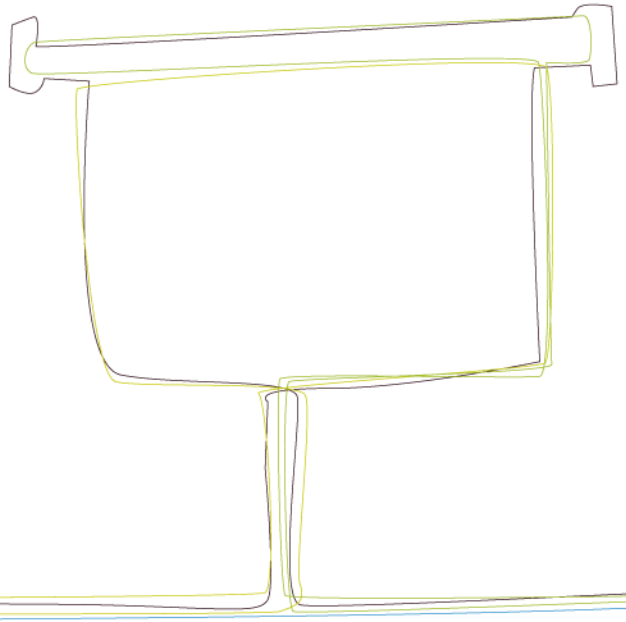
IDEA

International Dialogue for the Evaluation of Allergens

Transition to a world without animal testing

How the categorization of allergens can optimize the use of in vitro testing data



Hans Bender

The IDEA Categorization TF

- An IDEA Workshop dedicated to the characterization of fragrance allergens was organized in August 2013.
- One of the recommendations made by the workshop participants was to develop a robust and meaningful system for the categorization of allergens.
- The IDEA Categorization TF was formed to tackle this action item and had its kick-off webinar on April 28th, 2014.
- The starting point of a sound framework for the characterization and categorization of fragrance allergens was identified. The system to come will optimize the use of in-vitro testing data.

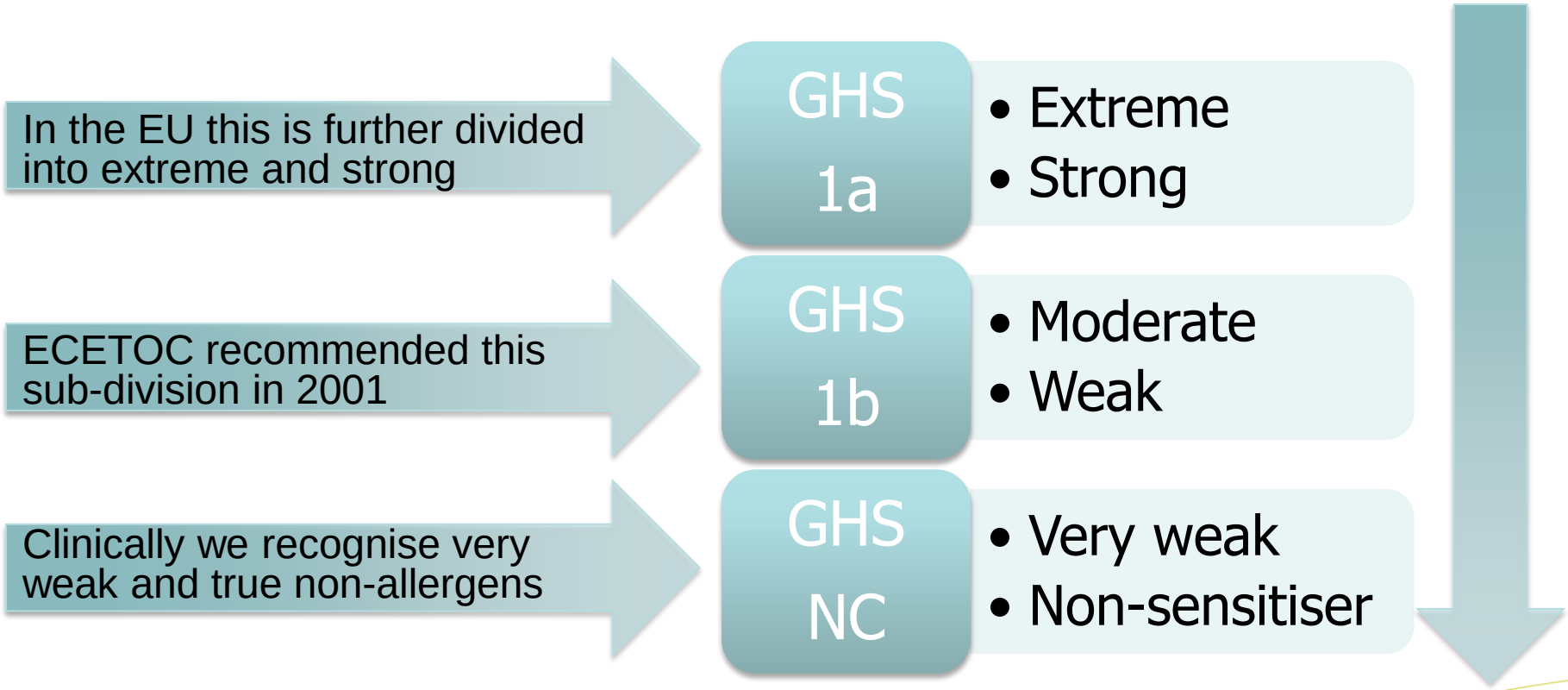
QRA methodology and in vitro testing

- The QRA methodology needs a quantitative expression of a skin sensitizer potency (NESIL).
- As of today, in vitro testing can successfully characterize allergens (yes / no answer) but remain of limited use for the determination of allergens potency or, at least, do not have the same predictability accuracy as traditional tools such as the LLNA.
- The best that can be achieved today with in vitro testing is qualitative determination of potency ranging from extreme to non-sensitizing.
- The development of a categorization system can help the development of in vitro testing and its use for RA purposes.

The article of D. Basketter et Al.

- An article of D. Basketter et Al. suggests the creation of six categories; each one corresponding to a specific skin sensitization potency.
- 131 known fragrance allergens were then assigned to these categories based on human data (NOEL, clinical reports, etc.) This complicated task implied expert judgment.
- The comparison of in vitro testing data from known and unknown allergens indicates the potency category in which unknown allergens could belong to.
- It is then possible to link each category to a default NESIL value. This value can be used to feed the QRA methodology and derive safe use levels.

Overview of regulatory classification categories



These are the 6 categories used for 131 substances in the human potency paper

Further refinements

- The group found this system adequate but suggested further refinements based on:
  - The concept of SEQ (Sensitization Exposure Quotient),
  - The ECHA guidance,
  - Other categorization systems (e.g. the one proposed by the MAK Commission),
  - The inclusion of all testing data (QSAR, in vitro and animal) rather than human data only and,
  - The SCCS Opinion on fragrance allergens (SCCS/1459/11).

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Thank you!