

THE CHEMICAL CONTROL SYSTEM IN KOREA

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Abstract: In Korea, seven ministries with their laws are involved in managing chemicals to protect human health or the environment from the hazard of chemicals. Also, further legislation will be enacted for the adoption of the international agreements and the globally harmonized system. The raw materials in industrial-use are regulated mainly under the Toxic Chemicals Control Law by the Ministry of Environment and the Industrial Safety and Health Law by the Ministry of Labor. Therefore, this presentation is focused on these two laws.

A. General Framework of Chemical Management in Korea

In Korea, the chemical industry has been an important role in national economy and the volume of chemicals in circulation (manufactured or imported) has increased on a year-by-year base with the average growth rate of more than 5% per year.

The tool for chemicals management should cover all stages of the chemical life cycle from production or import/export, transport, storage, and use to disposal. Korea has enforced a number of laws, regulations and standards for the sound management of chemicals according to the purpose of use and the physical properties. The competent authorities for health and safety matters related to chemicals are the Ministry of Environment (MOE), the Ministry of Health and Welfare (MOHW), the Ministry of Labor (MOL), the Ministry of Government Administration and Home Affairs (MOGAHA), the Ministry of Commerce, Industry and Energy (MOCIE), the Ministry of Agriculture (MOA), and the Ministry of Science and Technology (MOST). Table 1 represents a general overview of ministerial responsibilities related to the chemical management.

The raw materials for industrial use are regulated mainly under the Toxic Chemicals Control Law by the MOE and the Industrial Safety and Health Law by the MOL. While the MOE is authority dealing with the public health and the environment protection in general, the MOL handles the health and safety issues of the industry sector in particular, protecting the workers from hazardous facilities and materials related to the workplace.

More recently, further legislation has been enacted to adopt the related international agreements and conventions for the protection of human and the environment from hazards due to chemicals.

This presentation will be focus mainly on the Toxic Chemical Control Law and the Industrial Safety and Health Law.

Table 1. Overview of Laws Related to Chemicals in Korea

Products	Legislation	Authorities
Explosive, Oxidizing & Fammable Products	Fire Fighting Law	Ministry of Government Administration and Home Affairs

Gunpowder	Gun, Sword and Gunpowder Control Law	Ministry of Government Administration and Home Affairs
High-Pressured Gas	High-Pressured Gas Safety Control Law	Ministry of Commerce, Industry and Energy
Ozone Layer Depleting Substances (e.g. CFC)	Law Related to Manufacture Control of Specific Materials for the Purpose of Protecting Ozone Layer	Ministry of Commerce, Industry and Energy
Pesticides	Agricultural Chemicals Control Law	Ministry of Agriculture
Industrial Chemicals	Toxic Chemicals Control Law	Ministry of Environment
	Industrial Safety and Health Law	Ministry of Labor
Pharmaceutical Products	Pharmaceutical Affairs Law	Ministry of Health and Welfare
Cosmetics(2000)	Cosmetic Law	Ministry of Health and Welfare
Food Additives	Food Sanitation Law	Ministry of Health and Welfare
Radioactive Substances	Atomic Energy Law	Ministry of Science and Technology

B. Outline of the Toxic Chemicals Control Law and the Industrial Safety and Health Law

B.1 The Toxic Chemicals Control Law

The Toxic Chemicals Control Law ("TCCL") regulates the manufacture and import/export of virtually all chemicals. Chemicals are defined as "elements and substances created by chemical reaction" and are classified into four groups by the degree of hazards: Toxic Chemicals, Prohibited/Restricted Chemicals, Observational Chemicals, and Other Chemicals.

