Notification of New Chemical Substances in Japan

▪ Regulatory Background

Japan’s “Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances” (October 16, 1973, Law No. 117) was first enacted on October 16, 1973, and became effective April 16, 1974. This law is commonly known as the “Chemical Substances Control Law” (CSCL), and is administered by Japan’s Ministry of Economy, Trade and Industry (METI). The CSCL was amended in April 1986, and most recently in June 2003. The 2003 amendments extended the scope of the law to address persistent, bioaccumulative, and toxic substances and expanded already existing reduced notification requirements slightly.

Under the CSCL, any person who wishes to manufacture or import any “new” chemical substance must file a notification in advance. The term “chemical substance” includes “compounds obtained by causing a chemical reaction to occur in elements, a compound and/or compounds.” Excluded from this definition are radioactive substances, and certain substances regulated under other Japanese laws, including certain specified poisons, stimulants and their precursors, and narcotics and psychotropics.

Substances that are listed on a series of Inventories known as the Japanese list of Existing and New Chemical Substances (ENCS) are exempt from the new chemical notification requirement. This list identifies substances in Japanese commerce prior to 1974 as well as those notified under the CSCL and approved as “safe” after that time.

Substances can either be implicitly or explicitly listed in ENCS, and are listed in terms of classes. Because many ENCS listings are generic and can encompass a number of specific substances, determining whether a substance is covered by an ENCS listing can be difficult. Although the ENCS Inventory is not strictly based on CASRNs listings, there are cross-references to CASRNs contained in an authoritative reference on the Japanese Inventory, the “Handbook of Existing and New Chemical Substances,” 9th ed., The Chemical Daily Co., Ltd. (2002). There is no portion of the Japanese inventory that is confidential, but Japan does provide some protection from immediate disclosure of newly listed substances.

▪ New, Specified, and Designated Substances

“New” chemical substances are described in Article 3 of the CSCL. “New substances” that must be notified under the CSCL include all chemical substances except:

▪ substances listed on ENCS;

▪ “class I specified substances”;
• “class II specified substances”;

• “designated substances”; and

• published lists of notified new “safe” substances.

These “new” substances must be notified at least three months prior to manufacture or import.

Although they are exempt from notification as new substances, “class I specified substances,” “class 2 specified substances,” and “designated substances” have separate reporting requirements. A notified new substance may be classified as a “designated” or “specified substance,” and can be added to the lists of such substances. The list of “specified” and “designated substances” is publicly available. “Class I specified substances” are those that do not readily biodegrade under natural circumstances, are easily accumulated in biological organisms, and may be harmful to human health when continuously ingested. “Class II specified substances” are harmful to human health due to significant residue or anticipation that residue will result in the near future. Like “class I specified substances,” “class II specified substances” and their decomposition products do not lend themselves easily to chemical changes caused by natural effects and may be harmful to human health when ingested continuously. “Class II specified substances” exclude, however, those substances classified as “class I” based on their potential to bioaccumulate. A “designated chemical substance” is a substance that exhibits some but not all of the characteristics of a “class II specified substance.”

**Notification Thresholds and Data Requirements**

Substances that are not listed on the ENCS, and that are not “specified” or “designated,” are considered “new” in Japan and are subject to notification and testing according to a prescribed list of tests. This is known as testing using a base set. Notification must be made at least three months prior to manufacture or import.

Unique protocols must be used to conduct the base set testing required under the CSCL, and due to Japan’s focus on ecotoxicological effects, many of the test requirements hinge on the potential of a new substance to biodegrade. Required test protocols may differ from those established by the OECD. In many instances the CSCL test requirements are more stringent. A laboratory familiar with the Japanese test requirements and those in other jurisdictions of interest is recommended. Required tests include biodegradation, bioaccumulation, toxicological screening, and physiochemical properties. Substances shown to bioaccumulate are subject to a full toxicological evaluation.

All CSCL notification documents must be in Japanese. Prenotice communication with the Japanese Ministries is considered critical to the notification process, particularly if foreign studies are submitted. After the mandatory, three-month review period, the notifier is sent an official letter of judgment that permits or restricts manufacture or import. There can be a significant delay between commercialization of a substance and its addition to ENCS in that several years may elapse between the time a substance is notified and when it is officially added to ENCS. Until such time, only the original notifier can manufacture or import the substance.
The CSCL provides for a low volume exemption (LVE) that permits reduced notification requirements for a new substance manufactured or imported in quantities less than 1000 kg/yr. The 1000 kilogram limit applies to all manufacturers and importers combined. Importantly, applications can only be made during specified 10-day reporting periods (February 20 to March 1, June 1 to 10, September 1 to 10, and December 1 to 10). LVEs must be renewed each year and expire as a group March 31 each year, thus, an LVE application completed January 1st is valid only for three months. The following information generally is sufficient to support an LVE: chemical identity information, melting and boiling points, water solubility, use and application information, and information on stability.

