



EPAA activities on Optimised strategies for assessing Skin Sensitisation

**Irene MANOU
EPAA**

IFRA - IDEA Working Group meeting, Brussels, 26 April, 2016



EPAA skin sensitisation project team

Multi-sector team composed of members from:

- Raw material suppliers (e.g. BASF, Clariant, Evonik, Givaudan, Novozymes, Solvay, Symrise)
- Cosmetic or consumer product companies (e.g. Henkel, Kimberly Clark, L' Oreal, Unilever)
- Pharmaceutical companies (e.g. GSK)
- Trade associations (e.g. CEFIC, Cosmetics Europe, IFRA)
- EU agencies – regulatory bodies (e.g. ECHA, EMA, EURL ECVAM)
- and other interested experts and stakeholders

Co-chaired by **A. Mehling** (BASF) and **B. Hubesch** (Cefic LRI)

It provides a platform for regular **cross-sector dialogue** and **coordination**

A series of joint Workshops organised in 2010-2015



(Episode 0)

Cefic-LRI Workshop on skin sensitization methods for regulatory purposes

Brussels, 2-3 February 2010

2010

2011



EPAA cross-sector workshop

Optimized testing strategies for skin sensitization - LLNA and be

(Episode 1)



Episode 2: EPAA / Cefic LRI Workshop 2013

SKIN SENSITISATION TRAINING WORKSHOP
MOVING FORWARD WITH NON-ANIMAL TESTING STRATEGIES

Monday 4 February 2013
Helsinki, Finland
ECHA offices, Annankatu 18, FI-00120

2013

2015



Episode 3: 23-24 April 2015
Joint EPAA, Cefic LRI and CosmEU workshop,
ECHA offices, Helsinki

ALTERNATIVES
for Skin Sensitization Testing

2015 Workshop at ECHA

- Well attended and appreciated by experts from EU national competent authorities, ECHA, OECD, EC and industry
- Assessed ongoing efforts towards Integrated Approaches to Testing and Assessment (IATA) through case studies involving non-animal methods in testing strategies
- Discussed some of the challenges that these methods presented
- Press release and Flash Report available on Cefic LRI website (<http://cefic-lri.org/wp-content/uploads/2014/03/Joint-WS-Skin-Sensitisation-Alternatives-2015-Flash-report.pdf>)
- Full report from workshop published in RTP

Basketter D. et al. 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. Regulatory Toxicology & Pharmacology (2015). DOI: 10.1016/j.yrtph.2015.10.005

2015 Workshop Conclusions

- Need for greater clarity in the definition of **applicability domains**
- **No single method** but a tiered strategy based on the AOP for skin sensitisation may help to better characterise the skin sensitisation potential
- Other important issues identified: feasibility of using the new approaches by SMEs, especially when operating through CROs, monitoring the uptake in regulatory filings and ECHA acceptance.

2016 Focus & goals of the project team

2 current sub-projects with cross-sector stakeholders:

1. To continue sharing information about existing IATA for regulatory decisions on skin sensitisation for hazard classification in time for REACH 2018
2. To evaluate the predictivity of in vitro test methods based on 3D tissue models to assess the skin sensitisation potential of “difficult” to test substances (**new project in 2016**)

New 2016 project on “difficult substances”

- **Team members:** from chemical, cosmetic, fragrance and pharma sectors
- **Assays:** *SenCeetox* (by Cyprotex), *SensIS* (by ImmunoSearch, integrated in ongoing Cosmetics Europe program) and **RHE IL-18** (integrated in ongoing RHE IL-18 potency test validation study)
- **Status:** selection of test substances was just completed based on water solubility and additional parameters, e.g. color interference (e.g. dyes), presence of pre/prohaptens, metabolic activation, cytotoxic effects (e.g. surfactants). CosEU is in the process of checking the availability of test substances which can then be sent to the CROs for testing.

Acknowledgments

Many thanks to all members of the EPAA skin sensitisation project team for their active and constructive participation!

... and thank you for your attention!