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Market Access for Abalone - Biotoxins

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Australian Government
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An Australian Government Initiative

Non-Technical Summary

2010/737 Market Access for Abalone - Biotoxins

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PROJECT OBJECTIVES:

1. This project aims to reduce technical barriers to trade for Australian abalone in key markets such as China, Japan and the EU. This will be delivered by using the risk assessment output of the project to negotiate risk based international biotoxin standards (at Codex)

2. A secondary aim of this project is to enhance R&D capability on marine biotoxins and market access in Australia. This project will be a collaborative effort between experienced NZ researchers in this field and Australia, in order to facilitate knowledge transfer to assist in capability building for broader industry benefits in Australia

SUMMARY

A series of international and national events were precipitated following the discovery of paralytic shellfish toxins at concerning levels in abalone from Spain and Korea during the 1990's: the EU blocked market access for abalone that were not covered by biotoxin monitoring programs in 2007; PSTs were found in low levels in Australian abalone in 2009; and Codex proposed a draft abalone standard in 2009 that originally stipulated routine biotoxin monitoring in abalone harvest zones.

Major abalone stakeholders (regulatory and industry) in Australia and New Zealand recognised the need to instigate further research into biotoxins in abalone to address the identified data gaps to improve the initial risk assessment and extend it to other marine biotoxin groups and all formats of wild harvest abalone.Furthermore, there was an urgent need to improve the capability of dealing with marine biotoxins in Australia, with no laboratory in Australia capable of analysing all major toxin groups, and importantly, no laboratory capable of analysing for PSTs in seafood other than bivalve molluscs.

This research project examined all the available evidence for marine biotoxins in Australian and New Zealand abalone, and collected further evidence through a prevalence survey and through analysing abalone samples taken during toxin-producing phytoplankton blooms.

The risk to consumers through consumption of paralytical shellfish toxins (PSTs), amnesic shellfish toxins (ASTs), diarrhetic shellfish toxins (DSTs), and neurotoxic shellfish toxins (NSTs) via abalone was assessed using the standardised approach of hazard identification, hazard characteristation, exposure assessement (were data was available) and risk characterisation.

The conditions that must be met for abalone consumers to be at risk from any type of shellfish poisoning were identified. Firstly, high levels of the relevant toxin must be present in phytoplankton in the abalone growing area at the time of harvest or within a relatively short timeframe prior to harvest. Secondly the abalone must be able to accumulate significant amounts of this toxin in the edible tissues. Finally, there is a

requirement for individual human consumption of enough abalone to exceed the acute reference dose for that toxin by a margin significant enough to cause illness. The absence of any confirmed or probable cases or outbreaks of paralytic shellfish poisoning, diarrhetic shellfish poisoning, amnesic shellfish poisoning or neurotoxic shellfish poisoning linked to the consumption of abalone indicates that these conditions are rarely all met.

The outputs of this project demonstrate the usually extremely low to low risk of marine biotoxins in Australian and New Zealand abalone products causing human illness. Only one product format was identified as having a low to moderate risk with respect to PSTs only (viscera sashimi). From an industry perspective this translates to a relatively low level of risk of losing market access due to a harmful event such as a PST biotoxin event. Several knowledge gaps were identified that could build on improving these risk assessments, and potentially lead to quantitative assessments.

The project has contributed significantly to capability development in marine biotoxins in Australia: both in building analytical services, and in improving capability in the regulatory and research fields. This capability has already significantly aided in responding to standards being developed at Codex, and for incident response to a major event. The improved capability will continue to aid the provision of further research in this field for both the abalone sector and other seafood sectors.

From a direct benefit perspective the investment by the abalone industry of approximately $600,000 or approximately 0.27% of the average annual export sales of Australian abalone (2000/01 - 2011/12 est. $220m/yr) into the two risk assessments completed (2010 & 2013), the industry has not only ensured that it is able to retain market access to key export markets but has averted the short-mid term threat to market access by countering the adoption in the new Codex Standard for Abalone of onerous market access trade standards and monitoring requirements.

OUTCOMES ACHIEVED

- Acceptance at Codex of the usually low risk of marine biotoxins in abalone and the risk assessment approach to risk management
- Development of a laboratory service for marine biotoxin testing in Australia and improved capability in Australia and New Zealand for market access research
- Determination of the source of PSTs as marine phytoplankton, and of rates of accumulation and depuration of PSTs in abalone, providing increased options for risk management
- Demonstration of the low risk for marine biotoxins in Australian and New Zealand wild harvested abalone that can be used for trade negotiations
    - The risk of PSTs in Australian and New Zealand abalone products was found to be extremely low to low, with the exception of Australian abalone viscera sashimi which was found to have a low to moderate risk
    - The risk of DSTs in Australian and New Zeland abalone was found to be low, and the risk of these toxins in New Zealand paua neutracuetical products was found to be extremely low
    - The risk of ASTs in Australian and New Zealand abalone was found to be low
    - The risk of NSTs was unable to be judged in Australian abalone, but found to be low in New Zealand paua.
- Protection of market access to key international markets through the demonstration of low food safety risk. The direct benefit analysis showed that the investment by the abalone industry of approximately $600,000 or approximately 0.27% of the average annual export sales of Australian abalone has not only ensured that the industry is able to retain market access to key export markets but has averted the short-mid term threat to market access by countering the adoption in the new Codex Standard for Abalone of onerous market access trade standards and monitoring requirements.

LIST OF OUTPUTS PRODUCED

The following ten reports have been produced from this study:

- A National Survey of Marine Biotoxins in Wild Caught Abalone in Australia; suggesting that less than 1.6% (95% CI of 0% - 3.3%) of the commercially caught wild abalone population in Australia were contaminated with marine biotoxins at levels above the regulatory maximum level for bivalve molluscs during the survey period.
- Accumulation and Elimination of Paralytic Shellfish Toxins by *Haliotis rubra* during blooms of *Gymnodinium catenatum* and *Alexandrium tamarense* in Tasmania (also reported in FRDC report 2010-040); demonstrating that abalone can accumulate PSTs to significant levels in viscera tissue from toxic algal blooms. Toxins were retained for longer periods in abalone than in mussels, and accumulation and elimination rates of PSTs in mussels were greater than those in abalone viscera, which in turn were faster than those in abalone foot tissue.
- Provisional Risk Assessment of Paralytic Shellfish Toxins in Australian Wild Caught Abalone; demonstrating an extremely low risk of shellfish toxins in processed product, a low risk in unprocessed product and whole abalone, and a low to moderate risk in abalone viscera sashimi.

