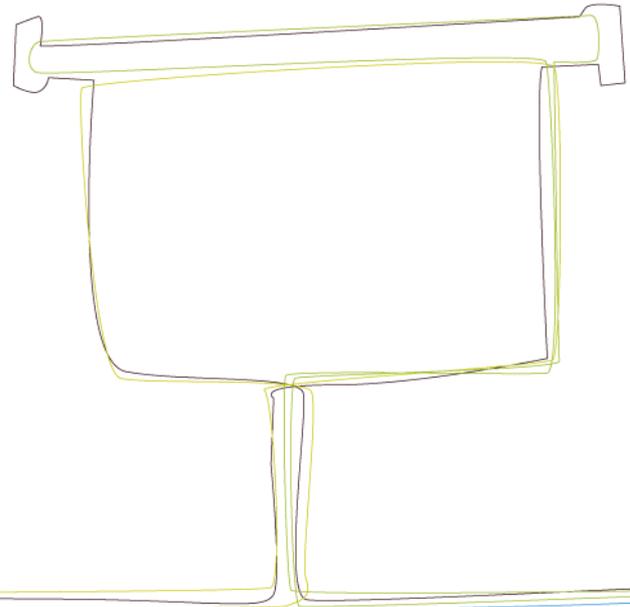


# UPDATE ON THE IDEA PROJECT (International Dialogue for the Evaluation of Allergens)

**Prof Jim Bridges**

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



# The original methodology (QRA1) used for risk assessment purposes prior to 2013



**Risk** is determined by identifying for each fragrance ingredient whether *induction* of sensitisation can occur and if so whether the *worst case exposure level due to consumer use* is sufficiently low that such an effect will not arise (the threshold dose)

## QRA 1. Hazard assessment (induction of sensitisation)

Animal data (e.g. LLNA) supported by a human volunteer study (HRIPT)

## QRA1. Exposure assessment

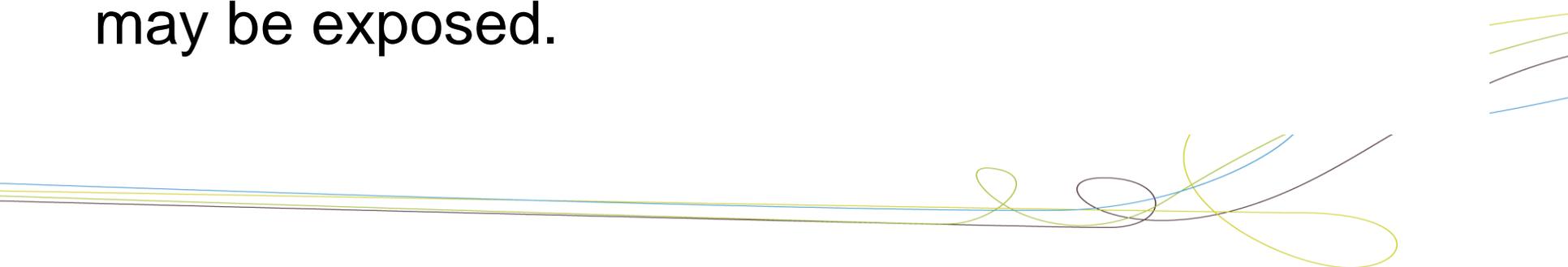
Each fragrance ingredient considered separately

# IDEA project 2013

## The aim of the project

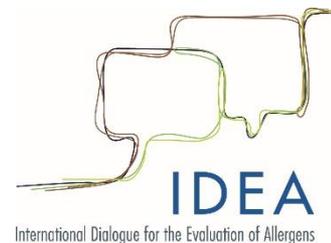


To establish and adopt a transparent and validated **risk assessment framework**, based on the best available science, for the identification of use conditions of individual and mixtures of fragrance ingredients (alone and in different formulations) that will, when properly utilised, **prevent induction**, and consequently skin sensitization (allergic contact dermatitis), of consumers and others who may be exposed.



# IDEA Project

## Operation of the scientific aspects



### To enable a strong and continuing scientific and clinical base:

All scientific and clinical aspects of the project are overseen by its independent **Supervisory Group (SG)**. SG's role includes identification of priorities, encouragement of involvement of leading experts and ensuring transparency of all the activities.

