Imported food risk statement
Bivalve molluscs and paralytic shellfish toxins

Commodity: Bivalve molluscs. This includes whole or portions of bivalve molluscs that are fresh, frozen, dried or canned, such as cockles, clams, mussels, oysters, pipis and scallops with roe on.

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

- Scallops where the only part of the product consumed is the adductor muscle, i.e. roe off
- Pearl oysters where the only part of the product consumed is the adductor muscle
- Spat
- Cephalopod molluscs (e.g. squid, octopus, cuttlefish) and jelly fish
- Food mixtures containing bivalve molluscs, e.g. marinara mix, comprising less than 50% bivalve molluscs by weight.

Analyte: Paralytic Shellfish Toxins (saxitoxin equivalent)

Recommendation and rationale
Are paralytic shellfish toxins in bivalve molluscs a medium or high risk to public health: ☑ *Yes* ☐ *No* ☐ *Uncertain, further scientific assessment required* **Rationale:** • Paralytic shellfish poisoning (PSP) is caused by eating bivalve shellfish and other molluscan shellfish (e.g. mussels, cockles, clams, oysters, pipis and scallops) containing paralytic shellfish poisons or toxins (PST). Symptoms of PSP intoxication vary from a slight tingling or numbness to complete respiratory paralysis. In fatal cases, respiratory paralysis occurs within 2 to 12 hours of consumption of the contaminated food. • PST are not inactivated by cooking. • Bivalve molluscs have been identified as the source of PST in Australia, the United States (US), Chile, Philippines, Taiwan and Nicaragua.

General description
Nature of the analyte: PST are a group of over 50 related analogues of saxitoxin that vary in toxicity (Kwong et al. 2006; Paredes et al. 2011; Munday and Reeve 2013; Thottumkara et al. 2014). Many members of the group are often found together in bivalve and molluscan shellfish and confer toxicity in an additive manner (EFSA 2009; Munday and Reeve 2013). 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. The level of dinoflagellates in an ecosystem fluctuates and is influenced by factors such as temperature, sunlight, nutrient quality of the water and shipping activities in the area including the release of ballast water (Hallegraeff 1998; Ferrante et al. 2013; Bouchouar et al. 2014; Farrell et al. 2015). During winter, resting cysts of some dinoflagellates (which can

contain high toxin levels) settle at the bottom of the ocean. Once conditions become favourable, the cysts activate and proliferate which can result in harmful algal blooms (HAB[1]) and waterway closures for both recreational and harvesting activities (FAO 2004; EFSA 2009; Bravo and Figueroa 2014).

Like other marine biotoxins, PST are heat and acid stable. Cooking does not inactivate the toxin but may concentrate it, particularly if the affected food is boiled and the broth is consumed (Lawrence et al. 1994; Vieites et al. 1999). There are some reports that PST levels are reduced during the process of canning (Berenguer et al. 1993; Vieites et al. 1999), however poisoning cases have been reported from the consumption of canned products (CDC 2014).

Adverse health effects:

Clinical signs and symptoms of acute toxicity associated with PST ingestion can include, but are not limited to: neurosensory effects such as, numbness or tingling around the mouth, face or extremities, unsteady walking, weakness and clumsiness, slurred/unclear speech, dizziness/vertigo, double vision, difficulty breathing, swallowing and paralysis. In less severe cases, symptoms generally resolve within a few days (Lawrence et al. 2011). The timeframe for the PSP effects is variable and dependent on the amount of PST consumed. Generally, effects can be observed rapidly, within minutes or hours in less severe cases.

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:

These include:

- The unpredictable influence external factors have on dinoflagellate cyst activation and subsequent proliferation in the marine environment
- Variability in rates of depuration
- Harvesting of shellfish from waterways that are not monitored for PST or that are not open for harvesting
- Reliance on visual colour change in water ('red tide') as an indicator for unsafe levels
- Individual consumer sensitivity to effects of PST.

Risk mitigation:

A number of risk mitigation strategies have been established. These include:

- A maximum level (ML) of 0.8 mg/kg for paralytic shellfish poisons (saxitoxin equivalent) in Schedule S19—5 of the Australia New Zealand Food Standard Code (the Code)
- Inclusion of food safety management requirements in Standard 4.2.1 of the Code for bivalve molluscs

[1] HAB are previously referred to as red tides, as in many cases the water appeared red. However, it has since been shown that HAB can appear green, brown, yellow and even clear. The term 'red tides' is no longer used as it misleading and not indicative of algal bloom levels.

- Regular routine phytoplankton monitoring programs of waterways used for harvesting bivalve molluscs
- Regular monitoring of PST in bivalve molluscs and other implicated species
- Prompt closure or waterways in response to algal blooms
- Effective communication to both professional and hobby harvesters for closed waterways.

Consumer information have also been released by many countries in relation to the consumption of bivalve molluscs containing PST. This advice has been in relation to:

- Consumer food recalls (CFS 2010; FSANZ 2012; FSANZ 2015)
- Media alerts in relation to PST in foods or poisoning cases (DPH 2008; NSW FA 2012; Health Canada 2013; FDA 2013; CFS 2014)
- Factsheets and other information (NSW FA 2005; CFS 2007; Palmer 2008; FOC 2009; NSW FA 2011; NSW FA 2013a; NSW FA 2013b; FOC 2015a; FOC 2015b).

