Imported food risk statement

Bivalve molluscs and saxitoxin-group toxins

Scope: Saxitoxin-group toxins in bivalve molluscs. This includes whole or portions of bivalve molluscs that are fresh, frozen, dried or canned, such as cockles, clams, mussels, oysters and scallops.

The following products are excluded and not covered by this risk statement:

- Cephalopod molluscs (e.g squid, octopus, cuttlefish) and jelly fish
- Scallops or pearl oysters where the only part of the product consumed is the adductor muscle (i.e. roe off)

Recommendation and rationale
Do saxitoxin-group toxins in imported bivalve molluscs present a potential medium or high risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • Paralytic shellfish toxins (PST) 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. • Fatalities resulting from PSP intoxication have been reported. • On the basis of the severity of disease, and available prevalence data, the risk to public health in Australia is currently considered medium to high.

General description
Nature of the toxin: Paralytic shellfish toxins (PST) are a group of over 50 related analogues of saxitoxin that vary in toxicity[1–3]. PST are produced by a range of unicellular dinoflagellate algae (generally from the *Alexandrium*, *Pyrodinium* or *Gymnodinium* genus) and one type of blue-green algae[4,5]. The levels of PST-producing dinoflagellates that exist in an ecosystem fluctuates and is influenced by factors such as temperature, sunlight, available nutrients and shipping activities in the area, including the release of ballast water[6–8]. Toxin accumulation is lower in the adductor muscle, minimising risk from PSP in bivalves consumed roe-off[5,9]. Toxin clearance (depuration) rates of PST vary between bivalve species, and in some cases the toxin can persist for up to two years after exposure to a harmful bloom of PST-producing algae[5]. PST is not diminished by rinsing, cleaning or freezing. There is limited evidence that PST will partly degrade at high temperatures and pressures, and there are reports that PST levels are reduced during the process of canning[9–11]. A small amount of PST can leach out of bivalves into the cooking medium, which can reduce the exposure to PST if the cooking medium is subsequently discarded[9].

General description

Adverse health effects:

People affected by PSP show symptoms that may include[12–14]:

- numbness or tingling around the mouth, face or extremities
- unsteady walking, weakness and clumsiness
- slurred/unclear speech
- dizziness/vertigo or double vision
- difficulty breathing, swallowing and paralysis.

Deaths have been reported in otherwise healthy adults as a result of PSP. The proportion of PSP cases that will result in death is significantly reduced when a local healthcare system is equipped to manage the paralytic symptoms and any resultant respiratory failure until the toxin is cleared[14].

In less severe cases, symptoms generally resolve within a few days. The onset of symptoms associated with PSP is variable and dependent on the amount of PST consumed. Effects can be observed rapidly within minutes or, in less severe cases, hours[12–14].

Consumption patterns:

In the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey), <1 % of children (aged 2 – 16 years), <1 % of adults (aged 17 – 69 years) and <1% of people aged 70 and above, reported consumption of bivalve molluscs (Australian Bureau of Statistics 2011)[15].

High level consumers of bivalve molluscs in Australia (97.5 percentile) consumed approximately 250 grams per day per consumer (across the whole population 2+ years)[15].

Mixed foods that contained bivalve molluscs and canned products were excluded from the analysis.

In the 2018-19 Australian Consumption of Selected Foodstuffs[14], the apparent daily consumption of crustacean and molluscs was estimated to be 2.1g per capita[16].

Risk factors and risk mitigation

Key risk factors:

- Consumption of bivalve molluscs (fresh or processed) from:
  - global regions where blooms of PST-producing microorganism species have been identified
  - areas where ballast water taken from areas historically associated with PSP outbreaks, has been discharged[6].
- There is a risk that PSP outbreaks will occur as a result of seafood produced in areas without a history of PST-producing algal blooms. The unpredictable occurrence and distribution of these events is linked with changing global temperatures and human activities[6,7,17].

Risk mitigation strategies:

- Batch testing samples of bivalve molluscs to verify that PST levels meet the Code specified ML of ≤0.8 mg saxitoxin eq/kg of mollusc flesh[18].
- Seafood management plans that monitor commercial and recreational harvesting sites for PST and associated algal species.
- Signage at sites historically associated with PSP outbreaks, warning of the risk of consuming bivalve molluscs (warning may need to be in several languages to allow for recreational harvest by tourists).

Surveillance information:

Food poisoning events associated with PSP is a notifiable condition in most states and territories in Australia, and in New Zealand. There are no documented cases of PSP in Australia as a result of imported bivalve molluscs.

In the period 2017/18, according to the then Australian Department of Agriculture, approximately 80% of imported bivalves into Australia came from either China (55%), Chile (16%) or Japan (8%)[19]. All three countries have documented cases of PSP resulting from the consumption of local bivalve molluscs (refer to Table A1, Appendix 1).

Determining regulatory limits for PST in bivalve molluscs varies between countries. This occurs because of differences in reporting units (specifying free base or the dihydrochloride salt in the maximum levels) or by applying different toxicity equivalence factors when calculating the contribution saxitoxin equivalents[20].

