IDEA
International Dialogue for the Evaluation of Allergens

Recommendations of the IDEA Workshop on

Validity of the QRA Methodology & Possibilities of Further Refinement

March 19-20, 2013

i) Risk assessment (RIFM):

- RIFM QRA Expert Group – reconvened to facilitate progress on the work on safety factors in particular to address the following:
    - Sensitization Assessment Factors - review the scientific basis for support of each of the adjustment/ default factors.
        - Inter-Individual Variability - This needs a better understanding of human variability in response and the elucidation of the reasons for this. Characterize the mode of action of chemically induced allergens and how (and why) it varies between humans and between humans and animals. Identify the potential hazard test replacements/ improvements and the implications for uncertainty of extrapolation.
        - Matrix Effects - processes by which matrix factors influence uptake. Characterize the influence of other factors in a product (e.g. irritants) on the allergenic potential of individual fragrance ingredients.
    - Use clinical data to identify the success or not of the safe levels set based on the QRA.
        - Design a prospective study in collaboration with the relevant stakeholders (e.g. ESSCA, IVDK)
        - How can retrospective data be used - What is the suitability of the current database to inform the process? Is it sufficient yet to enable SAR/QSAR?
    - Consider professional exposure from consumer products (e.g. professional use of hair care products or hand cleansers, etc.)
    - This Expert Group will come into operation as early as possible in order to deliver its first results at the next IDEA QRA Workshop taking place in March 2014. A status update is foreseen (most likely by conference call) before the end of the year.

- RIFM Aggregate Exposure Task Force – Continue to develop further the aggregate exposure model. Include co-exposure and cross reactivity of related chemicals.

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ii) Communication – improve the dialogue with the dermatologists (RIFM and IFRA):

- Expand the dialogue with the dermatologists (RIFM): RIFM has one formal avenue for a regular dialogue with European dermatologists (ESCD Fragrance Working Group). RIFM would like volunteers from the dermatology community to assist in establishing other dermatology working groups. This action is important to quickly and effectively obtain feedback from dermatologists and act as needed.

- Better involve the dermatological community in the Standards development process and ensure the possibility to comment on proposed risk management measures (during the consultation of IFRA Standards). The dermatologist community should be involved as best as possible during the Consultation period taking place before each new IFRA Amendment, by e.g. regularly sharing the proposed new Standards with ESCD, ASCD, EADV and other relevant groups (especially in Asia and South America). It may be envisioned that webinar could be scheduled to all interested parties on the rationale behind the IFRA Standards proposed in the Amendment.

iii) Risk management (IFRA):

- Address with the IFRA Scientific Committee the specific problem of the Maximum Pragmatic Level. This approach should be revoked and only the true QRA levels should be reported in all IFRA Standards.

- Ensure with the help of the IFRA Scientific Committee that all progresses made on the Dermal Sensitization QRA are implemented in the existing IFRA Standards without undue delay. The revision of SAFs and the development of the new RIFM aggregate exposure model should be carefully monitored.

- Set a working group to develop creative solutions in view to better inform the consumer on the presence of potential fragrance allergens in consumer products. The existing communication procedure between the dermatologists and the industry will be extended to more countries and strengthened in view to improve the flow of information between practitioners and the fragrance houses when a fragrance compound is the suspected cause of a skin reaction. The strategic intent behind this communication plan being to ensure that products on the market are safe and comply with scientifically well-founded risk reduction measures, keeping the risk of fragrance allergy to a minimum.

iv) Discussions with the regulators and trade associations (IFRA):

- Continue the dialogue with the regulators and explain that several markets (e.g. aromatherapy, OTC products) are independent of the fragrance industry.

- Continue the dialogue with the trade associations responsible of these markets (e.g. Association of the European Self-Medication Industry). Explain to these associations that the Dermal Sensitization QRA should be applied wherever it is applicable and appropriate risk management measures should be implemented elsewhere to prevent induction as much as possible.