The TCCL strictly regulates the manufacture and import/export of the regulated chemicals (i.e. Toxic Chemicals, Prohibited/Restricted Chemicals, and Observational Chemicals). The TCCL requires that any business entity that manufactures, distributes, holds, stores, or transports the Toxic Chemicals register with the MOE, except that such registration is not required for handling of Toxic Chemicals in an amount less than 240 ton per year or experimental usage of such chemicals. The MOE may prohibit or restrict the manufacture, import, or use of chemicals which are severely harmful to human health and the environment, and 55 chemicals are prohibited for this reason. For the Restricted Chemicals, business entity that intends to manufacture, use, import or export such chemicals must obtain the permit of such business from the MOE, and for the Observation Chemicals, annual amount for manufacture or import must be reported. Such business entity must keep records related to the appropriate business activities.

The presence of Toxic Chemicals must be identified on the containers or cases, at the place where they are stored or displayed, and on the transporting vehicles.

The TCCL imposes pre-manufacture/import notification requirements on persons handling new chemicals. Further, before they are manufactured or imported, such chemicals must pass a Toxicity Review administered by the MOE.

B.2 The Industrial Safety and Health Law

The Ministry of Labor (“MOL”) has the jurisdiction over the ISHL. This law requires that business owners take necessary measures to ensure that their workers are not exposed to dangers in their work environment arising from machinery, tools, hazardous materials, electricity, heat, improper work processes, etc. and to prevent the deterioration of workers' health due to dust, radiation, lack of oxygen, vibration, waste materials, etc.

The MOL provides technical guidelines and working environmental standards that are necessary to protect workers' safety and health. Pursuant to the ISHL, the MOL has also promulgated regulations on chemicals similar to those under the TCCL, which are designed to protect the workers exposed to hazardous chemicals at the workplace.

Subject to certain exceptions, before any chemical is manufactured or imported for use at a workplace, the business owner of the workplace must complete a Toxicity Review of such chemical and report the Review Results to the MOL together with descriptions of the production method, usage and handling of such chemical. The review of Toxicity Test Results of a new chemical is performed only by the MOE and a person who desires to import a new chemical is required to submit the Toxicity Data only to the MOE, which will then send a copy of its Toxicity Review Results to the MOL as well as to the applicant.

The manufacture or use of certain materials dangerous to workers' health is prohibited or requires approval by the MOL. Crocidolite (prohibited) and Polychlorinated Biphenyls (requiring permit) are examples of such substances.

Like the TCCL, the ISHL has also labeling requirements for hazardous chemicals. All hazardous chemicals used at the workplaces must be labeled properly, and appropriate precautions must be taken to protect the safety and health of those who work with such chemicals. Under the guideline prepared for mutual acceptance of labeling system between two laws, if a label is prepared pursuant to such guideline, it will be deemed to meet both the TCCL and the ISHL requirements.

“Material Safety and Health Data Sheet” (hereinafter “MSDS”) for chemical products (including a single compound or mixture) is managed under the ISHL. When any chemical product which MSDS is required under the related regulation is transferred or supplied to any other business owner, the MSDS must be transferred or supplied to him/her.

C. The Existing Chemicals List

Under the TCCL, “Existing Chemicals List” means the list of the chemicals that had been distributed domestically and commercially prior to the effective date (Feb. 2, 1991) of the TCCL. Under the ISHL, “Existing Chemicals” means the chemicals listed on the “Existing Chemicals List” among the chemicals which are not subject to Toxicity Review under Article 40 of the Law or the chemicals whose names had been proclaimed by the administrative organizations which enforce other laws prior to June 30, 1991.

The MOE published the Existing Chemicals List in Feb. 1991 under the TCCL, and also the MOL published the Existing Chemicals List in Dec. 1993 under the ISHL,

respectively. In Dec. 1996, the Combined Existing Chemicals List was published for users' convenience. Access to the Existing Chemicals List is available via Publication, STN or CHEMLIST on-line DB (of CAS), or CAS Surveyer CD rom (of CAS).