Continued below

- Risk Profile for Diarrhetic Shellfish Toxins, Amnesic Shellfish Toxins and Neurotoxic Shellfish Toxins in Commercially Harvested Australian Wild Abalone; demonstrating a low risk of diarrhetic and amnesic shellfish toxins in whole abalone, and an unknown risk of NSTs in whole abalone.
- Provisional Risk Assessment of Diarrhetic Shellfish Toxins in New Zealand Commercially Harvested Paua; demonstrating an extremely low risk of these toxins in neutracuetical paua products and a low risk in paua meals.
- Provisional Risk Assessment of Paralytic Shellfish Toxins in New Zealand Commercially Harvested Paua; demonstrating an extremely low risk of PSTs in neutracuetical paua products and a low risk in paua meals.
- Risk Profile: Brevetoxins in Commercially Harvested Abalone (Paua) in New Zealand; demonstating a low risk of brevetoxins in paua.
- Risk Profile: Domoic Acid in Commercially Harvested Abalone (Paua) in New Zealand; demonstrating a low risk of ASTs in paua meals.
- Impact of canning on paralytic shellfish toxin levels in abalone foot tissue: proposed experimental approach; presenting background information and an experimental design for conducting experiments to demonstrate the impact of canning on PST levels in abalone foot tissue.
- Benefit & Contribution of the Abalone Biotoxin Risk Assessments to the Industry (2010 & 2013); an independent analysis of the costs and benefits of the risk assessments conducted to date on marine biotoxins in Australian wild caught abalone.

A paper has been prepared for submission for the Journal of Shellfish Research:
A National Survey of Marine Biotoxins in Wild Caught Abalone in Australia

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1. Introduction and Background

International trade and market access of all food groups is underpinned by food safety regulations to ensure that the health of consumers is protected. One of the challenges of food safety regulation is to ensure the risk management response is commensurate with the level of risk. Excessive risk management regulations are an unnecessary cost burden on industry, whilst risk management systems that do not adequately address the risk endanger public health. The process of risk analysis is an integral part of risk management, and thus an important component of trade and market access.

Historically marine biotoxins in abalone have not been considered a hazard/food combination that presents a risk to consumers – marine biotoxins are more normally associated with bivalve molluscan shellfish. However, PSTs were discovered in abalone in Spain and South Africa in the 1990's at levels of concern for human health (Martinez et al., 1993, Pitcher et al., 2001). Following this, a trade mission from the European Commission (EC) in 2007 that evaluated the control systems in place for seafood in Australia found that abalone should undergo official controls equivalent to those of bivalve molluscs. This meant that abalone being exported from Australia to the European Union (EU) were required to be taken from classified production areas that had microbiological, chemical and biotoxin monitoring programs in place to control the food safety risks. Thus, from 2007 - 2010 Australian abalone was not eligible for export to the EU due to requirements to intensively monitor the coastline for contaminants, including marine biotoxins.

Marine biotoxins are divided into 8 groups based on their chemical structure (Anon 2004). The regulated groups for bivalve molluscan shellfish in Australia and New Zealand are shown in Table 1 below, along with the causative toxins and associated illnesses. These are the toxin groups considered in this research project.

Table 1. Regulated marine biotoxin groups in bivalve molluscan shellfish in Australia and New Zealand

Syndrome	Causative toxins	Symptoms
Paralytic Shellfish poisoning (PSP)	Paralytic Shellfish Toxins (PST) = saxitoxin group (STX)	Variety of neurological symptoms, ranging from mild (e.g. tingling sensations in extremities, headaches, dizziness, nausea) through mild (e.g. muscle/limb paralysis) to severe (e.g. respiratory distress and in extreme cases death).
Diarhhetic Shellfish Poisoning (DSP)	Diarhhetic Shellfish Toxins (DSP) = OA group toxins: okadaic Acid (OA), dinophysistoxins (DTX) and derivatives	Predominant symptoms are diarrhoea, nausea, vomiting and abdominal pain. Symptoms are dose dependent, but are not considered lethal, and hospitalisation is not normally required.
Amnesic Shellfish Poisoning (ASP)	Amnesic Shellfish Toxins (AST) = domoic acid and isomers (DA)	Characterised by a number of clinical symptoms and signs involving multiple organ systems, including the gastrointestinal tract, the central nervous system and the cardiovascular system In severe cases death may ensue, or neuronal damage can persist for years after exposure to the toxin.
Neurotoxic Shellfish Poisoning (NSP)	Neurotoxic Shellfish Toxins (NST) = brevetoxin group (BTX)	Acute neurological and gastrointestinal effects (e.g. nausea, diarrhoea, numbness, temperature reversal, slurred speech, respiratory distress). Multiple symptoms often occur at the same time, with neurological symptoms lasting longer Neurological symptoms can be serious (seizures

In 2009, SARDI undertook research to determine the risk to consumers from PSTs in Australian canned abalone (ASCRC Project 2008/909). This preliminary assessment demonstrated that PSTs in Australian canned abalone were of negligible risk. However, during the project PST was identified in low levels in wild Australian abalone and significant data gaps that adversely affected the strength of the risk assessment were found (Homan et al. 2010). The major data gaps identified were:

- Insufficient data on levels of marine biotoxins in wild-caught Australian abalone.
- Limited data available on depuration dynamics of toxins from abalone.
- No data available on the effect of the canning process on the levels of toxins in abalone (canned product is a significant product form).

The large data gaps identified in the initial risk assessment, together with the developing Codex requirements in this area with the potential to mandate routine biotoxin monitoring in abalone harvest areas, prompted major abalone stakeholders in Australia to instigate further research to improve the accuracy of the initial risk

assessment. The need for accurate risk assessments for abalone was not unique to Australia, and the NZ paua industry, which has strong links to the Australian abalone-processing sector, also requested further research in this area.

This impetus culminated in an Australia-New Zealand collaborative research program which was jointly funded by a range of stakeholders including: the Abalone Council of Australia, the Paua Industry Council (NZ), the Australian Seafood Cooperative Research Centre, the Fisheries Research and Development Corporation, and the Department of Further Education, Employment, Science and Technology.

At the same time Australia was lacking in capability for marine biotoxin analysis. No laboratory could conduct confirmatory analysis for all the major toxin groups, and importantly, no laboratory could analyse PSTs in seafood by modern chemical means. The Australian Shellfish Quality Assurance Advisory Committee (ASQAAC) was undertaking a feasibility study to encourage marine biotoxin laboratory services in Australia and it was recognised that this research project would provide significant advantage to the process by increasing the viability of such a service through both increased sample throughput and the recognition of another potential income stream (i.e. supplying analytical services to satisfy future research needs).

1.1 Need

As discussed above, major abalone stakeholders (regulatory and industry) in Australia and New Zealand recognised the need to instigate further research to address the identified data gaps to improve the initial risk assessment and extend it to other marine biotoxin groups and all formats of wild harvest abalone. This followed the following series of events:

- The discovery of PSTs at concerning levels in abalone from Spain and Korea in the 1990's;
- The blocking of trade to the EU in 2007 in the absence of marine biotoxin monitoring;
- The initial PST risk assessment by SARDI in 2009 that found PSTs in low levels in wild harvest abalone and identified several large data gaps for marine biotoxins in abalone; and
- The proposed draft abalone Codex Standard in 2009 that originally stipulated routine biotoxin monitoring in abalone harvest zones. Data on the level of risk associated with abalone was required to support the argument for an alternative risk assessment approach.

The need for the improved risk assessments has also been recently highlighted in the report of the Interim Inspector General of Biosecurity (IIGB) into biosecurity controls associated with the export of Australian abalone to China and Hong Kong, which notes: "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." (Department of Agriculture 2012).

Furthermore, there was an urgent need to improve the capability of dealing with marine biotoxins in Australia. When the project began there was no laboratory in Australia capable of analysing all major toxin groups (PSTs, DSTs, ASTs, and NSTs), and importantly, no laboratory capable of analysing for PSTs in seafood other than bivalve molluscs. Time delays caused by shipping samples to New Zealand for analysis were significant (up to one week in transport alone). This placed restrictions on the seafood industry, researchers and regulators for their risk management

responses to marine biotoxins, affecting routine monitoring, investigative research and incident response.

