

Background information: Validation of new test strategy for skin sensitisation / allergy

Chemicals may cause allergic reactions when they get in contact with the skin. For this reason skin sensitisation testing is an important component in the safety assessment process of new products. The EU legislation on Registration, Evaluation and Authorisation of Chemicals (REACH) foresees that substances marketed at 1 ton per year or more are evaluated for their potential to induce skin sensitisation. It has been estimated that 30,000 existing chemicals lack information on this human health effect. Since currently there are no validated alternative methods for the identification of skin sensitisation hazard, this will result in the use of thousands of laboratory animals.

For many decades, chemicals with sensitising ability were identified with the use of guinea pig test. Only recently, the local lymph node assay (LLNA) has been validated (2000) and accepted (2002) in the regulation as an alternative approach since it lowers the number of animals required and provides a reduction in the trauma to which animals are potentially subjected. This method implies that at least 3 concentration of test material, plus the concurrent solvent control, are used to treat groups of 4 or 5 mice each, resulting in a total use of 16-20 animals. From an evaluation of historical data it has been suggested make predictions of sensitising activity by applying only the top dose of the tested chemical plus the solvent control, thus reducing the number of animals for sensitisation by half for REACH. This approach reduces also the associated testing costs.

The cut-down version of the standard LLNA has undergone a peer-review process and a statement on the validity of the approach will be released at the forthcoming ESAC meeting on 27th of April. The test is already foreseen in the REACH testing strategy, which was developed from 2005-2007 coordinated by ECVAM.