Training and Knowledge-sharing Workshop: Applying non-animal strategies for assessing skin sensitisation

A joint EPAA/Cefic-LRI/IFRA Europe workshop

FLASH REPORT

The most recent in a continuing series of workshops on skin sensitization was co-organised by EPAA, Cefic LRI and IFRA Europe and once again hosted in Helsinki by the European Chemicals Agency (ECHA) on February 7th and 8th, 2019. More than 60 participants participated in the event, half from ECHA and EU member state regulatory agencies and the other half from a variety of industry sectors. Progress on the use of non-animal test data in hazard identification and classification, including for potency sub-categorisation and risk assessment was presented and discussed, particularly with regard to the practical experience that has been generated in the almost 4 years since the previous event.

Since the last workshop, several tests addressing key events (KE) 1, 2 or 3 of the adverse outcome pathway (AOP) have been adopted as OECD Test Guidelines. **Moreover, since 11 October 2016, the new REACH requirements for skin sensitisation entered into force making non-animal testing the default requirement.** In addition, the concept and examples of defined approaches for skin sensitization were presented (DASS). Some of these may, in the future, achieve OECD test guideline status and be accepted under the MAD (Mutually Accepted Data) criteria. In response to these developments, on the 7th February, industry and regulatory groups gave presentations outlining their experience with these alternative methods, particularly in respect of hazard identification and potency sub-categorisation. It became clear that the experience has been both positive and negative: ECHA noted the increasing emergence of submissions which use in vitro skin sensitisation data, sometimes exclusively, to make decisions; the SCCS representative reported that they had yet to see such a submission; industry sectors detailed how certain classes of substance were easier to test compared to the older in vivo methods, whereas others have proven problematic. Finally, industry presentations provided some insights into aspects that may be relevant in potency characterisation.

On February 8th, three break-out groups addressed key questions, which were followed by an open workshop discussion. These questions were largely of a practical nature, exploring how to deal with difficult substances, with conflicting/discordant data and how to progress from hazard identification, through potency subcategorization to full spectrum potency determination as a prelude to (quantitative) risk assessment.

The overall output from the break out groups was collated into a number of key points:

- On the topic of difficult substances to test and/or assess, the general feeling of the Workshop was that the first response should be intellectual, rather than simply carrying out more test work. To this end, increasing the focus on understanding the relevant chemistry underlying a particular skin sensitisation problem was encouraged, as was understanding the (physicochemical) properties leading to difficulties.

- There was general agreement that the existing in vitro methods and defined approaches would be able to deliver sufficient knowledge to permit potency sub-categorisation, but there remains a need to build confidence.
- Related to the above, the Workshop recognised the need for a reliable and substantial database of substances, categorised according to potency, using all the available data (mouse, human, guinea pig).
- There was a general consensus that, after validation/acceptance, new methods should be reviewed after perhaps 3-5 years to gain a better understanding of their real life performance with a wider range of substances.
- The review mentioned above should also be used to refine the original applicability domain of a test (or, if appropriate, a defined approach).
- In order to progress the evaluation of different approaches for the characterisation of potency and risk assessment, the participants highlighted the benefit of sharing case studies between the users and regulators.
- All participants agreed that the series of meetings offered a valuable opportunity for industry and regulators to have a free and unfettered discussion. However, there was also agreement that there was a need for a "user forum", where those doing and interpreting tests would be able to regularly exchange best practice and experience and to debate individual sets of test results. Such a forum would help to build confidence and develop consensus approaches.
- The meeting also noted several ongoing activities (e.g. the OECD activity on Defined Approaches) and planned events (e.g. the EPAA Forum event on skin sensitisation on 28 October 2019).