1.2 Objectives

1. This project aims to reduce technical barriers to trade for Australian abalone in key markets such as China, Japan and the EU. This will be delivered by using the risk assessment output of the project to negotiate risk based international biotoxin standards (at Codex)

2. A secondary aim of this project is to enhance R&D capability on marine biotoxins and market access in Australia. This project will be a collaborative effort between experienced NZ researchers in this field and Australia, in order to facilitate knowledge transfer to assist in capability building for broader industry benefits in Australia

2. Methods

A baseline survey was conducted to determine the prevalence of PSTs, ASTs and DSTs in Australian wild caught abalone. The sampling program aimed to test ~200 samples representing around 75 % of fished abalone production. This is a standard baseline survey approach (testing 200 samples will ensure detection of at least one sample that contains detectable levels of marine biotoxins if ~1.5% of the abalone are contaminated). Testing included each of the major Australian abalone species (*H. laevigata, H. roei, H. rubra*) and covered key fishing zones (SA, Tasmania, Western Australia and Victoria) throughout Australia. Sample sites were selected on the basis of production level (see Appendix 1. A National Survey of Marine Biotoxins in Wild Caught Abalone in Australia for detailed methods).

The propensity for abalone to concentrate marine biotoxins was investigated through sampling during four PST-producing phytoplankton blooms (three in Australia and one in New Zealand) and one DST-producing bloom in New Zealand. Abalone and bivalve samples were taken in the lead up to the bloom events to establish residual baseline levels. Following this, abalone sample collection was undertaken when toxin-producing plankton were detected at high levels in the water and when bivalve shellfish were known to be contaminated (via the routine state bivalve shellfish monitoring programs). Abalone samples were then taken on multiple occasions throughout the blooms. The foot and visceral portions of the abalone were tested separately to determine comparative rates of accumulation and depuration in each tissue (see Appendix 2. Accumulation and elimination of paralytic shellfish toxins by *Haliotis rubra* during blooms of *Gymnodinium catenatum* and *Alexandrium tamarense* in Tasmania and Appendix 5. Provisional Risk Assessment of Diarrhetic Shellfish Toxins in New Zealand Commercially Harvested Paua for more detail).

Preliminary studies were undertaken to determine the most appropriate way to investigate the impact of canning on PST levels in abalone. Results informed an experimental approach which was to be undertaken if PSTs were detected at high levels in abalone (see Appendix 9. Impact of canning on paralytic shellfish toxin levels in abalone foot tissue: proposed experimental approach).

An outline of the proposed risk assessment approach for each toxin group in Australian abalone and New Zealand paua was drafted and circulated to a Reference

Group composed of representatives from the following agencies and associations: the Australian Department of Agriculture, Food Standards Australia New Zealand, the Tasmanian Department of Health, the New Zealand Ministry of Primary Industries, the Abalone Council of Australia, the Australasian Abalone Association and the Paua Industry Council. The Reference Group provided feedback on the proposed objectives and approach, and these were amended accordingly.

The sections on hazard identification and hazard characterisation were collated from literature searches, unpublished reports from relevant authorities and industry sources, and the survey and accumulation/depuration work conducted above. Where enough data was available exposure assessments were conducted, i.e. for PSTs in Australian and New Zealand abalone, and DSTs in New Zealand abalone. The methodology used in the exposure assessment was a deterministic approach in which volume estimates were made for 'typical', 'large' and 'small' meals (serving size) for abalone foot and viscera, and whole abalone. The serving size was then multiplied by the maximum concentration recorded for PSTs in abalone foot and viscera tissues in each country, as determined during toxic phytoplankton blooms. Using this approach, doses (µg toxin kg^{-1} body weight) potentially consumed were derived for a range of meal types, serving sizes and people of different body weights. These doses were then compared to the provisional Acute Reference Dose (ARfD) (a dose at which no adverse effects should occur) and to a Reference Dose (RD) that was derived from the ML for bivalves.

In order to maintain consistency in interpretation of risk across all reports, a standardised approach was developed. This approach evaluated the severity and likelihood of the hazard based on the following factors:

- Severity of hazard
- Prevalence of the toxins in commercially harvested wild abalone
- Propensity of abalone to accumulate the toxins
- Likelihood that abalone are exposed to the toxins
- Impact of primary processing
- Impact of consumer/chef meal preparation
- Number of meals consumed
- Linkage with illness

A quantitative risk characterisation was not undertaken, as we found insufficient data for some of the above risk factors.

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The value and benefit of the research conducted was examined in a cost-benefit analysis by David Hudson, an external consultant from SGA Solutions Pty. Ltd. that included the following factors:

- *Direct:* To be considered 'direct,' the possibility of benefit to the stakeholders must be fairly immediate and the expectation of success should be well-founded scientifically;
- *In-direct:* Stakeholders may obtain other forms of in-direct benefits from the risk assessment, these may not necessarily be immediate or they can be transferred to alternate aspects of the stakeholders activities;
- *Others:* Information gleaned from the risk assessment may be of use to third parties who are not directly related to stakeholders of the risk assessment.

3. Results

The Australian survey of marine biotoxins in abalone conducted over the 16 month period from September 2012 to December 2013 included the collection and analysis of 190 abalone samples for marine biotoxins, in order to determine a prevalence estimate. No PSTs, DSTs, or ASTs were detected above regulatory levels in any sample.

The survey suggests that less than 1.6% (95% CI of 0% - 3.3%) of the commercially caught wild abalone population in Australia were contaminated with these toxins at levels above the regulatory maximum level for bivalve molluscs during the survey period (see Appendix 1 A National Survey of Marine Biotoxins in Wild Caught Abalone in Australia for more detail). A previous National Residue Survey of marine biotoxins in abalone in 2002 to 2004 did not find any PSTs, ASTs, DSTs or NSTs.

Paralytic Shellfish Toxins

In Australia PSTs in abalone have been monitored across PST-producing phytoplankton blooms (*G. catenatum* and *A. tamarense*). Analysis of the viscera and foot tissue of abalone collected from south-east Tasmania during significant blooms of *G. catenatum* showed a maximum confirmed value of PST in the viscera of 2.44 mg STX eq kg^{-1}, approximately three times the bivalve mollusc maximum level (0.8mg STX eq kg^{-1}). Accumulation of PST in foot tissue was much lower with a maximum confirmed value detected of 0.54 mg STX eq kg^{-1}. The study found that toxins were retained in the abalone for a longer period than in mussels, with the foot retaining toxins longer than the viscera. PSTs were identified at low levels in abalone during the *A. tamarense* event in Tasmania (see Appendix 2. Accumulation and elimination of paralytic shellfish toxins by *Haliotis rubra* during blooms of *Gymnodinium catenatum* and *Alexandrium tamarense* in Tasmania for more detail).

