Imported food risk advice

Listeria monocytogenes in human milk and human milk products

Context of this risk advice

- Human milk means expressed milk collected from lactating women to be fed to infants that are not the biological infants of the women supplying the milk.
- Human milk products means products derived from human milk that have been specially formulated to meet the specific nutritional needs of infants such as fortifiers and formula.
- The level of risk for this hazard in human milk and human milk products was determined assuming that the most vulnerable category of infants (preterm infants in hospital neonatal intensive care units) would be receiving the products.

Nature of the hazard

Listeria monocytogenes is a Gram-positive, non-spore forming rod-shaped bacterium that can grow in both aerobic and anaerobic conditions. *L. monocytogenes* is sensitive to heat and is able to grow at refrigeration temperatures between 4 and 8°C in foods that support its growth (FSANZ 2013; ICMSF 1996). *L. monocytogenes* is a severe hazard for susceptible populations, including new-borns, as it can cause life threatening illness and chronic sequelae (Bell and Kyriakides 2005).

L. monocytogenes has the ability to form biofilms on food-processing equipment surfaces (Colagiorgi et al. 2017), and therefore could become a continuous source of contamination in the human milk processing environment.

Transmission

The most common transmission route of *L. monocytogenes* is via the consumption of contaminated food. However, *L. monocytogenes* can be transmitted directly from contact with animals, through hospital acquired infections and via mother-to-infant transmission (FSANZ 2013). Mother-to-infant transmission can occur *in utero* (early onset) from maternal bacteremia (Drevets and Bronze 2008), and less commonly after birth (late onset), which is assumed to occur during passage through the birth canal (Painter and Slutsker 2007; Poulsen et al. 2013).

Human milk is not typically associated with transmission of *L. monocytogenes* (Bortolussi 2008), although a case of neonatal listeriosis in a 24 day old infant has been linked with contaminated human milk (Svabic-Vlahovic et al. 1988). In Australia, some jurisdictions consider that the risk of transmitting *L. monocytogenes* to a new-born infant through human milk is extremely low (DoH WA 2018; NSW FA 2014). The role of human milk in the transmission of *L. monocytogenes* is therefore unclear.

Disease severity

Listeria monocytogenes is a severe hazard in new-borns as it causes potentially life threatening illness with chronic sequelae. When listeriosis is acquired by new-born infants due to postnatal infection from the mother or other infected infants, it can cause meningitis (67-93%) and less commonly septicaemia (17-95%), with a case fatality rate of around 20-30% (Bell and Kyriakides 2005; Okike et al. 2013). A high rate of infants with postnatal listeriosis develop severe and chronic neurological complications like delayed mental development and blindness (Mateus et al. 2013). The incubation period of postnatal listeriosis ranges from seven to ninety days (Bortolussi 1999).

Infectivity

The infective dose of *L. monocytogenes* in human milk is not known as the role of human milk in transmission is unclear. When *L. monocytogenes* is transmitted through the consumption of contaminated food, the infectious dose depends on factors like the virulence of the infecting strain, the type and amount of food consumed, the levels of the organism in the food consumed and the immune status of the host.

Infectious dose models for *L. monocytogenes* predict that for susceptible populations, the consumption of a very large dose (>10^5) of cells is required to cause illness (Farber et al. 1996). However, epidemiological data from large documented foodborne outbreaks and sporadic cases of listeriosis where *L. monocytogenes* has been recovered from the food implicated in illness, reported the levels detected are usually >10^3 cells/g (European Commission 1999).

Risk mitigation

Controls are needed to minimise contamination of human milk with *L. monocytogenes*. The safe production of human milk and milk products is dependent on maintaining a high level of hygiene control during collection, handling, processing, storage and transport to minimise the contamination of milk with *L. monocytogenes*. This is achieved by obtaining and treating donor human milk according to best practice guidelines followed by international donor milk banks, including those in Australia. Milk must be collected hygienically from the donors, with donors instructed about the importance of hand washing, cleaning and sterilising pumps, and the use of appropriate containers. Donor milk should be refrigerated (4^{o}C) immediately after collection and then stored frozen at -20^{o}C (Hartmann et al. 2007; HMBANA 2015; UKAMB 2003).

