Annual report on the Japanese Center for the Validation of Alternative Methods (JaCVAM) in 2019

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Abstract

In 2019, 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* Cytotoxicity Assay for Estimating Acute Oral Toxicity, 2) *In Vitro* Test Method Predicting Ocular Irritation Potential: Isolated Chicken Eye (ICE) Test, 3) *In Vitro* Test Method Predicting Skin Sensitization Potential: ARE-Nrf2 Luciferase LuSens Test Method (LuSens Test Method).

Furthermore, JaCVAM contributed to approve OECD (Organisation for Economic Co-operation and Development) four Test Guidelines (TGs) showing below, 1) LabCyte EPI-MODEL for *In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method: TG431, 2) Vitrigel-Eye Irritancy Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage: TG494, 3) Amino acid Derivative Reactivity Assay (ADRA) for *in Chemico* Skin Sensitisation Assays Addressing The Adverse Outcome Pathway Key Event On Covalent Binding To Proteins:TG442C, 4) Reactive Oxygen Species (ROS) Assay for Photoreactivity: TG495.

In the OECD Work plan, Japan has proposed five test methods: 1) Hand1-Luc EST (Embryonic Stem Cell Test) for the Developmental Toxicity Screening, 2) Amendement of TG437: Including of Histopathlogi-cal Examination on Bovine Corneal Opacity and Permeability (BCOP) Test Method, 3) Amendment of TG458 : Androgen Receptor (AR)-EcoScreen™ Test Method to Performance-Based Test Guideline (PBTG) , 4) Amendment of TG491: Short Time Exposure (STE) Test Method for Eye Irritaion and 5) De-tailed Review Paper (DRP) for *In Vitro* Immunotoxicity Test.

Additionally, JaCVAM is coordinating, along with several other international collaborators, in ongoing validation studies and peer reviews, which include Multi-ImmunoTox assay (MITA) IL-2 Luc Assay and IL-1β Luc Assay for Immunotoxicity, LbL-3D Skin Skin Irritation Test (SIT) and EpiSensA for Skin Sensitisation Testing.