COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Exposure estimates from a possible source of exposure for fumonisins via consumption of infant formula (Matters arising)

1. A discussion paper was presented to the COT in the February 2019 meeting[1], which reviewed the potential risks from fumonisins in the diet of infants aged 0 to 12 months and children aged 1 to 5 years. Following that, the Committee wished to further review the relevant exposure data for infant formulae.

2. Zimmer *et al*., (2008) reported a median level of 2.5 µg/kg and a maximum level of 403 µg/kg fumonisins in a food group that includes infant formulae. The authors provided further information that the infant food was follow-on formulae for children aged from 6 months – all fumonisin positive results contained maize grit. High level of positive fumonisins resulted from mainly one producer. Frequency of positive samples and levels of fumonisins strongly declined since the producer was more vigilant in selection of the raw maize material (Table 1). The exposures were calculated using the most recent 2001 data.

3. Exposure estimates for 6-12 month olds were calculated for exclusive feeding on infant formulae using the default consumption values of 800 and 1200 mL for average and high-level consumption, respectively. Consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) were used to estimate exposures for 6 to 18-month olds (DH, 2013). The infant formulae analysed were dry powder, therefore consumption data has been based on the dry powder content of made-up formula.

4. Exposures have been estimated for a range between the median (2.5 µg/kg – taken from the food group that includes infant formulae) (Zimmer *et al*., 2008) and the maximum levels of fumonisins reported in 2001 (179 µg/kg) (Usleber, personal communication 2019). Given that the occurrence data was derived from follow-on formulae for infants aged from 6 months, the exposure estimates for 0 to 6 month-olds are unlikely to occur.

Table. 1 Levels of fumonisins in follow-on formulae for children aged from 6 months in years 1999-2001 (µg/kg).

Years	Maximum	90th percentile	Median
1999	955	422	114
2000	913	337	95
2001	179	152	10

[1] https://cot.food.gov.uk/sites/default/files/tox2019-02_0.pdf

Table. 2 Estimated exposures to fumonisins from infant formulae for 6 to 12-month olds from using consumption data from DNSIYC.

Food	Fumonisins Exposure (µg/kg bw/day)			
	6 to <9 Months (n=606)		9 to <12 Months (n=686)	
	Mean	97.5th	Mean	97.5th
Infant formula [a, b] (median level)	0-0.023	0-0.042	0-0.018	0-0.035
Infant formula [b] (maximum level)	0-1.7	0-3.0	0-1.3	0-2.5

[a] Exposure based on dry infant formula using fumonisins concentrations of 0 (lower-bound) and 2.5 (upper-bound) µg/kg
[b] Exposure based on dry infant formula using fumonisins concentrations of 0 (lower-bound) and 179 (upper-bound) µg/kg

Table 3. Estimated exposures to fumonisins from infant formulae in children aged 12 to 18 months using consumption data from DNSIYC.

Food	Fumonisins Exposure (µg/kg bw/day)			
	12 to <15 Months (n=670)		15 to <18 Months (n=605)	
	Mean	97.5th	Mean	97.5th
Infant formula [a, b] (median level)	0-0.013	0-0.029	0-0.012	0-0.023
Infant formula [b] (maximum level)	0-0.96	0-2.1	0-0.83	0-1.6

[a] Exposure based on dry infant formula using fumonisins concentrations of 0 (lower-bound) and 2.5 (upper-bound) µg/kg
[b] Exposure based on dry infant formula using fumonisins concentrations of 0 (lower-bound) and 179 (upper-bound) µg/kg

5. 6-9 months old infants at the 97.5th percentile whom are exclusively fed infant formula at the maximum level of 179 µg fumonisins/kg exceed both the EFSA TDI (1 µg/kg bw/day) and JECFA PMTDI (2 µg/kg bw/day) at 3.0 µg/kg bw/day.

6. In the previous paper presented[2]; fumonisin exposures, for all age groups, the mean values were all below 0.089 µg/kg bw/day and the 97.5th percentile exposures were all below 0.188 µg/kg bw/day, whilst the total fumonisin (combined FB1, FB2 and FB3 exposures) mean values were under 0.247 µg/kg bw/day and under 0.517 µg/kg bw/day for the 97.5th percentile. Therefore, exposures from the diet were below both the EFSA TDI and JECFA PMTDI.

7. Based on the available data, fumonisins in certain food groups, for example, infant formulae may result in exceedances in the PMTDI or TDI set by JECFA and EFSA respectively. However, exposure to infant formulae is considered short when compared to a lifetime period. Therefore, it can be concluded that occasional exceedances are unlikely to result in adverse toxicological effects.

8. Questions to be asked of the Committee:

i). Do the Committee have any further comments on infant formula exposure to fumonisins?

[2] https://cot.food.gov.uk/sites/default/files/tox2019-02_0.pdf

ii). Do the Committee have any other comments on this paper?

Secretariat
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References

Lennox A, Sommerville J, Ong K, Henderson H, Allen R. (2013) Diet and Nutrition Survey of Infants and Young Children. URL: https://www.gov.uk/government/publications/diet-and-nutrition-survey-of-infants-and-young-children-2011

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Zimmer, I., Usleber, E., Klaffke, H., Weber, R., Majerus, P., Otteneder, H., Gareis, M., Dietrich, R., Märtlbauer, E. (2008) Fumonisin intake of the German consumer. Mycotoxin Research 24, pp. 40-52.