MECHANICAL AND ELECTRICAL EQUIPMENT AFFECTED BY CHEMICAL LEGISLATION

An Update on Chemical Substance Law 117 - 1

by

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A year and a half ago the Diet enacted the law "Concerning Screening of Chemical Substances and Regulation of Their Manufacture, Importation and Use". Certain Cabinet and Ministerial decisions have altered or tempered the impact of this legislation as it would affect importers of American products or firms with operations or joint ventures in Japan.

Firstly, let us review the intent of this legislation. It was established to control chemical substances not already regulated by other laws (e.g. "specified poisons", "stimulents", "narcotics"). In addition there are some exclusions where the end use of the substance is in the fields of foodstuffs, agricultural chemicals, ordinary fertilizers or medical supplies.

This law established the definition of a "Specified Chemical Substance, as a substance which "does not lend itself easily to chemical changes caused by natural effects (e.g. biodegradation), is easily accumulated in biological organisms, and which, if ingested continuously, may be harmful to human health". The definition also covers substances which may be broken down partly but whose breakdown products meet the definition.

List of "Existing" Chemicals

MITI'S first step in administering the law was to require firms to submit the names of "existing chemical substances". These were compiled into a Provisional List of Existing Chemical Substances. Industry was given a month to examine this list and submit additional compounds. The Official List of Existing Chemical Substances was then issued. MITI intended to issue a translation by August of last year, but the business downturn interceded. They still hope to budget it soon, but no specific date has been announced.

A private organization, Nihon Lobby, translated the Provisional List. To our knowledge no translation of the Official List has been made. The Official List, Kizon Kagaku Busshitsu Meibo, may be purchased from Ohkura-Sho Insatsu Kyoku, 2-Banchi, Aoi-cho, Akasaka, Minato-ku, Tokyo, Telephone (03) 582-4411: the price is ¥2,300.

There were a number of deletions between the Provisional List and the Official List. In most cases these changes reflected an effort to reduce redundant listings of the same compound or to simplify it in similar ways. For example:

1. In some cases the Provisional List included the Geneva nomenclature and several trivial names for the same compounds. MITI has attempted to reduce them to one name for each substance.
2. Several isomers have been brought under one listing, e.g. 1, 2 dichloroethylene and 1.1 dichloroethylene are now shown only as dichloroethylene; ortho, meta and para isomers of

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aromatic compounds have been consolidated.

3. Related compounds have been reduced to one listing, e.g. diethylene glycol mono methyl, mono ethyl, mono isopropyl and mono butyl ether have been replaced by "diethylene glycol mono alkyl (C=1-4) ether".

Two substances inadvertently included in the Provisional List were actually dropped. Alpha and beta naphthlyamine were deleted because of their urinary carcenogenic properties.

5,997 new entries appear in the Official List. There were 15,091 in the Provisional List.

Cabinet Order 202 Identifies PCB

On June 7, 1974 the Cabinet promulgated Cabinet Order 202, titled, "Enforcement Order of the Law Concerning the Examination and Regulation of Manufacturing, Importation and Use of Chemical Substances". It officially identified poly chlorinated biphenyl (PCB) as falling within the definition of a "Specified Chemical Substance". To date no other substance has been so "honored", though several are being studied. PCB has been found to be non-biodegradible, is accumulated in the tissues of flora and fauna, and, when ingested regularly, is harmful to human health.

Products vs. Chemical Substances

Early in the life of the Law it was decided that commercial mixtures with three or more ingredients would be classified as "Products" rather than as "Chemical Substances", meaning that their manufacturers or importers would not be compelled to disclose the formulation to MITI or Customs.

However, Cabinet Order 202 specifies that certain "Designated Products" which *may* contain PCB fall under the control provisions of the Law. This action was taken because of the fact that these were "Products" in which PCB had most frequently been incorporated in the past, resulting in the objectional build up of PCB in the environment in Japan. These "Specified Products" are as follows:

1. Lubricating oil, cutting oil and hydraulic oil.
2. Adhesives (except for those of animal or vegetable origin), putty and filling materials for closing and sealing.
3. Paints (except water thinnable paints), printing inks and pressure-sensitive copying paper (carbonless copy paper).
4. Heat transfer equipment, for heating or cooling, using a liquid heat transfer medium.
5. Oil-immersion transformers, paper capacitors, oil-immersed capacitors and plastic film capacitors.
6. Air conditioning equipment, TV sets and micro-wave ovens.

