

**Imported food risk statement**  
**Processed ready-to-eat finfish and *Listeria monocytogenes***

**Commodity:** Processed ready-to-eat (RTE) finfish, such as RTE finfish that are cooked, cured or smoked. RTE finfish that are dried, pickled, salted or fermented and RTE finfish 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 processed RTE finfish 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>Human illness has been associated with processed RTE finfish contaminated with <i>L. monocytogenes</i>. For susceptible populations, infection with <i>L. monocytogenes</i> can have severe consequences</li> <li>Compliance data in Australia and European countries, food recall data in Australia and international surveillance data have shown detections of <i>L. monocytogenes</i> in processed RTE finfish</li> <li>Growth of <i>L. monocytogenes</i> can occur in this commodity during refrigeration storage</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 between 1.5 – 45.0°C, pH of 4.0 – 9.6 and a minimum water activity of approximately 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 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).</p> <p>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</p>

meningitis with symptoms of fever, malaise, ataxia and altered mental status. The onset of illness of invasive listeriosis generally ranges from 3 days to 3 months after infection. 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). However, some foods support the growth of *L. monocytogenes*, enabling high levels of *L. monocytogenes* to be achieved that may lead to illness.

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 pattern:**

In the 2007 Australian National Children’s Nutrition and Physical Activity Survey, <1% of children aged 2 – 16 years reported consumption of smoked finfish (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% of people aged 70 and above reported consumption of smoked finfish (Australian Bureau of Statistics 2011-12).

For both the 2007 and the 2011 – 2012 surveys, mixed foods that contained processed RTE finfish 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:**

Live fish can harbour *L. monocytogenes* if the water environment inhabited by the fish is contaminated by *L. monocytogenes*. The bacteria can spread from the intestinal contents to other fish tissues (including muscles) (Jinneman et al. 2007; Jami et al. 2014).

The cold-smoking process (<50°C) does not generate sufficient heat to inactivate *L. monocytogenes* that may be present on the fish. Inadequate temperature and time control during cold-smoking and inadequate cooling applied post-smoking could exacerbate the number of *L. monocytogenes* on the final product (ICMSF 2000; Codex 2003a; Jinneman et al. 2007).

*L. monocytogenes* does not survive the hot-smoking process (>75°C). Post-processing contamination including cross-contamination can occur as *L. monocytogenes* is a ubiquitous organism and can become established in the processing environment. *L. monocytogenes* can grow slowly at refrigeration temperatures in smoked finfish, however, this is dependent on the product characteristics (e.g. pH, water activity and the addition of inhibitory substances) (ICMSF 2000; IFT 2001; Jinneman et al. 2007).

#### **Risk mitigation:**

To manage *L. monocytogenes* contamination in the production of processed RTE finfish, source raw fish that has been produced such that the potential for *L. monocytogenes* contamination is minimised. Good hygienic practices in food manufacturing and food handling will minimise *L. monocytogenes* contamination of processed RTE finfish.

In Australia Division 2 of [Standard 4.2.1 of the Australia New Zealand Food Standards Code](#) (the Code) states that a seafood business must systematically examine all of its primary production and processing operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risk, and must take all necessary steps to prevent the likelihood of seafood being or becoming contaminated.

[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

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, salted or fermented RTE finfish have either low water activity and/or low pH. Fully dried or salted fish products contain low levels of water, for example dried bonito and anchovies have water activities of 0.76 and 0.79, respectively. Semi-preserved fish products (such as pickled fish) 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 – June 2013 showed that of the 1101 *L. monocytogenes* tests applied to processed RTE finfish there were 29 fails, representing a 2.6% failure rate (test limit of n=5, c=1, m=0, M=100 applied; where *L. monocytogenes* was enumerated the levels were <100 CFU/g). Most of the failed samples were smoked salmon imported from European countries. Of the 703 *L. monocytogenes* tests applied to dried, pickled, salted or fermented RTE finfish, there were 7 fails, representing a 1% failure rate (test limit of n=5, c=1, m=0, M=100 applied; where *L. monocytogenes* was enumerated the levels were <50 CFU/g).

There have been 223 notifications on the European Commission’s Rapid Alert System for Food and Feed (RASFF) for *L. monocytogenes* in processed RTE finfish during the period January 2007 – July 2015. Most of the notifications were for smoked salmon originating from European countries. Among the notified products the level of *L. monocytogenes* detected ranged from presence in a 25g sample to 3 x 10<sup>5</sup> CFU/g. During the same time period there was one notification on RASFF for *L. monocytogenes* in raw pickled sliced rainbow trout fillet from Estonia. The level of *L. monocytogenes* detected was in the range of 580 – 5000 CFU/g. There were no notifications for dried, salted or fermented RTE finfish samples.

There has been one food recall in Australia due to the presence of *L. monocytogenes* in processed RTE finfish from January 2007 – July 2015. The recall was for domestically produced smoked salmon. During the same

time period there were no food recalls in Australia for dried, pickled, salted or fermented RTE finfish.

#### **Surveillance information:**

Listeriosis is a notifiable disease in all Australian states and territories with a notification rate in 2014 of 0.3 cases per 100,000 population (80 cases). This was a decrease from the previous five year mean of 0.4 cases per 100,000 population per year (ranging from 0.3 – 0.4 cases per 100,000 population per year) (NNDSS 2015).

