Imported food risk statement

Bivalve molluscs and okadaic acid-group toxins

Scope: Okadaic acid-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 therefore not covered by this risk statement:

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

Recommendation and rationale
Do okadaic acid-group toxins in imported bivalve molluscs present a potential medium or high risk to public health: ☐ *Yes* ☑ *No* **Rationale**: • Okadaic acid-(OA) group toxins are heat stable toxins, naturally produced by ocean dwelling algae. • OA group toxins consumed in bivalve molluscs can cause Diarrhetic Shellfish Poisoning (DSP). DSP is characterised by symptoms such as diarrhoea, nausea, vomiting and abdominal pain. • Symptoms occur shortly after consumption of contaminated bivalve molluscs and usually resolve within 3 days. No fatalities have been associated with DSP caused by OA-group toxins and hospitalisation is rare. • Globally OA-group toxins are one of the most common causes of poisonings associated with marine biotoxins. • Reported cases of OA related DSP have reduced over time with implementation of monitoring programs, although cases continue to be reported in some countries. No suspected cases have been reported in Australia since 1998. • Schedule S19-5 of the Australian New Zealand Food Standard Code specifies a maximum level (ML) of 0.2 mg/kg OA-equivalents for DSP in bivalve molluscs. • On the basis of the historically low reported incidence of DSP associated with OA group toxins in Australia, and available international prevalence data, the risk to public health in Australia is currently considered low.

General description
Nature of the toxin: Okadaic acid-(OA) group toxins are naturally occurring lipophilic, heat-stable, polyether compounds produced by ocean dwelling algae, primarily dinoflagellates of the genera *Dinophysis spp.* and *Prorocentrum spp*[1]. OA and its analogues dinophysistoxins 1 and 2 (DTX1, DTX2)[1,2,3] are considered to be the primary OA-group toxins. A third group of analogues, DTX3, may be metabolised to OA, DTX1 and/or DTX2[4,5] in the gastrointestinal tract. OA-group toxins are rapidly accumulated in bivalve molluscan tissue but removal rates are variable, between 1 week to 6 months[2]. The mode of action of OA-group toxins is not well understood; however, studies indicate multiple complex events, including inhibition of the digestive enzyme system, effects on lipid, amino acid and sugar metabolism and oxidative stress,[2,7] are likely to be factors. The lowest observed adverse effect level for human illness has been calculated to be in the region of 50 µg OA-equivalents/person, or approximately 0.8 equivalents µg/kg bodyweight for adults[1]. OA-group toxins may pass the placenta and into the foetus, however no further details on developmental toxicity were found[1,4].

General description
The OA-group toxins are heat stable at both high and low temperatures. OA degrades at temperatures of 120⁰C and above, DTX2 starts to degrade at 100⁰C and OAs as a group are highly stable in the frozen state (-20-80⁰C) for several months[1]. The effect of processing on OA-group toxins is not known[1].

Adverse health effects:

People affected by DSP caused by OA-group toxins typically show symptoms which may include:

- diarrhoea
- nausea
- vomiting
- abdominal cramps

The onset of symptoms has been reported from 30 minutes after ingestion to 5 hours, with complete recovery usually reported within three days[2,4,8,9]. The symptoms of OA-group toxin can be severe and cause dehydration, although hospitalisation is rare and no fatalities have been reported[2,4,5,9,10]. No particular population group was identified, from the literature, as being particularly susceptible to DSP from ingestion of OA-group toxins.

No long term effects in humans have been reported for OA-group toxins[1,2,5].

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).[13].

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).

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

In the 2018-19 Australian Consumption of Selected Foodstuffs[13], the apparent daily consumption of crustacean and molluscs was estimated to be 2.1g per capita.

Risk factors and risk mitigation

Key risk factors:

- Harvesting shellfish from waterways with a known history of OA-group toxin producing phytoplankton that are not effectively monitored or where harvesting is not permitted.
- Eating shellfish caught in areas where ballast water taken from areas contaminated with OA-group toxins producing phytoplankton, has been discharged.
- The unpredictable influence external factors have on proliferation of OA-group toxin producing phytoplankton i.e. there is a risk that DSP outbreaks will occur in non-historic areas.

Risk mitigation Strategies:

- Monitoring of areas historically associated with DSP outbreaks caused by OA-group toxins for levels of *Dinophysis spp.* and *Prorocentrum spp.* cell counts and OA-group toxin levels in the water column and bivalve molluscs.
- Monitoring of commercial bivalve production marine environments for levels of *Dinophysis spp.* and *Prorocentrum spp.* cell counts and OA-group toxins.
- Signage at sites historically associated with OA-group toxin DSP outbreaks, warning of the risk of consuming bivalve molluscs (warning may need to be in several languages to allow for recreational harvest by tourists).
- Testing samples of bivalve molluscs to verify OA-group toxin levels meet the maximum level (ML) of ≤0.2 mg/kg OA-equivalents outlined in Schedule S19-5 of the Australian New Zealand Food Standard Code.

