

MANAGEMENT OF CHEMICALS IN JAPAN



Chemicals Evaluation office
Environmental Health Department
Ministry of the Environment, Japan

1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8975 JAPAN
TEL: +81-3-5521-8253 FAX: +81-3-3581-3370
E-mail: chem@env.go.jp <http://www.env.go.jp/en/>

Chemicals Evaluation Office
Environmental Health Department
Ministry of the Environment, Japan

Published in October 2014



Ministry of the Environment
Government of Japan

Introduction

Various chemical substances have contributed to make our daily lives convenient. However, some of these have adverse effects on human health and the environment. Chemicals may be released to the environment in various stages of their lifecycles starting from manufacturing, during the stages of import, processing and usage of these chemicals or products containing these chemicals and subsequently during recycling and disposal. Some chemicals may also be formed unintentionally through the combustion of other materials. Furthermore, chemicals vary in their forms, their distribution characteristics in the environment, the hazard they possess, etc. It is therefore necessary to take the required measures against these chemicals to protect human health and the environment. This can be done through scientific evaluation of the possibility of adverse effects (risk) posed by the chemicals to human health or the environment with due consideration of hazard characteristics of the chemicals, the level of exposure to humans and other organisms and (based on the evaluation results) by reducing the risk as much as possible. During this process, it is essential to share accurate information among the stakeholders and to maintain proper communication.

In addition, to reduce the total risk posed by these chemicals, it is important to strategically promote a comprehensive approach that combines various measures in all the stages of their lifecycles.

The main laws of Japan that deal extensively with chemicals are (1) Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law: CSCL) and (2) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Law concerning Pollutant Release and Transfer Register: PRTR Law). CSCL establishes the necessary regulations relating to manufacture, import, use, etc. of chemicals in Japan, whereas the PRTR law promotes voluntary improvement of management of chemicals by businesses and helps prevent environmental pollution through management of chemicals release. These two laws help promote the comprehensive management of chemicals in Japan.

CONTENTS

1 Current status of management of chemicals	1
(1) Risk assessment	1
(2) Risk management	2
2 Major laws and regulations for chemical substances	4
3 International cooperation in Asia related to chemicals management	5

1 Current status of management of chemicals

(1) Risk assessment

Newly manufactured or imported general-purpose (industrial) chemicals are regulated by the government under the CSCL through the review of notifications provided by the business operators in advance (prior examination). For existing chemicals already manufactured or imported at the time of enactment of this law (1973), the government has conducted safety evaluations and taken necessary regulatory measures as required. The government in partnership with the industry sector has made effort to accelerate the safety evaluation process through participation in the High Production Volume (HPV) Chemicals Program of the Organization for Economic Cooperation and Development (OECD). In 2009, CSCL was partially amended to subject even the existing chemicals to notification requirements from 2011. Screening assessment has so far resulted in 169 priority chemicals (as of September 2014).

Screening assessment will continue to be carried out, leading to addition of chemicals to the list of priority chemicals for which risk assessment will also be conducted.

