Imported food risk statement

Cut ready-to-eat melon and *Listeria monocytogenes*

Scope: Ready-to-eat (RTE) melon (including, but not limited to, rockmelon (cantaloupe), watermelon, and honeydew melon) that has been pre-cut, including product with skin on and/or off, and is stored chilled or frozen. Product that has been further processed, such as puréed melon, is not covered by this risk statement.

Recommendation and rationale
Does *Listeria monocytogenes* in imported cut RTE melon present a potential medium or high risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • *L. monocytogenes* is a moderately infectious pathogen that can cause severe disease in susceptible populations, with a case fatality rate of 15–30%. • There is evidence that *L. monocytogenes* has caused foodborne illness associated with consumption of cut RTE melon. • The method of production (e.g. growth on ground) and handling of the whole fruit can introduce surface contamination, which can result in post-processing contamination occurring during cutting and packaging. As melons pose a medium-high risk, a through-chain, multi-hurdle management approach is required to minimise risk. Cut RTE melons generally do not undergo any pathogen elimination step prior to consumption. • Growth of *L. monocytogenes* can occur both on the surface of the melon and in melon flesh, i.e. on the cut melon surface, including when stored at refrigeration temperatures. • Current evidence supports a higher risk from *L. monocytogenes* to be associated with cut RTE melons specifically with a netted and/or rough surface, or from melons grown on the ground regardless of surface type, However, all melons are susceptible to *L. monocytogenes* contamination during primary production and processing and can support the growth of *L. monocytogenes* both on the rind and in the flesh of melons at temperatures ≥4°C.

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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 growth temperature being 30–37°C (FSANZ 2013). Temperatures above 50°C are lethal to the bacterium, but it can survive for long periods at temperatures below freezing. *L. monocytogenes* is relatively tolerant to acidic conditions and 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 reasonably 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: For 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, neonates, the elderly and immunocompromised individuals

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(such as cancer, transplant and HIV/AIDS patients). Patients with diabetes, asthma, cirrhosis and ulcerative colitis are also at a greater risk (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 foods responsible for foodborne listeriosis usually contain levels of *L. monocytogenes* >100 cfu/g (Ryser and Buchanan 2013). Exposure to *L. monocytogenes* usually has minimal impact on the general healthy population. If infection does occur, it can be asymptomatic or present as a mild febrile gastrointestinal illness that can be mistaken for a viral infection (FSANZ 2013).
