Imported food risk statement

Ready-to-eat cooked crustaceans in which growth of *Listeria monocytogenes* can occur

Scope: Ready-to-eat (RTE) cooked crustaceans, such as prawns and crabs, in which growth of *Listeria monocytogenes* can occur. These products have physico-chemical characteristics (pH and water activity) such that growth of *L. monocytogenes* can occur, and are sold refrigerated. Although these products may be stored frozen, they are thawed prior to sale. RTE cooked crustaceans that are dried or in ambient stable sealed packages are not covered by this risk statement.

Recommendation and rationale
Does *Listeria monocytogenes* in imported RTE cooked crustaceans in which growth of *L. monocytogenes* can occur present a potential medium risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • *L. monocytogenes* is a moderately infectious pathogen that can cause severe disease in susceptible populations and is potentially life threatening. • There have been a limited number of listeriosis outbreaks associated with consumption of RTE cooked crustaceans in which growth of *L. monocytogenes* can occur, and limited detections of *L. monocytogenes* in these products. • Although the cooking step should eliminate the hazard, there is potential for post-processing contamination as *L. monocytogenes* is ubiquitous in the environment and can become established in food processing environments. RTE cooked crustaceans are often eaten with no further cooking or other pathogen elimination step before consumption. • Due to the physico-chemical characteristics of this category of product, growth of *L. monocytogenes* can occur at refrigeration temperatures.

General description
Nature of the microorganism: *Listeria monocytogenes* is a Gram-positive, non-spore forming rod-shaped bacterium that is found throughout the environment. *L. monocytogenes* has been isolated from domestic and wild animals, birds, soil, vegetation, fodder and water; and from the floors, drains and wet areas of food processing factories (FSANZ 2013). *L. monocytogenes* is a hardy organism. The temperature range for growth is between –1.5 and 45°C, with the optimal temperature being 30–37°C (FSANZ 2013). Temperatures above 50°C are lethal to *L. monocytogenes*, however it can survive for long periods frozen. *L. monocytogenes* will grow in a broad pH range of 4.0–9.6. It can grow at a water activity (a_w) as low as 0.90 and survive for extended periods of time at an a_w of 0.81. *L. monocytogenes* is moderately salt-tolerant, having been reported to grow in 13–14% sodium chloride (Farber et al. 1992; Lado and Yousef 2007). It grows well under both aerobic and anaerobic conditions (Sutherland et al. 2003).
Adverse health effects: In susceptible populations, *L. monocytogenes* can cause severe disease that is potentially life threatening. 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 3 days to 3 months after infection. Invasive listeriosis has a fatality rate of 15 – 30% (FDA 2012; FSANZ 2013).

Published data indicate that contaminated food responsible for foodborne illness usually contain levels of *L. monocytogenes* >100 cfu/g (Ryser and Buchanan 2013).

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% children (aged 2 – 16 years), 1% of adults (aged 17 – 69 years) and 1% of people aged 70 and above reported consumption of RTE cooked crustaceans (Australian Bureau of Statistics 2011). Mixed foods that contained RTE cooked crustaceans were excluded from the analysis. Survey data was derived from one day of dietary recall data.

Risk factors and risk mitigation

Cooking of RTE crustacean products is a listericidal process. However, re-contamination can occur after this cooking step as *L. monocytogenes* is an ubiquitous organism and can become established in processing environments. Contamination can occur through poor hygienic practices of food handlers or by exposure of product to contaminated air, water, raw materials or food-contact surfaces (Codex 2007).

L. monocytogenes can grow on some cooked crustacean products at refrigeration temperatures (Kataoka et al. 2017; Paranjpye et al. 2008; Parveen et al. 2017). The extent to which growth of *L. monocytogenes* occurs is dependent on the characteristics of the food and the conditions and duration of refrigerated storage (FAO/WHO 2004). Growth can be slowed or prevented by modifying the product characteristics through the addition of inhibitory substances or by freezing (Jinneman et al. 2007; Kataoka et al. 2017).

