reaching Japan  Timing of submission of samples from SBS, delayed analysis by AST, combined with failure by DHHS to demand test results and lack of policies to enable closure of areas when no test results available, led to the bloom being missed allowing time for violative product to reach Japan		

AAA — Advanced Analytical Australia  
 AST — Analytical Services Tasmania  
 DAFF — Department of Agriculture, Fisheries and Forestry  
 DHHS — Department of Health and Human Services  
 FSANZ — Food Standards Australia and New Zealand  
 SBS — Spring Bay Seafoods  
 TSQAP — Tasmanian Shellfish Quality Assurance Program

*Note:* Factors that have been identified as major contributors leading to the non-compliance event are shown in red cells

Table 2 Timeline of actions leading up to and subsequent to the non-compliance event for mussels (cont.)

Date (2012)	30 October		31 October			1 November	2 November		12 November
<b>Activity</b>	Japanese Ministry of Health, Labour and Welfare (MHLW) notifies DAFF of violative levels — non-compliance occurs ↓ TSQAP Manager contacts DAFF ↓ TSQAP Manager closes SBS growing area ↓ Violative levels confirmed by Japan	AST tests water samples submitted by SBS on 14 and 21 October ↓ SBS submits mussel sample from 21 October harvest to AAA for analysis	Biotoxin screen (AAA) — mussels from same Japanese batch screen positive over FSANZ level	AST re-tests SBS phytoplankton samples from 14 and 21 October	SBS commences voluntary recall of product with use by dates of between 22 October 2012 and 10 November 2012 (harvested 21 October)	AAA confirms biotoxin levels in mussel flesh	FSANZ/ DHHS issue recall notice  DHHS initiates enhanced surveillance for human cases of PSP	DHHS issues public health alert and closes shellfish growing areas along east coast of Tasmania (did not include commercial scallop harvest area, which was subsequently closed on 13 November)	Follow-up mussel flesh testing
<b>Contribution to non-compliance event</b>	No locally-confirmed PST levels yet available as a result of TSQAP not demanding earlier results combined with unacceptable delays at AST for perishable exported product  As such, no plankton level analysis has been carried out for six weeks  <i>(major contributing factor)</i>		Results confirmed 1 November	AST analyst re-tested sample from 14 October now reported positive (1400cells/L) — above trigger level for closure of 500cells/L		Maximum level in mussels exported was confirmed by AAA as 10mg/kg from samples collected 21 October (acceptable level 0.8mg/kg)			
<b>Comments</b>	Prioritisation process at AST not in alignment with service standards to underpin public health and export standards  If not requested there is uncertainty as to the length of the delay	False negative from AST potentially serious if repeat bloom and ONLY water sampling used for routine monitoring	Demonstrates capability for rapid flesh biotoxin testing in Australia	Mixed results highlights capability issue at AST		Serial water phytoplankton and biotoxin data from SBS indicates bloom was in decline around 21 October — height of bloom may have been missed	Action carried out as required by <i>Biotoxin Management Plan</i> via a DHHS public health order	No violation of PST levels since 12 November Samples (n=17) < 0.8 mg/kg up to 27 December  Growing area re-opened 3 December	

AAA — Advanced Analytical Australia  
 AST — Analytical Services Tasmania  
 DAFF — Department of Agriculture, Fisheries and Forestry  
 DHHS — Department of Health and Human Services  
 FSANZ — Food Standards Australia and New Zealand  
 SBS — Spring Bay Seafoods  
 TSQAP — Tasmanian Shellfish Quality Assurance Program

Note: Factors that have been identified as major contributors leading to the non-compliance event are shown in red cells

# The undetected *A. tamarensis* bloom

## How was it missed?

Among the questions the non-compliance event has raised, a number relate to the *A. tamarensis* algal bloom, not least of which is: “how did the HAB remain undetected for so long?”.

It is the view of the Review team that the HAB remained unidentified in part due to the frequency of sampling (i.e. every four weeks during winter) not being aligned with the level of risk. Secondly it took AST 13 days to analyse and report the results of the samples collected on 14 October and 21 October. This resulted in a six-week period without any biotoxin or phytoplankton monitoring data with which to verify the safety of food products harvested from the area.

Discussions around the adequacies of the current TSQAP monitoring program and laboratory capability and capacity are covered in detail in Section 2 of this report, however, to fully answer this question it is important to take a closer look at the history of similar HABs in the region, and the monitoring and testing activities in place leading up to the time of the event.

Further discussion of the 2012 HAB bloom has included whether this particular occurrence of *A. tamarensis* could have been anticipated in these waters and whether it could have been expected to produce PST.

### Risk classification

Under TSQAP, bivalve production areas along the east coast of Tasmania are assigned a risk classification for biotoxins (see Figure 2).

High-risk areas are concentrated in the south-east of the state due to the seasonal occurrences of *Gymnodinium catenatum* blooms during the autumn (March–May) and occasionally during spring (September–November).

Occurrences of *G. catenatum* are rare for the Spring Bay region, with some present during 2004 and an event during 2005 that caused a two-week closure. One other phytoplankton sample with high algal cell counts was observed during 2008 however flesh tests were non-toxic.

Areas are typically classified as medium-risk zones if they have ever had a harvest closure due to a HAB event. Risk levels along the east coast during winter and early spring are considered low to medium and as such routine phytoplankton testing under the TSAQP is carried out using monthly water samples until the start of October and then fortnightly between October and May (see Appendix 2, page 70).

The Review team noted that regardless of the risk classification of bivalve production areas along the coastline of Tasmania, no flesh testing is undertaken as a primary risk management tool in the first instance. Phytoplankton testing is currently the primary risk management tool, followed by flesh testing if phytoplankton cell counts reach a predetermined trigger level.

An evaluation of this approach is presented in Section 2 of this report.

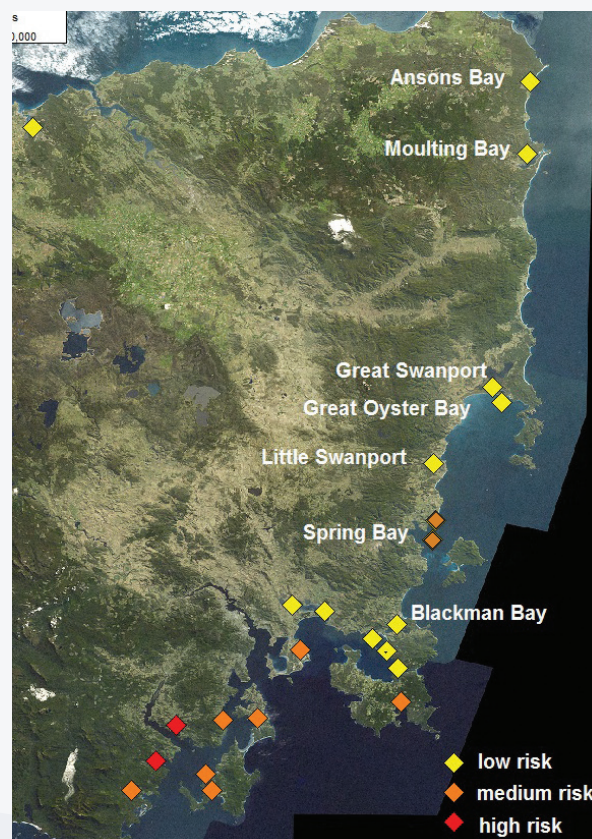


Figure 2 TSQAP risk classification of east coast fisheries prior to October 2012 (Source: TSQAP, 2012)

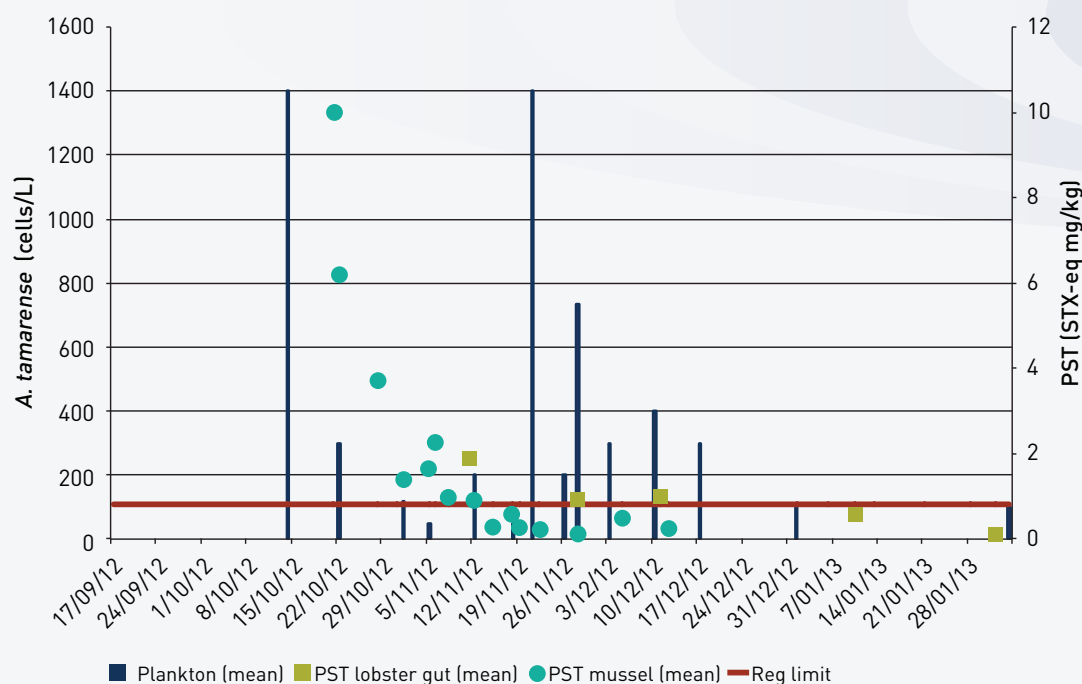


Figure 3 *A. tamarensis* cell counts and PST levels in mussels and rock lobster from Spring Bay and closely-associated areas

### *A. tamarensis* – a historical perspective

*Alexandrium tamarensis* is included in the ASQAP and TSQAP phytoplankton action tables as it has been documented to produce PSTs and been involved in the accumulation of PSTs by bivalve shellfish previously.

In surveys of cysts in sediments, between 1997 and 2003, *A. tamarensis* was detected at three locations on the north coast of Tasmania and three locations on the east coast of the island; including Spring Bay during 1997 (Bolch and de Salas 2007). Furthermore, the Spring Bay strain detected during 1997 was known to produce PSTs (de Salas et al 2001).

Prior to October 2012 there was one recorded detection of *A. catenella* in Spring Bay, which was not associated with PST levels in harvested seafood. *A. tamarensis* had never been detected by TSQAP in routine water monitoring.

In relation to the source of this HAB, the extent of the bloom (see Figure 1) indicates it originated off-shore and was advected to the east coast of Tasmania, rather than arising from in-shore cyst beds that would typically show up as localised blooms.

In the 2005 review of the *Plan*, the TSQAP management noted:

***“Miguel de Salas from the University of Tasmania has isolated cultures of *A. cf. tamarensis* and *A. ostenfeldii* from cysts found in the D’Entrecasteaux Channel in 2003. Both cultures proved highly toxic. These algae have potential to cause closures in Tasmania in the future.”***

In view of these reports and the recognition of potential risk by the TSQAP management during 2005, it is the view of the Review team that the 2012 *A. tamarensis* bloom was not entirely unexpected.

### Under the radar

As shown in Table 2, pages 18–19 the SBS fortnightly sampling program started on 14 October 2012, four weeks after the previous sample was collected on 17 September 2012. Sampling results from the period between 14–21 October 2012 (see Figure 3), and subsequent results, show declining levels of phytoplankton cells and PSTs across SBS harvesting sites, indicating that routine phytoplankton testing potentially missed the peak of the bloom.

Based on results from this event and analysis of similar events it is reasonable to predict that this places the 21 October 2012 mussel harvest at a time when unacceptable PST levels in shellfish could reasonably have been expected.



### ***A. tamarensis* toxicity – what is known**

Current knowledge on the toxicity level of *A. tamarensis* reveals that some strains (for example, those belonging to Group II) have been found to not produce PST, while other strains (for example, those belonging to groups I and IV) are known to produce PST. The toxicity of other strains (such as, *A. tamarensis* groups III and V) is less clear (Murray et al 2012).

It is reasonably well established across dinoflagellates that toxin production is highly variable. In general the toxin profile of strains of toxic species appears to remain relatively constant over time. However, the amount of toxin produced has been found to vary over time (Murray et al 2012).

In Australia PST production by an *A. tamarensis* group V isolate, which was previously thought to be non-toxic, has been reported (Murray et al 2012). *A. tamarensis* is on the potentially toxic species list in the *Plan* as some toxic strains internationally are highly potent. These studies indicate that over-reliance on phytoplankton counts for closures should be resisted (see Table 3).

The major biotoxin congeners detected in the consignment of mussels tested by the Japanese import authorities were identified as STX, GTX1, GTX2, GTX3, and GTX4. These congeners are considered to be of medium to high toxicity by intra-peritoneal mouse bio-assay (Oshima 1995). The PST levels initially detected were up to 12.5 times the acceptable level outlined in the *Food Standards Australia New Zealand (FSANZ) Food Standards Code* (Standard 1.4.1). This underscores the potential for a public health risk from eating shellfish affected by this bloom.

Given the recent documentation of an Australian group V isolate that was thought to be non-toxic, but was actually a PST producer, combined with the previous history of *A. tamarensis* in the area, it is reasonable to expect a precautionary approach be taken in relation to detection (i.e. if *A. tamarensis* cells are identified at or above the *Plan* trigger levels, then fisheries should be closed until further investigation into the specific toxicity of the detected strain).

Consistent with this, feedback from international shellfish safety experts who attended the *International Conference on Molluscan Shellfish Safety (ICMSS)* workshop (March 2013) on this event is best expressed by the following quote from Ireland.

***“Regarding the discussion around whether it is toxic or non-toxic A. tamarensis, fundyense or any other species is interesting, but from a regulatory perspective we do not await confirmation of the species, once it is detected as Alexandrium sp. we go to alert status and get samples of flesh. We have the facility to carry out PCR to ID cells to species level, but rarely do this unless there was an unusual occurrence.”***

*(Joe Silke, Marine Institute Ireland pers comm)*

## Response to the non-compliance event

To evaluate whether the response to the non-compliance event was effective it is important to understand the key objectives of any response.

In the event a contaminated food product enters the market place (either domestic or export market) the most common key objectives are to:

- Minimise the risk to public health (and therefore the incidences of illness)
- Minimise the impacts on domestic and export trade

An effective response will be the planned execution of clear and effective messages from pre-determined lead agencies to clearly identified key target audiences. Success can be measured by the ability of the target audiences to make decisions that meet the original objectives.

In reviewing the communication relating to the non-compliance event, the Review team asked the following questions:

- Did the risk information reach the target audience?
- Did the target audience understand the risk information?
- Did the information improve the target audience's knowledge of the topic?
- Did the information inform the target audience to change their behaviour or take action?

The initial responses to the identification of PST levels above the allowable limit included:

- Notification of the incident (target audiences: non-compliant supplier, federal and state governments, seafood R&D, industry supply chain and public).
- Management of potential risks to public health (target audiences: public, industry supply chain, customers).
- Minimising impacts on trade: (seafood suppliers and customers — both domestic and export).

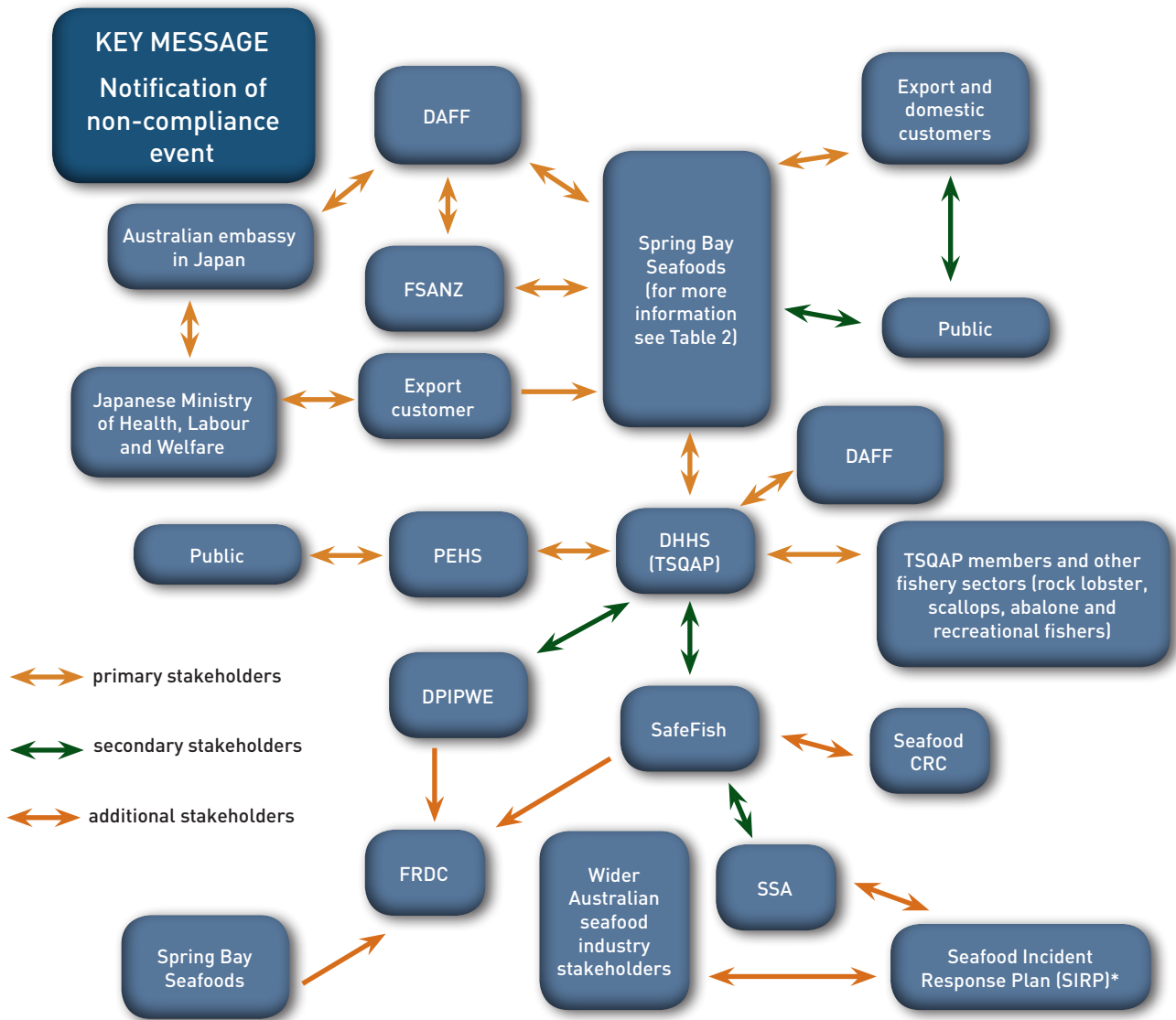
An evaluation of the response of key event stakeholders to minimise impacts to domestic and export trade is covered in Section 3.

### Target audiences

The target audiences identified by the Review team for this non-compliance incident include:

- Public
- Industry (both local and interstate)
  - Bivalves (oysters, mussels, clams, pipis, scallops)
  - periwinkles
  - abalone
  - rock lobster
  - giant crabs
- Recreational fishers
- National seafood associations
- Domestic supply chain (for example, processors, retailers, food service, public)
- Export supply chain (for example, customers, Government)
- Impacted state government
- Other state government
- Federal government
- R&D providers and funders
- Analytical laboratories (AST, AAA, Cawthron)
- Medical sector (for example, GPs and hospitals)

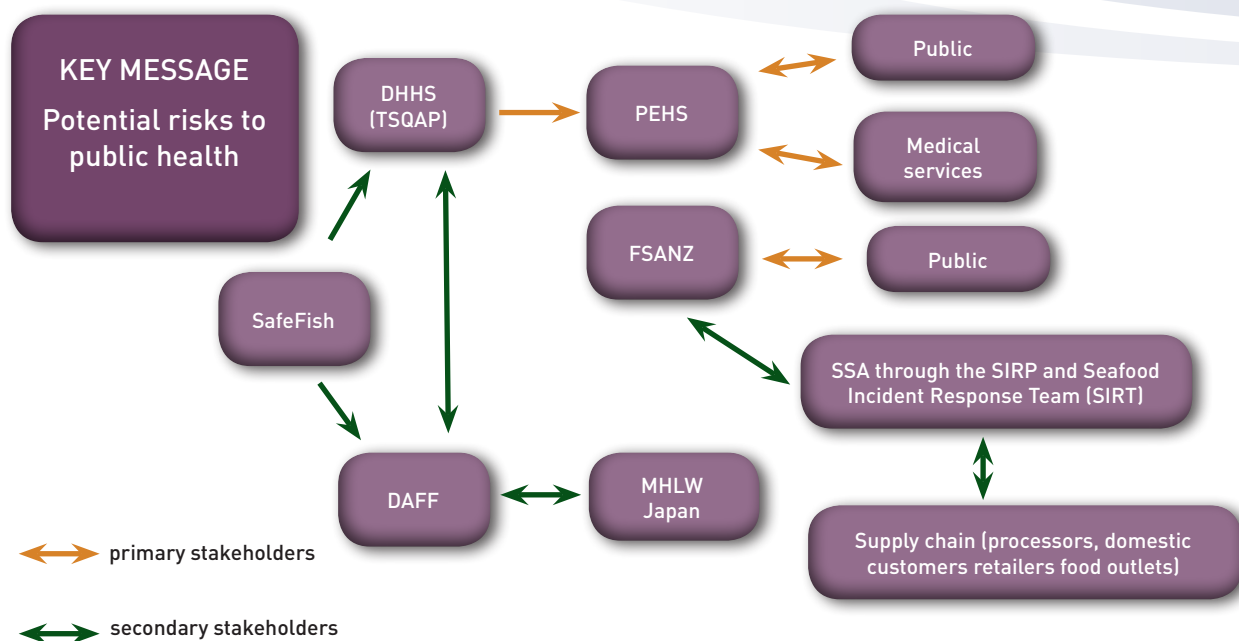
During the investigation the Review team interviewed members from all key identified target audiences.



**Figure 4** Communications flow to stakeholders immediately following the Tasmanian PST non-compliance event

\* The role of the Seafood Incident Response Plan (SIRP) in responding to the non-compliance incident is discussed separately on page 37.





**Figure 5** Communications taken to manage public health risks relating to the Tasmanian PST non-compliance event

\* The role of the Seafood Incident Response Plan (SIRP) in responding to the non-compliance event is discussed separately on page 37.

## Risk management response

The immediate responses taken following the non-compliance event to notify key stakeholders and manage the risks to public health are outlined in Figures 4 and 5.

