Epidemiological studies

In this guide

In this guide

- 1. Introduction TOX/2025/16 Annex A
- 2. Toxicity TOX/2025/16 Annex A
- 3. <u>Health based guidance value TOX/2025/16 Annex A</u>
- 4. Publications since the EFSA 2012 opinion TOX/2025/16 Annex A
- 5. Epidemiological studies TOX/2025/16 Annex A
- 6. Exposure Assessment TOX/2025/16 Annex A
- 7. Risk characterisation TOX/2025/16 Annex A
- 8. Conclusion TOX/2025/16 Annex A
- 9. List of Abbreviations and Technical Terms -TOX/2025/16 Annex A
- 10. References TOX/2025/16 Annex A

37. CIT and DH-CIT have been reported in urine from different human cohorts from Belgium, Czech Republic, Portugal, Germany, Haiti, Bangladesh, Nigeria, Turkey, and Tunisia (Narváez et al., 2021). CIT has been detected in the breast milk and urine of mothers and the urine of exclusively breastfed infants (Ezekiel et al., 2022).

38. Three biomonitoring studies were carried out to measure the concentration of CIT and DH-CIT in pregnant women, infants and children in Bangladesh (Ali and Degen, 2020; Kyei et al., 2023, 2022). CIT was detected in 61% of the urine samples collected from pregnant women and dietary exposure to CIT, based on urinary levels, was estimated to exceed the level of no concern for nephrotoxicity set by EFSA (2012) in 16% of pregnant women. No evidence was found for an association between higher maternal daily intakes of CIT, and duration of pregnancy, birth weight, birth length, and head circumference at birth.

39. Overall, the new data published since the 2012 EFSA opinion supports previous findings or adds to the overall knowledge base of CIT. CIT is acutely nephrotoxic, and both in vitro and in vivo studies have provided clear evidence

for reproductive and developmental toxicity. CIT's potential genotoxicity remains uncertain.

40. The COT agrees with EFSA that a HBGV cannot be set and that it was appropriate to use a level of no concern for nephrotoxicity to characterise the risk of CIT to consumers. The doses administered in the available reproductive and developmental studies were higher than the level of no concern for nephrotoxicity, and so this level would be adequately protective for maternal, reproductive and developmental toxic effects.