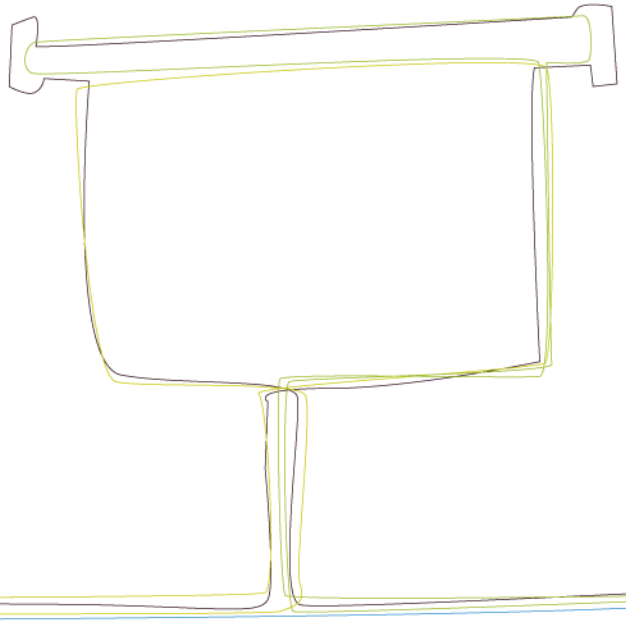
IDEA
International Dialogue for the Evaluation of Allergens

Future plans for IDEA



Prof Jim Bridges

Emeritus Professor of Toxicology and Environmental Health and Chair of the IDEA Supervisory Group

Continuing activities for IDEA

- Completion of the revision of QRA2 following the meeting with SCCS WG and JRC.
- Finalisation of framework for incorporation of pre-and pro- haptens into the QRA.
- Implementation of a prospective assessment of the effectiveness of the QRA in preventing sensitisation, based on clinical experience.
- Further extension of the aggregate exposure model to include household and detergent products and to cover teenagers and professional users.

Considerations in determining the next stages of the IDEA project

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i) Many fragrance ingredients have not been assessed for sensitization using the QRA1. A prioritisation framework is needed.

ii) In the EU and a number of other countries the use of animals for the testing of cosmetics ingredients is banned.

iii) The use of HRIPT like tests on human volunteers in many countries is regarded as unacceptable on ethical grounds.

Framework for identifying priority fragrance ingredients for assessment

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i) Development of a structure activity tool (SAR).

Requirement:

- A comprehensive, accessible data base

ii) Identification of a generic threshold of induction.

Additional requirement:

- Use of the aggregate exposure model

iii) A weight of evidence format that utilises all the available data.

Requirement:

- Utilisation of ongoing work in other domains on WoE /systematic review.

Replacement of the LLNA test (move into integration of AAT in previously untested fragrance ingredients)

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The challenge:

There are a number of *in vitro* tests in an advanced state that may be suitable for identifying fragrances 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).

Short term:

Use of combinations of existing *in vitro* tests with (Q)SAR for toxicokinetics and hazard?

IDEA: The longer term objectives+

- Improvement of understanding of the mode of action of haptens and pre- and pro- haptens in initiating induction and elicitation in man.
- Development of *in vitro* methodology to provide relevant dose response data.
- Utilisation of this understanding to develop improved risk assessment methods.

+ requiring collaboration with other organisations

QRA 3 (201?)

Internal exposure

(total aggregate exposure 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 clinics and consumers

THE GROUND STATE OF THE BIOLOGICAL SCIENCES IS UNCERTAINTY AND WISDOM IS DEFINED BY HOW WE COPE WITH IT

Adapted from A. Gawande

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Thank you for your attention