Risk characterisation

In this guide

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53. CIT is nephrotoxic but has also been reported to affect liver function. Exposure to CIT has also been associated with reproductive toxicity and teratogenic and embryotoxic effects albeit usually at doses that were maternally toxic. It is therefore uncertain whether these adverse effects were secondary to maternal toxicity.

54. Based on the data available, including data published since the most recent EFSA opinion in 2012, the COT did not think it appropriate to establish a HBGV but agreed with EFSA's approach of using a level of no concern for nephrotoxicity in humans of 0.2 µg/kg bw per day. Whilst the BMDL of 48 µg/kg bw per day derived by the RIVM was specific to reproductive effects, EFSA's level of no concern is notably lower and would therefore be adequately protective for maternal, reproductive and developmental toxic effects. Any other adverse effects reported after CIT exposure occurred at higher doses.

55. In 2012, EFSA did not consider there to be sufficient data to conclude on the immunotoxic effects of CIT. While some additional data has been published

since EFSA’s opinion, the database is still very limited and did not allow the COT to draw any conclusions.

56. The available data did not indicate that CIT caused gene mutations, but CIT may have a threshold effect on microtubules and/or spindle assembly. The COT noted that the renal adenomas detected in rats in the Arai (1983) study were uncommon, but the (short) study duration did not allow for firm conclusions to be drawn. Due to the limitations in the database, the COT concluded that a risk of genotoxicity and carcinogenicity cannot be excluded although citrinin showed no evidence of DNA-reactive mutagenicity.

57. Mean and 97.5th percentile total estimated exposures for CIT were 0-17 and 0- 43 ng/kg bw respectively and are below the level of no concern for nephrotoxicity of 0.2 µg/kg bw per day set by EFSA. This is also below the BMDL of 48 µg/kg bw per day set by the RIVM based on reproductive effects. Hence, the estimated exposures were not of toxicological concern for nephrotoxicity as well as reproductive and developmental effects.