

Overall conclusion by the COT

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This is a background paper for discussion. It has not been finalised and should not be cited.

63. Following the publication of the most recent EFSA evaluation (2023), the COT agreed that there was a requirement to assess the new evidence on BPA and adjust the current TDI. To ensure timely consumer protection, rather than undertaking a lengthy assessment, the COT instead assessed the weighing of evidence and approaches taken by both EFSA and the BfR. However, a non-systematic literature search was also undertaken to ensure no new data had been published since the BfR assessment in 2023.

64. The COT agreed with EFSA and the BfR that adverse effects of BPA, other than immunological effects and effects on reproduction, occurred at higher concentrations and were therefore not of direct relevance, i.e. a HBGV derived on either of these endpoints would also be protective for other toxicological effects. The COT was further in agreement that BPA did not demonstrate genotoxic or carcinogenic potential.

65. While the COT acknowledged that there was a clear effect of BPA on the immune system, the evidence, i.e. effects on an intermediate endpoint, was not sufficient to consider immunotoxicity as the key adverse effect. The available data were not sufficiently robust to demonstrate a clear progression from an intermediate endpoint to a continuous apical effect. The COT instead agreed with the BfR that adverse effects on male reproduction, i.e. sperm count and motility, were the critical endpoint and should be applied to derive a HBGV. This was in line with previous COT assessments.

66. The studies published since the BfR assessment were informative and added to the overall knowledge base, but did not contain sufficient evidence to alter the view of the COT regarding the critical endpoint or effect dose.

67. Although the COT considered the BfR's TDI highly conservative, in comparison to EFSA's, their approach avoided unnecessary conservatism. Hence, after evaluating the available information, the COT considered the endpoint selected and approach applied by the BfR scientifically robust and hence agreed to adopt the TDI of 0.2 µg/kg bw per day derived by the BfR.