JaCVAM-organized international validation study of the in vivo rodent alkaline comet assay for the detection of genotoxic carcinogens: I. Summary of pre-validation study results

Abstract:
The in vivo rodent alkaline comet assay (comet assay) is used internationally to investigate the in vivo genotoxic potential of test chemicals. This assay, however, has not previously been formally validated. The Japanese Center for the Validation of Alternative Methods (JaCVAM), with the cooperation of the U.S. NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)/the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the European Centre for the Validation of Alternative Methods (ECVAM), and the Japanese Environmental Mutagen Society/Mammalian Mutagenesis Study Group (JEMS/MMS), organized an international validation study to evaluate the reliability and relevance of the assay for identifying genotoxic carcinogens, using liver and stomach as target organs. The ultimate goal of this validation effort is to establish an Organisation for Economic Co-operation and Development (OECD) test guideline. The purpose of the pre-validation studies (i.e., Phases 1 through 3), conducted in four or five laboratories with extensive comet assay experience, was to optimize the protocol to be used during the definitive validation study.

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