Conclusions - Statement on the risk assessment of cow’s milk in children aged 1 to 5 years, in the context of plant-based drinks evaluations

In this guide

161. The COT reviewed an extensive range of chemical compounds that could be present incidentally or as contaminants in cow’s milk to allow comparison with plant-based dairy alternatives.

162. As can be seen in the summary tables, the vast majority of these potential contaminants present no risk of adverse health effects in children aged 6 months to 5 years of age at the levels observed within cow’s milk.

163. The exceptions are iodine, BaP and PAH4, AFM1 specifically and total aflatoxins due to the contribution of AFM1, for which any risk to health in children aged 6 months to 5 years of age is unlikely but cannot be completely excluded. The possible risks to health in these age groups from exposure to isoflavones in cow's milk is unknown, as no HBGVs have been established for these compounds in young children and hence there is a lack of knowledge on the toxicological significance of the levels that might be found in milk.

Table 17. Summary of risk assessment conclusions for selected compounds and their occurrence levels within cow's milk based on previous authority opinions.

Compound (s)	**HBGV, (endpoint)**	**Effect (s)**	**Authority**	**COT Conclusion: Health risk from cow's milk**
Nitrite	n/a	Methemoglobinemia	EFSA	No health concern

Bisphenol A	4 µg/kg bw (Increase in mouse kidney weight.	Kidney weight; endocrine perturbation with potential effects on metabolism, growth, sexual development, stress response, insulin production, gender behaviour, reproduction, and fetal development.	EFSA	Currently, no health concern (However, the COT is currently in the process of producing an interim position paper capturing the COT's views and next steps following EFSA's 2023 updated position on BPA.).
DBP, BBP, DEHP, DINP (Summed as DEHP equivalents)	0.05 mg/kg bw (reproductive effects in rats).	Reproductive effects, hepatic effects.	EFSA / COT	No health concern.
DEP	5 mg/kg bw (maternal adrenal and kidney weight changes, fetal weight in mice).	Increased maternal adrenal and kidney weights, decreased fetal weight.	WHO / COT	No health concern.

NDL-PCBs	n/a. Minimal effect dose of 2 mg/kg bw per day, expressed as body burden (liver and thyroid in rat).	Liver and thyroid effects.	JECFA	No health concern.
Isoflavones GEN, EQU, FOR, DAI	0.07 mg/kg bw (GEN only) (accelerated pubertal development in female mice).	Endocrine effects (oestrogenic effects) effecting thyroid and immune function and sexual development.	Nordic Council	Any risk to health is uncertain as HBGVs have not been established for young children.
Lead	None, BMDL01 of 0.5 µg/kg bw per day ((development of intellectual function).	Multiple toxic effects.	EFSA/COT	Unlikely to be a health concern.
Inorganic Arsenic	None. BMDL0.5 of 3 µg/kg bw per day JECFA / COT (lung cancer).	Multiple toxic effects including carcinogenicity.	EFSA/COT	No health concern.
Inorganic Mercury	TWI – 4 µg/kg (kidney weight change in rats).	Multiple toxic effects including renal, haematological, hepatic and gastrointestinal effects.	EFSA / COT	No health concern.

Cadmium	TWI – 2.5 µg/kg (urinary β-2-microglobulin (B2M) as a marker for kidney damage).	Multiple toxic effects including renal toxicity, hepatotoxicity, osteoporosis and osteomalacia.	EFSA / COT	No health concern.
AFM1	None. Guidance value of 4 µg/kg bw per day derived from a BMDL10 based on liver tumour incidence for AFB1 in rats with a 0.1 potency factor applied.	Multiple effects such as immunotoxicity, carcinogenicity and mutagenicity.	EFSA / COT	Health risk cannot be excluded, but exposure estimate uncertain.
AFB1	None. BMDL10 of 0.4 µg/kg bw per day based on liver tumour incidence in rats after AFB1 exposure.	Multiple effects such as immunotoxicity, carcinogenicity and mutagenicity.	EFSA / COT	Health concern unlikely, rarely detected.
Total aflatoxins	None. BMDL10 of 0.4 µg/kg bw per day based on liver tumour incidence in rats after AFB1 exposure.	Multiple effects such as immunotoxicity, carcinogenicity and mutagenicity.	EFSA / COT	Health risk cannot be excluded, but exposure estimate uncertain, driven by AFM1 occurrence in milk.

