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**Department of Agriculture,
Fisheries and Forestry**

INTERIM INSPECTOR GENERAL OF BIOSECURITY

**An examination of biosecurity controls associated with the
export from Australia of live abalone to
China and Hong Kong**

**INTERIM INSPECTOR GENERAL OF BIOSECURITY
INCIDENT REVIEW**

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Contents

Executive summary	4
Objective	4
Scope	4
Key findings	5
First reported incident in Australia of PST-affected abalone	5
Recent recurrence of toxic algal bloom in Tasmanian waters	5
No breach of any legislative requirements for live abalone exports	6
Incidental discovery of harmful levels of PST in abalone	7
Response of Tasmanian state authorities to the discovery of PST in abalone	7
Involvement of the abalone industry in the incident and in management of future risks	8
Role of DAFF in managing the risks	8
Revised import conditions in China	10
Further research on PST in abalone	10
Recommendations	11
Conduct of incident review	12
Role of the IIGB	12
The IIGB's program	12
Methodology	14
Out of scope	14
Background and context	15
Australian abalone industry: production and export	15
Tasmanian abalone sector	15
Paralytic shellfish toxins	15
Human health risks from ingestion of PST-affected shellfish products	16
Standards for PST levels in shellfish destined for human consumption	16
Australian abalone export sector and the role of DAFF	17
Legislative arrangements	17
DAFF approval processes for exporters	17
DAFF's certification processes for abalone exports	19
Monitoring and management controls for shellfish growing areas in Australia	20
Australian Shellfish Quality Assurance Program (ASQAP)	20
Tasmanian Biotxin Management Plan (for bivalve molluscs)	20
The incident	22
Sampling and testing procedures and results	23
Response by importing countries to the incident	23
Resumption and suspension of Australian abalone exports	23
Observations and findings	25
Risk management measures undertaken by DAFF following detection of harmful levels of PST in abalone from bloom-affected catch zones	25
Export of one live abalone consignment to Hong Kong after suspension of export	27
Australian standards and testing for PST in abalone	27
Chronology of events	30
Appendix A Abalone catch zones in south-east Tasmanian waters	32
Appendix B Approved arrangements	34
Appendix C Photographs and illustrations of live and processed abalone	35
Appendix D Legislative arrangements and assurance programs	38
Appendix E Tasmanian abalone fishery	39
Appendix F Tasmanian Shellfish Quality Assurance Program (TSQAP)	40
References	42
Glossary	43

Figures

Figure 1 List of stakeholders consulted	29
Figure C1 Live Australian blacklip abalone	35
Figure C2 Abalone body and shell	35
Figure C3 Anatomy of an abalone	36
Figure C4 Abalone foot	36
Figure C5 Abalone cleaned of its gut	37
Figure D1 Shellfish quality assurance model	38
Figure E1 Abalone: quota managed fishery (Tasmanian model)	39

Maps

Map A1 Abalone fishing region, south-east Tasmania	32
Map A2 Catch reporting blocks and sub-blocks, south-east Tasmania	33

Executive summary

At the request of the Minister for Agriculture, Fisheries and Forestry, the Interim Inspector General of Biosecurity (IIGB) included in his 2011–12 audit work plan an incident review to examine the biosecurity controls associated with the export from Australia of live abalone that may have been contaminated by paralytic shellfish toxin (PST).

Objective

This incident review was undertaken to examine biosecurity/sanitary controls associated with the export, from Australia to China and Hong Kong, of live abalone consignments that may have contained harmful levels of PST.

Scope

The review examines the activities of Department of Agriculture, Fisheries and Forestry (DAFF) as they relate to biosecurity controls associated with export from Australia of live abalone, including:

- export procedures, operations and documentation, such as permits, certifications and declarations
- import conditions imposed by China and Hong Kong on Australian abalone products
- biosecurity and related human health risks (excluding IIGB analysis of samples), including the likelihood of severe human health issues arising from the ingestion of PST-affected abalone products
- whether improvements are required to Australia's export procedures, operations and documentation for abalone and other relevant fish and other fish product consignments to mitigate the risk of biosecurity, quarantine and human health risks from PST occurring in the future.

This incident review focuses on circumstances surrounding the export, from Australia in April and May 2011 to China and Hong Kong, of live abalone that may have been affected by harmful levels of PST. The abalone of concern in this incident were sourced from the D'Entrecasteaux Channel in Tasmania. Maps indicating the location of the channel and the area where the affected abalone were harvested are at Appendix A.

Under the *Australian Export Control Act 1982*, fish and fish products for export must not be sourced from areas where there are reasonable grounds to believe that potentially harmful pathogens or potentially harmful substances, such as pesticides, fungicides, heavy metals, natural toxicants or other contaminants are present and could result in unacceptable levels in the fish and fish products.

During this review, the IIGB consulted stakeholders and examined appropriate documents (Figure 1). Findings and recommendations are based on the analysis of documents, in-person and telephone interviews, and discussions with an expert and several stakeholders in Hobart and at the South Australian Research and Development Institute (SARDI) in Adelaide.

Key findings

Several stakeholder organisations are involved in the management and export of abalone. A lack of clear documentation about how DAFF interacts with these stakeholders poses difficulties for anyone seeking assurance that PST risk management is effective in the abalone industry. This review includes IIGB recommendations aimed at enhancing DAFF's export certification and verification processes.

First reported incident in Australia of PST-affected abalone

Before the April and May 2011 export incident, levels of marine biotoxins in abalone harvested in Australian waters were considered safe for human consumption. However, on 20 May 2011 DAFF was advised that, following a localised algal bloom in the D'Entrecasteaux Channel in Tasmania (Map A1), harmful levels of PST had been detected in abalone sampled from the area. It is believed that the algal bloom elevated levels of PST in abalone harvested in the D'Entrecasteaux Channel, making the abalone unsuitable for human consumption.

The finding was the result of an industry-initiated surveillance project. It is the first reported and documented incident in Australia involving PST detection in abalone intended for live export.

DAFF immediately announced a temporary suspension of live exports of abalone from affected fishing areas.

However, on 23 May 2011, in contravention of the suspension order, an exporter sent an additional consignment of 384 kilograms of live abalone to Hong Kong. DAFF initiated regulatory action against this exporter.

Between 21 April and 20 May 2011, 14 consignments of live abalone harvested from the D'Entrecasteaux Channel had been exported to China and Hong Kong. Nine of the consignments (4824 kilograms) went to China and five (2904 kilograms) to Hong Kong.

Recent recurrence of toxic algal bloom in Tasmanian waters

The IIGB notes that the D'Entrecasteaux Channel (and adjacent marine waters) is the one location in Tasmania where the issue of PST in abalone is of concern. In April 2012 another toxic algal bloom in that area resulted in suspension of live abalone exports.

A public health alert issued by the Tasmanian Department of Health and Human Services (DHHS) in April 2012 warned against eating the gut of wild abalone from Port Esperance, Hastings Bay (Southport) and the coastline between (Map A1).

By June 2012 the algal bloom had extended to the Huon Estuary, including Port Cygnet, and along the west coast of the D'Entrecasteaux Channel through Port Esperance to Southport and Hastings Bay. An updated DHHS public health alert advised against eating wild abalone from Port Esperance. The alert stated that abalone from other areas was safe to consume if the gut was first removed (Figure C5).

Following the algal bloom in 2012 exports were suspended for live/whole, chilled and frozen abalone—with or without viscera (gut and reproductive organs)—sourced from catch zones

14A, 14B, 14D, 14E and 15 (Map A2). As of 11 May 2012 these catch zones remained closed for abalone export.

No breach of any legislative requirements for live abalone exports

The IIGB notes that the April and May 2011 incident involved no breach of any existing legislative requirements for exporting live abalone to China and Hong Kong. Under the Export Control (Fish and Fish Products) Orders 2005, DAFF has an obligation to facilitate trade by ensuring that exports of live abalone:

- are fit for human consumption
- have a complete and accurate trade description and their integrity is assured
- meet import country requirements
- are accurately identified for effective traceability and recall, if required.

The Orders require fish and fish products intended for export for human consumption comply with food standards specified by the Australia New Zealand Food Standards Council (ANZFS), such as Standard 1.4.1: Contaminants and Natural Toxicants. The exception is where the importing country specifies a food standard that is different to the ANZFS code.

At the time of the incident, neither China nor Hong Kong had standards for PST levels in abalone. There was consequently no requirement for testing or other specific controls for marine biotoxins in abalone exported to these markets from Australia.

Australia does not have a regulatory standard for PST levels in abalone. The ANZFS and the Australian Shellfish Quality Assurance Program (ASQAP) Export Standards 2004 define shellfish as all 'edible molluscan bivalves'. It is an Australian standard that these animals be sourced from classified areas that have routine maritime biotoxin monitoring programs in place. The standard is a maximum PST level of 800 µg/kg. However, both the ANZFS code and ASQAP exclude univalves, such as abalone, from their definition of shellfish.

