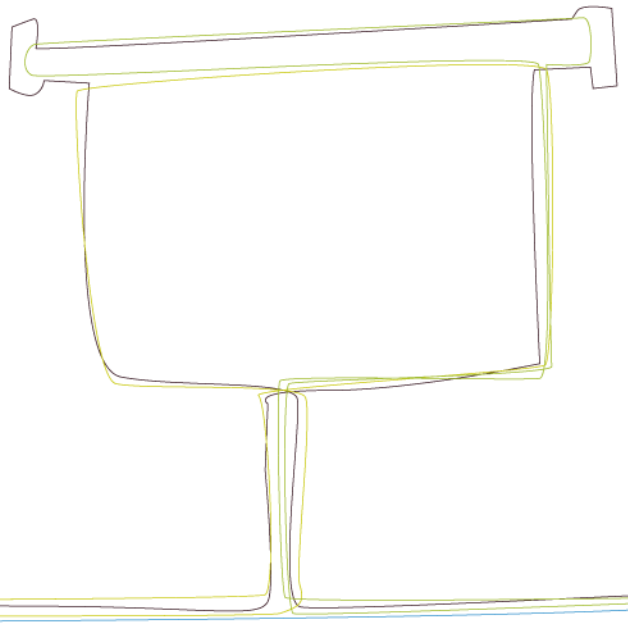
IDEA
International Dialogue for the Evaluation of Allergens

IDEA 'Expert' Workshop on pre- and prohaptens



Hans Bender

Moderator of the IDEA Workshops

16 and 17 June, 2015 Genval (Belgium)

Key conclusions of the IDEA Workshop on

Risk Assessment of Pre-& Pro-Haptens

May 28-29th 2013

Dolce La Hulpe Brussels
Chaussée de Bruxelles, 135
B-1310 La Hulpe, Belgium

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

- There is clear qualitative indication that sensitizers can be formed in some formulations under realistic conditions as a result of abiotic **hydrolysis** of fragrance ingredients. The importance of biotic **hydrolysis** in the epidermis will require further investigation.
- Contact allergy (positive patch-tests) to **oxidation** products of some fragrance ingredients is common. There is presently insufficient data on exposure to these **oxidation** products to make a correlation to disease (allergic contact dermatitis).
- On biotic and abiotic **oxidation**, the data show the complexity with great challenges for predictability and analytical testing:
    - The models do not sufficiently reflect exposure conditions or co-factors that interfere with sensitization.
    - There is a need for more rigorous protocols (including ROAT) for clinical studies.
    - Different concepts of relevance (individual, group-related and epidemiologic data) need to be refined.
- The development of new analytical methodologies such as HR MAS-NMR is a key requirement to elucidate in situ phenomena.
- The workshop produced a range of recommendations to identify and characterize pre- & pro-haptens, ranging from chemical characterization to confirmation through clinical studies.
- Future work should be conducted in transparency and with participation from stakeholders with relevant expertise.

The participants

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Objective

- The WS will address concerns about sensitization with haptens that are being formed shortly prior to, or during exposure to consumer products due to chemical or biochemical processes – so called pre & prohaptens – with specific interest in the best documented examples in the clinics namely oxidization products of monoterpenes (like Limonene or Linalool). Ultimately, this effort is expected to lead the development of predictive models to assess the potential of fragrance ingredients to act as pre- and pro-haptens to an adequate understanding of the underlying sensitization risks to humans as the basis for appropriate risk management measures,

Objective

- The workshop is intended to bring together experts in the field of chemical and biochemical transformation processes in consumer products and humans with clinical researchers. This knowledge on transformation will be complemented by analytical and theoretical chemistry expertise to enable verification of postulated models. Finally, it will be discussed how these findings and models are best translated into practice.

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Thank you for your attention