CHEMICAL MANUFACTURERS

The Chemical Manufacturers Committee appreciates the inter-agency cooperation by the Environmental Protection Administration (EPA) and Ministry of Labor (MOL) to develop a harmonized and transparent approach to the Chemical Substances Nomination and Notification (CSNN) process. We look forward to continued initiatives by the EPA and MOL to share proposed new measures related to chemical management with the relevant industrial

associations, allowing sufficient time for comments and suggestions. In the interest of the smooth and positive development of the industry, we request that the EPA and MOL make public their plans for future evolution of the regulatory structure. We also recommend that the implementation of new regulations and guidelines be treated the same way as with proposed new legislation, with a public hearing conducted at least one month in advance and with a grace period of a minimum of one year provided to industry before the new procedures are implemented.

Suggestion 1: Improve the protection of Confidential Business Information (CBI) with regard to chemical substance disclosure.

1.1 Chemical substance disclosure through the Safety Data Sheet.

Taiwan launched Phase 4 of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) on January 1, 2016, providing a one-year grace period. In line with GHS classification standards, on January 1, 2017 Taiwan will also require chemical companies to make full disclosure of health hazards on a Safety Data Sheet (SD0053). However, the level of disclosure planned for the Taiwan SDS will far exceed what is required in any other country, with some serious consequences.

The purpose of the SDS is not chemical substance disclosure but to protect labor safety, and the health and safety statements on the SDS are sufficient to indicate the degree of hazard posed by a given product. Disclosing the amount of hazard for each individual chemical substances contained in the product would misrepresent the danger posed by the product as a whole, and could cause misunderstanding and even anxiety among business customers and consumers.

Whether the disclosure of low-hazard ingredients would bring any benefit to the public is uncertain, but such disclosure could easily damage the rights and interests of manufacturers. Over-disclosure would undermine the ability to protect CBI, which is a serious issue because the process in Taiwan for applying to the authorities for CBI protection is extremely difficult and burdensome. This difficulty may deter many companies from applying, and may negatively impact innovation in Taiwan and the willingness of manufacturers to offer products in this market. If industry is unable to adequately protect its trade secrets, the introduction of new technology would be discouraged, to the detriment of the long-term competitiveness of the Taiwan industry. Moreover, it could also be seen by other countries as a trade barrier, leading to potential trade disputes.

We recommend easing the CBI application process, which can be done in ways that bring no added risk to the public. The practice in other countries, including the United States, Japan, Korea, and China can serve as reference, and a positive list of chemical substances could be disclosed with generic names. In addition, implementation next year of the Phase-4 GHS requirements will enhance public safety and help align Taiwan's practice with other countries.

1.2 CBI with regard to New Chemical Substance Notification.

Applicants for CBI protection for New Chemical Substance Notification are required to pay a fee when first applying and an equal amount again in future to extend the protection period for the same substance or to move the substance to another level of registration, for example from Simplified Registration to Small Quantity Registration, or from Small Quantity Registration to Standard Registration.

A change in the level of registration or extension of the CBI protection period should not be considered a new CBI application. For those cases, the fee should be much less than for a new application.

Suggestion 2: Reduce the requirement for toxicity tests on animals.

With increased international attention to animal rights, the global trend is to limit toxicity tests on animals to the minimum that is absolutely necessary. In the meantime, many new and advanced alternative methods are being developed for toxicity testing to reduce the need to expose animals to these risks.

In Taiwan, the Guidance for New and Existing Chemical Substance Registration issued in August 2015 permits the use of (Quantitative) Structure Activity Relationship (QSAR/SAR Estimation) methodology, a simulation software to estimate toxicity, instead of animal testing – but only for tests on physiochemical properties or for skin irritation/corrosion and eye irritation studies. For tests for toxicokinetics or TK (defined as "how a substance gets into the body and what happens to it in the body"), Taiwan continues to require reports based on extensive animal testing, which is very time-consuming and resource-intensive.

