Imported food risk advice

Mycobacterium tuberculosis 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

Mycobacterium tuberculosis is an aerobic Gram-positive, non-spore forming, non-motile rod-shaped bacteria belonging to the family *Mycobacteriaceae*. Mycobacteria are easily killed by heat but not by freezing or desiccation. Humans are the only reservoir for *M. tuberculosis*, although many animals are susceptible to infection (Fitzgerald et al. 2010; Pfyffer 2007). *M. tuberculosis* causes tuberculosis (TB), a potentially life threatening illness that can cause substantial sequelae.

Transmission

M. tuberculosis is generally transmitted between humans by aerosolised droplets; in rare cases congenital transmission can occur (Aquilina and Winkelman 2008; Mathad and Gupta 2012). Mothers with latent or active TB disease do not typically shed tubercle bacilli in their milk. Transmission of *M. tuberculosis* via human milk only occurs when the mother has TB mastitis and lesions on the breast (Lawrence and Lawrence 2001, 2004). TB mastitis is a rare condition, with an incidence of <0.1% of all breast lesions examined in Western countries (Hale et al. 1985; Kalac et al. 2002). There is a higher rate (3%) of TB mastitis in TB endemic countries (Khanna et al. 2002; Tewari and Shukla 2005).

Disease severity

M. tuberculosis is a severe hazard as it causes the potentially life threatening illness TB, with 250,000 child fatalities worldwide in 2016, and can have substantial sequelae (Anderson et al. 2010; WHO 2018). Immunocompetent infants less than one year of age have a 50% probability of no disease developing (latent infection), 3-40% risk of pulmonary disease and a 10-20% risk of developing miliary (disseminated) disease which may lead to TB meningitis (Mandalakas and Starke 2005; Marais et al. 2006). Most children develop pulmonary TB with the common symptoms in infants being persistent cough and shortness of breath, fever, weight loss, rales[1], wheezing and diminished breath sounds (Lamb and Starke 2017; Rigouts 2009). TB is a treatable and curable disease, however multi-drug resistant strains of *M. tuberculosis* have emerged (WHO 2018).

Infectivity

The infective dose of *M. tuberculosis* in human milk is not known. When inhaled via aerosol droplet, *M. tuberculosis* is highly infectious with <10 infectious particles causing infection in 50% of people and <5 infectious particles able to infect a child (Marais et al. 2006; Pfyffer 2007).

[1] Abnormal lung sounds, e.g. clicking, rattling or crackling

Risk mitigation

Controls are needed to minimise contamination of human milk with *M. tuberculosis,* including pasteurisation of the milk. An early study by Harrington and Karlson (1965) demonstrated that pasteurisation of artificially inoculated skim milk at 62.8^{o}C for 30 min destroyed *M. tuberculosis* present in the milk. Holder pasteurisation (62.5^{o}C, 30 min) eliminates *M. tuberculosis* contamination of milk (Tully et al. 2001). 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). Also, the guidelines for human milk banks in the UK and in North America recommend temporarily excluding mothers with mastitis from donating milk (HMBANA 2015; UKAMB 2003).

Evaluation of uncertainty

There is uncertainly around the transmissibility of *M. tuberculosis* through human milk. Transmission through human milk can occur when the mother has TB mastitis (Lawrence and Lawrence 2001, 2004), but the number of infectious particles required to cause infection is unknown. If assumed to be the same as aerosol droplet transmission, then infectivity in human milk would be considered to be high.

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).

Risk characterisation

In mothers with TB mastitis, *M. tuberculosis* can be transmitted to infants through human milk, with potentially only very small quantities required to cause illness. However there is very low likelihood of exposure due to the incidence of TB mastitis and breast lesions being rare. TB is a severe disease and can be fatal. *M. tuberculosis* in imported human milk and human milk products presents a potential medium or high risk to public health and safety.

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