General description

Illness associated with consumption of bivalve molluscs contaminated with PST

On the basis of a search of the scientific literature via PubMed, US CDC National Outbreak Reporting System Online Database (NORS)[21], European Rapid Alert System for Food and Feed online consumer portal (RASFF)[22] and other publications up to April 2021, it appears that PSP outbreaks associated with consumption of bivalve molluscs are relatively rare, but are serious life threatening events (refer to Table A1, Appendix 1).

Data on the prevalence of PST in bivalve molluscs

There are a number of ongoing programs worldwide to monitor the levels of biotoxins in shellfish and phytoplankton levels in harvesting waters. Nevertheless, recall events still occur. Between 2011 and 2020, there were 26 recalls due to PST across all seafood in Australia[23] and 15 notifications on the European Commission's RASFF portal referencing PST in bivalve molluscs[22].

Standards or guidelines

Australia and New Zealand

Schedule S19-5 of the Australian New Zealand Food Standard Code specifies a maximum level of 0.8 mg/kg of saxitoxin-equivalents in bivalve molluscs. This deviates from the maximum level specified by Codex, which includes the mass of the dihydrochloride salt when calculating the maximum limit[18,24].

The use of the FAO/WHO Toxicity Equivalence Factors is specified in the Australian Seafood Quality Assurance Program (ASQAP) manual, which is the Australian national guideline for monitoring marine biotoxins[25].

New Zealand

The Ministry of Primary Industries specified a maximum limit of ≤0.8 mg saxitoxin.2HCl equivalents/kg of edible portion, which is consistent with the maximum limit specified by Codex[24,26].

Codex

Codex Standard 292-2008 for live and raw bivalve molluscs specifies a ML of ≤0.8 mg saxitoxin.2HCl equivalents/kg of mollusc flesh for PST. The codex standard does not specify the toxicity equivalence factors[24].

The following Codex Standards are also relevant in the prevention of PSP from consumption of bivalve molluscs:

- Codex general principles of food hygiene (CXC 1-1969)
- Codex code of practice for fish and fishery products (CXC 52-2003)
- Codex guidelines for the sensory evaluation of fish and shellfish in laboratories (CXG 31-1999)

Other countries

USA - National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish specifies a guidance/action level of ≤0.8 mg saxitoxin equivalents/kg for bivalve shellfish[27].

European Union (EU) countries – Chapter 5 of Regulation (EC) No. 853/2004, gives a maximum limit of 0.8 mg saxitoxin equivalents/kg, measured in whole body or any part edible separately[28].

Europe – the European Food Safety Authority (2009) established an acute reference dose of 0.5 µg saxitoxin equivalents/kg bw[29].

Management approaches used by overseas countries

New Zealand - has specific monitoring programmes for both recreationally and commercially harvested shellfish, which includes monitoring at specified sites for saxitoxin-group toxins and associated phytoplankton species[26].

USA – The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan shellfish; 2019 revision requires as a minimum, a contingency plan for proactive management for PST. A management plan is required where there is a history of closure due to PSP incidents or saxitoxin-group toxin producing phytoplankton are known to occur in the growing area[27]

Chile – The Food Safety and Certification Manual outlines the standards and procedures to ensure safety in fishery and aquaculture products in Chile[30]. The Canadian government audited the Chilean bivalve mollusc sanitation program in 2018, concluding that the system in Chile is effective at managing food safety risk associated with bivalve molluscs[31].

Management approaches used by overseas countries
China – No details of monitoring or management programmes for biotoxins in bivalves harvested in China were found in a literature search.

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Appendix 1 – International paralytic shellfish poisoning events resulting from the consumption of bivalve molluscs that were sourced from countries who produce the majority of Australia's bivalve mollusc imports ǂ

Table A1 – Overview of PSP cases attributed to saxitoxin-group toxins located in the literature.

Country of origin	Year	Product	Number of cases	Comments
United States[21]	2017	Mussels	5	
United States[21]s	2017	Clams	3	
United States[21]	2013	Clams	2	
United States[21]	2012	Mussels	7	4 hospitalised
United States[21]	2010	Clams	3	2 hospitalised
United States[21]	2008	Mussels	3	3 hospitalised
United States[21]	2007	Mussels	4	4 hospitalised
United States[21]	2002	Mussels	4	1 hospitalised
Chile[14]	2002	Mussels	4	All 4 hospitalised
Chile[13]	2002	Mussels	2 (2 deaths)	Death occurred within 4 hours
United States[21]	2000	Mussels	9	6 hospitalised
United States[21]	1998	Mussels	6	
Japan[32]	1997	Oysters	26	16 hospitalisations
China[33]	2005	Clams	More than 20	
USA[12]	1994	Mussels	11	4 hospitalisations
Japan[32]	1991	Oysters	5	
Chile[34]	1991-1992	Unspecified	150 (11 deaths)	30% hospitalisation rate
China[35]	1991	Mussels	2 deaths	
China[35]	1989	Clam	5	
China[35]	1986	Clam	136 hospitalisations (1 death)	
Canada	1957	Clams	20	

ǂ Between 2017-2018, China (55%), Chile (16%), Japan (8%), Vietnam (5%), United States (4%), Thailand (4%) and Canada (3%) made up 95% of bivalve mollusc imports into Australia, not including imports from New Zealand[19].