Consumption patterns: 2.8% of children (2-5 years), 1.7% of children (aged 6–16 years), 2.3% of adults (aged 17–69 years) and 3.5% of people aged 70 and above reported consumption of fresh rockmelon from all sources (peeled, raw, and in mixed foods). Further, the mean amount of rockmelon consumed by both age groups of children is significantly higher than for the other age classes (6.8/3.2 compared to 1.6/1.5 g/kg bw/day respectively for single and mixed foods). 6.8% of children (2-5 years), 4.3% of older children (6-16 years), 2.7% of adults (aged 17–69 years) and 1.9% of people aged 70 above reported consumption of fresh watermelon (peeled and raw as a single item). Watermelon was less frequently consumed as a mixed food with <2% reported consumption across all age groups. Overall, 8.2% of children (2-5 years), 6.0% of older children (6-16 years), 4.3% of adults (aged 17–69 years) and 3.4% of people aged 70 above reported consumption of fresh watermelon. Further, the mean amount of watermelon consumed by both age groups of children is significantly higher than for the other age classes (5.4/4.7 compared to 1.8/1.4 g/kg bw/day respectively for single and mixed foods). Honeydew melon was the least consumed of the specified melons with <1% of children (2-5 years), <1% of older children (6-16 years), 1.2% of adults (aged 17–69 years) and 1.5% of people aged 70 above reporting consumption (peeled and raw as a single item or as part of a mixed food item). No significant difference was noted in the amount consumed (g/kg bw/day), however this may be due to the lower number of people reporting consuming honeydew melon. Data is from the 2011–12 Australian National Nutrition and Physical Activity Survey (ABS 2014). The reported percentages are based on a single day of consumption information from the above survey, and do not indicate the frequency of consumption of fresh melon.
Risk factors and risk mitigation: The safety of all melon varieties relies on a consistent and well managed through-chain, multi-hurdle approach to minimise risk (FSANZ 2021). There are multiple sources and routes for melon contamination in the supply chain from primary production to the point of sale. To minimise contamination of melons with *L. monocytogenes* effective control measures are necessary during primary production and processing. This involves the application of Good Agricultural Practices (GAP) on-farm, Good Hygienic Practices (GHP) throughout the supply chain and Good Manufacturing Practices (GMP) during processing, as well as controlling inputs through-chain (Bowen et al. 2006; Codex 2017; FSANZ 2021; Singh 2019). Key factors that contribute to contamination are the proximity of melons to soil during production and the structure of the surface of the melon (netted and rough versus smooth). Melon rind ground spots have been demonstrated to have significantly greater microbial populations than other areas of the rind and may therefore be susceptible to microbial contamination (Codex 2017). Given that *Listeria* is commonly found in the soil, melons which are grown on the ground are therefore at a higher risk of *Listeria* contamination than those grown suspended above the ground. Other risk factors during primary production of all melons include the quality of water used for irrigation and application of water-soluble agricultural chemicals; use of untreated, inadequately treated or re-contaminated manure as fertiliser; animal intrusion; and environmental factors, such as site location and extreme weather events (e.g. dust storms, heavy rainfall, floods). Risk can be managed by application of GAP, including the use of water of suitable quality (e.g. clean or potable water for application of agricultural chemicals and direct contact irrigation water); minimising contact of melons with soil, soil amendments[1] and irrigation water (i.e. use of sub-surface or drip irrigation rather than overhead irrigation); proper

