IDEA
Vision for 2017 and beyond

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Considerations for the future work on the IDEA project

IDEA
International Dialogue for the Evaluation of Allergens

- Many (majority) fragrance ingredients have not been assessed following QRA methodology.
- In the EU and elsewhere, the use of LLNA for the testing of cosmetic ingredients is prohibited.
- The use of HRIPT is regarded as unethical in many countries.

<u>Prioritisation framework required</u>

Potential approach to identify priorities for assessing individual fragrance materials

- Application of a structure activity tool (SAR):

  Requirement: comprehensive and accessible database

- Identification of a threshold of induction:

  Requirement: application of the aggregate exposure model

- Transparent weight of evidence format that utilises **all** available data:

  Requirement: consideration of utilisation of ongoing work in other domains on WoE /systematic review

Ongoing activities for IDEA

- Incorporation of pre- and pro- haptens into QRA2
- Assessment of the effectiveness of the QRA2 in preventing sensitisation, based on clinical experience.
- Identification of the most suitable *in vitro* replacement for the LLNA test.
- Extension of the aggregate exposure model to children and inclusion of additional consumer product categories.

Replacement of the LLNA test

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The challenge:

There are a number of *in vitro* tests in an advanced state that may be suitable for identifying fragrance substances that could give rise to induction. None of these tests appear to have the potential to provide the necessary information on potency for risk assessment purposes (a general problem with current *in vitro* tests).

A way forward?:

Use of combinations of *in vitro* tests with (Q)SAR?

‘QRA3’ (?)

Internal exposure

(total aggregate (cumulative) and toxicokinetics)

Hazard assessment

Non-animal evaluation (SAR/ MoA based?)

↓ ↓

↓ ……..WoE evaluation ……..**NESIL**

↓ ↓ ↓

→ **CEL** → → → → ↓ ← ← ← ← ← ← **AEL**

↓ uncertainty analysis

Risk assessment

↑ assessment of the effectiveness of the QRA

Feedback from dermatology clinics

Needed now!

- Surveillance data to feed back into QRA2.
- Understanding compliance to QRA2 for each fragrance substance.

"Agile & lean"