PFAS (PFHxS, PFOS, PFOA and PFNA)	TWI of 4.4 ng/kg bw (reduced antibody levels against diptheria vaccine in 1-year old children).	increased relative liver weight, effects on the immune system.	EFSA	No health concern.
HBCDDs	None. Human equivalent body burden of 2.35 µg/kg corresponding to LOAEL in mice (neurodevelopmental effects).	Neurodevelopmental, immune system effects, reproductive system effects, liver effects and effects on thyroid hormone homeostasis.	EFSA	No health concern.
PBBs	None. NOEL of 0.15 mg/kg bw per day (hepatic carcinogenicity).	Multiple effects (dioxin like) such as altered vitamin A homeostasis, chloracne and body weight changes, carcinogenicity.	EFSA	No health concern.
PBDEs	None. Range of BMDL10 s between 12 and 1,700 µg/kg bw per day (neurodevelopmental effects).	Neurodevelopmental, immune system effects, reproductive system effects, liver effects and thyroid hormone homeostasis.	EFSA	No health concern.
TBBPA	None. BMDL10 of 16 mg/kg bw per day (thyroid hormone homeostasis).	Thyroid hormone regulation.	EFSA	No health concern.

Table 18. Summary of risk assessment conclusions on potential chemical contaminants of cow’s milk, a comparing the highest estimated mean exposures

(occurrence and consumption) to their health-based guidance values, from exposure assessments presented in this paper and its annex.

Compound (s)	HBGV, (endpoint)	Authority	Highest Exposure (mean consumption), kg bw per day	% HBGV or MOE	Highest exposure age range (months)	Effect
Nitrate	3.7 mg/kg bw per day (growth retardation in dogs and rats).	EFSA	0.00416 mg	0.112	12 – <18	Methemo
Dioxins plus DL-PCBs	2 pg/kg WHO-TEQ, (reproductive effects in rats).	EFSA	1.024 pg	51.2	12 – <18	Range of effects in chloracn reproduc effects.
Benzo[a]pyrene (BaP)	None, BMDL10 of 70 µg/kg bw per day (total tumour-bearing animals)	EFSA	0.00128 µg	54,688 (MOE)	12 – <18	Carcinog
Sum of BaP, BbF,ChR and BaA (PAH4)	None, BMDL10 of 340 µg/kg bw per day (total tumour-bearing animals).	EFSA	0.0032 µg	106,250 (MOE)	12 – <18	Carcinog

Iodine	EVM: Guidance level of 15 µg/kg bw per day EFSA: TUL of 200-250 µg/day. JECFA: PMTDI 17 µg/kg bw per day (Alterations in serum thyroid hormone levels from human studies).	COT / EVM / EFSA / JECFA	15.2 µg	102 (EVM guidance value).	12 – <18	Varied ef depende previous to iodine
Perchlorate	0.3 µg/kg (inhibition of radiolabelled iodine uptake by the thyroid).	EFSA	0.179 µg	59.6	12 – <18	Inhibition uptake, c thyroid h
Chlorate	TDI of 3 µg/kg bw per day. (Read across from perchlorate with a 0.1 potency factor, inhibition of radiolabelled iodine uptake by the thyroid).	EFSA	0.544 µg	18.1%	12 – <18	Inhibition uptake, c thyroid h

Naturally occurring oestrogens within cow’s milk.	ADI – 0.05 µg/kg bw per day for 17β-oestradiol (NOEL based on multiple hormone dependent parameters in postmenopausal women. To protect sensitive population subgroups an uncertainty factor of 10 was applied.).	JECFA	0.0875 µg	17.5%	12 – <18	Suggeste in childre developr effects ir urogenit hormona central n systems mamma The COT any genc 17β-oest indirect i

Table 19. A summary of information for compounds within cow’s milk where a formal risk assessment could not be performed.

Compound (s)	**Literature evaluation**	**Effect**	**Conclusion: Health risk from cow’s milk**
Veterinary Medicines	Between 2015 and the end of 2020, only 24 of 21,574 samples of cow's milk analysed returned a positive result (above the maximum residue level). Only 2 of these were considered to pose a potential health risk but this was without taking any dilution effect e.g. from bulk tanks, into account.	Various effects	No health concern.

Pesticides	Between 2015 and the end of 2020 only 1 of 1,723 samples of cow’s milk returned a positive result (above the maximum residue level). The risk from residues of pesticides from drinking cow’s milk is negligible.	Various effects	No health concern.
IGF-1	IGF-1 supplementation is unlikely to generate a risk to consumer health. In addition milk from IGF-1 treated cow’s is unlikely to enter the UK as fresh milk in significant quantities.	No substantiated carcinogenic effects	No health concern.
Other mycotoxins	Milk is considered unlikely to contain significant amounts of other mycotoxins. Specific information was not available for the transfer of 3-Ac-DON, 15-Ac-DON and DON-3-glucoside to cow’s milk, but transfer of these seems unlikely, given their hydrophilicity.	Effects including immunotoxicity, carcinogenicity and mutagenicity.	Health concern considered unlikely, though specific information on some metabolites is lacking.
Microplastics	A lack of toxicokinetic and toxicity data in general, the paucity of currently available data for microplastics in different food types and difficulties in performing an accurate exposure assessment, however levels of microplastics in milk are lower than in other areas of the diet.	Various, depending on type.	No known health concern.