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Environmental pharmacology

Editorial

Genetic toxicology provides important information about the biological activity of new chemicals planned for introduction into the marketplace and their potential appearance in the environment as general environmental agents. The methods used are versatile and can be adapted to most chemical forms (for example, solids, liquids, and gases) and even extracts and/or mixtures of chemicals. In vivo models are available for confirmation of in vitro results and to develop information related to genetic hazard potential. New models using PCR or shuttle vectors have improved the ability of the genetic toxicologist to conduct relevant hazard assessments. Risk analysis for the induction of genetic disease is possible using models such as the parallelogram or the ICPEMC model using mouse-heritable-translocation or specific-locus test data. Systems for testing genetic toxicology are components of carcinogenic and genetic risk assessment. Present routine genotoxicity-testing is based on at least 20 years of development during which many different test systems have been introduced and used. Today, it is clear that no single test is capable of detecting all genotoxic agents. Therefore, the usual approach is to perform a standard battery of in-vitro and in-vivo tests for genotoxicity. Work-groups of the European Union (EU), the Organization for Economic Co-operation and Development (OECD), and, very recently, the work-group of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have defined such standard battery tests. These and some currently used supplementary or confirmatory tests are briefly discussed here. Additional test systems for the assessment of genotoxic and carcinogenic hazard and risk are seriously needed. These tests must be more relevant to man than are current assays and less demanding in respect of cost, time and number of animals. Another aspect for reassessment derives from the actual situation in the pharmaceutical industry. Companies have to prepare for the world economy of the 21st century. Therefore, pharmaceutical research is speeding up tremendously by use of tools such as genomics, combinatorial chemistry, high throughput screening and proteomics. Toxicology and genotoxicology need to re-evaluate their changing environment and must find ways to respond to these needs. In conclusion, genetic toxicology needs to answer questions coming from two major directions: hazard and risk identification and high throughput testing. Genetic toxicology data in cancer and genetic risk assessments, the mechanisms underlying genetic toxicology assays, the assays that can be used for detecting genotoxic endpoints, the use of the same assays for better understanding mechanisms of mutagenesis, and new methods for the assessment of genetic alterations. The field is evolving rapidly, and a review of its past and present state will set the stage to allow for a consideration of what are likely next major landmarks.