The IDEA Project after four years

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The primary aim of the IDEA Project

IDEA
International Dialogue for the Evaluation of Allergens

A long term project aiming to establish and adopt a transparent and validated risk assessment methodology, based on the best available science, for the identification of use conditions of individual and mixtures of fragrance substances (alone and in different formulations) that will, when properly utilised, prevent induction of skin sensitisation in consumers.

IDEA: general mode of operation

- Open, multi-stakeholder discussions in workshops/working groups meetings on specific topics relating to the QRA, with participants from many disciplines, countries and organizations. Meeting reports are circulated to all participants for comments before posting on the IDEA website.
- Task forces/working groups are established to follow up actions identified at the workshops. Progress posted on the website.
- Annual Meeting:
  - Enables views of other interested stakeholders on the project's progress to be stated and addressed.
  - Provides an opportunity to chart the best way forward.
- Key role of the IDEA Supervisory Group is monitoring progress.

IDEA: the first year

- The focus of the first year of IDEA was:
  - Build an effective collaboration between stakeholders (industry and academic scientists, dermatologists and regulators).
  - Draw on their expertise to identify the actions needed for a major revision of the original QRA (‘QRA1’ published in 2008) to be provided to DG Sanco by July 2014.

Agreed major revisions on QRA1

QRA1 is a model that attempts to predict the risk of contact allergy developing from individual fragrance substances in individual products.

Agreed priority was to develop an improved QRA model, which includes the identification of the total exposure to each fragrance substance from all consumer products.

This required:

i) Re-evaluation of uncertainties where a safety assessment factor (SAF) is warranted and the scientific basis for the assignment of each SAF value.

ii) Development of an aggregate exposure model based on actual consumer use of products.

Models must be tested

IDEA: the second year

The primary aims were to:

- To progress on development QRA2 method.
  - Interim report on QRA2 was submitted in July 2014 to DG Sanco.
- To further improve transparency of the project and effective collaboration between stakeholders.
- To review priorities for further work.

IDEA: the third year

The priorities were:

- Provide an interim QRA2 report based on the evaluation by the JRC (on behalf of DG Sanco) and further work conducted by IDEA on the SAFs, etc. This included responses to suggestions for improvements.
- To critically examine how pre- and pro- haptens could be incorporated into the QRA. This included a task force to develop an analytical methodology for the quantification of hydroperoxides (limonene and linalool).
- To consider the practical evaluation of QRA2 in preventing contact allergy (and associated dermatitis) in consumers exposed to fragrances.
- To identify the priorities for the next stage of IDEA.

IDEA: the fourth year

- To progress on the incorporation of pre- and pro- haptens into QRA2. This included several ‘ring tests’ for the development of the analytical method to quantify hydroperoxides.

- To establish a methodology to assess the effectiveness of QRA2 to prevent induction of contact allergy as measured by absence or reduction in contact allergy in the clinical situation.

- To examine, via a landscape assessment, how developments in *in vitro* tests can be utilised to replace the *in vivo* Local Lymph Node Assay’.

Testing the effectiveness of QRA2 is mandatory!

"Faith in their models' predictive powers led them to ignore what was happening in the real world…."

'Blinded by science'. Leader, New Scientist, 27 Sept 2008