Establishment of a Health-Based Guidance Value (HBGV) - Statement on the safety of Titanium Dioxide (E171)

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280. The Committee concluded that, 1,000 mg/kg bw per day was a robust Point of Departure (POD). This was based on the EOGRT study findings as well as studies by Warheit, Donner and Brown, 2015 and Lee et al., 2019 that reported no effects up to the same dose. There was variability noted in the other studies, but nothing that would undermine the value of 1,000 mg/kg bw per day to be used as the POD. It was also noted by the COT that this is the highest dose of E171 or equivalent TiO2 tested in a study of this quality.

281. A standard uncertainty factor of 100 (10 for inter-species differences and 10 for interindividual variability) was agreed by Members and applied to the POD which results in a HBGV of 10 mg/kg bw per day. There is likely to be additional conservatism in the application of this uncertainty factor to the NOAEL of E171 because this was the highest dose of TiO2 tested and hence the LOAEL (lowest observed adverse 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.