

Annual report on the Japanese Center for the Validation of Alternative Methods (JaCVAM) in 2018

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Abstract

In 2018, JaCVAM (Japanese Center for the Validation of Alternative Methods) proposed three test methods accepted by the JaCVAM Regulatory Acceptance Board to the regulatory agency, including: 1) In Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation: U937 Cell Line Activation Test (U-SENSTM), 2) Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals, 3) Reconstructed human Cornea-like Epithelium Eye Irritation (RhCE) test with LabCyte CORNEA-MODEL24 EIT (Eye Irritation Test) method.

Furthermore, JaCVAM contributed to approve OECD (Organisation for Economic Co-operation and Development) Test Guidelines (TGs). This is OECD Test No. 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage with LabCyte CORNEA-MODEL24 EIT. In the OECD Work plan, Japan has proposed six test methods: 1) ADRA (Amino acid Derivative Reactivity Assay) for skin sensitization testing, 2) the Reactive Oxygen Species (ROS) assay for photosafety assessment, 3) Hand1-Luc EST (Embryo Stem cell Test) for the developmental screening, 4) Vitrigel-EIT for the eye irritation testing, 5) LabCyte EPI-model24 SCT (Skin Corrosion Test) and 6) Amendment of TG437: Including of histopathological examination on BCOP (Bovine Corneal Opacity and Permeability test method).

Additionally, JaCVAM is coordinating, along with several other international collaborators, in ongoing validation studies and peer reviews, which include MITA (Multi-ImmunoTox assay) IL-2 Luc assay and IL-1 β assay for immunotoxicity, SIRC-CVS (Crystal Violet Staining) for eye irritation testing, LbL model for skin irritation testing and EpiSensA for skin sensitisation testing.