Developing a Defined Approach for Eye Irritation Testing

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Regulatory acceptance and implementation of new approach methodologies depend on public-private partnerships, which allow communication and cooperation among federal agencies and the private sector. To that end, the PETA International Science Consortium Ltd., the Interagency Coordinating Committee on the Validation of Alternative Methods, the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, and CropLife America companies are collaborating on a three-phase evaluation to assess the applicability of in vitro eye irritation test methods to assess eye irritation potential for agrochemical formulations. Six formulations with existing in vivo data, classified as non-irritating (US Environmental Protection Agency [US EPA] Category IV) or severely irritating (US EPA Category I) were tested in Phase 1. The formulations were tested in the bovine corneal opacity and permeability (including histopathology), neutral red release, isolated chicken eye (including histopathology), EpiOcular (eye irritation test and time-to-toxicity protocols), and porcine cornea reversibility test methods. Each method predicted the same category as the rabbit test for most of the tested formulations, showing promise for further testing. Ten additional agrochemical formulations with in vivo data, representing a wider range of eye irritation classifications (US EPA Categories I, II, III, and IV), were evaluated in Phase 2. While none of the methods directly correlated with the in vivo results, several methods showed potential for use in a defined approach to assess agrochemical formulations. Phase 1 and 2 results will be used to identify which methods will be evaluated in Phase 3 and can form the basis of a defined approach for testing of agrochemical formulations for eye irritation potential. This project was funded with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C.

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