

JaCVAM annual report in 2013

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Summary

In 2013, a Japanese Center for the Validation of Alternative Methods (JaCVAM) has been accepted five test methods by the JaCVAM regulatory acceptance board, including: 1) *In vitro* skin irritation - Reconstructed human epidermis test method, 2) Bovine corneal opacity and permeability test method for identifying i) Chemicals inducing serious eye damage and ii) Chemicals not requiring classification for eye irritation or serious eye damage; 3) Acute eye irritation/corrosion; 4) BGI-Luc estrogen receptor transactivation test method for identifying estrogen receptor agonists and antagonists, and 5) Skin absorption: *In vitro* method.

Furthermore, JaCVAM contributed to establish four OECD (Organisation for Economic Co-operation and Development) Test Guideline (TG). There is TG439 *In Vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method. In the OECD work plan, JaCVAM has proposed six test methods: 1) *In vivo* comet assay for genotoxicity testing, 2) Bhas 42 cell transformation assay, 3) Short time exposure (STE) assay for eye irritation testing, 4) Human cell line activation test (h-CLAT) assay for skin sensitization assay, 5) Endocrine disruptor screening stable transfected transcriptional activation (STTA) antagonist assay, and 6) Androgen disruptor screening Stable transfected transcriptional activation (STTA) assay (AR-Ecoscreen). The reactive Oxygen Species (ROS) assay for phototoxicity testing also described at the ICH S10 Guideline on Photosafety Evaluation. Additionally, JaCVAM is participating, along with several other international collaborators, in on-going validation studies, which include STTA antagonist test, AR-Ecoscreen, Hand1-Luc EST for the development testing, the IL-8 Luc assay for the skin sensitization testing, and SIRC-CVS test and Vitrigel-EIT for the eye irritation testing.