The Cabinet Order goes on to establish that the use of PCB in the maintenance of oil-immersion transformers and rectifiers of railroad rolling stock comes under the Law. Subsequent Ministerial orders set up a complete set of procedures for the use of PCB by the railroads, e.g. conditions for storage, waste disposal (including wiping rags), spill systems, container identifications, record keeping, etc.

Procedures for Importation of "Designated Products".

MITI'S Order of July 30, 1974, titled, "On the Import of Products Designated by the Enforcement Order of the Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances", establishes the procedures to be followed in importing "Designated Products" (lubricants, adhesives, paints, oil immersion transformers, Air Conditioners, T.V. Sets, etc.) The Order reads as follows:

1. In ordering the cabinet-order-designated products from overseas supplier, the importer should, as far as possible,
   (i) let them confirm that no specified chemical substances are used in the products, and
   (ii) let them assure this by statement on the right side of the invoice.
2. In performing at customs-clearance for the cabinet-order-designated products, the importer should state, on the reverse side of one of the invoices to be delivered to MITI, that no specified chemical substance is used in the products imported, in the manner prescribed separately.

On the reverse side of the invoice the importer must state:

1. "Product A, stated on the front of the invoice, does not conain PCB".
2. BTN and SITC Number of Product A
3. The measures taken by the importer to confirm the non-inclusion of PCB in Product A.

With respect to the last item, most importers rely upon the assurances of the manufacturer with respect to compliance with the regulations limiting the importation of "Designated Products" containing

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PCB. It is not a general practice for importers to order independent tests, especially since PCB tests cost from ¥18,000 to ¥30,000 each. However, importers are well advised to protect themselves by requiring manufacturers to present results of periodic checks of "Designated Products" by independent laboratories. There have been cases in which manufacturers have given their assurances to importers in good faith, only to find, later, that PCB had crept its way into the raw materials which they purchased from their suppliers. While the monetary costs of the product recalls are substantial, the effect upon "Good Will" and product image can be even greater.

New Products

Under "Ministered Order Concerning the Notification etc., of Manufacture or Import of New Chemical Substances", Amended June 10, 1974, there are only four "Windows" each year during which "New Products" may be submitted, i.e. the first ten days of each quarter. This condition *could* be a formidable one for industry. However, the provisions for importing small quantities for "testing and research" and as "reagents", can provide enough time for full certification before commercial quantities need to be imported. Many chemical firms are finding that, when they submit a "New Substance", MITI is able to find a suitable classification for the candidate, so that it may be treated as an "Existing Chemical Substances". Chemistry may be a Science, but chemical nomenclature often permits numerous "readings" for the same compound, much like the multiple readings for a kanji.

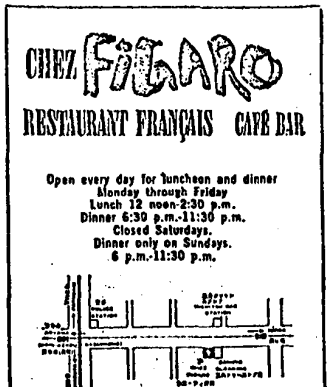
Conclusion

The foregoing resulted from a request to discuss this subject at an American Chamber Briefing Breakfast. In our reexamination of the Law we were pleased that we did not find that any American Chemical firm had experienced serious difficulties as a result or its provisions. One Chemical manufacturer stated that the only effect they noticed was that they had to prepare one additional form when clearing an import through Customs.

There have been cases in which importers have been unwilling to disclose valuable proprietary data on new concepts involving chemical substances. After sufficient tests to assure itself that no environmental problem would result, the government has agreed to permit introduction of new technologies without endangering their proprietary natures. In some cases this has taken the form of importing mixed chemicals as "Products" and in other cases clearing limited quantities of unidentified substances for specific applications under controlled conditions.

However, several importers of commercial mixtures falling under the classification of "Designated Products" have experienced expensive product recalls, and the full costs, including the effect upon "Good Will" and product image, can never be measured.

Members interested in staying abreast of these developments should order *"Kagaku Busshitsu Shinsakisei-ho Jitsumu Teiyo"* (Summary of Law and Practical Use Concerning Chemical Substances); Edited by the Chemical Safety Section, Bureau of Basic Industry Products, MITI; Distributed by Daiichi Hoki Shupan K.K., 17-1-2-chome Minami-Aoyama, Minato-ku, Tokyo 107; Telephone (3) 404-2251; Price ¥4,200. Purchasers are automatically placed on a mailing list to receive new orders, amendments, background material and other pertinent information on the Law. Most of the text is in Japanese, starting from the right hand cover. However, translations of the Law and the Orders are found inside the left hand cover. Firms potentially affected by this legislation should find this a valuable service.



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