The processes and procedures around managing non-compliance events for food products entering domestic and export markets are well understood by the responsible regulatory authorities on a Federal and State government level (DAFF, FSANZ and DHHS).

As such, the procedures around event notification, product recall and public health warnings are documented and delivered by regulatory agencies through appropriate channels including:

- Telephone notification and teleconferences — DAFF, TSQAP
- Email confirmation — DAFF, FSANZ, TSQAP
- Public health alerts — DHHS
- Fisheries closures — DHHS, TSQAP, DPIPWE and DAFF (see Appendix 3, page 71)
- Media releases — DHHS, SBS and their customers
- Export industry advice notices — DAFF
- Website information — DHHS, TSQAP, DAFF, FSANZ, SBS, SBS customers
- Social media — SBS (twitter, facebook)

The key strengths and weaknesses, relating to the notification of the non-compliance event and initial public health risk management are outlined below:

### Strengths

- For product recalls, response protocols were in place across the lead agencies (FSANZ, DHHS, SBS and their customers) to manage communications around public health and enact product recalls for most species.
- Delivery channels for communications were well recognised, accessible and populated by key target audiences.

Interviews with key stakeholders reveal that messages regarding event notification were pitched at the right level, allowing an understanding of the issues and the ability to make appropriate decisions.

The measure of success of immediate response to the Tasmanian PST non-compliance event is reflected in the immediate and appropriate action taken by:

- DAFF, FSANZ and DHHS (via TSQAP and the PEHS)
- SafeFish
- SSA (via the initiation of the SIRP)
- SBS and its customers.

### Weaknesses

- For non-TSQAP species (fisheries) there was a lack of clarity over what legislation could be used to close and open fisheries on public health grounds and who would be the lead agency managing these fisheries. While DHHS had an emergency response protocol in place, it was not employed at the time.
- Delayed response for some species (including scallops and giant crab) led to delayed closure of relevant commercial fisheries. Further discussion is covered in Section 2 and Appendix 3, page 71
- No product recalls were undertaken for some species (including scallops, oysters, clams and giant crabs), which may have contained elevated levels of PSTs.
- Feedback from SSA suggested the supply chain was unclear as to the cause and extent of the problem. The role of the SIRP is covered on page 37

Despite these weaknesses relating to delayed responses for some species, there were no recorded illnesses directly attributable to the event. More details on the public health impacts of the event are provided in Section 3.

## What happened and what was the response?

### Summary of key findings

- Japanese import authorities identified PST levels above the regulatory limit in a shipment of fresh mussels from the east coast of Tasmania during late October 2012.
- Further investigations identified a previously undetected bloom of toxic *A. tamarense* off the east coast of Tasmania, which had impacted several commercial seafood species including mussels, oysters, rock lobsters, clams and scallops.
- A combination of inadequate testing protocols, delayed water sampling and slow laboratory analysis led to fisheries remaining open for harvest while trigger levels for closure were being experienced in the field.
- Public health warnings were delayed for some species and product recalls not implemented (except for mussels).

## Why did the event occur and how was it managed?

The following section details the factors identified in Section 1 that contributed to the non-compliance event and provides further discussion around the ongoing risk management of the HAB.

This analysis provides the rationale for recommendations presented in Section 4.

### The *Biotoxin Management Plan for the TSQAP* (TOR One)

Following a review of the response by regulators and industry to the HAB event the Review team considers the current policies and procedures outlined in the *Plan* fail to adequately manage HAB events and protect public health.

During 2001 the FRDC commissioned the Cawthron Institute to recommend requirements for the *Australian Shellfish Quality Assurance Program (ASQAP)* to underpin the national Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) *Export Standard*.

The resulting report — *Model Australian National Marine Biotoxin Management Plan, Cawthron Report No. 646, [2001]* (see Appendix 4, page 76 for the Executive summary and recommendations) — outlines policies and interventions considered commensurate with risk and food safety regulations internationally, which are based on the levels of toxins in shellfish.

**Note:** While the Cawthron Report provided useful information, which underpinned a revision of ASQAP at the time, ASQAP does not have legislative underpinning (i.e. the Report is a guidance document only).

However, the Review team has the view that the levels of toxins in shellfish, outlined in the *Cawthron Report*, should generally be used for regulatory decisions.

When looking at the primary risk management approach of relying on phytoplankton monitoring to ensure safety of the harvested product, the *Plan* has deviated from internationally-acknowledged risk management protocols.

It is the view of the Review team that TSQAP's lack of adoption of procedures outlined in the *Cawthron Report 646 (2001)*, (as highlighted in Table 3, page 28) contributed substantially to the likelihood of the 2012 PST non-compliance event in Tasmania.

The Review team considers the application of the *Cawthron Report 646 (2001)* recommendations, especially the use of flesh testing for biotoxin monitoring, has been substantially eroded in subsequent shellfish safety policies (including the *Export Standard 2004*; *Review of the Biotoxin Management Plan for the TSQAP 2005*; *ASQAP Operations Manual 2009*; *Biotoxin Management Plan for the TSQAP (2012)* (see Table 3, page 28).

Following the International Conference on Molluscan Shellfish Safety (ICMSS) workshop on this event during April 2013, international food safety experts provided feedback to the TSQAP Manager with regards to best practice (see Appendix 6, page 89). While more detailed than the *Cawthron Report 646 (2001)*, the feedback concurs with the Report recommendations in terms of providing a framework for best practice.

### Current TSQAP procedures in detail

The procedures for managing HABs outlined in the *Plan* are outlined below:

*“When toxic algae have been identified in the water column in the growing area, the rate of sampling will increase to at least weekly.*

*In the event of a bloom, all areas will be reassessed. Areas adjacent to the bloom will have their risk status temporarily increased with a corresponding increase in sampling frequency.*

*If toxic algae cell numbers are above closure levels the area will be closed immediately pending meat results. An area may be re-opened if toxin levels in the meat are below regulatory limits given in Appendix 4, page 76. Meat samples will be taken on a regular basis while harvesting continues (at least weekly if the algae are present) until toxin levels indicate the area should be closed, or algal samples indicate the danger has passed.”*

*Biotoxin Management Plan for the TSQAP (2012) Appendix 4, page 76 trigger levels for *A. tamarense**

*Alert level to initiate flesh testing (cells/L) — 200 cells/L*

*Alert level to initiate closure pending flesh testing results (cells/l) — 500 cells/L*

**Table 3 Comparison of TSQAP with national ‘policies’ showing comparative practices**

Criteria	<i>Cawthron 646 2001 (recommendations FRDC Project 1999/332)</i>	<i>DAFF ASQAP Export Standard (2004)</i>	<i>National ASQAP Operations Manual (2009)</i>	<i>The Biotoxin Management Plan for The TSQAP (2012)*</i>
Routine flesh testing	Routine weekly or fortnightly flesh testing	Shellfish and/or water are collected during all harvest periods  (Clauses 4.5 and 15.20)	ASQAP does not specify one method over the other but suggests phytoplankton and/or flesh testing is appropriate	No routine flesh testing in current monitoring program.  Flesh test implemented only after phytoplankton trigger level is exceeded
Role of phytoplankton testing	Weekly phytoplankton sampling  Closure of areas on flesh results only	Phytoplankton results used as early warning and also as support information for decision making and the increasing of flesh testing  Allows for closure of harvesting area when phytoplankton counts exceed trigger levels (Clause 16.3 e)	Option for phytoplankton testing as primary risk management tool	Phytoplankton as primary risk management tool with flesh testing after triggers met
Monitoring of medium-risk and high-risk areas	Weekly flesh and phytoplankton testing	Flesh testing and/or phytoplankton testing, which takes account of seasonal variability and the capacity of toxic algae that have been previously unknown in the area to appear  (Clause 4.5)	To be determined by the state shellfish authority	Fortnightly phytoplankton testing for high-risk and medium-risk areas and no routine flesh sampling across all risk classification areas
Use of flesh testing to close area	Closure of areas on flesh results only	Harvesting area closed when level of biotoxin in flesh is sufficient to cause a public health risk <i>(but option to close on counts above trigger levels too)</i> (Clause 16.3 d)	Can use either flesh or phytoplankton testing	Used to support phytoplankton closure
Use of flesh testing to re-open area	Reopening should be based on flesh testing results	Reopened when sufficient time has elapsed to allow flesh to reduce to acceptable levels of biotoxins  (Clause 16.11 b)	Optional phytoplankton or flesh testing results below FSANZ standards	Phytoplankton below trigger level and flesh testing results below FSANZ standards
Validation and formal approval required for use of in-house methods	Validation of alternative methods for biotoxins required**	No specific mention	No specific mention	No specific mention

\* Note: The review of the *Biotoxin Management Plan for TSQAP (2005)* notes the use of flesh testing in routine monitoring was not adopted by TSQAP on the basis of budgetary constraints.

\*\* Note: Validation and official approval process for in-house methods included in New Zealand Food Safety Authority Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006 (Section 88, Laboratory methods).

The implications of the current *Plan* procedures are:

- Frequency of flesh sampling zero unless cell trigger level is exceeded, meaning months can pass without any flesh testing.
- Areas can be closed due to presence of algae and then reopened if flesh levels are not above the regulatory level. However, if during the following week algae levels are high again, the area is closed until flesh sample results confirm it can be reopened. This presents a conflict.
- There is no requirement for paired water and flesh samples to be submitted at the same time, enabling rapid flesh testing if cell counts are at trigger levels.

### Deviation from the *Plan*

As identified in Section 1, SBS operates in a 'medium-risk' classified area under the *Plan*. This 'medium-risk' classification requires the changeover from monthly phytoplankton testing to fortnightly phytoplankton testing during October each year.

In the lead-up to the changeover, a routine reminder about the onset of the 'summer' fortnightly testing was not sent by TSQAP staff. Consequently there was no data available to trigger weekly water testing and to initiate flesh testing for biotoxins as required by the *Plan*.

Evidence presented to the Review team confirmed that the TSQAP Scientific officer had not sent reminders to SBS to initiate 'summer sampling' in the first week of October, even though the TSQAP Manager had requested this reminder be sent on a number of occasions.

Compounding the issue is the lack of clarity around the procedures for managing the absence of routine sampling and resulting test results. The *Plan* states:

*"Each week the sample table will be checked for currency. Any samples that have not arrived on schedule will result in a phone call or email to the sampler in question requesting a sample as soon as possible.*

*Growing areas that continue for two weeks running without an algal sample will receive a written request by email, followed by a closure the next week if a sample is not forthcoming.*

*During high-risk or bloom periods, lack of samples for over a week may result in the closure of the growing area as a precautionary measure."*

There is ambiguity around what constitutes potential closure. The use of the word 'may' means that during harvest at least two weeks *may pass* without samples being analysed, inviting system failures (as occurred during October 2012).

The Review team does not consider a week's notice before a reminder letter is sent, and another week's grace given, to be a solid platform for sound practice.

### Delayed water sampling results

The Review team notes the delay in carrying out the phytoplankton analysis may have been another key factor contributing to the non-compliance event. The subsequent failure to close the area in the extended absence of results demonstrates a lack of compliance to TSQAP procedures.

As previously identified in Table 2, even after SBS collected water samples on 14 October (lodged at AST 17 October) and 21 October, Analytical Services Tasmania (AST) failed to deliver any result until prompted in writing by the TSQAP Manager after the official notification of the Japanese flesh testing result on 30 October 2012.

The lack of access to results allowed SBS to harvest product on 21 October 2012 without receiving any supporting verification data since samples collected on 17 September 2012 — clearly sufficient time for a substantial HAB to occur.

During the period 17 September to 30 October 2012 SBS exported about 12 tonnes of mussels to Japan, Hong Kong, Singapore, Thailand, and China with smaller quantities going to New Caledonia and Vietnam. Over the same period about 120 tonnes were harvested. Of this product 76% was harvested between 17 September and 15 October.

This highlights the scope for potential impact of inadequate monitoring coupled with poor turnaround time for sample analysis during the time period in question.

The Review team noted that interviews with key bivalve stakeholders supported evidence that these delays are a systemic problem for Tasmanian bivalve producers — they are commonplace, not isolated to this event.

However, as highlighted above, irrespective of the delays, the *Plan* failed to meet policies and interventions considered commensurate with risk and food safety regulations internationally.

Following a review of the documentation relating to the event and interviews with relevant stakeholders, the observations made by the Review team regarding the testing process include:

- Inappropriate internal laboratory prioritisation processes not commensurate with verifying safety requirements of perishable high-risk product and inappropriate to underpin exports (for example, concurrent high demand for testing for another concurrent fish disease took priority over routine water sample testing for TSQAP).
- No formal performance-based contract or agreed maximum turnaround time is in place between TSQAP and AST. Poor turnaround times for results are systemic.
- Insufficient staff resources — backlog at the time indicates laboratory staff working under substantial pressure, with the false negative result potentially indicating insufficient resourcing and high-pressure environment.

These observations highlight both capacity and capability issues at AST which, if left unaddressed, may compound in the future as industry stakeholders intensify their sampling and testing regimes as a result of their expectation that there will be a re-occurrence of the event in the future.

### Testing capacity

The Review team considers that a number of the issues surrounding the lack of timeliness in sampling and testing results can be attributed to insufficient resourcing, both within the laboratory and in the TSQAP.

The delay in analysis at AST (as discussed) was compounded by the TSQAP Manager not following up with the laboratory to complete overdue testing in a timely manner (i.e. written follow-up in this instance was prompted by the notification by Japan of the non-compliance event).

For the six months before the event AST states that the average turnaround time was six days. This reflects feedback given to the review team by AST that “TSQAP samples are not necessarily a top priority”. Given that algal blooms can come and go within a period of a week, this represents an unacceptable turnaround time — a two-day turnaround time should be the aim (refer to ‘*Performance based contracts*’, page 62).

### Testing capability

On 30 October AST issued a negative phytoplankton result on the water sample collected by SBS on 14 October 2012. Subsequently on 31 October 2012 AST retested the water sample from 14 October and reported a positive result (1400 cells/L) — above the trigger level for closure of 500cells/L.

With regard to the initial incorrect identification, AST implemented and documented a ‘corrective action’ process and concluded that possible factors contributing to the problem included:

- The incorrect sample was counted on 30 October 2012 (i.e. the wrong sample was selected and analysed in the laboratory).
- Sub-sampling variation between tests could have led to the discrepancy in counts.
- The laboratory manager noted pressure on the main analyst to complete routine TSQAP work due to a major event in another sector creating high workload.



Interviews at the laboratory were undertaken and the laboratory manager provided information that the same analyst counted the sample on 30 and 31 October. Evidence was also provided to the Review team by external parties that indicated the recount at the laboratory may have been undertaken by a new staff member.

It is the view of the Review team that the false negative did not contribute directly to the event occurring, or contribute significantly to the delay in public health warning on 2 November, three days after notification from Japan. However, in a program that relies on phytoplankton as the primary risk management monitoring tool, it is feasible an error such as this could lead to a bloom being missed, non-compliant product being harvested and subsequent public health ramifications.

### Additional observations

During investigations, the Review team noted that AST is using an in-house sample analysis method that is different from the accepted Intergovernmental Oceanographic Commission (IOC) method. The TSQAP manager reported that this had been validated and formally accepted by TSQAP during 2001.

As previously noted, additional issues with laboratory service provision by AST, including turn-around time and sample analysis prioritisation, were also raised with the Review team by industry and regulators.

The non-compliance event occurred when the establishment of biotoxin testing at AAA was in its early stages (biotoxin analysis started early July 2012). Consequently, as the first event requiring rapid turnaround of a large number of shellfish samples two issues arose:

- A capacity issue led to delay in analysis of non-bivalve shellfish samples (for example, abalone, rock lobster) further delaying regulatory interventions by DPIPW (see Appendix 3, page 71).
- An error in interpreting abalone data led to the reporting of a false positive. This was subsequently remedied by sending samples to Cawthron Institute, New Zealand.

In response to these teething issues AAA have employed an additional analyst and commissioned additional analytical instruments. Evidence has been provided to the Review team that turn-around times for analytical results post the non-compliance event have improved from 3.9 to 2.6 business days for fisheries products and 3.9 to 3.7 days for bivalves.

AST also report improved turn-around time post the HAB event (time not specified), but also 'that routine TSQAP samples are not necessarily top priority'.

### Managing the ongoing *A. tamarense* bloom

During the period following the initial non-compliance event and the detection of water column cell counts and PSTs in a range of fish products, TSQAP and DPIPWE Marine Farming and Wild Fisheries managers had to address the public health risk associated with species other than shellfish.

The legislation that was invoked to facilitate regulatory closures of marine farming and fisheries areas and to issue public health warnings can be found in Appendix 3, page 71).

#### The role of TSQAP in risk management

TSQAP is a risk management system supported by a 'Partnership Agreement' between the Government of Tasmania and the Tasmanian Aquaculture Council (TAC).

The Partnership Agreement outlines responsibilities in relation to managing risks associated with HABs in relation to marine farmers and commercial wild harvest bivalve shellfish (excluding scallops). These parties are to maintain a critical event communications protocol (Clause 14.3)

The protocol followed during the non-compliance event was the PEHS event response protocol.

Regulatory arrangements under the Partnership Agreement include:

- DHHS administers the *Plan* under the *Tasmanian Food Act 2003*, and the *Public Health Act 1997*.
- Maximum biotoxin levels in shellfish are set by FSANZ in the *Australia New Zealand Food Standards Code*.
- Standards relating to shellfish harvested for export are given in the *DAFF Export Control Orders 2004*.
- The *Plan* is informed by the requirements of *Australian Shellfish Quality Assurance Manual of Operations (ASQAP) Version 2006-01* (see pages 27–28 for more commentary).
- Marine Farming Branch of DPIPWE administers Marine Farming Licenses under the *Living Marine Resources Management Act 1995*.

For the purposes of managing a HAB in marine farmed and commercial wild harvest bivalve shellfish excluding scallops, the aforementioned regulatory arrangements provided the necessary powers to TSQAP and DHHS (through PEHS) to protect public health.

An example noted by the Review team of the apparent breakdown in DHHS was the apparent delay in issuing a public health alert on 2 November 2012, on the second day following confirmation of violative results on 30 October (see Section 1, Table 2).

#### TSQAP auditing process

In relation to auditing TSQAP to underpin export certification the TSQAP Partnership Agreement stipulates that TSQAP will comply with the requirements of ASQAP (Version 2006-01).

DAFF annually audits TSQAP to ensure compliance with the ASQAP – Export Standards (and export legislation). Following audits to date, DAFF remained confident in providing export certification. Some non-compliances were raised during the last review.

During the review it was highlighted that the ASQAP – Export Standard is outcome based and the auditor requires an understanding of public health risk management. It was noted that the audit by DAFF focuses upon whether the state is complying with their own system and the export standard and does not focus on specific technical requirements. Staffing changes during the past five years have seen a reduction in relevant expertise on assessing the ability of state-managed programs to meet the ASQAP – Export Standard



## Cross-sector HAB management

A hierarchical risk-based approach, starting with rock lobster and abalone, was undertaken by DPIPWE in consultation with DHHS to address uncertainties facing fisheries products not covered by TSQAP. This included implementing flesh sampling programs to determine biotoxin levels and potential for market access impact (see Table 4).

PST exceeding FSANZ acceptable levels were detected in the hepatopancreas of rock lobsters sampled on 11 November 2012 and in scallops obtained at retail premises (reported on 12 November 2012).

DAFF confirmed that during the period of the event only Tasmanian abalone was exported (in addition to mussels), with one consignment on 6 November 2012 and another on 24 November 2012.

It is unclear to the Review team whether the abalone exported was from the affected region of Tasmania. Given that abalone was found to contain negligible levels of PST, this wouldn't have posed a risk.

Clams (covered by TSQAP) were found (one sample) to exceed the regulatory limit of 0.8 mg/kg (note, this was an HPLC screen test result and the confirmed level was likely to be significantly lower).

Decisions around sampling various fish species were made based on consultation between DPIPWE and DHHS. Restrictions on fishing activities were made in response to test results (see Appendix 3, page 71).

These interventions included a range of regulatory actions for:

- **Oysters and mussels** —under the *Public Health Act 1997*, DHHS enacted a *Public Health Order* closing the bivalve fisheries from 2 November 2012 through to 3 December 2012. It is possible non-compliant mussels were in the domestic market from at least 15 October to 22 October (recall date) and oysters from 15 October to 2 November.
- **Clams** — Under the *Public Health Act 1997*, DHHS enacted a *Public Health Order* closing the clam fisheries from 2 November 2012 to 13 December 2012 and to close exports of **farmed abalone** from 5 November to 13 December 2012. It is possible non-compliant clams were in the domestic market from at least 15 October to 2 November.

Table 4 PST flesh results for species from east coast fisheries and marine farming sectors\*

Species	Number of screen tests undertaken	Number of confirmatory tests	Number of positive tests	Number of samples above max limit (0.8 mg/kg)	Maximum value (mg/kg)
Mussels	10	29 (=10MBA**)	38	15	10 (confirm)
Rock lobsters	11	98	71	27	3.9 (confirm)
Oysters	28	19	11	5	3.24 (screen)
Scallops	21	9	30	5	2.85 (confirm)
Clams	6	3	5	1 (screen)	1.1 (screen)
Giant crab	0	8	4	0	0.5 (confirm)
Abalone	5	39	24	0	0.3 (confirm)
Banded morwong	0	6	0	0	0 (confirm)
Calamari	0	5	0	0	0 (confirm)
Flathead	0	10	0	0	0 (confirm)
Periwinkles	3	3	0	0	0
Sea urchins***	1		0	0	0

\*Data from October 2012 through to February 2013 inclusive \*\*Mouse bioassay \*\*\* Another two sea urchin samples were collected, however results have not been supplied.

- **Rock lobster** — DPIPWE invoked provisions of the *Living Marine Resources Management Act 1995* and attendant fisheries Rules to delay opening the commercial rock lobster fishery planned for 13 November and to close the non-commercial fishery due to PST concerns with respect to rock lobster on 22 November. The delay in closing the non-commercial fishery seems at odds with the earlier precautionary approach taken with the commercial fishery. This was due to the controlling authority waiting to receive laboratory results confirming unacceptable levels for this fishery.
- **Scallops** — DHHS enacted the *Food Act 2003* to close the scallop fishery early in the season, on 13 November 2012, as product at retail exceeded acceptable levels of PST, however, industry had voluntarily closed before this date as a precautionary response. The *Public Health Act 1997* was used to issue public health warnings. It is possible non-compliant scallops were in the domestic market from at least 15 October to 13 November, as confirmed by samples collected from retail outlets on 2 November.
- **Wild harvest abalone** — the Tasmanian Abalone Council (TAC) implemented a voluntary closure on 2 November 2012 as a precautionary approach to protect public health and market access.
- **Sea urchins, periwinkles and giant crabs** — DPIPWE invoked the *Living Marine Resources Management Act 1995* and attendant fisheries Rules to close the commercial fisheries from 24 November 2012 and to reopen on the 5 and 13 February 2013.
- **Recreational and indigenous fisheries** — DPIPWE closed affected fisheries under provisions of the *Living Marine Resources Act 1995* in consultation with DHHS (details in Appendix 3, page 71).