The composition of the Existing Chemicals List is as follow:

- A total of 35,661 chemicals are listed in alphabetical order, with each chemical being described by its KE serial number (KE No.), chemical name, CAS registry number and molecular formula.
- The Existing Chemicals List is indexed by CAS registry numbers. Therefore, whether any chemicals are listed or not can be confirmed by the CAS registry number.
- IUPAC (International Union of Pure and Applied Chemistry) names, CA (Chemical Abstracts) names or the common names used internationally are listed.

D. New Chemical Notification

D.1 Outline of New Chemical Notification

At present, a person who intends to manufacture or import the new chemical must file the new chemical notification with the National Institute of Environmental Research ("NIER"), to which the MOE has delegated its authority for the Toxicity Review of new chemicals since 1995 and the MOL, respectively. The review period is max. 45 days for the two procedures. This duplicating submission requirement to the MOL and MOE will be changed this year by the amendment of the TCCL and the ISHL and the proposed amendment will unify the two procedures and designate the MOE as one channel for such application.

Under the TCCL, there are three types of notification: Full Notification, Reduced Notification, and Polymer Notification. The chemicals subject to the "Reduced Notification" refer to the chemicals which are listed on the Chemicals List of two or more foreign countries (the European Union is regarded as one nation) prior to Feb. 2, 1991. The "Polymer Notification" is applied to the chemicals which fall under OECD's polymer definition. For the polymer, notifier may submit the "Reduced Notification" submitting the pertinent toxicity data or biodegradability test data.

For each notification type, in addition to application form, and information regarding exposure to the environment (i.e. route, released amount, etc), the following test data are required:

Table 2. Data Requirement for notification under the TCCL

Type	Basic Test Data Set
Reduced Notification	One of following sets - Acute oral test + Ames test; - Acute oral test + Chromosomal aberration test ; or - Biodegradability test
Polymer Notification	- Number average molecular weight and GPC Data - Content(%) of low molecular weight species (lower than 1,000) - Amount of residual monomers - Stability test in acidic & basic condition * monomers' identity, constitutional ratio (%) of monomers
Full	Acute oral test + Ames test + Chromosomal aberration test

Notification	+ Biodegradability test
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For the New Chemical Notification under the ISHL, report form, MSDS, flow chart of manufacturing or use process, and matters for Use & Handling are required.

D.2 Confidentiality Claim


In case the notifier requests Confidential Claim for the protection of information submitted to the NIER and the MOL, the authority protects the information from being disclosed to the public. Under the TCCL, the claimed information has protected for 5 years and under the ISHL, for 3 year, respectively. In case an applicant wishes to extend the protection period, the applicant must request such extension prior to the expiration date of the protection period. The protection of chemical Identity, testing data, use, etc. may be protected. However, the protection of information on chemicals of which chemical names are disclosed on the lists of foreign countries or on chemicals which are classified as the regulated chemicals from the Toxicity Review Result is not granted.

E. Warning Label


Warning labels attached on the container or package of chemical products for industrial use (including a single compound or mixture) are regulated under the TCCL, the ISHL and the Fire Fighting Law, by which the legal responsibility is imposed on a business owner in Korea.

The warning label is almost the same in terms of classification in the TCCL and ISHL, but it is quite different in the Fire Fighting Law. Under the TCCL and the ISHL, warning labels consist of "Classification," "Symbol," "Hazard," and "Handling Precaution." The background of a hazard symbol must be in yellow or orange and borders and pictures in black with certain exception for the small sized case or package. Fig 1 represents an example for warning label of a Toxic Chemical, Methyl Alcohol

Methyl alcohol



Toxic substances
Substances



Extremely flammable

Hazard	<ul style="list-style-type: none"> - Highly flammable - Toxic if inhaled or swallowed
Precautions in Handling	<ul style="list-style-type: none"> - Keep locked up and out of the reach of children - Keep container tightly closed - Keep away from sources of ignition (no smoking) - Avoid contact with skin - If you feel unwell, seek medical advice (show the label on the container or package, if possible)

