

**Imported food risk statement**  
**Ready-to-eat processed bivalve molluscs and *Listeria monocytogenes***

**Commodity:** Ready-to-eat (RTE) processed bivalve molluscs (e.g. clams, mussels, oysters and scallops). This includes bivalve molluscs that have undergone a processing step, such as heating or smoking. Bivalve molluscs that are raw, dried, pickled, fermented and/or in ambient stable sealed packages are not covered by this risk statement.

**Microorganism:** *Listeria monocytogenes*

Recommendation and rationale
<p>Is <i>L. monocytogenes</i> in RTE processed bivalve molluscs a medium or high risk to public health:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Uncertain, further scientific assessment required</p> <p><b>Rationale:</b></p> <ul style="list-style-type: none"> <li>• <i>L. monocytogenes</i> is a severe hazard for susceptible populations as it can cause life threatening illness.</li> <li>• Human illness has been associated with RTE processed bivalve molluscs contaminated with <i>L. monocytogenes</i>.</li> <li>• <i>L. monocytogenes</i> is a ubiquitous organism and can become established in the processing environment.</li> <li>• Although processing steps, such as cooking and smoking, involve a heat treatment step which can inactivate <i>L. monocytogenes</i>, post-processing contamination can occur.</li> <li>• RTE processed bivalve molluscs are able to support the growth of <i>L. monocytogenes</i> during the shelf-life of the product and <i>L. monocytogenes</i> is able to grow at refrigerated temperatures.</li> <li>• Compliance and food recall data in Australia and microbiological surveys have shown detections of <i>L. monocytogenes</i> in RTE processed bivalve molluscs.</li> </ul>

General description
<p><b>Nature of the microorganism:</b></p> <p><i>L. monocytogenes</i> is a Gram-positive, non-spore forming rod-shaped bacterium that can grow in both aerobic and anaerobic conditions. It is found throughout the environment and has been isolated from domestic and wild animals, birds, soil, vegetation, fodder and wet areas of food processing environments (FSANZ 2013).</p> <p>A distinguishing feature of <i>L. monocytogenes</i> is its ability to grow at refrigeration temperatures. Growth can occur at temperatures ranging between 1.5 – 45.0°C, pH of 4.0 – 9.6 and a minimum water activity of 0.90 when other conditions are near optimum. Temperatures above 50°C are lethal to <i>L. monocytogenes</i>, however, it is able to survive frozen storage at -18°C (ICMSF 1996; FSANZ 2013).</p>
<p><b>Adverse health effects:</b></p> <p>For susceptible populations, <i>L. monocytogenes</i> is a severe hazard as it can cause life threatening illness (ICMSF</p>

2002). People at risk of invasive listeriosis include pregnant women and their foetuses, newborn babies, the elderly and immunocompromised individuals (such as cancer, transplant and HIV/AIDS patients). Less frequently reported, but also at a greater risk, are patients with diabetes, asthma, cirrhosis and ulcerative colitis (FSANZ 2013).

In pregnant women invasive listeriosis can cause spontaneous abortion, stillbirth or neonatal infection. Influenza-like symptoms, fever, and gastrointestinal symptoms can also occur in the mother. In immunocompromised individuals and the elderly, invasive listeriosis can cause potentially fatal bacterial meningitis with symptoms of fever, malaise, ataxia and altered mental status. The onset of illness of invasive listeriosis generally ranges from three days to three months after exposure to an infectious dose. Invasive listeriosis has a fatality rate of 15 – 30% (FDA 2012; FSANZ 2013).

Nearly all cases of listeriosis in susceptible people result from the consumption of high numbers of the pathogen (Chen et al. 2003; FAO/WHO 2004). Some foods support the growth of *L. monocytogenes*, enabling high levels of *L. monocytogenes* to be achieved during storage that may lead to illness through exposure to these higher levels.

Exposure to *L. monocytogenes* has minimal impact on the general healthy population. If illness does occur, it is often mild and may be mistaken for a viral infection or flu (FSANZ 2012).

#### **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 this category of bivalve molluscs (Australian Bureau of Statistics 2011). Mixed foods that contained this category of bivalve molluscs were excluded from the analysis. Survey data was derived from one day of dietary recall data.

#### **Key risk factors:**

A key risk factor for bivalve molluscs is microbiological contamination of the waters in which they grow. As bivalve molluscs are filter feeders they can accumulate bacteria such as *L. monocytogenes* from polluted aquatic environments (Codex 2013; Jami et al. 2014).

Processing steps, such as cooking and smoking, involve a heat treatment step which can eliminate *L. monocytogenes*. However, post-processing contamination including cross contamination can occur as *L. monocytogenes* is a ubiquitous organism and can become established in the processing environment (Jinneman et al. 2007; Jami et al. 2014). *L. monocytogenes* can grow slowly at refrigeration temperatures in RTE processed bivalve molluscs, such as cooked mussels (Hudson and Avery 1994). The pH and water activity of steamed and smoked mussels is above those known to inhibit *L. monocytogenes* growth (Sengor et al. 2004). The potential for growth of *L. monocytogenes* in RTE processed bivalve molluscs cannot be excluded based on available data.

