February, 2019
National Institute of Technology and Evaluation

Rationalization of operations in Japan's chemical management laws in 2019

From the perspective of NITE, to support implementation of CSCL and the PRTR Law

This article provides the latest information on the Chemical Substances Control Law (CSCL) and the PRTR Law, which the National Institute of Technology and Evaluation (NITE) supports in their operation.

CSCL is a law to prevent environmental pollution by chemical substances that may affect human health and ecosystems, consisting of 1) pre-marketing review of new chemical substances, 2) continuous management for chemical substances after marketing, and 3) regulatory measures depending on the properties of chemical substances. The authorities are the Ministry of Economy, Trade and Industry (METI), the Ministry of Health, Labour and Welfare, and the Ministry of the Environment, and NITE is involved in all operations of the law.

Based on the latest amendment of 2017, the system of 1) concerning new chemical substances will be partially changed in order to increase business predictability. The procedures of the confirmation system for both small-amount (1t/y) and low-volume (10t/y) new chemical substances, which is one of systems exempt from the regular notification for new chemical substances, will be changed. The former type of application for confirmation will be changed from January 2019, and the latter will be changed from March 2019.

Major changes for such exceptional systems, i.e., the one specified above for both types of applications include:

(1) The nationwide quantity limit will be changed from "Manufactured/Imported Quantity" to "Environmental Emission Quantity" calculated based on "Use Information"

(2) The application methods and times will be diversified to promote electronic application.
- Electronic application for small-amount new chemical substances will be increased from four times to ten times a year.
- Electronic application will also be introduced for low-volume new chemical substances.
- Application for small-amount and low-volume new chemical substances by optical disk will be newly accepted.

(3) The application form will be modified and additional information will be required for both small-amount and low-volume new chemical substances.
- An application in principle includes one substance with one use. It will also be acceptable to include multiple uses (up to six uses) in an application. In the latter case, the maximum emission factor among those uses will be applied.
- Attachment of the Use Certificate will in principle be necessary. If the applicant does not submit the Use Certificate, an emission factor of 1.0 shall be applied.
- For small-amount new chemical substance applications, a chemical structural formula file (MOL file) should be submitted by electronic media. The "NITE MOL file creation system" and its instructions are provided on the NITE website.

For the procedures of 2), toward achievement of WSSD 2020 goals, and in order to advance risk assessment of existing chemical substances for which were difficult to identify, information required for the annual reporting of manufactured and/or imported quantities of general chemical substances, etc., will be added or changed from April 2019.

(1) The annual reporting form and the use category code will be modified.
(2) The reporting for certain mixtures of “salts etc. which are not considered as a new chemical substance” will be changed from as multiple substances to as one substance.
(3) In order to conduct risk assessment, a list of substances for which chemical structure and constituent information are additionally required is published on METI's website in advance.

Under the CSCL, those who intend to manufacture/import a small amount or low volume of new chemical substances can manufacture or import up to the approved amount without regular new chemical substance review by submitting a small-amount application or low-volume application to the competent authority.

In recent years, however, because the Japanese chemical industry has shifted to small-quantity production with multiple varieties, the number of applications for small-amount and low-volume new chemical substances has been increasing year by year. Along with this, the number of volume adjustments by the authorities to adjust the total domestic volume to 1 ton or 10 tons has also been increasing. This raises concerns that manufacturers and importers will not be able to secure their planned volumes and might lose business opportunities in the entire supply chain.

Therefore, the nationwide quantity limit was changed from "manufactured/imported quantity" to "environmental emission quantity considering usage information". It is expected that this will reduce the number of quantity adjustments while ensuring safety for human health and ecosystems, and increase predictability for business planning for the chemical industry.

PRTR law
The PRTR Law aims to promote voluntary improvement of the management of chemical substances by business operators as a pillar of the PRTR system and the SDS delivery system, and to prevent impediments to environmental preservation in advance. After a certain period of time, the authorities review the law, including the substances subject to PRTR. The latest reviewing discussion started in 2018 and will continue in 2019.

URLs:
METI’s website: http://www.meti.go.jp/policy/chemical_management/kasinhou/index.html
Procedure explanation
NITE (Chemical management center): https://www.nite.go.jp/en/chem/index.html
NITE-MOL file creation system: https://www.nite.go.jp/chem/kasinn/syouryou/mol/
Instructions for NITE-MOL file creation system: https://www.nite.go.jp/chem/kasinn/mol_movie_menu.html
Substances with structure and constituent information should be attached: http://www.meti.go.jp/policy/chemical_management/kasinhou/information/kouzou_sosei_tempusyorui.html