

## Japan - Low Volume Exemptions

### Background Information

Regarding chemical substances in Japan, there are two separate and distinct schemes.

The Industrial Safety and Health Law (ISHL) covers substances manufactured in Japan or used in the workplace. It is administered by the Ministry of Health, Labor and Welfare (MHLW).

The "Law Concerning the Examination and Regulation of Manufacture of Chemical Substances etc", which is more typically referred to as simply the Chemical Substances Control Law (CSCL) covers substances manufactured or imported into Japan and is jointly administered by the Ministry of Economy, Trade and Industry, the Ministry of Health, Labor and Welfare and the Ministry of Environment (METI / MHLW / MOE).

Each law/scheme maintains a separate and distinct inventory of existing substances.

Within the Japan chemical control scheme, there is a focus on environmental fate and ecotoxicological effects.

### Low Volume Exemptions Overview

Under the CSCL, there are two types of exemptions allowing for smaller volumes of a new chemical substance to be manufactured/imported into Japan; (1) Small Quantities Exemption (SQE) for substances up to 1 MT per year and (2) a Low Quantity Exemption (LQE) for substances up to 10 MT per year. Both exemptions apply to the yearly total domestic import/manufacture of the new chemical substance in Japan. That is, if there are multiple applicants, the ministries share the total allowed domestic volume between all applicants.

#### Small Quantity Exemption (≤1 MT per fiscal year)

There are four opportunities a year to submit the SQE application to METI/MHLW/MOE. The submission and anticipated clearance dates are as follows;

Submission Dates	Anticipated Clearance Dates
Jan. 20 – Jan. 30	April 1
June 1 – June 10	July 1
Sept. 1 – Sept. 10	October 1
Dec. 1 – Dec.10	January 1

The notification is valid until the next upcoming March 31<sup>st</sup> date. Therefore, a notification clearing on April 1 will allow 1 MT of substance to be imported during the 12 month period of April 1 – March 31 of the following year, whereas one clearing on January 1 is for just three months (Jan. 1 – March 31 of the same year); however, if you are the sole notifier, the total allowed volume during the 3 month period from Jan. 1 until March 31 will be 1MT and then you will need to immediately reapply during late January to renew the 1 MT SQE for the next April 1 – March 31 period. Annual renewal is required to allow continued import.

Generally, the following information is sufficient;

Company Name & Location

Chemical Name (IUPAC nomenclature is requested but in experience, CAS nomenclature is accepted)

Structure (If its structure is not completely known, then a description of the manufacturing method)

Component Composition (including impurity profile)

Physical Form

Appearance

Density

Viscosity

Year of planned import/manufacture

Intended use information/Use code

Country of Manufacture (only if imported)

Name and location of manufacturing site (only if manufactured in Japan)

Person responsible for notification and contact information

Past Quantity information – if applicable

This information must be in Japanese and submitted to METI/MHLW/MOE on the appropriate form (attached).

Under the separate ISHL, MHLW restricts the 1 MT allowance to an annual 100 kg per registered office/facility that the notifier owns in Japan (up to 10 sites) until a full ISHL notification has also been completed. The 100 kg/yr/site allowance can be applied concurrently along with the CSCL application or at any time during the year 30 days before it is to be used at the site. No test data is required. The information provided with the SQE under the CSCL will suffice.

For full notification under the ISHL, the additional information required is an Ames test. If the Ames test is positive, then additional testing (Chromosomal Aberration) may be required as well. The full notification under the ISHL can also be applied for at any time 30 days in advance; however, even when a full ISHL notification has been completed, METI/MHLW/MOE will still restrict the total quantity placed on the market to 1 MT per year until either a 10 MT LQE or full notification under the CSCL is approved.

### Low Quantity Exemption ( $\leq 10$ MT per fiscal year)

Under the CSCL, manufacturers or importers can apply for a LQE of up to 10 MT/yr (total domestic volume) if the substance is judged to either be not persistent (i.e. if the METI ready biodegradation test shows  $> 60\%$  biodegradation then the substance is considered not) or persistent but not highly bioaccumulative, and considered not to present significant risk to human health or the environment based on information already known about the substance.

