# A Concept Regarding the Use of Information Obtained through the Existing Chemicals Survey Program Conducted by the Japanese Government

May 11, 2007

Office of Chemical Safety, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Chemical Safety Office, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry

Chemicals Evaluation Office, Policy Planning Division, Environmental Health Department, Environmental Policy Bureau, Ministry of the Environment

#### 1. Basic Concept

Based on the incidental resolution of the Diet in 1973, the existing chemicals survey program has been conducted by the Japanese Government (Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment). In the program, the three Ministries have been conducting safety testing and gathering safety information on existing chemicals that had already been manufactured or imported in or before 1973, when the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (the Chemical Substances Control Law) was promulgated. The three Ministries have also been disclosing the results of the testing by reporting to the relevant councils and by posting numerical data on the websites of the three Ministries.

Safety information on chemicals is basic information that is necessary for the proper use and management of chemical substances or products containing them. Such information is considered to be public property and is essential not only to companies handling chemicals but also to general consumers. Therefore, in principle, chemical safety information should be available to the public as widely as possible. Regarding detailed results obtained in the existing chemicals survey of which the three Ministries possess the property rights, it is desirable to make them available to a wide variety of stakeholders, as pointed out in the

<sup>1</sup> Note of translation: <a href="http://www.meti.go.jp/policy/chemical\_management/english/laws.html">http://www.meti.go.jp/policy/chemical\_management/english/laws.html</a>

\_

Interim Report for the Fundamental Issues Subcommittee, Chemicals and Bio-industry Committee, Industrial Structure Council issued in February 2007.

Based on the principles described above, the three Ministries will authorize the utilization of those survey results of which the three Ministries possess the property rights, and will further promote the release of chemical safety information.

### 2. Utilization/citation of the Results of the Existing Chemicals Survey

Citizens, NGOs, NPOs, businesses, etc., are free to utilize and cite the results of the existing chemicals survey conducted by the three Ministries for any purpose including for the template entry for the "Japan Challenge Program". At the time of citation, users must be aware of the following:

- The user must clearly state that the information cited by him/her is referred to the results of existing chemicals survey conducted by the Japanese Government.
- The user shall be responsible for any losses that may occur through the use of the information.

#### 3. Enhancement of the joint Database by the three Ministries

The three Ministries have created a joint database to promote dissemination of chemical safety information. The contents of the database will be enhanced as much as possible to support the optimal and smooth utilization of the results of the existing chemicals survey conducted by the Japanese Government. The three Ministries will promote disclosure of information mainly at the level of summary of study reports.

## <Contact details for inquiries>

Office of Chemical Safety, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Address: 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo 100-8916

Phone: +81-3-3595-2298 Fax: +81-3-3593-8913

E-mail: exchpro@mhlw.go.jp

Chemical Safety Office, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry

Address: 1-3-1, Kasumigaseki, Chiyoda-ku, Tokyo 100-8901

Phone: +81-3-3501-0605 (direct)

Fax: +81-3-3501-2084 E-mail: qqhbbfa@meti.go.jp

Chemicals Evaluation Office, Policy Planning Division, Environmental Health Department,

Environmental Policy Bureau, Ministry of the Environment Address: 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo 100-8975

Phone: +81-3-5521-8253 Fax: +81-3-3581-3370 E-mail: chem@env.go.jp

Reference: Interim Report for the Fundamental Issues Subcommittee, Chemicals and Bioindustry Committee, Industrial Structure Council (summarized in March 2007) [Excerpt]

In Japan, from this time on, the fundamental rule should be to make safety information that is specific to chemical substances (such as the hazard data mentioned above) public to ensure that this information is widely and commonly accessible to Japanese citizens, NGOs, NPOs, businesses, etc., from the public benefit point of view, regardless of whether the information belongs to the private sector or the Government.

In the course of disclosure, the information should be categorized into the following levels: hazard data; study summary; and primary data (study report). At the same time, it is expected that some consideration will have to be given to information for which the rights of the party bearing the cost for the information should be preserved.

In particular, a close study of the protection of property rights to primary data submitted to the Government by businesses which hold the property rights to such information is required. At the same time, consideration should be given to approving that the use of the primary data for which the Government holds the property rights under a certain level of Government involvement.