Imported food risk statement
Bivalve molluscs and domoic acid

Commodity: 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
- marinara mix.

Analyte: Domoic acid (DA)

Recommendation and rationale
Is DA in bivalve molluscs a medium or high risk to public health: ☑ *Yes* ☐ *No* ☐ *Uncertain, further scientific assessment required* **Rationale:** • Consumption of seafood containing DA has resulted in human poisoning incidents and deaths. DA is a potent neurotoxin that causes amnesic shellfish poisoning (ASP) within 24-48 hours following ingestion. There is no antidote for ASP. • DA is not destroyed by cooking, freezing or other food processing.

General description
Nature of the analyte: DA is a water-soluble, non-protein amino acid. It is produced by some marine diatoms of the genus *Pseudo-nitzschia spp.*, which are likely to be present to some extent in most coastal marine environments. Isomers of DA are less toxic. Domoic acid is not reliably destroyed by common cooking methods (Vidal et al. 2009) or by autoclaving (McCarron and Hess 2006).
Adverse health effects: DA is a potent neurotoxin that causes amnesic shellfish poisoning (ASP) within 24-48 hours following ingestion. There is no antidote for ASP. Clinical signs of acute DA toxicity (or ASP) are mild gastrointestinal symptoms (vomiting, diarrhoea, and abdominal pain) from an oral dose ranging between 0.9 and 2 mg DA/kg bw. At doses ranging between 1.9 and 4.2 mg DA/kg bw neurological effects such as confusion, short-term memory loss, disorientation, seizure and coma may occur (Pulido 2008; FDA 2012). ASP effects are frequently more pronounced in the elderly and they may include symptoms similar to those observed in Alzheimer's disease. Additionally individuals with impaired renal function are thought to be more susceptible to adverse effects because they have a reduced capacity to excrete unchanged DA in their urine (Pulido 2008).

All humans are susceptible to DA poisoning, with affected people from the vulnerable populations generally experiencing more severe illness. Vulnerable populations include the elderly and immunocompromised; pregnant women and children are also likely to be more susceptible to ASP.

Consumption patterns:

In the 2007 Australian National Children's Nutrition and Physical Activity Survey, <1% children aged 2-16 years reported consumption of bivalve molluscs (DOHA 2008). 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% for adults aged 70+ years reported consumption of bivalve molluscs. However, high level consumers (97.5 percentile) consumed approximately 250 grams per day per consumer (across the whole population 2+ years) (ABS 2014).

For both the 2007 and the 2011 – 2012 surveys, mixed foods that contained bivalve molluscs were excluded from the analysis. The 2007 survey derived data from two days of dietary recall data for each respondent (a respondent is counted as a consumer if the food was consumed on either day one or day two, or both days), compared with only one day of dietary recall data for the 2011 – 2012 survey. Using two days of data will result in a higher proportion of consumers compared to a single day only, meaning the results are not directly comparable.

Key risk factors:

Harvesting of bivalve molluscs during periods of high algal growth increases the risk of DA poisoning.

Risk mitigation:

Schedule S19—5 of the Australia New Zealand Food Standard Code specifies the maximum level (ML) of ASP (DA equivalents) to be 20 mg/kg in bivalve molluscs. The ML applies to bivalve molluscs, whether imported or domestically produced.

There is speculation that algal blooms are occurring with increasing frequency around the world, which in turn increases the potential threat to human health from dietary exposure to DA (Lefebvre *et al*. 2010). Following the Canadian poisoning incident in 1987 which resulted in three human deaths and 105 cases of acute ASP, there have been no further documented severe outbreaks (Bates et al. 1989). This has been attributed to the adoption of safe harvesting programs and practices, including ongoing monitoring of coastal water quality (algal blooms) and vigilance by the seafood industry. However, algal bloom monitoring is not without problems because different strains of the same species of *Pseudo-nitzschia* have varying toxin-producing abilities (Lundholm et al. 1994).

For international trade, Codex has specified an ML of 20 mg/kg for DA in live and raw bivalve molluscs.

The most accepted regulatory method for detecting DA in seafood is a reversed-phase HPLC method with ultraviolet (UV) or photodiode array (PDA) detection. There is also an AOAC International approved enzyme linked immunosorbent assay (ELISA) available for the detection of DA (EFSA 2009). The mouse bioassay for DA is not sufficiently sensitive and does not provide a reliable estimate of potency.

Compliance history:

Compliance data sourced from the Australian Department of Agriculture and Water Resources, Imported Food Inspection Scheme, for the period October 2005 to January 2016, show that of 1786 tests performed on imported seafood products (bivalve molluscs, scallops and marinara mix), no products failed. Approximately 45% of the test results related to marinara mixes, 35% to bivalve molluscs and 20% to scallops. The majority of the samples tested contained <2 mg/kg DA; the highest levels were <5 mg/kg in two samples (clam fillet) from Korea. DA was not detected in 5% of products. The imported products were from 19 countries across the globe (Asia, Europe, North and South America).

Positive detections are also infrequent in overseas jurisdictions. For example, there were three notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for DA in 2010; two notifications were in scallops from the UK, one notification was in various bivalve molluscs from France.

According to the RASFF Annual Report for 2014, there were no notifications relating to DA in shellfish in that year.

Between January 2007 and March 2016, there were no food recalls in Australia of imported or domestically produced shellfish due to the presence of DA.

Surveillance information:

The first report of DA poisoning in humans occurred in Canada in 1987. In 1991 in parts of the United States, high levels of DA were found in razor clams and Dungeness crabs. Some consumers experienced gastrointestinal disturbances; however ASP was not confirmed at that time.

ASP generally is associated with consumption of contaminated mussels. Other bivalve molluscs of interest include oysters, scallops, clams and cockles. Due to routine monitoring of coastal water quality and active management of fishing zones in which bivalve molluscs are harvested for human consumption, there have been no further cases of ASP reported in the literature.

Other relevant standards or guidelines

Effective codes of practice for industry have been developed and implemented in most fishing regions around the world:

- Codex Alimentarius (2009) *Code of Practice for Fish and Fishery Products*, World Health Organisation
- Australian Shellfish Quality Assurance Program Operations Manual November 2009 Version 2009-01
- Seafood Services Australia: *Blue Mussels - Post-harvest Code of Practice*. SSA Product Code PDF-PU031 (2003).

Approach by overseas countries

Europe, the United States and Canada, have established a regulatory limit for DA and have restrictions on harvesting conditions:

EU – limit of 20 mg/kg DA in shellfish flesh

USA – the FDA action level for ASP is 20 ppm DA (except in the viscera of Dungeness crab, for which the action level is 30 ppm)

Canada – action level is 20 mg/kg.

Government authorities and industry bodies promote Good Manufacturing Practice by publishing detailed guidelines on the harvesting and cleansing of bivalve molluscs. Example: Seafish, representing the UK Seafood Industry, Industry Guidance Note: Amnesic Shellfish Poisoning (October 2011).

Other considerations

Biosecurity restrictions apply to certain products under this commodity classification. Refer to the BICON database.

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