Food preservatives can reduce the growth and survival of *L. monocytogenes* on food products. The effect of preservatives on the growth of *L. monocytogenes* is influenced by temperature, pH, salt content and water activity. For example, sodium nitrite is more effective at preventing growth of *L. monocytogenes* at lower temperatures and pH, or when the sodium chloride concentration is increased (Lado and Yousef 2007).

Several countries, including Australia, permit the use of a specific bacteriophage as a processing aid to eradicate or decrease *L. monocytogenes* on various RTE food products for human consumption, including RTE cooked crustaceans.

The application of HACCP and good hygienic practices in food manufacturing and throughout the supply chain minimise the potential for re-contamination of cooked RTE crustaceans with *L. monocytogenes*. Control measures that prevent the growth of *L. monocytogenes* to high levels in the food are particularly effective at reducing rates of listeriosis, as nearly all cases of listeriosis result from the consumption of high numbers of the pathogen (FSANZ 2013).

Public information for vulnerable populations to avoid consumption of RTE food, including cooked prawns, that supports the growth of *L. monocytogenes* is available on various government websites including FSANZ's website.

Surveillance information:

Listeria monocytogenes is a notifiable disease in all Australian states and territories with a reported incidence in 2018 of 0.3 cases per 100,000 population (73 cases), which includes both foodborne and non-foodborne cases. The previous five year mean was 0.32 cases per 100,000 population per year (ranging from 0.3 – 0.4 cases per 100,000 population per year) (Department of Health 2019).

Listeriosis associated with consumption of RTE cooked crustaceans in which growth of *L. monocytogenes* can occur

A search of the scientific literature via EBSCO, US CDC National Outbreak Reporting System and other publications from 2000 to July 2019 identified there have been a limited number of listeriosis outbreaks associated with consumption of RTE cooked crustaceans in which growth of *L. monocytogenes* can occur. Examples are provided below:

The EFSA Panel on Biological Hazards et al. (2018) reported three European outbreaks associated with the product category: crustaceans, shellfish, molluscs and products thereof. Two of these were linked to crab meat sold from a mobile retailer or market/street vendor which had contributing factors of cross-contamination and inadequate chilling (not stated if the products were cooked and RTE). The third outbreak occurred in a household and no specific food commodity was reported

(not stated if the product was cooked and RTE). Each of the outbreaks were small in size (n = 10 total cases across the three outbreaks) with only three or four cases involved per outbreak.

Data on the prevalence of *L. monocytogenes* in RTE cooked crustaceans in which growth of *L. monocytogenes* can occur

A search of the scientific literature via EBSCO and other publications from 2000 to July 2019 identified six surveys of *L. monocytogenes* in cooked crustaceans at the end of processing (Gudmundsdóttir et al. 2006; Hatha et al. 2003; Jinneman et al. 2007; Lappi et al. 2004; Pagadala et al. 2012; Thimothe et al. 2002). The prevalence of *L. monocytogenes* ranged from 0-15% of samples, with an estimated prevalence of 0.7% (95% CI 0.1% - 4%) determined using a random effects meta-analysis of the six surveys. No surveys were identified for RTE cooked crustaceans from retail settings. Cooking methods for crustaceans described in the studies included boiling, steaming and retorting (followed by further processing and packing). Growth of *L. monocytogenes* has been shown to occur in cooked crab, crawfish, lobster and shrimp (Dorsa et al. 1993; Farber 1991; Rawles et al. 1995) and the samples from the six surveys are assumed to support the growth of *L. monocytogenes*. Examples of survey findings include:

