FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk advice

Lead 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

Lead occurs in the environment both naturally and, to a greater extent, from human activities such as mining and smelting, battery manufacturing and the use of leaded petrol (WHO 2011). Human exposure to lead can occur via food, water, air, soil and dust (EFSA 2010).

Lead exposure is associated with a wide range of adverse effects on multiple body systems, with young children particularly susceptible to harmful effects on the brain and central nervous system.

Presence in human milk

Lead is mobilised from bone during lactation and some of this lead, as well as lead from other maternal exposure sources, is excreted through human milk (EFSA 2010).

Human milk from Asia, Australia, Europe, Latin America, North America and the Middle East has been reported to contain lead (Bansa et al. 2017; Bassil et al. 2018; Chao et al. 2014; EFSA 2010; Rebelo and Caldas 2016; Sakamoto et al. 2012).

Levels of lead have been found to be higher in milk from women living near sources of lead such as tin smelters or woman who are occupationally exposed. Lead levels in milk are also associated with the period of residence in a contaminated region (Counter et al. 2014; Marques et al. 2013).

Use of lead-glazed ceramic pottery, consumption of lead-contaminated drinking water, use of traditional remedies or imported cosmetics and renovation of older homes without lead hazard controls in place are other risk factors for lead exposure in pregnant and lactating women (Committee on Obstetric Practice 2012).

Adverse health effects

The World Health Organization (WHO) reports that few, if any, adverse effects have been associated solely with consumption of human milk containing background levels of environmental chemicals. This is in contrast to the established evidence that human milk and the practice of breast-feeding confer significant health benefits to infants (WHO Undated).

Exposure to high levels of lead can cause a wide range of adverse effects including vomiting, encephalopathy and death (American Academy of Pediatrics 2016). Low level lead exposure is a risk factor for impaired neurodevelopment (American Academy of Pediatrics 2016; WHO 2011). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has concluded that based on the available data it is not possible to identify a threshold below which adverse effects of lead do not occur. JECFA calculated that a lead exposure of 0.6 µg/kg bw/day is associated with a decrease of one intelligence quotient (IQ) point (WHO 2011). The European Food Safety Authority (EFSA) calculated a similar value, 0.5 µg/kg bw/day (EFSA 2010).

The available data suggest that lead in human milk has a relatively small impact on infant blood lead levels, and the primary source of exposure in very young children is ingestion of lead-contaminated house dust and residential soil (American Academy of Pediatrics 2016; CDC 2010). The US Centers for Disease Control and Prevention (CDC) reports that biologically significant increases of lead in human milk are not considered to occur in lactating women at the blood lead concentrations typical of women with long-term residence in developed countries, but does not include discussion of lead concentrations in women living in developing countries (CDC 2010).

EFSA also found that estimated dietary exposures to lead for infants consuming average or high amounts of human milk were below the exposure level calculated to be associated with a population decrease of one IQ point. It was concluded that the risk from effects of lead is likely to be low in breastfed infants (EFSA 2010).

Risk mitigation

Australian and overseas milk bank guidelines do not include recommendations to specifically screen donors for levels of lead (Hartmann et al. 2007; HMBANA 2015; NICE 2010). However, some guidelines recommend consideration of whether a donor has any significant exposures to environmental or chemical contaminants that can be expressed in human milk, through for example contamination of the local water supply (NICE 2010).

General screening to identify significant exposures to environmental or chemical contaminants would be expected to be sufficient to take into account any potential risks of there being a significant source of exposure to lead in imported human milk and human milk products.

The American Academy of Pediatrics notes that the pooling process with donor milk makes it very unlikely that non-infectious contaminants will represent a significant exposure risk (Committee on Nutrition, Section on Breastfeeding, Committee on Fetus and Newborn 2017). Pooling of human milk from multiple donors is common practice amongst many human milk banks, 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).

Evaluation of uncertainty

There is uncertainty as to the concentrations of lead that may be in human milk and human milk products. This would be expected to vary depending on whether individuals donating milk have any risk factors for high levels of lead exposure.

Many studies on the presence of lead in human milk are based on a small number of samples. The analytical methods used vary between studies, with differing limits of detection and quantification (Rebelo and Caldas 2016).

Risk characterisation

The available data suggest that lead in human milk has a relatively small impact on infant blood lead levels (American Academy of Pediatrics 2016; CDC 2010), while EFSA found that estimated dietary exposures to lead for infants consuming average or high amounts of human milk were below the exposure level calculated to be associated with a population decrease of one IQ point (EFSA 2010).

Overall, based on the available evidence FSANZ concludes that lead in imported human milk and human milk products is unlikely to present a potential medium or high risk to public health and safety.

This is consistent with WHO advice which notes that few if any adverse effects have been associated with consumption of human milk containing background levels of environmental chemicals, in contrast to the established evidence that human milk confers significant health benefits to infants.

This risk advice was compiled in: March 2019, updated October 2019

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