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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 1

Risk assessment

Application A1243

Harmonisation of the marine biotoxin standards for bivalve shellfish

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Executive summary

Application A1243 sought amendment of Schedule 19 of the Australia New Zealand Food Standards Code (the Code) to define paralytic shellfish toxins (PST) as measured in mg saxitoxin dihydrochloride equivalents per kilogram; and to lower the ML for diarrhetic shellfish toxins (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 risk to public health and safety, and the incidence of PSP and DSP in Australia and New Zealand.

FSANZ Proposal P158 and subsequent Joint FAO/IOC/WHO ad hoc Expert Consultation and European Food Safety Authority (EFSA) risk assessments indicate that there is a low margin of safety between exposure to PST and DST at current regulatory levels and the acute reference dose (ARfD) and lowest observed adverse effect level (LOAEL) at which mild signs of toxicity may occur.

The Joint FAO/IOC/WHO ad hoc Expert Consultation has clarified that analytical data for PST for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh. For DST analytical data for all methods should be expressed as mg okadaic acid (OA) equivalents per kg of whole flesh.

The 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

After reviewing the best available evidence, FSANZ concludes that there is a low margin of safety associated with current regulatory levels for shellfish for PST and DST. However since 2012, there have been no reported cases of PSP or DSP associated with commercial bivalve production in Australia.

Analytical data for PST for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh. For DST analytical data for all methods should be expressed as mg okadaic acid (OA) equivalents per kg of whole flesh.

Harmonising levels with Codex would clarify the units for expressing PST and effectively reduce the MLs for PST and DST thereby increasing the margin of safety associated with PSP and DSP in Australia.

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Introduction

Application A1243 requested that Schedule 19 of the Australia New Zealand Food Standards Code (the Code) be 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 toxins (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 (OA) 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 underway 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.

Risk to public health and safety

Paralytic shellfish poisoning

FSANZ considerations in Proposal P158

Proposal P158 – Review of the Maximum Permitted Concentrations of Non-Metals in Food (FSANZ 1999), established an ML of 80 µg saxitoxin (STX) equivalents per 100 g edible shellfish flesh (0.8 mg/kg) to be adopted as the joint Australia/New Zealand standard.

The report is silent on the intended units but notes that the available data suggest that moderate symptoms of toxicity can occur at intake levels of 120 µg of STX. At a regulatory level of 80 µg/100 g of edible shellfish flesh, this level could be reached after consuming 150 g of contaminated shellfish. The margin of safety in this case, therefore, is very small.

Several overseas organisations have established health-based guidance values (HBGVs) for PSTs since the P158 report was published. These are discussed further below.

Report of the Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs

Exposure to STX was estimated in several case studies on PSP in Canada, involving about 60 persons, age 3-72, and covering some 20 incidents of poisoning between 1970 and 1990, (FAO/IOC/WHO 2004). For the affected persons, the symptoms of PSP were classified as mild, moderately severe or extremely severe. Mild cases generally had consumed 2-30 µg/kg bw, while the more severe cases generally involved exposure > 10-300 µg/kg bw. Based on these data a provisional lowest observed adverse effect level (LOAEL) of 2.0 µg/kg bw was established by the Expert Consultation. A provisional acute reference dose (ARfD) of 0.7 µg STX equivalents/kg bw, was established based on the LOAEL of 2 µg STX equ/kg bw and a safety factor of 3 because documentation of human cases includes a wide spectrum of people (occupation, age and sex) and mild illness is readily reversible.

FSANZ notes that this ARfD could be exceeded by the consumption of ~ 53 g of shellfish at the current regulatory limit in the Code (0.8 mg/kg STX). The LOAEL (mild cases of illness) could be exceeded by consumption of 150 g of shellfish at the current regulatory limit. Again the margin of safety is very small.

The Expert Working Group clarified that analytical data for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh.

EFSA, 2009

From the available reports on intoxications in humans, comprising more than 500 individuals, a LOAEL in the region of 1.5 µg STX equivalents/kg bw was established by the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel; EFSA 2009). Because many individuals did not suffer adverse reactions at higher intakes, it was expected that this LOAEL is close to the threshold for effects in sensitive individuals. Therefore the CONTAM Panel concluded that a factor of 3 was sufficient to move from this LOAEL to an estimated no observed adverse effect level (NOAEL) of 0.5 µg STX equivalents/kg bw.

The CONTAM Panel) noted that consumption of a 400 g portion of shellfish meat containing STX-group toxins at the current EU limit of 800 µg STX equivalents/kg shellfish meat would result in an intake of 320 µg toxin (equivalent to 5.3 µg /kg bw in a 60 kg adult).