Regulatory action was not taken for the calamari, flathead or banded morwong fisheries.

A full breakdown of the risk management actions and the legislation supporting fisheries closures during the event is outlined in Appendix 3, page 71.

### Evaluation of the risk management response

Although regulators rapidly identified the appropriate regulatory rationales for risk management actions following the non-compliance event, the view of the Review team is that the critical event communications protocol, referred to in Clause 14.3 of the *Partnership Agreement*, is lacking in its ability to support a coordinated and cohesive response.

Figure 6 outlines the key paths of communication following the non-compliance event used to ensure all relevant stakeholders were kept abreast of developments and to allow risk management actions to be taken in an efficient and timely manner.

Anecdotal comments to the Review team during the interview process would suggest that following the initial event notification, as the awareness of the undetected HAB and potential risk across various seafood sectors increased, a wider range of stakeholders was drawn into the communications process.

Messages regarding the ongoing management of the HAB spread quickly across the state and seafood sectors through a mix of formal procedures and informal networks and delivery channels (phone calls, face to face meetings, emails, SMS, twitter and website updates).

Interviews with a range of key stakeholders provided a mix of views on the relative success of the risk management response following the event.

The key strengths and weaknesses identified by the Review team relating to the risk management response are outlined below:

#### Strengths

- Strong industry networks, personal relationships, and individual commitment to protecting public health and industry against negative impacts played a key role in the success of communications following the event.
- The TSQAP Manager went above and beyond expectations in terms of communication and dedication to industry.
- Strong industry networks and relationships allowed for cohesion and cooperation in the absence of a formal event response protocol.

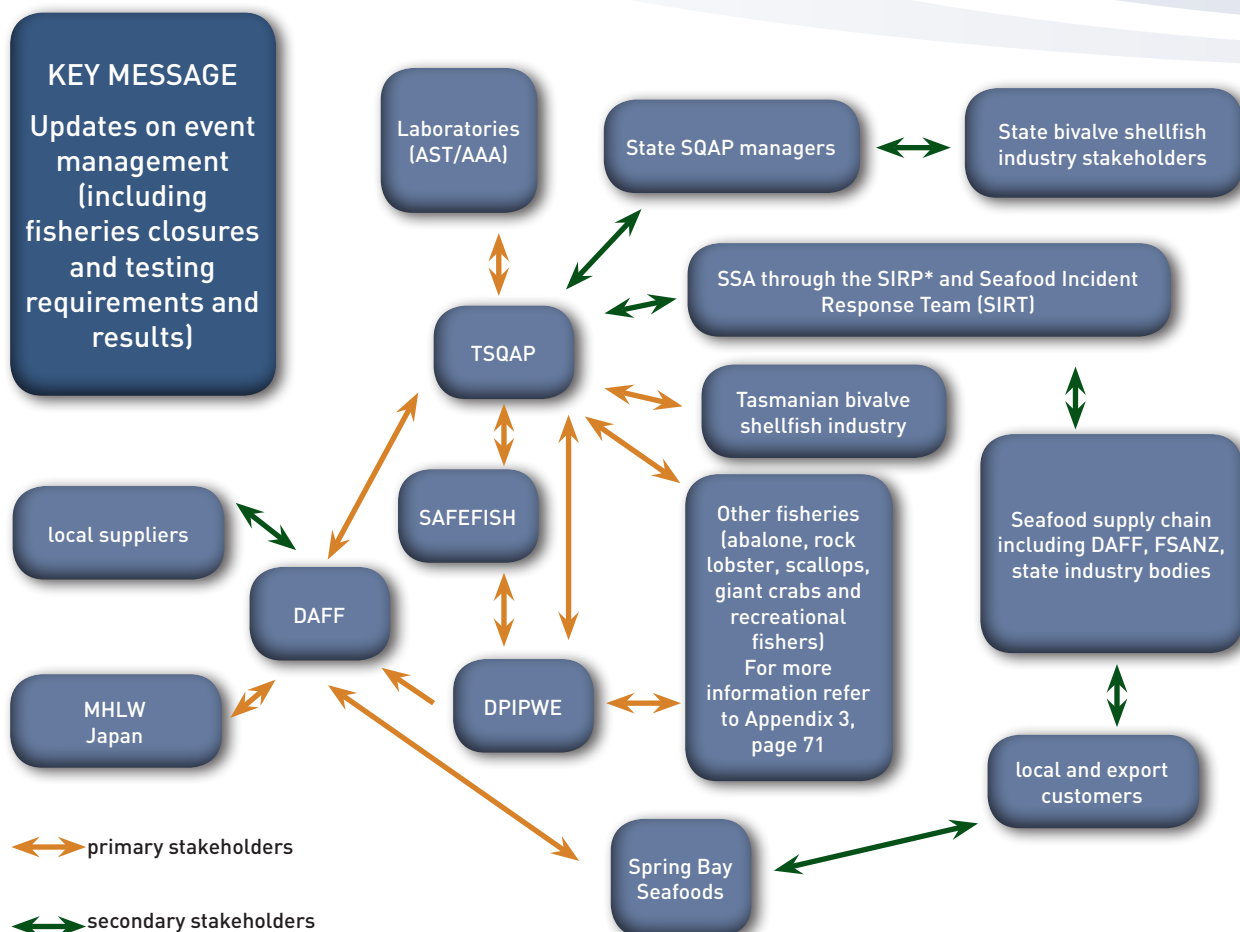


Figure 6 Communications flow to stakeholders following the Tasmanian PST non-compliance event

\* The role of the Seafood Incident Response Plan (SIRP) in responding to the non-compliance event is discussed separately on page 37.

**Weaknesses**

- Limited available resources placed TSQAP under undue risk. During the interview process several industry contacts shared their concerns at the lack of resourcing and support within and around TSQAP. Tangible evidence of this was that the program only employed 1.5FTE, and part way through the event this dropped back to 1 FTE.

*“If she had fallen over there was no-one to step in and take her place.”*

*(Scallop Industry representative pers comm)*

- One-deep systems in key state regulatory bodies and industry organisations, exposed industry and agencies to significant risk.
- An inadequate event communications protocol left individual agency personnel unclear as to the appropriate cross-sector response management. Confusion over roles and responsibilities within state regulatory departments impeded regulatory action.

*“Nobody was stepping into the hole – other species were being dragged and I felt we needed to understand whether other species were a risk.”*

*(TSQAP Manager pers comm)*

Consequently, without an event response plan the response:

***“relied on good will between departments”***

and was acknowledged as:

***“hopelessly inefficient”***

*(DPIPWE Manager pers comm).*

These sentiments were backed up by a lack of clear regulatory framework for the food safety management of fisheries products other than bivalves.

The Review team notes that while on the surface communications could be regarded as successful, with minimal impacts to domestic trade and no reported illnesses, high levels of overtime were undertaken by key staff, who, because of the lack of an adequate event response protocol, were subjected to unacceptable levels of stress and exhaustion during and following the event.

Lack of knowledge about the causative agent and previous experience combined with slow turnaround time by AST and AAA further impeded regulators' ability to clearly communicate the impacts to industry and led to frustration over unknown length of closure times.

During stakeholder interviews, the need to develop an overarching event response plan that includes all potentially 'at risk' fisheries and government departments was highlighted.

However, during the review process, government officials acknowledged that even an 'interim plan' had not yet been developed due to limited time and resources (staffing levels were repeatedly described as 'one-deep').

Recommendations for improvement in communication and ongoing HAB management are presented in Section 4 of this report.

## Why did the event occur and how was it managed?

### Summary of key findings

- The *Biotxin Management Plan for the TSQAP (2012)* testing protocols were not in line with key recommendations made in the *Cawthron Report 646 (2001)*
- Current protocols in the *Biotxin Management Plan for the TSQAP 2012* are contradictory and ambiguous with regard to fishery closures pending sample results.
- Phytoplankton laboratory performance at the time of the HAB was insufficient to protect public health.
- There is a lack of an industry-wide emergency response protocol to direct coordinated and cohesive risk management and communications effort in the event of a novel HAB.

## Role of the Seafood Incident Response Plan (SIRP)

### Background

The Seafood Incident Response Plan (SIRP) ([www.seafood.net.au/page/?pid=385](http://www.seafood.net.au/page/?pid=385)) was developed by Seafood Services Australia Ltd (SSA) in consultation with the seafood industry and relevant agencies to:

- provide a proactive, easy-to-follow response to adverse events in the seafood industry
- maintain Australia's reputation as a provider of safe, high-quality seafood to its customers
- strengthen consumer confidence in Australian seafood.

The SIRP provides a framework for management teams at national and state levels to respond to an event, and create clear and defined objectives for recovery.

The SIRP defines an event as:

*“Any actual or potential event or occurrence which may affect the operations and reputation of the Australian seafood industry. These situations may be real or perceived and have a consequential impact on public health, public perception, domestic markets and international trade.”*

The Plan is not intended to replace existing event response processes but to:

*“co-exist and support the existing processes which have been specifically developed to protect public health and safety and recall product quickly. The aim of the Seafood Incident Response Plan in the event of an adverse seafood related event is to minimise bad publicity to the whole seafood industry and ensure that consumer confidence is not eroded.”*

Within the context of the 2012–13 Tasmanian PST event, a decision was made that the event had national implications and the national response would be initiated under the SIRP, with SSA as the coordinator.

Guidelines on the role of the SIRP in the context of other national and state event response protocols are yet to be developed and may be informed by the findings of this Review.

### Internal review

As required by the SIRP, SSA carried out a review of the SIRP in relation to its performance during the PST non-compliance event in Tasmania. The findings of this review are provided in Appendix 5, page 82.

For the purposes of this Review, a range of interviews with stakeholders across key lead agencies and seafood sectors, both within and external to the impacted state were undertaken. The key findings of these interviews are summarised below.

#### Strengths:

- The SIRP provided a forum outside the immediate area of impact for information to be shared regarding progress and management of the non-compliance event and HAB.
- Helped keep Federal agencies (DAFF, FSANZ) abreast of industry actions and challenges throughout the event.

#### Weaknesses:

- Lack of funding for the facilitation and coordination of the SIRP limited the ability of the SIRT to provide professional public relations support to the broader national seafood industry during the event, including the inability to produce a FAQ fact sheet in a timely manner.
- The running sheet SIRP produced during the event and the draft FAQ factsheet (which was not released due to delays in production) contained technical inaccuracies. This created the potential for misinformation to be released into the public arena and was identified as a concern by a number of stakeholders (including TSQAP, DAFF, SafeFish).
- Lack of understanding and commitment from various seafood stakeholders of the financing, role, purpose and procedures surrounding the SIRP.
- The lack of technical expertise within SSA limits the benefits of the SSA facilitating the SIRP in its current format.
- SIRP teleconferences impeded the ability of key regulators in the affected state to focus on day-to-day management of the event and ongoing HAB.

# Impacts resulting from the event

## Economic analysis and public health impacts

### Economic impact analysis

The aim of this analysis is to establish an estimate of the economic impacts of the HAB event on stakeholders who were affected along the east coast of Tasmania.

The objective of the assessment is to develop estimates of the direct and indirect economic impacts from the perspectives of:

- public health
- commercial fisheries/marine farming
- recreational fishers
- regulators.

The estimated direct and indirect economic impacts for each of these stakeholders has been estimated through the use of industry-generated data obtained through personal interview, industry estimates, literature reviews and accessing industry/ government databases.

Indirect economic impacts (flow-on disruption to participants in the value chain) from the loss of landed catch entering the market have been assessed through the application of an economic multiplier.

The outcomes of the economic impact assessment have been exemplified through the presentation of two case studies (see pages 54–57), which through personal interview and telephone surveys detailed information relating to the operational and management impacts of the event on i) commercial oyster producers and ii) tourism operators located along the east coast of Tasmania.

### Public health impacts

Cases of sickness and death from shellfish toxins are probably the most visible among the different types of public health impacts related to HAB events. Illness cases, usually when severe, are recorded by public health agencies in individual states and at the federal level.

Public health impacts as a result of consuming infected seafood can cause a range of other impacts in addition to illness and death, including: loss of work days, medical treatment and foregone wages.

The primary authority responsible for monitoring and recording the public health impacts of the HAB event in Tasmania was the DHHS.

The DHHS instigated an epidemiological investigation to ascertain the occurrence of genuine illness cases in response to the algal bloom event. The catalyst for the investigation was that PST had been detected up to 12.5 times the acceptable level and the congeners were relatively toxic.

Upon awareness of the risk of PSP, widespread alerts went out that were expected to draw cases of PSP to the attention of public health agencies. These alerts included the product withdrawal process, emails direct to supermarkets and extensive media coverage. The peak national food-borne disease surveillance group (OzFoodNet) was informed and their epidemiologists, situated in each jurisdictional health department, were well positioned to receive reports of possible PSP cases in their jurisdictions.

At the outset of the warning it was not clear how far back in time the risk of PSP extended. Putative cases were not excluded from consideration simply because they occurred before 21 October. The investigation also included a “non-recall-related” category, which offered the prospect of capturing such cases. However, it is worth noting that clear recollection of symptoms and food consumption by consumers is notoriously problematic as the number of weeks since an illness occurred increase.

All reports were considered from clinical (symptoms, incubation period) and epidemiological (particularly the likelihood of exposure to implicated product) perspectives. While symptoms restricted to the gastrointestinal tract do occur in PSP, these are often associated with a range of other common illness, viral gastroenteritis in particular. DHHS concluded that gastrointestinal symptoms alone were insufficient to make a compelling argument for a PSP case.

Of the 13 reports to 20 November 2012, 11 included enough information to evaluate the likelihood of PSP. Only three of these reported altered sensation or numbness typically regarded as prominent features of PSP. One of these three cases also reported gastrointestinal symptoms and was subsequently shown to have a norovirus infection. The other two had multiple medical problems that could plausibly have caused their symptoms, and which started 11 or more hours after shellfish consumption (longer



than usual for PSP). Although neither ate the recalled product, both cases were retained as possible non-recall-related PSP (albeit with more likely alternative causes). The remaining eight cases had had prominent gastrointestinal symptoms and lacked the cardinal neurological manifestations of PSP.

The lack of reported public health cases contrasts to the outcome of a toxicological risk assessment completed by DHHS which concluded:

*“At the maximum level of toxin, an adult would only need to consume 3.5 g mussels (less than one mussel) to reach the acute reference dose. Similarly, at the mean level of toxin, an adult would only need to consume 6.9 g mussels (less than one mussel) to reach the acute reference dose. Note: adult body weight is taken to be 70kg and one mussel is taken to be 14 g meat. Consumption of just one of these mussels would result in an exceedence of the acute reference dose.”*

This assessment agrees with a separate assessment undertaken by Japanese authorities, which suggests the consumption of three mussels would be sufficient to cause severe illness.

The Review team makes the following observations:

- A conservative approach to case **inclusion** was taken; however an alternative approach based on conservative case **exclusion** is arguably valid. The former strategy will have high specificity, i.e. likely to exclude cases not caused by exposure to saxitoxins but may also exclude actual cases. The latter approach would have high sensitivity, i.e. include most genuine cases of STX intoxication, but may also include some non-STX cases. It is the trade-off between sensitivity and specificity.
- The follow-up focuses largely on suspect cases associated with recalled products i.e. those harvested from 21 October and consumed up to 18 November 2012.
- Declining levels in product indicates depuration during late October. This suggests levels at or above these with potential for cases in the weeks leading up to 21 October (see Figure 3). From these limited data it is not possible to predict the timing of the peak of the bloom.

- As product had been widely distributed nationally and internationally, the occurrence of any potential cases may have been sporadic and not detected as an outbreak i.e. incidence and severity may have been below the sensitivity of the public health surveillance system. However, the absence of unambiguous cases of PSP identified by jurisdictional and national food-borne diseases surveillance systems mechanism suggest disease, if it occurred, was not common.
- Vomiting and other gastrointestinal symptoms can be part of the picture of PSP and cases that didn't necessarily present with the typical neurological symptoms (paraesthesias, localised anaesthesia, ataxia etc) still may have been caused by the consumption of PSTs. However, it is not unusual in food-borne illness events that likely causation is unable to be determined through a lack of corroborating evidence, or low numbers of case, or no cases, presenting
- The presentation of a tiered interpretation, at the top being 'probable cases' and then a second tier of 'suspect cases', as well as the excluded group may be an approach that could be trialled for future investigations.

Despite the foregoing, as there are no confirmed public health cases there are no direct economic impacts able to be attributed to the event.

The toxicity of the PST congeners has been determined by intra peritoneal inoculation studies in mice. There is considerable uncertainty around the potency of the congeners via the oral route. This uncertainty may also be a factor in the apparent lack of illness observed during this outbreak. Current research is being undertaken to investigate the oral toxicity through a significant research program being undertaken in Canada and New Zealand.

During the Review process the Review team observed additional human health impacts of the combined events. Qualitative evidence collected by the Review team in discussions with DHHS, DPIWPE and AST indicated that throughout the event, staff operated under extreme pressure, which led to stress and inefficiencies in managing and completing tasks.

### Commercial fishery/marine farming impacts

The commercial wild catch bivalve shellfish, and crustacean fisheries and bivalve shellfish marine farms located along the east coast of Tasmania are a key source of supply for the major species which are harvested and supplied to the major export and domestic markets for Tasmanian seafood.

The HAB event of October–December 2012 economically impacted both commercial and recreational fishers harvesting wild catch (including rock lobster, giant crab, scallops, bivalve shellfish and abalone) and marine farmers producing shellfish species (for example, oysters, mussels and abalone) along the east coast of Tasmania (see Figure 7).



**Figure 7** Area of coastline determined to be affected by the 2012 bloom of toxic dinoflagellate algae *A. tamarense* [Source: DHHS, 2013]

The HAB event closed a number of key bivalve shellfish and marine farming production areas for a range of periods during the October 2012–February 2013 period. Of the marine farming production areas (i.e. commercial and juvenile) along the east coast affected with the algal bloom, most of those located close in-shore and in adjacent estuaries had already experienced closures earlier in the year (see Figure 8).

The impact of the closure of these harvest areas on the shellfish marine farming sector is exemplified in Table 5, which demonstrates that up to 38% of the oyster production area and 95% of the mussel production area was closed due to the HAB event.

#### Landed catch/marine farming production

Direct economic losses as a result of commercial harvest area closures due to HAB events generally are a result of the coincidence of timing between environmental conditions and market demand (which typically peaks during the spring and summer tourist season).

Even though PST does not kill shellfish, the primary product form is a live product sold in a market with a distinct seasonal demand. This means that production and revenue losses due to the PST event in the spring or summer may not always be able to be offset by increasing harvest later in the year because of much lower demand for live shellfish.

Such was the case with the HAB event present along the east coast Tasmania in October–December 2012. This event coincided with the commencement of the peak harvest and supply period for both the domestic and export markets for a number of marine farmed and commercial wild catch crustacean species.

For example, within the commercial oyster sector the event occurred at the same time as the sector was due to supply product to the thoroughbred spring racing carnival in Melbourne and the mainland pre-Christmas and New Year festive season.

For the commercial giant crab and rock lobster sectors, the closure of the harvest area coincided with the onset of supplying product into the Chinese New Year — a discrete market in terms of availability and premium prices paid.



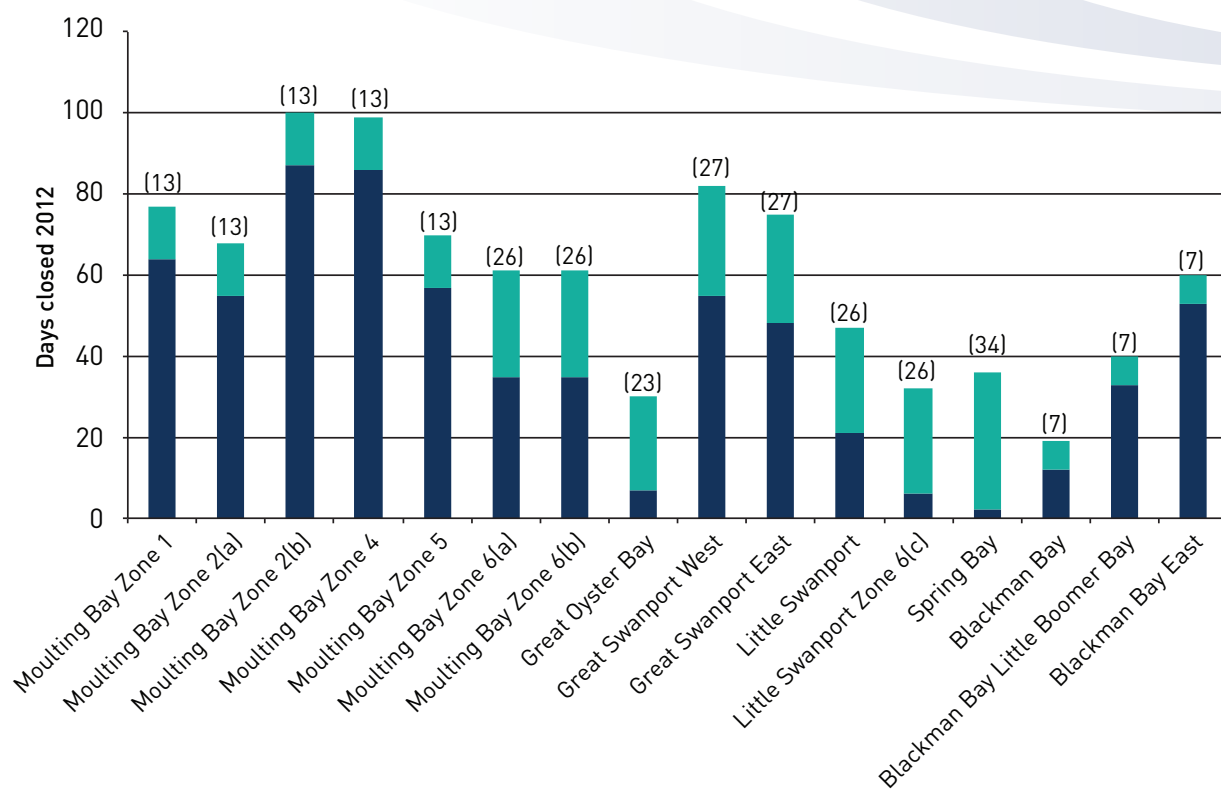


Figure 8 East coast Tasmania oyster production areas closed due to algal bloom PST event.

Region	Oyster licenses	Area (ha)	Mussel licenses	Area (ha)
Whole of state	104	1482.8	12	1840
Blackman Bay	9	158.1		
Great Oyster Bay	12	311.7	4	1754.7
Georges Bay	11	100.8		
<b>Closure area total (ha)</b>	<b>32</b>	<b>570.6</b>	<b>4</b>	<b>1754.7</b>
<b>Closure area of state (%)</b>		<b>38.5</b>		<b>95.4</b>

To further accentuate the impact of the HAB event, it occurred at the same time as SBS was launching its new pre-packed product lines into supermarkets in Australia and fresh mussels into supermarkets in Japan.

