

Contribution to 3Rs by Japan Cosmetic Industry Association

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3Rs' activities by Japan Cosmetic Industry Association (referred as JCIA hereto) is featured mainly by the development of alternative testing (for the Replacement of animal testing), as well as other activities such as collection of information related with Alternative Testing. These are tasks of Alternatives for Animal Testing Task Force as well as Safety Subcommittee which is the superior organization of the task force. JCIA has been contributed to the development of alternative methods by participating to the validation of *In vitro* eye irritation test, drafting the guidelines incorporating this validation results, submitting comments to draft OECD safety guidelines, and also participating to the Scientific Research Group of the Ministry of Health, Labour and Welfare. JCIA takes an active role from the beginning as one of special supporting members in the Japanese Society for Alternatives to Animal Experiments (JSAAE) providing updated information on alternative methods and international regulatory progress related with animal testing. JCIA also published a document titled "The present status of alternatives to animal experiments" in JCIA Technical Bulletin (No.91) in 1990, followed by "Guidance for Cosmetic Safety Evaluation 2001", incorporating alternative testing methods. This Guidance has been revised in 2008.

JCIA member companies have actively engaged in development of alternative tests as seen with various publications in the Journal of JSAAE. They are playing important roles in various committees organized in JSAAE, not only scientific contribution to researches, but also to the management of this society. There are 2 types in the development of new alternative methods by JCIA member companies: inter-laboratories research and individual in-house research. As inter-laboratories research, there are the validation of a skin irritation alternative method using 3D human skin model (commercialized kit), 3T3 NRU PT assay, and *In vitro* sensitization tests using expression patterns of CD86/CD54 in cultured cells as indices. As JCIA member companies' individual in-house research, various methods substituting Acute toxicity, Eye irritation test, Skin irritation test, Phototoxicity test, Sensitization test, Skin absorption tests, etc have been studied since years, as ways to assess the safety of cosmetic products.

At present, there are not many alternative methods in OECD guidelines applicable to cosmetics and quasi-drugs. JCIA has established Task Force groups organized by experts of each testing method, and participate to JaCVAM Peer Review Panels and Regulatory Acceptance Board for the contribution to the adoption of OECD guidelines. However, further step is needed in the application of OECD guidelines in the safety assessment of cosmetics and quasi-drugs because these guidelines have been developed to identify the hazard with new chemicals. To solve these issues, JCIA is engaged with positive contribution to a committee organized by Ministry of Health, Labour and Welfare, titled "Committee for examination how to compile safety reports for the application of the marketing approval for quasi-drugs (referred "Committee" herein after").

As stated so far, JCIA and JCIA member companies have been made devoted contribution to substitute animal tests, by participating validation process as well as drafting of OECD guidelines, and also by having an important part in the Committee. However, it is extremely difficult to abolish all animal tests with scientific level we have today. To promote further the development and use of alternative methods, the support from various social sectors which enable further studies of basic sciences, and also in-depth discussion how to utilize the developed methods are now awaited. I believe this meeting will become the first milestone for this discussion.