[1] Soil amendments: physical, chemical and biological materials added to the soil to improve the health, nutrition and crop productivity of the soil, e.g. inorganic fertilisers, manure and compost (Singh (2019).

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management of fertiliser storage and treatment facilities; knowledge of previous land use; minimising wildlife access to the growing field; and the use of windbreaks to provide a buffer between wind and crops (Codex 2017; FSANZ 2021; Singh 2019). When melons are harvested, a stem scar is left on the fruit, and this may provide a route for the entry of foodborne pathogens. Svoboda et al. (2016) and others have noted that watermelon rind, although considered smooth, can suffer damage to the outer waxy coating during production and harvesting, allowing ingress of surface contaminating microorganisms to the pulp where growth can occur. Post-harvest handling practices should be implemented to minimise stem scar and rind infiltration of foodborne pathogens into the edible portions of melon flesh, such as during washing operations (Codex 2017). During the washing procedure there is the risk of internalisation of pathogens, with greater temperature differences between the fruit and wash water more likely to result in the fruit absorbing water from the surrounding environment. However, *L. monocytogenes* has been shown to internalise into whole rockmelons via dump tank wash water even without a temperature differential. Ideally melons should be pre-cooled prior to washing and sanitising to reduce the temperature differential (Bowen et al. 2006; FSANZ 2021; Singh 2019). Potable water containing a sanitiser (e.g. chlorine) should be used to wash the fruit, and the sanitiser must be effective and at an appropriate concentration. Melons may have smooth or netted rough rind surface; microbial pathogens more easily adhere to the latter, survive and become more difficult to eliminate during post-harvest practices (Codex, 2017). Cut RTE netted or rough surfaced melons are more often associated with listeriosis outbreaks than smooth rind melons. Postharvest, melon can also be contaminated by *L. monocytogenes* present in niche sites, such as processing equipment, during fruit cleaning, packing and storage of melons (McCollum et al. 2013). Melons should be cooled following processing, and the cool chain maintained throughout distribution, to reduce the potential for internalisation during washing and sanitising, and to prevent or slow the growth of *Listeria* on the flesh of cut melons (FSANZ 2021; Singh 2019). Adequate sanitation and handwashing facilities should be available for staff harvesting melons in the field, and for staff handling melons in packing facilities. A well-designed environmental monitoring program can reduce the risk of pathogens colonising the processing environment and subsequently contaminating produce (Singh 2019). Cut melon flesh can be contaminated by transfer of *L. monocytogenes* from the rind during cutting or via contaminated food contact surfaces (Shearer et al. 2016; Ukuku et al. 2015). Risk can be minimised by application of GHP during the preparation of pre-cut melon, including washing and sanitising melons in potable water prior to cutting; ensuring all equipment and utensils are thoroughly cleaned and sanitised; and storing pre-cut product under refrigeration (Codex 2017; Singh 2019). Melons have been demonstrated to support the growth of *L. monocytogenes*, both on the rind and in the flesh of melons at temperatures ≥4°C (FSANZ 2021). Experimental studies have shown that *L. monocytogenes* can grow on the rind of netted rockmelon but also on the smoother waxy surface of canary melons at temperatures ≥4°C, with increasing storage temperature resulting in increased growth rate of *Listeria* (Scolforo et al 2017; Marik et al 2020). With a pH of 5.2-6.7 and a water activity of 0.97-0.99 melon pulp can support the survival and growth of foodborne pathogens such as *Listeria* if this is contaminated during processing or from external rind damage allowing entry (Fang and Huang, 2013; Danyluk et al, 2014; Scolforo et al 2017). Therefore *L. monocytogenes* can grow on melon flesh even when stored under refrigeration (Fang and Huang, 2013; Heredia et al. 2016; Salazar et al. 2017; Ukuku et al. 2012). Due to the physical similarities between different types of melons, it is likely that *L. monocytogenes* may be able to survive and grow on the rind and within the pulp of most other melons. Freezing cut melon will not inactivate *L. monocytogenes.* Although frozen foods do not allow the growth of *L. monocytogenes* while kept at freezing temperatures, *L. monocytogenes* can survive freezing for extended periods (EFSA Panel on Biological Hazards, 2020). Cut RTE melons are generally consumed without further processing treatment that would eliminate or inactivate pathogens if present (Codex 2017). Public information for vulnerable populations to avoid consumption of RTE foods that supports the growth of *L. monocytogenes* (e.g. cut rockmelon) is available on various government websites including FSANZ's website.
Surveillance information: *L. monocytogenes* is a notifiable disease in all Australian states and territories. In 2021 the reported incidence rate was 0.2 cases per 100,000 population (44 cases), this includes both foodborne and non-foodborne cases[2]. The foodborne rate is estimated to be 98% (90% Crl 90-100%) for *L. monocytogenes* cases in Australia (Kirk et al. 2014). The previous five year mean reported incidence rate was 0.3 cases per 100,000 population per year (ranging from 0.2–0.4 cases per 100,000 population per year)[2]. It is not anticipated that the global coronavirus disease pandemic had a significant impact on the number of

[2] Data on the number of listeriosis cases provided by the National Interoperable Notifiable Disease Surveillance System with population data from the Australian Bureau of Statistics (accessed 25 March 2022)

