

FAR EAST REPORT

By
ROBERT F. CONNELLY, ASLE
Barclay & Co., Inc.
Tokyo, Japan



New Japanese Law "Concerning Screening of Chemical Substances and Regulations of Their Manufacture, Importation, and Use"

For twenty years, Japan has been subjected to an increasing number of chemical substances with questionable or unknown toxicity. As a result, a whole spectrum of pollution-related diseases has been discovered and chronicled. Many of these have been traced to specific chemical substances. Since the same substances are being used in the United States, the measures enacted by the Japanese Government to prevent further harm to the lives of its citizens should be of interest. In addition, firms whose products are used in Japan will need to comply with the provisions of this legislation.

NATURE OF CHEMICALLY INDUCED DISEASES

There are four major types of "pollution diseases" associated with specific chemical agents ingested by the victims of the diseases (Table 1). In addition, there are other "pollution diseases" resulting from the inhalation of, or contact with, the irritant. The latter groups

have been omitted since they hold less significance for readers of LE.

Because of the nature of these chemical agents, great public concern has been generated. The present law was written as one of the government's reactions to public demonstrations and political activity aimed at correcting some of these abuses.

EFFECT OF THIS LAW ON CHEMICAL AND LUBRICANT MARKETERS

Legislation was enacted on September 18, 1973, and officially announced on October 16. The act and its background are available in a government publication, "An Explanation of the Law Concerning Screening of Chemical Substances" (204 pp., 1,400 yen, U. S. \$4.67). It was edited by the Chemical Safety Group of the Basic Industry Bureau of the Ministry of International Trade and Industry (MITI). In this volume, the authors have summarized the problems which the government was attempting to overcome

by the enactment of this legislation. They explain the procedures established by the United States, the European Economic Community, and Sweden to check the encroachment of persistent chemicals into the environment. The volume is written in Japanese but contains twenty-seven pages of English. The English portion includes a translation of the Japanese act and a partial copy of the American "Toxic Substances Control Act of 1972" (Sections 2, 3, 4, 5, 6, 7, and 9).

It would appear from the Japanese law that they drew upon, but did not copy, the American act. Perhaps the most notable exception is found in the fact that they required that industry, in the short period of five weeks, submit lists of all chemical substances manufactured, imported, or used prior to (October 16, 1973). Those chemicals which the government agreed should be listed have been granted a "limited grandfather's clause" for continued use provided they do not offend their privileged position. This part of the act will be explained further below. Except where noted, all chemical substances and animal, vegetable, and mineral substances within the provisions of this law, be they pure compounds, industrial grades, or mixtures such as lubricants, greases, or commercial chemical mixtures (waxes, cleaning compounds, degreasers, refrigerants, etc.) though certain mixtures containing three or more ingredients may be classified as "products" rather than "chemical substances."

SCOPE AND DEFINITIONS

The act contains certain definitions which must be explained before the

TABLE I	
DISEASE	IRITANT
Minamata Disease	Mercury, largely as methyl mercury, ingested in fish or crustaceans
Itai-itai disease (Oosh-Oosh disease)	Cadmium and perhaps lead and zinc
Morinaga Arsenic Milk Poisoning	Powdered milk containing impure disodium phosphate extender
Kanemi Rice Oil Disease	<u>Polychlorinated biphenyl (PCB)</u> leaked from heat exchanger
PCB accumulation	<u>PCB</u> ingested in fish, fowl and meat

balance of the provisions can be interpreted correctly. It defines a "chemical substance" as a "compound obtained by a chemical interaction of an element or elements or a compound of compounds (excluding radioactive substances)." As interpreted by MITI, this definition includes all manmade products and many natural substances (solvents, oils, asphalt, etc.). However, one of the supporting documents states that it does not include natural substances or compounds obtained from natural substances by separation accompanied by no chemical reaction.

In Article 2, it excludes certain compounds which are covered by existing legislation, namely "specified poisons," "stimulants," and "narcotics." Also excluded from coverage are: (1) chemical substances intended for use in "testing and research"; (2) reagents (used in detection or measurement or for synthesis); and, (3) compounds "prescribed by government ordinances." Near the end of the act, Article 33 provides for the exclusion of "chemical substances" when they are used while being taken under legislation controlling: (1) feedstuffs including additives, containers and wrappings, playthings, and detergents; (2) agricultural chemicals; (3) "ordinary fertilizers," and (4) medical supplies (including pharmaceuticals, nonpharmaceuticals, cosmetics, and medical implements). The placement and contents of this Article bear a close parallel to the U. S. Act.

"Chemical substances" are broken down further into "existing chemical substances," "new chemical substances," and "specified chemical substances." In theory, all chemicals manufactured or imported prior to October 16, 1973, are "existing." However, if no one submitted them in time to be listed in the "List of Chemical Substances," they are now treated as "new."

Because of the complexity of the translated definition of a "specified chemical substance," it has been paraphrased as follows:

A nonbiodegradable chemical substance ("does not lend itself easily to chemical changes caused by natural effects") is easily accumulated in "biological organisms" and which, if ingested continuously, may be "harmful to human health." If the chemical substance is readily changed by "natural effects" but the resulting chemical substances ("or elements") can be accumulated in "biological organisms" and "if ingested continuously, may be harmful

to human health," it also is classified as a "specified chemical substance."