### For priority topics this is achieved by:

- Open discussions in interdisciplinary workshops with participants from many countries and organizations.
- Task forces
- Utilising of the latest research findings

### To ensure transparency to all stakeholders:

- All activities are published on the web site ([www.ideaproject.info](http://www.ideaproject.info))
- Papers are given at scientific conferences and publications encouraged
- An Annual Review with all stakeholders

# IDEA Project: Phase 1 (2013-2016)

## A more comprehensive exposure assessment



### Approach:

- i) Introduction of an aggregate (total) exposure model to a fragrance ingredient based on actual consumer use of products
- ii) Re-evaluation of the scientific basis for the sensitisation assessment factors used (SAF values)

### Achievement:

This work has now been completed and the report (QRA2) has been reviewed by the JRC on behalf of the Commission. The final version will be issued by the end of September

# IDEA project phase 2A: On-going work on exposure



## i) Valuation of QRA2:

Implement a prospective clinical assessment of the effectiveness of QRA2 in preventing sensitisation

## ii) Determination of exposure of other population groups:

Extend the utility of the aggregate exposure model through its validated application to children, professional users and other exposure sources (e.g. household and detergent products)

## iii) Formation of abiotic and biotic products:

Develop a protocol for incorporation of pre- and pro-haptens into QRA2

# IDEA project phase 2B: Factors influencing the SG's choice of priorities



i) **The ban on animal tests for cosmetic ingredients and products by the EU**

QRA2 currently depends on an animal test (LLNA) to identify and determine the potency of individual fragrances ingredients

ii) **Restriction on human testing**

To support this, QRA2 currently uses human volunteers (HRIPT). Such testing, in the EU, is increasingly regarded as unethical

iii) **The very large number of ingredients requiring assessment**

Many fragrance ingredients have not been assessed to date

**Conclusion:** an entirely new methodology is required for hazard assessment

# Replacement of the animal (LLNA) test

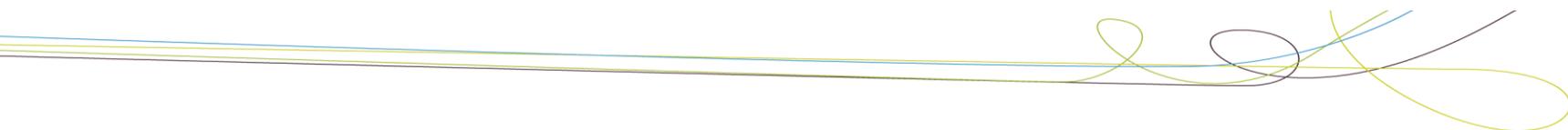


## The present state of the science:

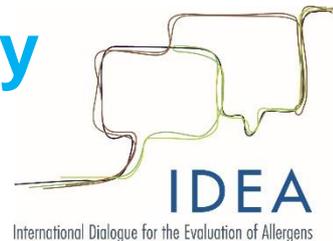
There are a number of *non-animal* tests in an advanced state that appear suitable for **identifying** fragrance ingredients that could give rise to induction. However, none of these tests alone yet provides a reliable estimate of **potency**, which is essential for risk assessment purposes

## IDEA involvement:

There is much work around the world on this issue. IDEA is already active in building collaboration and facilitating dissemination of research findings



# Components of an integrated methodology for prioritisation and quicker assessment



## i) Identification of a threshold of toxicological concern for induction:

Based on worst case thresholds for induction and used in conjunction with the aggregate exposure model

## ii) Simple *non-animal* tests for specific properties:

Require a battery of chemical and in vitro tests

## iii) Bridging data gaps:

A reliable basis for read across from fragrance ingredients with good data, to those with very limited data, needs to be established based on physico-chemical and simple test findings

## iv) Weighing **all** the evidence available:

Requires a transparent, consistent, science based procedure (WoE)

# IDEA Project

## Summary of the first 3 years and current work



### 1. What has been achieved:

A reliable means of estimating total exposure of consumers to each fragrance ingredient. The consequent revision of the QRA (QRA2), that incorporates the JRC comments, is issued by the end of the month.

### 2. Current work:

- a) Examination of the value of QRA2 in preventing sensitisation of consumers
- b) Extension of exposure aspects to additional population groups, other consumer products and pre- and pro- haptens
- c) Collaboration with other organisations in developing suitable non-animal tests and other methodology for hazard characterisation

Adapted from A Gawande

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

