Conclusion on hazard identification for genotoxicity effects of BPA

In this guide

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119. In 2015, the CEF Panel concluded that: The available data support that BPA is not mutagenic (in bacteria or mammalian cells), or clastogenic (MN and CAs). The potential of BPA to produce aneuploidy in vitro was not expressed in vivo. The positive finding in the post labelling assays in vitro and in vivo is unlikely to be of concern, given the lack of mutagenicity and clastogenicity of BPA in vitro and in vivo.

120. Based on the scientific literature considered in the previous EFSA opinions and published thereafter until 21 July 2021, the CEP Panel concluded 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 the DNA damaging and clastogenic activity elicited by BPA in vitro;

- there is some evidence for DNA and chromosomal damaging activities of BPA in vivo following repeated administrations, but not following single administrations;
- the available studies do not provide evidence of aneugenicity of BPA in germ cells in vivo.

121. 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.