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## **Supporting document 1**

### **Paralytic Shellfish Poisoning and Diarrhetic Shellfish Poisoning Cases in Australia and New Zealand – Application A1243**

#### **Harmonisation of the marine biotoxin standards for bivalve shellfish**

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## **Executive summary**

Application A1243 is requesting that Schedule 19 to Standard 1.4.1 of the Australia New Zealand Food Standards Code (the Code) is amended to define Paralytic shellfish toxins (PST) as measured in mg saxitoxin dihydrochloride equivalents per kilogram; and to lower the ML for Diarrhetic shellfish toxin (DST), expressed as okadaic acid-equivalents, from 0.20 to 0.16 mg/kg in bivalve molluscs.

PST and DST are both heat stable toxins naturally produced by ocean dwelling algae. PST consumed in bivalve molluscs can cause paralytic shellfish poisoning (PSP), with symptoms that vary from a slight tingling or numbness to complete respiratory paralysis. DST can cause Diarrhetic Shellfish Poisoning (DSP), with symptoms including diarrhoea, nausea, vomiting and abdominal pain.

This document examines currently available information on the incidence of PSP and DSP in Australia and New Zealand.

The case report data collected and food recall data for Australia and New Zealand shows there have been few suspected or confirmed cases of either illness, and no confirmed cases of PSP or DSP in commercially produced bivalves where routine biotoxin monitoring has been conducted. One suspected case in New Zealand involved an individual treated for PSP in Wellington (NZ) after purchasing and consuming oysters. However, due to the limited case data available, FSANZ is unable to confirm if this represents an isolated failure of risk management measures for PST in bivalves.

After reviewing the best available evidence, FSANZ concludes the current risk management strategies for commercially produced bivalve molluscs are effective measures for protecting public health and safety from PST and DST.

## Table of contents

<b>EXECUTIVE SUMMARY</b> .....	<b>1</b>
<b>INTRODUCTION</b> .....	<b>2</b>
<b>KNOWN CASES</b> .....	<b>2</b>
<b>PRODUCT RECALLS</b> .....	<b>6</b>
<b>DISCUSSION</b> .....	<b>6</b>
<b>CONCLUSION</b> .....	<b>6</b>
<b>REFERENCES</b> .....	<b>7</b>

# Introduction

Application A1243 is requesting that Schedule 19 to Standard 1.4.1 of the Australia New Zealand Food Standards Code (the Code) is amended to define Paralytic shellfish toxins (PST) as measured in mg saxitoxin dihydrochloride equivalents per kilogram rather than mg saxitoxin equivalents/kg, lowering the effective maximum level (ML) for PST by 24% in bivalve molluscs; and to lower the ML for Diarrhetic shellfish toxin (DST), expressed as okadaic acid-equivalents, from 0.20 to 0.16 mg/kg in bivalve molluscs.

PSTs are a group of over 50 related analogues of saxitoxin, which are heat stable toxins naturally produced by ocean dwelling algae. PST consumed in bivalve molluscs can cause paralytic shellfish poisoning (PSP). Symptoms of PSP vary from a slight tingling or numbness to complete respiratory paralysis. Deaths from PSP have been recorded overseas.

DSTs are okadaic acid-group toxins, which are also heat stable toxins naturally produced by ocean dwelling algae. DST consumed in bivalve molluscs can cause Diarrhetic Shellfish Poisoning (DSP). Symptoms of DSP include diarrhoea, nausea, vomiting and abdominal pain. Symptoms occur shortly after consumption and usually resolve within 3 days.

The current MLs for PST and DST in bivalve molluscs in Schedule 19 were established under Proposal P158 – Review of the Maximum Permitted Concentrations of Non-metals in Food. (ANZFA 1999). Neither the PST or DST ML has been reviewed since that time.

As part of the assessment of A1243, available information on the incidence of PSP and DSP in Australia and New Zealand was reviewed to understand the efficacy of current risk management strategies for PST and DST in bivalve molluscs.

