

Ensuring Transparency and Rigor in the Peer Review of New Approach Methods for Skin Sensitization Assessment

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As new methods to assess chemical safety are developed, independently conducted validation and peer review panels provide the necessary oversight and guidance to confirm that a new method is robust, reliable, relevant, and reproducible. Historically, these efforts have been conducted under the oversight of validation organizations such as those overseen by government bodies of the European Union, the United States, and Japan. These organizations conduct comprehensive validation and review processes under the guidance of a validation management team and peer review panel. However, historic approaches often fail to keep pace with the rapid development of new methods. To address this need, the Organization for Economic Cooperation and Development (OECD) has called for increased validation funding and expanded activities outside of the validation organizations. Without proper structure and oversight, this could result in the absence of a formalized validation management team and peer review panel. Given the need for a comprehensive peer review process to assure validity of new methods, this raises questions of how to support an independent peer review without creating a conflict of interest associated with the funding source, particularly when the validation is funded by the test developer. In this presentation, we will discuss the design, conduct, and lessons learned from a first-of-its-kind test method developer-funded peer review. We will focus on how the peer review panel approached the initial request, designed a transparent process, and conducted the peer review while ensuring independence of the panel and the peer review report. The talk will highlight areas where steps could be streamlined to increase efficiency of the panel and document review, including recommendations on timing of data audits, packet completeness assessments, validation document review and updating, and formal development of the report.

While in this review the panel maintained its independence and transparency, there was the potential perception of a conflict of interest given that the review was funded by the test method developer. These perceptions required the review organizers to plan carefully to alleviate independence concerns. This aspect of the review will be the focus of a discussion on a proposed new paradigm for peer review. Throughout this talk and after, participants in the session will have opportunities to address questions raised by the case study and discuss future directions and ideas to both improve the efficiency and clarify the appropriate approaches to support new ideas around formal validation that can be adopted by OECD and regulatory authorities. 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.