With regard to the abalone consignments involved in this incident, the registered exporters were responsible, under Approved Arrangements (Appendix B), for ensuring that food safety requirements were met. Each registered export establishment operates under an Approved Arrangement that sets out its quality management system. DAFF assesses and audits Approved Arrangements to ensure production of safe food. Food safety standards with regard to biotoxin in seafood (other than abalone) are specified in the ANZFS code, while other provisions are specified in the Export Control (Fish and Fish Products) Orders 2005.

The IIGB notes that this incident and research findings to date underscore the need for further research into PST and other marine biotoxins in abalone. Further research may identify a need to extend the standard to univalves such as abalone, especially those sourced from the D'Entrecasteaux Channel and adjacent marine waters. DAFF, as a national stakeholder in setting ANZFS standards, should continue to monitor developments in this area, especially in view of the abalone industry's export focus.

Incidental discovery of harmful levels of PST in abalone

In late November 2010 a *Gymnodinium catenatum* algal bloom was detected in the lower reaches of the Huon Estuary in Tasmania. By mid-March 2011 the bloom had extended further downstream into the D'Entrecasteaux Channel. Results of laboratory testing of bivalve shellfish by DHHS under its Tasmanian Shellfish Quality Assurance Program (TSQAP) confirmed the presence of significant levels of PST. Under TSQAP arrangements, harvesting of bivalve molluscs for human consumption was suspended from the affected areas.

Since November and December 2010 researchers at SARDI had been periodically sampling abalone in the D'Entrecasteaux Channel, in off-channel embayments and along the southern shore of Bruny Island as part of a project it was undertaking for the Abalone Council Australia Ltd. Results provided to DAFF on 20 May 2011 showed significant levels of PST in the sampled abalone, with the highest readings being in the viscera and foot. Confirmatory testing on the abalone foot and viscera samples confirmed they contained 586 µg/kg and 2437 µg/kg, respectively. The regulatory limit for PST in bivalve shellfish is 800 µg/kg. PST levels found in abalone were generally two to three times lower than levels found in mussels from the same area during that period.

Response of Tasmanian state authorities to the discovery of PST in abalone

In response to the bloom in the D'Entrecasteaux Channel, DHHS issued periodic public health notices. The first of these notices, issued on 25 March 2011, alerted recreational harvesters and domestic consumers about the harmful effects of wild caught shellfish. The warning did not include abalone or rock lobster.

Following the detection of significantly high PST levels in abalone, the notice was updated on 24 May 2011 to advise the public that until further notice, abalone harvested from affected areas in the D'Entrecasteaux Channel should not be consumed unless the viscera had been removed.

On 11 July 2011 DHHS announced that the naturally occurring algal bloom appeared to have dissipated and that, while testing indicated bivalve shellfish such as oysters and mussels had flushed the toxins from their tissues, it was still advisable to remove the gut of wild abalone, crab and crayfish harvested from the affected area, before eating the meat. Another notice issued on 13 October 2011 advised that the commercial fishing industry was monitoring harvest zones and that toxins were still present in abalone from some areas, even though the bloom had dispersed in June 2011.

The IIGB notes that the existing TSQAP biotoxin management plan (Figure D1) provided an extremely useful source of expertise and data that was immediately applied, in this incident, to the risk management of PST in abalone. The TSQAP monitors algal concentrations across many sites in the Huon Estuary and D'Entrecasteaux Channel throughout the year. It provides a good predictive capability for PST risk in shellfish, making it possible to implement appropriate risk management measures in a timely manner.

The Tasmanian Department of Primary Industries, Parks, Water and Environment (DPIPWE) regulates the abalone fishery in Tasmanian waters. This includes the application of harvest

quotas and the delineation of marine geographical areas in which harvest is controlled. Although its defined geographical areas (a system of zones, blocks and sub-blocks) are in place for quota management purposes, at the time of the incident DPIPWE and DAFF worked together using these boundaries to define restricted zones for harvesting wild abalone for export (Map A2).

The IIGB notes that the DPIPWE quota management system appears to be well controlled and that the use of established DPIPWE geographical areas by DAFF minimised the risk of noncompliance by abalone harvesters in the export-restricted zones.

Involvement of the abalone industry in the incident and in management of future risks

The abalone industry in Tasmania (and other states) is almost totally export focused. This incident surprised the industry, which had previously considered the risks of PST in Australia were limited to the bivalve shellfish industry. To its credit, the abalone industry encouraged the surveillance project to sample abalone in D'Entrecasteaux Channel. It was the results from this sampling that alerted stakeholders to the presence of significant levels of PST in wild abalone. The IIGB noted that, in response to the 2011 events, the industry held a view that the incident was associated with exceptional circumstances and that a regulatory overreaction must be avoided. The Tasmanian abalone industry continues to co-sponsor research in PSTs that aims to enable it to better assemble its risk picture.

Until that risk picture is clearer, the IIGB sees benefit in the Tasmanian abalone industry collaborating with the TSQAP. The TSQAP biotoxin management plan can provide the abalone industry with a PST predictive capability for risk management measures. This would provide DAFF with a greater basis of confidence to certify abalone (live or processed) for export in the future. This would also strengthen the assurance that can be given to export markets, such as China, that have expressed an interest in enhanced monitoring for PST in exported product.

The IIGB also notes that the industry was generally satisfied with the DAFF response to the incident and with the levels of communication and consultation throughout.

Role of DAFF in managing the risks

DAFF has an obligation to advise importing countries when an exported Australian product has been certified and subsequently found to be a risk to human health and safety.

Between 21 April and 20 May 2011, DAFF certified live abalone consignments from D'Entrecasteaux Channel as fit for human consumption.

SARDI's findings of elevated levels of PST in abalone from D'Entrecasteaux Channel were reported to DAFF on 20 May 2011. Exports of all abalone products (live/whole and processed) from the affected harvest areas were suspended on the same day by DAFF who then initiated trace-back and trace-forward activities on product harvested from that area for export between 21 April and 20 May 2011. Relevant government authorities in China and Hong Kong were informed and given assurances about the action being taken to manage the

issue. DAFF also provided information for those government authorities to implement appropriate product trace-forward and other actions.

DAFF also issued a notice to all export registered fish establishments not to receive any abalone for export from the specified catch area. Establishments that had received abalone from this catch area after 21 April 2011 were asked to advise DAFF so that a trace-back and trace-forward process could be instigated. DAFF also advised that no abalone were to be sourced from these harvest areas until the industry was notified by DAFF that test results showed PST levels were within acceptable limits.

Under the *Export Control Act 1982* DAFF is responsible for registering export processing facilities and certifying export consignments for abalone. The IIGB notes that despite the suspension of export of live abalone, one consignment certified as being fit for human consumption was exported to Hong Kong on 23 May 2011. The IIGB notes that DAFF had issued suspension notices to all export establishments on 20 May 2011. This particular consignment was certified because the exporter was not aware of the suspension of live abalone export. DAFF has since taken regulatory action against this exporter and undertaken an audit of the establishment to ensure remedial actions are in place to avoid such incidents occurring in the future.

The IIGB is satisfied there was no breach of legislative requirements in regard to exported consignments of live abalone to China and Hong Kong. DAFF's response to this incident provided prompt and appropriate biosecurity safeguards after the incidental detection of harmful levels of PST. Nevertheless, DAFF's export documentation system (EXDOC) requires updating to provide greater assurance that export health certificates cannot be issued once the suspension of export from certain abalone harvest areas has been announced.

The IIGB was unable to find any information on whether consumption of the live abalone consignments caused any human health issues in China and Hong Kong and is therefore unable to comment further on this matter. In one response, Chinese authorities expressed satisfaction with the DAFF response to the incident. No response was received from the relevant authority in Hong Kong.

The IIGB notes that management controls to ensure that abalone meets required PST standards for China and Hong Kong (and other export destinations) involves industry and certain state government agencies. The IIGB was unable to sight DAFF documentation that clearly articulates the risk management inputs required by relevant stakeholders to enable DAFF to confidently certify abalone exports as fit for human consumption with regard to PST risks. Having such documentation in place could assist DAFF in assuring overseas abalone markets that appropriate control measures are operating. The IIGB is therefore recommending that DAFF clearly documents its PST risk management processes and procedures.

The IIGB notes that at the time this report was finalised, DAFF has implemented an interim policy—developed in consultation with relevant State regulators and industry representatives—to manage abalone exports from Tasmania when algal blooms are detected in the D'Entrecasteaux Channel.

Revised import conditions in China

The IIGB notes that following the incident, China adopted a new regulatory maximum PST level of 800 µg/kg for all aquatic products. This standard took effect on 27 June 2011. China now has the same PST regulatory requirement as the EU markets. China has advised DAFF that it has increased testing of import consignments of Australian abalone for PST.

IIGB notes that at the time this report was finalised, Hong Kong had not changed its import requirements for Australian abalone.

Further research on PST in abalone

The IIGB notes that this was the first reported incident of elevated PST levels in Australian abalone. However, given the recurrence of algal blooms in 2012, the IIGB recognises it is appropriate to consider extending or adapting the various shellfish quality assurance programs relating to bivalve molluscs to address risk management of marine biotoxins in abalone.

There are significant gaps in scientific knowledge about PST in abalone. For this reason, the IIGB believes that any changes to quality assurance programs should be based on sound scientific evidence, including an assessment of the risks.

