Imported food risk advice

Cadmium 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

Cadmium is a metallic element which is naturally present at low levels in the environment. Human activities such as tobacco smoking and various industrial processes including mining, manufacture of metals and fossil fuel combustion are also considered to be significant contributors to environmental cadmium levels.

Food is the main source of cadmium exposure among the non-smoking general population, while smoking and/or occupational exposure (if present) may contribute more than food for some individuals (EFSA 2009).

Cadmium exposure is associated with adverse effects on the kidney, skeletal and respiratory systems and it is also classified as a human carcinogen (WHO 2011).

Presence in human milk

The presence of cadmium in human milk has been reported in studies from Asia, Europe, South America, the Middle East and Africa (Bansa et al. 2017; Bassil et al. 2018; Chao et al. 2014; EFSA 2009; Rebelo and Caldas 2016). Many studies are based on a small number of samples and the analytical methods used vary, with differing limits of detection and quantification.

Cadmium concentrations in human milk are generally considered to be fairly low, with some studies reporting higher exposures in infants consuming infant formula composed of ingredients (e.g. wheat or soy) with a higher cadmium content than human milk (EFSA 2009; Eklund and Oskarsson 1999).

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 laboratory animals and humans indicate that the kidney is the critical target organ for chronic cadmium toxicity, resulting in histopathological changes and renal tubule dysfunction.

The Joint Food and Agriculture Organization (FAO)/WHO Expert Committee on Food Additives (JECFA) established a health based guidance value (HBGV) for cadmium in 2010. JECFA noted that because cadmium has a long half-life (~15 years in human kidneys), daily intake in food only has a small or even negligible effect on overall exposure. As a result the long- or short-term risks to health from cadmium exposure should be assessed by considering intake over a period of at least one month. The HBGV was therefore expressed as a provisional tolerable monthly intake (PTMI) of 25 µg/kg bw.

Estimated average monthly intakes of cadmium from human milk in studies from Greece, Slovakia, Poland, Saudi Arabia, Turkey, Lebanon and Ghana have recently been reported (Bansa et al. 2017; Bassil et al. 2018; Rebelo and Caldas 2016). The estimated exposures of infants in all these countries were below JECFA's PTMI of 25 µg/kg bw.

Risk mitigation

Australian and overseas milk bank guidelines do not include recommendations to specifically screen donors for levels of cadmium (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 would be expected to be sufficient to take into account any potential risks of there being a significant source of exposure to cadmium 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; NICE 2010). 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 cadmium 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 cadmium 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.

Risk characterisation

Cadmium concentrations in human milk are generally considered to be fairly low, with some studies reporting higher exposures in infants consuming infant formula composed of ingredients with a higher cadmium content than human milk. A recent review indicates that estimated exposures to cadmium from human milk in almost all identified published studies were below the PTMI established by JECFA, and therefore not of public health concern.

On the basis of the available evidence FSANZ concludes that cadmium 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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