Imported food risk advice

Mercury 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

Mercury occurs naturally in the environment and is widely distributed via natural processes such as volcanic activity and erosion. It also enters the environment through human activities including mining, coal-based power production and waste incineration. Mercury occurs in three chemical forms: elemental mercury, inorganic mercury and organic mercury.

The main dietary source of methylmercury (the most common form of organic mercury in the environment) is from fish and shellfish, while foods other than fish and shellfish are the main dietary sources of inorganic mercury (WHO 2007, 2011). Exposure to elemental mercury from dental amalgam is also believed to strongly contribute to inorganic mercury exposure (EFSA 2012).

Mercury has the potential to adversely affect the central and peripheral nervous systems, the digestive and immune systems, and the lungs and kidneys. Inorganic mercury and methylmercury have different biological effects. The most sensitive target for toxicity of inorganic mercury is the kidney (WHO 2011). Developmental neurotoxicity of the embryo and fetus is the most sensitive effect of methylmercury in humans (WHO 2007).

Presence in human milk

Inorganic mercury and methylmercury may be excreted into human milk. Mercury has been found in human milk samples from a range of countries in Asia, Europe, Latin America, the Middle East and Africa (Bansa et al. 2017; EFSA 2012; Park et al. 2018; Rebelo and Caldas 2016; Sakamoto et al. 2012). Some, but not all studies have shown positive associations between fish consumption and mercury levels in human milk (García-Esquinas et al. 2011; Miklavčič et al. 2013; Rebelo and Caldas 2016; Song et al. 2016; Valent et al. 2013). Positive correlations between mercury concentrations in human milk and the number of amalgam dental fillings have also been reported (Björnberg et al. 2005).

The majority of available studies report the total mercury concentration in human milk, but some also measure the concentration of methylmercury. A recent literature review reported that the proportion of methylmercury in human milk ranged from 0 – 60%, with most studies reporting that around 50% of total mercury was methylmercury (Rebelo and Caldas 2016).

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).

Studies in experimental animals and human case reports indicate that the most sensitive target for inorganic mercury toxicity is the kidney. At higher exposure levels a variety of other adverse effects have been observed in animal studies, including decreases in body weight gain, changes in clinical and haematological parameters and effects on reproduction. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a provisional tolerable weekly intake (PTWI) for inorganic mercury of 4 µg/kg bw, based on kidney weight changes in male rats (WHO 2011).

The most sensitive health effect of methylmercury is on neurodevelopment, with development *in utero* the most sensitive period of exposure. JECFA has established a PTWI of 1.6 µg/kg bw for methylmercury, based on epidemiological studies of neurodevelopmental effects in children from the Faroe Islands and the Seychelles. This PTWI is considered to be sufficient to protect the developing embryo and fetus (WHO 2007).

The JECFA evaluation found that postnatal exposure to methylmercury in breastfed infants is considerably lower than exposure *in utero*. A study of infants in the Faroe Islands with a high prenatal exposure to methylmercury reported that breastfed infants reached developmental milestones earlier than formula-fed infants, and no independent association between breastfeeding and neurological deficits at age 7 years was observed. The study authors suggested that breastfeeding is beneficial even in a population with a relatively high prenatal exposure to methylmercury, consistent with other evidence of the benefits of breastfeeding for cognitive development (WHO 2007).

The European Food Safety Authority (EFSA) has established tolerable weekly intakes (TWIs) for inorganic mercury and methylmercury that are the same as or similar to those set by JECFA (4 µg/kg bw and 1.3 µg/kg bw, respectively). Estimated exposures of European infants to methylmercury and inorganic mercury from human milk were below the respective TWIs (EFSA 2012).

A recent review paper estimated mean intakes of methylmercury in breastfeeding infants in Iran, Europe, Japan, Africa, Saudi Arabia, Brazil and Taiwan, based on published concentration data and assuming that 50% of total mercury was present as methylmercury. Estimated mean intakes of methylmercury were at or below the JECFA PTWI of 1.6 µg/kg bw/week for the studies from Iran, Europe, Japan, Saudi Arabia and Africa, while several studies from Brazil and one from Taiwan indicated mean exposures above the PTWI (Rebelo and Caldas 2016). Assuming that 50% of total mercury in human milk is methylmercury, 95th percentile exposures of infants in the Republic of Korea were slightly under the PTWI (Park et al. 2018). A study of 183 samples donated to human milk banks in the Federal District of Brazil found that mean and median methylmercury intakes for premature or low birth weight babies were 8.3% and 2.2% of the PTWI respectively, and only one sample would have resulted in an intake exceeding the PTWI (123% of the PTWI) (Rebelo et al. 2017).

Overall the available evidence indicates that in the majority of groups studied, estimated dietary exposures of breastfeeding infants to mercury are below the PTWI established by JECFA.

Risk mitigation

Australian and overseas milk bank guidelines do not include recommendations to specifically screen donors for levels of mercury (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 mercury 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 mercury that may be present in human milk and human milk products. This would be expected to vary depending on the geographic location of the individuals donating milk, and whether they may have any risk factors for high levels of exposure.

Many studies of the presence of mercury 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. Most studies only report the total mercury concentration, which results in uncertainty as to the levels of exposure to methylmercury (Rebelo and Caldas 2016).

Risk characterisation

The majority of studies of inorganic mercury and/or methylmercury in human milk indicate that infants' exposures from human milk are likely to be below the health-based guidance values for these substances established by JECFA. A review by EFSA also found that estimated exposures of European infants to methylmercury and inorganic mercury from human milk were below the respective European TWIs.

On the basis of the available evidence FSANZ concludes that mercury 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.

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