Based on the findings of the incident review, the IIGB recommends DAFF consider a risk assessment of ASQAP Export Standards 2004 that includes abalone.

Recommendations

Number	Recommendation
1	That DAFF, in consultation with relevant Tasmanian stakeholders, develops a paralytic shellfish toxin (PST) risk management process map indicating control and decision points in the abalone harvesting and export processes.
2	That the minister considers communicating with the Tasmanian Abalone Council Ltd to acknowledge and further encourage the abalone industry's continued collaboration with the Tasmanian Shellfish Quality Assurance Program (TSQAP) to develop a PST predictive capability for the implementation of risk management measures for abalone.
3	That DAFF considers modifications to its export documentation system (EXDOC) to allow automated control checks before issuing export certificates for abalone.
4	That DAFF considers undertaking a risk assessment for revision of the Australian Shellfish Quality Assurance Program (ASQAP) Export Standards 2004 to include abalone in the definition of shellfish.

[signed]

Dr Kevin Dunn
Interim Inspector General of Biosecurity

Conduct of incident review

Role of the IIGB

As part of its preliminary response to the 2008 review of Australia's quarantine and biosecurity arrangements (the Beale Review), the Australian Government agreed to establish a statutory office of Inspector General of Biosecurity. The role would be established under new biosecurity legislation currently being developed. In advance of this enabling legislation, interim administrative arrangements are in place.

On 1 July 2009 the government appointed an Interim Inspector General of Biosecurity (IIGB). The scope of the role covers those systems and their risk management measures for which DAFF is responsible.

The role also includes biosecurity measures relating to human health and environmental responsibilities undertaken by DAFF on behalf of the Department of Health and Ageing, and the Department of Sustainability, Environment, Water, Population and Communities.

The IIGB works on a cooperative basis with DAFF, relevant Australian Government departments, competent authorities and organisations/companies involved in the biosecurity continuum.

The IIGB is independent from the organisational and functional arrangements of Biosecurity-related divisions within DAFF and reports to the Australian Government Minister for Agriculture, Fisheries and Forestry.

IIGB reports are publicly available unless they contain confidential information.

The IIGB's program

The IIGB's program of activities includes a comprehensive agenda of systems performance audits designed to provide assurance of biosecurity systems and risk management measures across Australia's biosecurity continuum.

To form the program, the IIGB collates potential audit/review topics from a variety of sources, including:

- consultation with DAFF and relevant industries
- outcomes of other relevant reviews/inquiries, such as the Australian National Audit Office and internal DAFF audits
- observations from previous IIGB audits
- expert advice
- media coverage.

The IIGB also considers the minister's requests to undertake specified audits or reviews of the biosecurity system.

The IIGB prioritises audit/review topics. This includes an indicative qualitative risk assessment to assess the effects and likelihood of breakdowns in the biosecurity systems being audited.

The IIGB also:

- manages its resources
- avoids duplication with other biosecurity-related assurance/audit activities
- balances effort and coverage over the biosecurity continuum and sectors
- balances effort and coverage of the elements of the risk management processes outlined in the ISO 31000:2009 standard.

Methodology

The methodology for this review included:

- conducting an entry meeting and subsequent in-person/phone meetings with key stakeholders (Figure 1) to enable the IIGB to
 - communicate the review’s objectives and scope
 - outline responsibilities
 - identify the risks to the review and any appropriate mitigation strategies
 - obtain initial background information about the export consignments
 - provide an opportunity for all parties to discuss the review and seek points of clarification from the IIGB about the proposed review process
- conducting a desktop review of relevant DAFF data and documentation (such as, standard operating procedures, work instructions and communications material), and inspection and verification procedures relevant to the export control system for abalone
- conducting discussions with relevant DAFF staff to understand what had been done to review the circumstances of the consignments
- conducting discussions with relevant Australian, state Government departments and/or agencies (outside DAFF) to understand their role in the incident and in PST risk management
- conducting an incident review briefing with DAFF to enable
 - the IIGB to provide an overview of the incident review findings
 - discussion on how this type of incident can be prevented in the future
- fact checking desktop and fieldwork findings, to inform any misinterpretation of data and provide additional evidence and feedback on the incident review fieldwork process
- developing and providing the IIGB’s incident briefing report and recommendations to the Deputy Secretary—DAFF
- providing the completed report to the Minister to formally seek response from DAFF management.

Out of scope

The areas not within the scope of this review are:

- policy in relation to abalone exports
- international trade
- commercial matters and trade illegality
- costs or other financial matters
- IIGB analysis of samples.

Background and context

Australian abalone industry: production and export

Australia supplies almost 50 per cent of the world's supply of wild caught abalone. In 2009–10 the Australian abalone fishery provided an economic benefit to the Australian community of approximately \$216 million—18 per cent of the total value of Australia's fisheries export products (ABARES 2011).

The Australian abalone industry comprises a wild capture fishery and an aquaculture sector. Both sectors are managed under state government fishery management plans. The wild capture fishery in each producing state is managed by a quota management system. The Australia-wide abalone quota harvested each year represents 5600 metric tonnes.

Abalone is processed for sale to domestic and international markets, with the international market absorbing 90 per cent of total production. Abalone is sold live, dried, frozen or parboiled, as well as hermetically sealed in cans and plastic pouches. The viscera or gut may or may not be removed during processing.

Photographs of abalone are provided in Appendix C.

Tasmanian abalone sector

Tasmania is Australia's major abalone producer and exporter, accounting for about 50 per cent of the annual Australian abalone harvest and approximately 25 per cent of the annual world harvest. In 2009–10 abalone represented 18 per cent of the value of Tasmania's fisheries production (ABARES 2011).

The two abalone species commercially harvested in Tasmanian waters are:

- blacklip abalone, *Haliotis rubra*
- greenlip abalone, *Haliotis laevis*.

Abalone is harvested manually by licensed divers. In 2009–10 there were 122 dive license holders in Tasmania, with 70 per cent of the catch processed by the state's 12 largest operators (ABARES 2011).

The Tasmanian Government manages the Tasmanian abalone fishery under the *Living Marine Resources Management Act 1995* and the *Marine Farming Planning Act 1995*.

Paralytic shellfish toxins

Paralytic shellfish toxins (PSTs), often referred to as saxitoxins, are the most common and widespread of known marine shellfish biotoxins. Water soluble and heat stable, PSTs may cause the toxic syndrome paralytic shellfish poisoning (PSP) in humans who eat contaminated bivalve shellfish, such as mussels, clams, oysters, scallops and univalve shellfish, such as abalone. Through feeding, these shellfish can ingest and accumulate toxins produced by microscopic algae, including dinoflagellates, diatoms and cyanobacteria.

It is normal for biotoxin-producing algae to be present in marine water, usually at very low concentrations that pose no human health problems. However, under favourable ecological conditions (for example, optimal water temperature, micronutrient abundance following heavy rainfall and calm, stable water columns) algae concentration in water increases dramatically, creating so-called blooms. The increased algal concentration provides a greater food source for shellfish. The higher the algal intake during feeding, the more biotoxins the shellfish accumulate. Biotoxins do not harm shellfish, and the level in their tissue continues to climb until the bloom subsides.

When the number of toxin-producing algal cells returns to normal low levels, the shellfish eventually flush the toxin from their tissues. It can be several days to several months or longer before PST levels in shellfish are satisfactorily reduced. The time frames for elimination of PST from abalone tissue are less well understood than they are for bivalve molluscs.

Human health risks from ingestion of PST-affected shellfish products

In humans, PST affects the nervous system and paralyzes muscles. Early symptoms include tingling of the lips and tongue, which may begin within minutes of eating contaminated shellfish or may take an hour or two to develop. Symptoms may progress to tingling of fingers and toes and then loss of control of arms and legs, followed by difficulty breathing. High levels of PSTs in consumed shellfish can cause numbness of the extremities, respiratory paralysis, severe illness and death, particularly in immunocompromised individuals.

Laboratory analytical testing of shellfish meat is the only method of detecting PST because product containing toxic levels does not look or taste any different from shellfish meat that is safe to eat.

Standards for PST levels in shellfish destined for human consumption

The international food standards body Codex Alimentarius Commission (CODEX) has a set of standards for live and raw bivalve molluscs (CODEX STAN 292–2008). However, there is no CODEX standard for a safe level of biotoxins in abalone.

A standard does exist for abalone exported to the European Union. The European Commission regulation 854/2004 of the European Parliament stipulates that molluscs must not exceed a PST level of 800 µg/kg and it must be harvested from production areas that are classified and that have biotoxin monitoring programs in place (with a baseline of weekly monitoring).

In Australia, the ANZFSC code and ASQAP Export Standards define shellfish as all ‘edible molluscan bivalves’ and set a maximum PST level of 800 µg/kg. For these animals, it is an Australian standard that they be sourced from classified areas with maritime biotoxin management plans in place (Dowsett et al. 2011). Univalves, including abalone, are not defined as shellfish.

Details on minimum testing requirements for products to be eligible for the EU are provided in DAFF’s *Product standards—Verification testing for sourcing and handling of fish & fish products—A guideline to compliance with the Export Control (Fish & Fish Products) Orders*

2005, Version 7 (2011). The publication specifies the size of the sample meat and frequency of testing, and recommends annual biotoxin testing in harvest areas.

