

Integrating NAMs for Quantitative Skin Sensitization Potency Assessment into Regulatory Frameworks: Experience from the Work in OECD TG 497

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Understanding the potential for skin sensitization hazard and potency of chemicals is required for their acceptance and use. This need applies to a range of consumer use products and agricultural and industrial chemicals, all having different regulatory contexts. As animal testing is being limited or eliminated globally, the need for harmonized nonanimal testing approaches to address these endpoints has increased. The Organisation for Economic Cooperation and Development (OECD) develops test guidelines that fulfill these needs. These guidelines fall under the OECD principle of Mutual Acceptance of Data, a system that ensures that quality data produced within one country is accepted in other countries subscribing to the system. OECD Guideline 497, “Defined Approaches on Skin Sensitisation,” published in 2021 was a first-of-its-kind guideline that provided three defined approaches (DA) for predicting skin sensitization hazard and potency categorization under the United Nations Globally Harmonized System of Classification and Labelling of Chemicals. DAs apply fixed data interpretation procedures to data generated with a defined set of information sources and derive predictions without the need for expert judgment. Recently, OECD has undertaken the evaluation of skin sensitization models that can predict a quantitative point-of-departure (PoD) for inclusion in Guideline 497, adding an additional endpoint to the guideline. These models can provide human-relevant PoDs that can be subsequently applied within regulatory risk assessment frameworks. This presentation will provide a brief outline of the process by which new test guidelines are evaluated by OECD for development, using Guideline 497 and its ongoing expansion as a case study. The specific focus of the discussion will be OECD evaluation of new DAs for inclusion in a test guideline, using the Skin Allergy Risk Assessment – Integrated Chemical Environment (SARA-ICE) DA as an example. The presentation will also consider how to utilize this quantitative PoD in a subsequent risk assessment. This project was funded in whole or in part with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C. The views expressed above do not necessarily represent the official positions of any federal agency.