Health based guidance value

In this guide

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16. EFSA concluded that the derivation of a health-based guidance value (HBGV) would not be appropriate, given the available data on genotoxicity and the limitations and uncertainties in the current database.

17. For compounds that are potentially genotoxic or carcinogenic EFSA recommends the use of the margin of exposure (MOE) approach. However, for CIT, EFSA did not consider an MOE approach appropriate due to the lack of human dietary exposure data. Instead, EFSA decided to characterise the risk of CIT and determine a level of no concern for nephrotoxicity in humans of 0.2 µg/kg bw per day. A level of no concern for nephrotoxicity is less secure than a HBGV and is a concentration at below which there is no appreciable concern for nephrotoxic effects. This level does not specifically address other end points.

18. The level of no concern was based on a no observed effect level (NOAEL) of 20 µg/kg bw per day determined from a study in rats by Lee et al. (2010). In this study, CIT was given in the form of fermented RMR containing different concentrations of CIT (1, 2, 10, 20 and 200 mg/kg) and at the highest dose tested (equivalent to 20 µg CIT/kg bw per day) no toxicologically significant

alterations were observed for any dose group. EFSA applied a default uncertainty factor (UF) of 100 for interspecies and interindividual variation.

19. EFSA concluded that a concern for genotoxicity and carcinogenicity could not be excluded at the level of no concern for nephrotoxicity.