

Background information: High-speed acceptance for a new “in vitro” method to test genotoxic potential of chemicals

The European Commission's Joint Research Centre (JRC) European Centre for the Validation of Alternative methods (ECVAM) recently completed a validation study of a new 'in-vitro' test for the assessment of genotoxicity. On the 17th of November, the Scientific Advisory Committee, composed of representatives from all EU Member States, academia, industry and animal welfare organizations has unanimously given green light for this new in vitro method to be used Europe-wide. Instantly, this led to inclusion in the REACH legislation in December 2006 and OECD plans a workshop for finalisation of a test guideline in fall.

All chemicals, cosmetic ingredients and drugs are thoroughly tested for their safety of use before reaching the market. In particular, the identification of genotoxic effects is critical in the assessment of a new substance, since it is also indicative of carcinogenic potential. The “in vitro” micronucleus test (MNT) is designed to identify genotoxic effects and to be used within the existing basic battery of “in vitro” tests.

The European Commission's European Centre for the Validation of Alternative methods (ECVAM) at the Joint Research Centre in Ispra, Italy, successfully finished the first retrospective validation study on a reliable 'in-vitro' model for testing the potential genotoxicity of chemicals. The MNT test was found to be able to reliably identify clastogenic and most of the known aneugenic chemicals 'in vitro' and was therefore recommended as a scientifically valid alternative to the 'in vitro' chromosome aberration assay for genotoxicity testing. The 'in vitro' MNT already gained widespread international interest, particularly by industry as it offers significant advantages over the 'in vitro' chromosome aberration test. It is less expensive and time-consuming, requires less investment in training, and has the potential to enhance the basic package of 'in vitro' tests to detect aneugens.

The outcome of this study is a very important contribution to the ECVAM validation process because for the first time a test has been validated based on existing data only. This will therefore, lay the ground for future retrospective validation studies. Thus, this will be instrumental in the validation of alternative methods that will contribute in finding more effective ways of testing and assessing the toxicological and health impacts of all chemicals under the new European chemicals legislation ('Regulation Evaluation Authorisation of Chemicals', REACH).

The successful validation of the MNT “in vitro” led to EU regulatory acceptance and to the quick integration of the test in the REACH legislation already one month after completion of validation in December 2006. Furthermore, the validation study will support the finalisation of the test guideline and its regulatory acceptance by the Organisation for Economic Co-operation and Development (OECD). OECD acceptance of this method will lead to its widespread international application.