The acute exposure assessment for PSTs in Australian abalone suggests that potential ingested doses derived for people between 40 and 100kg who consume meals made from processed abalone meat (foot) do not exceed the reference dose (RD) for small (50g) and typical (100g) meal sizes. The dose consumed when a large meal (300g) is eaten marginally exceeds the RD for people of weights ≤60kg, when no reduction for cooking during processing or meal preparation is considered. Similar to processed abalone meat, doses for meals composed of unprocessed meat do not exceed the RD for typical and small serving sizes (with the exception of a 100g meal consumed by people who are ≤40kg, when no reduction is considered for cooking). However, the RD was exceeded for people between 40 and 100kg who consume meals ≥300g (regardless of whether reduction for cooking is considered or not). For meals composed of whole abalone (e.g. whole steamed abalone or abalone foot served with a viscera sauce/puree), the RD was exceeded for typical and large meal sizes for people between 40 and 100kg, and for a small meal consumed by a 40kg person (when no PST reduction is considered for cooking). Doses for meals composed of abalone viscera, either lightly steamed or consumed raw as sashimi, exceeded the RD for people ≤60kg for small (37.5g), typical (75g) and large (225g) meals sizes. The RD was also exceeded for people between 80 and 100kg for typical and large viscera meals, but not for small meals.

Other findings of the risk characterisation suggest that primary processing of abalone meat products results in a significant reduction in PSTs (approximately 75%), and that the volume of whole abalone and abalone viscera consumed is very low. These findings, together with the lack of confirmed human illness, have primarily led to the qualitative risk estimates for PST in all abalone products being extremely low or low,

with the exception of Australian viscera consumed as sashimi which is considered a low to moderate risk.

In New Zealand PST was detected in one paua viscera sample out of a total of 382 samples taken as part of routine marine biotoxin monitoring. At a PST level of 0.36 mg STX eq kg^{-1} (detected by mouse bioassay), this represents the highest PST level recorded in any paua sample in New Zealand. PST has not been detected in paua foot from New Zealand. The maximum level of PST detected in paua viscera during PST-producing phytoplankton blooms is 0.24 mg STX eq kg^{-1}detected during a *G. catenatum* bloom. This result is likely to significantly overestimate the real toxicity as no confirmatory testing was done to resolve the high toxicity analogues from the more predominant low toxicity analogues known to occur in these species.

The acute exposure assessment for PSTs in New Zealand paua suggests that potential ingested doses derived for people between 40 kg and 100 kg who consume paua viscera as part of a paua meal do not exceed the RD for small, typical or large meal sizes. It is noted that consumers of 40 kg and 60 kg eating large meal sizes would exceed the acute reference dose (ARfD) suggested by FAO/WHO (Lawrence et al 2011), and consumers of 80 kg and 100 kg eating the same meal would exceed the ARfD suggested by EFSA (2009).

The exposure assessment suggests that people of all weights consuming a large meal of paua viscera (i.e. three whole viscera) would exceed the FAO/WHO ARfD, and the 40 kg consumer would also ingest PSTs in excess of the RD.

The final assessment of risk also took into account the likely exposure of paua in New Zealand to PSTs, the propensity of paua to accumulate toxins, and the likelihood of humans consuming meal sizes able to result in illness. Although PSP-producing blooms do occur frequently in some areas in New Zealand, the impacted areas are predominantly areas of very low paua production. Thus even in the absence of any monitoring for marine biotoxins in harvest areas, based on historic data, the percentage of production likely to be impacted by PSTs is low. For paua foot, there is no evidence of the accumulation of significant levels of PSTs, even during dense PST-producing phytoplankton blooms. Similarly, PSTs in excess of the ML of 0.8 mg STX eq kg^{-1} have never been recorded in paua viscera, even during dense PST-producing phytoplankton blooms. Based on the maximum observed PST value, the volume of PSTs ingested in paua viscera consumed in meals is unlikely to cause illness in consumers, and the risk to consumers of paua viscera in nutraceutical products is considered to be extremely low. Paua viscera destined for human consumption represents a very low proportion of total consumed paua product.

Diarrhetic Shellfish Toxins

OA group toxins (DSTs) were not detected in the Australian abalone prevalence survey, nor in the previous National Residue Survey in 2002 to 2004. OA group toxins were detected on one occasion through routine monitoring in New Zealand paua at 0.39mg/kg, approximately twice the regulatory maximum level (0.2mg/kg in Australia and 0.16 mg/kg in New Zealand). DSTs were not detected in paua during monitoring of two DST-producing blooms.

The risk of illness associated with OA group toxins in Australian abalone is suggested to be low. This is based on the low prevalence of OA group toxins in Australian abalone, the fact that internationally OA group toxins have only been found in abalone viscera, and the lack of confirmed illness associated with abalone consumption despite the large volume of product harvested. Viscera products and live product may represent a higher risk than product from the foot only, although this is yet to be confirmed for Australian abalone.

The exposure assessment for DSTS in New Zealand paua showed that the ARfD is not exceeded for consumers of any weight who consume small meal sizes of abalone containing viscera. The ARfD is exceeded for consumers of 40 kg consuming a typical meal size, and the EFSA ARfD would also be exceeded by a 60 kg consumer eating this meal size. The ARfD would be exceeded in consumers of all weights who consumer a large portion of paua containing viscera. The ARfDs are not exceeded in consumers of any weight at any portion size for paua nutraceutical products.

The overall risk associated with DSTs in commercially harvested paua is considered to be low for both paua foot and paua viscera, but for different reasons. Although a very high proportion of paua products consumed contain paua foot, there is no evidence to date for occurrence of DSTs in these tissues. This is supported by the absence of any confirmed outbreaks or cases of DSP associated with the consumption of millions of meals of paua foot consumed in the last 20 years. Although the risk of DST contamination in paua viscera is higher than in foot tissues, occurrence of DST >ML is likely to be rare, the proportion of harvested paua contaminated with DSTs would be very low because of the spatial distribution of DST-producing blooms, and importantly, the proportion of paua meals that contain viscera from commercially harvested paua is likely to be extremely low. The risk of DSTs in nutraceutical products made from paua viscera is even lower due to the low portion size, which even in a worst-case scenario, results in an ingested dose well below that likely to cause illness in consumers.

Amnesic Shellfish Toxins

Domoic Acid (AST) was detected in trace levels in both the foot and viscera of Australian abalone during the prevalence survey, but was not found during the previous National Residue Survey study. DA has not been detected in paua in New Zealand to date. No samples have been analysed for DA in abalone during DA-producing phytoplankton blooms.

The risk of illness associated with DA in Australian abalone and New Zealand paua is suggested to be low. This assessment is based on the low prevalence of DA in abalone and paua, and the lack of confirmed illness associated with abalone consumption despite the large volume of product harvested. No comment can be made on the relative risk of viscera or foot tissue, as no rigorous study has been undertaken on the relative accumulation of toxins in these tissues.

Neurotoxic Shellfish Toxins

Brevetoxins (BTXs) that cause NSP were not tested in the prevalence survey of Australian abalone due to the lack of testing facilities in Australia. They were not detected during the National Residue Survey of Australian abalone. They have not been detected in New Zealand abalone to date.

The Australian risk profile has identified that information on BTXs in Australia is sparse. Literature reviews show that the international distribution of BTXs is generally restricted to the Gulf of Mexico. However, BTXs have potentially been identified in two Australian states, although only eight shellfish samples have been tested to date. Despite lack of biotoxin data, phytoplankton monitoring data from the bivalve monitoring programs show potential BTXs producing species are found in Australian states, although infrequently. The scarcity of information does not allow a risk evaluation for this toxin group in Australia at this time.

