Overall conclusions on genotoxicity

In this guide

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125. The analysis of the available literature data indicate that BPA does not induce gene mutations in bacteria. BPA induces DNA strand breaks, clastogenic and aneugenic effects in mammalian cells in vitro. Oxidative stress-related mechanism(s) are likely to be involved in this DNA damaging and clastogenic activity.

126. In contrast with consistent positive in vitro findings, the in vivo findings in several studies with high/limited reliability were inconsistent. The CEP Panel concluded that the evidence does not support an in vivo genotoxic hazard posed by BPA through direct interaction with DNA.

127. The CEP Panel concluded that it is unlikely to very unlikely that BPA presents a genotoxic hazard, the causes of which include a direct mechanism, and that the balance of evidence allows a HBGV to be established.

Questions for the Committee

128. Members are asked to consider the following questions.

1) Do Members have any comments on the approach taken by the EFSA panel to assess genotoxicity? Including the weight of evidence and uncertainty analyses?

2) Do Members have any comments on the overall conclusions reached by EFSA ?