Fig. 1. An Example for Warning Label of a Toxic Chemical, Methyl Alcohol

Under the TCCL, the "Toxic Chemicals" are subject to the Labeling requirement. Under the ISHL, physically hazardous substances (explosive, oxidizing, extremely flammable, highly flammable, flammable and water prohibiting substances), hazardous substances

to health (highly toxic, toxic, harmful, corrosive, irritating, sensitizing, carcinogenic, mutagenic substances and toxic substances for reproduction) and substances hazardous to the environment as classified by the relevant regulation, "Standards for Preparing and Keeping on File the Material Safety Data Sheet, etc. (on Apr. 9, 1996, last amended on Oct. 17, 1997; The MOL's Public Notice No. 97-27)" are subject to the Labeling Requirement. Also, oxidizing solids and liquid, combustible solids, auto-ignitable substances, water prohibiting substances, flammable liquids, self-reacting substances, and oxidizing liquids are subject to the Labeling Requirement under the Fire Fighting Law. In case a warning label is attached properly under one law among the three laws mentioned above, the warning label is admitted mutually under the three laws.

F. MSDS

The business owner has a legal responsibility to prepare and keep on file the MSDS for physically hazardous substances, substances hazardous to health, and substances hazardous to the environment as classified by the relevant regulation, "Standards for Preparing and Keeping on File the Material Safety Data Sheet, etc. (on Apr. 9, 1996, last amended on Oct. 17, 1997; The MOL's Public Notice No. 97-27)." However, a business owner who intends to use, transport or store such substances or products is deemed to have fulfilled such obligation, if he/she obtained the MSDS from the manufacturer or the importer. However, in such cases, MSDS should be also prepared based on the same standards.

Following 16 Items must be included in the MSDS:

- _ Chemical products and company identification
- _ Information/content of components
- _ Risk/hazard identification
- _ First aid measures
- _ Explosion/fire fighting measures
- _ Accidental release measures
- _ Methods of handling and storage
- _ Exposure controls/personal protection tools
- _ Physical and chemical properties
- _ Stability and reactivity
- _ Toxicological information
- _ Effects on the environment
- _ Precautions for disposal
- _ Information necessary for transportation
- _ Regulatory information
- 16 Other information of reference

G. Customs Clearance of Chemical Products.

For Customs Clearance of chemical products, importers must have an "approval number" from a "Confirmation Certificate" which is issued by the Korea Chemical Management Association ("KCMA").

In order to receive a "Confirmation Certificate" from the KCMA, the following two methods are available: The first method is for the applicant to submit the information on components disclosing all components of the imported chemical product, and import-

related document. The Second method is for the applicant to submit an application, a "Self-Certification" in which no component is disclosed, and import-related documents. Upon KCMA's approval, the "Confirmation Certificate" is then issued.

Where confidentiality of the components of the imported chemical product is to be protected, an applicant may directly send the information on components to the KCMA without any intermediary. Alternately, the applicant may also choose to employ the "Self-Certification" for the complete protection.

H. Further Direction

The MOE is currently considering the whole amendments of the TCCL this year and the amended law will be enforced from next year (2003). The purpose of amendment is to strengthen chemical accidents-response system and information management system on chemicals, to improve the existing management system for hazardous chemicals and new chemical notification, and to establish a system to adopt international agreements and conventions.

Following is a summary of major change related to the trade in the proposed amendment:

- The proposed Amendment of TCCL states confirmation on the components of chemical products by manufacturer or importer (i.e. Self-Certification). "Confirmation Certificate" can be issued and used according to their need.
- The MOE will also impose a duty for Record-Keeping of documents pertaining to confirmation on chemical products, PMN, etc. on manufacturers and/or importers.
- Under present system, notifier must submit PMN to both the Ministry of Environment ("MOE") and the Ministry of Labor ("MOL"). The proposed Amendment will unify two procedures and designate MOE as the only channel for PMN. Also, the Industrial Safety and Health Law of MOL also will be amended to reflect TCCL's amendment.