There is more information available on BTXs in New Zealand. The propensity for paua to accumulate BTXs to levels of significance to human health is currently unknown, but the risk of occurrence of blooms of BTX-producing phytoplankton in New Zealand most major paua harvesting areas appears very low based on historic data from bivalve and phytoplankton monitoring. If a BTX-producing bloom were to occur in a paua harvest area, epidemiological data indicate that the possibility of NSP associated with paua consumption cannot currently be discounted, however the suggested risk is low.

The results of the risk analysis for marine biotoxins in Australian commercial wild caught abalone in New Zealand commercially harvested paua, are given in appendices 3 to 8, and summarised in Table 1 below. Significant data gaps were identified in each analysis (see discussion).

Table 1. Summary of suggested risk associated with marine biotoxins in commercially harvested abalone from Australia and New Zealand.

Product	Toxin Group	Risk
Processed Australian abalone (e.g. canned, dried and frozen meat)	PSTs	Extremely low
Unprocessed Australian abalone food products	PSTs	Low
Whole steamed/boiled Australian abalone or abalone with viscera puree	PSTs	Low
Australian abalone viscera sashimi	PSTs	Low-moderate
Whole Australian abalone	DSTs	Low
Whole Australian abalone	ASTs	Low
Whole Australian abalone	NSTs	Unknown
New Zealand paua viscera in neutracuetical products	PSTs	Extremely low
New Zealand abalone meals	PSTs	Low
New Zealand paua viscera in neutracuetical products	DSTs	Extremely low
New Zealand abalone meals	DSTs	Low
New Zealand whole abalone	ASTs	Low
New Zealand whole abalone	NSTs	Low

4. Discussion

Currently there is no definitive epidemiological evidence to suggest that marine biotoxins in commercially harvested abalone/paua in Australia or New Zealand represent a significant risk with respect to illness. Millions of meals of abalone have been consumed with no reports of illness other than four unsubstantiated cases purportedly linked to paua, each harvested from widely separated regions in New Zealand within a four-week period in early 1993.

A number of conditions must be met for abalone consumers to be at risk from any type of shellfish poisoning. Firstly, high levels of the relevant toxin must be present in phytoplankton in the abalone growing area at the time of harvest or within a relatively short timeframe prior to harvest. Secondly the abalone must be able to accumulate significant amounts of this toxin in the edible tissues. Finally, there is a requirement for individual human consumption of enough abalone to exceed the acute reference dose for that toxin by a margin significant enough to cause illness. The absence of any confirmed or probable cases or outbreaks of PSP, DSP, ASP or NSP linked to the consumption of abalone indicates that these conditions are rarely all met.

Paralytic shellfish toxins

The exposure assessment suggests that consumption of large meals of abalone meat (foot) containing the highest level of PSTs detected in Australian abalone to date (0.59 mg STX eq kg^{-1}) may result in doses that exceed the provisional ARfD and RD. Additionally, consumption of large, typical and sometimes small meals of whole abalone and abalone viscera containing the highest levels of PSTs may also exceed the provisional ARfD and RD. These findings may be a concern for human health if such doses were to be frequently consumed. However, as mentioned above, there are a number of conditions must be met if abalone consumers are to be at risk of PSP. In evaluating the risk of PSP to abalone consumers, these conditions must be considered, in addition to the findings of the exposure assessment.

While the exposure assessment demonstrated that on some occasions the provisional ARfD and RD for PSTs may be exceeded, other data on the prevalence of PSTs in Australian abalone suggest that high levels of PSTs rarely occur; no abalone were found to exceed the ML in the one prevalence survey undertaken to date. Other findings of the risk characterisation suggest that primary processing of abalone meat products results in a significant reduction in PSTs (approximately 75%), and that the volume of whole abalone and abalone viscera consumed is very low. These findings, together with the lack of confirmed human illness, have primarily led to the qualitative risk estimates being relatively low. It is suggested that the relative risk of PSP related to consumption of processed (e.g. canned, dried and frozen meat) and unprocessed abalone foot products (meat derived from the export of whole abalone) is ***extremely low*** and ***low*** respectively. The relative risk of PSP from consuming whole steamed/boiled abalone or abalone meat served with viscera puree is considered to be ***low,*** and the relative risk from consuming viscera sashimi is considered ***low-moderate***. These risk ratings are consistent with those proposed in the risk assessment undertaken in 2010, which suggested that the risk of PSP related to the consumption of canned abalone in China and the EU were extremely low.

Although the overall likelihood of PSP related to abalone consumption is thought to range from “extremely low” to “low to moderate” (PST in Australian viscera products only), there are significant data gaps that may impact the accuracy of this

assessment. Notably, there are limited data pertaining to PST levels in abalone during *Alexandrium* sp. blooms, and little data with which to evaluate the occurrence of PSTs in abalone from some areas in Australia from which large volumes of abalone are harvested i.e. the western coast of Tasmania. There are also significant data gaps relating to abalone consumption, particularly meal types consumed and the associated serving sizes.

In New Zealand, PSTs in paua foot and viscera tissues have been monitored across blooms of all the PST-producing phytoplankton known to have been associated with significant toxicity in bivalve shellfish, from a variety of regional locations encompassing paua habitats in different environmental conditions, from the extreme exposure of the west coast to more sheltered conditions within the Marlborough Sounds. To date there is no evidence of uptake of PSTs into paua foot tissues, and only low levels of STX have been found in paua viscera (maximum level 0.24mg/kg). Currently it is uncertain why these observations are different from those of overseas studies, where significant uptake of PSTs has been observed in abalone species. This difference may relate to lower ingestion of PST-contaminated material (for example, through lower availability in paua habitat, or feeding preferences during blooms or because it is not available in paua habitat), or physiological differences between species.

Monitoring across PST-producing phytoplankton blooms has shown that PSTs can be accumulated in paua viscera to low levels, well below the current maximum level. Assuming the current maximum level for PSTs in bivalve shellfish is protective of consumers, based on the maximum PST level recorded in paua viscera to date, a consumer of 60kg eating a meal of paua viscera three times the typical meal size is unlikely to become ill with PSP. Based on current data and product information, the risk of becoming ill with PSP arising from paua viscera in nutraceutical products is negligible because of the low ingested dose.

There are places in New Zealand where the risk of PST-producing blooms is high, however, the areas from which the majority of paua are harvested are at low risk of such blooms. In addition, the risk of PSTs associated with paua consumption is further reduced by the very low proportion of viscera consumed in relation to total paua consumption. The current control measures also potentially contribute to reducing the risk to consumers of PSTs in paua viscera, although it is noted that the controls are not comprehensive in terms of geographical range in relation to paua harvest areas, and assumptions made about the effectiveness of the marine biotoxin monitoring programme for bivalves as an indicator of the risk of PSTs in paua have not been tested.

Although the likelihood of human illness arising from PSTs in paua is thought to be low, there are significant data gaps that may impact on the accuracy of this assessment. Most particularly these include the absence of quantitative data regarding the volume and mode of human consumption of paua viscera. In addition, given the observations made with respect to PSTs in abalone overseas, there is some uncertainty as to whether the observations made here represent a “worst-case” scenario. If stakeholders wish to strengthen the risk assessment, filling these key information gaps would be beneficial. Should it be evident from such additional information that PSTs in paua might present a significant risk then further investigation, including investigation of the prevalence of PST in paua from high production harvest areas where there are currently few monitoring data would be prudent.

