ALTERNATIVES
for Skin Sensitization Testing

The European Partnership for Alternative Approaches to Animal Testing

European Commission

Cosmetics Europe
the personal care association

cefic

LRI
Long-Range Research Initiative

Workshop Introduction and Objectives

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…after which the theory is that things should get a bit more interesting…

What has gone before…

- First guinea pigs, then mice (55y + 25y)
- The challenge to replace animal tests – now!
- Workshop 1
  - Basketter D, Crozier J, Hubesch B, Manou I, Mehling A and Scheel J (2012) Optimized testing strategies for skin sensitization: the LLNA and beyond. Regul Toxicol Pharmacol, 64, 9-16.
- Workshop 2
  - Basketter D, Alepee N, Casati S, Crozier J, Eigler D, Griem P, Hubesch B, de Knecht J, Landseidel R, Louekari K, Manou I, Maxwell G, Mehling A, Netzeva T, Petry T and Rossi L. (2013) Skin sensitisation – moving forward with non-animal strategies. Regul Toxicol Pharmacol, 67, 531-535.

Workshop outcomes

1: No toxicology test is perfect, an experience brought into focus by issues of false positives and, to a lesser extent, false negatives in the LLNA. Use of weight of evidence arguments for classification and labelling, as well as for risk assessment was emphasised and it was also noted that a sufficient body of evidence now exists for conduct of methods other than the LLNA for carefully defined chemical classes. In terms of in vitro alternatives, progress towards methods which will deliver mainly hazard identification is being made, with some entering the final stages of validation…

2: It is already recognised that information produced from non-animal assays can be used in regulatory decision making, notably in terms of classifying a substance as a skin sensitiser. The evolution into a full replacement for hazard identification, where the decision is not to classify, requires the generation of confidence in the in vitro alternative, e.g. via formal validation, the existence of peer reviewed publications and the knowledge that the assay(s) are founded on key elements of the Adverse Outcome Pathway for skin sensitisation. It is foreseen that the validated in vitro assays and relevant QSAR models can be organised into formal testing strategies to be applied for regulatory purposes by the industry.

Workshop 3?

- The primary objective is to undertake a critical assessment of how in vitro skin sensitisation can be used in a weight of evidence approach to enable a defensible classification decision on a substance.

- Key strengths and limitations, plus future needs will be identified.

Workshop outline

- Introduction and background
- In vitro sensitisation basics/experience
- Some strategies for hazard and/or potency
- 6 case studies on the above
- Analysis in BOGs
- Conclusions and recommendations
- Go home!

The outputs?

- An industry Flash Report (1-2 pages) (very soon!)
- An internal ECHA report (1 page) (fairly soon)
- Approved slide sets on two websites (quite soon)
- A peer reviewed publication (this year)

THANK YOU !


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