

Uncertainty analysis for the genotoxicity assessment

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122. It was concluded that it is Unlikely to Very Unlikely (5 – 30% probability) that BPA presents a genotoxic hazard, the causes of which include a direct mechanism (combining subquestion 1 and 2 ([Annex A](#))). Accordingly, it was concluded that it is Likely to Very Likely (70 - 95% probability) that BPA either presents a genotoxic hazard only through indirect mechanism(s) or is not genotoxic. The likelihood terms used in these conclusions are taken from the approximate probability scale, which is recommended by EFSA (EFSA Scientific Committee, 2018) for harmonised use in EFSA assessments.

123. EFSA Scientific Committee (2017) has advised that, where the overall evaluation of genotoxicity for a substance leaves no concerns for genotoxicity, HBGVs may be established. However, if concerns for genotoxicity remain, establishing a HBGV is not considered appropriate and a Margin of Exposure (MoE) approach should be followed.

124. Considering the WoE for probabilities closer to either 70% or 95% that BPA does not present a genotoxic hazard by a direct mechanism, the CEP Panel concluded that probabilities close to 95% are more strongly supported by the evidence than probabilities close to 70% and, therefore, the balance of evidence allows a HBGV to be established.