Diarhhetic shellfish toxins

The risk analysis for DST in abalone suggest that the risk of DST occurring in commercially harvested abalone at levels that could potentially cause human health issues from either Australia or New Zealand is low. However, it is known that DSTs can be accumulated in abalone viscera to levels at which consumers of meals containing viscera are likely to become ill, both in New Zealand and overseas. The potential for DST accumulation at this level in Australian abalone is currently unknown and represents a significant data gap for this assessment.

The major contributing factors to this assessment for Australia abalone are the low prevalence of DST in abalone, and an absence of reported shellfish poisoning cases associated with Australian abalone. In New Zealand this assessment is based on the exposure assessment showing that the levels of DST detected in paua viscera and foot tissues are unlikely to cause illness across a range of products and consumption levels, and the likely temporal and spatial rarity of DSTs in paua growing areas.

Amnesic shellfish toxins

It is noted that in Australian abalone species, extremely low levels of DA were detected in not only viscera, but also foot tissues during prevalence study. This suggests that in some species of abalone there may be transfer of DA into the foot tissues. The potential level of accumulation is unknown as no studies have examined accumulation of DA in abalone throughout the course of a DA-producing phytoplankton bloom. Although the foot is the portion of paua in Australian abalone that is most commonly consumed, currently there is no information to suggest that this is of significance to the health of consumers. Similarly the risk analysis of ASP occurring in New Zealand abalone is regarded as low.

The major sources of uncertainty for these assessments relate to the propensity for abalone to accumulate and retain DA from DA-producing phytoplankton blooms, and the prevalence of DA in paua foot harvested for sale in New Zealand. There are no data from monitoring of DA levels in any abalone tissue types across the course of a DA-producing *Pseudo-nitzschia* bloom in Australia or New Zealand, and although there have been no DA levels of human health significance detected during either the prevalence survey in Australia or through long-term regular monitoring of paua viscera in New Zealand, relatively few samples of foot have been tested.

Neurotoxic shellfish toxins

The authors were unable to assess the risk of BTXs in Australian abalone due to significant data gaps for this toxin group. There is no information about the propensity for abalone to take up BTXs, commercial bivalve shellfish biotoxin monitoring programs do not routinely monitor for BTXs, and the national prevalence survey for marine biotoxins in abalone did not include BTXs due to a lack of testing facilities for this toxin group in Australia. However, the absence of reported NSP illness in Australia, and the restricted distribution of BTXs internationally is noted.

Despite the absence of information, the absence of any reported illness definitively linked to abalone consumption across a time period in which many millions of meals have been consumed, suggests that the risk of NSP arising from the consumption of abalone/paua harvested commercially in is low. This is particularly true in New Zealand, where regular monitoring of bivalves and some monitoring of paua, combined with the epidemiological data demonstrates a low risk for NSP illness through abalone consumption.

Canning experiment

The project plan included experiments to investigate the change in concentration and composition of PSTs in abalone foot tissue following a typical canning process. During the early stages of the project in 2011, significant levels of PSTs were unexpectedly detected in abalone from the D'entrecasteaux chanel region. The identification of elevated levels of PSTs was of concern to public health regulators and the industry and culminated in a series of zone closures to ensure product compliance with international standards and to ensure safety of abalone for sale. While the presence of PSTs in abalone from Tasmania was of concern, this discovery also created an opportunity for the proposed canning experiments to proceed. Therefore, SARDI biologists and statisticians developed an experimental design for the canning studies (see Appendix 9). PST levels in abalone foot tissue collected were initially thought to be very high, however these were based on PST screen tests and subsequent confirmatory testing showed that PSTs in abalone foot tissue reached a maximum confirmed level of 0.59 mg/kg, compared with the regulatory level of 0.8 mg/kg. The finding that levels in abalone foot were lower than initially expected and the need for further monitoring in the Channel region to support the industry's commercial operations culminated in the decision to divert project resources from the canning study to additional monitoring in the Channel region. While the canning study did not proceed as planned, the draft experimental design may provide a useful resource to other scientists who may plan on similar studies in the future.

Development of national capability

The ASCRC Marine Biotoxin Capability Project (ASCRC 2008/799) identified the level of marine biotoxin testing required in Australia for a viable laboratory service to be initiated and maintained. The Australian Marine Biotoxin Partnership, consisting of the bivalve shellfish industries, regulators and researchers, combined their sampling requirements in order to produce a tender for services with enough volume of work to attract suitable laboratories to offer services. The volume of analysis from this research project was a critical element of that tender. The volume of work was also an indication of potential future work arising from the research field.

The tender process was successful in attracting four bids from competing laboratories. Advanced Analytical Australia (AAA) was the successful tenderer, and began services in July 2012, just prior to the start of the abalone prevalence survey. The service was immediately utilised by the bivalve shellfish industry and by this project.

The value of this new capability in Australia was demonstrated a few short months after in October 2012 when Tasmania experienced an unprecedented marine biotoxin event, affecting multiple fisheries, with a direct cost to industry of $6.3 million. Without laboratory capability in Australia to analyse for toxins during this event, extended turn-around times would have resulted in significantly increased costs to industry and potentially increased risk for human health. The availability of testing services also means that all industries are able to improve monitoring and management of marine biotoxins, and a substantial volume of data is now being collected that will aid in future management of bloom events.

Since inception AAA has analysed considerably more samples than originally tendered for, and is proving to be a viable business. Turn-around times are improving and will continue to do so as the volume of samples continue to rise. Regular

proficiency testing provides assurance that the laboratory is operating at a suitable standard.

In addition to laboratory services, this project has built awareness of marine biotoxins in non-traditional vectors in seafood sectors, regulators and researchers. Australian expertise has been developed in marine biotoxin risk assessments through working on the project and working in collaboration with New Zealand partners. This expertise has proven invaluable in providing support to industry and regulators during the 2012/2013 Tasmanian bloom event, and is now being used to address marine biotoxins in other seafood sectors such as Southern Rock Lobster. Key regulators of domestic and export product have gained significant knowledge during the project resulting in better informed management practises.

Cost benefit analysis

A detailed assessment of the costs and benefits of this research is given in Appendix 10. Benefit & Contribution of the Abalone Biotoxin Risk Assessments to the Industry (2010 & 2013).

Given the scale and value of the Australian abalone industry (2000/01 - 2011/12 estimated $220million per year) any potential threat to the production, supply and ultimately market access for abalone from external factors such as abiotic or biotic stress can and would have severe impacts on the commercial viability of the industry. These impacts in the short term result in a loss of market access, reduced industry revenue, decline in infrastructure utilization and loss of employment. In the mid-long term there is a potential loss of market access due to competitor replacement as a supplier, the loss of breeder and production stock, the cost of re-entry into the market and the economic losses during the period of recovery and replenishment of the fishery until it had reached such a state where commercial harvesting can recommence.

