

IDEA Workshop

Validity of the QRA Methodology & Possibilities of Further Refinement

March 19-20, 2013

Dolce La Hulpe Brussels
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Final Programme

Monday, March 18th

- 4:00 - 6:30 p.m. Welcome and registration at the IDEA Workshop
- 6:30 - 9:30 Reception (walking dinner)

Tuesday, March 19th (9:00 a.m. to 5:00 p.m.) – Session 1 (Formal presentations)

Each presentation consists of a 40 minutes lecture followed by 20 minutes of questions

- 9:00 - 9:30 a.m. Opening of the meeting – H. Bender and M. Vey
- 9:30 - 10:30 *Scientific basis, details and evolution of the QRA methodology* – A.-M. Api
- 10:30 - 11:00 Coffee break
- 11:00 - 12:00 *The QRA methodology such as used today by IFRA to set Standards based on induction levels* – G. Ellis
- 12:00 - 1:00 Lunch



1:00 - 2:00	<i>Potential areas of improvement of the current QRA methodology – SCCS Member (J. Duus Johansen)</i>
2:00 - 3:00	<i>Assessment of the effectiveness of the QRA methodology – A.-M. Api</i>
3:00 - 3:30	Coffee break
3:30 - 4:30	<i>Recent progresses in the calculation of the aggregate exposure to fragrance ingredients – B. Safford</i>
4:30 - 5:30	Moderated Discussion with the Lecturers and conclusions of Day 1
5:30 p.m.	End of the Session
6:30 - 7:30	Champagne tasting
7:30 - 9:30	Dinner

Wednesday, March 20th (9:00 a.m. to 4:30 p.m.) – Session 2 (Open discussion)

9:00 - 9:30 a.m.	Adoption of the agenda and wrap-up of Day 1
9:30 - 10:30	Consumer exposure <i>Improved exposure data (Hall, 2011) is being incorporated into the QRA methodology. In addition, RIFM has sponsored work to investigate the effects of aggregate dermal exposure.</i> <i>The outcome of this work is being accounted for in the methodology and we suggest that an open discussion be held on the validity of the QRA and on this initiative in particular.</i>
10:30 - 10:45	Coffee break
10:45 - 11:45	Acceptable Exposure Levels (AEL) and Exposure Data <i>A more detailed explanation of AELs and how they are applied should be provided. There also is a need for more details on the pragmatic approach and a review of aspects of having high calculated values in (mainly) rinse-off products.</i>
11:45 - 12:30	Dose Response Assessment - Safety Assessment Factor (SAF) <i>A paper which specifically addresses the use of uncertainty factors in QRA for skin</i>

sensitization has been published (Felter, et al., Contact Dermatitis, 2003, 47:257-266). However it is acknowledged that further dialogue on SAFs would be appropriate. This would include better clarification of what the SAFs are applied to (e.g. not to clinically diseased skin).

12:30 - 1:15

Lunch

1:15 - 2:15

Assessment Tools of the QRA Methodology (LLNA, HRIPT, etc.) and Retrospective Analysis (Diagnostic patch test)

The aim of this session is to address the necessary tools for the QRA methodology and controlling its effectiveness.

LLNA and HRIPT studies have been and are still used as the basis to identify the “No Expected Sensitization Induction Level” of fragrance allergens.

Diagnostic patch test data from dermatology clinics provide a means to investigate whether thresholds of use based on the QRA have been successful. Also company post-market surveillance data can be used for this purpose.

2:15 - 2:30

Coffee break

2:30 - 3:30

Current Boundaries of the QRA Methodology

While occupational exposures to consumer products can be an important source of exposure they are not considered in the current QRA. This mainly stems from a lack of adequate exposure data.

Furthermore the QRA methodology does not cover aromatherapy (neither workers nor consumers). These currently not reflected exposures remain a potential area of research.

3:30 - 4:30

Conclusions of the Workshop and Next Steps

4:30 p.m.

End of the Session and Workshop Closing

List of participants (28):

Dr.	Anne Marie	Api	RIFM
Dr.	David	Basketter	Consultant
Dr.	Hans-J.	Bender	Consultant (<i>Moderator of the QRA Workshop</i>)
Prof.	Donald	Belsito	Columbia University Medical Center and RIFM Expert Panel Member
Dr.	Christophe	Brault	LVMH
Prof.	James	Bridges	University of Surrey and SCENIHR Chair (<i>Rapporteur of the QRA Workshop</i>)
Prof.	Magnus	Bruze	Lunds Universiteit and RIFM Expert Panel Member
Prof.	Pieter-Jan	Coenraads	University Medical Centre Groningen
Prof.	Wolfgang	Dekant	University of Würzburg, SCHER Member and RIFM Expert Panel Member
Prof.	Thomas	Diepgen	Ruprecht-Karls University
Prof.	Jeanne	Duus Johansen	University of Copenhagen and Member of the SCCS WG on Fragrance Allergens
Mr.	Graham	Ellis	Givaudan
Dr.	Federica	De Gaetano	EU Commission – DG Sanco – Risk Management Unit
Dr.	Nicola	Gilmour	Unilever
Dr.	Peter	Griem	Symrise
Dr.	Petra	Kern	Procter & Gamble
Dr.	Christine	Lafforgue	Université Paris sud 11
Dr.	Fred	Lebreux	International Fragrance Association
Dr.	Cronan	McNamara	Crème Global
Prof.	Hans	Merk	Universitätsklinikum Aachen
Prof.	David	Roberts	Liverpool John Moores University and Member of the SCCS WG on Fragrance Allergens
Prof.	Vera	Rogiers	Vrije Universiteit Brussel and SCCS Vice-chair
Dr.	Bob	Safford	Consultant
Dr.	Florian	Schellauf	Cosmetics Europe
Prof.	Axel	Schnuch	IVDK / University of Göttingen
Prof.	Wolfgang	Uter	University Erlangen and Member of the SCCS WG on Fragrance Allergens
Dr.	Matthias	Vey	International Fragrance Association
Dr.	Ian	White	Guy's & St Thomas' NHS Hospitals and SCCS Chair