

Current Activities on Alternative Research in Japan

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ABSTRACT

For the promotion of 3R's principles of alternative methods, EU and US established ECVAM and ICCVAM for the evaluation and validation of alternative methods, respectively. This is because reliability and relevance of alternative methods should be determined by intra- and inter-laboratory validation for their regulatory acceptance. Appropriate procedures of the validation and regulatory acceptance of alternative methods were recommended by OECD in 1996. It is difficult to prepare data to satisfy the requirement by single laboratory or company. Therefore, it is recommended to establish similar institute in Japan like Japanese Center for the validation of alternative methods (JaCVAM). However, there is not enough resources in Japan. It is necessary to cooperate with Japanese Society of Alternatives to Animal Experiments (JSAAE) and Japanese industry group like Japanese Cosmetic Industry Association (JCIA). JSAAE is the only scientific community that is specified to research on alternatives. It has been contributing to the communication between scientists and animal protection groups during these 20 years. Research group supported by the Ministry of Health, Labor, and Welfare has been cooperating with JSAAE to develop and evaluate new alternative methods. We are expecting that the establishment of JaCVAM will contribute to the valid alternative test methods originated in Japan. JaCVAM is going ahead according to current Validation or Peer Review as shown in Table 1.

Table 1 Current Validation or Peer Review in JaCVAM

Test method	Maerial	Current
Photoxicity	Yeast-RBC	Planning on Step-up Validation
Skin sensitization	LLNA-DA	Validation in progress
	LLNA-BrdU	Planning on Validation
	H-CLAT	Pre-validation in progress
Corrocivity	Culture model	Peer Review
Skin irritation	Culture model	Planning on Peer Review
Endocrine distrupter	Lumi-cell"ACER-estrogen reporter assay	Planning on Validation(International)
Mutagenicity	Comet assay	Planning on Validation(International)

EDUCATION

1982 Gifu University, Gifu, Japan

Biochemistry Bachelor

1984-1986 National Institute of Genetics, Mishima, Shizuoka, Japan

Mutagenicity

1996 Nagasaki University, Nagasaki, Japan

Mutagenicity Ph.D.

EXPERIENCE

2001,5-2005,11 Assistant Manager, Research Laboratories, Nippon Menard Cosmetic Co, Ltd

2003.2-current Visiting Lecturer, School of medicine, Fujita Health University 2005.11-current National Institute of Health Sciences Director, JaCVAM

PUBLICATION

- 1. <u>H. Kojima</u>, T. Katada, S. Nakata and H. Konishi, Which cytotoxicity tests are useful for prediction of skin irritation by surfactants? *Altern. Animal Test.* EXperiment, 6,79-88 (2000)
- Z. Xie, R. Hayakawa, M. Sugiura, <u>H. Kojima</u>, H. Konishi, G. Ichihara and Y. Takeuchi, Experimental study on skin sensitization potencies and cross-reactivities of hair-dye-releated chemicals in guinea pigs, Contact Dermatitis, 42, 270-275 (2000)
- 3. N. Akaza, <u>H. Kojima</u>, T. Katada, S. Nakata, H. Konishi, T. Ishizeki, Bokinbobai, 1, 3-11 (2002)
- 4. <u>H. Kojima</u>, Inhibitory effects of plant extracts on photoxicity of environmental air pollutants, Fragrance Journal(in Japanese), 2002-7, 44-50
- I. Sonoda, H. Kojima, A. Sato, M. Terasawa, M. Goda, M. Hori, Y. Okamoto, M. Mizuno, N. Imai, M. Takei, N. Uetake, M. Goto, R. Kawabata, Y. Sasaki, K. Ukawa, N. Ozawa, T. Suzuki, M. Usami, T. Kasahara, K. Goto, H. Torishima, H. Takahashi, T. Ishibashi, N. Morikawa and I. Yoshimura, A prevalidation study for three-dimensional cultured human skin models as alternative to skin irritation testing, Altern. *Animal Test*. EXperiment, 8, 91-106 (2002)
- K. Kawai, I. Yoshimura, I. Sonoda, M. Nakagawa, K. Suzuki, M. Kaniwa, N. Katoh, H. Itagaki, M. Okuda, <u>H. Kojima</u>, K. Matsunaga, K. Washizaki and M. Ito, Study on the reliability and reproducibility of visual assessment for human skin irritation test,

- Environ Dermatol, 10, 145-155 (2003)
- H. Kojima, Present and future of alternative to skin irritation testing in Japan, Fragrance Journal (in Japanese), 2005-2, 43-52
- 8. <u>H. Kojima</u>, Considerations regarding the importance of *in vivo* data for the development of an alternative to conventional skin irritation testing *Altern. Animal Test. Experiment*, 11, 31-38 (2005)
- N. MORIKAWA, K. MOROTA, M. SUZUKI, H. KOJIMA, S. NAKATA, and H. KONISHI Experimental study on a novel chemical application procedure for in vitro skin corrosivity testing using the Vitrolife-SkinTM human skin model, *Altern. Animal Test.* EXperiment, 11, 68-78 (2005)
- K. Futaki, N. Akaza, <u>H. Kojima</u>, I. Ishi, S. Nakata, H. Konishi, H. Akamatsu, R. Kamide, The effects pf Vitamins on the growth and lipase activity of Propionibacterium acnes, J. Dermatology, 115, 1805-1813 (2005)
- 11. N. Akaza, H. Kojima, I. Ishi, S. Nakata, H. Konishi, H. Akamatsu, T. Nishijima, DNA-typing of Propionibacterium acnes, J. J. Dermatology, 115, 2381-2388 (2005)
- 12. K. Kubo, F. Hamajima, M. Katoh, KI. Hata, H. Kojima and H. Konishi, Comparative study of 3-mimensional culturede epidermal model and skin model for an alternative to skin irritation, Fragrance Journal (in Japanese) 2006-1, 56-60 (2006)