Surveillance information:

More than 1200 cases of DSP due to OA-group toxins have been reported world-wide, mainly in Europe and the Americas, which makes it, along with Ciguatera poisoning, the most common poisoning associated with marine biotoxins[7].

In 2017-18, China accounted for 55% (3,107 tonnes) of imported bivalve molluscs into Australia, (mainly scallops), Chile accounted for 16% (881 tonnes, mainly mussels) and Japan 8% (475 tonnes, mainly scallops)[19].

General description

Illness associated with consumption of bivalve molluscs contaminated with OA-group toxins

The first outbreaks of OA-based DSP were reported in the Netherlands in 1961 and the illness has now been reported in many geographical regions including Australia, New Zealand, Japan, USA, China, Canada, South America and Europe[1,2,4,9].

A search of the scientific literature via EBSCO, US CDC National Outbreak Reporting System Online Database (NORS), European Rapid Alert System for Food and Feed online consumer portal (RASFF) and other publications up to June 2020, indicated that OA-group toxin based DSP outbreaks associated with consumption of bivalve molluscs have been reducing over time. This is most likely to be a consequence of more robust monitoring programmes, both at the sites of harvest and as part of import/export controls[24].

A summary of some DSP cases classed as being attributable to OA-group toxins from 1976 onwards is provided in Table A1, Appendix 1 [2,9,10,15,16,17,18,25,26,27].

Data on the prevalence of OAs in bivalve molluscs

A search of public literature and the European RASFF consumer portal provided analytical concentrations of OA-group toxin levels in bivalve molluscs. These are presented in Tables A2-A4, Appendix 1.

Standards or guidelines

Australia

Schedule S19-5 of the Australian New Zealand Food Standard Code specifies a ML of 0.2 mg/kg OA-equivalents for diarrhetic shellfish poisons in bivalve molluscs.

New Zealand

Ministry of Primary Industries, Animal Products Notice: Bivalve Molluscan Shellfish for Human Consumption, August 2018, specifies a ML of 0.16 mg OA equivalents/kg of edible portion (equivalents include OA, DTX1, DTX2 and pectenotoxins (PTX1 and PTX2))[20].

Codex

Codex Standard 292-2008 for live and raw bivalve molluscs specifies a ML of ≤0.16 mg/kg molluscs flesh of OA-equivalents for the OA biotoxin group.

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

Codex general principles of food hygiene CAC/RCP 1 – 1969 (Codex 2003)

Codex code of practice for fish and fishery products CAS/RCP 52 (Codex 2003)

Codex guidelines for the sensory evaluation of fish and shellfish in laboratories (Codex 1999)

Other countries

Canada - Health Canada has established a ML of 1.0 mg/kg in bivalve shellfish digestive tissue and 0.2 mg/kg in bivalve shellfish edible tissue for DSP (being the sum of OA and DTX1, DTX2 and DTX3)[23].

USA - National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish specifies a guidance/action level of ≤0.16 mg/kg OA equivalent, (combined free OA, dinophysistoxins-1 and -2, and their acyl-esters); applies to clams, mussels, oysters, and whole and roe-on scallops, fresh, frozen, or canned[11].

European Union (EU) countries and the UK – Regulation (EC) No. 853/2004 , Chapter V gives a ML of 160 µg OA equivalents/kg (measured in whole body or any part edible separately). Equivalents include OA, dinophysistoxins and pectenotoxins* together[22].

* EFSA (2008) recommended that due to a difference in mechanism of action, pectenotoxins should not be included in the regulatory limit of OA-group toxins.

Acute Reference Dose (ARfD)

European Food Safety Authority (EFSA, 2008) proposed an acute reference dose (ARfD) of 0.3 µg OA eq/kg bw[1].

The Joint FAO/IOC/WHO *ad hoc* Expert Consultation on Biotoxins in Bivalve Molluscs proposed an ARfD of 0.33 µg OA eq/kg bw[5]

Neither Expert group recommended a Tolerable Daily Intake due to a lack of data on chronic toxicity.