The closure of the commercial harvest areas along the east coast of Tasmania resulted in the commercial fishing and marine farming sectors (for example, oysters, mussels and rock lobster) adopting alternate harvest management strategies to minimise the impact of the event on supply to export and domestic market customers (see Table 6).

The impact of these strategies on the volume of landed catch/production varied between sectors during and immediately after the closure periods.

The scallop sector was the most significantly impacted sector with an industry estimated loss of 363 tonnes in landed catch, followed by mussels (125 tonnes) and rock lobster (15 tonnes).

It is estimated that during the closures the oyster sector loss in landed catch represented about 550,000 dozen.

Despite the loss of bivalve shellfish production during the closure periods, on a state-wide and on a quarter basis (October–December) there were minimal impacts on the total volume of landed catch/production during 2012 compared with the previous year's catch/production for the same quarter (see Figure 9).

### Market access

The loss of bivalve shellfish production during the HAB event led to varying levels of market access impacts in the domestic and/or export markets for the bivalve shellfish harvested along the east coast.

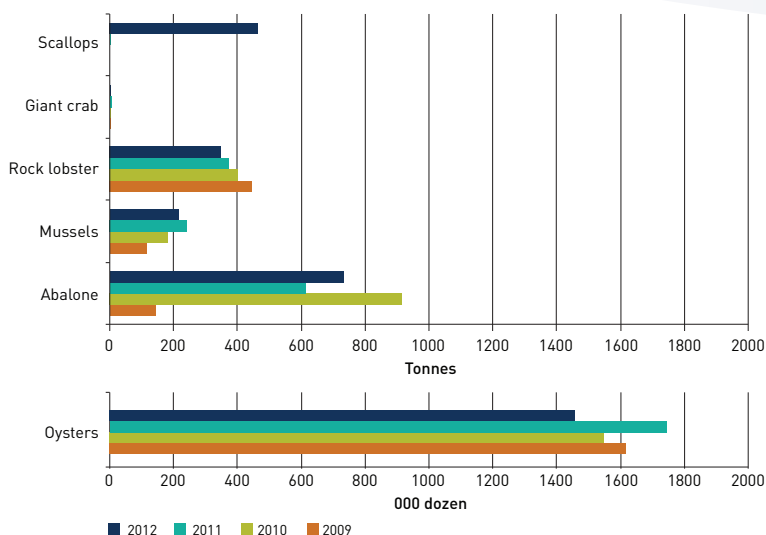
Anecdotal comments from domestic wholesale seafood market operators interviewed in Melbourne and Sydney suggest that despite the lack of supply from the east coast of Tasmania, they maintained supply by accessing bivalve shellfish from other parts of Tasmania and/or from interstate areas, such as the coastal bays of South Australia.

The major impact on supply for wholesalers was the need to 'work harder than normal' (i.e. make more phone calls) in order to obtain supply.

**Table 6 Commercial seafood sector harvest strategies — operating revenue and expenditure impacts**

Commercial sector	Harvest strategy adopted during HAB event
Oysters (32)*	<ul style="list-style-type: none"> <li>Retain stock – manage growth</li> <li>Increased % of larger oysters to sell</li> <li>Sell when clear</li> </ul>
Mussels (1)	<ul style="list-style-type: none"> <li>Retain stock — manage growth</li> <li>Sell when clear</li> </ul>
Rock lobster (10)	<ul style="list-style-type: none"> <li>Relocate fishing effort to open areas — fringes of closed off areas</li> <li>Transfer/lease quota from smaller local operator to larger operator</li> </ul>
Giant crab (3)	<ul style="list-style-type: none"> <li>Relocate fishing effort to open areas - fringes of closed off areas</li> </ul>
Scallops (15)	<ul style="list-style-type: none"> <li>Unable to relocate from predetermined harvest area</li> </ul>
Abalone (5)	<ul style="list-style-type: none"> <li>Relocate harvest activities to open areas</li> </ul>
Urchins, periwinkles ( 5)	<ul style="list-style-type: none"> <li>Relocate harvest activities to open areas.</li> <li>Harvest alternate species and areas unaffected by closure.</li> </ul>

\*Number of commercial license holders directly affected by the HAB event.



**Figure 9** Volume of landed shellfish catch: October – December quarter (2009–2012)  
[Source: DPIPWE 2013]

Market data from the Sydney Seafood Centre for September 2012–February 2013 confirms the anecdotal comments from fishers and wholesalers that there was no supply or price impact in the domestic market as a result of the HAB event or the need to access alternate sources of product supply.

The Sydney Seafood Centre further confirmed that following the ending of the closures bivalve shellfish products from the east coast of Tasmania re-entered the market without any market access penalty.

The main comment to emanate from the domestic wholesale seafood market operators interviewed related to the lack of confidence such events raise in consumers as to the safety of eating the species as distinct from where it was sourced.

### Scallops

With regard to the scallop sector, the inability to supply the wild catch domestic market for the remainder of the season following closure enabled 'cheap overseas competitors' to take advantage of the loss in supply and to gain market share in traditional export markets over the premium priced local product.

### Rock lobster

As most operators in the commercial rock lobster industry had the capacity and resources to relocate their fishing activity outside the closed areas there was minimal impact on their ability to service the export and domestic markets.

The main impact was the inability of the rock lobster fleet to fill the season quota (1100 tonnes), which fell short at the end of the season by 15 tonnes.

### Mussels

The major domestic market access issue related to the temporal loss of market access for fresh and processed mussels. For example, SBS had just launched a new range of pre-packed mussel products into a major supermarket chain in Australia and had ongoing fresh mussels being delivered into a major supermarket chain in Japan.

Apart from the costs incurred as a result of product recall and disposal, the major market access impact for SBS was the loss of consumer confidence in the product and potentially the supermarket chain.

With regard to the export market for mussels, the Japanese have not placed a ban on export of bivalves to Japan, rather a 100% 'test and hold' arrangement is currently required for Tasmanian bivalves.

While this can be met by oyster exporters, it is impractical to hold live mussels. Initially the 'test and hold' arrangement was applied to all states, however DAFF successfully negotiated reduction (return to normal) for bivalve import requirements for SA and NSW; therefore at the time of submitting this Review, Tasmania, Victoria, WA, NT and Queensland are still subject to the 100% 'test-and-hold' regime. No other country is applying entry restrictions related to this event.

### Evaluation of the risk communication response

The risk communication strategies implemented to minimise the impacts to domestic and export market access is shown in Figure 10.

As discussed in Section 1, the protocols governing the risk management responses around non-compliance events taken by key regulatory agencies (DAFF and FSANZ) are well developed and effective. Where impacts to fisheries exports extended outside the immediate impact zone due to export customer concern, these impacts were quickly managed and access regained.

The key strengths and weaknesses of the risk communication strategy implemented are outlined below:

#### Strengths

- Communication of comprehensive risk management protocols with key export regulators (DAFF, FSANZ) protected local suppliers outside the immediate area of impact.

- Proactive risk communication action taken by SBS (contracted professional PR company) to ensure control over messages to media of non-compliance event and product recall protected domestic mussel market.
- Coordinated approach by Australian Mussel Industry Association to manage media messages through selected media spokespersons.

#### Weaknesses

- Limited understanding by export customers over localised nature of event.
- Lack of accessible material available to industry to disseminate along the supply chain to reduce confusion of source of contamination and impact across species.

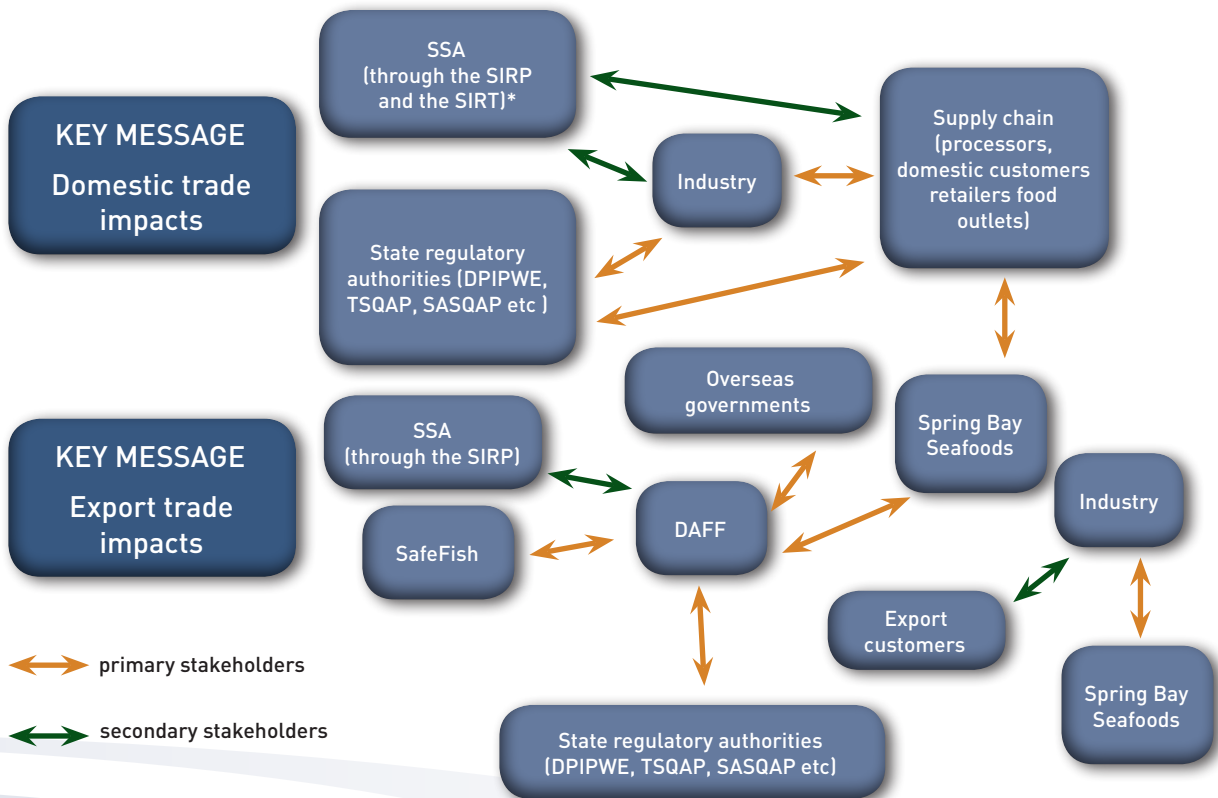


Figure 10 Communications taken to manage trade risks relating to the Tasmanian PST non-compliance event

\* The role of the Seafood Incident Response Plan (SIRD) in responding to the non-compliance event is discussed separately on page 37.

## Revenue and expenditure impacts

Industry estimates of the loss in production/landed catch suggest the overall direct loss in revenue to the wild catch fisheries and marine farming sectors as a result of the HAB event equated to an estimated \$6,308,700.

Of the sectors affected, the scallop sector was most reliant on the closed areas for its commercial harvest.

The inability to harvest an estimated 363 tonnes of scallops represented an estimated loss of \$798,600 in landed catch (see Table 7)

By contrast the rock lobster sector, through relocating its fishing effort, just fell short (by 15 tonnes) in harvesting the forecast landed catch (250 tonnes) to be derived from the closed harvest areas along the east coast.

While being a much smaller volume of foregone harvest, when compared to the scallop sector, the value of loss in revenue to the rock lobster sector equated to an estimated \$780,000.

In the absence of resources to undertake a detailed review of the indirect revenue and expenditure impacts resulting from the HAB event, industry sector representatives nominated a range of operational and management impacts, which led to further loss of revenue and/or the need for incremental expenditure. (Table 8, page 46)

Across most of the affected bivalve shellfish marine farming sectors was the commitment by operators to:

1. retain their full time employees, and
2. ensure their infrastructure was maintained throughout the period of the event.

This approach was based on the expectation that when the closure was lifted they would accelerate their harvest operations to compensate for the down time during the closure period.

**Table 7 Estimated direct revenue impacts for each commercial sector of interest**

Sector	Closure area production of state-landed catch (%)	Industry landed catch disposal		Estimate of loss in landed catch	Estimate of direct revenue loss (\$)
		Domestic market share (%)	Export market share (%)		
Oysters	35	90	10	550,000 dozen	3,575,000
Mussels	90	85	15	125 tonnes	650,000
Rock lobster	25	2	98	15 tonnes	780,000
Giant crab	35	100		4 tonnes	200,000
Scallop	65	100		363 tonnes	798,600
Abalone	25	5	95	Minimal	
Periwinkles, urchins, cockles	60 (periwinkles) 100 (urchins) n/a (cockles)	100 (periwinkles) 100 (cockles)	100 (urchins)	28.5 tonnes (periwinkles) 720 kilograms (urchins) 4.8 tonnes (cockles)	190,000
Clams (wild catch)	100	100		10 tonnes	140,000
<b>Total direct revenue loss</b>					<b>6,308,700</b>

Table 8 Indirect revenue and expenditure impacts		
Commercial sector	Revenue impacts	Expenditure impacts
Oysters	Revenue loss from 'recall' stock in market at time of closure Increase production post event to compensate Delay revenue until post event	Maintain maintenance costs — staff and equipment No casual employment Delay purchase or generation and introduction of spats and juveniles
Mussels	Revenue loss from 'recall' stock in market at time of closure (\$110,000) Loss in revenue due to scaled back market growth (\$300,000+ for 2013)	Send permanent staff on leave No casual employment Close down production line Delay generation and introduction of juveniles
Rock lobster		Increase expenditure on fuel, labour and consumables to meet travel requirements
Scallops		Maintain maintenance costs No casual employment Cease harvest until next season
Abalone	Loss of revenue until relocation occurred Minimal impact as end of season Revenue generated from alternate species	Increase expenditure on fuel, accommodation and consumables to meet travel requirements
Urchins, cockles periwinkles	Loss of revenue until relocation occurred Revenue from alternate species	Increase expenditure on fuel, accommodation and consumables to meet travel requirements

As a result of this commitment to retain staff and maintain infrastructure, commercial operators were forced to either draw down on cash reserves or use bank draw-down facilities in order to maintain operations until such time as the closure was withdrawn.

## Value chain impacts – economic multiplier

In addition to the direct loss of landed catch/production and revenue to marine farmers and commercial fishers, the magnitude of the event's impact extended to those engaged in providing services (for example, freight operators, couriers) and goods (for example, nets, pots, bags, fuel etc) as well as down-stream value chain stakeholders such as wholesalers, processors, restaurants/cafes and supermarkets.

At each link in this value chain, a portion of the value of output from each sector can be traced back to capture fisheries/marine farming sectors, with this share decreasing the further down the chain it goes. This approach reveals a great deal of economic activity supported by the commercial fishers/marine farmers (Dyck and Sumaila 2010).

Where the supply of seafood product is interrupted by an event such as the HAB event, there is an economic impact along the value chain that goes beyond the loss of revenue to commercial fishers/marine farmers and represents flow-on impacts to the value chain.

The economic impact of such an event along the value chain is calculated by applying an impact (output) multiplier to the total revenue of a fishery/marine farming sector.

The impact (output) multiplier is used in fisheries research to emphasise that the industry has many linkages throughout the economy. Such multipliers are a factor by which we can multiply the value of final demand for an economic activity's output to obtain its total contribution to economic output including activities directly and indirectly dependent on it (Sumaila et al 2007).

The total economic impact of the HAB event was calculated using an economic impact multiplier for the Australian seafood industry of 3.69, which represents the average fisheries/marine farming output multiplier weighted by landed value<sup>5</sup> (see Table 9).

Of the shellfish sectors impacted by the HAB event, the oyster sector suffered from most of the loss in direct revenue (\$3,575,000) and the expanded economic impact (\$13,192,000) of the HAB event on the oyster value chain.

This outcome reflects the timing of the closure of oyster harvest areas coinciding with peak supply into the domestic market during November and December.

Because of the fixed nature of oyster production, oyster producers were unable to implement an alternate harvest and market access strategy until such time as the closure was lifted.

This picture was similar for SBS although the economic impact was elevated due to not only the loss of revenue but also the loss of market share and brand position for its recently-established markets in Australia and Japan.

The sector that incurred the most significant economic penalty both in terms of lost revenue and market access was the scallop sector. Where other sectors could implement strategies to either transfer revenue generation during the closure by way of moving to alternate species or harvest areas or maintain commercial stock until such time as the closure was completed, the scallop sector was forced to close down the entire season without having access to either option.

The scallop sector incurred a further economic penalty as for some time scallop harvesting vessels remained in Triabunna in the expectation that the harvest season was imminent.

In summary the overall economic impact of the algal bloom event in terms of the direct loss of revenue is estimated to be approximately \$6,308,700 primarily as a result of the loss on landed catch/marine farming production and revenue from commercial harvesting during the period of the closure.

In addition to the loss of revenue the gross margins retained for products such as mussels, and oysters were decreased once re-entering the market due to the absorbed costs of managing product through the closure. A similar loss of gross margin was absorbed by rock lobster fishers due to their need for incremental expenditure in order to access harvest areas outside of the closure areas.

When the economic multiplier is applied to the loss of revenue from landed commercial catch/marine farming production, the economic impact on the value chain is estimated to increase the economic impact of the event to \$23,279,000, which demonstrates the capacity of such an event to significantly impact on stakeholders beyond those whose operations are situated within the closure area along the east coast.

<sup>5</sup> The economic impact multiplier for the Australian fishery industry is derived from Dyck and Sumaila (2010) who as the basis of their computations accessed economic flow data extracted from the input-output tables within the Global Trade Analysis Project (GTAP) which is located at Purdue University.



**Table 9 Value chain — economic multiplier impact for affected commercial sectors**

Sector	Industry estimate of loss in landed catch	Industry estimate of direct loss in revenue (\$)	Economic multiplier impact (\$)
Oysters	550,000 dozen	3,575,000	13,192,000
Mussels	125 tonnes	625,000	2,306,250
Rock lobster	15 tonnes	780,000	2,878,200
Giant crab	4 tonnes	200,000	738,000
Scallops	363 tonnes	798,600	2,947,000
Periwinkles, urchins, cockles	Periwinkles: 28.5 tonnes Urchins: 720 kilograms Cockles: 4.8 tonnes	190,000	701,100
Clams	10 tonnes	140,000	516,600
<b>Total loss</b>		<b>6,308,700</b>	<b>23,279,000</b>

## Recreational and indigenous fishery impacts

Recreational and indigenous fishing activities in Tasmania involve a variety of fishing techniques and equipment targeting a diverse range of fish and invertebrates in freshwater, estuarine and marine environments (Yamazaki et al 2011).

Tasmanians have access to a wide range of popular recreational species, such as flathead, Australian salmon, bream, tuna, rock lobster and scallops using a variety of fishing gear including rod and line, nets and pots (DPIPWE 2013).

It has been estimated by the Tasmanian Association of Recreational Fishers (TARFish) that about 125,000 Tasmanians (or one in four) participate in recreational fishing, most (75%) of which actively engage in saltwater fishing.

The participation rate of Tasmanians in recreational fishing is the highest of all states in Australia (Skirtun et al 2012).

Fishers who wish to catch shellfish species such as rock lobster, abalone and scallops, are required to obtain a recreational fishing license, with an endorsement for the respective species, from DPIPWE.

Of the TARFish estimated recreational fishers in Tasmania during 2012–13, about 16.7% held recreational fishing licenses with one or more endorsements (see Table 10).

Indigenous fishers undertaking customary fishing are exempt from holding a licence but must comply with all other fisheries rules that apply to recreational fishing, such as gear restrictions, possession limits, and size and seasonal restrictions.

Table 10 DPIPWE recreational fishing licenses endorsed for rock lobster, abalone and scallops

Year	Total number of license holders	Number of additional licenses endorsed				
		Rock lobster (dive)	Rock lobster (ring)	Rock lobster (pot)	Abalone	Scallop
2008–09 <sup>6</sup>	22,463	9,184	5,514	18,105	12,869	3,062
2009–10	23,021	9,172	5,477	18,199	13,152	4,286
2010–11	20,762	8,259	4,940	16,709	11,927	1,900
2011–12	21,583	8,168	4,999	16,527	11,744	1,469
2012–13 <sup>7</sup>	20,824	7,786	4,659	15,530	11,164	1,307

(Source: DPIPWE, 2013)

The peak harvest season for recreational fishers catching abalone and rock lobster in Tasmania is around Christmas–New Year (85%) and Easter (15%), with the major (75%) harvest areas being located along the east coast where the HAB event occurred.

Despite the DPIPWE recreational fishing license figures for 2012–13 being for an incomplete year, the number of licenses endorsed year-to-date indicates a decline compared with previous years.

When compared with 2011–12 the number of rock lobster-related licenses has declined by 1719, which represents a loss of licence revenue of \$12,377.

When combined with the decline in recreational fishing licenses issued (759) the total loss in revenue to DPIPWE for recreational shellfish-related licences equates to \$50,508 on a year-to-year basis.

Anecdotal discussions with DPIPWE indicate the revenue loss may have been significantly higher (\$100,000+) if not for a late run of license applications before Easter 2013.

The period of the closures, together with the loss of days available due to poor weather/sea conditions and prior commitments, significantly reduced the days available for recreational fishers.

The loss of access to traditional harvest areas for a period of 80 days during the months of November 2012 to February 2013 prevented recreational fishers from relaxing, socialising with friends, catching lobster to eat, experiencing nature and enjoying the experience of catching lobster.

The potential impact of the closure is exemplified by TARFish's estimate that of the annual 85 tonne catch of rock lobster by recreational fishers 50 tonnes are harvested from the closure area along the east coast.

Anecdotal evidence from discussions with recreational fishers and DPIPWE staff suggests that due to the recreational rock lobster fishery closure being instigated on 22 November, (season opening 3 November 2012) and continuing until 9 February 2013, the landed catch of rock lobster by recreational fishers is likely to have been reduced by as much as 70–80% (35–40 tonnes) by the end of the harvest season — post Easter 2013.

<sup>6</sup> Licence Year: 1 November to 31 October

<sup>7</sup> Licence Year to Date: 1 November 2012 to 15 May 2013

The economic impact as a result of lost access to the east coast for recreational fishers primarily relates to the anticipated expenditure that would have occurred if the harvest area had of been open for a 'normal' 2012–13 harvest season.

Previous reports assessing the fishery activities of rock lobster and abalone recreational fishers (Lyle and Tracey 2010) and the socio-economic assessment of rock lobster recreational fishers (Frijlink and Lyle 2010) have identified that the activities and related expenditure of recreational fishers can be related to:

- **Non-trip-related expenditure.** Non-trip-related expenditure items include lobster fishing equipment purchases and maintenance costs.
- **Trip-related expenditure.** Trip-related expenditure refers to costs incurred for items consumed during lobster fishing trips, including food, beverage, fuel etc.

