

# Annual report on the Japanese Center for the Validation of Alternative Methods (JaCVAM) in 2021-2022

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## Abstract

As domestic activities in 2021-2022 1Q, JaCVAM (Japanese Center for the Validation of Alternative Methods) proposed to the regulatory agency two test methods approved by the JaCVAM Regulatory Acceptance Board, i.e., “Alternative Method for Assessing Skin Corrosion Potential Using a Reconstructed Human Epidermis (RHE), LabCyte Epi-MODEL24” and “Alternative Method for Assessing Eye Irritation, Vitrigel®- EIT Method”.

As activities in OECD, first, JaCVAM contributed to review two Test Guidelines (TGs) and their approval by OECD (Organisation for Economic Co-operation and Development), i.e., 1) Vitrigel®-EIT Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage: TG494, 2) *In Chemico* Skin Sensitisation: Assays addressing the Adverse Outcome Pathway Key Event on Covalent Binding to Proteins, the Amino Acid Derivative Reactivity Assay (ADRA): TG442C .

The second, JaCVAM is cooperating with OECD to develop the TGs and Guidance Documents (GDs) for their approval after July 2022, in accordance with the OECD Work Plan. The Work Plan includes seven test methods proposed by Japan: 1) Amendment of TG437: Including of histopathological examination on Bovine Corneal Opacity and Permeability (BCOP) test method, 2) Amendment of TG442E: Modification of IL-8 Luc assay for skin sensitisation, 3) EpiSensA for skin sensitisation, 4) Integrated Approaches to Testing and Assessment (IATA) for photosafety test, 5) Immunotoxicity test IL-2 Luc assay, 6) Immunotoxicity test IL-2 Luc Leukocyte Toxicity Test (LTT), 7) Detailed Review Paper (DRP) for *in vitro* reproductive and developmental toxicity test using pluripotent stem cell.

In addition, JaCVAM is conducting validation studies and peer reviews through international collaboration, which include Multi-ImmunoTox assay (MITA) IL-2 Luc LTT and MITA IL-1 $\beta$  Luc assay for immunotoxicity, EpiSensA for skin sensitisation and MylcMAT for pyrogenicity.