#### **Risk mitigation:**

Good hygienic practices in food manufacturing and food handling minimise *L. monocytogenes* contamination of food. Control measures that prevent the growth of *L. monocytogenes* to high levels in the food are expected to have the greatest impact on reducing rates of listeriosis, as nearly all cases of listeriosis result from the consumption of high numbers of the pathogen.

To manage *L. monocytogenes* contamination in the production of RTE processed bivalve molluscs, live and raw bivalve molluscs should be sourced from harvest areas where the potential for *L. monocytogenes* contamination is minimised, for example, away from sewage effluent (FDA 2011; ICMSF 2011; Codex 2013; ASQAAC 2016).

In Australia Division 3 of [Standard 4.2.1 in the Australia New Zealand Food Standards Code](#) (the Code) requires businesses engaging in the primary production, processing, or manufacturing activities concerning bivalve molluscs to implement a documented food safety management system that effectively controls the hazards. The food safety management system incorporates the conditions of the [ASQAP Manual](#) for managing

risk in the harvesting, relaying, depuration and wet storage of shellfish.

[Schedule 27 of the Code](#) contains microbiological limits for *L. monocytogenes* in RTE food based on whether growth can occur or not:

- For RTE food in which growth of *L. monocytogenes* can occur n=5, c=0, m=not detected in 25g
- For RTE food in which growth of *L. monocytogenes* will not occur n=5, c=0, m=10<sup>2</sup> CFU/g.

Section 1.6.1–4 of [Standard 1.6.1 of the Code](#) states:

- (1) For the purposes of the table to section S27–4, growth of *L. monocytogenes* will not occur in a \*RTE food if –
  - (a) the food has a pH less than 4.4 regardless of water activity; or
  - (b) the food has a water activity less than 0.92 regardless of pH; or
  - (c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
  - (d) the food has a refrigerated shelf life no greater than 5 days; or
  - (e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
  - (f) it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log CFU/g over the food’s stated shelf life.
- (2) For the purposes of the table to section S27–4, a \*RTE food that does not receive a \*listericidal process during manufacture is taken to be a food in which growth of *Listeria monocytogenes* will not occur if the level of *Listeria monocytogenes* will not exceed 100 CFU/g within the food’s expected shelf life.
- (3) For the purposes of subclause (2), a \*RTE food that does not receive a listericidal process during manufacture is taken to include:
  - (a) RTE processed finfish; and
  - (b) fresh cut and packaged horticulture produce.

It is considered unlikely that *L. monocytogenes* growth will occur in RTE foods consumed frozen and those intended to be thawed just before consumption (to be eaten cold or re-heated). However, final use of the frozen product and instructions for use should be taken into consideration, for example whether the product is intended to be thawed and chilled for retail sale (where growth of *L. monocytogenes* can occur).

Additional information can be found in the FSANZ document [Guidance on the application of microbiological criteria for \*Listeria monocytogenes\* in RTE food](#).

Public information for vulnerable populations to avoid consumption of RTE food in which growth of *L. monocytogenes* can occur is available on various government websites [including FSANZ’s website](#).

Dried, pickled or fermented fish products have either low water activity and/or low pH. Fully dried fish products have a uniform moisture content, low water activity (generally close to or below 0.75) and are shelf stable, whereas, partially dried fish products may have water activity in the range (>0.92) that supports the growth of *L. monocytogenes*. Semi-preserved fish products (such as pickled product) have high salt and acid levels, and fermented fish products have a low pH (during fermentation the pH should decrease to below pH 4.5 in 1-2 days) (Doe 2002; ICMSF 2011).

#### **Compliance history:**

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture and Water Resources for January 2007 – May 2016 showed that of the 616 *L. monocytogenes* tests applied to RTE processed bivalve molluscs there were 14 fails, a 2.3 % failure rate. The failed samples were from Chile, China and Japan and included mussel meat, scallops and oysters.

There was one notification on the European Commission’s Rapid Alert System for Food and Feed (RASFF) for *L. monocytogenes* (<10 CFU/g) in scallops from the United States from January 2007 – May 2016, however it was not stated if this product was RTE.

There has been one food recall in Australia of smoked mussels due to the presence of *L. monocytogenes* from January 2007 – May 2016. This recall was for domestic product; there have been no recalls due to imported product.

### Surveillance information:

Listeriosis is a notifiable disease in all Australian states and territories with a notification rate in 2015 of 0.3 cases per 100,000 population (70 cases). This is the same as the previous five year mean (ranging from 0.3 – 0.4 cases per 100,000 population per year) (NNDSS 2016).