When assessing the impact of the HAB event on recreational rock lobster fishers it was estimated that for the 2008–09 season, 24.8% of licence holders did not fish. This is a key consideration when assessing the economic impact of the HAB on non-trip and trip-related expenditure as to include this group of fishers would overestimate the likely economic impact.

It has been estimated that for the 2006–07 season the average daily expenditure attributed to lobster fishing was \$34.98 for pot fishers, \$45.71 for dive fishers and \$69.61 for multiple licence fishers (Frijlink and Lyle 2010).

When this is extrapolated to the recreational fishers along the east coast who would have been expecting to catch rock lobster during the closure period of the 2012–13 harvest season (mid-November 2012 – February 2013) the trip-related expenditure for the period would have equated to about \$1,776,656.

Despite the lack of similar socio-economic data for abalone recreational fishers, a similar approach was applied adopting the values applied for recreational rock lobster dive licenses. When this is extrapolated to the recreational fishers who would have been expecting to catch abalone during the closure period of the 2012–13 harvest season the non-trip-related expenditure would have equated to \$664,597 and the trip-related expenditure would have equated to approximately \$165,895.

When assessing whether this was foregone expenditure as a result of the HAB event, caution is warranted, as anecdotal evidence suggests some rock lobster and abalone recreational fishers redirected their harvest activities to areas that had not been closed.

The proportion of recreational fishers who chose not to relocate their activities and forego the recreational activities compared with those who relocated is unknown and is the subject of a further study<sup>8</sup>.

*In summary the economic impact on the recreational fishery sector consolidates the loss incurred by DPIPW in commercial fishing/marine farming licenses together with a pro-rata allocation of non-trip and trip-related expenses for the period of closure along the east coast represents an economic impact from the HAB event of \$1,992,600.*

<sup>8</sup>IMAF is proposing to carry out further investigations in 2013.

## Regulatory impacts

Responses by regulators and industry stakeholders to non-compliance events that impact on market access, production, harvesting and consumption of food, especially seafood by consumers in domestic and/or export markets often has two elements:

- A short-term element, which focuses on assessing the quantum and impact of the event followed by the implementation of strategies to resolve the event and bring the situation into compliance.
- A medium-term to long-term element, which focuses on identifying, evaluating and implementing strategies, which if adhered to, will reduce the risk of a re-occurrence of the non-compliance event.

By way of the nature of non-compliance events, the costs associated with monitoring and managing the event into compliance will lead to increases in unbudgeted expenditure, particularly for regulators and stakeholders directly affected by the event.

As the non-compliance event related to both domestic and export markets and a range of shellfish and crustacean species, there were a significant number of public and private sector stakeholders involved in the response process.

The regulatory monitoring and management responsibilities for the event resided with DHHS and DPIPW at a state level and with DAFF and FSANZ at a national level.

This initial response was followed by an ongoing monitoring and testing program until such time as the impact of the HAB had dissipated and it was safe for harvesting and consumption of the shellfish from the closure areas along the east coast.

Due to the magnitude of the HAB event and its occurrence coinciding with an event within the salmon sector there was significant competition for access to facilities at AST for testing.

In addition regulators utilised the services of SafeFish to assist in the development of monitoring programs, the management of the non-compliance and ongoing HAB events and to undertake confirmatory testing of some shellfish species.

The expenditure associated with the monitoring and testing program implemented by the regulators and commercial fishing/marine farming sector stakeholders included the following elements:

- Sample collection
- Sample preparation
- Courier sample to laboratories
- Sample testing and reporting.

Incremental expenditure incurred by regulators in managing the event included advertising the closure and opening of areas for harvest.

In addition to the monitoring and testing undertaken by the regulators, companies such as SBS implemented monitoring programs during the event that led to additional expenditure of about \$20,000 when sampling, preparation, courier and testing costs are aggregated.

Based on data supplied by DHHS, DPIPW and SafeFish the incremental expenditure incurred as a result of the event was about \$320,268 of which testing and sampling (\$235,720) represented the bulk (73.6%) of total expenditure. Of the regulatory agencies involved in sampling and testing DPIPW (58.1%) was the major contributor, drawing largely on industry levy fund reserves.

Of the species tested, most of the sampling and testing expenditure was for flesh testing rock lobster (31.5%), oysters (13.0%), mussels (9.9%) and scallops (8.0%).

Water sample testing for the presence of phytoplankton represented 9.6% of the expenditure on sampling and testing (see Table 11, page 52).

<b>Table 11 Estimated incremental regulatory monitoring and management expenditure</b>				
<b>Expenditure</b>	<b>DHHS (\$)</b>	<b>DPIPWE (\$)</b>	<b>SafeFish (\$)</b>	<b>Total (\$)</b>
<b>Sampling and testing</b>				
Plankton testing	17,715	4,873		22,588
Oysters	30,685			30,685
Mussels	18,360	4,936		23,296
Clams	8,100			8,100
Rock lobster		74,453		74,453
Giant Crab		4,350		4,350
Scallops		18,816		18,816
Abalone		13,256	24,000	37,256
Periwinkles		3,280		3,280
Sea urchins		1,513		1,513
Banded morwong		3,252		3,252
Calamari		2,710		2,710
Flathead		5,420		5,420
<b>Sub-total</b>	<b>74,860</b>	<b>136,860</b>	<b>24,000</b>	<b>235,720</b>
<b>Communications</b>				
Advertising	1,000	25,426		26,426
<b>Management</b>				
Consultants		6,000	7,500	13,500
Salary contribution (DHHS/SafeFish)		44,622		44,622
<b>Sub-total</b>		<b>50,622</b>	<b>7,500</b>	<b>58,122</b>
<b>Total</b>	<b>75,860</b>	<b>212,908</b>	<b>31,500</b>	<b>320,268</b>

## Impacts resulting from the event

### Summary of key findings

The economic impacts resulting from the HAB event primarily relate to stakeholders who require access to the closure areas including commercial fishers who rely on harvest areas to generate landed catch for supply into domestic and export markets (landed catch) and recreational/indigenous fishers who rely on access to the harvest areas for relaxing, socialising with friends, catching shellfish to eat and experiencing nature.

In addition there are flow-on economic impacts on consumers eating catch from the closure areas (i.e. public health impacts) and value chain participants who derive value from the activities of commercial and recreational fishers including goods and service providers and tourism operators.

A critical aspect of the economic impact analysis is that the closure coincided with the period of peak demand for shellfish supply into markets such as the Melbourne thoroughbred spring carnival, Christmas–New Year and the Chinese New Year.

In addition, the mussel sector was further impaired as it coincided with the entry of new products into supermarket chains in Australia and Japan.

The Review team estimates the direct economic impacts of the algal bloom event, where such impacts were measurable, was undertaken with a fair degree of confidence.

Due to the report limitations in collecting information directly attributable to the indirect economic impacts, the overall estimate of economic impact, which is an aggregate of these two components, may underestimate the true economic impacts.

A further contributor to the understatement of the overall economic impact of the algal bloom event is the lack of public health-related costs. As noted by the Review team for a range of reasons it would be anticipated there was some level of impact that remained unreported.

On a direct economic basis, the cost of the algal bloom event was estimated at \$8,620,000 representing both revenue and expenditure impacts across all stakeholders. From a revenue perspective the commercial fishery sector losses based on reductions in landed catch equated to \$6,308,700 (see Figure 11).

By contrast the recreational fishery sector was impacted due to the foregone trip-related expenditure (an estimated \$1,992,600).

When an economic multiplier is applied to the revenue loss of the commercial fishery sector the economic impact of the HAB event increases to an estimated \$25,591,600.

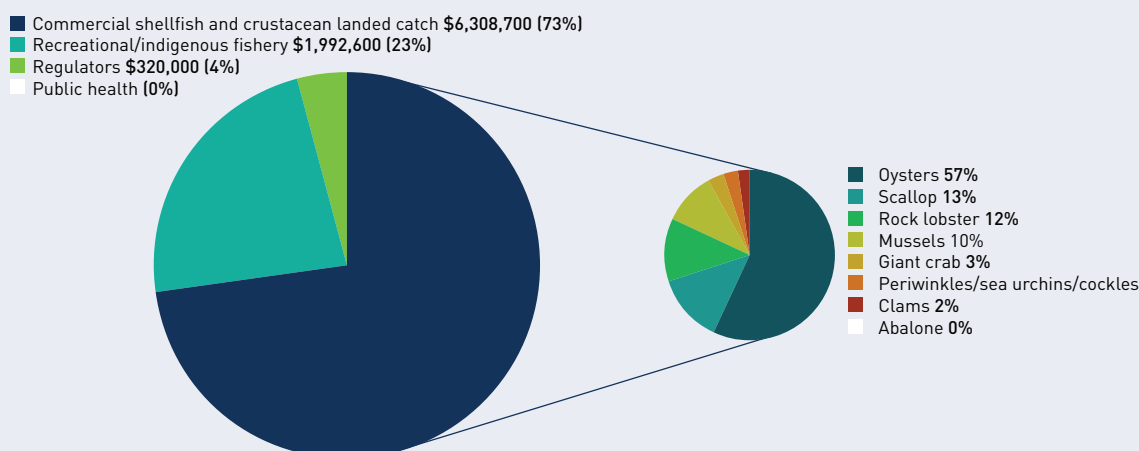


Figure 11 Estimated direct economic impact of the 2012 HAB event on Tasmanian shellfish and crustacean industry stakeholders (\$8,620,000)

# Case Study:

## East coast oyster producers

**T**he Tasmanian oyster industry is a vibrant and developing marine farming sector which currently provides direct employment for more than 300 people. Tasmania's commercial oyster producers harvest about 4 million dozen oysters each year, with an estimated 'farm gate' value of \$24 million.

Oyster production from the coastal bays and estuaries situated along the east coast of Tasmania represents an estimated 35% of the state's annual production.

While east coast oyster producers are familiar with closures due to the impact of 'rainfall events', the closure of the commercial, juvenile and spat production leases during November–December 2012 was the first occasion they were forced to close down operations due to the onset of an ocean-generated algal bloom.

Due to public health concerns related to the presence of PST toxins in oyster flesh, DHHS, under the auspices of the TSQAP closed down, for various periods of time, oyster leases located within the coastal bays and estuaries along the east coast of Tasmania.

Personal interviews (3) together with a survey of oyster producers within the affected area were undertaken to assess at an operational level the impact of the HAB event.

### Survey respondents

Of 31 lease holders contacted, a total of 17 (54.8%) completed the survey, of which 13 (41.9%) were involved in oyster production activities and operated a total of 32 leases. Of the 13 oyster producers, 12 were engaged in commercial harvesting, seven in juvenile production and two produced spat.

All 13 oyster producers indicated they were affected by the algal bloom by way of closure of their leases and their inability to supply oysters to the market at a peak demand period – Melbourne spring racing carnival in Victoria and the pre-Christmas, Christmas and New Year festive season.

### Industry impacts

Oyster producers reported that as a result of the closure about 540,000 dozen oysters valued at \$3.6million were withheld from markets in Melbourne (50.5%), Brisbane (19.6%), Sydney (13.1%), Adelaide (9.4%) and Tasmania (3.4%).

Compounding the direct loss of revenue to oyster producers were the flow-on effects to third parties such as service providers. For example, based on the volume of commercial oysters withheld from the market it is estimated that freight operators servicing the various markets were impacted by an estimated \$625,000 in forgone income during the closure period.

Oyster producers indicated that following the opening of the east coast for oyster harvest there were no major barriers to re-entry into the markets where they had previously marketed their oysters. Some, but not all producers indicated that they had obtained a premium due to the increased size of the oysters that were entering the market.

### Management strategies

As a result of the closure and loss of market access commercial oyster producers implemented a range of management practices, which would ensure the maintenance of stock and at the same time minimise expenditure until such time as the leases were open for commercial production.

In order to manage the growth rate of the oysters during the closure period 70% of the survey respondents indicated they increased the frequency of grading and racking. The extra handling for these oyster producers led to an incremental cost of about 50 cents/dozen, which equates to an incremental \$240,000 in expenditure for these oyster producers.



## Unexpected costs

Although the extra grading and racking enabled producers to manage oyster growth rates, the downside of the activity was that 90% of the oyster producers indicated the practice increased the rate of mortality by on average 6%. For oyster producers reporting increased mortality this resulted in an estimated incremental loss in production of 24,500 dozen, valued at approximately \$160,000.

## Protection through the TSQAP

When asked to provide additional comments oyster producers indicated that now the HAB event had occurred they wanted to ensure in the future the focus by government and industry was on ensuring product and public safety through the TSQAP.

Oyster producers indicated the industry is no longer a 'cottage industry' therefore to continue to grow market access it requires a focus on producing a high-quality product that is safe for the consumer.

## Increasing understanding of HABs

Oyster producers wanted to learn more about why and how the event occurred — they want more information. Survey respondents wanted to know what can be put in place to identify when these type of algal bloom events are likely to occur and what management strategies can be implemented to reduce the impact of the event on oyster production.

Some commercial oyster producers indicated they expect this type of event to become more frequent and as a result they may consider changing their management and marketing strategies so as to offset the risk associated with relying on their current production plans. Examples of strategies include:

- the increased use of estuaries to grow out commercial oysters rather than relying solely on open water production,
- shifting oyster production peaks to avert alignment with peak algal bloom risk periods, or
- increasing the use of triploid breeding and production stock versus diploids.

## Proactive monitoring

As part of this approach most (62%) oyster producers indicated they would re-evaluate their monitoring programs and would increase their frequency of water sampling and testing. Some oyster producers believed the increase in sampling and testing (both water and flesh) would be inevitable as a result of the proposed changes to the TSQAP program. Others indicated they would voluntarily evaluate and implement extra sampling and testing especially at peak production periods.

## Key questions for change

Oyster producers indicated that key questions to be addressed by the Tasmanian Government and the oyster industry include:

1. Is the current TSQAP of a standard that it will ensure the industry markets product that meet consumer expectations for delivering a safe product?
2. Are the capacity and capability of the current testing facilities in Tasmania commensurate with what the future demand on these resources will be for both phytoplankton (water) and flesh testing?

# Case Study:

## East coast Tasmania tourism

The economic impact of HAB events not only impacts directly on the shellfish sector but also there are associated indirect economic losses known as the 'halo effect'. A halo effect occurs when economic losses are collateral to (but not directly the consequence of) a HAB event. Examples of halo effects include reduced consumption of all seafood (not just shellfish) and fewer tourists visiting areas known to be experiencing a HAB event.

### Tourism

Apart from the east coast of Tasmania being a significant contributor to the Tasmanian economy through the economic contribution of its commercial fishing/marine farming industry, it is also an important destination for Tasmanian holiday makers and recreational fishers as well as for international and interstate tourists. For example, it was estimated by Tourism Tasmania that during 2012 approximately 247, 000 visitors spent between 2-3 days travelling and holidaying along the east coast<sup>9</sup>.

The tourism industry along the east coast of Tasmania comprises a diverse range of participants including tourist operators, restaurants/cafés together with recreational fishing goods and service providers (for example, tackle shops, service stations, news agencies). The tourism industry also includes a wide range of accommodation providers including motels/hotels, flats, caravan and camping parks.

A telephone survey of tourism operators located along the east coast was undertaken with the objective of identifying the level of awareness and impact that the algal bloom event had on their business activities during November and December 2012.

### Survey results

Of the 60 tourism operators contacted 48 (80%) responded to the survey. The breakdown of the respondents by their tourism enterprise activity is provided in Table 12).

Most of the tourism industry respondents indicated they were aware of the algal bloom event. They became aware of the event from a range of sources including friends (4%), media (35%) and a range of other sources (62%), which included the local chamber of commerce and tourism authorities, local police and seafood suppliers. In addition to these sources of information a number of respondents noted they had become aware of the event through the posting of signs by marine police around jetties and boat ramps.

Most respondents across each of the tourism sectors indicated they were not impacted by the algal bloom event in either November (74%) or December (67%). However, of the total respondents a number indicated their level of business activity declined during the months of November (13%) and/or December (19%) when compared to recent years' level of activity. Most of these were from the accommodation sector, where five operators in November and four operators indicated a decline in business activity (see Table 13).

**Table 12 East coast tourism survey respondent by business enterprise**

Tourism sector	Enterprise	(n)	(%)
Accommodation	Motel/hotel	4	8
	B & B	7	15
	Flats	11	23
	Caravan/camping	8	17
Food	Cafes	4	8
	Restaurants	6	13
Tourist attraction	Various	8	17
<b>Total</b>		<b>48</b>	<b>100</b>

**Table 13 Respondents experiencing a decline in business activity during November–December 2012**

Tourism sector	November		December	
	(n)	(%) of all respondents in sector	(n)	(%) of all respondents in sector
Accommodation	5	20	4	16
Food	0	0	2	20
Tourist Attraction	1	13	3	38
<b>Total</b>	<b>6</b>	<b>13</b>	<b>9</b>	<b>19</b>

<sup>9</sup> Tourism Tasmania Snapshot, www.tourismtasmania.com.au

Of the tourism operators indicating that their level of business activity had declined, the average decline equated to between 10-15%, which was a consistent range reported across each of the sectors.

The economic impact of the decline in activity during the period of the algal bloom in November and December for accommodation and restaurant/café operators ranged between \$2000 and \$10,000 per month. For tourist attraction operators the economic impact ranged between \$15,000 and \$96,000 per month.

When asked to comment on the impact of the algal bloom event, the major and most common comment related to the loss of local access to fresh seafood products, such as oysters, mussels and rock lobster. Restaurants and cafes were either forced to change menus or had to source product from other non-affected areas in the state. Likewise respondents commented that loss of access to oyster and mussel operators as a tourist attraction affected how long tourists remained in the area.

Although not part of the survey, respondents commented that the flow-on effects of the algal bloom went into January 2013, as this is the major month when local holiday makers descend upon the east coast for their post school-Christmas holidays. For example, a survey respondent reported that sales of fishing-related merchandise, such as fishing tackle, knives, rods, reels etc were down significantly during January 2013.

Beyond this period the impact of the algal bloom event is clouded due to the onset of the Tasmanian bush fires and a recent change in school holidays in Tasmania from a three-term year to a four-term year which affected accommodation bookings.

# Opportunities for improvement

## Lessons and summary

### The bigger picture – international non compliance events

#### The New Zealand experience

Biotoxin events, such as the one that occurred during October 2012 in Tasmania are not rare internationally. There are several examples of situations where both industry and their associated monitoring programs were unprepared for the onset of a marine biotoxin event.

During 1994 in New Zealand, an unknown neurotoxic shellfish poison-like (NSP) toxic event unfolded and caught the NZ industry and Government agencies completely off guard. Before this event, NZ's biotoxin program was minimal.

The event resulted in a three-month closure of the entire NZ coastline, with all shellfish industry operations suspended while the cause and management issues were sorted out.

As a result, NZ implemented a completely revamped marine biotoxin plan and program introducing current technology and knowledge available to all shellfish sectors. NZ drew heavily on international experience at the outset, and help was provided by one of NZ's largest trading partners at the time, the United States, in the form of one of the US Department of Agriculture's (USDA) foremost practitioners in this field at the time.

The event also initiated a period of research and development to solve some of the dilemmas arising from the methodology being used, specifically mouse bioassay techniques.

#### The Irish experience

Ireland also experienced a similar problem with the emergence of a toxin, Azospiracid Acid (AZP) in Irish water, which was previously unknown. The causative organism was not obvious, yet the contaminated shellfish were causing illness in the international marketplace; the EU specifically.

The industry suffered from closed markets while this issue was resolved, and a revamped biotoxin management plan and monitoring regime introduced.

Now, chemical-based technology of liquid chromatography coupled with mass spectrometry (LC-MS) enables the fast and reliable detection of such toxins.

### Widespread adoption of LC-MS

NZ and Ireland have both embraced this technology early on in its development, with NZ adopting the routine use of LC-MS in place of mouse bioassays during 2001. The rest of the shellfish world has now also embraced LC-MS and the EU recently announced the addition of this technology for use within the EU for regulatory biotoxin monitoring purposes.

One of the advantages of LC-MS is that it can detect extremely low levels of contaminants, in this case marine biotoxins. It has proved highly valuable in the early detection of toxin accumulation in shellfish and has enabled the early shutdown of industry harvesting as levels were seen to be increasing to close to the regulatory levels on many occasions. This has ensured consumer health is protected and has prevented contaminated product from entering both domestic and export markets.

As a result, the use of LC-MS has prevented expensive recalls and enabled the proactive management of commercial fisheries and early warnings to be sent to recreational and customary gatherers of shellfish. By achieving these aims, LC-MS contributes significantly to brand integrity, both of processing companies, but also the nominated country's reputation as a food producer. A rigorous sampling regime is important also and early detection is contingent upon regular and frequent testing.

## International practice to protect public health

Earlier sections and feedback from two international shellfish safety experts, Joe Silke, Section Manager, Marine Institute, Ireland, and Jim Sim, Principal Advisor, NZ Ministry for Primary Industries, provide detail of current practices. These comments from international experts were elicited by a request from the TSQAP Manager regarding international best practice.

Both experts outline the details around the role of flesh and phytoplankton in the management of HABS and marine biotoxins (see Appendix 6, page 89). Their advice touches on sample frequency and conservative predetermined responses to findings of elevated phytoplankton counts and international best practice for marine biotoxin management.

The recommendations provided by Joe Silke and Jim Sim are summarised in the following statements:

- **Regular and frequent sampling** — Sampling of flesh and phytoplankton need to be regular and frequent. This can vary, but is seldom less frequent than fortnightly. Most programs sample weekly phytoplankton and most complete weekly flesh tests as well; particularly where a complete risk assessment indicates medium or high risk. Most operate this way year-round, while commercial harvesting is occurring, or customary and recreational gathering is common. The program should reflect the risk to the consumer. In this regard it is a 'public health' program.
- **Laboratory capability** — Technology employed should meet internationally-accepted operational capability. This includes technically competent laboratories and laboratory scientists and taxonomists. Turnaround times should meet the expected outcomes of the industry. This is particularly difficult where live product is involved. Many processors and exporters use such technologies as modified atmospheres and superchilling to buy extra time to achieve transport and satisfactory shelf life at destination. Alternatively, added value steps are employed to increase per unit value, but also time available for decision-making around laboratory results and transport issues.

- **Legislative backing** — Any management plan governing the program is underpinned by legislation and all steps are clear and agreed by all parties to the plan. Decisions to close and reopen shellfish growing areas and wild harvest fisheries are based on flesh results, Australian requirements are detailed in Table 14.

**Table 14 Maximum levels of marine biotoxins as specified in the *Australia New Zealand Food Standards Code* (Standard 1.4.1)**

Toxin group	Maximum limit
Paralytic shellfish poison (PSP) (saxitoxin equivalent)	0.8 mg/kg
Amnesic shellfish poison (ASP) (domoic acid equivalent)	20 mg/kg
Diarrhetic shellfish poison (DSP) (Okadaic Acid equivalent)	0.2 mg/kg
Neurotoxic shellfish poison (NSP)	200 MU/kg

Internationally, both flesh and phytoplankton are used in biotoxin monitoring programs. Table 15 (on page 60) shows several different countries and their approaches, but all are similar.

