

Imported food risk statement

Bivalve molluscs and domoic acid

Scope: Domoic acid 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 therefore not covered by this risk statement:

- Cephalopod molluscs (e.g squid, octopus, cuttlefish) and jelly fish

Recommendation and rationale

Does domoic acid in imported bivalve molluscs present a potential medium or high risk to public health:

Yes

No

Rationale:

- Domoic acid is a heat stable neurotoxin naturally produced by ocean dwelling algae.
- Ingestion of domoic acid in contaminated bivalve molluscs can cause amnesic shellfish poisoning (ASP).
- Symptoms of ASP range from gastrointestinal upset through to severe neurological symptoms.
- Permanent neurological damage and fatalities resulting from domoic acid 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:

Domoic acid is a neurotoxic non-protein amino acid. It is produced primarily by members of the genus *Pseudo-nitzschia*, *Nitzschia*, or *Chondria*. These organisms present to some extent in most coastal marine environments^{1,2}.

Domoic acid is a potent neurotoxin that causes amnesic shellfish poisoning (ASP) within 24-48 hours following ingestion. There is no antidote for ASP^{2,3}

Domoic acid is not reliably destroyed by common cooking methods or by autoclaving. Domoic acid can leach out of some bivalves species into the cooking medium, which can reduce the exposure to domoic acid if the cooking medium is subsequently discarded^{4,5}.

Some vulnerable subpopulations generally experience more severe illness including the elderly, immunocompromised, pregnant women and children^{2,6,7}.

Toxin clearance (depuration) rates of domoic acid from affected bivalves can be rapid after a harmful algal bloom compared with other biotoxins, but varies between bi-valve species making analytical testing appropriate².

Adverse health effects:

People affected by ASP show symptoms that may include⁶⁻⁸:

- Gastrointestinal symptoms (vomiting, diarrhoea and abdominal pain)
- Neurological effects (confusion, short-term memory loss, disorientation and seizure).
- Permanent brain damage
- Unconsciousness or death.

General description

Some reports indicate that the effects of ASP are more pronounced in the elderly and they may include symptoms similar to those observed in Alzheimer's disease. Individuals with impaired renal function may be more susceptible to adverse effects because they have a reduced capacity to excrete unchanged domoic acid in their urine³. Pregnant women and children are also a subpopulation that are more vulnerable to ASP².

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)⁹.

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)⁹.

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

In the 2018-19 Australian Consumption of Selected Foodstuffs, the apparent daily consumption of crustacean and molluscs was estimated to be 2.1g per capita¹⁰.

Risk factors and risk mitigation

Key risk factors:

- Consumption of bivalve molluscs (fresh or processed) from:
 - global regions where blooms of domoic acid-producing microorganism species have been linked to domoic acid accumulation in harvested bivalves
 - areas where ballast water taken from areas historically associated with ASP outbreaks, has been discharged¹¹.
- There is a risk that ASP outbreaks will result from seafood produced in areas without a history of domoic acid-producing algal blooms. The unpredictable occurrence and distribution of these events is linked with changing global temperatures and human activities¹¹⁻¹³.

Risk mitigation strategies:

- Batch testing samples of bivalve molluscs to verify domoic acid levels meet the Code specified ML of ≤ 20 mg domoic acid/kg of mollusc flesh¹⁴.
- Seafood management plans that monitor commercial and recreational harvesting sites for domoic acid and associated algal species
- Signage at sites historically associated with harmful algal blooms that produce domoic acid, 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:

ASP is not specifically listed as a notifiable disease in any Australian states or territories or New Zealand. However, if a food poisoning incident is linked to domoic acid, there are requirements to notify health authorities. There are no documented cases of ASP 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%). Domoic acid producing algal species have been located in the coastal waters of all three producers, but only Chile has evidence of domoic acid entering the food chain^{13,15,16}.

Illness associated with consumption of bivalve molluscs contaminated with domoic acid

On the basis of a search of the scientific literature via EBSCO, US CDC National Outbreak Reporting System Online Database (NORS)¹⁷, European Rapid Alert System for Food and Feed online consumer portal (RASFF)¹⁸ and other publications up to April 2021, it appears that ASP outbreaks associated with consumption of bivalve molluscs are very rare, but can result in permanent neurological damage or death (Table A1, Appendix 1).

Data on the prevalence of domoic acid in bivalve molluscs

Between 2011 and 2020, there were 21 notifications on the European Commission's Rapid Alert System for Food and Feed referencing domoic acid (referred to as amnesic shellfish poison) in bivalve molluscs¹⁸. No recalls have been triggered in Australia relating to domoic acid in that time¹⁹.

Standards or guidelines

Australia and New Zealand

Schedule S19-5 of the Australian New Zealand Food Standard Code specifies a maximum level of 20 mg/kg of domoic acid in the edible portion of bivalve molluscs¹⁴.

New Zealand

The Ministry of Primary Industries specified a maximum limit of ≤ 20 mg domoic acid/kg of edible portion²⁰.

Codex

Codex Standard 292-2008 for live and raw bivalve molluscs specifies a ML of ≤ 20 mg domoic acid/kg of mollusc flesh for domoic acid-group toxins²¹.

The following Codex Standards are also relevant in the prevention of ASP 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 ≤ 20 mg domoic acid/kg for bivalve shellfish²².

European Union (EU) countries – Chapter 5 of Regulation (EC) No. 853/2004, gives a maximum limit of 20 mg/kg domoic acid (measured in whole body or any part edible separately)²³.

Europe – the European Food Safety Authority (2009) established an acute reference dose of 30 μ g domoic acid/kg bw²⁴.

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 domoic acid and associated algal species²⁰.

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 domoic acid. A management plan is required where there is a history of closure due to ASP incidents or domoic acid-group toxin producing algal blooms are known to occur in the growing area²².

Chile – The Food Safety and Certification Manual outlines the standards and procedures to ensure safety in fishery and aquaculture products in Chile²⁵. 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 molluscs²⁶.

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 amnesic 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 †

Table A1 – Overview of ASP cases attributed to domoic acid located in the literature.

Country of origin	Year	Product	Number of cases	Comments
United States ¹⁷	2013	Mussels	2	Both hospitalised
Canada ⁶⁻⁸	1987	Mussels	107 (3 deaths)	19 hospitalised. Permanent neurological effects were documented

† 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 Zealand²⁷