The 2003 amendments continue to allow new substances with total domestic manufacturing and import quantities of 1 ton or less per year to forego a hazard and toxicity evaluation. However, existing test data which a submitter has for a new substance must be provided to the authorities, even for substances that qualify for reduced notification. In addition, the amendments establish a system of “prior confirmation and post-monitoring.” Under this system, certain substances escape the requirement for new toxicity data:

- “low risk” new substances for total manufacturing and import quantities of 10 tons or less if the substance is judged to be persistent but not highly bioaccumulative, and considered not to present significant risk to human health and living organisms based on already known information. Again, in cases, import could proceed without obligatory submission of toxicity data; and

- new substances for which there is “little or no possibility of exposure.” The following cases are offered by the authorities to illustrate this category: chemical intermediates that are wholly reacted to form another chemical substance, substances processed in a closed system, and substances for export only to a country with a well-established prior evaluation system. While the translation is not as clear as we would like, it appears that these are the only circumstances that would qualify under this particular provision.

There is no general “de minimis” exemption from notification under the Japanese system either in the past or as a result of the 2003 amendments. The 2003 amendments simply reaffirmed and slightly expanded the reduced notification program in this respect.

- **Notification of Polymers**

Japan generally considers polymers as substances with number-average molecular weights over 10,000, but it also will consider a substance as a polymer if it has a molecular weight greater than 1000 and if it has other properties characteristic of polymers. For purposes of the CSCL, polymers generally have molecular weight distributions. Standard new chemical tests are required for polymers unless they are shown to meet certain criteria upon testing. Specifically, if a polymer is shown to be (1) stable in accordance with a specific stability test, (2) is insoluble in water and eight organic solvents, and (3) has structural characteristics of a polymer, it is deemed to be “safe” and no further tests are required. If the polymer is soluble or does not have the required structural
characteristics, additional tests (e.g., oligomer levels, solubility in acid and bases) are required. Depending on the results of these tests, the polymer is either deemed to be “safe” or subject to the tests required for non-polymers.

Japan has a rule under which an “organic high molecular compound” manufactured from four or more precursors (or classes of precursors), all of which are existing substances, is deemed to be the same as the polymer manufactured from just three of those precursors (or classes of precursors) if the three precursors chosen are the most characteristic of the polymer in question. 10 “Classes of precursors” refers to the categorical listing of certain precursors (e.g., C2-8 acrylates). In many cases, where none of the precursors have intrinsic importance, such as a group of alkyl acrylate and methacrylate esters, the three precursors deemed to be “important from the characteristics of the high polymer” are those which are incorporated at the three highest levels. Japan also has a rule under which a salt (excluding metal salts) of an organic compound is not notifiable if the corresponding acid and base are existing substances.

• Workplace Chemicals Notification

Under its Industrial Safety and Health Law (ISHL), Japan imposes separate notification requirements for chemical substances used in Japanese workplaces. Normally only an Ames test is required for this notification. If positive results are obtained, additional testing is required.

While certain exemptions do exist, there are no exemptions for pharmaceutical intermediates, cosmetic ingredients, or site-limited intermediates. There is an exemption for R&D substances, but it is restricted to chemicals used in a research facility. Workplaces also can request a low volume exemption for substances used up to 100 kg/yr per factory (application must be made annually 30 days before use). Certain reduced notification requirements exist for certain polymers with number-average molecular weights greater than 2000. The reduced notification request is made without submission of test data.

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

1 These classes include: low molecular carbo?polycyclic organic compounds; inorganic compounds; low molecular chain?like organic compounds; low molecular carbo?monocyclic organic compounds; low molecular heterocyclic organic compounds; organic high polymers obtained by addition polymerization; organic high polymers obtained by polycondensation; chemically modified starches, oils and fats, etc.; compounds of unknown structure; and color indices.

2 The corresponding requirements of the CSCL triggered by the presence of a “class I” or “class II specified substance” in a product are: (1) Art. 13, restrictions on imports of products containing “class I substances”; (2) Art. 14, regulations on the use of class I substances; (3) Art. 22, orders relating to “class I substances”; (4) Art. 26, restrictions on products containing “class II substances”; (5) Art. 28, orders relating to “class II substances”; (6) Art. 29, limitations on other components contained in these products; and (7) Art. 30, guidance concerning restrictions or related laws and regulations for “class I” and “class II substances.“
3 See “Enforcement Order of Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances,” Cabinet Order No. 202, June 7, 1984.

4 CSCL, Art. 2, Para. 2.

5 CSCL, Art. 2, Paras. 3 & 4.

6 “Enforcement Order of Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances,” June 7, 1984, Cabinet Order No. 202.


9 This phrase is not defined but can be reasonably interpreted to mean an organic high polymer.

10 “Interpretation & Application of Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances,” Pharmaceutical Affairs Bureau, MHW, No. 291, Basic Industries Bureau, METI, No. 171, March 24, 1987, at II.1.(2)-3(d).