

Key conclusions of the IDEA Workshop

Validity of the QRA Methodology & Possibilities of Further Refinement

March 13th, 2014 – La Hulpe

The workshop participants identified a set of elements that should be taken into consideration for the development of a QRA 2.0.

The starting point of the QRA is the NESIL which is defined as the threshold known not to induce skin sensitization, considering all available hazard data in a weight of evidence approach, under the specific exposure conditions of a standard protocol HRIPT.

- Considerations related to Humans:
 - The variation in individual human susceptibility to skin sensitization is substantial. The biological basis of this variability is largely unknown, with ethnicity, gender, age (including infants), genetics each making only a minor contribution.
 - Regarding skin diseases / conditions:
 - Atopic dermatitis, psoriasis and dry skin have probably no impact on skin sensitization.
 - Irritant dermatitis is known to promote skin sensitization.
 - The inter-individual variability not accommodated in the NESIL is reflected by a SAF of 10.
- Considerations related to Products:
 - The impact of product use factors such as degree of occlusion, frequency / duration of product use and the product matrix itself are reflected in SAFs that range between 0.3 and 3.
 - The role of skin condition / site is determined by a stepwise consideration of pre-existing inflammation, irritation by product, and penetration / permeation of product and is reflected in SAFs each between 1 and 3.

In conclusion, the assumptions for the SAFs underpinning QRA 1.0 have been reviewed: QRA 2.0 represents a more detailed and transparent assessment with regard to aggregate exposure, skin condition, product type and site of application.

The participants

Attachment: Table of new proposed product use SAF values

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Factor	Consideration	Influence	New proposed SAF values
Occlusion	Some areas of skin are semi-occluded by clothing, or product with moisturising agents may lead to semi-occlusion.	Semi-occluded = Non-occluded ↓	1 0.5
Product matrix	Role of vehicle	Delivery	0.3 or 1 or 3
Frequency / duration of product use	Products may be used over extended periods of time resulting in bio-accumulation	↑	1 or 2
Skin condition / site	Pre-existing inflammation Irritation by product Penetration / permeation of product	Increase of induction susceptibility	1 or 3 1 or 3 1 or 3