Ideally, for the 10 MT LQE, the biodegradation study is conducted first using METI Biodegradation test guidelines. If the substance is readily biodegradable ( $> 60\%$  biodegradation), then no further testing is required. If the substance is not readily biodegradable, then discussion with METI/MHLW is required to determine whether further testing can be conducted on simply the parent substance and/or if environmental degradants (“children”) will be further evaluated as well. Dependent upon the substance type, it is possible to negotiate not running a full fish bioaccumulation study if certain other data is available. The requirements here vary and are described in the summary table below.

Type of Chemical	Ready Biodegradation	Bioaccumulation	Other Data
Non-ionic, non-polymeric substance. MW $< 800$	Required Testing  If not readily biodegradable then bioaccumulation data may be required.	Likely to be required. Possible to negotiate based on $\text{Log } P_{\text{ow}}$ and/or read-across from similar substances.	Could be requested if there is a concern based on structural concerns but unlikely.
Non-ionic, non-polymeric substance. MW $> 800$	Required Testing  If not readily biodegradable then bioaccumulation data may be required.	Unlikely to be required unless there are structural concerns (e.g. halogenated compounds)	Could be requested if there is a concern based on structural concerns but unlikely.
Ionic, non-polymeric substance where the ionic species have a MW $< 800$	Required Testing  If not readily biodegradable then bioaccumulation data may be required.	Likely to be required. Possible to negotiate based on Low $P_{\text{ow}}$ and read-across from similar substances.	Likely to be required. Possible to negotiate based on read-across from similar substances.
Ionic, non-polymeric substance where the ionic species have a MW $> 800$	Required Testing  If not readily biodegradable then bioaccumulation data may be required.	Unlikely to be required unless there are structural concerns (e.g. halogenated compounds)	Could be requested if there is a concern based on structural concerns but unlikely.

Polymer meeting polymer definition and meeting PLC criteria	Not formally required if concluded as non-biodegradable	Not required for polymers of low concern (PLC).	Data from the Polymer flow scheme will suffice.
Polymer meeting polymer definition but NOT meeting PLC criteria	Required Testing	Not required if it can be demonstrated that there is a low presence of MW species at $\leq 800$	Could be requested based on structural concerns but unlikely especially if species of $\leq 800$ are present at $< 1\text{wt}\%$ .

When considering the possibility of using “read across” data on similar substances, only fish bioaccumulation data conducted under the METI test guidelines is likely to be admissible but none-the-less, it is possible to consult and negotiate with METI as they may agree to a shortened version of the bioaccumulation study.

If assessment of bioaccumulation by read across to similar substance is not possible, the next option to consider is using Log  $P_{ow}$  data (suitable for meeting the METI test guidelines). Log  $P_{ow}$  is considered a predictor of bioaccumulation only if the substance satisfies certain conditions, as specified in the CSCL. The shake-flask method must be used and for substances with ionizable groups there are equations based on the measured pH of the aqueous phase in the Log  $P_{ow}$  test. This will determine if the substance is not ionized and whether Log  $P_{ow}$  can be used as a valid indicator of bioaccumulation.

If these approaches to assessing bioaccumulation are not successful, then the bioaccumulation potential must be determined via a fish bioaccumulation study. Analytical difficulties may be encountered because the test substance has to be measured at low concentrations in both the water and fish tissue.

If the bioconcentration factor (BCF) is  $< 1000$ , then the substance is regarded as “not highly bioaccumulative”. An elimination test must be incorporated into the study if the BCF is determined to be  $\geq 1000$ . METI will reach a decision on whether a substance is bioaccumulative based on all the measured parameters. If the substance is deemed to be bioaccumulative, then a 10 MT LQE will not be issued.

If the substance is deemed persistent and not bioaccumulative, METI may possibly require further testing if it is uncertain as to whether or not certain functional/structural aspects of the substance pose a concern for human health or the environment.

Annual renewal of the 10 MT LQE is required to allow continue import.