Establishment of a Health-Based Guidance Value (HBGV)

In this guide

29. The Committee concluded that on the basis of the available evidence, 1,000 mg/kg bw/day was a robust Point of Departure (POD). This was based on the EOGRT study findings (Leuschner, 2020) as well as studies by Warheit et al., 2015b and Lee et al., 2019 that reported no effects up to the same dose. There was variability noted in the other studies, but nothing which would alter the proposed POD for food grade TiO2 (E171).

30. A standard uncertainty factor of 100 (10 for inter-species differences and 10 for inter-individual variability) was agreed by Members and applied to the POD which results in a HBGV of 10 mg/kg bw/day. There is likely to be additional conservatism in the application of this uncertainty factor to the NOAEL of E171 because 1,000 mg/kg bw per day was the highest dose of TiO2 tested and therefore the LOAEL (lowest observed adverse effect level) could actually be appreciably higher and, because there is no metabolism of TiO2 particles, the inter-/intra-species kinetic differences are likely to be lower than the defaults.