Thermal inactivation studies involving several strains of *L. monocytogenes* indicate that whole milk artificially inoculated with approximately 10^6 cells/ml do not survive heat treatment at 62.8°C for 30 min (Bunning et al. 1988; Donnelly and Briggs 1986). Holder pasteurisation (62.5°C for 30 min) is currently one of the preferred commercial practices to inactivate contaminating non-spore forming pathogens, including *L. monocytogenes*, in raw milk for human consumption (Kornacki and Gurtler 2007). International human milk banks, including those in Australia, routinely perform Holder pasteurisation on milk to ensure the microbiological safety of donor human milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003).

Human milk products should be produced from milk that has been subjected to Holder pasteurisation or an equivalent thermal treatment during processing to eliminate microbiological contamination. However, if human milk is heavily contaminated with microorganisms, Holder pasteurisation used by international human milk banks may be ineffective. Therefore, pre- and post-pasteurisation microbiological criteria are used for human milk as described in international best practice guidelines to ensure the effectiveness of Holder pasteurisation and the microbiological safety of donor human milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003). Process hygiene criteria are also useful to verify that the hygiene measures in place in the manufacturing facility are working as intended (FSANZ 2018).

Milk banks and manufacturers of human milk products should utilise Good Manufacturing Practices, Good Hygienic Practices and an internationally recognised hazard management tool, such as the hazard analysis and critical control points (HACCP) process to identify, evaluate and control hazards (Codex 2008; Hartmann et al. 2007; HMBANA 2015; PATH 2013). Specifically, facilities and equipment used to process human milk and human milk products should be designed, constructed and laid out to prevent the entry of pathogens into high hygiene areas and to minimize their establishment or growth in harbourage sites, including the prevention of biofilm formation, and designed to facilitate appropriate cleaning (Codex 2008; Marchand et al. 2012).

There may be a risk of post-processing contamination of human milk. However, there would be limited opportunity for *L. monocytogenes* to grow given that pasteurised human milk is immediately frozen at -20^{o}C and distributed frozen at the same temperature. Once thawed, human milk should be kept refrigerated (4^{o}C) until use, and should be used within 24 hours (insufficient time at 4^{o}C for *L. monocytogenes* to grow to levels of concern). The human milk should be discarded after completion of the initial feed. If fortifiers are added to the human milk, the fortified human milk should be kept refrigerated and used within 24 hours. Thawed pasteurised human milk and fortified human milk should not be refrozen (Hartmann et al. 2007; HMBANA 2015; Jones 2011; Ryser 2007; UKAMB 2003).

Evaluation of uncertainty

There is uncertainly around the transmissibility of *L. monocytogenes* through human milk and the infectious dose required for this potential mode of transmission. If assumed to be similar to the minimum levels of *L. monocytogenes* recovered from food implicated in foodborne illness outbreaks and sporadic cases of listeriosis, then infectivity would be considered low.

Pooling of human milk from multiple donors is common practice amongst many human milk banks and would dilute the bacterial load from a single donor, however some milk banks only pool milk from individual donors (Haiden and Ziegler 2016). The Australian Red Cross milk bank pasteurises human milk in single donor batches (Australian Red Cross 2018). However, potential environmental contamination of the human milk during collection, processing and/or post-processing may increase the bacterial load of the milk.

Risk characterisation

There is limited evidence that the transmission of *L. monocytogenes* can occur from mother-to-infant through human milk and large doses would potentially be required to cause illness. There is a very low likelihood of exposure as there is limited evidence that *L. monocytogenes* has caused foodborne illness associated with human milk, and there is limited opportunity for this bacteria to grow as the product is kept frozen and only thawed immediately prior to use. Therefore, while *L. monocytogenes* causes severe disease in new-borns and can be fatal, *L. monocytogenes* in imported human milk and human milk products does not present a potential medium or high risk to public health and safety.

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