Monitoring for marine biotoxins in molluscs has been going on for decades in most states. The incidence data provided in the application was collected as part of the state Shellfish Quality Assurance Programs' biotoxin risk management. Biotoxin risk management requirements are detailed in the Australian Shellfish Quality Assurance Program (ASQAP) Manual of Operations. These requirements are set by the ASQAAC: a government-industry cooperative program that assures food safety of shellfish when grown, harvested and handled in accordance with its operational guidelines.

## Known cases

Relevant data on known cases of PSP and DSP in bivalve molluscs was identified from publicly available grey literature (OzFoodNet through CDI<sup>1</sup>, NSFS<sup>2</sup>, ESR<sup>3</sup>) and scientific case reports (PubMed<sup>4</sup>, Web of Science<sup>5</sup>).

Only cases from Australia and New Zealand for individuals that had consumed bivalves were considered. Cases needed to be suspected or treated for PSP or DSP to be included. The presence of PST or DST did not need to be identified analytically, but symptoms or known algal blooms must be consistent.

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<sup>1</sup> <https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdi-search>

<sup>2</sup> <https://www.mpi.govt.nz/science/food-safety-and-suitability-research/human-health-surveillance-and-attribution-programme/foodborne-disease-annual-reports/>

<sup>3</sup> [https://surv.esr.cri.nz/public\\_health\\_surveillance/public\\_health\\_surveillance.php](https://surv.esr.cri.nz/public_health_surveillance/public_health_surveillance.php)

<sup>4</sup> <https://pubmed.ncbi.nlm.nih.gov/>

<sup>5</sup> <https://www.webofscience.com/wos/author/search>

## **Paralytic Shellfish Poisoning**

A total of 65 known or probable cases of PSP were identified in Australia and New Zealand in the past 40 years (Table 1). More cases were identified in New Zealand than Australia (56 of 65; 86%), which is likely the result of higher reporting of nationally notifiable toxic shellfish poisoning events in New Zealand, and that wild harvesting shellfish from non-commercial sources is a more common cultural practice in New Zealand (MacKenzie 2014).

Where details are available to understand the food source of a known or suspected PSP case, all but one case involved recreationally harvested bivalves. The single suspected case of PSP occurred following the purchase and consumption of fried oysters in Wellington, New Zealand in 2007 (ESR 2007). There was no information on the commercial production source of the oysters implicated, if the event was linked to a known algal bloom, nor was the presence of PST confirmed.

## **Diarrhetic Shellfish Poisoning**

A total of 84 known or probable cases of DSP were identified in Australia and New Zealand in the past 40 years (Table 2), with another 46 anecdotal cases. The majority of these cases are associated with two outbreaks occurring in pipis from the NSW mid-north coast in 1997 (56 cases) and 1998 (23 cases). These outbreaks occurred before the introduction of routine biotoxin monitoring programs in NSW. Only four suspected cases of DSP were identified in New Zealand.

**Table 1 – Known or suspected cases of PSP in Australia and New Zealand.**

<b>Year</b>	<b>Product</b>	<b>Origin</b>	<b>Cases</b>	<b>Comments</b>	<b>References</b>
1980	Unknown	Bellerive, TAS	2 cases	Possible cases identified from historical records. Outbreak occurred prior to routine biotoxin monitoring.	Hallegraeff and Sumner (1986)
1986	Unspecified shellfish	Cygnet, TAS	2 cases	Possible cases identified from historical records. Outbreak occurred prior to routine biotoxin monitoring.	Hallegraeff and Sumner (1986)
2007	Oysters (commercially purchased)	Wellington, NZ	1 case	Case hospitalised and treated for PSP, toxin was not confirmed.	ESR (2007)
2009	Clams (recreationally harvested)	Papamoa Beach, NZ	1 case	Case hospitalised and treated for PSP, toxin was not confirmed.	ESR (2009)
2010	Unknown	Unknown, NZ	4 cases	Suspected cases occurring over year. Limited detail available.	ESR (2010)
2011	Mussels (recreationally harvested)	Port Esperance, TAS	1 case	Case hospitalised	Turnbull et al. (2013)
2011	Unknown shellfish	Unknown, NZ	1 case	Suspected case. Limited detail available.	ESR (2011)
2012	Clams (recreationally harvested)	Bay of Plenty, NZ	29 cases	17 hospitalised	Hallegraeff et al. (2021); MacKenzie (2014)
2013	Clams	Bay of Plenty, NZ	1 case	Source unconfirmed	MPI (2013)
2014	Clams (recreationally harvested)	Bay of Plenty, NZ	7 cases		ESR (2014a)
2014	Mussels (recreationally harvested)	Bay of Plenty, NZ	5 cases		ESR (2014a)