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listeriosis cases reported in 2021, as listeriosis is not generally a travel-associated illness and people would still seek medical care due to the severity of the illness. **Illness associated with consumption of cut RTE melon contaminated with *Listeria monocytogenes*** A search of the scientific literature from January 2000 to January 2022 via EBSCO; the US CDC National Outbreak Reporting System; and other publications identified two listeriosis outbreaks associated with consumption of cut RTE rockmelon. These are listed below: • Australia (2018): 22 cases of listeriosis (including 7 deaths and 1 miscarriage) were linked to consumption of rockmelon across four Australian states. *L. monocytogenes* was detected on whole and half (i.e. cut) rockmelons at several retail outlets, including where the listeriosis cases had shopped. Contaminated rockmelons were traced back to a single farm in New South Wales. Heavy rain followed by dust storms prior to rockmelon harvest and involvement of a dirty fan were identified as risk factors that contributed to the outbreak (NSW DPI 2018). • Australia (2010): Nine cases of listeriosis were linked to consumption of rockmelon and/or melons contained within fruit salad across three Australian states. There were two different outbreak-related subtypes of *L. monocytogenes*, both were isolated from fruit salad samples from delicatessens prepared at the premises from whole fresh fruit. Trace back investigation indicated a common source for some of implicated melons in south central New South Wales (OzFoodNet 2010, Popovic et al 2014). **Data on the prevalence of *Listeria monocytogenes* in cut RTE melon** A search of the scientific literature from January 2000 to January 2022 via EBSCO and other publications identified four surveys for *L. monocytogenes* in cut RTE melons: • Canada (2012-2016): *L. monocytogenes* was isolated from 0.72% (n=699) of fresh-cut rockmelon samples collected from retail stores in major Canadian cities (Zhang et al. 2020). • Canada (2009–2013): *L. monocytogenes* was isolated in 1.4% (n=140) of fresh-cut rockmelon samples collected from retail stores in major Canadian cities (CFIA Personal communication; Denis et al. 2016). • Portugal (2011-2014): *L. monocytogenes* was not detected in fresh-cut rockmelon (n=7), galia (n=16), green melon (n=9) and watermelon (n=13) samples collected at retail (Graca et al. 2017). Note that this was a very small study. • USA (2017): *L. monocytogenes* was detected in 0.5% by PCR and isolated in 0.37 samples of cut low acid melons (Honeydew, cantaloupe and watermelon) at retail (Luchansky et al 2017). The prevalence of *L. monocytogenes* ranged from 0–1.4% in cut melon samples which included cantaloupe, muskmelon, honey dew and watermelons. An overall estimated prevalence of 0.6% (95% CI 0.0–1.1%) was determined using a random effects meta-analysis. However, given the risk factors associated with netted/rough rind melon grown on the ground or soil there is the potential for contamination of the fruit during cutting. Further, due to the surface features of this group of melons, anti-microbial washes may not be as effective as for smooth rind melons. The bulk of the evidence is for rockmelon and watermelon as these are the most frequently consumed as a RTE product.

Standards or guidelines

In Australia:
 	
• Schedule 27 of the Australia New Zealand Food Standards Code (the Code) contains limits for *L. monocytogenes* in foods based on whether or not growth can occur[3]:
  ○ For ready to eat (RTE) food in which growth of *L. monocytogenes* will not occur n = 5, m = 10^2 cfu/g
  ○ For RTE food in which growth of *L. monocytogenes* can occur n = 5, m = not detected in 25g
 	
These limits 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 *CXG 61-2007* (Codex, 2009).
 	
To manage food safety risks with melons, FSANZ has developed a new standard for the primary production and processing of melons, including watermelon, rockmelon, honeydew and piel de sapo.[4] Standard 4.2.9 – Primary Production and Processing Standard for Melons was included in the Australia New Zealand Food Standards Code (the Code) on 12 August 2022, with a

[3] For these limits: n = number of sample units, m = the acceptable microbiological limit
[4] Proposal P1052 – PPP Requirements for Horticulture (Berries, Leafy Vegetables and Melons) www.foodstandards.gov.au/code/proposals/Pages/P1052.aspx

