Changes in REACH requirements and implications

IDEA Working Group meeting on the inclusion of animal testing alternatives into QRA for skin sensitisation – 26 April 2016

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REACH Committee voting 20 April 2016

- Currently, standard information requirement is in vivo skin sensitisation test according to LLNA
- On 20 April 2016 REACH Committee voted on the revision of skin sensitisation information requirements
  (http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.dossierdetail&d+sMcTgQ8srjWjmmShg+GNN/RF3yZkLQq6UcVWvaXEWVl5Yg9827r2pFAHfU6zyn)
- Major changes included
  - In case of skin sensitisation effects noted, assessment whether the substance is presumed to be a strong sensitiser (Cat 1A) or not
  - Generation of new data shall start with non-animal testing methods, unless it can be justified that the test methods are not suitable for the substance or for C&L and risk assessment.

Implications

- Good in sense of promoting non-animal testing approaches and moving forward with the scientific developments

- Difficulties:
  - No formally approved way to address potency, few approaches proposed in the public literature
    - Implications for the registrants and regulators
  - CLP criteria based on *in chemico/in vitro* methods missing, however the general criteria of CLP allows the use of e.g. in vitro methods (Art. 5(1), 7(1), 8 and 9(1) of CLP Regulation) → inclusion into CLP (GHS) needed.

What is needed, the way forward

- As the new information requirement will came into force in Autumn 2016, reliable way to address potency is needed as soon as possible.
- To select most predictive approaches based on current knowledge and width of data sets available → however what would be the best way to get "formal" regulatory acceptability?
  - More peer-reviewed publications?
  - Narrowing the scope of the approach by substance types, as currently approaches mainly use the whole data set as it is?
  - Involving member states, and if so, in which context?

Thank you!

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