### Illness associated with consumption of RTE processed bivalve molluscs contaminated with *L. monocytogenes*

A search of the scientific literature via Web of Science, PubMed, CAB abstracts, Scopus, US CDC Foodborne Outbreak Online Database and other publications during the period 1990 - June 2016 identified limited reports of listeriosis outbreaks associated with consumption of this category of bivalve molluscs:

- Outbreak in New Zealand in 1992 – four perinatal cases and two fatalities linked to consumption of smoked mussels. The outbreak strain of *L. monocytogenes* was isolated from unopened product and from the processing factory (Baker et al. 1993; Brett et al. 1998; Jinneman et al. 2007).
- Outbreak in Australia (Tasmania) in 1991 – three cases of illness linked to consumption of cryopacked smoked mussels. The outbreak strain of *L. monocytogenes* was isolated from unopened product obtained from another retail food outlet. The batches had been labelled with the incorrect use-by date resulting in overestimation of shelf life by three months or more (Misrachi et al. 1991; Mitchell 1991).

### Prevalence of *L. monocytogenes* in RTE processed bivalve molluscs

A search of the scientific literature via Web of Science, PubMed, CAB abstracts, Scopus and other publications during the period 1990 - June 2016 identified that data on the prevalence of *L. monocytogenes* in this category of bivalve molluscs is limited:

- Survey in Europe (Hungary and Spain) in 2012 – *L. monocytogenes* was not detected in cooked molluscan shellfish samples (n=62) (EFSA 2014).
- Survey in Hungary in 2010 – *L. monocytogenes* was isolated from 1.2% of cooked molluscan shellfish samples (n=81); levels were not enumerated (EFSA 2012).
- Survey in Europe (Italy and Poland) in 2005 – *L. monocytogenes* was not detected in cooked molluscan shellfish samples (n=209) (EFSA 2007).
- Survey in New Zealand – *L. monocytogenes* was isolated from 35.7% of smoked mussels (n=14); levels were not enumerated (Hudson et al. 1992; Jinneman et al. 2007).

### Other relevant standards or guidelines

- Codex general principles of food hygiene *CAC/RCP 1 – 1969* follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage (Codex 2003).
- Codex guidelines on the application of general principles of food hygiene to the control of *L. monocytogenes* in foods *CAC/GL 61 – 2007* states:
  - For ready-to-eat foods in which growth of *L. monocytogenes* can occur the microbiological criterion for *L. monocytogenes* is n=5, c=0, m=absence in 25g
  - For ready-to-eat foods in which growth of *L. monocytogenes* cannot occur the microbiological criterion for *L. monocytogenes* is n=5, c=0, m=100 CFU/g (Codex 2009).
- Codex code of practice for fish and fishery products *CAC/RCP 52-2003* applies to the growing, harvesting, handling, production, processing, storage, transportation and retail of fish, shellfish and aquatic invertebrates and products thereof from marine and freshwater sources that are intended for human consumption. Section seven of *CAC/RCP 52-2003* is specific to processing of live and raw bivalve molluscs and describes control at individual processing steps (Codex 2013).
- Codex standard for live and raw bivalve molluscs *CODEX STAN 292-2008* covers the production and processing of live and raw bivalve molluscs, including those intended for further processing (Codex 2015).
- Codex standard for fresh and quick frozen raw scallop products *CODEX STAN 315-2014* covers production and processing of fresh and quick frozen raw scallop products, including those intended

for further processing (Codex 2016).

#### Approach by overseas countries

Many countries and regions, such as the United States, Canada and the European Union, have HACCP-based regulatory measures in place for production of this commodity.

The European Commission regulation on microbiological criteria for foodstuffs specifies that  $n=5$ ,  $c=0$ ,  $m=100$  CFU/g as food safety criteria for *L. monocytogenes* in RTE foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes. This criterion applies to products placed on the market during their shelf-life. In RTE foods that are able to support the growth of the bacterium, *L. monocytogenes* may not be present in 25 g at the time of leaving the production plant. However, if the producer can demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 CFU/g throughout its shelf-life, this criterion does not apply (European Commission 2007).

The Canadian policy on *Listeria monocytogenes* in RTE foods (Health Canada 2011) classifies RTE foods into categories, based upon health risk. Category 1 contains RTE foods which can support the growth of *L. monocytogenes* throughout the stated shelf-life of the product. The microbiological compliance criteria for *L. monocytogenes* in Category 1 RTE foods is absence in 125g (5 x 25g). Category 2A contains RTE food products in which limited growth of *L. monocytogenes* to levels not greater than 100 CFU/g can occur throughout the stated shelf-life of the product. The microbiological compliance criteria for *L. monocytogenes* in Category 2A RTE foods is  $\leq 100$  CFU/g (Health Canada 2011).

#### Other considerations

Biosecurity restrictions apply to products under this commodity classification. Refer to the [BICON database](#).

**This risk statement was compiled by FSANZ in: November 2016**

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