



MAKE SURE YOU KNOW THE ESSENTIALS

TRADING CHEMICALS IN JAPAN

Chemical Substance Control Law (CSCL) and Industrial Safety and Health Act (ISHA) are the two most relevant regulations governing marketability of chemicals in Japan.

Chemical Substance Control Law (CSCL)

Japan Chemical Substances Control Law (CSCL) is intended to manage risks of industrial chemicals manufactured and imported in Japan in order to prevent environmental pollution and to control chemical risks to human health.

Japan CSCL controls both new and existing substances.

- ▶ For new substances, i.e. a substance not yet listed in the Japan Existing and New Chemical Substance (ENCS) Inventory, a strict pre-manufacture/-importation evaluation system is implemented.
- ▶ For existing substances, manufacturers or importers are required to report their quantity and uses annually (based on the fiscal year: April to March) if the volume of the substance exceeds a certain amount.
- ▶ Depending on their properties, some substances are defined as 'specified chemical substances' and require special attention or a 'priority risk assessment'.

Required documentation

Depending on the category your substance falls into, you will be required to provide different documentation. At knoell, our local experts can support you with the following:

New chemical substances

- Small Volume Permit (SVP): ≤ 1 t/fiscal year
- Low Volume Exemption (LVE): 1–10 t/fiscal year
- Full notification: > 10 t/fiscal year; following approval, it will take 5–6 years until the substance will be listed on the inventory
- Confirmation for Polymers – Polymers of Low Concern (PLC)

Existing chemical substances

- Depending on the classification, the submission of the notification for 'Report of annual quantity General Chemicals': > 1 t/fiscal year

Most important substance properties that need to be addressed are

Property (substance volume)	Related test	OECD (Reference TG ¹)
Biodegradation (> 1t)	Biodegradation test	TG301C
		TG301F
Bioaccumulation (> 1t)	Partition coefficient test	TG107
	Bioaccumulation in Fish test	TG305
Toxicity (> 10t)	Ames test	TG471
	Chromosomal aberration test	TG473
	28 days repeated dose toxicity test	TG407
Eco-toxicity (> 10t)	Acute fish toxicity test	TG203
	Acute daphnia immobilization test	TG202
	Algae growth inhibition test	TG201
Polymer	Polymer Flow Scheme test (PFS test)	

¹ CSCL defines the testing methods, therefore the above guideline numbers are for reference only.



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Industry Safety and Health Act (ISHA)

The Industry Safety and Health Act (ISHA) deals with the safety of workers in the workplace / occupational health. Similar to Japan ENCS Inventory, ISHA has its own inventory, the so called ISHA List. This list is updated approx. every 3 months. In addition to this list, ISHA also identifies substances that require safety data sheets and labelling, depending on their properties.

In general, all *new chemical substances*, i.e. chemicals not yet on the ISHA List, need to be notified in accordance with ISHA. Depending on the volume, different notification types are required, and this is where you can benefit from our team's experience – efficient preparation of the required documents by knoell frees your capacities and helps you to notify as quickly as possible:

- ▶ Notification of Small Quantity Permit (SQP):
≤ 100 kg/year/site
- ▶ Full notification: >100 kg/year/site

For full notification, the most relevant substance property that requires testing is toxicity (Ames test, reference: OECD TG471). ISHA defines the exact testing method, therefore the OECD guideline number should be considered as reference only. The substance will be listed on the inventory approx. 1 year after the submission.

Your benefit – local support

Take advantage of our local team of registration experts. Preparation and submission of the required documents, information on inventory/list updates and answers to any other pressing question related to chemicals regulations in Japan. Contact us: info@knoell.com

