Annual report on the Japanese Center for the Validation of Alternative Methods (JaCVAM) in 2017

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Abstract

In 2017, JaCVAM (Japanese Center for the Validation of Alternative Methods) proposed five test methods accepted by the JaCVAM Regulatory Acceptance Board to the regulatory agency, including: 1) *In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER), 2) *In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method, 3) *In Vitro* Membrane Barrier test method for skin corrosion, 4) Reconstructed human Cornea-like Epithelium Eye Irritation (RhCE) test method, SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Test (EIT) and 5) Syrian Hamster Embryo Cell Transformation Assay (SHE CTA) .

Furthermore, JaCVAM contributed to approve OECD (Organisation for Economic Co-operation and Development) Test Guidelines (TGs). They are OECD Test No. 442E: *In Vitro* Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation, (iii) the Interleukin-8 Reporter Gene Assay or IL-8 Luc assay. In the OECD Work plan, Japan has proposed two test methods: 1) 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(Eye Irritation Test), and 2) the Reactive Oxygen Species (ROS) assay for photosafety assessment. Additionally, JaCVAM is coordinating, along with several other international collaborators, in ongoing validation studies and peer reviews, which include MITA (Multi-ImmunoTox Assay) for immunotoxicity、ADRA (Amino acid Derivative Reactivity Assay) for skin sensitization testing, Hand1-Luc EST (Embryo Stem cell Test) for the developmental screening, SIRC-CVS (Crystal Violet Staining) and Vitrigel-EIT (Eye Irritation Test) for the eye irritation testing、and LbL model for skin irritation testing.