Complying with CSCL

JAPAN'S CHEMICAL SUBSTANCES CONTROL LAW (CSCL)

CSCL is one of the oldest chemical regulations in the world, adopted in 1973. The focus of the CSCL is on the prevention of environmental pollution by chemicals and minimizing the impact of chemicals on human health, fauna, and flora. All chemical substances, including industrial chemicals, manufactured in or imported to Japan are in scope of the CSCL, with the exception of chemical substance regulated by other laws, such as pharmaceuticals and pesticides.

Chemical substances not listed under the CSCL require a notification to and evaluation by the Japanese government before importing or manufacturing. For chemical substances listed under the CSCL, a mandatory annual report on the import/manufacturing volume needs to be submitted to the Japanese government. Following this, the authorities conduct risk assessments based on the volume of chemical substances placed on the market. They also may request additional data regarding the toxicity of the chemical substance from manufacturers or importers.

Three different ministries are in charge of the CSCL implementation:

- The Ministry of Economy, Trade and Industry (supported by NITE) is responsible for biodegradability and persistence.
- The Ministry of Health, Labor and Welfare is responsible for human toxicity.
- The Ministry of the Environment is responsible for ecotoxicity.

With the responsibilities split among 3 ministries, a company will have to consult and confirm every step with all stakeholders involved.

Regulatory Process under CSCL

The overall regulatory process under CSCL can be roughly divided in the following three parts:

1. Preliminary examination system for newly manufactured or imported chemical substances
2. Risk assessment based on manufacturing or import volumes (after notification), including available and reported hazard information.
3. Implementation of specific regulations and control measures based on the properties of the chemical substances assessed. The government looks specifically at biodegradability, bioaccumulation, toxicity and residual status in the environment.

   Chemicals considered PBT (persistent, bioaccumulative and toxic to the environment) are considered "Class 1 Specified Chemical Substances" and require the highest degree of control measures.

As part of the CSCL, the Japanese government conducts risk assessments before and after placing the chemical substance on the market. Based on the result of these risk assessments, the government may take measures to control risks associated with the chemical substance.

When a foreign company intends to import a new chemical substance to the Japanese market, the above-mentioned step 1, the preliminary examination, is required before import. However, after import, companies based in Japan are required to support the Japanese government with steps 2 and 3.

There are different types of notifications, depending on the volume of manufacture or import and the use of the chemical, see Table 1.

Table 1 Types of notifications under the CSCL

CSCL				
Type (volume limit)	**Process**	**Data required**	**Information required**	**Timelines**
Full (≥ 10 t/a)	Notification (open to foreign co.)	Biodegradability Partition coefficient Bioaccumulation Toxicity/Ecotoxicity Polymer Flow Scheme	Use, planned quantity, etc.	10 times per year
Low volume chemicals (<10 t/a in Japan)	Notification Confirmation	Biodegradability Partition coefficient Bioaccumulation	Use, planned quantity, etc.	13 times per year
Small volume chemicals (<1 t/a in Japan)	Confirmation	No test required	Use, planned quantity, etc.	4 times per year (10 times online)
Polymers of low concern (none)	Confirmation	Polymer Flow Scheme	MW, physico-chemical, stability, etc.	Any time
Intermediate, closed system, export only (none)	Confirmation	No test required	Handling, facility, etc.	Any time
Small quantity Intermediate, closed system, export only (<10 t/a company)	Confirmation	No test required	Use, planned quantity, etc.	Any time

