Fourth IDEA Workshop on pre- and pro-haptens

Key conclusions at the Workshop

Risk assessment framework for pre- and pro- haptens under QRA2

December 13th, 2016
The Hotel, Brussels

Framework for QRA2 – General approach

– Preamble:

The current evidence with the 3 OECD validated in-vitro tests for skin sensitization hazard indicates that approximately 80% of pre- and pro- haptens are correctly identified (following the classification strategy outlined in ECHA guidance 2016).

(Natsch et al., 2014; Patlewicz et al., 2016; Urbisch et al., 2016)

Framework for QRA2 – General approach

- Evaluate the chemistry to prepare in-vitro study plan
  - Structural alerts, in-silico tools, read-across materials
  - Physicochemical data
  - Expert judgement
- In-vitro testing adapted according to the outcome of the evaluation
  - DPRA, KeratinoSens and hCLAT
  - Consider S9 activated assays, peroxide/peroxidase assay and/or probable oxidized products
- Further considerations to refine the risk assessment
  - To what extent does the transition from pre-/pro- hapten to putative hapten occur

Framework for QRA2 – General approach

- Once the hazard is identified, there is no difference in the QRA approach for pre- and pro- haptens vs. haptens
- On pre- haptens, exposure assumptions based on analytical quantification of oxidation product with sensitizing properties together with its NESIL (derived from LLNA or alternative methods) will allow for a QRA.
- On pro- haptens, direct use of LLNA data (or alternative methods) will allow for a QRA.

Framework for QRA2 – General approach

- Examples: one slide per material
  - Linalool – (action for Andreas Natsch)
  - Isoeugenyl acetate - (action for Andreas Natsch)
  - Cinnamyl alcohol - (action for Petra Kern)

IDEA

International Dialogue for the Evaluation of Allergens

Thank you very much for your attention