IDEA workshop on Characterization and Categorization (C&C) of allergens

December 12, 2018

Key conclusions at the workshop

Key conclusions

- To set the scene, the group reemphasized that potency assessment (for definition of a point of departure in risk assessment e.g. NESIL) is such a complex task that all relevant data (weight of evidence) need to be considered to address the nature and degree of uncertainty.
- Doing potency assessment without animal testing, logically requires the same weight of evidence approach and reference needs to be made equally to LLNA EC3 and/or to human data on intrinsic potency.
- For the development of non-animal alternatives for potency assessment, there is a need for a reference chemical potency database integrating human, animal and *in vitro* evidence.
- As far as current validated or nearly validated methods are concerned:
  - They will not suffice alone for potency assessment.
  - Dose responses are not easily derived from current methods, but for example kDPRA could be helpful.
  - Those current methods together with other sources of information for selected chemical classes can be exploited for predicting potency in a WoE way whilst the uncertainties need to be characterised.
  - Sharing and analysing of specific case studies will help understand their applicability domain and acceptability.
  - The group recommends to assess current and future methodologies for predicting a NESIL against the reference chemical potency database.

Key conclusions

- Other groups are already looking at protein binding in the context of potency, but it might be profitable to look at other aspects of adduct formation as a correlate of skin sensitizing potency.
- There is an opportunity to explore in greater detail a possible correlation between aspects of danger signal formation (quality and quantity) and skin sensitizing potency.
- An evaluation of associations between features of dendritic cells responses and potency merits consideration. It might be useful to combine consideration of danger signal metrics with dendritic cell activation.
- It might be necessary to have a 2 tiered approach where in tier 1 hazard is identified and in tier 2, potency is assessed.

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Thank you for your attention