Australian abalone export sector and the role of DAFF

DAFF's Fish Export Program is responsible for the management of exports of fish and fish products and for ensuring food is fit for human consumption. This assurance is provided by export certification and is underpinned by:

- registration or licensing of establishments intending to prepare fish and fish products for export
- licensing of exporters intending to export
- auditing and/or inspecting registered establishments and licensed exporters to assess compliance with standards
- inspection of fish and fish products, as required.

The program provides operational and technical advice, and inspection and certification services to the export seafood industry to help maintain export market access.

Legislative arrangements

All seafood exports (including abalone) must comply with national legislation for export control, which is administered by DAFF. This legislation includes the:

- *Export Control Act 1982*
- Export Control (Prescribed Goods—General) Order 2005
- Export Control (Fish and Fish Products) Orders 2005.

Part 1 Division 1 of the Export Control (Fish and Fish Products) Orders 2005 states that trade should be facilitated by ensuring that fish and fish products for export as food:

- are fit for human consumption
- have a complete and accurate trade description and their integrity is assured
- meet import country requirements
- are accurately identified for effective trace and recall, if required.

The Orders require that fish and fish products for export for human consumption comply with ANZFS food standards. The exception is where the importing country has a different food standard with which the export product must comply.

In order to prepare fish and fish products for export, land-based establishments and vessels, that undertake processing—as defined in Export Control (Fish and Fish Products) Orders 2005—must be registered with DAFF as per Export Control (Prescribed Good—General) Order 2005.

DAFF approval processes for exporters

Under the *Export Control Act 1982* fish are described as 'prescribed goods', which means premises that prepare the product for export must be registered and approved by DAFF.

It is a condition of registration that the establishment have an Approved Arrangement (AA). An AA is a DAFF approved food safety management system that meets the requirements of Export Control (Fish and Fish Products) Orders 2005.

An AA provides a documented system to ensure the wholesomeness and integrity of fish and fish products are maintained during preparation for export.

Under the AA, registered establishments produce seafood in accordance with a hazard analysis and critical control point (HACCP) program that is incorporated into their food safety management system. The AAs set out the quality management systems that the establishment will use to ensure that products presented for export meet Australian export standards and importing country requirements.

DAFF's role is to approve the AA as documented to meet the requirements of export legislation and to assess industry compliance with documented procedures to ensure production of safe food. However, primary responsibility for meeting food safety and importing country requirements lies with the registered establishment and or the exporter, which is often one and the same. See Appendix B for further details on AAs.

To ensure ongoing compliance with the *Export Control Act 1982* and other legislation, DAFF undertakes audits of registered establishments and AAs. The frequency of these audits is based on the level of risk of the products processed by the establishment and its compliance history, that is, the rating achieved at the last audit. Establishments can be rated from A to E. An E rating means that the establishment presents a risk to public health and safety and would be unable to continue to process food for export until it can demonstrate that adequate controls have been put in place.

Based on the approach to risk assessment developed by the International Commission on Microbiological Specifications for Foods, establishments that produce 'ready to eat' fish products are classed as high risk. An establishment rated A on its previous audit is audited every six months, whereas a high risk establishment rated D on its previous audit is audited once a month. For accessibility reasons, vessels rated from A to D are audited annually and required to test/sample products. Vessels rated E are not permitted to process or export product until they have met specific conditions.

The minimum testing requirements for DAFF-registered establishments that source and prepare fish and fish products for export are outlined in DAFF's *Product standards—Verification testing for sourcing and handling of fish & fish products—A guideline to compliance with the Export Control (Fish & Fish Products) Orders 2005, Version 7 (2011)*. Testing is required to verify compliance with food safety requirements under the Orders and to satisfy importing country authority requirements for the European Union. At the time of the incident, the European Union was the only authority with specific requirements for testing PST levels in abalone; neither China nor Hong Kong had standards for allowable PST levels in live or processed abalone. There is still no Australian standard.

Only those Australian establishments with approved food safety programs that comply with export legislation are eligible to export seafood.

DAFF's certification processes for abalone exports

All licensed abalone processors who export abalone must be registered with DAFF. Upon registration they receive a registered establishment number. Legislation requires that this number be permanently applied to each primary package destined for export.

As abalone is a prescribed good, an export clearance number for clearance through the Australian Customs Border Protection Service's EXIT system is required. Documentation can be lodged electronically with DAFF via the EXDOC system. EXDOC, a central database that generates export certification for eligible clients, is used by DAFF's Fish Exports Program, accredited export permit issuers and registered establishments. DAFF also maintains the Establishment Register, which is accessed by EXDOC to validate the eligibility of establishments to produce the product nominated for export (Figure E1).

Exporters use EXDOC to submit, amend, forward or transfer request for permit, which is the legal notification by the exporter of intention to export. It describes the product, when and where it was processed and its overseas destination. DAFF endorses a request for permit once it is satisfied that the product has been produced to Australian and overseas destination standards.

DAFF can place control measures in EXDOC that prevent documentation being raised. For shellfish export certification there is provision in EXDOC to automatically check whether the shellfish harvest areas are open or closed for harvesting. EXDOC will prevent export documentation being raised when harvest areas are closed and shellfish are deemed unsuitable for human consumption. However, this automated checking option is not available in EXDOC for abalone exports. Had the automated checking option included abalone, an export health certificate would never have been issued for the abalone consignment exported to Hong Kong on 23 May 2011. DAFF officers used the directions issued by DAFF's Animal Export Program to industry to check whether establishments had complied with the suspension.

There is no requirement for DAFF to inspect each consignment before export. With the legislation, audit and certification systems focusing on the management and prevention of food safety issues, exporters have more responsibility for quality and compliance with overseas government requirements. The AA does not require establishments to test abalone (either live or processed) for PST.

Monitoring and management controls for shellfish growing areas in Australia

In Australia, food safety standards are set by ANZFSO and ASQAP Export Standards 2004. Flowcharts indicating the relationships between legislative arrangements and the various assurance programs are in Appendix D and Appendix E.

Australian Shellfish Quality Assurance Program (ASQAP)

The ASQAP is a government–industry cooperative program designed to assure the food safety of shellfish managed in accordance with its operational guidelines. ASQAP Export Standards 2004 comprise the ASQAP-based procedures and administrative practices necessary to meet legislative requirements prescribed by the Orders under the *Export Control Act 1982*, and to satisfy the food safety expectations of importing countries.

DAFF administers the ASQAP Export Standards 2004. It is mandatory for all shellfish producing states and territories to implement ASQAP Export Standards. However, while bivalve shellfish are covered by ASQAP Export Standards, abalone is not. The following is the definition for shellfish under ASQAP:

Shellfish means all edible species of bivalve molluscs such as oysters, clams, scallops (except when the consumed product is only the adductor muscle), pipis and mussels, either shucked or in the shell, fresh or frozen, whole or in part or processed. The definition does not include spat.

The requirements set out in ASQAP Export Standards 2004 flow through to the Tasmanian Shellfish Quality Assurance Program (TSQAP); hence, abalone are not covered in that state's monitoring program. A summary of the TSQAP is in Appendix F.

Tasmanian Biotoxin Management Plan (for bivalve molluscs)

The Biotoxin Management Plan (BMP) was developed as a key component of the TSQAP during the 1990s. It superseded a biotoxin monitoring program established in 1986 to routinely test for the levels of paralytic shellfish poisoning in shellfish from bloom-affected farms and others around Tasmania. During the 1990s TSAQP changed the emphasis from routinely testing shellfish flesh for toxin levels to a management program more focused on plankton sampling and supported by flesh testing when needed (Figure D1). Development and implementation of the plan is 70 per cent funded by the Tasmanian bivalve shellfish industry. The remainder of its funding and stewardship of the program are provided by the Tasmanian Government.

The plan aims to protect consumers of bivalve molluscs only—that is, it excludes univalves such as abalone—from the risk of biotoxin poisoning. At the time of the incident, no paralytic shellfish toxin monitoring program was in place for wild or farmed abalone harvested for either export or domestic markets. By contrast, commercially important bivalve shellfish harvested from Tasmanian waters are regulated through a TSQAP BMP (Appendix F).

If the information collected through the sampling program indicates potentially toxic algae are present in levels above those listed in the BMP, TSQAP notifies producers in the affected areas, relevant Tasmanian state government agencies, shellfish processors and DAFF.

On the basis of information from TSQAP, DAFF initiated consultations with industry and DPIPWE about how to respond to high levels of marine biotoxins found in abalone harvest areas in 2011.

The incident

On 20 May 2011 DAFF was advised that, following a localised algal bloom, PST had been detected in abalone harvested from certain areas in the D'Entrecasteaux Channel in eastern Tasmania.

In response to this advice, DAFF:

- immediately suspended the export of all product (live/whole and processed) harvested from the affected areas
- conducted a trace-back and trace-forward investigation into all abalone sourced from the affected areas and harvested for export between 21 April 2011 (when the first sample was taken) and 20 May 2011 (when DAFF suspended exports)
- confirmed and monitored the situation through a testing regime conducted in conjunction with the Australian abalone industry and scientific experts.

