IDEA Annual Review 2013

EUROFORUM building (EUFO)
10, rue Robert Stumper
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During the Annual Review several issues were highlighted by the attendees. In particular:

General remarks

- The IDEA project is an excellent initiative but the process, at least for some aspects and to ensure delivery of quality results, will take several years – this should not hinder important interim measures to be taken.
- Measures taken by the industry on the specific material HICC maybe not always have been adequate or timely in the past. This experience is maybe not a good example to judge on effectiveness of risk management measures but can serve as an excellent case study for the IDEA project.
- The QRA is a promising tool but still to be regarded as under development and further refinement is needed. -Based on the recommendations made in March 2013, the Industry has invested a lot of resources in revamping the QRA. Most of the work is now completed and a comprehensive report of the improvements incorporated into the methodology will be presented at the second QRA workshop to be held in March 2014. The basic elements of the QRA approach were shortly summarized, for more information on the QRA methodology see: http://www.ideaproject.info/QRA-methodology
- As a not directly related topic, challenges to performing risk assessments on fragrance compounds (trade secret protection limited resources and expertise of SME's etc.) were mentioned.
- The new regulation on fragrance allergens for some elements will rely on the QRA methodology, which requires the availability of a revised QRA methodology by June 2014.

Involvement of SCCS, JRC and the Supervisory group

- The respective roles of JRC and SCCS will have to be clarified for what concerns the scientific assessment of the QRA and its subsequent application.

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- SCCS members pointed out that in the IDEA Annual Review their role would be that of observers. In parallel the Chair of the IDEA Supervisory Group reminded all the IDEA workshop participants that their contribution as experts was expected.
- Jim Bridges, Chair of the IDEA supervisory Group offered to be in dialogue on any concerns regarding transparency of the process or other concerns related to how IDEA is executed, as we are still on a learning curve.
- Role of the Supervisory Group might further evolve.

Human data

- Good human data are of highest relevance - Patch testing (properly conducted diagnostic patch tests) is the gold Standard for clinical data requiring expertise and should only be done by experienced dermatologists.
- Contact allergy is the relevant endpoint, when there is a rise following exposure to a particular fragrance this is a demonstration that consumers have been exposed to a too high level.
- Establishment of contact points to scrutinize clinical reports for plausibility is most welcomed; industry needs to critically follow the published literature and dermatologists should be encouraged to participate in projects to feedback to the industry the results of patch testing before publication.
- Retrospective analysis on important datasets from trusted data centers such as ESSCA (European Surveillance System of Contact Allergies) are essential to understand the skin sensitization potential of individual fragrance allergens, inform the risk assessment process and, possibly develop structure-activity models.

HRIPT

- The HRIPT is not used as a predictive tool by the industry but only as a confirmative tool, this should address ethical concerns.
- An HRIPT on 100 people needs to be critically looked at with regard to its predictive value for the general population.
- Common practice is to test the finished product in HRIPT to ensure that it does not cause induction of skin sensitization. However, while an HRIPT conducted on 100 volunteers (and resulting in no reaction) can be regarded as a good background, it does not offer the guarantee that the finished product will never cause skin sensitization issues. Therefore, cosmetovigilance is a very important post-marketing tool to ensure that the safety assessment of products adequately protect consumers.

Inter-individual differences

- Inter-individual variability, which came up at all three workshops, is important to look into more deeply It is recognized that in the clinics there is a focus on the high end of sensitization due to the selected population.

- The observation that some people are sensitized to a chemical and do not develop the pathology and why others do is an important topic still to be better understood.

Exposure

- Clinical data should be linked as much as possible with information about exposure of a material to the general population as this leads to additional important information in ranking priorities.
- Assessing consumer exposure adequately and with a set of harmonized tools remains a big challenge across all types of industry sectors and regulations – A broad EU survey to generate a standard set of habits and practices of consumers would be very useful.
- The Industry has developed a promising model aiming to evaluate the aggregate exposure of consumers to fragrance allergens – this model was presented at the first IDEA workshop and a proposal made for its incorporation into the QRA will be presented at the March 2014 workshop.

Pre- and pro-haptens

- For the pre- and pro-hapten discussion it was recommended to also look into the role of transporters. The question will be posed to the workshop participants and addressed at the next IDEA workshop on pre- and pro-haptens if needed.
- The pre- and pro-hapten problematic is not specific to fragrance ingredients and most of the conclusions developed during this workshop are also valid for other types of substances.
- Many uncertainties remain on the complicated topic of pre- and pro-haptens. Further scientific investigations and deeper insight will be necessary before usable risk assessment methods become available.
- Some materials can be both pre- and pro-haptens, which can be activated inside and outside the skin – while pre-hapten formation can be prevented, that of pro-haptens most likely cannot.
- Oxidation might not only contribute to increased haptens but consideration should also be given to other effects potentially caused by the radical mechanism linked to it.
- The work on a joint development of a broadly applicable analytical method for the determination of hydroperoxides has not yet started. There will be an open call to the IFRA workshop participants for participation. Many hurdles need to be addressed, starting with the availability and even transportation of adequate standards.