Japan’s Regulatory Scheme for Workplace Chemicals Under the Industrial Health and Safety Law

Japan’s Industrial Safety and Health Law (ISHL) applies to chemicals that are manufactured or used in the workplace. The ISHL became effective on June 30, 1979, and was formerly administered by Japan’s Ministry of Labour (MOL). Though it is currently administered by Japan’s Ministry of Health, Labour and Welfare (MHLW), it is commonly referred to as the “MOL” scheme.

The MOL scheme is independent of Japan’s Chemical Substances Control Law (CSCL), which is jointly administered by Japan’s Ministry of Economy, Trade and Industry (METI) and MHLW. The MOL scheme requires separate registration for “new” chemical substances used in Japanese workplaces. Substances already in use in Japan when the ISHL came into effect, and substances subsequently notified and published as “safe” on the “MOL Inventory” do not have to be notified. Thus, substances must be notified if they are not included on any of the following lists:

- METI List of Existing Chemical Substances
- METI List of New Chemical Substances published before June 29, 1979
- MOL List of Existing Chemical Substances
- MOL Inventory

MOL notification is less demanding and much quicker than notification under the CSCL. Once MOL notification is made, the notifier meets with an MHLW official, who reviews the documentation and makes an immediate determination as to whether the substance is approved or requires further testing.

Data requirements for MOL notification are generally minimal. Because MOL notification focuses on mutagenicity and carcinogenicity, usually only an Ames test is required. A notification is normally approved if the Ames test is negative, or positive <1000 revertants/mg. However, if the test is close to or above 1000 revertants/mg, an in vitro chromosome aberration test will likely be requested. If this test is negative, it is likely that the notification will be approved without further data requests. If it is positive, certain conditions may be imposed on the notifier (referred to as “Administrative Guidance”), such as product labeling or informing employees of the substance's potential risks. In vivo testing, such as a mouse micronucleus test, may also be required. If these tests are positive, rigorous conditions for production and distribution of the substance will likely be imposed.

Test guidelines for the Ames test and the chromosome aberration test under the MOL scheme are somewhat different than those of METI under the CSCL. Impurities of up to 10% are acceptable under MOL scheme; thus, these studies may not be acceptable for purposes of METI notification under the CSCL.

Once approved by MHLW, the substance is assigned an MOL registration number, which is different than the METI registration number. Unless explicit conditions are imposed on the substance, it can then be freely imported,
manufactured or handled.

There are several exemptions from the MOL notification requirements; however, no exemptions exist for pharmaceutical intermediates, cosmetic ingredients, or site-limited intermediates. An exemption is provided for "research and development" substances, but only if such substances are used in a research facility.

Workplaces can request a low volume exemption for substances used up to 100 kg per year per factory. Thus, the same company can claim several exemptions for different factories. The application for exemption must be made 30 days prior to use and it must be annually renewed. Only technical, administrative, and available physico-chemical data must be provided to support the exemption.

Certain polymers with number-average molecular weights greater than 2000 are eligible for reduced notification under the MOL scheme. The reduced notification request is made by application to MHLW, and test data is not required to be submitted. However, the following types of polymers are not eligible for this exemption:

- polymers having positive charge;
- polymers in which the carbon in the total weight is below 32%;
- polymers having covalent bonds with elements other than oxygen, sulphur, silicon, hydrogen, carbon or nitrogen;
- polymers having ionic bonds with metal ions (including complex metal ions) other than aluminum, potassium, calcium, sodium, or magnesium;
- polymers extracted from living beings and their reaction products, or similar polymers;
- polymers with specific reactive groups, if the number-average molecular weight divided by the number of reactive groups is <10,000; and
- polymers that may decompose or depolymerize at room temperature or under atmospheric pressure.

For more information, please contact Tom Berger at 202-434-4285 or berger@khlaw.com.

---


2 Japan's “Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances” (October 16, 1973, Law No. 117) is commonly referred to as the Chemical Substances Control Law (CSCL).