Compliance history:

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture and Water Resources for October 2005 – August 2013 showed that of the 609 samples tested under the risk category for PST applied to bivalve molluscs and marinara mix there were no fails.

There were 24 notifications on the European Commission's Rapid Alert System for Food and Feed for PST in bivalve molluscs from January 2006 – August 2015. There was also a report of PST at levels almost twice the ML in Australia, in Conch (*Murex spp*., a type of gastropod - sea snail).

There have been no food recalls in Australia of imported bivalve molluscs and one food recall of domestic bivalve molluscs (mussels) due to the presence of PST from 2007 – August 2015 (FSANZ 2015).

Surveillance information:

Illness associated with consumption of bivalve molluscs contaminated with PST

Cases implicating bivalve molluscs harvested and consumed during an algal bloom in Australia have been reported (Turnbull et al. 2013). Cases in the US, Chile, Philippines, Taiwan and Nicaragua identified bivalve molluscs as the source of PST (Garcia et al. 2005; CDC 2011; Lin and Hwang 2012; CDC 2014; Hurley et al. 2014; Ching et al. 2015; Callejas et al. 2015). The case in the Phillipines was instigated following the death of two individuals (Ching et al. 2015).

Non-traditional vectors that have been found to take up the PST or that have been implicated in cases of human illness include: gastropods (e.g. whelks, moon snails, conch, abalone), crustaceans (e.g. lobster, crab, crayfish, shrimp and barnacles) and fish (e.g. atlantic mackerel, chub mackerel, sardinella, saury, cod, salmon shark, chum salmon, parrotfish, puffer fish, anchovy). PST in these vectors are thought to have acquired it by feeding on bivalve molluscs or phytoplankton (FAO 2004; Choi et al. 2006; Jen et al. 2007; Oikawa et al. 2008; Deeds et al. 2008; Jester et al. 2009; Lin and Hwang 2012; Hsiao-Chin et al. 2014; Malhi et al. 2014).

Data on the prevalence of PST in bivalve molluscs

There are a number of regular ongoing programs to monitor the levels of biotoxins in shellfish and phytoplankton levels in harvesting waters. Examples of such programs in a range of countries or regions include:

- Australia
    - NSWFA marine biotoxin management plan – NSW shellfish program – monitors levels of phytoplankton (NSW FA 2014)
    - Tasmanian shellfish quality assurance program – Biotoxin management plan (DPIPWE 2015)
    - South Australian Shellfish Quality Assurance Program (SASQAP) (PIRSA 2015)

- Canada
  - Marine Water Quality Monitoring program (MWQM) (Health Canada 2014)
  - Canadian Shellfish Sanitation Program (CSSP) (CFIA 2015)
- US
  - US Federal water pollution control Act 2002 (U.S GPO 2002)
  - US National Shellfish Sanitation Program (FDA 2014)
- European Union (EU) countries
  - FSA shellfish monitoring and end-product testing (EC 2004a; EC 2004b; FSA 2015a; FSA 2015b)
  - Most countries in the EU have monitoring programs in place (FAO 2004; Hinder et al. 2011).

Other relevant standards or guidelines

- Codex Standard for live and raw bivalve molluscs (Codex 2014)
- Codex standard for live and raw abalone for direct consumption or for further processing (Codex 2013)
- Codex general principles of food hygiene CAC/RCP 1 – 1969 (Codex 2003a)
- Codex Code of practice for fish and fishery products implemented in 2003 (Codex 2003b)
- Codex guidelines for the sensory evaluation of fish and shellfish in laboratories (Codex 1999).

Approach by overseas countries

A number of countries have a ML of 0.8 mg/kg of PST (often saxitoxin equivalents in bivalve molluscs). This ML is established in: South Africa (AFF 2012), Wales and Ireland (FSA 2015a), Scotland (FSS 2015), Hong Kong (CFS 2007), Canada (Health Canada 2012) and NZ (MPI 2015). The US[2] and China have an analogous PST regulatory level, however it is applied to all aquatic products, not just bivalve molluscs (DA 2011; FDA 2011). The EU regulatory levels are numerically equivalent but applied to bivalve molluscs, live echinoderms, tunicates and marine gastropods (including abalone) (EC 2004a; EC 2004b; EFSA 2009). Japan has a regulatory value of 4 mouse units/g (MU/g) in all edible parts of shellfish, which is considered equivalent to 0.8 mg/kg of saxitoxin (MHLW 2015).

Some countries permit the harvesting of molluscs and gastropods (for those countries where a maximum level has been set) with PST levels higher than the regulatory level. This is on the basis that the molluscs and gastropods are processed according to the countries specifications and is canned prior to human consumption. Canned products must undergo end product testing to demonstrate that the PST levels are below the regulatory level for the specific country. This approach is in place for a number of countries and include those in the EU, Canada, USA and Argentina (FAO 2004).

Other considerations

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

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[2] In accordance with Title 21 of the Code of federal regulations Part 123 – Fish and fishery products, Subpart A, section 123.3d, 'fish' is defined as *"fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption" (FDA 2011).*

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