Alternatives for skin sensitisation: Hazard identification and potency categorisation: Report from an EPAA/CEFIC LRI/Cosmetics Europe cross sector workshop, ECHA Helsinki, April 23rd and 24th 2015

Abstract:
In the two years since the last workshop report, the environment surrounding the prediction of skin sensitisation hazards has experienced major change. Validated non-animal tests are now OECD Test Guidelines. Accordingly, the recent cross sector workshop focused on how to use in vitro data for regulatory decision-making. After a review of general approaches and six case studies, there was broad consensus that a simple, transparent stepwise process involving non-animal methods was an opportunity waiting to be seized. There was also strong feeling the approach should not be so rigidly defined that assay variations/additional tests are locked out. Neither should it preclude more complex integrated approaches being used for other purposes, e.g. potency estimation. All agreed the ultimate goal is a high level of protection of human health. Thus, experience in the population will be the final arbiter of whether toxicological predictions are fit for purpose. Central to this is the reflection that none of the existing animal assays is perfect; the non-animal methods should not be expected to be so either, but by integrated use of methods and all other relevant information, including clinical feedback, we have the opportunity to continue to improve toxicology whilst avoiding animal use.

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