Validation of the Electrophilic Allergen Screening Assay (EASA)

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The electrophilic allergen screening assay (EASA) is an in chemico assay to assess skin sensitization potential. The EASA uses nitrobenzenethiol (NBT) or pyridoxylamine (PDA) probes as surrogates for thiol- or amine-based proteins to mimic chemical binding to proteins, the initial key event in the adverse outcome pathway for skin sensitization. Probe depletion is measured by absorbance or fluorescence. A test substance is positive when it meets the positive depletion criterion for either NBT or PDA but negative when the depletion fails to meet the positive criterion for both probes. The U.S. Consumer Product Safety Commission (CPSC) and the National Institute of Standards and Technology (NIST) modified the original cuvette-based EASA into a 96-well format. Four laboratories participated in a validation study of the 96-well test: the Food and Drug Administration Center for Devices and Radiological Health, the U.S. Department of Defense Public Health Center-Aberdeen, Burleson Research Technologies, and CPSC/NIST (lead laboratory). The laboratories tested 20 coded reference chemicals from the OECD performance standards for the direct peptide reactivity assay and amino acid derivative reactivity assay test methods. Of these, 12 chemicals were tested three times to evaluate intralaboratory reproducibility. Performance of the EASA was evaluated by comparison with local lymph node assay outcomes. The results suggest that the EASA may be a useful non-animal alternative to identify potential skin sensitizers. This project was funded by NIEHS under Contract Nos. HHSN273201500010C and HHSN27320140017C. The views expressed above do not necessarily represent the official positions of any federal agency.