Imported food risk statement

Bivalve molluscs and azaspiracid-group toxins

Scope: Azaspiracid-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 azaspiracid-group toxins in imported bivalve molluscs present a potential medium or high risk to public health: ☐ *Yes* ☑ *No* **Rationale**: • Azaspiracid-(AZA) group toxins are heat stable toxins, naturally produced by ocean dwelling algae. • AZA group toxins consumed in bivalve molluscs can cause azaspiracid poisoning (AZP). AZP is characterised by symptoms such as diarrhoea, nausea, vomiting, abdominal cramps and headache. • Symptoms occur in humans shortly after consumption of contaminated bivalve molluscs and usually resolve between 15 hours and 5 days. Hospitalisation is rare and no fatalities have been associated with AZP. • Notified cases of poisoning associated with AZA in bivalve molluscs have only been associated with shellfish from Ireland. The last reported outbreak was in 2008. No cases have been reported in Australia or New Zealand. • Schedule S19-5 of the Australian New Zealand Food Standards Code does not specify a maximum level (ML) for AZA-group toxins. • On the basis of the historically low reported incidence of AZP associated with AZA-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: Azaspiracid-(AZA) group toxins are naturally occurring lipophilic, heat stable, nitrogen containing polyether compounds, produced by ocean dwelling algae, primarily dinoflagellates of the genera *Azadinium spp.* [1,2,3,4,5]. Currently over 40 analogues have been identified, with AZA-1, AZA-2 and AZA-3 being the most toxicologically important[3,4,5]. It has been suggested that AZA-group toxins elicit cytotoxicity by targeting receptors which are involved in apoptosis (controlled cell death). Effects on ion channels causing decreased cell volume via the efflux of potassium and chloride from cells has also been proposed as a possible mechanism[1,3,7]. The mean dose associated with human toxicity has been calculated to be 51.7 mg/person AZA (range 23 to 68)[1]. AZA-group toxins rapidly accumulate in bivalve molluscan tissues but removal rates are slow, up to 6 months for some mussel species [1,5]. AZA group toxin levels in bivalve molluscs are not diminished by rinsing, cleaning, cooking, freezing or steam autoclaving[3].

General description

Adverse health effects:

People affected by azaspiracid poisoning (AZP) show symptoms which may include[1,2,3,9]:

- nausea
- vomiting
- diarrhoea
- stomach cramps
- headaches

The onset of symptoms of AZP occurs from about 3 hours after ingestion and last for approximately 15 hours[1,2,3] . Full resolution of clinical effects generally occurs within 2-5 days[2,9].

The symptoms of AZP are generally mild and reversible, hospitalisation is rare and no fatalities have been reported[3,6,7]. The US National Shellfish Sanitation Program (NSSP) Guide for the control of molluscan shellfish[8] states that AZA is less dangerous than NSP (neurotoxic shellfish poison), PSP (paralytic shellfish poison) and ASP (Amnesic shellfish poison).

No long term effects in humans have been reported for AZA-group toxins.

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).[11]

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).[11]

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.

Risk factors and risk mitigation

Key risk factors:

- Consumption of bivalve molluscs (fresh or processed) from:
  - Ireland, especially when harvested during the northern hemisphere summer and autumn (June-November)*.
  - from the rest of Europe, particularly when harvested during June-November (AZA-producing species have been detected in these regions)[1]
  - from other global regions where blooms of AZA-producing dinoflagellate species have been identified
  - areas where ballast water taken from areas historically associated with AZP outbreaks has been discharged.
- Mistaking symptoms for diarrhetic shellfish poisoning, giving rise to under reporting of AZP reporting.
- Sampling only the hepatopancreas during toxin detection analysis procedures (unlike other bivalve toxins, AZA-group toxins are not just confined to the hepatopancreas[6])
- The unpredictable influence external factors have on proliferation of AZA producing harmful algae blooms i.e. there is a risk that AZP outbreaks will occur in non-historic areas.

Risk mitigation strategies:

- Monitoring of the commercial bivalve production marine environments for levels of AZA-producing dinoflagellate species.
- Signage at sites historically associated with AZA 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 AZAs-group toxins levels meet the Codex specified ML of ≤0.16 mg AZA eq/kg of mollusc flesh.

* All AZP outbreaks found in the literature originated in Ireland (refer to Table A1, Appendix 1). In the period 2017/18 imported bivalves from Ireland into Australia accounted for less than 0.1% of the total tonnage, (7 tonnes of clams in total; no mussels were imported)[15].

General description

Surveillance information:

AZP is not specifically listed as a notifiable disease in any Australian states or territories, New Zealand, UK, Ireland or the rest of Europe. However, in many jurisdictions, including Australia and New Zealand and particularly UK and Ireland, if there is evidence the AZA-group toxins are the cause of a food poisoning incident, there are requirements to notify the appropriate authorities.

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

On the basis of a search of the scientific literature via EBSCO, US CDC Foodborne Outbreak Online Database, EU Rapid Alert System for Food and Feed database and other publications up to July 2020, it appears that AZP outbreaks associated with consumption of bivalve molluscs occurred intermittently from 1995 until 2000, with the largest recorded outbreak in 2008. Since that time no further outbreaks have been identified.

