# Imported food risk advice

## *Staphylococcus aureus* 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**

*Staphylococcus aureus* is a Gram-positive, non-spore forming spherical bacterium that belongs to the *Staphylococcus* genus. *S. aureus* is commonly found in the environment (soil, water and air), and in the nose and on the skin of humans. *S. aureus* is a severe hazard in at risk populations including neonates as it causes potentially life threatening illnesses (Chen et al. 2016; Kempley et al. 2015). Some strains of *S. aureus* produce staphylococcal enterotoxins (SE) and are responsible for almost all staphylococcal food poisoning (FDA 2012; Montville and Matthews 2005). SEs are resistant to heat inactivation and remain stable under frozen storage.

**Transmission**

The primary modes of *S. aureus* transmission in infants are from skin contact between mother and infant and from the ingestion of contaminated human milk. *S. aureus* is the most common cause of mastitis in women and one of the most commonly isolated pathogens found in human milk. Barbe et al. (2008) reported on a study of expressed breast milk intended for the mother's own baby in a neonatal intensive care unit (samples were collected from mothers regardless of health status). Of the 2351 samples tested before pasteurisation, 12.3% were positive for *S. aureus*. No *S. aureus* was recovered from the (hygienically extracted) breast milk, 5 days after birth (colostrum), between 6 and 15 days (transition milk) and after 15 days (mature milk) from healthy mothers without mastitis (Boix-Amorós et al. 2016). This suggests that apart from mastitis, poor hygiene measures, unsafe handling and/or suboptimal collection and storage are risk factors for *S. aureus* contamination in human milk. Studies using molecular techniques have found that the same strains are isolated from the mother, breast milk and the infant (Benito et al. 2015; Chen et al. 2016).

**Disease severity**

*Staphylococcus aureus* is a serious hazard for pre-term infants and neonates as it causes potentially life-threatening illness. A number of diseases are associated with *S. aureus* including diarrhoea, skin infections, pneumonia, bacteraemia, sepsis and endocarditis[1] (Chen et al. 2016; Kempley et al. 2015). Adverse outcomes of *S. aureus* bacteraemia from all sources were found in 44% of cases with a fatality rate of 8% (Kempley et al. 2015). Low birth weight is a risk factor for adverse outcomes.

SE poisoning is characterized by rapid onset gastroenteritis that appears around three hours after ingestion of preformed SE (normal range of 1 – 6 hours). Common symptoms of SE poisoning include nausea, vomiting, abdominal cramps and diarrhoea. Recovery in neonates is usually between 1 – 3 days after the commencement of antibiotic therapy (Chen et al. 2016). The severity of symptoms may vary depending on the amount of SE consumed and the general health status of individuals.

[1] Infection of the inner lining of the heart

**Infectivity**

No dose response information could be identified for *S. aureus* infections in neonates.

The dose response of SE toxin in human milk consumed by neonates is not known. However, information is available on the dose response of SE from food outbreak data.

More than 20 SEs have been identified: SE toxin type A (SEA) to SEIV (Hennekinne et al. 2012). A dose response model for SEA has been developed using food outbreak data for the general population (Guillier et al. 2016). The predicted lower 95%-confidence interval at which 10% of people would become ill following the ingestion of toxin was around 6 ng of SEA. This estimated dose was not adjusted for body weight. SEs are produced during the exponential phase of *S. aureus* growth, with the quantity of toxin produced being strain dependent (Seo and Bohach 2007; Montville and Matthews 2008). SE toxin is typically detected when the *S. aureus* concentration is $>10^5$ cfu/ml.

**Risk mitigation**

Controls are required to minimise contamination of human milk with *S. aureus*. Experimental studies using Holder pasteurisation (62.5$^{o}$C, 30 min) have been shown to kill *S. aureus* in human milk (Jones et al. 1979; Wills et al. 1982). 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).

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 or if heat stable bacterial toxins such as SE are present, 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 minimize 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 uncertainty around the infectivity of *S. aureus* in human milk and the bacterial load required for this transmission route. The SE toxin dose response model was based on epidemiological evidence from food outbreaks for the general population and not specifically for neonates consuming human milk. Epidemiological evidence from outbreaks has found that SE toxin is only detected in food when large numbers of *S. aureus* cells are found. The dose response model developed for SEA using epidemiological data from outbreaks did not adjust for body weight. Infants would have a greater body weight adjusted exposure and probability of illness compared to adults for the same dose of toxin. The SEA dose response model would likely underestimate the probability of illness for neonates compared to the general population.

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**

*S. aureus* is one of the most common pathogens found in human breast milk. Milk can be contaminated through skin exposure and by mastitic tissue. Large doses of *S. aureus* cells would potentially be required to cause infections, while a very low dose of SE toxin would result in illness. There is a high likelihood of exposure of *S. aureus* through human milk in the case of mastitis or inadequate hygiene practices during collection, handling and storage. *S. aureus* is a serious hazard which can result in infections which can be fatal. Holder pasteurisation does not inactivate pre-formed SE.

*S. aureus* in imported human milk and human milk products presents a potential medium or high risk to public health and safety.

**This risk advice was compiled in:** November 2018, updated October 2019

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