The use of flesh testing is the cornerstone of the regulatory approach, while phytoplankton monitoring provides a support role, particularly in the early detection of impending blooms.

Phytoplankton blooms are notoriously 'patchy' and for this reason water sample results showing cell counts cannot be totally relied upon. The samples of phytoplankton are merely a moment in time, i.e. a grab sample.

Shellfish bioaccumulate toxins through the filtration/feeding process. The samples analysed tell the story of what has been in the water for the past few days. In this regard they are a time weighted sample process, and as such a lot more reliable. They are also what people will consume, and so much more relevant in terms of public health decision making.

**Table 15 Comparative practise of flesh and phytoplankton Internationally**

Criteria	Ireland	New Zealand	Japan	Canada
Role of phytoplankton monitoring	Supportive role and some substitution of flesh testing where good evidence supports reduction. Weekly testing	Supportive role and some substitution of flesh testing where good evidence supports reduction. Weekly testing	Not widely used, but is utilised in response to particular export market requirements, for example EU specifies weekly testing	Not specified in manual of Operations. Support information only
Role of flesh testing	Weekly or fortnightly depending on risk analysis. Primary risk management tool (for example, open and close on flesh results)	Weekly, fortnightly or monthly depending on risk analysis <sup>10</sup> and toxin group	During high-risk periods weekly testing of flesh. Primary risk management tool. Open and close on flesh results	Weekly or fortnightly testing of flesh as primary risk management tool. Open and close on flesh results

<sup>10</sup> Risk assessment is rigorous and based on review of many years (up to 10 or more) paired flesh and phytoplankton data. Reduction of flesh testing based on history to date, and always conservative.

## Biotoxin management improvements for bivalve shellfish

As a result of this review, the overarching recommendation, which has national implications for biotoxin risk management, is the critical need to reform the national regulatory framework and associated policies that ensure the ASQAP provides the foundation for internationally acceptable public health protection and going market access.

Given the high-risk status of bivalve molluscan shellfish the Review team strongly recommends any revised national regulatory framework incorporates some prescriptive elements common to appropriate international shellfish programs. This recommendation will provide the underpinning to support implementation of changes needed in each Australian jurisdiction as appropriate, including TSQAP, as outlined in the review.

The recommendations outlined in the following report have been developed with the express aim of ensuring production of seafood in a manner that protects public health, ensures continued market access for commercial producers and access for recreational and indigenous fishers' activities.

The Review team provides the following recommendations to the TSQAP management committee for immediate consideration to reduce the likelihood of a non-compliance event of this nature occurring again and to reduce the impact of such an event in the future:

## Short-term priorities (0-6 months)

### The Tasmanian Shellfish Quality Assurance Program (TSQAP) (TOR Two)

Ensure the TSQAP is adequately resourced to:

- Design and implement an interim Management Plan that will deal with the current year, incorporating issues arising from this report where possible. *(Note: wild harvest scallops must be included in such a plan).*
- Deliver services to a level that adequately protects public health at all times.
- Provide a service level to industry that will ensure TSQAP is based on currently-recognised global best practice.
- Minimise the impact of non-compliance events on market access.
- Develop a succession plan for the ongoing delivery of the TSQAP with a focus on decision making and resources. The Review team is concerned most of the knowledge is held in one person (the TSQAP Manager). A succession plan needs to be implemented and key decision processes recorded and disclosed, if they are not already. During the course of the October November 2012 event, the TSQAP Manager reportedly worked in isolation, and often in areas of work not mandated by the position. Clearly this is inappropriate, and raises workplace health and safety (WHS) implications.



### **The Biotoxin Management Plan for the TSQAP<sup>(TOR Two)</sup>**

As discussed in Section 2, the *Plan* in place in Tasmania before and during 2012 placed a reliance on the performance of phytoplankton monitoring as the primary risk management tool for marine farmed bivalve molluscan shellfish.

In view of the recommendations of the *Model Australian National Marine Biotoxin Management Plan, Cawthron Report No. 646, (2001)* evaluated as part of this Review (see Appendix 4, page 76) the Review team considers this to be unreliable, particularly when combined with long turnaround times in laboratory results are considered.

The Review team makes the following recommendations to improve the *Plan*:

- Review the recommendations outlined in the FRDC-funded *Cawthron Report No. 646, (2001)* and where appropriate adopt and implement recommendations within the TSQAP.
- Incorporate within the *Plan* an event response protocol for non-compliance events, which identifies a structured process for addressing the event.
- Replace phytoplankton testing as the primary risk management tool with shellfish flesh testing, retaining phytoplankton testing as a predictive early warning tool. Adopt the established published flesh standards as listed in the *Australia New Zealand Food Standards Code (Standard 1.4.1 – Contaminants and Natural Toxicants Clause 3(3))*. (Note: This should also remove illogical and conflicting actions in the *Plan* such as the closure by phytoplankton and subsequent reopening if the flesh result is below regulatory level. In addition, this should not prevent industry performing its own additional risk management strategies over and above the regulatory requirements.)
- Increase the frequency of sampling (and testing) in medium-risk and high-risk areas in line with policies and interventions considered commensurate with risk and food safety regulations internationally. Irrespective of whether flesh tests are scheduled, sample flesh weekly, along with a paired phytoplankton sample, and hold product pending phytoplankton results. In the event a trigger is breached, the flesh sample will then immediately be available to the laboratory and relevant to the phytoplankton sample.
- Ensure unambiguous policies are put in place regarding times at which samples should be collected year-round.
- Review and revise current ambiguous guidelines relating to the closure of marine farms covered by the *Plan* to provide clarity around implementing regulatory responses where samples or test results are not forthcoming within expected time frames. A useful example for similar circumstances can be found in the New Zealand arrangements (*NZ Food Safety Authority Animal Products, Specifications for Bivalve Molluscan Shellfish Notice 2006 Part 6 Clause 45, (7) and (8)*). The application of these closure arrangements has been extended with a direction that failure to sample in any week will result in closure until samples can be procured and analysed.
- Ensure proposed changes to any aspect of the *Plan* (for example, marine farm closure trigger levels) are rigorously peer reviewed to ensure the approach is scientifically justified with technical and/or public health rationale.
- Replace existing agreements with laboratory testing service providers with a performance-based contract that encompasses capability and key performance indicators (KPIs). Considerations for developing such a contract are outlined on page 62.
- Review current protocols and communication channels for the delivery of laboratory test results to ensure continuity and consistency in communicating results to regulators and industry stakeholders. Consider a web-based pathway, or mobile phone technology, for direct delivery of results to regulators, sample providers and industry stakeholders.



# Performance-based contracts

## Key considerations for TSQAP

Throughout the Review a number of issues relating to the provision of adequate laboratory testing have been identified. To overcome these issues the following performance standards provide a basis for contracting appropriate services. The TSQAP Management Committee should consider adopting these KPIs to better protect public health through a revised biotoxin management plan.

The Review team recommends the TSQAP Management Committee considers and adopts the following performance indicators:

- Growing area and flesh sampling coordinated to suit laboratory throughput and achievement of agreed turnaround times — also linking in with couriers.
- Paired samples of water and flesh provided to facilitate rapid flesh testing if phytoplankton levels reach trigger level; implies a laboratory with both capabilities or storage capability so they can send product to the flesh lab.
- Contracted transport services or Australia Post overnight delivery to capital city. The logistics around sample delivery is an integral part of sampling activities and one for all parties in the chain of sample handling to carefully consider.
- Strict compliance with sample labelling requirements.
- Labs will participate in proficiency testing programs for phytoplankton screening.
- Use of IOC training course.
- NATA accreditation for biotoxins and phytoplankton analysis (ISO 17025).
- Two-day turnaround time for phytoplankton analysis from receipt of sample.
- A 2-3 day turnaround time for biotoxin analysis (flesh testing) from either arrival at lab or decision to test based on cell counts.

- Provision of services 52 weeks of the year to ensure services underpin commercial activities.
- Electronic delivery of results direct to submitter and TSQAP.
- Clear documentation of supplementary testing and/or actions required if a trigger level is exceeded.

Much of the foregoing can be found in the *Cawthron Report 646* (see Appendix 4, page 76). Recommendations specifically relating to laboratories include:

- An approval system for laboratories and methods, in order to perform testing for the monitoring program is implemented for both phytoplankton and biotoxin laboratories. At a minimum this should be NATA accredited and have directly relevant training (for example, USFDA, as necessary).
- Laboratories need to be able to offer expert advice, and have directly relevant training (for example, attendance at UNESCO courses).
- Proficiency testing programs for laboratory personnel involved in identification of marine microalgae.
- Biotoxin laboratories need to participate in national and international inter-laboratory calibration programs.

Note: Although outlined in the Cawthron report (2001) these recommendations were not adopted in the *ASQAP operations manual* (November 2009 Version 2009-01) or the *Biotoxin Management Plan for the TSQAP* (2012).

### **Biotoxin management improvements for other Tasmanian fisheries**

No fishery is immune from an unexpected marine biotoxin event and phytoplankton can bloom anywhere, anytime. International experience supports this. It is unwise to believe that because a toxic bloom has never occurred in a situation it never will.

To inform the development of appropriate risk management plans for fisheries products, the Review team recommends the following work is prioritised for action by regulators and industry:

1. A risk ranking exercise for fisheries species to ascertain which ones should be included in the 'cross-sector fisheries biotoxin management plan'.
2. Concurrent sampling of potential bivalve sentinel species (for example, mussels) alongside higher-risk fisheries species (for example, lobster, abalone) during algal blooms to ascertain usefulness of sentinel species in predicting the risk of contamination of fisheries products.

### **Communications <sup>(TOR One)</sup>**

- Create and implement an interim communications response protocol across all sectors for the coming season, which covers the immediate event response and ongoing HAB management, together with a database of key contacts within each target audience (for example, industry stakeholders, government, tourism operators and public).
- Ensure the event response protocol clearly articulates communication responsibilities and processes for all lead agencies, including communication around fishery closures.
- Review and evaluate the adoption of modern social networking channels (facebook, twitter, SMS messages) in addition to existing channels (media release, radio, television, newspapers, websites).
- Prepare and file for future use a library of broad-based factsheet templates, on all identified potential marine biotoxins, which can be quickly adapted for individual event response and delivery to industry stakeholders.
- Implement a media training program for key industry leaders to ensure cohesive leadership and consistent media communication in the event of a future non-compliance event.

### **Seafood Incident Response Plan <sup>(TOR One)</sup>**

- Clarify and communicate to regulators and industry stakeholders the triggers that determine when the SIRP is enacted regarding a non-compliance event.
- Clarify within the SIRP how the Plan will operate alongside existing response and risks management plans.
- Evaluate and confirm the future role of SIRP including resources (infrastructure and finance) available for responding to similar events in the future.

### Longer-term priorities (+6 months)

In the longer term the Review team recommends a state-wide cross-sector biotoxin management approach that incorporates a strategic inter-agency and industry stakeholder event response protocol with a structured process to address events, together with roles and responsibilities (regulatory and industry) and a built-in post-event review process.

The current management plan being prepared by the Tasmanian Abalone Council (TAC) may provide a useful template for the development of the cross sector plan.

### State-wide biotoxin management

In the medium to long term:

- Review current legislation governing cross-sector management of marine biotoxin events and ensure lead agencies are critically aware of the legislative framework that underpins the applicable regulations, level of authority together with the roles and responsibilities of the agencies during such an event. Deciding the parties that will take carriage of the cross-sector management plan is a critical first step. The review team notes the willingness from industry and government stakeholders for this to be done.
- Use data gathered from monitoring fisheries products to inform comprehensive risk assessments to ascertain the potential impact that PSTs could have on public health.
- Evaluate the opportunity to use routine TSQAP data to inform management of other fisheries. The co-ordination of monitoring programs across species can uncover synergies. The use of sentinel species (for example, mussels) can be incorporated into management plans for closure. Fishery re-openings can be specified species by species, where science and results support this.
- Prepare a risk-based plan that identifies how to manage new algal species and toxins not seen before in Tasmania. Identify the agency responsible for managing the event response protocol and the appropriate division of resources. Ensure the plan outlines a strategy for determining appropriate risk management responses required to be adopted and implemented.
- Implement the development of a 'library system', which provides storage of in-house fishery samples from successive harvests as part of an industry-wide management plan, for retrospective analysis to inform product recall in the event of a marine biotoxin event.

### Lessons for other states and DAFF

As stated, in light of the above issues being raised the Review team recommends all states take this opportunity to review their current biotoxin management and the underpinning regulatory framework to protect public health.

In particular all states should review their respective current biotoxin programs against the *Cawthron Report 2001* recommendations.

DAFF annually audits the TSQAP to ensure compliance with the *ASQAP Export Standards* (and export legislation). During the review it was highlighted that the *ASQAP Export Standards* are outcome based and the auditor requires an understanding of public health risk management.

It was noted that staffing changes during the past five years have seen a reduction in relevant expertise on assessing the ability of state-managed programs to meet the *ASQAP Export Standards*.

In conclusion, the Review team recommends that given the impacts on export-bound product and the findings of the Review, DAFF assesses its role and responsibilities within the auditing and certification process.

### Cost : benefit of implementing recommendations

As to the investment required to implement the recommendations of the Review, the decision as to what level of investment should occur either through regulation (for example, TSQAP) or through voluntary adoption of appropriate strategies by the wild fishery/ marine farming sector stakeholders should be commensurate with the likely frequency and severity of potential HABs (i.e. the level of risk) and the quantum of the economic impact of the event on public health, commercial operations, recreational fishers and regulators.

The risks managed by commercial operators are often held at a much higher level than those considered by governments in managing recreational gathering activities. For example, initial anecdotal evidence from discussions with stakeholders within the oyster and mussel sectors suggests that as a result of the HAB event some operators are now planning to implement voluntary incremental sampling and testing programs in their juvenile and commercial harvest production areas.

Any increase in monitoring, particularly on the scale proposed by this Review, has significant cost implications. While this is recognised, it is not within the ToR of the Review to determine who should fund and how to fund an enhanced monitoring program. However, there are obvious risks to all stakeholders in Tasmania's marine resource to consider in terms of public health and economic impacts if another HAB event were to occur and there had been no change to current practices.

When the HAB event is considered in the context of its economic, public health, recreational and market access impacts, it would suggest that independently and collectively governments and bivalve molluscan shellfish and broader fishing industry stakeholders need to consider the recommendations of the report. By implication, stakeholders need to determine an appropriate level of investment to adopt and implement the recommendations from the Review.

### Short-term and long-term strategic research and development issues

Considerable discussion has taken place around the information gaps and future needs surrounding the biotoxin management issues described in this Review. These should be considered in relation to science funding in future research grant allocation.

The Review team recommends that research efforts following the HAB event are focused on short-term – high-impact outcome-driven research.

The Review team has identified the following research priorities for industry stakeholders to consider:

- Develop a preliminary risk ranking for marine biotoxins in non-bivalve species to provide a science-based justification for inclusion or exclusion of different fisheries species in a state-wide cross-sector marine biotoxin management plan.
- Develop an understanding around the uptake and elimination rates of toxins within high-risk fisheries species. This relates to not only bivalve shellfish, but also other high-risk species of commercially and recreationally gathered seafood, (for example, scallops, abalone, giant crab, lobster etc). Such data will inform the potential use of sentinel indicator species in the management plan.
- Develop sampling plans for fisheries products to inform DPIPW, DHHS and DAFF risk management policies.
- In the longer term, develop risk assessments for each high-risk fisheries species (for example, rock lobster, scallop and giant crabs) with a view to assessing the appropriateness of the bivalve regulatory limits for non-bivalve species (noting that a risk assessment for abalone is underway).

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## Appendix 1

### Review of the 2012-2013 paralytic shellfish toxin non-compliance incident in Tasmania Terms of Reference (ToR)

#### 1. TOR One: Non-compliance event evaluation

- Undertake an evaluation of the sequence of events that lead to the detection of PSTs by the Japanese import authority, with a focus on compliance to the TSQAP biotoxin management plan.
- Identify the key factors that contributed to the non-compliance event, in particular identifying how the bloom remained undetected for long enough to produce violative PST levels and if/why the TSQAP biotoxin management plan protocols were breached.
- Undertake a review of the respective response and management of the non-compliance event, including:
  - Monitoring (effectiveness, efficiency, resources)
    - Response time
    - Strategy
      - Leadership/teams
      - Action plans/protocols
      - Participants
      - Non-compliance sign off
    - Laboratory testing and turn-around times
    - Results reporting
  - Communication (frequency, content, communications channels, effectiveness)
    - Customers/public
    - Industry
      - Customers
      - Stakeholders
      - Government
      - Inter-fisheries
    - Government agencies
      - Public
      - Inter-agency communication;
      - Industry (Shellfish)
      - Industry (Other fisheries)
    - Review of the national Seafood Incidence Response Plan
    - Review of incident notification process, including key regulatory agencies.
- Undertake a quantitative and qualitative evaluation of the economic impacts of the non-compliance event along the shellfish supply chain as a result of the shellfish recall, including impacts on:
  - supply chain stakeholders
  - the Tasmanian and Australian shellfish industry, and
  - Tasmanian government agencies.



## 2. TOR Two: Biotoxin monitoring and management plans

Within the context of the non-compliance event the review will:

- undertake an appraisal of the effectiveness of the current TSQAP management plan for addressing the biotoxin risk and non-compliance events in Tasmanian shellfish growing areas.
- undertake a review of the TSQAP management plan and its capacity to prevent future biotoxin incidents and/or manage future non-compliance events, incorporating:
  - Identifying if the current management plan has sufficient capacity and resources to deal with such an event.
  - Identifying potential “gaps” in the current management plan.
  - Identifying potential strategies and/or policies to address ‘gaps’ within the management plan.
  - Identifying and assessing if additional risk management communication strategies are required relating to public health protection (domestic and export) with respect to the occurrence of marine biotoxins in Tasmania.
  - Undertaking a cost/benefit analysis for the adoption of additional strategies within the current TSQAP management plan for marine biotoxins in Tasmanian shellfish industry.
- Provide recommendations to the stakeholders for enhancing the current non-compliance response management plan for biotoxins in the Tasmanian shellfish industry.

## 3. TOR Three: Impacts and implications for other Tasmanian fishery stakeholders

At an industry peak body level identify and evaluate quantitative and qualitative stakeholder impacts (i.e. economic, market, social) of the biotoxin non-compliance event in shellfish on other Tasmanian fisheries (i.e. abalone, southern rocklobster and potentially periwinkles and sea urchins) and recreational fishers, including industry and government agency co-ordination and response.

## Appendix 2

### Growing areas risk and sampling details

[Source: *Biotoxin Management Plan for the Tasmanian Shellfish Quality Assurance Program 2012*]

Area	Risk	Rate (winter/ summer) <sup>1</sup>	Sampler	Sample method
Montagu	Low	Monthly <sup>2</sup>		Bottle
Duck Bay	Low	Monthly <sup>2</sup>		Integrated 3m
Port Sorell	Low	Monthly <sup>2</sup>		Integrated 3m
Ansons Bay	Low	Monthly		Bottle
Moulting Bay sub-tidal	Low	Monthly		Integrated 8m
Moulting Bay inter-tidal	Low	Monthly		Bottle
G. Swanport	Low	Monthly		Bottle
G. Oyster Bay	Low	Monthly		Integrated
L. Swanport	Low	Monthly		Integrated 3m
Spring Bay	Medium	Monthly/Fortnightly		Integrated 15m
Blackman Bay	Low	Monthly		Bottle
Fulham Island	Low	Monthly		Integrated 8m
King George Sound	Low	Monthly		Integrated 8m
Norfolk Bay	Low	Monthly		Integrated 5m
Port Arthur	Medium	Monthly/Fortnightly		Integrated 8m
Pitt Water	Low	Monthly		Integrated 4m
Island Inlet	Low	Monthly		Bottle
Pipe Clay Lagoon	Low	Monthly		Bottle
Great Bay	Medium	Monthly <sup>4</sup>		Integrated 3m
Fleurty's Point	Medium	Monthly <sup>4</sup>	Bottle	
Little Taylors Bay	Medium	Monthly <sup>4</sup>		Bottle
Cloudy Bay	Medium	Monthly/Fortnightly		Bottle
Gardners Bay	High	Monthly/Fortnightly		Bottle
Deep Bay	High	Monthly/Fortnightly		Integrated 8m
Port Esperance	High	Monthly/Fortnightly/Weekly <sup>3</sup>		Integrated 10m
Hastings	Medium	Monthly/Fortnightly <sup>4</sup>		Integrated 3m

<sup>1</sup> winter = June to September, summer = October to May

<sup>2</sup> monthly between October and May, once only over winter

<sup>3</sup> winter = June to September, summer = October to May, weekly from mid February to mid May

<sup>4</sup> part of the D'Entrecasteaux network. Move to more frequent sampling if *Gymnodinium catenatum* is found in general area.

## Appendix 3

### 2012–13 PST event in Tasmanian — legislation and regulatory response actions

Sector	Legislation used for fishery closure	Lead agency	Date closed	Date opened	Comment/rationale
Abalone • Commercial farmed	<i>Public Health Act 1997</i> Export Orders DAFF	DHHS	5 November 2012	13 December 2012	Public health order to close exports from abalone marine farms located in the affected area.
Abalone • Commercial wild caught	Voluntary	DHHS	2 November (voluntary closure)		Liaison between DPIPWE, DHHS and Tasmanian Abalone Council Limited (TACL). TACL provided advisory information to divers not to harvest in blocks between Deep Glen Bay and Eddystone Point.
Abalone • Non-commercial	<i>Living Marine Resources Management Act 1995</i>	DPIPWE	23 November 2012		Following consideration of results of abalone samples collected from areas adjacent to Maria Island and consultation with DHHS, the DPIPWE determined to close the non-commercial abalone fishery between Marion Bay and Eddystone Point due to the potential human health risks.  Public Health warnings
				14 December 2012	Following consideration of analysis results of abalone samples taken from the area and in consultation with DHHS, DPIPWE acted to open the non-commercial abalone fishery between Marion Bay and Eddystone Point.
Clams • Commercial • Non-commercial	<i>Public Health Act 1997</i>	DHHS	2 November 2012	13 December 2012	As required by TSQAP — Public Health Order Non-commercial fisheries provided with public health warnings by DHHS
Giant crab • Commercial	<i>Living Marine Resources Management Act 1995</i>		24 November 2012		DPIPWE following consultation with DHHS acted to close the commercial giant crab fishery between Marion Bay and Eddystone Point due to concerns regarding the potential public health risk attendant with PST and serious market supply chain issues.
			25 December 2012		Based on the analysis of rock lobster samples collected from north of Eddystone Point and following consultation with DHHS, DPIPWE acted to close the commercial giant crab fishery between Eddystone Point and Banks Strait in the north and Waterhouse Island in the west.

