

GLOBAL SKIN HEALTH

NEXT GENERATION RISK ASSESSMENT FOR CONSUMER PRODUCTS

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Introduction: A key principle of Next Generation Risk Assessment (NGRA) is that modern, non-animal risk assessments should be exposure-led. This means that in vitro methods that are used to make decisions about human safety must be quantitative, so that any predictions relating to dose can be interpretable in the context of actual levels of consumer exposure. Interpreting dose-response data from in vitro toxicity assays requires an understanding of both cellular exposure in the in vitro assays and how these relate to in vivo concentrations (local or systemic).

Objective: To demonstrate NGRA approaches through application in risk assessment case studies for inclusion of ingredients in cosmetic product scenarios to assure consumer safety without the use of any animal data.

Materials and methods: An exposure-led, tiered NGRA approach was applied. Initial assessment of applied dose was refined using in silico modelling approaches e.g.: Physiologically Based Kinetic (PBK) Modelling. Dose response information relating to toxicity was generated using several in vitro approaches e.g.: cell stress responses.

Results: In vitro to in vivo extrapolation was achieved through appropriate experiment design and detailed knowledge of the consumer exposure habits and practices. Decisions on consumer safety were determined through integration of multiple data types from a variety of NGRA approaches.

Conclusions: The case study approach demonstrates our increasing confidence in the application of NGRA approaches for cosmetics consumer safety.