Confirmatory test results received by SARDI on 1 June 2011 showed that while PST levels in abalone meat (viscera removed) from the affected areas did not exceed 800 µg/kg, levels in the viscera itself exceeded the maximum.

The trace-back and trace-forward investigations found that 14 consignments of live whole abalone harvested from the D'Entrecasteaux Channel were exported to China and Hong Kong. Nine of the consignments (4824 kilograms) went to China and five (2904 kilograms) went to Hong Kong. However, in contravention of the suspension of exports, one additional consignment (384 kilograms) was exported on 23 May 2011 to Hong Kong. DAFF initiated regulatory action against this exporter.

At the time these consignments were exported, China and Hong Kong had a regulatory PST limit of 800 µg/kilogram for bivalve molluscs, but not for abalone.

In letters dated 6 and 8 June 2011 DAFF advised relevant authorities in Hong Kong and China of the incident and the response taken. The letters also advised that the suspension had been lifted on exports of abalone product that had the viscera removed during processing. The suspension remained in place for exports of viscera and for whole or live abalone sourced from the affected areas.

Chinese authorities acknowledged the DAFF response and expressed their intention to enhance monitoring of PST in abalone imported from Australia. They also asked DAFF to further strengthen monitoring and controls. DAFF is yet to receive a response from the relevant agency in Hong Kong to its letter of advice.

As part of the domestic response, the Tasmanian Department of Health and Human Services (DHHS) issued a public food safety notice on 25 March 2011 about wild caught bivalve molluscs. The notice was updated on 24 May 2011 to advise the public that until further notice, abalone harvested from affected areas in the D'Entrecasteaux Channel should not be consumed unless the viscera had been removed.

This was the first reported and documented incident where harmful levels of PST were detected in abalone in Tasmanian waters. At the time of the incident, biotoxin testing was not required for either wild capture or aquaculture abalone export products.

Sampling and testing procedures and results

In late November 2010 an algal bloom comprising low levels of *Gymnodinium catenatum* cells was first detected in the Huon Estuary in Tasmania. By mid-December 2010 the bloom had reached a size that was of concern and bivalve flesh testing commenced. On 25 March 2011 DHHS issued a public health warning advising against eating wild harvested shellfish. The warning did not include abalone or rock lobster.

When the bloom expanded further into the D'Entrecasteaux Channel the TSQAP undertook testing of bivalve shellfish (oysters and mussels). Testing continued throughout the bloom event and results showed that shellfish consistently contained levels of PST above the maximum regulatory limit of 800 µg/kg.

Given the significance of this bloom event, SARDI decided to sample abalone in the D'Entrecasteaux Channel as part of a research project for the Tasmanian Abalone Council Ltd. Two sites within the bloom-affected area were selected and five abalone specimens were collected from each. One sample was taken on 21 April 2011 and the other on 2 May 2011.

On 16 May 2011 SARDI received the results of separate tests on the viscera and foot tissue. Testing was undertaken at a New Zealand laboratory under contract to SARDI. The results from one site showed that PST levels in the abalone foot tissue ranged between 97 and 144 µg/kg, and in the viscera between 829 and 6711 µg/kg. Results from the other site indicated that PST levels in the abalone foot tissue ranged between 187 and 747 µg/kg, and in the viscera between 232 and 3251 µg/kg. All samples tested were positive. Confirmatory testing the abalone foot and viscera samples with the highest PST levels showed that these abalone contained 586 µg/kg and 2437 µg/kg in the foot and viscera, respectively. These results were received by SARDI on 19 May 2011.

During subsequent discussions between SARDI, the Tasmanian Abalone Council Ltd and local abalone processors it was agreed that further sampling and testing would be conducted later in May 2011, over a broader area. The results from this sampling showed that abalone from this area had accumulated levels of PST that in some cases exceeded the permissible level for shellfish.

SARDI advised DAFF of these results on 20 May 2011.

Response by importing countries to the incident

At the time of incident PST testing in abalone (for any product form) was not required for export to China and Hong Kong. However, China has since adopted a regulatory limit for PST in wild caught and aquaculture abalone (live and products) that is the same as the EU standard—a maximum of 800 µg/kg. Hong Kong has not yet established a regulatory level for PST in abalone.

Resumption and suspension of Australian abalone exports

On 1 June 2011, based on confirmatory testing, DAFF lifted the suspension on exports of certain type of abalone product. Exports recommenced of abalone that had had the viscera removed through processing.

DAFF was waiting on the results of further testing before lifting the suspension on export of other abalone products, including live/whole abalone. Abalone sourced from affected areas was approved if it had been processed to remove viscera and/or pigment. This suspension was not entirely lifted during the 2011 abalone harvesting season and has remained in effect—with intermittent opening and closure of harvest areas—until now.

At the start of the 2012 abalone harvesting season, DAFF issued advice to export registered fish establishments that PSTs had been detected in waters off Tasmania's east coast. A ban on exports of live, fresh, chilled or frozen abalone (with viscera) sourced from affected harvest areas was implemented in March 2012, following the recent bloom event in the D'Entrecasteaux Channel.

Observations and findings

At the time of the incident, unlike the European Union, neither China nor Hong Kong had standards for allowable PST levels in live or processed abalone. There is still no Australian standard.

Risk management measures undertaken by DAFF following detection of harmful levels of PST in abalone from bloom-affected catch zones

DAFF has an obligation to advise the authorities in importing countries when an exported Australian product has been certified and subsequently found to be a risk to human health and safety.

In the case of the incident, DAFF had certified the live abalone consignments to China and Hong Kong as fit for human consumption. On 20 May 2011, it was discovered that viscera of abalone in these consignments posed a risk to human health and safety. The product had been harvested from the same area where laboratory analysis had found harmful levels of PST in abalone.

As soon as the elevated levels of PST were reported to DAFF, relevant government authorities in China and Hong Kong were informed and given assurances about the action being taken to manage the issue. DAFF also provided information to enable those government authorities to implement appropriate trace-forward action on recently imported product.

Under the Export Control (Fish and Fish Products) Orders 2005, DAFF does not have the power to open or close harvest areas/waters. This responsibility lies with state authorities, who have the enabling legislation.

During the IIGB's discussions with relevant stakeholders, DPIPWE expressed concerns about possible increased abalone harvesting pressure in other catch zones as a result of closures. This meant that the state fisheries authority was hesitant to close the affected catch zones. As DAFF considered that PST levels greater than 800 µg/kg constituted a risk to human health and safety, DAFF issued a written direction under Schedule 5 Clause 1.1 of the Export Control (Fish and Fish Products) Orders 2005, ordering export establishments to cease sourcing abalone from specified affected catch zones.

While DAFF did implement the suspension of abalone exports, the IIGB found that there were no automatic control checks within EXDOC to prevent export documentation being raised for abalone deemed unsuitable for human consumption. At the time of export, checking relied entirely on written directions provided to registered export establishments and to relevant DAFF staff.

IIGB investigations revealed that DAFF processes used to verify and certify abalone exports as fit for human consumption are not clearly documented. This is in part due to the number of stakeholders involved in the decision-making process for harvesting, processing and exporting abalone. The IIGB considers that the certification and verification system for abalone exports could be enhanced by the development, and communication to relevant stakeholders, of a PST risk management process map showing control and decision-making points.

Recommendation 1

That DAFF, in consultation with relevant Tasmanian stakeholders, develop a paralytic shellfish toxin (PST) risk management process map indicating control and decision points in the abalone harvesting and export processes.

On 1 June 2011, following receipt of laboratory test results on product harvested from bloom-affected areas, DAFF lifted the export suspension for abalone products that had the viscera removed during processing.

A working group was convened comprising the Chief Executive Officer of the Tasmanian Abalone Council Ltd, a leading Australian expert engaged in PST abalone research from SARDI and DAFF representatives. A strategy was developed to progressively open affected catch zones once sampling results indicated that PST levels were below the regulatory level for bivalve molluscs (noting that there is currently no regulatory level for abalone or other univalves).

The IIGB noted that the existing Tasmanian Shellfish Quality Assurance Program (TSQAP) Biotoxin Management Plan provided an extremely useful source of expertise and data that was immediately applied in this incident for the risk management of PST in abalone. Put in place by the bivalve shellfish industry, together with DHHS, TSQAP monitors algal concentrations across many sites in the Huon estuary and D'Entrecasteaux Channel throughout the year. It provides an excellent predictive capability for PST risk that enables appropriate risk management measures to be implemented.

Bivalve industry assistance was provided on an informal collaborative basis during this incident. No similar biotoxin management plan is in place for abalone. This incident highlights a need to consider such a plan.

Recommendation 2

That the minister considers communicating with the Tasmanian Abalone Council Ltd to acknowledge and further encourage the abalone industry's continued collaboration with the Tasmanian Shellfish Quality Assurance Program (TSQAP) to develop a PST predictive capability for the implementation of risk management measures for abalone.

The IIGB is satisfied that DAFF's response to this incident provided appropriate biosecurity safeguards after incidental detection of harmful levels of PST in abalone harvested from the same areas as those that had been recently exported live to China and Hong Kong. The IIGB has no knowledge of whether the exported consignments of live abalone of concern caused any human health issues in China or Hong Kong because no information has been supplied by the authorities in those countries.

