



International Dialogue for the Evaluation of Allergens

IDEA Update

ESCD

October 19, 2018

Milano, Italy

CONTENT

- ▶ Recap of where we come from
- ▶ QRA2 SCCS review
- ▶ Surveillance project
- ▶ Integration of AAT into QRA2
- ▶ Pre- and pro haptens

IDEA

(International Dialogue for the Evaluation of Allergens)

- Formation expedited by the 2012 SCCS opinion
- Designed to provide a broadly agreed & transparent framework for assessing fragrance sensitizers in a global multi-stakeholder dialogue.
- Developed and conducted in partnership with the EU Commission
- Consisting of series of workshops bringing leading international experts together to reach consensus on developing or improving methodologies
- Governed by independent group of experts (Jim Bridges, Helmut Greim, Alain Khaiat, Thomas Rustemeyer, Ian White)
- Regularly a public Annual Review is taking place under the auspices of DG SANTE.

IDEA



Multi-stakeholder approach to allow on open exchange on different points of view on the same topic

MC Escher
1898 - 1972

QRA2 - SCCS review

- Comments in response to SCCS Preliminary opinion published on November 20, 2017 prepared under IDEA, submitted on time (January 19, 2018).
- Detailed and constructive feedback received from the SCCS on August 21, 2018 before final opinion was published on the website
- Although the conclusion of the opinion does not provide an unconditional endorsement of the QRA2, the majority of the SCCS comments are constructive (request for more information, clarification, e.g. on the use of HRIPT, SAF and the RIFM/Creme Model) and the door is kept open for its future endorsement, even beyond fragrance ingredients:
'If shaped up properly, this could be a useful methodology not only for risk assessment of fragrance allergens, but potentially also for other cosmetic ingredients.'

STATUS OF PREPARING FOR SURVEILLANCE PROJECT

- Industry is in final steps of preparing for a **surveillance system** as part of a product stewardship and early-alert-system
- This will be an industry-stakeholder partnership in data generation, analysis, and publication.
- Includes 30 existing materials (26 allergens, 2 mixes and oxidized limonene and linalool)
- Further 7 materials, so far not in the scope of systematic screening by the dermatological clinics, have been selected for inclusion in the investigation of contact allergy trends.
- Use new syringe dosing system for all materials (allowing more precise dosing)

STATUS OF PREPARING FOR SURVEILLANCE PROJECT

1. Final draft of Case Report Form (CRF) completed – final review within IDEA SG
2. Data management will be arranged either through the European Environmental and Contact Dermatitis Research Group (EECDRG) and/or the ESSCA (European Surveillance System on Contact Allergens) system.
3. Study to determine concentration for patch testing of the 7 materials. A protocol was developed and agreed with minor comments by IDEA WS participants.
4. Recent proposal to also use this as pilot study to iron out system bugs and to provide information on utility of both data reporting systems and indicate best system for selected study design.
5. In the process of reaching out to clinics that will participate in the dose range finding and pilot study.

IDEA ACTIVITIES ON INCLUSION OF AAT IN QRA2

- ▶ IDEA is committed to the integration of non-animal data to replace the LLNA as point of departure (PoD) in risk assessment.
- ▶ This is a goal shared by various stakeholders such as the EU Joint Research Centre (JRC), which therefore are liaising with IDEA.
- ▶ A workshop was organized May 16 – 17, 2018 in Brussels. The final report is available on the website.
- ▶ Key outcome:
 - The workshop revealed that there is a wide range of non-animal approaches that can predict sensitization potency of fragrance substances for use in risk assessment.
 - A justifiable point of departure (e.g. NESIL) can be obtained if:
 - Non-animal tests based on the Adverse Outcome Pathway are used,
 - A quantitative data integration procedure is applied, and
 - Uncertainty in the model can be assessed.

IDEA ACTIVITIES ON INCLUSION OF AAT IN QRA2

NEXT STEPS:

- ▶ A workshop is planned for December 12, 2018 with the aim to:
 1. review the scientific basis for the current in vitro test based IATA's (as discussed at the AAT workshop) for the identification and characterisation of human dermal fragrance sensitisers
 2. identify priorities, based on AoP considerations, for further work in this area.

This has relevance for the AAT work under IDEA as well as for the topic on characterization and categorization of allergens.

IDEA ACTIVITIES ON PRE- AND PRO-HAPTENS

Market study on hydro peroxide levels in consumer products

- ▶ Reports from dermatologist about positive patch test reactions to oxidized linalool and limonene remain frequent. These terpenes are important fragrance ingredients via their use as pure chemicals or as constituents of very important natural extracts (e.g. citrus oils, lavender oil, or coriander).
- ▶ Science indicates that the main sensitizing ingredients in the oxidation mixtures of these terpenes (as used in patch testing) are the hydroperoxides (HP) formed upon prolonged exposure to air.
- ▶ To better understand sources of exposure of consumers to sensitizing doses of HP a project analysing different consumer products was launched, the outcome of which will be presented by the chair of the IDEA HPTF, Andreas Natsch.

Muchas Gracias

DANKE SCHÖN

THANK YOU

www.ideaproject.info

MERCI
BEAUCOUP

GRAZIE

Arigatō