2014	Unspecified bivalves (recreationally harvested)	Unknown, NZ	4 cases		ESR (2014b)
2015	Mussels (recreationally harvested)	Little Swanport, TAS	4 cases	2 cases hospitalised	Edwards et al. (2018)
2016	Unspecified	Unknown, NZ	2 cases	Suspected cases occurring over year. Limited detail available.	ESR (2016)
2019	Clams (recreationally harvested)	Rarawa Beach, NZ	1 case	A shellfish biotoxin alert had already been issued	ESR (2019)

**Table 2 – Known or suspected cases of DSP in Australia and New Zealand.**

Year	Product	Origin	Cases	Comments	References
1997	Pipis	Ballina, NSW	56 cases	An additional 46 anecdotal cases identified; Outbreak occurred prior to routine biotoxin monitoring	Quaine et al. (1997)
1998	Pipis	Mid-north coast, NSW	23 cases	Outbreak occurred prior to routine biotoxin monitoring	Ajani et al. (2001)
2000	Pipis (recreationally harvested)	North Stradbroke Island, QLD	1 case		MacKenzie et al. (2002)
2006	Mussels	Unknown, NZ	1 case	No details on source	ESR (2006)
2007	Shellfish suspected	Taranaki, NZ	2 cases		MPI (2007)
2011	Unknown shellfish	Unknown, NZ	1 case	Suspected case. Limited detail available.	ESR (2011)

# Product recalls

## Australia

Between 2012 and 2021, FSANZ undertook 26 recalls due to PST across all seafood in Australia, which were predominantly associated with 14 recalled products in 2015 due to known or suspected PST contamination of shellfish.

In the same period between 2012 and 2021, there were 3 recalls due to DST contamination across all seafood in Australia.

## New Zealand

There were no consumer-level recalls for shellfish contaminated with PST or DST undertaken by New Zealand Ministry for Primary Industries between 2015-2022<sup>6</sup>

## Discussion

The above case report data and food recall data for Australia and New Zealand shows that there have been few cases of either PSP or DSP where biotoxin monitoring has been conducted using the current MLs specified in the Code, or Codex MLs under the Animal Products (Regulated Control Scheme - Bivalve Molluscan Shellfish) Regulations 2006 (New Zealand only).

A commercial biotoxin analytical service started in Australian in 2012 and all states with commercial bivalve production have been monitoring for marine biotoxins since that date. Since 2012, there have been no reported cases of PSP from commercial bivalve production, nor reported cases of DSP associated with bivalve consumption.

In New Zealand, a single case report was located where an individual was treated for PSP in Wellington, New Zealand after purchasing and consuming oysters. However, in the absence of further detail on the commercial production, if the event was linked to a known algal bloom, or if the presence of PST was confirmed; FSANZ is unable to confirm if this represents a failure of risk management for PST in bivalves. All remaining known or suspected cases identified in New Zealand, where details on the food source is described, involved bivalves that were harvested recreationally.

## Conclusion

The available evidence suggests the current risk management strategies for commercially produced bivalve molluscs are effective measures for protecting public health and safety from PST and DST.

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<sup>6</sup> <https://www.mpi.govt.nz/food-safety-home/food-recalls-and-complaints/recalled-food-products/>

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