However, inclusion of abalone in a management system similar to the TSQAP Biotoxin Management Plan may provide a more effective and timely process for responding to future incidents. The outputs from such a system could then be linked to EXDOC. Data on harvest area closures in EXDOC would give DAFF staff greater certainty in the certification process.

Export of one live abalone consignment to Hong Kong after suspension of export

The certification of export consignments for bivalve shellfish, such as oysters and mussels, is executed through DAFF's EXDOC. Authorised/approved user(s) at each export establishment must upload specific information to EXDOC regarding each export consignment. EXDOC then allows them to print off export health certificates.

However, the IIGB considers that the absence of control checks in EXDOC during closures of abalone harvest areas could lead to consignments being certified as fit for export. On 23 May 2011 the absence of controls led to, an export health certificate being issued for one live abalone consignment to Hong Kong. This was in spite of an existing export suspension on a product considered unsafe for human consumption.

Recommendation 3
That DAFF consider modifications to its export documentation system (EXDOC) to allow automated control checks before issuing export health certificates for abalone.

Australian standards and testing for PST in abalone

The IIGB consulted leading Australian marine biotoxin experts for this incident review. As an outcome of those consultations, the IIGB notes that:

- the toxic algal bloom in Tasmanian waters between March and June 2011 provided the first data for Australian abalone researchers and industry that demonstrated that PST can be a significant risk in blacklip abalone
- the D'Entrecasteaux Channel (including adjacent marine waters) is the location in Tasmania where the issue of PST in abalone is of most concern.
- limited research has been done to identify reason(s) for elevated PST levels in abalone
- further research, in the form of long-term monitoring and periodic analysis of wild abalone (especially from affected areas) is warranted to confirm whether PST poses a risk in other Australian abalone species.

While the toxic algal blooms in Tasmanian marine waters are thought to have caused elevated levels of PST in wild abalone harvests, other factors may have contributed. Data have not always provided a direct link between PST levels in live abalone and algal blooms. For example, New Zealand research has shown that Paua abalone did not take up the toxin during a recent algal bloom.

During his consultations with abalone PST experts, the IIGB noted significant data gaps concerning marine biotoxins in abalone, in particular:

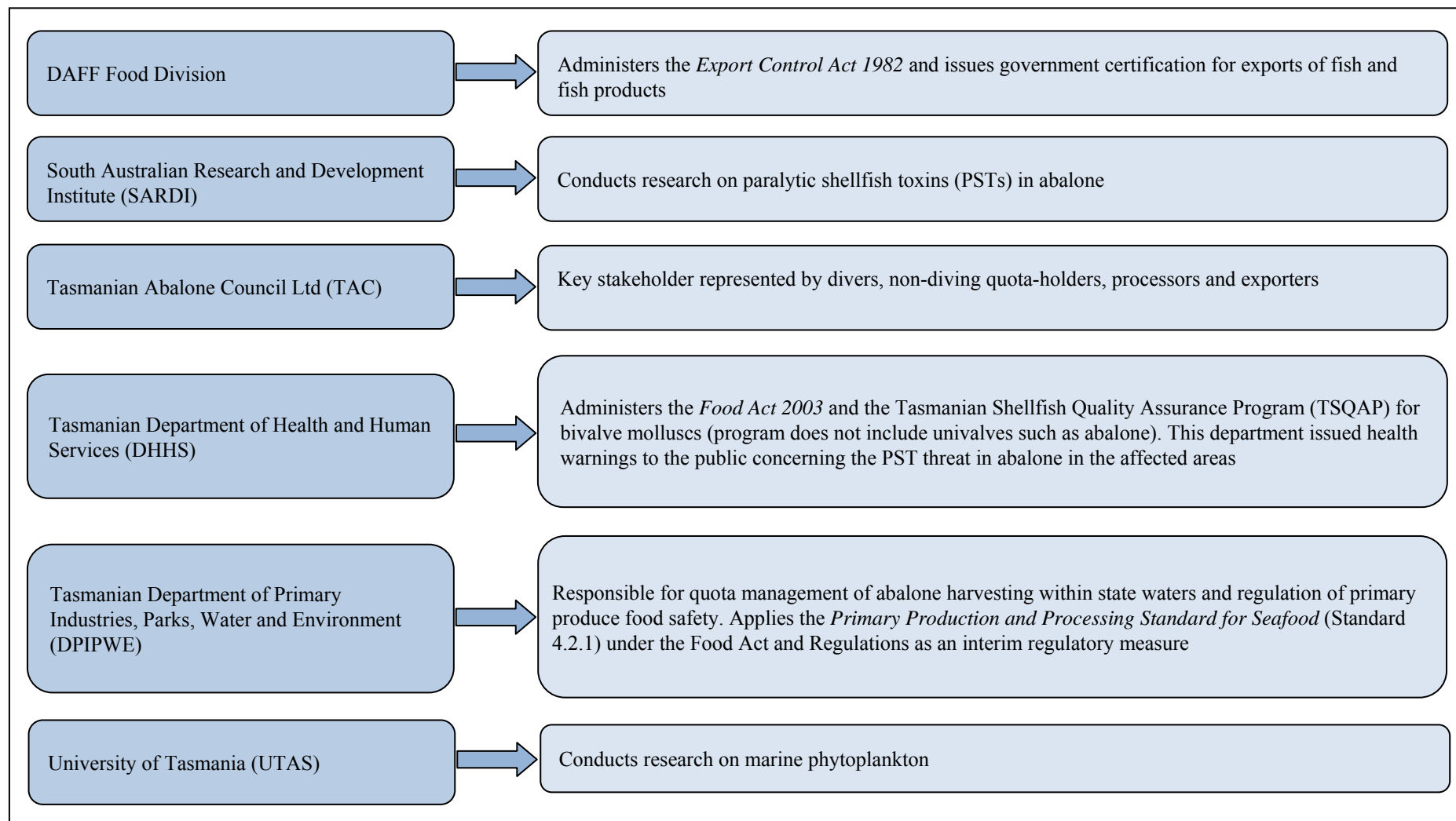
- the source of the PST detected in Tasmanian abalone (for example, *Gymnodinium catenatum*, cyanobacteria, macroalgae or other potential producer)
- the identity of the two unknown toxins identified during high-performance liquid chromatography screening of contaminated Tasmanian abalone
- the length of time for abalone to depurate PST

-
- whether the levels of PST in abalone foot tissue reduce through processing (for example, canning)
 - the most appropriate analytical method to use for PST testing of abalone.

This was the first reported incident of PST levels in abalone in Australia above the regulatory maximum that applies for bivalve shellfish. The IIGB therefore considers it would be premature to amend ASQAP Export Standard 2004 to include abalone at this stage, without a full assessment of the benefits and costs.

Recommendation 4
That DAFF consider undertaking a risk assessment for possible revision of Australian Shellfish Quality Assurance Program (ASQAP) Export Standards 2004 to include abalone in the definition of shellfish.

Figure 1 List of stakeholders consulted



Chronology of events

Late November 2010	Low levels of <i>Gymnodinium catenatum</i> cells first detected in Huon Estuary.
Mid-December 2010	Bloom develops and expands. Bivalve flesh testing commences. Note that Huon Estuary does not contain commercially farmed bivalve shellfish.
March 2011	Bloom extends to Roberts Point in the north and Hastings in the south.
25 March 2011	Tasmanian Department of Health and Human Services (DHHS) issues a public health warning against eating wild harvested shellfish—there is no mention of abalone or rock lobster.
21 April 2011	South Australian Research and Development Institute (SARDI) send five abalone specimens from Partridge Island for PST testing.
2 May 2011	SARDI send five abalone specimens and one mussel specimen from Garden Island to a New Zealand laboratory for PST testing.
16 May 2011	SARDI receive results of PST testing.
19 May 2011	Confirmatory results of PST testing received by SARDI.
20 May 2011	SARDI advises DAFF of the results. DAFF issues a notice to all export registered shellfish establishments (processors) advising that sourcing of abalone harvested from affected areas (defined by geographical area) be suspended immediately.
23 May 2011	DAFF directs processors to cease sourcing abalone in waters now defined as catch zones 13D, 13E, 14A, 14B, 14C, 14E and 15.
24 May 2011	DAFF notifies processors regarding transfer of all abalone products (sourced prior to notice to cease) that: <ul style="list-style-type: none">- abalone from non-affected areas can be exported- abalone origin is to be identified on transfer- abalone from affected areas (13D, 13E, 14A, 14B, 14C, 14D, 14E and 15) is not to be exported.
1 June 2011	DAFF notifies processors regarding sourcing resumption in some zones. Export permitted of product sourced prior to notice, subject to processing: <ul style="list-style-type: none">- canned abalone (pigment removed and scrubbed) from all affected zones are eligible for export- live abalone permitted to be sourced and exported from zone 13E- abalone may be sourced from 13D, 14A, 14B, 14C, 14D, 14E, 15 and 16A- exports permitted of abalone (sourced both before and after notice to cease) only where viscera is removed. Viscera must be disposed of by the processor.
27 June 2011	DAFF issues a Market Access Advice (No: 11/09) stating that: <ul style="list-style-type: none">- Chinese import and export inspection and quarantine agencies have enhanced their monitoring of paralytic shellfish toxin (PST) in Australian abalone- Chinese have set a regulatory level for PST of 800µg/kg in all aquatic products.
11 July 2011	DHHS issues a public health warning that while bivalve shellfish are safe to consume, it is advisable to remove the gut of wild caught abalone, crab and crayfish harvested from the affected area before eating the meat.

