

IDEA Workshop on QRA

Key conclusions
La Hulpe, March 20th, 2013

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

- 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.

The participants

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