The law goes on to: (1) set up procedures for screening "new chemical substances" to see whether they should be classified as "chemical substances" or "specified chemical substances"; (2) establish rules for the manufacture, import, and use of "specified chemical substances"; (3) provide for revising classifications when environmental effects reveal the need for such a change; (4) require that certain records be maintained; (5) permit inspection of facilities and records where "specified chemical substances" are manufactured or used to remove samples therefrom; and (6) impose penalties of "penal servitude" for up to three years and/or fines of up to 300,000 yen (\$1,000) or both.

PROVISIONAL LIST OF CHEMICAL SUBSTANCES

On December 31, 1973, MITI published a list of 15,001 "existing chemical substances" based upon the compounds which MITI had classified as "specified chemical substances." The presence of a particular compound, however, does not imply that it cannot, at a future date, be reclassified as a "specified chemical substance." As mentioned previously, the substances submitted must have been manufactured or imported prior to October 16, 1973. Many cables and phone calls have passed between Japan offices and American head offices over the question of disclosure of the structures of proprietary chemicals. The silicone industry and lubricating oil additive industry met with MITI to determine exactly just how they must define the structures of their compounds.

At one point, some silicone manufacturers advised that they would withdraw certain of their compounds from the Japanese market rather than disclose their exact compositions. Since some of these materials have unique properties important to various products manufactured in Japan, MITI permitted some companies to submit structures which were sufficiently generalized so that they would not reveal guarded proprietary information, provided that the spirit of the law would not be compromised. Further, rather than to extend the list beyond all reason, certain generalizations common to industrial chemical practice were permitted, e.g., alkyl chains have

been expressed as "C_nH_{2n+2}", halogens as "F, Cl or Br," etc.

After publication of the "provisional list," industry was given until January 23, 1974, to comment upon the list and recommend inclusion of substances which had been omitted. At this writing, the changes growing out of the industry review have not been released. In Japanese, the "Provisional List" is 146 pages long, costing only 980 yen (\$3.27). An unofficial English translation contains over 700 standard letter sheets and costs about 91,500 yen (\$905.00). An official translation has been promised in the near future.

There are nine major classifications in the Provisional list. They are as follows:

1. Inorganic compounds
2. Organic acyclic low-molecular compounds
3. Organic carbonaceous cyclic low-molecular compounds
4. Organic carbonyl cyclic low-molecular compounds
5. Organic heterocyclic low-molecular compounds
6. Organic polymeric high-molecular compounds
7. Organic polycondensate-type high-molecular compounds
8. Organic compounds such as prepared starch, fat, and oil
9. Miscellaneous

There are few keys to assist the user in finding a particular compound within its group. Indeed, a compound may be duplicated or may appear under "miscellaneous" rather than where one might expect to find it.

TESTING AND REVIEW

The law requires that MITI perform tests over the next three years to ascertain whether the listed substances truly comply with the requirements stating that they or their products of decomposition do not accumulate in tissues and if ingested continuously are not harmful to human health. It is anticipated that there will be numerous changes, especially within the first year of enforcement of this law. Chemical and lubricant manufacturers and importers dare not ignore these changes.

NEW PROCEDURES FOR IMPORTING "CHEMICAL SUBSTANCES"

This new law will have a strong and immediate impact upon firms who wish

to ship industrial and consumer chemicals and lubricants to Japan. Importers seeking to clear shipments after April 16, 1973, will need to identify to customs the ingredients in their products. These then must be located in the "Provisional List" as amended, and identified by code number. MITI states that they do not envision requiring importers to state the concentration of each chemical substance in mixtures.

A list of ingredients identified with their code numbers taken from the Provisional List will suffice to clear the mixture through customs. A more attractive procedure may be to request

that proprietary mixtures containing three or more ingredients be classified as "products" rather than as "chemical substances." Recently, the author's firm has been successful in clearing several lubricants in this manner.

The procedures for submitting "new chemical substances" have not been completely formulated at this writing. Readers requiring specific information may write to the author.

CONCLUSION

This new act must be looked upon as

a significant move toward the control of substances which could cause further environmental destruction of our "planet Earth." Industry which could have prevented some of these problems, must now face these new regulations in a positive, constructive manner.

EDITORS NOTE: LE will attempt to supply additional general information on this subject in future issues. Readers requiring specific information may write the author at (PO) Box 642, Tokyo 100-81.

Robert F. Connolly ASLE Far East Correspondent



Robert F. Connolly, ASLE, resides in Tokyo, where his principle activities are in the fields of pollution control and lubrication. He is a graduate in Chemistry from the California Institute of Technology.

Mr. Connolly is a member of the Society of Automotive Engineers, the American Society for Testing and Materials, the Japan Society of Lubrication Engineers, and is a Fellow of the Royal Society of Health. He has been a member of ASLE since 1954, and served as Western Regional Vice President in 1981-1982.

Mr. Connolly is employed by Barclay & Co., Inc., Tokyo, Japan. His previous employment includes Shell Oil Company, Bray Oil Company, Bray Chemical Company (now Chevron Chemical Co.), Emery Industries, Millipore Corporation and DuPont International, Inc.

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