## Appendix 3 (cont.)

Sector	Legislation used for fishery closure	Lead agency	Date closed	Date opened	Comment/rationale
<b>Giant crab</b> • Commercial (continued)				5 February 2013	On the basis of the analysis results of giant crab samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from with DHHS, DPIPWE acted to open the commercial giant crab fishery on the north east coast.
				13 February 2013	On the basis of the analysis results of giant crab samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from with DHHS, DPIPWE acted to open the commercial giant crab fishery on the section of the east coast from Marion Bay to St Helens Point.
<b>Oysters/mussels</b> • Commercial • Non-commercial	<i>Public Health Act 1997</i>	DHHS	2 November 2012	3 December 2012	As required by TSQAP — public health order
<b>Rock lobster</b> • Commercial	<i>Living Marine Resources Management Act 1995</i>	DPIPWE	Commercial rock lobster fishery was closed at the time PST concerns with respect to rock lobster identified		Following consultation with DHHS and the Tasmanian Rock Lobster Fishermen's Association, DPIPWE determined to delay the opening of the commercial rock lobster season due to the potential human health risks and serious market supply chain issues. The mechanism used to delay the opening was to close the fishery from the prescribed season opening date of 13 November 2012 on the section of east coast from Marion Bay to Eddystone Point
			22 December 2012		Following consultation with DHHS, the section of the north east coast north of Eddystone Point to Banks Strait and west to Waterhouse Island was closed to the commercial harvesting of rock lobster due to analysis of rock lobster samples collected from north of Eddystone Point returning PST levels above 0.8 mg/kg.

Sector	Legislation used for fishery closure	Lead agency	Date closed	Date opened	Comment/rationale
<b>Rock lobster</b> • Commercial (continued)			15 January 2013		Following consultation with DHHS, the waters north of Banks Strait and adjacent to the Furneaux Islands were closed for the commercial harvesting of rock lobster as a precautionary measure before samples were collected from the area for analysis for PST. This action was taken due to the experience gained from the closure of the section north of Eddystone Point to Banks Strait where rock lobster harvested from the area entered the supply chain despite warnings provided to fishers and processors that samples were being taken from the area and the implications if those samples were found to contain PST levels above 0.8mg/kg
				19 January 2013	On the basis of the analysis results of rock lobster samples collected in the area returning levels of PST less than 0.8 mg/kg, and having taken advice from DHHS, DPIPWE acted to open the commercial rock lobster fishery on that part of the east coast between St Helens Point and Banks Strait in the north and Waterhouse Island in the west
				25 January 2013	On the basis of the analysis results of rock lobster samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from with DHHS, DPIPWE acted to open the commercial rock lobster fishery in waters adjacent to the Furneaux Islands
				9 February 2013	On the basis of the analysis results from rock lobster samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from DHHS, DPIPWE acted to open the commercial rock lobster fishery in the waters between Marion Bay and St Helens Point

Sector	Legislation used for fishery closure	Lead agency	Date closed	Date opened	Comment/rationale
<b>Rock lobster</b> • <b>Non-commercial</b>	<i>Living Marine Resources Management Act 1995</i>	DPIPWE		Season opened as planned on 3 November 2012	DPIPWE closed the non-commercial rock lobster fishery on the section of the east coast between Marion Bay and Eddystone Point with the support of DHHS due to the concerns regarding risk to public health presented by PST.
			22 December 2012		DPIPWE, with the support of DHHS, closed the non-commercial rock lobster fishery north of Eddystone Point to Banks Strait and west to Waterhouse Island due to analysis of rock lobster samples collected from north of Eddystone Point returning levels of PST above 0.8 mg/kg.
				19 January 2013	On the basis of the analysis results of rock lobster samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from DHHS, DPIPWE acted to open the non-commercial rock lobster fishery on that part of the east coast between St Helens Point and Banks Strait in the north and Waterhouse Island in the west
				9 February 2013	On the basis of the analysis results of rock lobster samples collected in the area returning levels of PST less than 0.8 mg/kg and having taken advice from with DHHS, DPIPWE acted to open the recreational rock lobster fishery in the waters between Marion Bay and St Helens Point.  No PST related illnesses reported linked to the consumption of rock lobster.  Public Health warnings issued by DHHS regarding the consumption of rock lobster 22 November 2012

Sector	Legislation used for fishery closure	Lead agency	Date closed	Date opened	Comment/rationale
Scallops • Commercial	<i>Food Act 2003</i>	DHHS  DHHS	13 November 2013	Public health order not revoked	Retail samples returned PST exceeding acceptable levels 10 Nov. Public Health Warning issued 13 Nov. Not in TSQAP. Intention to harvest abandoned from 3 Dec with commercial season due to close on 31 December 2012 anyway.
Scallops • Non-commercial	<i>Public Health Act 1997</i>	DHHS	The non-commercial scallop fishery was not open at the time of the PST non-compliance event		
Sea urchins, periwinkles • Commercial	<i>Living Marine Resources Management Act 1995</i>	DPIPWE	24 November 2012		Commercial dive fishery between Deep Glen Bay and Eddystone Point closed by DPIPWE in consultation with DHHS based on assessment of public health risk relating to PST.
				14 December 2012	Commercial dive fishery between Deep Glen Bay and Eddystone Point opened by DPIPWE in consultation with DHHS based on the analysis results of samples collected from within the area closed.
Sea urchins, periwinkles • Non-commercial		DHHS			Public health warnings

<sup>1</sup> Includes recreational fishing and aboriginal cultural fishing



### Appendix 4

#### Executive summary and recommendations from the Cawthron Report No. 646 (2001)

[Extract from: *Model Australian National Marine Biotoxin Management Plan*, Cawthron Report No. 646, (2001) FRDC Project 1999/332]

Cawthron Report No. 645

Australian Marine Biotoxin Management Plan  
for Shellfish Farming

November 2001

#### EXECUTIVE SUMMARY

In Australia, as in many countries, aquaculture and wild harvest of shellfish is an economically important and growing industry. The safety of these products as a food source is of utmost importance from both public health and economic points of view. One of the potential problems faced by shellfish growers is the contamination of their product with marine biotoxins. These are chemical compounds (toxins) that are produced by specific naturally occurring marine microalgae. Most microalgae (a.k.a. phytoplankton) are actually an important food source of the shellfish. These biotoxins can induce human illness if contaminated shellfish are consumed. This is not only a problem for commercially produced or harvested shellfish; it is also a problem for recreational shellfish gatherers, for some of which this may be subsistence gathering.

Biotoxins are not only a problem for Australia, as most coastal countries in the world have had, or have the potential for, problems with marine biotoxin contamination in shellfish. In order to manage this problem, many countries have monitoring programs aimed at the detection of the species of microalgae that produce the toxins, and for the toxins themselves in the shellfish. Monitoring for the microalgae is a faster and cheaper test than shellfish testing, and may give an early warning of the potential for contamination of shellfish with marine biotoxins. However, the two types of testing need to be performed in conjunction with each other. Internationally, food safety regulations are based on the levels of toxins in shellfish, and it is these results that should generally be used for regulatory decisions. It is a common misconception that cooking or processing the shellfish in some way will remove the toxins and make the shellfish safe to eat, in some instances the toxin compounds can be converted into more toxic compounds by cooking.

Internationally the impacts of toxic microalgae on both public health and the economy are increasing in frequency, intensity and geographic distribution. As aquaculture expands, and its importance as both food and income sources increases for many countries, it is expected that these impacts will also increase. As international markets become more conscious of the safety of the foodstuffs they import, they impose safety regulations and can impose non-trade barriers.

Australia's shellfish industry's market has a large domestic component, with shellfish landings worth approximately \$90M per year. There is, perhaps, less external pressure on Australia to manage these problems. However the domestic market is large, and the consumers no less important than overseas consumers, and hence there remains the need for protection from marine biotoxins. There need to be controls in place between states, just as there need to be controls for exporting product. The USA has a similar political structure to Australia, with both state and national governments, and in order to protect the public health of shellfish consumers in other states, a model ordinance was implemented which all states must ratify to ensure meeting the standards set out in this document. This document is a voluntary agreement between states, and spells out the acceptable monitoring programs, controls and regulations that must be met in order to export shellfish to another signatory state. This model ordinance is fairly well accepted as an international standard for shellfish safety, along with the European Union directives, which must be met in order to export shellfish to the EU.

This report summarises the available information on:

- State marine biotoxin monitoring programs for cultured shellfish,
- Internationally recognised management practices,
- Methodologies for marine biotoxin analysis,
- The risk of marine biotoxins to public health,
- The microalgae posing the risk and their temporal and regional occurrences,
- The industries that are at risk, and • The food safety controls and regulatory mechanisms.

This report is in two part: Part A - A Review of Marine Biotoxin Management in Australia; and Part B - A Model Australian Marine Biotoxin Management Plan.

Currently Australia has no national guidance on marine biotoxin monitoring, although there are programs conducted in most states to varying degrees. One of the difficulties in implementation of a national strategy has been the lack of reliable information on and knowledge about the history of the occurrence of toxic microalgae and marine biotoxins in some shellfish growing areas. This project has involved a review of the monitoring programs and the history of potentially toxic microalgae for all the states. Victoria, Tasmania, South Australia and New South Wales have already experienced closures or human illness due to marine biotoxins. New Zealand has detected all temperate biotoxin producing microalgal genera, and has also found most of the tropical genera in the sub-tropical northern regions. The Australian coastline encompasses all climate zones and it is expected that all biotoxin producing species will be detected over time, and that they will bloom as conditions become favourable to them.

There is currently a lack of consistency in marine biotoxin management between the states, which must be addressed. For a national marine biotoxin strategy to succeed there needs to be commitment from all states to participate in and meet the requirements of the program.

One of the key aspects in successful monitoring programs is having ongoing research underpinning the program. There needs to be more investigation of the microalgae species that are present in Australian waters, including culturing them and testing for toxin production. It is only after this work is undertaken that action levels relevant to Australia can be set. In the meantime, action levels are based on international experience, and may not necessarily fit the Australian situation. Other important research that will strengthen monitoring programs is the investigation of the uptake, retention and biotransformation of toxins in shellfish; some species take up toxins more quickly, some depurate toxins more quickly, and some bio-transform toxins into different (and potentially more toxic) compounds. This research is on going internationally, and as more research is done, more questions are asked. Federal funding (eg Fisheries Research Development Corporation or Australia Research Council) is required for many of these research questions.

The funding of a monitoring program, however, is not the responsibility of such agencies. The costs of programs need to be shared by all users, which enhances the coverage of monitoring information, and reduces the direct cost for the industry. Internationally, shellfish safety tends to be managed by either Health or Fisheries Departments, however in Australia, the situation varies between states. There needs to be commitment and support from both state and federal governments, and in particular between fisheries and health agencies, but not excluding Environmental Protection Agencies, Sewage Authorities, Port Authorities, Aboriginal Commissions, and other stakeholders. Countries such as Canada, USA and New Zealand invest approximately 1-2% of the value of the industry in biotoxin monitoring. Currently Australia invests approximately 0.02% in biotoxin monitoring.

There needs to be the open sharing of data between all players in the monitoring, and this includes researchers. If there is a sharing of cost, then there also tends to be a sharing of information. One of the positive outcomes of this is that research can become targeted towards the real issues that the shellfish industry faces. In order to achieve this goal of openness, there need to be clear channels of communication, and roles and responsibilities clearly delineated. There also needs to be on going education of the industry, regulators and policy makers. A marine biotoxin monitoring program is a long-term commitment to protecting the public health of shellfish consumers, understanding more about the shellfish resource and assisting the industry to growing into the future. It requires regulatory commitment at federal and state government level to maintain and police biotoxin standards.

## RECOMMENDATIONS

- A Marine Biotoxin Monitoring Program (a model forms Part B of this report) is accepted and implemented nationally, and is included in the ASQAAC Program Managers manual.
- AQIS audits of the Shellfish Quality Assurance Program in each state or territory include auditing the marine biotoxin program against the Marine Biotoxin Monitoring Program.

### *Administration*

- An 'Australian National Biotoxin Program', a co-operative program requiring the support and commitment of the Federal Government and state and Northern Territory Governments, should be established either within or in close association with the Australian Shellfish Quality Assurance Program (ASQAP).
- The Ministerial Council on Agriculture, Forestry and Fisheries – Australia (AFFA), acting through the Standing Committee on Fisheries and Aquaculture (SCFA) (or the appropriate Standing Committee), should accept responsibility for the governance of the marine biotoxin issue.
- SCFA (or the other appropriate Standing Committee) should be strongly represented on the 'Natural Toxins Working Group' of the Standing Committee on Agriculture and Resource Management (SCARM), which would benefit the seafood industry by becoming more involved with the well-organised beef and grain industries.
- The Australian Shellfish Quality Assurance Advisory Committee (ASQAAC) should report directly to SCFA (or the other appropriate Standing Committee), not via a sub-committee of SCFA, to raise the profile of biotoxin management within Australia.
- ASQAAC membership should include representatives of commercial wild harvest shellfish industries (e.g. scallops and pipis).
- Biotoxin management sections (including Appendix VI 'Suggested Contingency Plan for Control of Marine Biotoxins') of the 'Operations Manual of the Australian Shellfish Sanitation Control Program' should be substantially revised and updated, especially to ensure that routine micro-algal monitoring and appropriate flesh testing is conducted.
- Agreements or Memoranda of Understanding concerning the interstate trading of shellfish, similar to that contained in the U.S. 'Model Ordinance' should be developed between the states and territories. All states and territories would then need to satisfy agreed standards in order to sell shellfish interstate.
- A national database of all microalgal, biotoxin, and related environmental data, and case history investigations, should be further investigated. This could be maintained by AFFA, and be funded by Federal Government.

### *Funding*

- Sufficient and equitable funding should be provided by relevant state government agencies (acting for “public good”) and by a levy on shellfish industries to implement an adequate biotoxin monitoring program in all shellfish harvesting areas.
- The roles and responsibilities of all Government agencies and shellfish industries should be clearly defined in each state to determine the basis for equitable funding contributions. A Premier’s Department or state Cabinet directive may be required to achieve the active participation of all relevant state government agencies in addition to the primary or lead agency.
- Other interested parties such as Environmental Protection Agencies, Water and Sewage Authorities, Port Authorities, Aboriginal Commissions and other relevant organisations should offer support and information sharing in future routine and contingency monitoring programs.
- Appropriate contingency funding should be available in each state to enable microalgal and biotoxin monitoring to be rapidly expanded in the event of a large toxic algal bloom.

### *Communication*

- Clear and open communication networks should be established both at national and state levels and written into management plans.
- A central state database (possible web based) must be established and maintained to store all the phytoplankton monitoring, biotoxin, related environmental data and suspected toxic shellfish poisoning case investigations.
- There must be clear definition of roles and responsibilities of all federal and state agencies involved in marine biotoxin monitoring.

### *Management Plans*

- For those states and territory that do not have a plan in place, a clear and comprehensive ‘Marine Biotoxin Management Plan’, which meets the needs of the state and is consistent with the requirements of the Australian National Biotoxin Program, must be implemented.
- For those growing areas in each state and territory that do not have a plan in place, a ‘Marine Biotoxin Management Plan’ relevant to that growing area, that includes routine (sentinel) monitoring and a contingency plan, must be implemented.
- All state monitoring programs and growing area management plans should be kept up to date and reviewed annually to ensure the plans are effective and reflect current operating procedures. All management plans should be audited annually as part of the SQAP AQIS audits.
- Pectenotoxins and yessotoxins should continue to be classified as DSP toxins, which have a regulatory limit of 20 mg okadaic acid equivalent/100 g as specified in the ‘Australia New Zealand Food Standards Code’. Internationally, there is a lack of epidemiological evidence on the human health effects of these toxins and their associated dose response characteristics. Draft EC guidelines have been released which set levels of 16 µg/100 g total content of okadaic acid, dinophysistoxins and pectenotoxins; and 100 µg yessotoxin equiv./100 g (See Author’s note page iv).
- Marine biotoxin controls for commercial wild harvest shellfish must be developed and included in the ASQAP requirements. Phytoplankton monitoring should be conducted weekly to be the most effective. This is the internationally accepted frequency, and should be increased when necessary due to blooms.
- Risk assessments should be undertaken for areas with no history of toxic algal blooms or biotoxins in shellfish. These assessments should involve weekly phytoplankton monitoring and shellfish monitoring for biotoxins and could involve sediment surveys for toxic algal cysts.

- In new areas, or in areas with little historic information, shellfish samples should be taken regularly (weekly or fortnightly) in association with water samples to collect data and increase knowledge of the area.
- Monitoring programs should include both routine phytoplankton monitoring and shellfish flesh testing. Regulatory decisions concerning the closure or re-opening of a shellfish growing area should be made based on flesh results. The phytoplankton data should be used to trigger further sampling and toxin testing.
- Regular and routine phytoplankton and biotoxin monitoring should be conducted to provide continuous public health protection.
- Biotxin safety limits documented in marine biotoxin management plans should conform to the regulatory limits specified in the 'Australia New Zealand Food Standards Code'. The Australia New Zealand Food Authority (ANZFA) standards are recognised internationally as having appropriate safety margins.
- All state and territory management plans should include closure and re-opening criteria for all marine biotoxins. Both sets of criteria, and guidelines for their application, should conform to the relevant requirements of the Australian National Biotxin Program.
- During a biotoxin event, as much information as possible should be collected, and should include phytoplankton and biotoxin monitoring data (including results from additional sampling), environmental data, and investigation reports on suspected poisoning cases.
- All states and territories should use a standard case investigation form for the investigation of suspected clinical cases of shellfish poisoning. A thorough investigation based on sound epidemiological principles should be followed in every case.
- Case investigation reports should be stored in a central state database along with phytoplankton, biotoxin and any other data pertinent to the investigation.
- The Northern Territory should develop a marine biotoxin management plan and a contingency plan to guide urgent management action in the event a biotoxin event should occur.
- NSW and Queensland should urgently implement routine phytoplankton monitoring and shellfish flesh testing in those growing / harvest areas where it is not already in place.
- Biotxin monitoring programs should have industry support, scientific input and direction from state government. Local shellfish industry members should be encouraged to play an active role in the implementation of all monitoring programs.
- Monitoring programs should be implemented for wild harvest shellfish industries and harvest areas not currently monitored in all states.

### *Education*

- Education and understanding of marine biotoxins is vitally important for all participants in a marine biotoxin monitoring program from industry personnel to program managers to regulators and policy makers.
- A regular meeting such as a workshop is a good forum for education. All parties should be invited such as research scientists, laboratory staff, program managers, industry personnel, regulators and other interested parties. People should be encouraged to give short presentations about their current work and issues of concern to them.
- Public education should be ongoing, in order to minimise the 'halo' effect of publicity of shellfish safety during marine biotoxin events.

### *Laboratories*

- An approval system for both laboratories and methods, in order to perform testing for the Monitoring Program is implemented for both phytoplankton and biotoxin laboratories. At a minimum this should be NATA accreditation, with additional market access requirements, e.g. USFDA, as necessary.
- Laboratories need to be able to offer expert advice, and have directly relevant training (e.g. attendance at UNESCO courses).
- Proficiency testing programs should be set up especially for the laboratory personnel involved in identification of marine microalgae.
- Biotxin laboratories need to participate in national and international inter-laboratory calibration programmes.
- There need to be more laboratories with a greater emphasis on marine phytoplankton. Laboratories need to clearly differentiate between NATA accreditation for freshwater and marine analysis.

### *Phytoplankton*

- Phytoplankton analysis needs to target all potentially toxic species.
- Many programs place a lot of emphasis on qualitative net tow sampling, which may fail to detect certain toxic species. Quantitative sampling methods such as bottle and hose sampling need to be implemented more widely.
- Sampling methods used should be standardised by all states, and training workshops should be held regularly to ensure accurate and consistent sampling.

### *Biotxin*

- Laboratories need to be able to analyse for all biotoxins, ensuring that all states have access to testing capability.
- Test results need to be available as soon as possible and freighting delays need to be minimised, in order for a management plan to work effectively.
- Management plans should incorporate testing for all biotoxins.

### *Research*

- A National research strategy should be put in place to avoid overlapping of research effort. Research priorities need to be established and funding needs to be made available to undertake the priority projects. This funding should come from Commonwealth agencies.
- Toxicity testing of cultured phytoplankton species needs to be undertaken for many species in all states.
- During marine biotoxin events, additional species of shellfish should be collected and tested to gain information about toxin uptake, retention times.



# Appendix 5

## DRAFT Seafood incident Response Plan (SIRP) Stand Down Review January 2013

### DRAFT Seafood Incident Response Plan (SIRP) Stand Down Review January 2013

#### Background

This review was conducted with SIRP participants following the implementation of the SIRP in response to an incident in November 2012 regarding the detection of PST in shellfish in E Tasmania. This incident was funded by SSA as the custodian of the process.

It is a requirement as part of SSA standing down the SIRP to review process and revise as necessary. Feedback was requested from participants to assess what worked in the SIRP and what needs to be improved as has happened on the 7 other occasions the SIRP has been implemented by SSA since 2001.

Feedback was received in response to these questions:

1. Timeliness of SSA's invoking the SIRP process and calling the initial conference
2. Interaction with industry and other SIRP members i.e. does industry want more or less support and involvement through a SIRP. The main areas of involvement cover open forum to allow communications through a teleconference and Fact Sheets so industry communicates a common message
3. Preference to meeting advices being distributed through Outlook Calendar or email or other
4. What areas need improvement with regards to the operation of the SIRP team and the responsiveness of SIRP plan?
5. Any other issues or comments

#### General Overview

The process was initiated as the PST detection in Shellfish was not just affecting Tasmanian trade but other states domestically and internationally. International market access restrictions were put in place by some countries with other countries making enquiries into the issue through DAFF. International orders were being cancelled. An international recall took place with Spring Bay Seafood. The issue and list of SIRP team was discussed with Spring Bay, FRDC and the SSA Chair; resulting in the initiation of the SIRP. The incident was seen as a high risk to the Australian seafood industry which required 'rapid response'.

Overall, the feedback was that SSA initiated the process in a timely manner, however, that the process was not flagged by the technical parties in the early stages as they had a lack of understanding of potential wider industry ramifications and a lack of belief that the SIRP needed to be initiated. The SIRP team put together reflected the situation and followed the agreed process reflected in the SIRP manual. This team was expanded due to apparent lack of communication downwards within the industry with SSA receiving many calls from consumers, retailers, distributors and fisheries and SIRP dysfunction in supporting the process with key facts to communicate to industry and media. Press releases were outputted out of most states by government and industry as a result and industry newsletters produced without formal output from the SIRP. Facts were verbally provided by the SIRP.

There seemed to be a lack of understanding of the impacts of timeliness of communications and a lack of general support to make them occur which is detrimental to an emergency management situation.

There also seemed to be a lack of understanding of the SIRP from participants which seemed odd when many of the „negative“ participants of SIRP had been involved in previous trials. Many calls of thanks were received by SSA by industry thanking them for the process as it had impacted their business and they had little to no understanding about what was going on. SSA have the contacts across industry groups nationally and internationally to facilitate the process.