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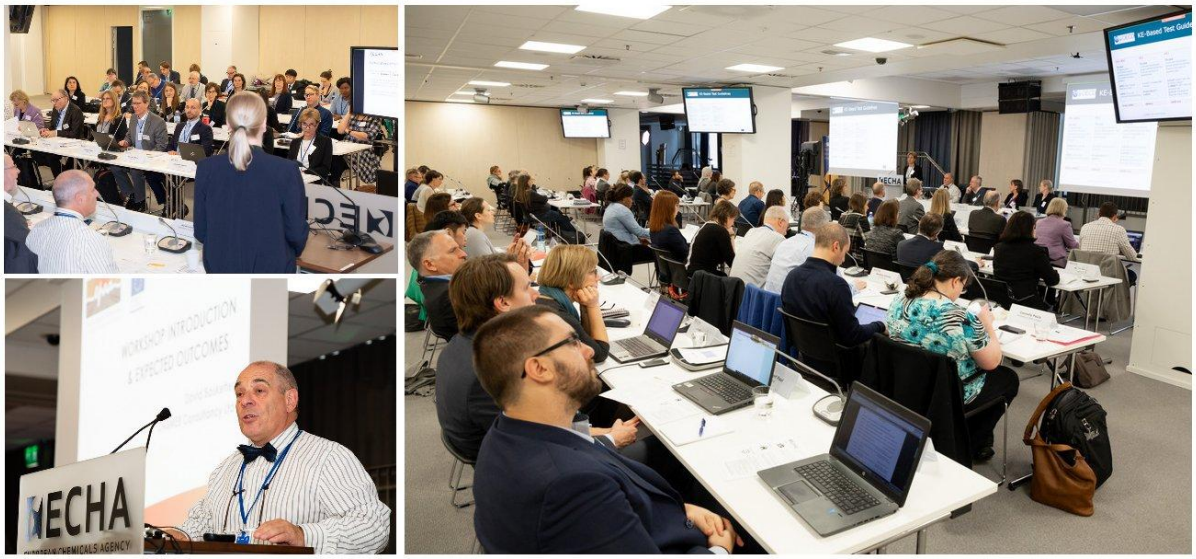

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About EPAA

EPAA is a Public-Private Partnership across seven industry sectors and between European Commission and Industry stakeholders. Launched in 2005, it gathers 36 companies, 7 European trade federations and 5 Directorates-General of the European Commission. Further information is available on https://ec.europa.eu/growth/sectors/chemicals/epaa_en

About Cefic-LRI

Launched 20 years ago, the Long-Range Research Initiative (LRI) is one of the major voluntary initiatives of the European chemical industry to support its competitiveness and innovation potential. LRI aims to identify and fill gaps in our understanding of the hazards posed by chemicals and to improve the methods available for assessing the associated risks.

LRI sponsors high quality research, published in peer-reviewed journals, and seeks to provide sound scientific advice on which industry and regulatory bodies will draw to respond more quickly and accurately to the public's concerns.

Further information is available on http://www.cefic-lri.org/

About IFRA Europe

IFRA Europe is the voice of fragrance ingredient manufacturers in Europe, the Middle East and Africa.

IFRA Europe is one of the four regional bodies of The International Fragrance Association (IFRA), which serves and advances the collective interests of the fragrance industry worldwide. IFRA's objective is to protect consumers, respect the environment and promote the safe use and enjoyment of fragrances.

IFRA acts as a self-regulatory and risk management body. IFRA members – representing 90 per cent of the world's fragrance production volume – adhere to local, national and international regulations as well as a strict Code of Conduct that includes the IFRA Standards. These 191 Standards govern which substances can be used, as well as the levels and circumstances of use.

IFRA develops the Standards based on scientific analysis provided by the Research Institute for Fragrance Materials (RIFM), under the supervision of an independent Expert Panel for Fragrance Safety composed of internationally renowned scientific experts.

Globally, IFRA comprises 21 national associations in four regions (Europe, Asia-Pacific, Latin America and North America) and eight regular, multinational members. We represent an industry worth approximately $10bn, serving the luxury and consumer goods sectors.

Further information is available on www.ifraorg.org