

## Process contaminants from oil refining in infant milks

There has been recent concern that formula fed infants may be exposed to harmful levels of Glycidyl fatty acid esters (GE) and 2- and 3-monochloropropanediol (2-MCPD and 3-MCPD) and their fatty acid esters. These substances are formed when palm oils and fats and other vegetable oils are heated to temperatures in excess of 200°C during the refinement process. These potentially harmful substances have subsequently been identified in a range of oils and fats and foods that are made from them, including infant and follow-on formula milks. A recent study conducted by the Dutch National Institute for Public Health and the Environment found that samples of powdered infant formula contained significant amounts of 3-MCPD, although the levels varied widely between different products (RIVM, 2016). The European Food Safety Authority (EFSA) panel on Contaminants in the Food Chain (CONTAM) recently delivered a scientific opinion on the risks to human health posed by the presence of these contaminants in food. Based on evidence from animal studies the CONTAM panel concluded that GE is potentially genotoxic and carcinogenic and that 3-MCPD can cause kidney damage. There was insufficient data available to come to any conclusions on the toxicity of 2-MCPD (EFSA, 2016).

3-MCPD was first identified in the late 1970's and since then, its presence has been monitored in specific foods where high levels have been reported. In 2001 the Scientific Committee on Food set a safe tolerable daily intake (TDI) for 3-MCPD of 2.0 µg/kg/bw per day (SCF, 2001). Based on the available evidence the CONTAM panel lowered the TDI to 0.8 µg/kg/bw per day (EFSA, 2016). From the dietary surveys included in their study, EFSA found that younger age groups were at greatest risk of exposure to 3-MCPD. In over half of the dietary surveys reviewed, the average exposure for infants, toddlers and other children up to ten years of age was at or above TDI. For infants who were exclusively formula fed, average exposure was more than three-times TDI at 2.4 µg/kg/bw per day and for those with greatest exposure more than four times TDI at 3.2µg/kg/bw per day. The CONTAM panel concluded that this level of exposure was cause for concern. It is worth noting that the TDI is set with a generous safety margin far in excess of the levels identified as causing harmful effects in animal studies.

Due to the potentially genotoxic and carcinogenic nature of GE, TDI are not set and the risk to consumers is expressed as a Margin of Exposure (MoE). The higher the MoE, the lower the level of concern and vice versa. An MoE of lower than 25,000 was considered by EFSA, to be a health concern. EFSA estimated a MoE for infants aged 0-3 years with average exposure to GE ranged from 11,300 to 25,500. Infants who were exclusively fed on infant formula were at significantly greater risk. The MoE for average exposure was around 5,400 and for high exposure 2,100. EFSA have said that in infants' MoE estimates were particularly low due to the contribution of glycidyl esters from infant formula and also point out that there were uncertainties involved in the setting of the level of MoE at 25,000.

The CONTAM Panel recommended that all potentially contaminated foods be included in future monitoring of 3-MCPD, 2-MCPD and GE. EFSA's scientific opinion was used to inform EU food safety regulators' considerations on how to manage the risk of exposure to these substances in foods. In 2020, the EU issued regulations setting maximum levels for the presence of GE and 3-MCPD and its fatty acid esters in vegetable, marine and fish oils and fats placed on the market for the final consumer or for use as an ingredient in food. Because

of the health concern for infants, toddlers and young children, stricter maximum levels were set for oils and fats destined for the production of baby food and processed cereal-based food for infants and young children. Taking into account the possible exposure to GE of infants solely fed on infant formula, a specific strict maximum level for infant formula, follow-on formula and foods for special medical purposes intended for infants and young children has been established. Regulation (EU) 2020/1322 stipulates a maximum level for GE of <50ug/kg in infant and follow-on formula milk powder and foods for special medical purposes intended for infants and young children, and a lower maximum level of <6ug/kg for liquid formulations (EFSA, 2020). A maximum level for 3-MCPD and fatty acid esters of 125ug/kg in infant and follow-on formula milk powder and foods for special medical purposes intended for infants and young children and a lower maximum level of 15ug/kg for liquid formulations has been established. The regulations can be found here:

<https://www.legislation.gov.uk/eur/2020/1322/introduction>

Given these concerns, the removal of palm oil from infant milks and baby foods would be a prudent response from industry. Some brands of infant milk in the UK do not use palm oil in their products, but the main brands (Aptamil, Cow & Gate, Hipp Organic and SMA) do still use palm oil in some or all of their products. You can find out which oils are used in infant milks on the UK market from the individual product datacards at [www.infantmilkinfo.org](http://www.infantmilkinfo.org).

## References

European Food Safety Authority (2016). Scientific opinion on risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food. *EFSA Journal*, 14 (5), 4426. Available at <https://www.efsa.europa.eu/en/efsajournal/pub/4426>

Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Health and Environment) (2016). Preliminary assessment of dietary exposure to 3-MCPD in the Netherlands. Available at [http://www.rivm.nl/en/Documents\\_and\\_publications/Scientific/Reports/2016/april/Preliminary\\_assessment\\_of\\_dietary\\_exposure\\_to\\_3\\_MCPD\\_in\\_the\\_Netherlands](http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/april/Preliminary_assessment_of_dietary_exposure_to_3_MCPD_in_the_Netherlands)