

Annual report in 2012 on the Japanese Center for the Validation of Alternative Methods (JaCVAM)

Hajime Kojima¹, Akiyoshi Nishikawa²

¹Japanese Center for the Validation of Alternative Methods,
National Institute of Health Sciences, Japan

²Biological Safety Research Center, National Institute of Health Sciences, Japan

Summary

During 2012, the JaCVAM (Japanese Center for the Validation of Alternative Methods) Regulatory Acceptance Board accepted five test methods, including 1) the reduced local lymph node assay (rLLNA), 2) the LLNA:DA, a non-radioactive modification of the LLNA, which quantifies adenosine triphosphate (ATP) content via bio-luminescence as an indicator of lymphocyte proliferation, 3) the LLNA:BrdU enzyme-linked immunosorbent assay (ELISA), a non-radioactive modification of the LLNA test method, which utilizes non-radiolabelled 5-bromo-2-deoxyuridine (BrdU) in an ELISA-based test system to measure lymphocyte proliferation, 4) the fluorescein leakage assay for eye irritation testing, and 5) the reconstructed human epidermis test method, EpiDerm and SkinEthics for *in vitro* skin irritation testing.

JaCVAM also contributed to the establishment of four Test Guidelines (TG) for the Organisation for Economic Co-operation and Development (OECD), including 1) TG No. 457, BG1Luc Estrogen Receptor Transactivation Test Method for Identifying Estrogen Receptor Agonists and Antagonists, 2) Revised TG No. 455, Performance-Based Test Guideline for Stably Transfected Transactivation *In Vitro* Assays to Detect Estrogen Receptor Agonists Test, 3) Revised TG No. 405, Acute Eye Irritation/Corrosion and 4) TG No. 460, Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants.

JaCVAM is currently coordinating and supporting the validation studies and peer review of several tests in accordance with the ICATM (International Cooperation on Alternative Test Methods) framework. Methods currently undergoing international peer review include the Bhas 42 cell transformation assay, the short time exposure (STE) test method for eye irritation testing, *in vivo* comet assay for genotoxicity testing, and the reactive oxygen species (ROS) assay for phototoxicity testing. Additionally, JaCVAM is currently collaborating with other international organizations in ongoing validation studies, which include the human cell line activation test (h-CLAT) for the skin sensitization testing, the IL-8 Luc assay for the skin sensitization testing, the stably transfected transactivation assay (STTA) antagonist test for screening of endocrine disruptors, and the Statens Seruminstitut rabbit cornea (SIRC) crystal violet staining (CVS) for eye irritation testing.