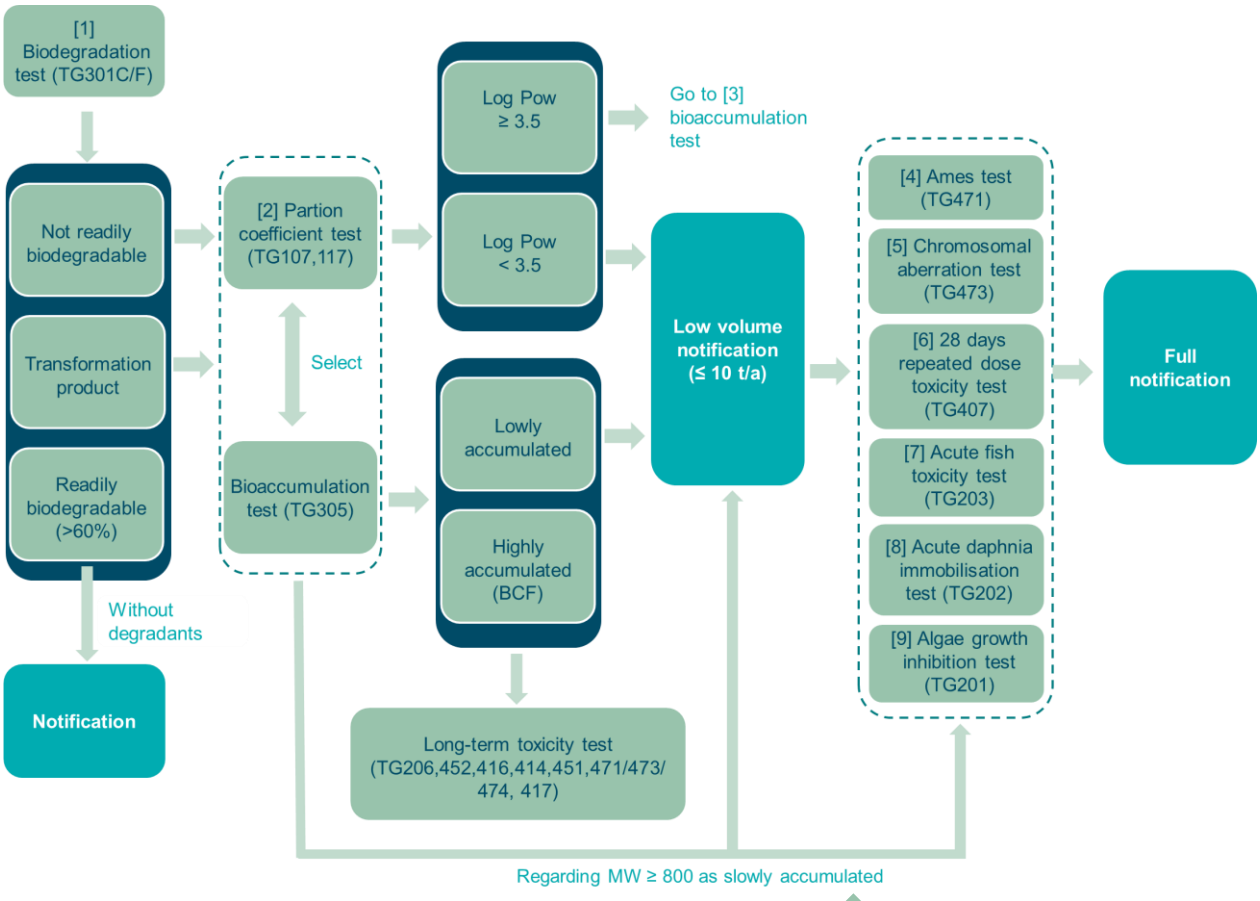
Foreign-based companies can only apply for a full notification (≧ 10t / y). As the CSCL does not have the Only Representative concept, all other notifications, such as the low volume or small volume, can only be done by a local Japanese legal entity.

If a foreign-based company is the applicant, it can freely export to Japan after having received a confirmation of a successful notification by the Japanese government. However, if the notification is held by an importer in Japan, a foreign-based company can only place their chemical substance on the Japanese market through this importer. Recently, the Japanese government has allowed for joined applications, however this does not require data sharing.

Several notifications require specific tests during the pre-examination phase. These include full notification and low volume notification. Both notifications require data on biodegradability and persistence. Biodegradability is mainly determined by OECD301C, and recently also OECD301F.

Persistence is determined via bioaccumulation studies, using LogPow or fish. LogPow can be determined via OECD107 or 117 compliant tests. If the LogPow is 3.5 or less, the chemical substance is considered to be non-bioaccumulative. If the results are 3.5 and more, an bioaccumulation study according OECD305 using fish is required, see Table 2.

Table 2 Flow of tests for Low Volume (<10 t/a) and Full Notification



In the past, the CSCL always required a bioaccumulation, human toxicity and ecotoxicity evaluation of both the chemical substance and its metabolites. This caused significant additional cost and time to run extra studies. Therefore, the government has implemented a new testing methodology. For chemical substances and/or its metabolites that are unlikely to remain in the environment, although detected during the biodegradation study, subsequent studies are no longer needed. This, however, needs to be consulted with and approved by the authorities in advance.

One of the latest developments under CSCL, is the acceptance of QSAR (Quantitative Structure-Activity Correlation) for biodegradability and persistence. If, after consultation with the Japanese government, the submitted information and arguments created by the QSAR are deemed appropriate, they can be submitted to the notification council. Upon approval by the council, they can be submitted as application materials.

With CSCL's strict requirements and high expectations on the data quality by the Japanese government , choosing the right strategy is crucial not only for a successful notification, but also for the effective reduction of cost and application time. This concerns data gap analysis, authority consultation, CRO selection (overseas, Japan) and study monitoring. SCC Japan can guide your through the complex world of CSCL and help you bring your chemical substance to the Japanese market in a cost-effective and timely manner.

If you have any questions or requests, please contact SCC Japan.

Contact our experts

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