Under normal conditions, highly reliable TK data can be derived from physiochemical properties and from toxicity data and models without animal testing. Besides, for non-CMR (carcinogenic, mutagenic and reprotoxic) I & II substances, TK data is not extremely significant for making final hazard, exposure, and risk assessments. In the EU's REACH system, 75% of the registration dossiers, amounting to a total of some 6,000 dossiers so far, apply read-across methodology – a technique for predicting information for one chemical by using data from another chemical that is similar in terms of structure, properties, and/or activities. In reviewing these dossiers, the European Chemicals Agency

(ECHA) panel has expressed a high level of confidence in the data. In addition, more than 400 chemical substances and 100-plus chemical categories have been reviewed with read-across methodology under ECHA's supervision.

The Committee therefore recommends eliminating unnecessary animal testing by referring to the EU REACH experience to adopt QSAR (SAR Estimation) methodology, enabling the use of TK data derived from physiochemical properties and respective toxicity data and models.

Suggestion 3: Provide a platform to facilitate Phase II joint registration for existing chemical registration.

In the registration process for chemical substances, if companies must apply individually for each chemical they manufacture or import, the duplication will lead to an unfortunate waste of time, effort, and money – representing a burden for the regulators as well as industry. In some other markets, the authorities have addressed that problem by permitting multiple companies to jointly register a single substance. Since only the government has data identifying the manufacturers and importers, however, it is necessary for the government to first set up a platform enabling companies to identify other makers/importers of the same chemical. In the European Union, the platform is the Substance Information Exchange Forum (SIEF). As another example, similar infrastructure has been established in South Korea. An opt-out mechanism is available for companies that do not want their business for a given substance to be made public, eliminating concerns about confidentiality.

For use in the upcoming Phase II registration stage, the Committee urges the EPA to consult with industry to design a joint registration program that includes a workable mechanism for matching potential participants.

Suggestion 4: Withdraw the recent guidelines on border control.

On April 1, without prior notice to stakeholders or the provision of a grace period, the EPA issued border control guidelines for Chemical Commodity Importation Pre-confirmation (CCIP), calling for the applicant importer to provide the approval number for every product component being imported, without exception. That task is fairly straightforward for items that have been registered under the New Chemical Substance or Existing Chemical Substance provisions, but it presents a major problem for substances that are not subject to registration requirements because the import volume is less than 100 kilograms per year. Compliance with the guideline would generate a huge workload for all stakeholders – not only for importers in collecting and analyzing the data and uploading it to the database, but also for Customs and the EPA. The new system also creates significant CBI concerns that competitors will be able to identify the formulation of products through the disclosed chemical registration numbers and information.

The above-mentioned program has been presented as optional rather than mandatory. But since companies that do not participate will be prioritized for market audits, importers will feel compelled to comply.

No such linkage of Customs control and chemical substance registration exists under the EU or Korean REACH registration systems, or in any other system around the world that the Committee is aware of. We urge cancellation of the new guideline requiring the provision of registration numbers for individual components, as it should be sufficient for importers to submit a declaration guaranteeing that the import products comply with CSNN.

Suggestion 5: Provide sufficient lead time for Existing Chemical Substance late pre-registration.

The deadline for CSNN pre-registration for Existing Chemical Substances was March 31. Under another new guideline (for CSNN Article 19) issued by the EPA in early April without prior consultation with industry, "late pre-registration" registrants (importers, manufacturers, or local representatives) are required to submit the dossier within 90 days of the date of customs clearance or local manufacture. During the regular "pre-registration" period, in contrast, companies were given seven months to submit the application. Even then, most registrants barely managed to meet the deadline owing to the complexity of the communications involved (with vendors and customers, both foreign and domestic) in preparing the authorization letter and CBI dossier.

For "late pre-registration," the challenge will be even more daunting. Unlike the one-time "pre-registration," the new phase is designed as a rolling registration. Companies will have to constantly check on whether the import volume for each product has reached the threshold (100 kilograms per year from 2016), triggering the registration requirement.

We strongly recommend allowing the import/manufacturing records from the previous year to be submitted for late pre-registration. Ending the current 90-day rolling registration would relieve industry of a nearly impossible burden.