- Iceland (1998-2001): *L. monocytogenes* was not isolated in the final product of cooked peeled shrimps (n = 82) collected from two processing plants (Gudmundsdóttir et al. 2006).
- USA (2000-2003): *L. monocytogenes* was isolated in 2.37% of cooked RTE crabmeat (n=632), 4.65% of cooked RTE shrimp (n=387), 3.80% of cooked RTE crawfish (n=79), 10% of cooked RTE lobster meat (n=30), 15.38% of cooked RTE langostinos (n=13) and not detected in cooked RTE spiny lobster (n=8) analysed by the US FDA (Jinneman et al. 2007).
- USA (2001-2002): *L. monocytogenes* was not isolated in the final product of RTE cooked crawfish collected from two processors (n = 102) (Lappi et al. 2004).
- USA (2006-2007): *L. monocytogenes* was isolated in one of 624 samples of cooked crab meat obtained from a survey of seven processors (Pagadala et al. 2012).

L. monocytogenes has been detected in cooked peeled shrimp obtained from a processor, however the prevalence of *L. monocytogenes* was not reported (this product was held from the market by federal and state regulatory agencies due to *L. monocytogenes* contamination) (Paranjpye et al. 2008).

Standards or guidelines

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.
- Standard 1.2.6 includes the labelling provisions for the directions for use and the statement of storage conditions.
- 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 *L. 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 *ready-to-eat 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.
- Schedule 27 contains limits for *L. monocytogenes* based on whether growth can occur or not:
  - For RTE food in which growth of *L. monocytogenes* can occur n=5, m=not detected in 25g
  - For RTE food in which growth of *L. monocytogenes* will not occur n=5, m=10^2 cfu/g
- Under Standard 1.3.3—Processing aids—of the *Australia New Zealand Food Standards Code*, *Listeria* phage P100 is permitted for use as a processing aid for listericidal treatment of a number of foods, including RTE cooked crustaceans.

Standard 1.6.1 and Schedule 27 mirror the microbiological criteria set out in the Codex guidelines on the application of general principles of food hygiene to the control of *L. monocytogenes* in foods (*CAC/GL 61 – 2007)*. Codex defines RTE food in which growth of *L. monocytogenes* can occur as a RTE food in which there is >0.5 log cfu/g increase in *L. monocytogenes*

levels over at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use, and is considered a food in which growth of *L. monocytogenes* can occur (Codex 2007).

The 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 Code of practice for fish and fishery products (*CAC/RCP 52-2003*) covers additional provisions for 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 (Codex 2016).

Management approaches used by overseas countries

- European Commission guidelines on microbiological criteria for foodstuffs No 2073/2005 (European Commission 2005) 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 (before the food has left immediate control of the food business operator who produced it)
  - 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
- In New Zealand, RTE crustaceans (lobsters, crabs, bugs, shrimps and prawns and their products) are classed as a food of high regulatory interest, with clearance limits for imported RTE crustaceans of *L. monocytogenes* not detected in 25g (New Zealand Ministry for Primary Industries 2019) .
- United States: zero tolerance in RTE foods (FDA 2015; FSIS 1989).
- Canada: End-product compliance criteria (Health Canada 2011):
  - For RTE foods in which the growth of *L. monocytogenes* can occur; or which have a shelf-life longer than 5 days; or which have not been validated as either Category 2A or 2B: absence in 5x25g samples.
  - Category 2A: RTE foods in which the growth of *L. monocytogenes* can occur but is limited to levels no greater than 100 cfu/g over the course of the stated shelf-life; or RTE foods which have a refrigerated shelf-life of 5 days or less: If shelf life >5 days, processors should validate and verify their processes to ensure that the levels of *L. monocytogenes* are consistently less than or equal to 100 cfu/g throughout the stated shelf-life. If shelf life is ≤5 days, no validation is required.
  - Category 2A: RTE foods in which the growth of *L. monocytogenes* cannot occur over the course of the stated shelf life. Such foods are frozen; or meet specified pH and/or water activity parameters. Processors need to monitor their products to ensure that they continue to meet the criteria (e.g., physicochemical parameters such as pH and a_w) that justify their classification.

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