The general consensus was that meeting advices be distributed through both Outlook Calendar and email, due to the fact that some people don't use the Outlook Calendar.

The unique approach taken in the SIRP is that it facilitates effective participation across state and territory boundaries and gives each participating industry a 'real voice' to protect the domestic and international market. However, some feedback indicated that the incident should have been dealt with locally at state level and provide clearer information to the public that it wasn't a national incident.

It is important to keep a key group of affected stakeholders. It was suggested to keep the group smaller and more relevant. This would work if a Fact Sheet was an output by the SIRP. Whilst SSA's EO did take a timely step in providing an industry-wide communication platform, SSA's role in managing this SIRP did not appear to be clear to either industry at large or the regulators and science providers involved. They were not supportive of the process and lacked commitment to SIRP. This made it difficult to make the SIRP fully effective and ensure objectives were achieved.

One of the things that was extremely difficult was managing the event and trying to get information out to this forum at the same time. A better way needs to be found to enable this to happen. Appropriate technical experts should be brought in to create the fact sheets if the technical expert is unable to contribute effectively and ensure the communications are technically correct. An icloud environment where all key people can input into updates as they occur and input into amendments on documentation would be useful.

It is also clear that any SIRP broadly involves two streams of communication; a stream of formal and rigidly formatted communication from government agencies relating to human health and trade issues, and a less formal stream of information aimed at keeping both directly involved and potentially affected seafood industry informed of developments. SSA needs to be extremely cautious as to whether anything emanating from SSA could be considered to be SSA information or advice on human health or trade issues.

Each incident is different and it is difficult to have a planned response that works in every situation. In this case, the fact that the SIRP had been mobilised and the team in place meant that, if there was to be a severe escalation of the incident, the team, was ready to deal with the issue appropriately.

Funding for trials was supported by FRDC, however, funding for the actual event was non-existent in this event so was supported by SSA.

SSA had no direct funding to perform this activity however SSA has a very good understanding of incident response procedures having developed the initial Seafood Incident Response Plan (Seafood Emergency Plan) in 1998 and having been the custodian of the plan since that time.

#### RECOMMENDATIONS FROM SIRP PARTICIPANTS

1. There should be a contractual arrangement that brings together the commonwealth, state and territory governments and seafood industry groups to collectively and significantly increase Australia's capacity to prepare for, and respond to, emergency incursions to manage domestic and international trade. This would ensure commitment to the process of the SIRP.
2. SIRP needs a multilateral agreement with the NSIA and DAFF that SSA is the custodian. This agreement needs to sort out roles and responsibilities and a funding source. Changes in the PIERD Act may provide for funding or a cost sharing initiative by government and industry could be defined.
3. Training is an essential part in ensuring the efficiency of a response. SSA should continue to provide the trials with funding from FRDC.
4. SSA work with a PR Consultant within the SIRP to manage communications.

**Author:** Olivia Callinan  
Independent Consultant

Question	Comments
1	Timeliness was good however there was room for improvement in getting a clear picture of the facts assembled and articulated well. Need to get facts out on the table and communication to a wider group of people.
	Despite enthusiasm and commitment of SSA didn't think chairing it nationally achieved anything. It was a state issue and would have been easier to deal with those within the state rather than having to go through teleconference. While it may have helped others interstate a smaller group of perhaps 6 people within the state would be better. From a practical time consuming point of view, it should have been handled within the state.
	Time delay within an organisation in getting information due to CEO being informed initially and delay in information filtering through caused delay in relevant people being involved.
	Timeliness was ok but a bit slow. An action plan needs to be put in place so when an incident happens customers can be advised in a way that is understandable. Customers had misinformation. Some areas (states) brought into this were not affected by the incident. It was a localised issue and should be kept localised to whatever area or state is affected and it should be advised that other areas are fine. However this took 2-3 weeks to be released to the public. The Government needs to come out and state the facts exactly rather than giving impression that all areas are affected. Something official needs to be released to customers. System was lacking in some ways.
	On Wed 31st Oct, detection of PST in shellfish in E Tas 'announced' by DAFF.  On Mon 5th Nov, acting on SSA's historic custodianship of SIRP (but without specific mandate) SSA EO called a teleconference for 6th Nov.  To date SSA has hosted a total of five teleconferences, and is scheduled to hold one more on Wed 20th Dec which hopefully will be the last one, at which this particular Incident Response will be stood down.  During this process SSA drafted an Incident Fact Sheet, and maintained an Incident Running Sheet and Teleconference Notes.
	As I understand the situation, Michelle invoked the SIRP immediately that SSA became aware that there was an incident with trade implications and a teleconference with all key stakeholders invited to participate. This is essentially a requirement under the SIRP.
	Timeliness was good. SSA handled it very well.
2	Same support of more if possible. Amount of industries affected was large and level of support was good. Was well done.
	Worked very well, good representation from Government and industry and open communication.
	Need to be kept informed. Need to be part of the teleconferences.
	There seemed to be a lack of understanding of the SIRP from participators which seemed odd when they had been involved in previous trials. Many calls of thanks were received by SSA by industry thanking them for the process as it had impacted their business and they had little to no understanding about what was going on. SSA have the contacts across industry groups nationally and internationally to facilitate the process.

2 (cont.)	Each incident is different and as such the response to the incident is determined on a case by case basis. In some situations, the Seafood Incident Response Team can be two or three people who then distribute information. In this situation, it was seen as important to share information with all key stakeholders through a teleconference. Looking through the list of participants, all relevant stakeholder groups from technical advisors, industry peak body leaders, government, and affected seafood businesses were involved or invited. At the 2012 Trial of the SIRP, the message was received loud and clear from the seafood industry that they would appreciate support in the event of an incident. That message was heeded by the custodians of the SIRP and industry was invited to participate in the teleconferences.
	One of my key learnings was that very quickly the regulator is in control ie. industry is a partner/facilitator; and (2) limited capacity in public health and fish disease areas ie. time poor. So the all generic work, eg facts sheets need to be done ahead of time. This will enable the regulatory to focus on providing real time data and issue management. Both of these learnings are a potential source of tension or conflict.
	SSA used its trusted networks and convening power to provide effective communication and information flow.
	Industry need to commit to the process and take all reasonable steps to minimise the risk of the occurrences in the first place. It is understood that Safefish are reviewing whether the testing and sampling processes are sufficient to manage the situation.
	Level of support was good, same level required again. If it happened again they will be more prepared.
3	No real preference but probably email.
	Both email and outlook calendar
	Would prefer Outlook Calendar but from experience can be a problem due to software issues and some people don't use calendar so email needs to be used as a backup
	Email would be preference.
	Greater attendance occurred through calendar where attendees were confused about days and times and missed the information when dispatched through general email.
	I have no great feelings one way or another but for me personally; I would prefer meetings to be logged in my Outlook Calendar
	Definitely through outlook
	Either method is good.
4	Responsiveness was well done. All went well for first time round.
	More clarification on the distribution as they dropped off the list a few times. Clear distribution up front is needed and also ensure reports are distributed.
	This unfamiliarity with the SIRP, together with the ad-hoc calling of meetings at short notice, created some angst among both Industry and Regulator parties who were either directly involved or felt they should be involved in this Response.
	There is a view amongst SSA Directors (and perhaps Members), that SSA should not undertake generic industry-good projects such as SIRP unless SSA is specifically funded to do so.

4 (cont)	<p>I think some modifications need to be made to <b><u>SP-3 Seafood Incident Response Checklist</u></b> to make some actions clearer. E.g. it should be made clear that not all steps have to be completed and it is legitimate to mark Not Applicable.</p> <p>It should, however, be very clear that completing <b><u>SP-2 Seafood Incident Response Plan Incident Running Sheet</u></b> is a must. This becomes a valuable historical document. This fact was reinforced at the 2012 Trial and recommended amendments to the form incorporated.</p> <p>I believe that the team functions that were agreed to at the 2012 trial worked quite well even though persons were not specifically appointed to the role (eh Technical advice function, etc)</p> <p>It was disappointing that a Fact Sheet was not available quickly as this is a key document to have ready. I was a participant at the first teleconference where a group was established to develop a fact sheet but to my knowledge one did not eventuate.</p> <p>It is crucial that a fact sheet be available immediately for distribution through media channels and to affected seafood peak bodies and businesses so that a common message is being stated.</p> <p>One additional step that should be included in the checklist is “Identify key stakeholders to participate in the teleconference/ briefing. This was essentially what happened but should be captured as a learning.</p>
	<p>It is unreasonable to expect the people dealing with the event to have the time to create or substantially edit these documents. Communications need to be carefully checked against those originating from the state concerned.</p>
	<p>SIRP needs a multilateral agreement with the NSIA and DAFF that SSA is the custodian. This agreement needs to provide sort out roles and responsibilities and a funding source to (1) maintain databases, preparedness of the industry and coordinate the SIRP in the case of any event; (2) prepare and maintain technical generic facts sheets for all likely food recall scenarios; (3) review the effectiveness of any use of the SIRP; (4) contacts business support and advisory/counselling services should the industry require them and (5) Awareness raising of the SIRP.</p> <p>The custodian needs to foster a relation with Animal Health Australia to build its emergency response capability.</p> <p>Appointments by email and outlook at least 48 hours notice, if possible.</p> <p>SIRP coordinator needs technical background and/or training in public health and fish disease matters to support them in chairing the meetings.</p>
	<p>There needs to be whole lot more collaboration and sharing of knowledge if things are to be improved. Every producer and every government official who is likely to be engaged should have it very clear in their mind of what needs to happen, so that processes are followed without question.</p>
	<p>No criticism of team at all, did very good job.</p>

5	Emails might have been a bit late in being received and teleconference was missed.												
	It worked very well and was one of the best she has been involved in.												
	<p>SSA initiated SIRP as it is the custodian of the process and is part of its business strategy, see <a href="http://Seafood.net.au/Safety">Seafood.net.au/Safety</a>.</p> <p>Suggested funding can be likened to safemeat whereby:</p> <p>Cost Sharing: Government Industry Funding</p> <p>Parties will apply Funding</p> <p>Principles of Cost</p> <p>Sharing for the</p> <p>Conduct of an SIRP</p> <p>In accordance with</p> <p>The following table:</p> <p>Category of</p> <p>Disease:</p> <table data-bbox="300 1167 689 1346"> <tr> <td>Category 1</td> <td>100%</td> <td>0%</td> </tr> <tr> <td>Category 2</td> <td>80%</td> <td>20%</td> </tr> <tr> <td>Category 3</td> <td>50%</td> <td>50%</td> </tr> <tr> <td>Category 4</td> <td>20%</td> <td>80%</td> </tr> </table> <p>This can be included into agreements across industry to support the SIRP. It is recommended that yearly trials occur funded by FRDC to keep industry „buying into“ the process and to redefine the SIRP.</p> <p>A further explanation of the cost sharing initiative that should be initiated: Whereby all parties commit to contribute to funding the eligible costs of responding to an SIRP. Some of the rules around cost sharing can be summarised as follows:</p> <ul data-bbox="368 1570 1364 1908" style="list-style-type: none"> <li>• Cost sharing is aimed at equitable contributions from all parties, commensurate with their respective resource base and status as a beneficiary of the response.</li> <li>• The total amount of response costs that government and industry parties share in the event of an SIRP is capped, depending on the size of the affected industry.</li> <li>• SIRPs are categorised according to the impact they can have on industry (through, for example, international trade losses, domestic market disruptions and production losses), human health and the environment. A SIRPs category determines how much of the response costs are borne by affected industries in aggregate, and how much by governments.</li> </ul>	Category 1	100%	0%	Category 2	80%	20%	Category 3	50%	50%	Category 4	20%	80%
Category 1	100%	0%											
Category 2	80%	20%											
Category 3	50%	50%											
Category 4	20%	80%											

	<p>SSA has done a commendable job in developing the SIRP, the stated purpose of which is to:</p> <ul style="list-style-type: none"> <li>• provide a proactive, easy-to-follow response to adverse incidents in the seafood industry</li> <li>• maintain Australia's reputation as a provider of safe, high-quality seafood to its customers</li> <li>• strengthen consumer confidence in Australian seafood.</li> <li>• (taken from May/June 2012 draft of the SIRP document)</li> </ul> <p>However, these are very broad aims, clearly requiring involvement of a number of organisations and agencies as well as varied expertise and significant funding.</p> <p>With that backdrop and taking into consideration SSA's current situation:</p> <p>1. What exactly is SSA's role in the custodianship and future deployment of a SIRP?</p> <ol style="list-style-type: none"> <li>a) Commit to custodianship and future deployment of the SIRP? (Resourcing?)</li> <li>b) Modify SSA's role to simply providing a teleconference meeting facility for interested parties in future SIR deployments? (ie. no responsibility for outgoing communications).</li> <li>c) Hand over entire SIRP to another entity?</li> </ol> <p>2. If option a) is considered, then significant additional resources must be found, for the purposes of:</p> <ol style="list-style-type: none"> <li>a) Better defining SSA's and other agencies role in deployment of a SIR</li> <li>b) Improving standard and process of communication relating to deployment of a SIR</li> <li>c) Communicating the above to a wide audience, repeatedly over time</li> <li>d) Engaging in periodic simulations of SIR's</li> <li>e) Maintaining a periodic review of the SIRP</li> <li>f) Etc.</li> </ol> <p>3. If option a) is considered, then where would the required funding come from?</p>
	<p>I understand that SSA had no direct funding to perform this activity but SSA has a very good understanding of incident response procedures having developed the initial Seafood Incident Response Plan (Seafood Emergency Plan) in 1998 and having been the custodian of the plan since that time.</p>
	<p>I appreciate that the communications were needed at the wider industry level, but it added substantially to my workload at the time. From the SIRP perspective it also creates a bottleneck, slowing the process down.</p>
	<p>I believe it to be an essential tool for everyone when such a crisis hits.</p> <p>Despite the funds spent on the Workshop(s) – there is still an amazing lack of understanding about how the system should operate.</p>
	<p>Perhaps Department of Fisheries could have done more and been more involved.</p>
	<p>This is definitely a job for SSA in looking after the SIRP in my book but without regular funding and agreement on yearly and longer outputs/outcomes then it would seem the whole thing will die in a ditch. Shame, shame, shame....</p>

## Appendix 6

### Feedback from international shellfish safety experts who attended the International Conference on Molluscan Shellfish Safety (ICMSS) workshop (March 2013)

**From:** Joe Silke  
**Sent:** 25 March 2013 12:20  
**To:** 'Turnbull, Alison R (DHHS)'  
**Cc:** 'McLeod, Cath (PIRSA-SARDI)'  
**Subject:** RE: sample frequency

Hey Alison

Monday morning here in Ireland, and am I so not going in to the office today !! A week flies and the whole conference was a blur with so many new ideas and concepts, renewal of old friendships and establishment of new ones. It was truly a great conference and ICMSS has proven once more to be the most relevant meeting for us on the regulatory / and on the development side for shellfish safety issues. For Australia to host the conference was very timely, with the recent droughts and floods indicative of serious change, of which the marine environment is a sensitive herald. Whether PSP in Tazzie associated with this climate upheaval is too soon to know, but look at the CO2 you tube video in Anthony Richardsons presentation and the message is loud and clear that there are major and rapid changes occurring, and on the regulatory side we need to be on alert to 'predict' what is around the bend as far as possible.

Regarding the round table on the Tassie outbreak, it was one of the most useful sessions of the week for me. Pity about the shortage of time for discussion but it was a big story and the review group that has been established is a great idea and will no doubt come up with useful advice on the event and how to assign appropriate controls going forward. Budgets are tight everywhere, but as you have seen a single event can cost many times the annual cost of running the entire program.

Ireland is around the same size as Taz but with a population some 8 times as many here, the shellfish aquaculture industry has taken off here in the past 30 years with a value of some 50 Million € per annum, located in sheltered coves and bays around the coast. As I showed on my presentation (attached) we do have a PSP problem here in Ireland, but I didn't spend much time on it because, so far, PSP is one of our small problems compared to the other shellfish biotoxins. To explain how we control it:

PSTs have been detected above regulatory levels of 80 ug several times since testing commenced on a regular basis in 2000, but fortunately restricted to one shellfish production area (Cork Harbour). Between 2000 and 2010 the PSP Mouse Bioassay was conducted, sometimes with additional Jellet Rapid Test strips (which we stopped because of some QC discrepancies). Since 2010 we have introduced the Lawrence method and that has replaced the MBA. Before 2000 MBA were only conducted in response to Alexandrium in Cork Harbour and rarely in other locations.

Because of the serious nature of PST around the year 2000 we reviewed the situation and decided that Phytoplankton was a useful indicator of potential toxicity, but supplementary controls were required. These changes made included:

- Supplementary additional weekly flesh testing during an assigned summer high risk period. We have only detected PST in shellfish in the month of July, but this high risk period was extended out from May until late September to be sure.
- An additional 13 sites (sentinel sites) were selected from our 60+ shellfish test sites for weekly flesh tests in addition to Cork Harbour.
- Phytoplankton testing is carried out from all (60+) shellfish growing areas and in response to detection of *Alexandrium* we request further flesh samples to be submitted.
- This year (2013) we are for the first time assigning a trigger level of 200 cells per litre before flesh will be requested, because we have enough history to show that this is safe, and will reduce the number of flesh tests considerably.



- If any area other than Cork goes above 80ug, in the future, that area will be assessed to decide whether it is a high risk area and should be tested to the same extent as Cork.

Regarding the discussion around whether it is toxic or non toxic tamarensis, fundyensis or any other species is interesting, but from a regulatory perspective we do not await confirmation of the species, once it is detected as Alexandrium sp. we go to alert status and get samples of flesh. We have the facility to carry out PCR to ID cells to species level, but rarely do this unless there was an unusual occurrence.

My own advice on what you are doing is good but I would seriously suggest that rapid turnaround flesh tests are also required at a higher frequency than monthly. The reason for this is twofold.

1. The levels of up to 8000+ cells per litre of Alexandrium that were detected seem very low to explain the event. If I saw 50,000 cells or more I would have been more satisfied that the Phytoplankton in some way "caught" the event, but I think that you missed the Phytoplankton trigger and just saw either the tail end of it, or were in the wrong place. There was possibly a bloom with a concentration in millions cells/l somewhere that made these shellfish toxic. This is not a criticism, you did everything right at the time and these comments are with the benefit of hindsight. Using Phytoplankton is not bulletproof and should be treated as additional information rather than your primary alert, particularly in the location(s) where PST exceeded 80ug.
2. High frequency flesh testing can be either temporal or spatial (or both if you can afford it). This will pick up low levels of the toxin at the onset of the bloom and using the HPLC will give head up information of an impending event maybe with a few vital days forewarning to take precautionary action, or to go to full alert and intensive testing. Perhaps the "sentinel site" approach would be useful in Taz if they are carefully selected and distributed at the highest risk areas around the coast. In any case I would suggest weekly testing during risk periods in particular at sites that were already toxic in the past season

Finally ... one other piece of the jigsaw that would be useful is a survey of Cysts in the sediment. There was some discussion that this was a shelf edge source, if that is the case, it would be beneficial to identify where the likely source is, and this can assist you in assessing risk and developing control measures. The offshore location of Phil Lambs farm is very interesting because I would have expected there is a good flushing of water through the site, suggesting the phytoplankton were advected into the area rather than from a local cyst bed.

So there you have it ! hope all goes well and I look forward to seeing how the unfortunate issues you have experienced are part of the solution you come up with. One small request... would it be possible to have a copy of your presentation on the Tazzie PST, I think it is relevant to our own situation here and would like to show some of the slides to some of my colleagues here.

Best regards

Joe

**From:** Jim Sim (Jim)  
**Sent:** Thursday, 28 March 2013 9:59 a.m.  
**To:** Turnbull, Alison R (DHHS)  
**Cc:** Brian Roughan  
**Subject:** RE: sample frequency [BT]

Hi Ali

Our experience suggests that phytoplankton samples should be taken weekly – even then, as you have found out, occasionally low cell counts of toxic species are missed (Or misidentified.) We do plankton weekly both in our commercial and non-commercial programmes. Plankton is a less reliable indicator of problems than shellfish testing – but it is a lot cheaper.

In the commercial programme we have quite strict rules on flesh testing frequency. These are set out in our BMS specifications which I have sent you previously.

Areas where we have had previous problems from a toxin above regulatory limits = weekly flesh samples for testing for that toxin

Areas where toxins have been detected below regulatory limits = fortnightly flesh samples for that toxin

Areas where toxins have not been detected are on a minimum of monthly flesh sampling to verify the phytoplankton data.

The shellfish specialists have scope to move from these if justified but it's hard to justify.

In the non-commercial (Public Health) programme we follow the same principle but focus on PSP problem areas and in order to save money we alternate the flesh sample points week and week about so every second site is sampled in a given week with plankton samples covering some areas that are typically harder to get regular shellfish samples from. This provides for at least some flesh information from an area every week and as soon as something undesirable is spotted in the plankton or flesh all sites are sampled every week. It would be ideal to have every site sampled every week but \$\$\$\$\$ rule and the non-commercial programme is more about detection of wide scale events than managing specific shellfish harvesting areas. The non-commercial programme generates public warnings rather than food recalls too so the risk from levels just over regulatory can be factored out..

If your goal is to avoid food recalls I'd suggest weekly flesh sampling in areas you have had problems – especially now you have instrumental analyses available so should see trouble brewing along with weekly phytoplankton. If its public health then you might like to consider the approach we use in our non-commercial programme.

Kind regards

Jim

### Appendix 7

#### Proposed case definition for PSP cases

[Extract from: *Updated summary of interviewed cases reported to DHHS and followed up in response to the Spring Bay Mussel Recall (20/11/12)*]

**Possible case of Paralytic Shellfish Poisoning (PSP), recall related:** A person who reports eating Spring Bay Mussels between 21/10/12 and 18/11/12, with the mussels consumed being one or more of the products detailed in the current recall notice (with the relevant use by dates), and who experiences an alteration in sensation (numbness or tingling of the mouth, or face, or legs or arms) and muscle in-coordination and/or muscle weakness of the limbs (within 15 minutes to 12 hours of eating the product concerned).

**Possible case of Paralytic Shellfish Poisoning (PSP), non recall related:** A person who reports eating any Tasmanian grown shellfish which are not part of the current recall and who experiences an alteration in sensation (numbness or tingling of the mouth, or face, or legs or arms) and muscle incoordination and/or muscle weakness of the limbs (within 15 minutes to 12 hours of eating the shellfish).

These working case definitions are sensitive but non-specific, and that the probability that a report which meets the criteria above for a “possible case of PSP” is true PSP depends on a report-by-report evaluation of:

- a. the symptoms described in the proposed case definitions,
- b. other symptoms that may increase or reduce the likelihood of true PSP, and
- c. other plausible differential diagnoses (of toxic, microbiological or other cause), and whether there is evidence for or against these possibilities. Testing faeces for viruses is particularly useful if this is a possibility (as it often will be).