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

A search of the scientific literature via the EBSCO Discovery Service, the US CDC Foodborne Outbreak Online Database and other published literature during the period 1990 – July 2015, identified there are limited reports of listeriosis outbreaks associated with consumption of processed RTE finfish:

- Increase in listeriosis incidence in Finland in 2010. Epidemiological investigation revealed that 31 of 54 immunocompromised cases (57%) reported eating gravad or cold-smoked fish (Nakari et al. 2014)
- Outbreak in Finland, five cases of non-invasive listeriosis linked to consumption of cold-smoked rainbow trout. The outbreak strain of *L. monocytogenes* was isolated from cold-smoked rainbow trout from the same production lot obtained from the same retail store as the cases (Miettinen et al. 1999).
- Outbreak in Sweden in 1994 – 1995, nine cases of illness including two fatalities linked to consumption of gravad or cold-smoked rainbow trout. The outbreak strain of *L. monocytogenes* was isolated from gravad and cold-smoked rainbow trout from the same implicated producer (Ericsson et al. 1997)

A similar scientific literature search did not identify any listeriosis outbreaks associated with consumption of dried, pickled, salted or fermented RTE finfish.

#### **Prevalence of *L. monocytogenes* in processed RTE finfish**

A search of the scientific literature via the EBSCO Discovery Service and other published literature during the period 1990 – July 2015, identified that surveys of processed RTE finfish have isolated *L. monocytogenes* in 0 – 78.9% of samples (Eklund et al. 1995; ESR 2011)

- Survey in Europe in 2012, *L. monocytogenes* was detected in 12% of smoked RTE fish samples (n=10,831) collected at retail or from processing plants. *L. monocytogenes* counts >100 CFU/g were found in 1.4% of the samples in which *L. monocytogenes* levels were enumerated (n=6,141) (EFSA 2014)
- Survey in Europe in 2010 – 2011, *L. monocytogenes* was detected in 17.4% of cold-smoked fish (n=599) and 6.3% of hot-smoked fish (n=525) collected at retail. *L. monocytogenes* counts >100 CFU/g were found in 1.7% of cold-smoked fish samples (n=599) and 1.3% of hot-smoked fish samples (n=525) (EFSA 2013)
- Survey in New Zealand in 2010, *L. monocytogenes* was isolated in 1.3% of cold-smoked salmon samples (n=598) and was not detected in hot-smoked salmon samples (n=614) collected at retail or from processors. *L. monocytogenes* counts >100 CFU/g were found in 0.5% of cold-smoked fish samples (n=598) (ESR 2011)
- Survey in the United States, *L. monocytogenes* was isolated in 78.9% of cold-smoked salmon samples (n=61) collected from processing plants. *L. monocytogenes* counts were all <100 CFU/g (Eklund et al. 1995)

A similar scientific literature search identified that surveys of dried, pickled, salted or fermented RTE finfish have isolated *L. monocytogenes* in 0 – 12.5% of samples, with generally low levels reported (Moharem et al. 2007; Soultos et al. 2014)

- Survey in Greece, *L. monocytogenes* was isolated from 12.5% of dried fish samples (n=16) and 11.1% of salted fish samples (n=18) collected at retail, the level of contamination was <100 CFU/g (Soultos et al. 2014)

- Survey in Estonia from 2008 – 2010, *L. monocytogenes* was not detected in dried fish (n=89) and was isolated from 9.7% of salted fish products (n=391) collected at processing or retail level. Enumeration analysis was performed on the last day of product shelf-life. Of the salted fish product samples that were enumerated, *L. monocytogenes* levels were <10 CFU/g for 92% of samples, 10-100 CFU/g for 6% of samples and 100-1000 CFU/g for 2% of samples (n=129) (Kramarenko et al. 2013)
- Survey in India from 2005 – 2006, *L. monocytogenes* was not detected in dried finfish samples (n=20) collected at retail (Moharem et al. 2007)
- Survey in Spain from 1998 – 2004, *L. monocytogenes* was not detected in salted anchovies (n=12) or salted herring samples (n=15) collected at processing or retail level (Cabedo et al. 2008)

#### Other relevant standard or guideline

- 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 2003b)
- Codex code of practice for fish and fishery products *CAC/RCP 52 – 2003* offers general advice on the production, storage and handling of fish and fishery products (Codex 2003a)
- Codex standard for smoked fish, smoked-flavoured fish and smoke-dried fish *Stan 311 – 2013* describes production and processing standards for smoked fish, smoke-flavoured fish and smoke-dried fish (Codex 2013)
- Codex guidelines on the application of general principles of food hygiene to the control of *L. monocytogenes* in foods *CAC/GL 61 – 2007* (Codex 2009) states:
  - For RTE 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 RTE foods in which growth of *L. monocytogenes* cannot occur the microbiological criterion for *L. monocytogenes* is n=5, c=0, m=100 CFU/g

#### Approach by overseas countries

Many countries, such as the European Union, the United States and Canada, have HACCP-based regulatory measures in place for processed finfish.

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, such as processed RTE finfish, 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; EFSA 2014).

The Canadian policy on *Listeria monocytogenes* in RTE foods (Health Canada 2011) classifies RTE foods into categories, based upon health risk. 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, e.g. cold-smoked salmon. The microbiological compliance criteria for *L. monocytogenes* in Category 2A RTE foods is ≤100 CFU/g (Health Canada 2011).

#### Other considerations

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

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