Taiwan Publishes New and Existing Chemical Notification Guidance

In August - September 2015, Taiwan’s Environmental Protection Agency (Taiwan EPA) published three guidance documents pertaining to the registration of chemicals under Taiwan’s “Regulation of Chemical Substance Registration and Management” (“Regulation”), specifically:

- Guidance for New Chemical Substances Scientific and Research Development (SRD) and Product and Process Orientated Research and Development (PPORD) Registration (“SRD/PPORD Guidance”)
- Frequently Asked Questions 100 for New and Existing Chemical Substances Registration

- Guidance for New and Existing Chemical Substances Registration (”Guidance”) These documents, available on the Chemical Registration Center’s Website, provide detailed explanations as to the scope of required registration, data requirements for different types of registrations, and procedures for preparation and submission of registration dossiers via the “CHEMIST” software program developed by Taiwan EPA. The authority has been accepting registrations for new chemicals since April 1, 2015, and for Phase 1 Registration for Existing chemicals since September 1, 2015.

Registrants and Representatives The guidance documents reiterate that only Taiwanese entities are eligible to register chemicals under the Regulation. Thus, overseas exporters of chemicals to Taiwan cannot act as registrants, but may only provide supporting data. If overseas companies wish to protect their confidential business information (CBI) such that it is not disclosed to a Taiwanese registrant, the registrant may authorize a third-party entity located in Taiwan to serve as the representative for handling the registration. In this case, the representative would obtain the CBI from the overseas data owner and submit it directly to Taiwan EPA. To use this procedure, the registrant and the representative must sign an authorization letter and have it notarized by the local court and an accredited notary in Taiwan. A template for such an authorization letter is provided in Appendix 5 of the Guidance.

SRD and PPORD Registrations According to the Regulation, new substances manufactured or imported for Scientific Research and Development (SRD), or Product and Process Orientated Research and Development (PPORD), are subject to reduced notification requirements. Specifically, a new SRD or PPORD substance can be notified using (1) a “Standard” Registration if the annual Taiwanese manufacture/import volume is 10 metric tons or more; (2) a “Simplified” Registration if the annual Taiwanese manufacture/import volume is 1 metric or more but is less than 10 metric tons; or (3) the “Small Quantity” Registration (PPORD substances) if the annual volume is less than 1 metric ton.

Taiwan EPA initially planned to limit the scope of SRD registrations and registrants to only allow colleges and institutes acknowledged by the Taiwan Ministry of Education. As described in the SRD/PPORD Guidance, however, industrial manufacturers and importers are eligible for SRD registration. Further, new substances manufactured or imported for SRD purpose and whose manufacture/import volume is less than 1 metric ton per year may be exempt from registration. However, various forms (depending on the type of business/activity in which the manufacturer or importer is involved), must be prepared and submitted to Taiwan EPA for eligibility verification. These forms, including: (1) SRD/PPORD Registration Form; (2) Application for Determination of SRD; (3) Authorization Statement (Inspection Agency); (4) Authorization Statement (Importer); and (5) Affidavit for Application Materials of SRD Substances, are provided in the five appendices to the SRD/PPORD Guidance, respectively. For convenient reference, below we summarize the required application forms for various scenarios.
Despite the favorable result that no registration may be required for SRD substances with volumes less than 1 metric ton per year, Taiwan EPA limits verification of eligibility for only one year. Should a company wish to continue using the substance for SRD purposes, it must re-apply for verification on an annual basis.

**Data Requirements for Standard Registration** The Guidance provides more detailed information on the physicochemical, toxicological, and eco-toxicological data required for Standard Registration. As set forth by the Regulation, the larger the tonnage, the more supporting data are required. The Guidance clarifies that the data included in the registration may be in the form of a standard test report (full study report or robust summary), Structure Activity Relationship (SAR) estimation, or test proposal. The last item may only be used in certain cases, such as toxicokinetics and carcinogenicity studies, as well as a number of eco-toxicological studies for Tier 2 or higher. Actual test reports will not be needed at the time of submission unless the authority deems otherwise.
Phase 1 Registration of Existing Chemical Substances  Phase 1 Registration of Existing Chemical Substances began on September 1, 2015, and will end on March 31, 2016. Existing substances for which annual average volume over the past three consecutive years prior to registration application exceeds 100 kilograms, or where at least one annual production volume during the three consecutive year period prior to registration application exceeds 100 kilograms, must be registered with Taiwan EPA. Once the registration is approved, the authority will issue a Phase 1 Registration Number to the registrant. Pursuant to Article 18 of the regulation, a manufacturer or importer selling or transferring an existing chemical substance must give the downstream customers the Phase 1 Registration Number, registration document or other identifiable labels, as granted under registration. If you have questions, or would like additional information, please do not hesitate to contact Tom Berger (Berger@khlaw.com) or Chen Hu (Hu@khlaw.com).

[1] “SRD by Industry” refers to the scenario that the SRD with the new substance is conducted by the registrant (Taiwanese manufacture or importer) itself; “SRD by Inspection Agency” refers to the scenario that the imported new substance will be provided by the registrant to testing labs and/or inspection agencies for analytical method research or analytical testing; and “Importer for SRD Substances” refers to the scenario that the new substances is imported by a trader, who files the registration in such case, and provided to downstream customer(s) for SRD.