In relation to market access, increasingly consumers, supply chains and governments in international export markets for Australian seafood products are looking to ensure and seek guarantees (as far as possible) that the food which they are resourcing is of the highest quality and safe for human consumption. This trend is evidenced by the increasing imposition by countries of targeted sampling and testing of imported products as occurred with Chinese and Japanese authorities in 2010, where they focused on Australian shellfish, including abalone. This is a major concern to the industry as Australia is a major exporter of ‘wild caught’ abalone, with over 70 % of Australian abalone caught between 2000/01 – 2010/12 exported to Japan, Hong Kong and China, equating to an average value in excess of AUD $229m in export sales annually to the industry.

By applying a *Risk Assessment Matrix* to map the contribution and benefit of the respective 2010 and 2013 risk assessments, the outcome would suggest that the initial risk assessment in 2010, and the current risk assessments have contributed significantly to the retention of market access for the Australian abalone industry in its major export markets. The risk assessments have achieved this by scientifically demonstrating the human health and safety status of the Australian abalone industry (see Appendix 10. Benefit & Contribution of the Abalone Biotoxin Risk Assessments to the Industry (2010 & 2013) for more detail).

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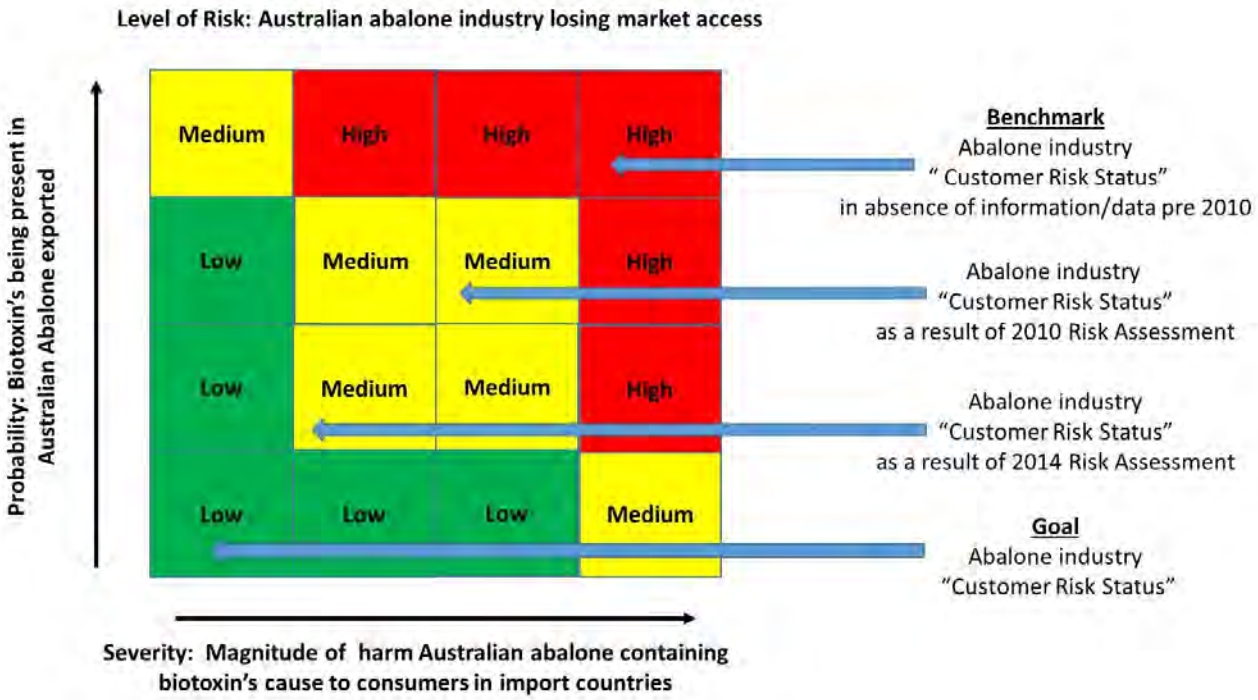

The respective risk assessments have independently and collectively generated information that demonstrates with a high level of confidence that the risk of harm occurring to consumers in export countries from the consumption of Australian abalone products is relatively low. From an industry perspective this translates to a relatively low level of risk of losing market access due to a harmful event such as a PST biotoxin event. This outcome is confirmed by way of the continued access to its major markets in Japan, Hong Kong and China, together with the growth in recently accessed markets in Vietnam, Malaysia, UK, Netherlands and France.

From a direct benefit perspective the investment by the abalone industry of approximately $600,000 or approximately 0.27% of the average annual export sales of Australian abalone (2000/01 - 2011/12 est. $220m/yr) into the two risk assessments completed (2010 & 2013), the industry has not only ensured that it is able to retain market access to key export markets but has averted the short-mid term threat to market access by countering the adoption in the new Codex Standard for Abalone of onerous market access trade standards and monitoring requirements.

In the absence of these risk assessments it would not have been possible for the Australian abalone industry and government to successfully argue for changes to the original position held by the EU and to influence the development and adoption of the The Codex Standard which was finalised in 2013[1]. The Codex standard now recommends countries to undertake risk assessments of marine biotoxins in abalone to determine if a risk exists in the geographical areas under its control, and if so to ensure that abalone comply with the bivalve shellfish maximum regulatory levels for biotoxins. In the absence of the change in the Codex standard for abalone it is estimated that in order to retain market access and meet the expectations of the EU and countries such as Japan, China and Hong Kong the industry would have had to establish a national monitoring program with an infrastructure investment of AUD$4-5 million and an estimated annual cost to the industry of approximately AUD$20m.

[1]Available at: http://www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1

Apart from the direct and in-direct benefits contributed to the abalone industry, the risk assessment process has generated a legacy for the Australian seafood industry in that it has built its overall biotoxin R & D capacity and capability which will not only service the abalone industry but also other seafood industries who seek to retain market access by way of demonstrating that their products are safe for human consumption in domestic and export markets through the application and reporting of research based risk assessments.

5. Benefits and Adoption

During the course of this project the Codex Committee on Fish and Fishery Products (CCFFP) was developing an international abalone standard. The *Standard for Live Abalone and for Raw, Fresh, Chilled or Frozen Abalone for Direct Consumption of for Further Processing* (CODEX STAN -312-2013)[2] was finalised in 2013, stipulating marine biotoxin risk assessment, followed by marine biotoxin testing if necessary. Input from this project assisted the Australian delegation to CCFFP to argue for this rational approach to risk management, i.e. that trade access requirements should be commensurate with risk and appropriate in scale.

In addition to the direct benefit of maintaining market access for this $220 million per annum industry, and the in-direct benefit from economic savings derived from averting the introduction of a national a monitoring scheme (costed at $20 million per annum), the risk assessments have also delivered further in-direct benefits by providing:

- a platform for discussion between regulators and industry on risk management options and the adoption of an approach that is commensurate with the suggested risk;
- a platform for the Australian abalone industry and government aims to defend and/or reduce technical barriers to trade by using the risk assessment output to negotiate risk based international biotoxin standards (at Codex);
- a platform to demonstrate compliance with the Codex Standard CODEX STAN 312-2013, Standard for Live Abalone and for Raw Fresh Chilled or Frozen Abalone for Direct Consumption or for further Processing;
- a platform for the Australian abalone industry to demonstrate compliance with the EU regulation 854/2004 including the 2010 amendment (EU 558/2010) which deals with laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;
- a base set of data against which future risk assessments can be correlated and assessed as to whether the risk profile for biotoxins in abalone has increased, remained static or increased. Thus allowing appropriate adjustment of risk management strategies which are commensurate with the recalibrated risk profile of the abalone industry.

