Evaluation of relevance of results of genotoxicity studies -general considerations

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4. The relevance of the study (high, limited or low) is based both on its reliability and on the relevance of the test results.

5. The relevance of the test results was mainly, but not exclusively, based on:

- Genetic endpoint (high relevance for gene mutations, structural and numerical chromosomal alterations as well as results obtained in an in vivo

comet assay, which belongs to the assays recommended by the EFSA Scientific Committee (2011) for the follow-up of a positive in vitro result; lower relevance for other genotoxic effects). Other test systems although potentially considered of limited or low relevance may provide useful supporting information.

- Route of administration (e.g. oral vs. intravenous, intraperitoneal injection, subcutaneous injection, inhalation exposure) in case of in vivo studies.
- Status of validation (e.g. for which an OECD TG exists or is in the course of development, internationally recommended protocol, validation at national level only, no validation)
- Reliability and relevance of the test system/test design irrespectively of whether a study has been conducted in compliance with GLP or not.
- Information on BPA purity grade and/or the supplier. If only the supplier was available, the company's website was consulted to retrieve the purity grade, or the authors were contacted to ask for it. If none of the two information were reported or obtained, the relevance was considered low and the study was excluded from the WoE assessment.

6. Studies for which the relevance of the result was judged to be low were not considered further.