

## **Reply to the Comments of the Regulation of New Chemical Substances Registration from JCIA**

Ministry of Labor (MOL) fully received and appreciated the comments from JCIA regarding the Regulation of New Chemical Substances Registration (hereinafter “the Regulation”).

Based on Article 13 of Occupational Safety and Health Act, the MOL promulgated the Regulation of New Chemical Substances Registration. It is regulated that for a new chemical substance not listed in the announced inventory, manufacturers or importers shall not manufacture or import any chemicals containing such new chemical substance prior to submitting a chemical safety assessment report and receiving registration approval for the new substance.

The device of new chemical registration is stipulated in both the Regulation and the Regulations on New Chemical Substance and Existing Chemical Substance Registration of the central authority in charge of environmental protection. To avoid the extra burdens of the registration requirements for the applicants, regulatory coordination between two agencies was considered and the registration tonnage band, registration types, and the terminologies have been greatly harmonized. However, given varying level of exposure towards the environment and the workers, tonnage bands set for information requirement on the hazard and exposure assessment are differently plotted under two regulations, to properly protect workers' safety.

With regard to the issue of the Inventory and the registration application window, two agencies are seeking continued corporation towards the frame work of “single Inventory “and a “single registration window”.

Besides, the Regulation itself does not set out relevant technical detail. Therefore, to make registration applicants have a better understanding of the compliance practices, guidelines well documenting related test standards, test exemptions, and the laboratory requirements have been announced in Chemical Registration Management Website. Related guidelines can be found at the Chemical Registration Management Website ([http : //csnn.osha.gov.tw](http://csnn.osha.gov.tw)). More unpublished practices like the CMR designated process will be revealed in the updated guidelines soon in the near future.

Lastly, MOL appreciated the work JCIA has been doing for assisting Japanese companies to have a better understanding and to comply with Taiwan's regulations. Any related inquiries and kind suggestions are welcomed through the effective channel in order to have continuing communication with MOL.