

Background and Purpose of the Workshop

IDEA RCPL Application 2nd Workshop

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Reference Chemical Potency List (RCPL): A new tool for evaluating the accuracy of skin sensitisation potency measurements by New Approach Methodologies (NAMs)

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Purpose

- Provide an informal platform for discussion of progress that is being made using different methods, and to explore whether the RCPL is of value in helping in the evaluation of approaches designed to measure sensitising potency.
- Explore whether the RCPL is helpful in allowing the users of NAMs/combination of NAMs and regulators / independent scientists to gain trust in these approaches so that they can be used with more confidence for new / data poor materials to derive a potency value that directly or after modification can be used as point of departure in the QRA.
- Workshop discussion dissemination plan.

Background

- Typically, safety evaluation addresses the safety of a specific ingredient that possesses a toxicological hazard in the context of an intended product type. In other words, such a question as “Is 0.2% of ingredient X safe in a skin cream?”
- However, for fragrances, the scope is much larger, in effect where the industry producing ingredient X proactively identifies safe use levels for a wide range of product types.
- QRA2 is applied, together with the most up to date aggregate exposure data, to define maximum acceptable concentrations for a wide range of products in the IFRA Standards.
- In the current framework, the point of departure for QRA2 calculations, is called the No Expected Sensitisation Induction Level (NESIL), to which Sensitisation Assessment Factors (SAFs) are applied.

Aim

- The challenge is to define a 'NESIL' from the outputs of NAMs.
- Therefore, characterisation of the potency output from NAMs by deriving a discrete value is key for the application of QRA.
- The question then is how accurate is NAMs output compared to reference in vivo animal and/or human data?
- Since RCPL is a carefully curated reference which is based on consideration of the best available human and animal data, could the RCPL PVs be used to help answer this? If so, how?
- This workshop aims to be a first step in addressing these questions.