29 July 2011	<p>DAFF notifies processors regarding changes to the 1 June 2011 sourcing restrictions:</p> <ul style="list-style-type: none"> - cease sourcing from 14E and isolate and identify any product held in tanks—contact DAFF for management advice - sourcing and export of all forms of product, including live, permitted from zones 13E and 14A - sourcing abalone from 13D, 13E, 14A, 14B, 14C, 14D, 15 and 16A permitted. Only canned product from these zones where pigment is removed and scrubbed are eligible for export. Viscera from abalone from these catch zones to be disposed of.
1 November 2011	<p>DAFF notifies processors that sourcing from 14E is permitted for export only, if viscera is removed.</p>
23 March 2012	<p>DAFF notifies processors that:</p> <ul style="list-style-type: none"> - sourcing and export of abalone in all forms, including live is permitted from zones 13D, 13E, 14A, 14B, 14C and 16A - sourcing from zones 14D and 14E is permitted and abalone may be exported if viscera is removed. Viscera from abalone from these zones must be disposed of.
27 April 2012	<p>DHHS issues a public health alert about algal blooms from Port Esperance, Hastings Bay (Southport) and the coastline between, and advises against eating the gut of abalone from these areas.</p>
4 May 2012	<p>DAFF advises processors about the suspension of exports of live, chilled and frozen abalone with viscera and all viscera products from catch zones 14A, 14B, 14D and 14E. However, export of abalone that has been processed (canned) to remove pigment (without viscera) continues.</p>
11 May 2012	<p>DHHS extends its shellfish health alert, advising against eating wild abalone from Port Esperance. For abalone from other areas, gut must be removed before eating the meat.</p> <p>DAFF advises processors about the suspension of export from catch zones 14A, 14B, 14D and 14E, of:</p> <ul style="list-style-type: none"> - live, chilled and frozen abalone (with or without viscera) - viscera and viscera products.
1 June 2012	<p>DHHS extends its shellfish health alert when the algal bloom spreads to Huon Estuary, including Port Cygnet, and down the west coast of the D'Entrecasteaux Channel through Port Esperance to Southport and Hastings Bay. This alert advises against eating wild abalone from Port Esperance. However, abalone from other areas may be consumed once the gut is removed.</p>

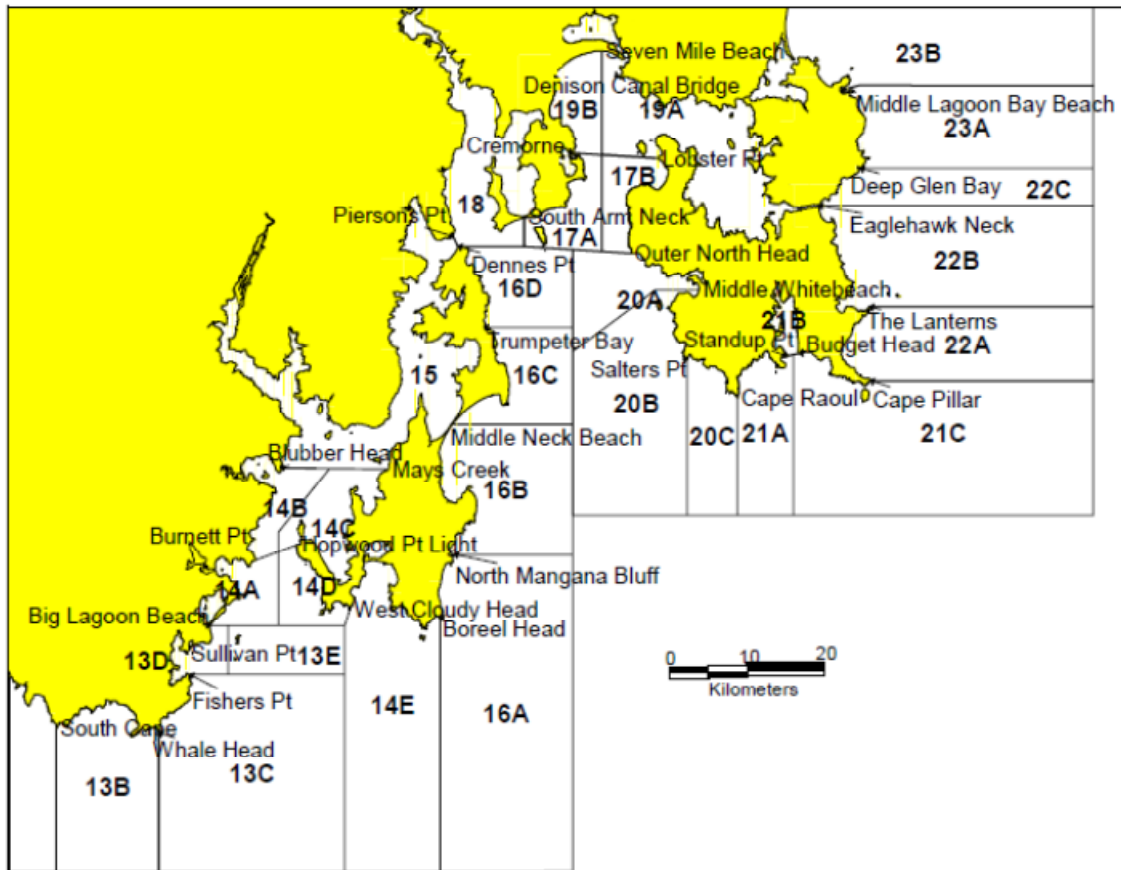
Appendix A Abalone catch zones in south-east Tasmanian waters

Map A1 Abalone fishing region, south-east Tasmania



Source: Tasmanian Department of Health and Human Services (DHHS)

Map A2 Catch reporting blocks and sub-blocks, south-east Tasmania



Source: Tasmanian Aquaculture and Fisheries Institute Fishery assessment report: Tasmanian abalone fishery 2009

Appendix B Approved arrangements

Primary responsibility for meeting food safety and importing country requirements rests with the occupier of a registered establishment and/or the exporter (usually one and the same). As part of the registration process, applicants are required to enter into an approved arrangement with DAFF (2010).

An approved arrangement provides a documented system to ensure that the wholesomeness and integrity of fish and fish products are maintained during their preparation for export.

An approved arrangement requires occupiers demonstrate a commitment to food safety principles through the application of hazard analysis and critical control points (HACCP), good manufacturing practice and hygienic practices to ensure that food safety outcomes are met.

Approved arrangements set out the quality management system that the occupier or exporter will use to ensure that products presented for export meet Australian export requirements and the importing country requirements.

An approved arrangement should adhere to the following principles:

- address the relevant requirements of the Act and importing country requirements
- provide details of how compliance with the legislation will be achieved and referenced to the requirements of the Act and relevant export orders
- be capable of being understood by all users of the system
- use a risk-based approach to food safety (HACCP)
- ensure full traceability throughout the chain
- be able to be audited
- be subject to formal internal review to maintain it in a current form.

DAFF is responsible for confirming that approved arrangements, as documented, meet export legislation requirements and assessing industry compliance with documented procedures so that production of safe food is ensured. This is achieved by auditing clients' approved arrangements and product inspections to verify that required standards have been met.

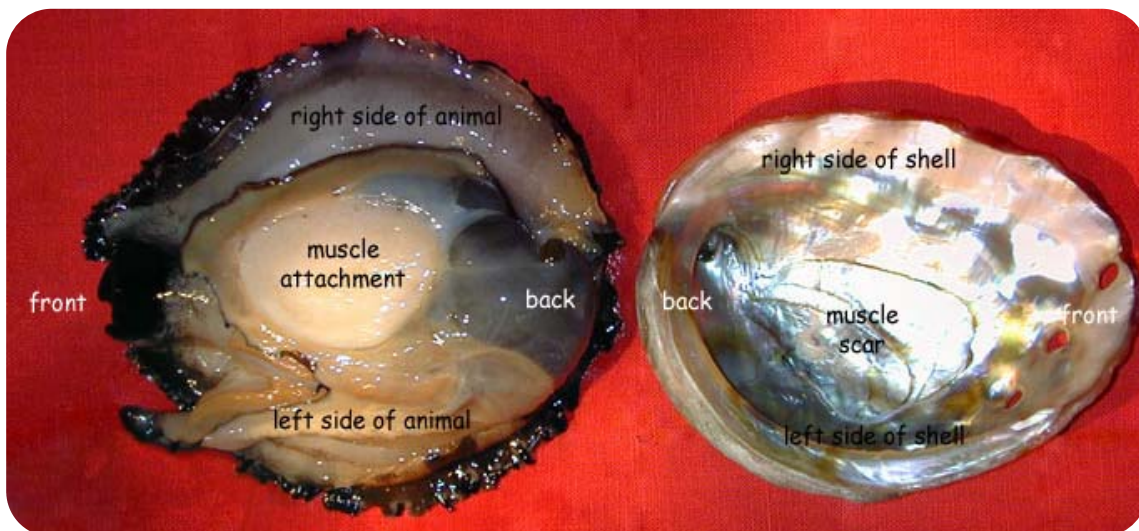
Appendix C Photographs and illustrations of live and processed abalone

