OECD Defined Approaches Focusing on Skin Sensitization

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Presenter biography

Dr. Judy Strickland is a Principal Toxicologist at Inotiv, Inc., with 21 years of experience in evaluating alternative test methods that reduce, refine, or replace animals in regulatory test methods on the support contract for the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). She is excited about recent developments in alternative approaches for skin sensitization assessment because non-animal methods are now accepted to meet some regulatory requirements. Methods for integrating multiple sources of non-animal data have effectively increased the confidence in relying on such information.

Dr. Strickland is currently coordinating a validation study of an *in chemico* skin sensitization method. She serves on the Organization for Economic Co-operation and Development (OECD) Expert Group on Skin Sensitization and the Expert Group on Defined Approaches for Skin Sensitization. In the past, she provided technical support to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) evaluations of multiple modifications of the local lymph node assay, an animal reduction method for regulatory skin sensitization assessment and served on the OECD Consultation on the Local Lymph Node Assay.

Dr. Strickland is a member of the Society of Toxicology and the American Society for Cellular and Computational Toxicology. She received a Ph.D. in pharmacology from East Carolina University and an A.B. in chemistry from Duke University. She is a Diplomate of the American Board of Toxicology.

Presentation abstract

There are multiple globally harmonized test guidelines for skin sensitization potential based on *in chemico* and *in vitro* methods that reduce the use of animals for skin sensitization testing, but none are recommended as a complete replacement for animal tests. However, this can now be accomplished thanks to defined approaches (DAs) that integrate data from multiple non-animal methods to make a classification decision. In 2021, the Test Guidelines Programme of the Organisation for Economic Co-operation and Development issued Guideline No. 497, Guideline on Defined Approaches for Skin Sensitisation, to implement these approaches for skin sensitization assessments. Development of the new guideline was sponsored by the United States in collaboration with scientists from Canada and the European Union. This guideline represents a new type of product for OECD and will enable a non-animal approach to identifying potential skin sensitizers to be used worldwide. The guideline currently includes the direct peptide reactivity assay, KeratinoSens™, the human cell line activation test (from Test Guidelines 442C, D, E, respectively), and two *in silico* models that are integrated into three DAs: one DA for hazard classification only, and two DAs that can predict both hazard and potency categorization. Validation against curated human and animal data sets indicate that these approaches predict human skin sensitization hazard and potency categories better than the preferred animal test, the local lymph node assay. Future work will evaluate additional individual *in chemico* and *in vitro* methods for inclusion in the defined approach test guideline as well as an approach to support quantitative potency assessments for risk assessment purposes. This work was supported with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C.