

The ICCVAM Process for Validation and Evaluation of New and Alternative Methods

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New and alternative test methods must undergo adequate validation and independent scientific peer review before they can be considered for regulatory acceptance. In the United States, ICCVAM is charged with reviewing and evaluating new, revised, and alternative test methods, and providing recommendations on their scientific validity to regulatory authorities. ICCVAM established and uses validation and regulatory acceptance criteria and processes that it developed in conjunction with federal agencies and other stakeholders. These criteria have now been incorporated into internationally harmonized guidance. The ICCVAM review and evaluation process is highly transparent and allows for public stakeholder involvement throughout. Independent scientific peer review panels of experts without conflicts of interest meet in public session to assess the adequacy of validation studies, and to make recommendations regarding the demonstrated usefulness and limitations of test methods. ICCVAM prepares final test method recommendations after considering the peer panel report, public comments, and comments from its advisory committee. The ICCVAM process facilitates the adoption of scientifically sound test methods that will reduce, refine, or replace animal use and ensure the continued protection of human and animal health and the environment. This abstract reflects the view of the authors and does not represent the official position of any federal agencies.