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 Break Out Groups

…where things really should get even more interesting…

Workshop 3

- The primary objective is to undertake a critical assessment of how in vitro skin sensitisation data 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.

Yesterday we concluded…

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 TODAY!***
- Conclusions and recommendations
- Go home!

The Break Out Groups

- **1 -** ITS/IATA
- **2 -** Hazard
- **3 -** Potency

Break Out Group 1 – ITS IATA

- OECD TGs and other non-animal methods for sensitization hazard and/or potency assessments now exist and should be used in the context of ITS/IATAs
  - a number of approaches have been presented - are they sufficiently transparent and convincing? If not what additional information would be needed?
  - the OECD IATA reporting templates being proposed represent a first step in facilitating harmonisation of IATA. What else can be done in the short term to help in the harmonisation process while assuring the necessary flexibility?
  - ITS/IATAs need to be flexible to best address the endpoint/purpose needed and the chemical under investigation. When integrating new methods what "quality control" criteria are needed?

BOG 1

- Robert Landseidel –moderator
- Kimmo Louekari – rapporteur
- With Silvia C, Joop, Ian, Karin, Peter G, Katy, Winfried, Silvia T, Petra, Meskerem, Silvia L and Katrin

Break Out Group 2 – Hazard

- Evidence is increasing that non-animal approaches may predict skin sensitization potential in humans more accurately than animal tests. How can they now be used to predict non-sensitizing substances and be accepted by regulatory bodies?
  - what are the strengths of the approaches?
  - how can the know limitations of these approaches be addressed in the short term?
  - what is the acceptable level of uncertainty (i.e. false positives/false negatives) for hazard identification?
  - give examples of chemicals and how to assess them

BOG 2

- Simone Hoffman-Doeur – Moderator
- Peter Baric – Rapporteur
- With Costanza, Philippe, George, Camelia, Dorothea, Andrea, Reinhard, Emiel, Henrik, Andrew, Miyazawa and Joanna

Break Out Group 3 – Potency

- Potency is not yet particularly well predicted by non-animal methods – with what level of (un)certainty can we accept?
- What options exist for the identification of extreme sensitisers (as per REACH guidance)?
- Does a sufficient body of human evidence exist to give reassurance that the potency predictions have merit?

BOG 3

- Dirk Petersohn – Moderator
- Laura Rossi – rapporteur
- With Renate, Jacek, Mathilde, Pascal, Susie, Takao, Bohumila, Thomas B, Dagmar, Els, Kaihsu and Thomas T

OK – BOG OFF!


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