

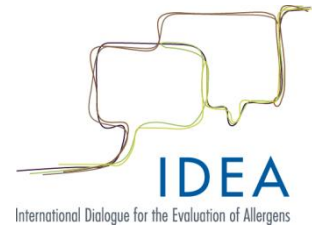


2nd IDEA WG meeting on the feasibility of a study to assess the effectiveness of the QRA

Breakout Group Surveillance system

Matthias Vey
IDEA WG Meeting
Leuven
February 15, 2017

Participants



Pieter-Jan Coenraads

Graham Ellis

David Gawkrödger

Nicola Gilmour

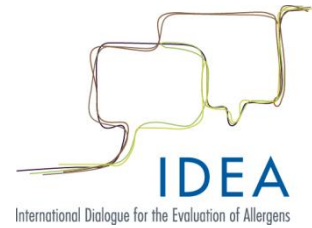
Karl-Heinz Jöckel

Boris Müller

Florian Schellauf

Hans Bender and Matthias Vey (moderation and reporting)

IDEA Surveillance System



Agreed aim:

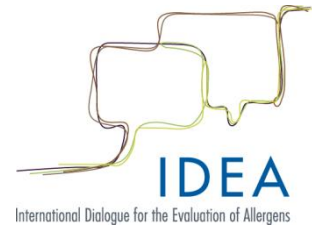
Inform overall risk assessment and management process

Good independent and reliable monitoring of the patch test system

Early alert system

Always need to interpret the result with in-depth insight on product use

IDEA Surveillance System



Material selection:

FM 1 and FM 2 plus the 26 individual fragrance materials

Considering practicalities of patch test routine add a well defined number (5 – 6) of new materials.

Criteria to apply to derive this subset:

Pooling from SCCS 2012 list and materials for consideration of getting new sensitization driven Standards in the 49th Amendment

Focus on synthetics; best not present in natural materials

Focus on ,potent' sensitizers

Material selection (continued):

Ensure use accross categories, with confirmed use in cosmetic products and focus on ,high exposure‘

- with regard to volume (EU)
- with regard to use in product types leading to high consumer exposure

Understanding other exposures is required and most relevant for data interpretation but not a criterion for excluding the material

IDEA Surveillance System



IDEA Management Team to manage the process of critical data collection and material selection for approval by the WG and endorsed by the SG.

Selection of clinics:

Geographical scope: balanced within Europe

Clinics having experience with routinely testing the 14 - 26 allergens

Minimum of 300 patients per year

Need to agree to follow the protocol; including quality criteria, management and allow quality control

Central data management with electronic data catchment

Surveillance frequency:

Run it continuously for several years