Establishment of Alternative Test Methods for Evaluation of Genotoxicity and Prediction of Carcinogenicity by International Collaboration

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Genotoxicity tests are not only to identify compounds with genotoxic damage but also to be used for the interpretation of carcinogenicity studies. Recently ICH genotoxicity test guideline is on the process of changing from 1997 version to new one (ICH S2(R1) step3, 2008) to improve the evaluation power of genotoxicity test system specifically suggesting to consider the mode of action of chemicals for evaluation. Considering in vivo target site of carcinogen, we tried to perform genotoxicity tests and systems approaches to predict or categorize both lung and liver cancer related chemicals. We performed conventional genotoxicity battery tests together with several new or alternative test methods including comet assay and micronucleus assay. In addition, we employed genomics, proteomics and ras-, E7-transgenic systems to understand the mode of action of chemicals. These studies have been carried out by intra- and extra mural projects including international bodies such as OECD/IPCS and national regulatory US_FDA/NCTR and Japan(JaCVAM). I will be presenting what we have carried out.

Understanding mutagenic mode of action using toxicogenomics approaches and genotoxicity testing in in vitro and in vivo study may provide more information useful for the risk assessment based on discrimination between genotoxicity and nongenotoxicity in carcinogens. (These researches were supported by grants (국제협 565, 561 & 나노독541) to S. Park and a grant(응용연510) to Y. Sheen from Korea Food & Drug Administration in 2008.)
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Mission of Div. Genetic Toxicology

- Establishment of genetic toxicological safety & efficacy evaluation methods on Food, Pharmaceuticals and etc.
- Researches on Mechanism on Genotoxicity induction or suppression on Food, Pharmaceuticals and etc.
- Researches on Oncogenesis and its Molecular Mechanism
- Studies on Toxicogenomics and Bioinformatics for carcinogenicity prediction
- Genetic toxicology Studies on Biotechnology Products
- Consolidation of researches into scientific evidence based task supporting for KFDA policy