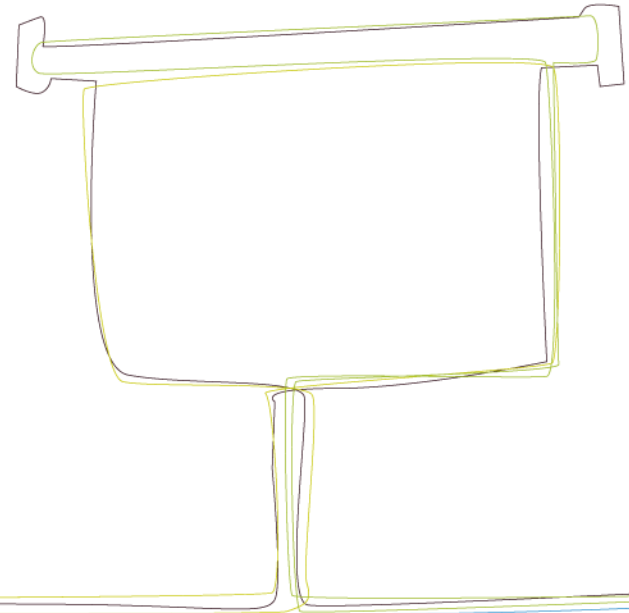




# Introduction to QRA II



# IDEA Annual Review 2013 – Adopted summary



- The IDEA Project is showing promise of delivering against its objectives of:
  - i. multi-stakeholder dialogue,
  - ii. common understanding of science and,
  - iii. an aligned set of actionsall this to minimize fragrance-induced contact allergy.
- The approach of multi-day workshops for a given topic is seen as effective to address key questions related to fragrance allergy as judged from the reports and the quality of recommendations and resulting action plans.
- All three topics covered in this year's workshops will require follow-up in next year's workshops, including questions raised at the IDEA Annual Review.
- The success of IDEA will largely depend on the ability to timely deliver against agreed recommendations and action plans.
- The IDEA Annual Review proved useful and is recommended also in future as the tool to monitor progress.

# IDEA QRA Workshop 2013 – Key conclusions



The workshop produced a number of key conclusions on the work to date and identified a range of specific action steps:

- On risk assessment:

QRA is seen as a promising tool to prevent induction of contact sensitization for people with normal skin. However, it requires further refinements for the general population as follows:

- Prospective and retrospective evaluation of its effectiveness by clinical and epidemiology data using sensitization as the relevant endpoint
- Review of underlying methodologies and assumptions:
  - SAFs (Safety Assessment Factors)
  - NESILs (No Expected Sensitization Induction Levels)
  - Exposure (accumulation, aggregate exposure, chemical analysis, usage, retention and professional exposure)
- Adaptation for people with compromised skin

# IDEA QRA Workshop 2013 – Key conclusions



- On risk management:
  - Commitment to act promptly on new insights
  - Labeling and Provision of information on ingredients as an important complement to QRA and in-market validation
- On prospective and retrospective evaluation:
  - For retrospective work, the group strongly encouraged to consider all available historical data. Data on preservatives might also contribute to validation of QRA for fragrances.
  - For prospective work, focus should be on compliance with IFRA Standards, sensitization trends in the general population confirmed by clinical epidemiology data.
  - For prospective work, clinical monitoring of new chemicals could provide important confirmation.

- On refinement of QRA for the general population
  - SAFs are seen as being set appropriately with current state of knowledge. Re-evaluation of the inter-individual variability factor with scientific rationale is considered essential.
  - An estimate of expected new induction when following QRA is encouraged.
  - There could be value in developing ‘QRA 2.0’, based on latest data and including aggregate / occupational exposure.

- Risk assessment (RIFM):
  - Sensitization Assessment Factors - review the scientific basis for support of each of the adjustment/ default factors.
  - Use clinical data to identify the success or not of the safe levels set based on the QRA (prospective studies).
  - Consider professional exposure from consumer products (e.g. professional use of hair care products or hand cleansers, etc.)
  - Continue to develop further the aggregate exposure model. Include co-exposure and cross reactivity of related chemicals.

# IDEA QRA Workshop 2013 – Recommendations



- Communication (IFRA and RIFM):
  - Expand the dialogue with the dermatologists
  - Better involve the dermatology community in the IFRA Standards development process
- Risk management (IFRA):
  - Address with the IFRA Scientific Committee the problem of MPL
  - Ensure that the revised QRA is properly implemented in the IFRA Standards
  - Develop a meaningful IFRA Compliance Program
- Dialogue with the regulators and trade associations (IFRA)



**Thank you for your attention!**

Dr. Hans Bender

+49 (0)228 53 88 13 33

[bender.hj@hotmail.de](mailto:bender.hj@hotmail.de)

