

Previous COT evaluation

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58. Following publication of a new WHO drinking water guideline value in 1993, which was lower than the UK regulatory limit for drinking water at the time, the COT was asked to consider the toxicity data. In 1994, the COT provisionally agreed with the WHO (1993) NOAEL of 8.8 mg/kg bw/day for boron and acknowledged that the testis was a target organ for boron toxicity. However, the COT requested further information before finalising its conclusions. This included considering a review of borates by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) and a US National Toxicology Program (NTP) developmental toxicity study in rats (that would later be published by Price et al., 1996a) that was a follow up to an earlier Heindel et al., 1992 developmental toxicity study in rats.

59. In 1995, the COT considered this additional information. The COT noted reported reduction in relative testis weight (without histological changes) following a dose of 4.4 mg/kg bw/day of boron in a 90-day oral study of boric acid in dogs (Weir and fisher 1972). However, this was not seen in a 2-year study in dogs at higher doses where no convincing evidence of testicular toxicity was observed at boron doses of 8 to 9 mg/kg bw/day (Weir and Fisher 1972). The COT considered that the dog studies reported by Weir and Fisher 1972 were unreliable due to small animal numbers in the experimental groups and inadequacies in the histopathological descriptions. The COT agreed that the follow up developmental study in rats was of good quality and demonstrated a NOAEL of 9.6 mg born/kg bw/day for adverse effects of boron. Overall, the COT concluded that a NOAEL of around 10 mg/kg bw/day could be set based on the rat developmental studies.