# Risk characterisation

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45. CIT is nephrotoxic, causing swelling and eventual necrosis of the kidneys, and in some studies was also reported to affect liver function. Exposure to CIT has also been associated with reproductive toxicity and teratogenic and embryotoxic effects.

46. Based on the data available, including data published since the EFSA s opinion, the COT did not think it appropriate to set a HBGV but continued to use EFSA’s approach, applying a level of no concern for nephrotoxicity in humans of 0.2 µg/kg bw per day.

47. While a number of studies reported developmental and reproductive toxicity of CIT it is not clear whether these effects might be secondary to maternal toxicity. A study reported by EFSA in 2012 failed to determine the amount of CIT that would cross the placenta, and no metabolites of CIT were detected in the foetus. However, as the doses administered in the available reproductive and developmental studies were higher than the level of no concern for nephrotoxicity, the COT considered the level of no concern for nephrotoxicity to be adequately protective for maternal, reproductive and developmental toxic

effects.

48. In 2012, EFSA did not consider there to be enough 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 a conclusive assessment cannot be carried out.

49. The available data demonstrates that citrinin does not cause gene mutations but may have a thresholded effect on microtubules and/or spindle assembly. However, due to the limitations in the database a risk of genotoxicity and carcinogenicity cannot be excluded.

50. Mean and 97.5$^{th}$ 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 set by EFSA. Hence, the estimated exposures are not of toxicological concern for nephrotoxicity and reproductive and developmental effects, but carcinogenicity and genotoxicity cannot be excluded.

51. It should be noted that the TDS data used to calculate exposure are from 2014 and changes in the prevalence of citrinin may have occurred since then. Dietary patterns may also have changed, for example the increased consumption of plant-based drinks, and vegan/vegetarian diets, which may not be fully represented in the data.

52. The current assessment was based on consumption data from the NDNS for women of maternal/childbearing age and therefore may not be representative of maternal diet. In addition, the NHS recommends that those who are pregnant or planning to become pregnant should not drink alcohol. The inclusion of the UB values for wine, beer, alcopops and cocktails in the assessment may therefore lead to an over estimation of exposure when considering pregnant women.