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 OA-group toxins and associated phytoplankton species[20].   **Canada** – Canadian Shellfish Sanitation Program (CSSP) includes monitoring of OA, dinophysistoxins and pectenotoxins in shellfish harvest areas[21].   **European Union** – The European Union Official Controls Regulation (OCR, 2017), Regulation (EU) 2017/625 and associated regulations, require monitoring of live bivalve molluscans and associated marine phytoplankton (algae) from harvest waters. This monitoring includes sampling of bivalves for DSP poisons[22].   **USA** – The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan shellfish; 2017 revision, requires as a minimum, a contingency plan for proactive management of OA-group toxins. A management plan is required where there is a history of closure due to OA-group toxin DSP incidents or OA toxin-group producing phytoplankton are known to occur in the growing area[11].   **Chile** – as part of the Latin America and Caribbean integrated regional network for early warning of HAB (harmful algae bloom) and biotoxins in seafood has a monitoring programme for potentially harmful phytoplankton species, including toxin analysis[14].   **China** – no details of monitoring or management programmes for biotoxins in bivalves harvested in China were found in a literature search.   **Japan** – no details of monitoring or management programmes for biotoxins in bivalves harvested in Japan were found in a literature search.

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Appendix 1 – Illnesses associated with consumption of bivalve molluscs contaminated with OA-group toxins and associated OA-group toxin levels

Table A1 – Overview of DSP cases attributed to OA-group toxins located from the literature

Country of origin	Year	Product	Number of cases	Comments
England[9]	2019	Mussels	6	Not found on RASFF consumer portal. *This is the same case as the first entry in Table A3*
New Zealand[16]	2018	Recreational shellfish (type not defined)	3	Symptoms typical of DSP, but presence of OAs not confirmed
Ireland[15]	2016	Frozen whole cooked mussels	Not given	Incident was in France, mussels sourced from Ireland
New Zealand[16]	2014	Not reported	13	
Scotland[10]	2013	Mussels	70	Not found on RASFF consumer portal.
New Zealand[16]	2012	Not reported	29	
China[17]	2011	Mainly mussels	approximately 220	
USA[9]	2011	Mussels	3 (one family, affected members ate between 8-15 mussels, unaffected member ate 4)	Incident not found on US NORS database. *This is the same case as the third entry in Table A3*
Canada[18]	2011	Mussels	62	
England[27]	2006	Mussels	159	
England[10]	1998	Mussels	49	
Australia[25,26]	1998	Pipis	23 cases	Incident of DSP in NSW linked to pipis
Australia[25,26]	1997	Beach-harvested pipis	56 hospitalisations	Incident of DSP in NSW, where OA-group toxins were suspected.
Chile[2]	1991	Mussels	approximately 120	
Japan[2]	1976-1982	Not reported	1300	Assumed the information below included in this total
Japan[2]	1976-77	Not reported	164	

The following two tables contain data retrieved from the European RASFF consumer portal; the first table was restricted to the period 2019/2020, whilst the second table provides annual summaries for the period 01/01/2015 – 31/12/2018.

Table A2 - RASFF 2019/2020 data – OA-group toxin levels in bivalve molluscs

Data presented period 01/01/2019 to 09/07/2020 and provides individual incident data

Country of origin	**Date**	**Product**	**Reported OA-group toxin level** (OA eqi µg/kg)
France	June 2020	Live cockles	501
France	May 2020	Live clams	Not given
Italy	May 2020	Live mussels	133
Italy	May 2020	Live mussels	267
Portugal	February 2020	Live saltwater clams	444
Italy	October 2019	Live mussels	>320
Italy	September 2019	Live mussels	>320
France	July 2019	Live cockles	181.1
France	July 2019	Live mussels	182
France	June 2019	Live saltwater clams	407.1
France	May 2019	Live cockles	270
France	May 2019	Live clams	388
Most cited country of origin	**Total number of incidents 2019/20** (ending 07 July 2020)	**Most common product**	**Range OA level**
France	12	Mussels	133-501

Table A3 - RASFF annual summaries, 2015-2018 – OA-group toxin levels in bivalve molluscs

Year	**Number of samples**	**OA range reported** (OA eqi µg/kg)	**Products –** (no of samples)	**Country(s) of origin**
2018	6	129-346 (4/5 results above 160 µg/kg – one sample no value provided)	Mussels (4) Cockles* (1) Clams (2)	France*:Italy: Sweden
2017	4	203-426	Mussels	Italy; Norway*
2016	6	214.2-920	Cockles (2) Mussels (4)	France; Slovenia*; UK; Greece
2015	7	178-613	Scallops (1)* Mussels (5) Clams (1)	Italy*; Slovenia; Denmark; Spain; Ireland

Table A4 – OA-group toxin level data in bivalve molluscs from other sources than RASFF

Year	**Country of origin**	**Product**	**Reported OA level** (OA eqi µg/kg)	**No of cases**	**Comments**
2019[9]	England	Mussels	499	6	Incident not found on RASFF portal. Twelve days post event OA levels reported as 121 µg/kg
2011[9]	USA	Mussels	376-1600 (DTX1 was the principal toxin)	3	Incident not found on US NORS database
1998[2]	Chile	Mussels	65-580 (DTX1 levels)	-	
1994-1996[6]	New Zealand	Bivalves – type not specified	-	-	69/10524 (0.7%) of samples exceeded ML