Imported food risk advice

Salmonella spp. (non-typhoidal) 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

Salmonella spp. are facultative anaerobic Gram-negative, non-spore forming rod-shaped bacteria belonging to the family *Enterobacteriaceae*. The primary reservoir of *Salmonella* spp. is the intestinal tract of warm and cold-blooded vertebrates. *Salmonella* spp. have also been widely isolated from the environment. *Salmonella* spp. are resistant to freezing, low water activity and acidic conditions. The heat resistance of *Salmonella* spp. is dependent on the composition, pH and water activity of the food. The thermal resistance of *Salmonella* spp. increases as the water activity of the food decreases (FSANZ 2013; Li et al. 2013). In neonates *Salmonella* spp. are a severe hazard and can cause life threatening illness.

Salmonella spp. can form biofilms on surfaces, such as stainless steel. Biofilms protect the bacteria from stressful environmental conditions and provide the bacteria protection against sanitizers (Carrasco et al. 2012; Hurrell et al. 2009; Kim et al. 2006; Speranza et al. 2011).

Transmission

Salmonella spp. are generally spread through the faecal-oral route via consumption of contaminated food or water, person-to-person contact, or contact with infected animals (FDA 2012; FSANZ 2013). *Salmonella* spp. can be transmitted from mother-to-infant via human milk. *Salmonella* spp. isolated from aseptically expressed breast milk from mothers with symptomatic or asymptomatic *Salmonella* infections have been associated with neonatal disease (Chen et al. 2005; Cooke et al. 2009; Mukerji et al. 2009; Qutaishat et al. 2003). *Salmonella* spp. can also be transmitted to infants from infected carers via poor hygienic practices such as inadequate hand washing (Vilca et al. 2015).

A small study by Keim et al. (2013) detected *Salmonella* spp. in 3% of internet-purchased human milk samples (n=101) but did not detect *Salmonella* spp. in unpasteurised human milk samples from a milk bank (n=20).

Disease severity

Salmonella spp. generally cause asymptomatic or gastroenteritis symptoms and can also cause mastitis (FSANZ 2013; Seah et al. 2015). However, in neonates *Salmonella* spp. are a severe hazard as they can cause potentially life threatening illness that requires medical intervention and hospitalisation. Neonates can develop severe symptoms such as septicaemia and meningitis (with subsequent postmeningitic hydrocephalus[1]), which can be fatal (Chen et al. 2005; Cooke et al. 2009; FSANZ 2013; Mukerji et al. 2009; Qutaishat et al. 2003).

[1] Abnormal increase in the amount of cerebrospinal fluid in the ventricles of the brain, often leading to skull enlargement and impaired brain function

Infectivity

The infectious dose of *Salmonella* spp. in human milk is unknown. However, in other food sources *Salmonella* spp. can be very infectious, with as few as 1 to 100 cells reported to cause illness. However, in most cases, significantly more cells are required for illness to occur. The particular food matrix, strain of *Salmonella* spp. and susceptibility of the host influence the level of *Salmonella* spp. required for illness (FDA 2012; ICMSF 1996).

Risk mitigation

Controls are needed to minimise contamination of human milk with *Salmonella* spp., including pasteurisation of the milk. Holder pasteurisation (62.5^{o}C, 30 min) kills most bacterial contaminants found in human milk (Baumer 2004; Picaud and Buffin 2017) and should inactivate *Salmonella* spp. International human milk banks, including those in Australia, routinely perform Holder pasteurisation on human milk to ensure the microbiological safety of donor human milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003).

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 *Salmonella* spp. 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).

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 milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003). Process hygiene criteria are 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 minimise their establishment or growth in harbourage sites, including the prevention of biofilm formation. Equipment should be designed, and appropriate procedures implemented, to facilitate effective cleaning and sanitising (Codex 2008; Marchand et al. 2012).

Pasteurised human milk is stored and transported frozen. Once thawed, human milk should be kept refrigerated (4^{o}C) until use and should be used within 24 hours. 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; Jones 2011; UKAMB 2003).

Evaluation of uncertainty

There is no evidence that infectivity through consumption of human milk is different to other food sources. 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 evidence that *Salmonella* spp. can be present in human milk and can be transmitted to infants via human milk. *Salmonella* spp. can be very infectious, with small quantities able to cause infection. There is a high likelihood of exposure as *Salmonella* spp. have caused illness in infants due to consumption of contaminated human milk. Also,

inadequate hygiene practices during collection, handling and storage, and/or inadequate processing or post-processing practices could facilitate the contamination of human milk with this bacterium.

In neonates *Salmonella* spp. can cause severe illness which can be fatal. *Salmonella* spp. in imported human milk and human milk products presents a potential medium or high risk to public health and safety.

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