Standards or guidelines
30 month commencement period. It therefore takes effect from 12 February 2025. It covers primary production and primary processing activities, having requirements for managing inputs (such as water, fertilizer, soil amendments), animals and pests, temperature of harvested melons, actions following weather events, washing and sanitizing of melons and health and hygiene of personnel and visitors, as well as compliance with the required food safety management statement set out by Standard 4.1.1. There are industry developed schemes to manage food safety in horticulture. These are audited by a third party against specific requirements. The main food safety schemes currently in use are the Harmonised Australian Retailers Produce Scheme (HARPS)[5] and four schemes internationally benchmarked to the Global Food Safety Initiative (GFSI)[6] (FSANZ 2020). Further, Chapter 3 Standards (Food Safety Standards) of the Code apply to food businesses that further process handle or sell horticultural produce (this could include processing of melons, i.e. cutting and/or freezing melons). Some requirements in these Standards (depending upon the local jurisdiction) can apply to activities such as transport and pack house activities (providing they are not considered to be "primary food production"). Some elements of traceability are also required to be met through the food receipt and recall provisions of Standard 3.2.2, and labelling requirements under Standard 1.2.2. There are also non-regulatory guidelines for melon safety in Australia. Melon Food Safety: A Best Practice Guide for Rockmelons and Speciality Melons (Singh 2019) is such a guide. Specific *L. monocytogenes* control measures recommended by this guide include: • develop an environmental monitoring program that aims to remove *Listeria* before it establishes and becomes a source of contamination • look for places where water is pooling or dripping and where condensate is collecting • implement and maintain a thorough cleaning and sanitising schedule that targets sites where *Listeria* could establish • ensure all floors, equipment and food contact surfaces are in good condition with no niches or porous surfaces • assess damaged, worn out, hard to clean and difficult to get to equipment, tools, sites and points of attachment • make sure all equipment or machinery is thoroughly cleaned and sanitised before bringing it into the processing area. These control measures would also be applicable for use with all melons during cutting and further processing. The Codex general principles of food hygiene *CXC 1 – 1969* provides a framework of general principles for producing safe and suitable food for consumption by outlining necessary hygiene and food safety controls to be implemented through the food chain from primary production through to final consumption (Codex 2020). The Codex code of hygienic practice for fresh fruit and vegetables *CXC 53-2003* addresses GAP and GHP that help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to consumption. Annex IV (Melons) of *CXC 53-2003* provides specific guidance on how to minimise microbiological hazards during primary production through packing and transport of fresh melons, including fresh melons processed for the pre-cut market and consumer use. Annex I (Ready-to-eat, fresh, pre-cut fruits and vegetables) of *CXC 53-2003* recommends the application of GHP for all stages involved in the production of ready-to-eat, fresh, pre-cut fruits and vegetables, from the receipt of raw materials to the distribution and consumption of finished products (Codex 2017).

Management approaches used by overseas countries
• Canada: Imported fresh fruit or vegetables must meet Canadian requirements as set out in the *Safe Food for Canadian Regulations* as well as the *Food and Drug Regulations*. Under Section 8 of the *Safe Food for Canadian Regulations* food that is imported, exported or inter-provincially traded must not be contaminated; must be edible; must not consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; and must have been manufactured, prepared, stored, packaged and labelled under sanitary conditions (CFIA 2020). • United States: The Produce Safety Rule of the *Food Safety Modernization Act* established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This includes requirements for water quality; biological soil amendments; sprouts; domesticated and wild animals; worker training and health and hygiene; and equipment, tools and buildings (FDA 2019b). The USDA has aligned the harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the requirements of the FDA Food Safety Modernization Act's Produce Safety Rule. While the requirements of both programs are not identical, the relevant technical components in the FDA Produce Safety Rule are covered in the USDA H-GAP Audit Program. However, the USDA audits are not regarded as a substitute for FDA or state regulatory inspections (FDA 2019a). In the US industry guidelines have been available for a number of years aimed to minimise *Listeria* contamination on

[5] HARPS: https://harpsonline.com.au/
[6] GFSI: https://mygfsi.com/

Management approaches used by overseas countries
rockmelons, for example the National Commodity-Specific Food Safety Guidelines for Cantaloupes and Netted Melons[7] developed in 2013, and references therein. • Some overseas countries have microbiological criteria for *L. monocytogenes* in ready-to-eat food (e.g. pre-cut melons) that is similar to the Codex *CXG 61-2007* guidelines, such as the European Union (European Commission 2019), Canada (Health Canada 2011) and the United States (FDA 2015; FSIS 1989).

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