Figure C1 Live Australian blacklip abalone



Source: Dr Isobel Bennett © [Australian Museum 2010](#)

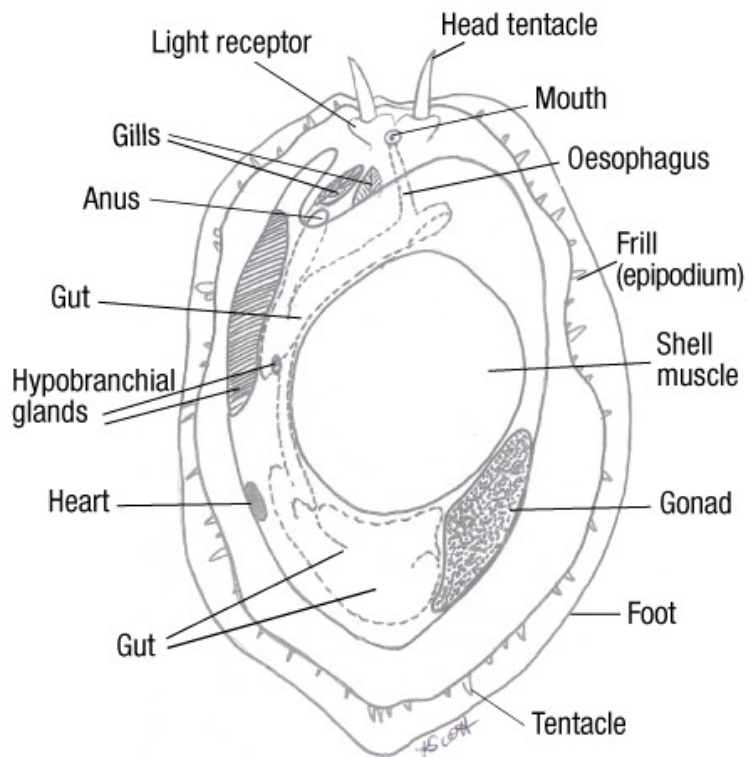
Figure C2 Abalone body and shell



Note: Red abalone body removed from shell by carefully scraping the muscle attachment from the shell. A muscle scar is left on red abalone species in this area of muscle attachment.

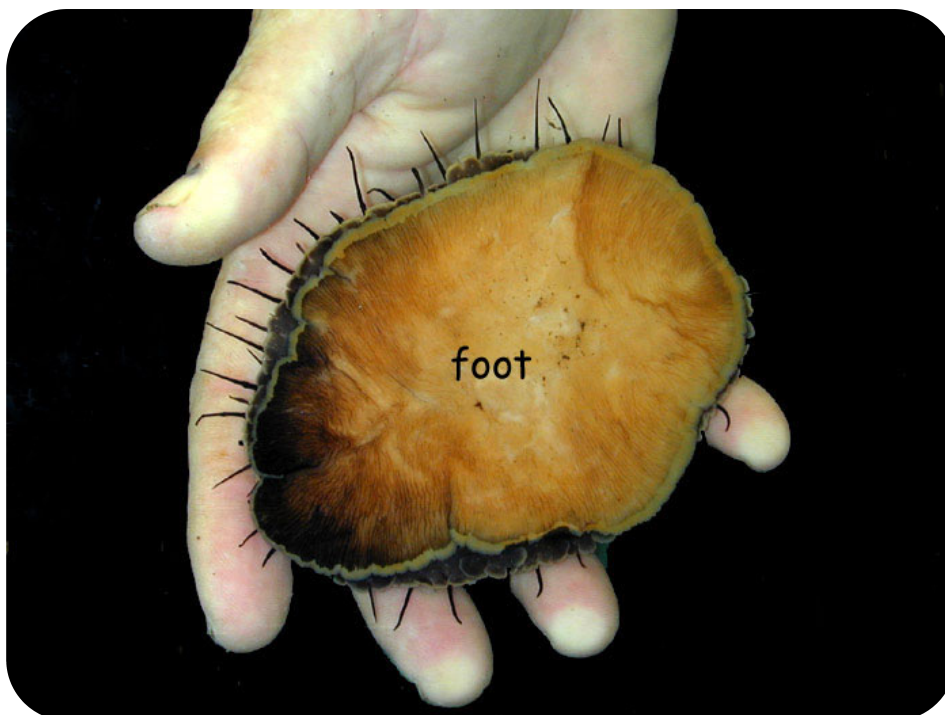
Source: Anderson 2012

Figure C3 Anatomy of an abalone



Source: DAFF

Figure C4 Abalone foot



Source: Anderson 2012

Figure C5 Abalone cleaned of its gut



Source: Anderson 2012

Appendix D Legislative arrangements and assurance programs

Figure D1 Shellfish quality assurance model

Source: Interim Inspector General of Biosecurity

Appendix E Tasmanian abalone fishery

Figure E1 Abalone: quota managed fishery (Tasmanian model)

HACCP = Hazard analysis and critical control point; CODEX = Codex Alimentarius Commission

Source: Interim Inspector General of Biosecurity

Appendix F Tasmanian Shellfish Quality Assurance Program (TSQAP)

Information in this appendix is sourced from the [Tasmanian Department of Health and Human Services](#) (DHHS 2012).

- The Biotoxin Management Plan (BMP) developed under the TSQAP aims at better protecting bivalve shellfish consumers from the risk of biotoxin poisoning. Abalone and other univalves are not included in the plan.
- The BMP focuses on algal monitoring supported by chemical testing, when required.
- Responsibilities of the TSQAP include:
 - Developing, maintaining and implementing the BMP in all Tasmanian commercial shellfish growing areas.
 - Overseeing the sampling program, training samplers and determining the locations and frequency of sampling.
 - Implementing closures and reopenings of catch zones affected by biotoxins, then notifying all parties concerned and maintaining records of these closures.
 - Carrying out surveillance of harvesting in closed areas to ensure illegal harvesting does not occur.
 - Organising marine farmers to take algal and meat samples from around marine farms, when required.
 - Recalling a product due to biotoxin issues. The TSQAP liaises with marine farmers and the State Food Officer to ensure as many shellfish as possible are recalled.
 - Coordinating 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 reopening conditions.
 - Liaising with appropriate agencies and companies and any other body collecting algal and/or algal toxicity information around the state (for example, salmon producer and exporter TASSAL, CSIRO, University of Tasmania).
- TSQAP implements the objectives and strategies of the Australian Shellfish Quality Assurance Program (ASQAP). The program aims to ensure that shellfish are only harvested from waters shown to be free of harmful contaminants. Shellfish grown in clean unpolluted waters should be safe to eat (TSQAP 2008).
- The implementation of ASQAP strategies requires each shellfish growing area to have:
 - a comprehensive sanitary survey that includes classification and management plan development
 - an ongoing water and shellfish bacteriological monitoring program
 - a continuous environmental monitoring program to ensure that harvesting only takes place within management plan criteria
 - a biotoxin monitoring program and management plan
 - a chemical residue testing program
 - an annual review of recent data collected and the current management plan.

TSQAP—Delineation of production areas

- Each growing area has undergone a risk assessment based on historical data of algae identified in water and cysts identified in sediments.
- Particular attention is paid to the history of the toxic dinoflagellate *G. catenatum*.
- Such assessments are an ongoing process as data becomes available. Risk assessments are updated every third year in the triennial data review for each growing area.
- The state has been divided into areas of low, medium and high risk:
 - low risk areas have no history of potentially toxic algae or toxic algal cysts being present in high enough numbers to be of concern.
 - medium risk areas may have had *G. catenatum* cysts identified in the sediments, or cells in the water column. They may have been affected by blooms in the past, but these have always been seeded from surrounding areas. Such blooms have been infrequent (once every 5–10 years) and some closures have occurred.
 - high risk areas have experienced frequent biotoxin closures in the past. Usually they are areas where *G. catenatum* blooms are initiated and where there is a history of high toxin levels in the shellfish during algal blooms.

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Glossary

AAC	Australian Abalone Council Ltd
ANZFSC	Australia New Zealand Food Standards Council
ASQAP	Australian Shellfish Quality Assurance Program
BMP	Biotxin Management Plan
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department of Agriculture, Fisheries and Forestry
DHHS	Department of Health and Human Services
DPIPWE	Tasmanian Department of Primary Industries, Parks, Water and Environment
EXDOC	Export documentation system, DAFF
HACCP	Hazard analysis and critical control point
PST	Paralytic shellfish toxin
SARDI	South Australian Research and Development Institute
TAC	Tasmanian Abalone Council Ltd
TSQAP	Tasmanian Shellfish Quality Assurance Program