

# Genotoxicity - Background

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## Previous 2015 EFSA conclusion

1. In the 2015 EFSA opinion on BPA (EFSA CEF Panel, 2015), the CEF Panel concluded that BPA is not mutagenic (in bacteria or mammalian cells), or clastogenic (micronuclei and chromosomal aberrations). The potential of BPA to produce aneuploidy in vitro was not expressed in vivo. The positive findings in the post labelling assays in vitro and in vivo were judged unlikely to be of concern, given the lack of mutagenicity and clastogenicity of BPA in vitro and in vivo.

## **Current new data examined, literature search timeline and screening methodology**

2. For the health outcome category (HOC) genotoxicity, the time span of the literature search was extended until 21 July 2021 and the studies assessed in the 2015 EFSA opinion were re-considered.

3. The methods that were used for data collection through literature searches were conducted in the following bibliographic databases: PubMed, Web of Science and Core Collection.

4. For the additional time span considered in the literature search, the screening question was: 'Is the paper reporting information about exposure to BPA and genotoxicity?'

5. For screening the additional genotoxicity studies, the categorisation was made into different subgroups of genotoxicity endpoints (genotoxicity, epigenetics, oxidative stress). An additional screening of the relevance of the studies was done by experts in this field following the full-text screening.

6. A specific internal validity approach was applied and a specific Weight of Evidence (WoE) approach was applied, as described in detail in [Annex A](#). The CEP Panel examined whether new data from the published literature could provide new evidence on the potential genotoxicity of BPA. The references from the previous CEF Panel opinion (EFSA CEF Panel, 2015) have also been included in the current assessment using the same appraisal criteria applied to the newly published data and considering the EFSA Scientific Committee guidance documents on genotoxicity published after 2015 (EFSA Scientific Committee, 2017, 2021).