

# Micronucleus tests' controls: a new idea on their use

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The micronucleus test is recognized as one of the most successful and reliable assays for genotoxic carcinogens used in toxicological screening, e.g., in development of human and veterinary medication as well as of pesticides to be used in agriculture. An increase in the frequency of micronuclei in treated animals is an indication of a potentially harmful substance. Although challenged by some "concurrent positive and solvent/vehicle controls ... are required in each experiment" (DOI 10.1007/978-1-61779-421-6\_7).

The relevant guideline (OECD 474, paragraph 46) requires relating concurrent control results to historical controls of the same laboratory. Commonly this is done by applying a statistical procedure for both negative and positive controls independently of each other, being interpreted later in relationship to each other. This has shown to lead to conflicts between a lab and a regulatory authority.

The presentation wants to discuss whether an approach employing the "distance" between positive and negative control as "response window" has the potential to lead to better comparability between historical and concurrent experimental results.