Risk characterisation

In this guide

53. Citrinin is nephrotoxic and has been reported to affect liver function. It has also been associated with reproductive toxicity and teratogenic and embryotoxic effects, usually at doses that caused maternal toxicity. These adverse effects may be 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 BMDL05 of 48 µg/kg bw per day derived by the RIVM was specific to reproductive effects, EFSA's level of no concern was lower and was considered adequately protective for maternal, reproductive and developmental toxic effects. All other adverse effects reported after citrinin exposure occurred at higher doses.

55. In 2012, EFSA did not consider there to be sufficient data to conclude on the immunotoxic effects of citrinin. 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 citrinin caused gene mutations; however, citrinin may have a threshold effect on microtubules and/or spindle assembly. The COT noted that the renal adenomas detected in rats in the Arai and Hibino (1983) study were uncommon, but the duration of the study did not allow 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 shows no evidence of DNA-reactive mutagenicity.

57. Mean and 97.5th percentile total estimated exposures for citrinin were 0-17 and 0-43 ng/kg bw respectively, below the level of no concern for nephrotoxicity of 0.2 µg/kg bw per day set by EFSA.

58. While EFSA did not establish a human HBGV, the estimated exposures were over 1000-fold lower than the POD derived by the RIVM from an animal study (48 µg/kg bw per day) based on reproductive effects. Hence, the estimated exposures here were not of toxicological concern for nephrotoxicity or reproductive and developmental effects.