

## Imported food risk advice

### *Treponema pallidum* 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

*Treponema pallidum* is an anaerobic motile bacteria belonging to the family *Spirochataceae* and is the causative agent of syphilis. *T. pallidum* is a human commensal organism and is not known to have any animal or environmental reservoirs (Madigan et al. 2009; Pope et al. 2007; Tramont 2010). The organism is extremely sensitive to environmental stress, and is easily killed by heat, drying, soap and water (Kollman and Dobson 2011; Madigan et al. 2009). *T. pallidum* causes syphilis, a potentially life threatening illness with chronic sequelae.

#### Transmission

*T. pallidum* infection can be transmitted sexually, by direct contact with an infective lesion or secretions from the lesions, and via mother-to-infant transmission (predominantly *in utero* or during delivery) (CDC 2018; Lawrence and Lawrence 2004). Postnatal transmission of *T. pallidum* can occur from mothers with infectious lesions on their breast or nipple. However, there is no evidence for transmission of *T. pallidum* in human milk in the absence of these lesions (Civardi et al. 2013; Lanari et al. 2012; Lawrence and Lawrence 2004). It is unclear if mothers with breast or nipple lesions shed *T. pallidum* in their milk or if direct contact of the infant with the lesions is required for transmission. Extragenital lesions can appear on the breasts, lips, tongue, palate, face, conjunctiva, neck, abdomen, arms, hands and thighs, and occur in 2-31% of cases (Dourmishev and Dourmishev 2005; Mindel et al. 1989).

*T. pallidum* seroprevalence in potential human milk donors ranges from 0.5-0.9% (Cohen et al. 2010; Kupek and Savi 2017).

#### Disease severity

*T. pallidum* is a severe hazard as it causes potentially life threatening illness with chronic sequelae. Untreated individuals who acquire syphilis during childhood progress through four stages of disease – primary, secondary, latent and tertiary. Syphilis has an average incubation period of three weeks (range 10-90 days). In the primary stage individuals develop one or more primary lesions (known as chancres) at the site of infection, although some children are asymptomatic. Even without treatment the primary lesion(s) typically resolve spontaneously. After a six week to six month interval patients progress into the secondary stage. This is characterised by lesions of the skin and mucous membranes, with some patients developing neurosyphilis<sup>1</sup>. Secondary lesions resolve, even without treatment, and the infection then enters the latent stage. After many years, approximately 40% of untreated individuals progress to the tertiary stage. Tertiary syphilis can involve any organ system and can manifest as neurosyphilis<sup>1</sup>, cardiovascular disease and gummata<sup>2</sup>. Untreated syphilis can be fatal (Heston and Arnold 2018; Kollman and Dobson 2011; Peeling and Hook 2006; Woods 2005).

<sup>1</sup> *T. pallidum* infection of the brain and spinal cord

<sup>2</sup> Lesions of the internal organs, bone and skin

## Infectivity

The infective dose of *T. pallidum* in human milk is not known. When administered intracutaneously *T. pallidum* is very infectious. In human trials performed in the 1950's, inoculation of volunteers with as few as 10 cells (via intracutaneous inoculation) produced lesions in some individuals. The number of organisms required to cause infection in 50% of people was determined to be 57 cells (Magnuson et al. 1956).

## Risk mitigation

Controls are required to minimise contamination of human milk with *T. pallidum*. Pasteurisation of the milk is a primary control, however donor screening to exclude *T. pallidum* seropositive individuals can reduce the bacterial load in the donor milk to be pasteurised. Early studies showed that temperatures below 37°C are required for continued survival of *T. pallidum* (Baseman and Hayes 1974; Fieldsteel et al. 1982); and a very early study by Boak et al (1932) on the effect of fever temperatures showed that 41.5°C for 1 hour inactivated *T. pallidum* in extracts from rabbit lesions. Holder pasteurisation (62.5°C, 30 min) kills most bacterial contaminants found in human milk (Baumer 2004; Picaud and Buffin 2017). As such, Holder pasteurisation (62.5°C, 30 min) should inactivate *T. pallidum*. International human milk banks, including those in Australia, routinely perform Holder pasteurisation on human milk and serologically screen donors for syphilis to ensure the microbiological safety of donor human milk (Bharadva et al. 2014; Hartmann et al. 2007; HMBANA 2015; UKAMB 2003).

## Evaluation of uncertainty

There is uncertainty around the transmissibility of *T. pallidum* through human milk. Postnatal transmission of *T. pallidum* can occur from mothers with infectious lesions on their breast or nipple (Lanari et al. 2012; Lawrence and Lawrence 2004), but the number of infectious particles required to cause infection is unknown. If assumed to be similar to intracutaneous inoculation, only small quantities of bacteria would be required for illness. Also, it is unclear if mothers with breast or nipple lesions shed *T. pallidum* in their milk or if direct contact with the lesions is required for transmission to the feeding infant.

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

Postnatal transmission of *T. pallidum* can occur from mothers with infectious lesions on their breast or nipple, with potentially only small quantities of bacteria required to cause illness. However, there is a very low likelihood of exposure as there is a very low prevalence of syphilis amongst potential donors, and it is unclear if transmission requires direct contact with the lesions. Syphilis is a severe disease and can be fatal. *T. pallidum* 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:** August 2018, updated October 2019

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