All reported outbreaks have been associated with mussels and/or scallops harvested in Ireland (refer to Table A1 of Appendix 1).

Due to the symptoms of AZP being consistent with those of DSP caused by the Okadiac acid toxin-group (OAs), it is possible that some shellfish poisoning outbreaks have been miscategorised as being attributable to OAs rather than AZA-group toxins[13].

Data on the prevalence of AZA in bivalve molluscs

A search of the public literature revealed limited information on the reported analytical concentrations of the AZA-group toxins in bivalve molluscs. These are presented in Table A2, Appendix 1.

Standards or guidelines

Australia and New Zealand

Schedule S19-5 of the Australian New Zealand Food Standard Code does **not** specify a ML for AZA-group toxins in bivalve molluscs.

New Zealand

The Ministry of Primary Industries, Animal Products Notice: Bivalve Molluscan Shellfish for Human Consumption, August 2018, specifies a ML of ≤0.16 mg AZA-equivalent/kg of edible portion (equivalents include AZA1, AZA2 and AZA3)[10].

Codex

Codex Standard 292-2008 for live and raw bivalve molluscs specifies a ML of ≤0.16 mg/kg molluscs flesh for AZA-group toxins.

The following Codex Standards are also relevant in the prevention of AZP 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 52-2003

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

Other countries

USA - National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish specifies a guidance/action level of ≤0.16 mg/kg AZA-1 equivalents (i.e. combined AZA-1,-2, and -3), for bivalve shellfish[8,12].

European Union (EU) countries (including Ireland) and UK countries – Chapter 5 of Regulation (EC) No. 853/2004 , Chapter V gives a maximum limit of 160 µg AZA equivalents/kg (measured in whole body or any part edible separately).

Europe – the European Food Safety Authority (2008) established an acute reference dose of 0.2 µg AZA eq/kg bw.

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 AZA-group toxins and associated phytoplankton species[10].

Management approaches used by overseas countries
Ireland – The Irish shellfish Monitoring Programme has a code of practice dealing with biotoxin and plankton monitoring, which includes monitoring for AZA group toxins, (https://www.fsai.ie/uploadedFiles/About_Us/Industry_Fora/MSSC/CoP_Biotoxin_Monitoring.pdf).
USA – The National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan shellfish; 2017 revision[8], requires as a minimum, a contingency plan for proactive management of AZP based toxins. A management plan is required where there is a history of closure due to AZP incidents or AZA-group toxin producing phytoplankton are known to occur in the growing area[8]

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

Table A1 – Overview of DSP cases attributed to AZP located from the literature

The DSP classification was based on symptoms. Further analysis attributed the cases to AZA.

Country of origin	Year	Product	Number of cases	Comments
Ireland[8]	2008	Cooked ready-made frozen meal containing mussels	2 (husband and wife)	Cases were in USA, but mussels harvested in Ireland. (Same incident as 4th entry in Table A2 below).
Ireland[3]	2008	Mussels	219	Cases were in France but mussels harvested in Ireland.
Ireland[3]	2000	Mussels and scallops	12-16	Cases were in UK but products harvested in Ireland.
Ireland[3]	1998	Mussels and scallops	20-30	Cases were in France but mussels harvested in Ireland.
Ireland[3]	1998	Mussels and scallops	Approx.10	Cases were in Italy but mussels harvested in Ireland.
Ireland[3]	1997	Mussels and scallops	At least 20	Mussels harvested in Ireland.
Ireland[3]	1995	Mussels	At least 8	First reported cases of DSP attributable to AZP. Cases were in the Netherlands but mussels harvested in Ireland.

Table A2 – Prevalence data

Country of origin	Year	Product	Reported value (µg/kg AZA equiv)
Ireland[4]	2013	Shellfish (no further details)	Maximum level 3.35 (results from routine monitoring. 8.84% of samples were above the 0.16 µg/kg)
Ireland[4]	2012	Shellfish (no further details)	Maximum level 7.5 (results from routine monitoring. 17.9% of samples were above the 0.16 µg/kg)
Ireland[4]	2011	Shellfish (no further details)	Maximum level 0.27 (results from routine monitoring. 0.35% of samples were above the 0.16 µg/kg)
Ireland[9]	2008	Mussels	0.086-0.244 (2/5 samples were above 0.16 µg/kg)
Ireland[1]	1997	Mussels	1.36
Ireland[1]	1996	Mussels	1.4
Ireland[1]	1996	Mussels	0.6 (mussels collected from harvest site for first recorded outbreak in 1995. Analysed value was 0.15 MU/g which was then converted to AZA equiv).

MU – Mouse Unit. This value gives an estimate of the total toxicity of the extract when tested in mice. The test does not provide information on amounts of individual AZA-group toxins which may be present.
AZA equiv – this value is the total AZA-group toxins content in the sample. It is the sum of AZA toxins present after applying the appropriate toxin specific toxic equivalency factor (TEF) for each toxin. Codex Stan 292-2008 states that only internationally validated TEFs should be used.