Dioxins and dioxin-like polychlorinated biphenyls 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

Polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDFs), referred to as dioxins, are by-products of combustion as well as various industrial processes. Polychlorinated biphenyls (PCBs) were previously manufactured for a range of industrial purposes until their manufacture was banned by most countries in the 1970s (WHO 2002).

These substances are persistent, widely dispersed in the environment and accumulate in the food chain (EFSA 2015). Therefore, some level of human exposure is unavoidable. Coplanar PCBs have a common mode of action with PCDDs and PCDFs, and their biological and toxic effects are similar (WHO 2002). These coplanar PCBs are referred to as 'dioxin-like PCBs'.

In laboratory animals, dioxins and dioxin-like PCBs have been shown to cause a range of adverse effects, including developmental toxicity, immune toxicity and several types of cancer (WHO 2002).

Presence in human milk

The main source of exposure to dioxins and dioxin-like PCBs is through the diet. Following ingestion these substances accumulate in fatty tissues due to their hydrophobic nature (Ulaszewska et al. 2011). They also concentrate in human milk.

The World Health Organization (WHO) coordinates a global monitoring programme which aims to identify the impact of measures taken to reduce or prevent environmental exposure to dioxins and PCBs. Human milk is used for biomonitoring because it is easily available, collection is non-invasive and its high lipid content facilitates extraction. PCDDs, PCDFs and PCB levels in human milk are also a good reflection of the body burden (van den Berg et al. 2017). Results from the monitoring programme indicate that levels of dioxin-like compounds, measured as WHO toxic equivalents (TEQs[1]), in human milk from Australia and New Zealand (1-10 pg/g lipid) are generally lower than those reported in several European and Asian countries (11-20 or 20-30 pg/g lipid) (van den Berg et al. 2017).

A downward trend in dioxin and PCB levels in human milk over time has been reported for many countries including Germany, Norway, the Netherlands, Japan, the USA, Canada and New Zealand in which time trend data are available (Ae et al. 2018; Mannetje et al. 2013; Rawn et al. 2017; van den Berg et al. 2017).

[1] The potency of dioxin-like compounds varies. The Toxic Equivalent (TEQ) value represents the total concentration of dioxins and dioxin-like PCBs, with weighting factors (known as Toxic Equivalency Factors (TEFs) applied to account for the relative potency of each substance. The WHO has established TEFs that are used by a number of international authorities.

Adverse health effects

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a provisional tolerable monthly intake (PTMI) of 70 pg/kg body weight for dioxins and dioxin-like PCBs (WHO 2002). The critical endpoint used to establish the PTMI was adverse effects on the reproductive tract of prenatally-exposed male rats. The PTMI represents the amount of dioxins and dioxin-like PCBs that can be consumed safely over a lifetime and is intended to protect against the human maternal body burden reaching a concentration where adverse effects may occur in the developing foetus.

Estimated dioxin exposures of breastfed infants in all countries studied are higher than the PTMI established by JECFA (van den Berg et al. 2017). However, exceedance of the PTMI through consumption of human milk is for a relatively short period and international bodies have consistently concluded that the substantial health benefits of breastfeeding outweigh the toxicological risks (COT 2004; Fromme et al. 2011; OCS 2004; van den Berg et al. 2017; WHO 2002).

Some associations between perinatal exposure to dioxins and dioxin-like PCBs and health effects have been reported in epidemiological studies. However these effects were generally subtle and of uncertain clinical significance (Mocarelli et al. 2008; Mocarelli et al. 2011; Tai et al. 2013; Tusscher and Koppe 2004; Weisglas-Kuperus et al. 2000; Weisglas-Kuperus et al. 2004). Overall, the WHO recommends that low birth weight infants, including those with very low birth weight, who cannot be fed their mother's own milk should be fed donor human milk, in settings where safe and affordable milk-banking facilities are available or can be established (WHO 2012).

Risk mitigation

Australian and overseas milk bank guidelines do not include recommendations to specifically screen donors for levels of dioxins and dioxin-like PCBs (Hartmann et al. 2007; HMBANA 2015; NICE 2010). However, some guidelines recommend consideration of whether a donor has any significant exposures to chemicals, through for example contamination of the local water supply (NICE 2010). Such general screening would be expected to be sufficient to take into account any potential risks of there being a significant source of exposure to dioxins and dioxin-like PCBs 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 regarding the amount of dioxins and dioxin-like PCBs present in the donor milk. However, it is reasonable to assume that levels are likely to be similar to those measured in human milk surveys conducted in the countries where the donors reside.

Although studies, including some in Australia and New Zealand, have regularly shown that infants' exposures via human milk are greater than the PTMI (van den Berg et al. 2017), human epidemiology studies have found that any potential associated health effects are subtle and of unknown clinical significance.

Risk characterisation

Estimated exposures of breastfed infants to dioxins and dioxin-like PCBs in all countries studied, including Australia and New Zealand, exceed the PTMI established by JECFA (van den Berg et al. 2017). This exceedance occurs for a relatively short period such that any potential risks from temporarily exceeding the PTMI for dioxins during breastfeeding are outweighed by the substantial health benefits of breastfeeding (COT 2004; Fromme et al. 2011; OCS 2004; van den Berg et al. 2017; WHO 2002). Overall, the WHO recommends that low birth weight infants, including those with very low birth weight, who cannot be fed their mother's own milk should be fed donor human milk, in settings where safe and affordable milk-banking facilities are available or can be established (WHO 2012).

FSANZ considers that dioxins and dioxin-like PCBs in imported human milk and human milk products are unlikely to present a potential medium or high risk to public health and safety.

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