EFSA observed that this intake is considerably higher than the ARfD of 0.5 µg STX equivalents/kg bw (equivalent to 30 µg STX equivalents per portion for a 60 kg adult) and is a concern for health. In order for a 60 kg adult to avoid exceeding the ARfD of 0.5 µg STX equivalents/kg bw, a 400 g portion of shellfish should not contain more than 30 µg STX equivalents corresponding to 75 µg STX equivalents/kg shellfish meat.

Diarrhetic Shellfish Poisoning

FSANZ considerations in Proposal P158

Cases of DSP poisoning causing severe vomiting, nausea and diarrhoea symptoms in shellfish consumers were first recorded in the Netherlands in the 1960s and in Japan in the late 1970s. Since then similar problems have been recognised in Spain, France, Scandinavia, Thailand, Chile, Canada and New Zealand.

The clinical symptoms of DSP often may have been mistaken for those of bacterial gastric infections and the problem may be much more widespread than currently thought. Unlike PSP, no human fatalities have been reported and patients usually recover within 3 days. However, some of the toxins involved could act as stomach tumour promotors and thus produce chronic problems in shellfish consumers.

The then current New Zealand Ministry of Agriculture and Fisheries (MAF) standard of 20 µg okadaic acid per 100 g of the edible shellfish flesh (0.2 mg/kg) was adopted as the joint Australia/New Zealand standard.

Several overseas organisations have established HBGVs for DSTs since the P158 report was published. These are discussed further below.

Report of the Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs

Human data from Japan (8 persons from 3 families, age 10-68) indicated a LOAEL of 1.2 to 1.6 µg/kg bw OA. In a second study from Norway, 38 of 70 adults were affected at levels ranging from 1.0 to 1.5µg/kg bw. The expert consultation established a ARfD of 0.33 µg OA equivalents/kg bw, based on the LOAEL of 1.0 µg OA/kg bw, and a safety factor of 3 because of documentation of human cases including more than 40 persons and because DSP symptoms are readily reversible. Analytical data for all methods should be expressed as mg OA equivalents per kg of whole flesh.

FSANZ notes that this ARfD could be exceeded by the consumption of ~ 100 g of shellfish at the current regulatory limit in the Code (0.2 mg/kg). The LOAEL could be exceeded by consumption of 300 g of shellfish at the current regulatory limit. The margin of safety is very small.

EFSA, 2008

The EFSA Panel established an ARfD based on the available human data. A LOAEL for human illness was identified in the region of 50 µg OA equivalents/person, which equates to approximately 0.8 µg OA equivalents/kg bw for a 60 kg adult. An uncertainty factor of three was applied to extrapolate this LOAEL to a NOAEL which resulted in an ARfD of 0.3 µg OA equivalents/kg b.w.

The EFSA Panel noted that a 400 g portion of shellfish meat containing OA-group toxins at the current EU limit of 160 µg OA equivalents/kg shellfish meat would result in a dietary exposure of 64 µg toxin. For a 60 kg adult this is equivalent to approximately 1 µg/kg b.w. This figure exceeds the ARfD by approximately 3-fold and is in the region of the LOAEL as derived from the human case studies.

Known cases

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

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.

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.

[1] https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdi-search
[2] https://www.mpi.govt.nz/science/food-safety-and-suitability-research/human-health-surveillance-and-attribution-programme/foodborne-disease-annual-reports/
[3] https://surv.esr.cri.nz/public_health_surveillance/public_health_surveillance.php
[4] https://pubmed.ncbi.nlm.nih.gov/
[5] https://www.webofscience.com/wos/author/search

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

Year	Product	Origin	Cases	Comments	References
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[6]

Discussion

The available information from P158 and subsequent Joint FAO/IOC/WHO ad hoc Expert Consultation and EFSA risk assessments indicate that there is a low margin of safety between exposure at current regulatory levels and the ARfD and LOAEL at which mild signs of toxicity may occur.

The Joint FAO/IOC/WHO ad hoc Expert Consultation has clarified that analytical data for PST for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh. For DST analytical data for all methods should be expressed as mg OA equivalents per kg of whole flesh.

The 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.

[6] https://www.mpi.govt.nz/food-safety-home/food-recalls-and-complaints/recalled-food-products/

Conclusion

After reviewing the best available evidence, FSANZ concludes that there is a low margin of safety associated with current regulatory levels for shellfish for PST and DST. However since 2012, there have been no reported cases of PSP or DSP associated with commercial bivalve production in Australia.

Analytical data for PST for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh. For DST analytical data for all methods should be expressed as mg OA equivalents per kg of whole flesh.

Harmonising levels with Codex would clarify the units for expressing PST and effectively reduce the MLs for PST and DST thereby increasing the margin of safety associated with PSP and DSP in Australia.

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