In addition to the direct and in-direct value and benefits that the risks assessments have contributed to the Australian abalone industry during the process of undertaking the assessments SARDI and its partners in the projects have had to invest in building capacity and capability that would allow the adoption and implementation of various methodologies for generating the breadth of information and data collected and collated for the risk assessment. In so doing the risk assessment process built an Australian based R & D platform that will:

[2] Available at: http://www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1

- allow ‘on-shore’ testing for the presence of biotoxins in abalone (vs Cawthorne, NZ);
- enable pro-active testing regimes to be implemented in advance of potential biotoxing outbreaks;
- improve the efficiency, effectiveness and economics associated with testing for biotoxins in Australia;
- reduce the time required for industry stakeholders to respond to biotoxin outbreaks;
- enable expanded R & D in relation to biotoxins across a range of shellfish species;
- generate the technical platform for future risk assessment and the establishment of technical standards relating to market access.

As biotoxins are an issue for all bivalve molluscs, and potentially for other seafood species such as rock lobster, the methodologies and knowledge developed in the research element of the risk assessments will inform and progress further trade access and food safety policy and regulation for the broader Australian seafood industry. Therefore, although abalone is a test case the outcomes of the risk assessments completed will support other Australian Seafood Industry sector efforts to further develop new markets and retain market access in established markets.

6. Further Development

The qualitative evaluation of the human health risk presented in these risk profiles could be considerably strengthened by stakeholders in the future by focusing on key knowledge gaps. Notably, there are limited data pertaining to PST levels in abalone during *Alexandrium* sp. blooms, and little data with which to evaluate the occurrence of marine biotoxins in abalone from some areas in Australia from which large volumes of abalone are harvested i.e. the western coast of Tasmania. There are also significant data gaps relating to abalone consumption, particularly meal types consumed and the associated serving sizes. Also of significance is the scarcity of information on the propensity of abalone species to accumulate and retain OA group toxins, DA and BTXs during toxin-producing phytoplankton blooms. International studies have shown that some species of abalone are able to accumulate significant levels of OA group toxins in the viscera, but no information is available for Australian species. There is no information available nationally or internationally about the propensity for abalone to accumulate DA or BTXs during toxin-producing phytoplankton blooms; although DA has been found in abalone during this study, indicating that accumulation of DA is possible. The propensity to accumulate toxins is a key component of determining if a hazard exists; without this there is no hazard/food pairing of relevance.

It is recommended that stakeholders consider whether further research to address key data gaps is warranted in order to strengthen the risk assessments. The monitoring of marine biotoxins in abalone tissues during toxin-producing phytoplankton blooms could provide this data whilst reducing trade and market access risk. Alternatively, improving data on the prevalence of marine biotoxins in abalone may be logistically simpler and enable a quantitative risk assessment in the future. Further work on consumption patterns would provide value information for future exposure assessments.

The risk assessments have also provided a platform for discussions between regulators and industry to determine the appropriate level of management required

(and if the current controls in place in New Zealand are appropriate or need reviewing).

7. Planned Outcomes

Public Benefit Outcomes

- New marine biotoxin analytical capability in Sydney
- Increased expertise in marine biotoxins risk assessment in Australia and New Zealand

Private Benefit Outcomes

- Risk assessments available for use by industry for determining options for risk management based on considerations of productivity of harvest blocks, level of knowledge of marine biotoxins in Australia and New Zealand, and the product formats exported
- Reports available for use in trade and market access negotiations
- Acceptance at Codex of the risk assessment approach to risk management
- Knowledge of the presence of important information gaps and where future research is best invested

Linkages with CRC Milestone Outcomes

2.2 - Diagnostic systems to assure seafood quality and integrity

2.2.4 - Diagnostic technologies and capabilities developed for at least one chemical or residue hazard to support technical market access of Australian seafood

2.4 - Optimised technical market access

2.4.2 - Two completed, internationally reviewed, integrated health benefit and risk assessments available for market access negotiations and for consumer risk advisories

8. Conclusion

In conclusion, the outputs of this project demonstrate the usually extremely low to low risk of marine biotoxins in abalone products causing human illness. Only one product format was identified as having a low to moderate risk with respect to PSTs only (viscera sashimi). Several knowledge gaps were identified that could build on improving these risk assessments, and potentially lead to quantitative assessments.

The project has contributed significantly to capability development in marine biotoxins in Australia: both in building analytical services, and in improving capability in the regulatory and research fields. This capability has already significantly aided incident response to a major event, and will continue to aid the provision of further research in this field for both the abalone sector and other seafood sectors.

The project was able to contribute expertise and results to the international discussions at Codex, demonstrating that a risk management approach could be a successful route for determining the risk management of marine biotoxins in abalone, and thus avoiding the requirement of regular marine biotoxin monitoring in the Codex abalone standard.

The respective risk assessments have independently and collectively generated information that demonstrates with a high level of confidence that the risk of harm occurring to consumers in export countries from the consumption of Australian and New Zealand abalone products is relatively low. From an industry perspective this

translates to a relatively low level of risk of losing market access due to a harmful event such as a PST biotoxin event. This outcome is confirmed by way of the continued access to its major markets in Japan, Hong Kong and China, together with the growth in recently accessed markets in Vietnam, Malaysia, UK, Netherlands and France.

From a direct benefit perspective the investment by the abalone industry of approximately $600,000 or approximately 0.27% of the average annual export sales of Australian abalone (2000/01 - 2011/12 est. $220m/yr) into the two risk assessments completed (2010 & 2013), the industry has not only ensured that it is able to retain market access to key export markets but has averted the short-mid term threat to market access by countering the adoption in the new Codex Standard for Abalone of onerous market access trade standards and monitoring requirements.

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10. Appendices

Appendix 1. A National Survey of Marine Biotoxins in Wild Caught Abalone in Australia

Appendix 2. Accumulation and elimination of paralytic shellfish toxins by *Haliotis rubra* during blooms of *Gymnodinium catenatum* and *Alexandrium tamarense* in Tasmania (also reported in FRDC report 2010-040)

Appendix 3. Provisional risk assessment of paralytic shellfish toxins in Australian wild caught abalone

Appendix 4. Risk profile for diarrhetic shellfish toxins, amnesic shellfish toxins and neurotoxic shellfish toxins in commercially harvested Australian wild abalone

Appendix 5. Provisional Risk Assessment of Diarrhetic Shellfish Toxins in New Zealand Commercially Harvested Paua

Appendix 6. Provisional Risk Assessment of Paralytic Shellfish Toxins in New Zealand Commercially Harvested Paua

Appendix 7. Risk Profile: Brevetoxins in Commercially Harvested Abalone (Paua)

Appendix 8. Risk Profile: Domoic Acid in Commercially Harvested Abalone (Paua)

Appendix 9. Impact of canning on paralytic shellfish toxin levels in abalone foot tissue: proposed experimental approach

Appendix 10. Benefit & Contribution of the Abalone Biotoxin Risk Assessments to the Industry (2010 & 2013)