Integration of non-animal data into QRA

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(Report on the key outcome of the first IDEA Working Group meeting of April 26, 2016)

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Background

- In the context of a revision of the QRA (SAF and integration of aggregate exposure), and based on the exchange with the JRC, integration of non-animal data to replace the LLNA was identifed as an area of future work and co-operation.

- IDEA committed to place particular focus on this goal.

Status

First IDEA initiative: landscape meeting on 26th April 2016.

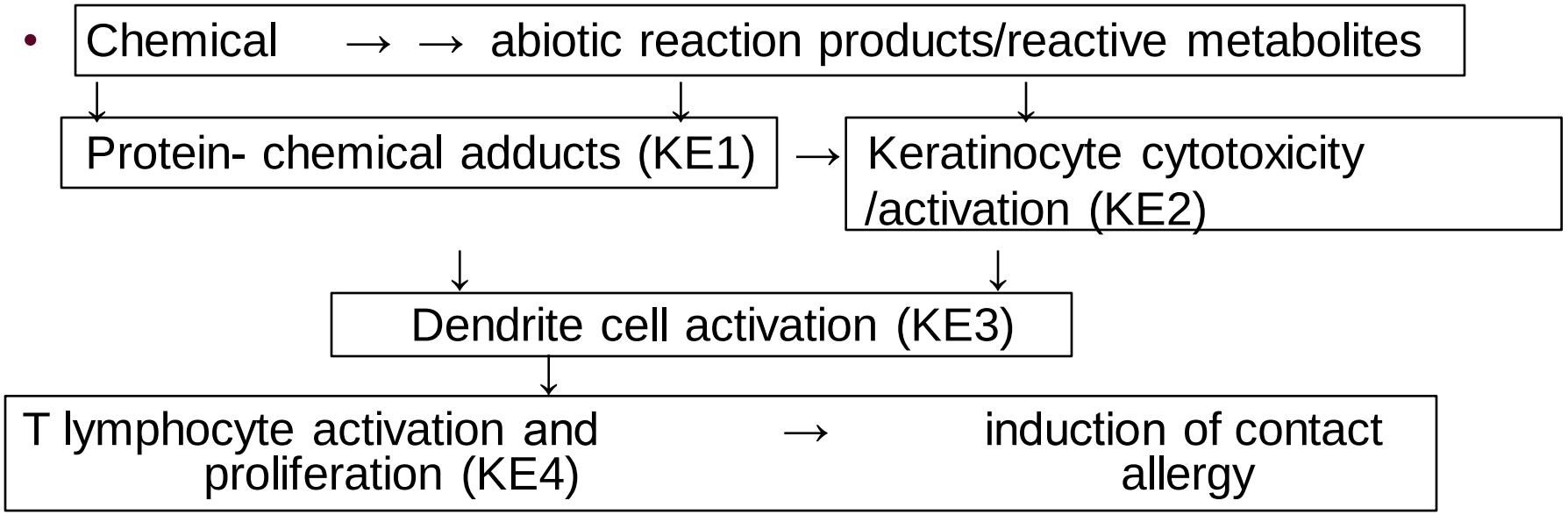
The main objectives of the meeting were to:

- Gather experts who are active in the area (present were representatives from CAAT, Cosmetics Europe, ECHA, EPAA, JRC and the fragrance industry).
- Identify the nature of the tests that are already available and/or at an advanced stage of development, and their current areas of application.
- Discuss how they should be best applied and any general issues in their application.
- Discuss how the findings of such studies should be integrated with other data for hazard/risk assessment purposes.

The meeting conclusion was that assessment of potency is still under development and to date only limited achievements have been made in this area.

Status

- General acceptance: test development and acceptance should be based on current understanding of the adverse outcome pathway(s) (AOP) / mode of action (MOA) / sequence of key events (KE's).

- 

- KE4 is nearest equivalent endpoint to that measured in the LLNA.
- However, test development has concentrated on the preceding critical events KE1, KE2 and KE3 (KE4 remains challenging).

Status

Consequently, the combination of non-animal assays representing KE1, KE2, KE3 (and KE4):

- Is largely suitable to identify hazard and perhaps hazard sub-categorization.
- Is not yet sufficiently developed to generally derive more differentiated quantitative information on potency and therefore act as point of departure for applying QRA.

Outlook

The role of IDEA would be to help identify and enable broad acceptance of an approach to skin sensitization risk assessment (QRA) in the absence of animal data, by potentially:

- Serving as organizer of meetings to review findings, identify needs and prioritize them.
- Acting as a reference point for who is doing what in the industry, research organizations and collaborative partnerships.
- Acting as provider of reference chemicals.
- Being a source of reference data (LLNA and human)
- Providing support (financial and/or administrative) for specific research and/or development topics

Outlook

Building on existing initiatives would be also fully in line with the JRC report ‚*Reducing animal testing through better knowledge sharing'* published on February 20, 2017, stating:

'There needs to be better awareness and coordination between existing knowledge sources… This could be achieved through the fostering of a network of leading knowledge providers.'

A second IDEA AAT meeting will be arranged in Q2 2017

The aim will be to agree on priority areas, identification of resources and strategy in order to move forward.

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International Dialogue for the Evaluation of Allergens

Thank you for your attention