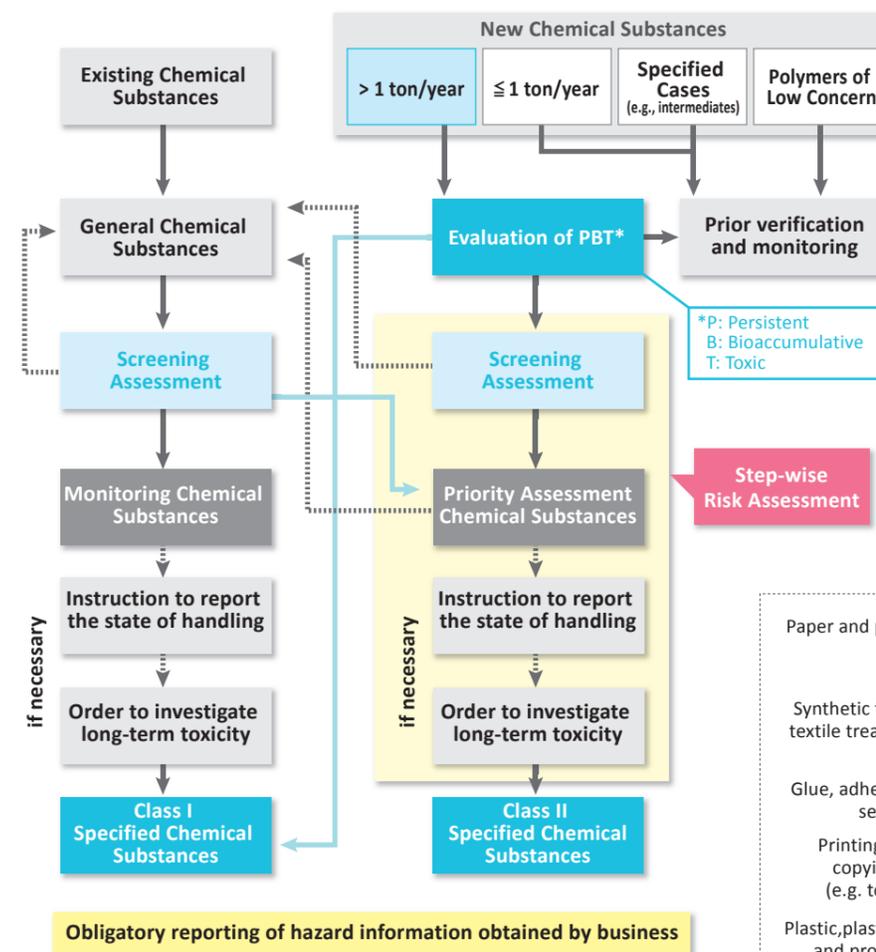


Fig.1 Overview of CSCL

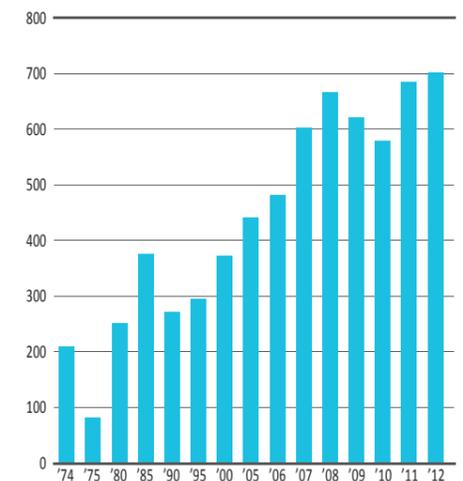


Fig.2 Annual trend of notification numbers of new chemical substances (Includes notifications for same substance)

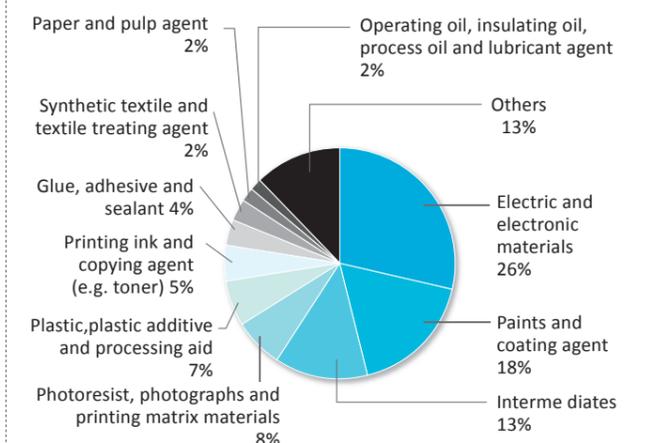


Fig.3 Primary usage of new chemical substances (2012) reference: METI Chemical Substances Council (2nd Council, FY2013)

Exposure assessment

The prerequisites for risk assessment, in addition to toxicity data collection and assessment of hazardousness, include understanding the environmental persistence of chemicals and the subsequent exposure assessment. Hence, various studies, monitoring, etc. as listed below, are carried out: (i) Environmental Survey of Chemical Substances, (ii) Hazardous Air Pollutant Monitoring Survey, (iii) Water Quality Measurement in Public Water Areas and Groundwater. Utilization of chemical release amount data (obtained from PRTR) in exposure assessment has been promoted. Efforts have been made to improve concentration prediction models. Environmental Survey of Chemical Substances has been carried out since 1974 and in order to ensure that these results are utilized effectively by the CSCL and the PRTR systems, the survey system has been reviewed several times in the past. At present, the environmental survey has 3 main components: initial environmental survey, detailed environmental survey and monitoring survey. Residual conditions of 1,236 substances have already been understood by Fiscal year (FY) 2012. Furthermore, environmental persistence of POPs is being monitored since FY 2002 as a part of the monitoring survey in order to monitor the existence of POPs-related pollutants and to confirm the effectiveness of measures implemented to eliminate and reduce POPs.

(i) Environmental Survey of Chemical Substances: The MOE has been examining the levels of chemical substances present in the environment since fiscal year 1974.

(ii) Hazardous Air Pollutant Monitoring: In compliance with the Air Pollution Control Act, local governments have been monitoring Hazardous Air Pollutants in the atmosphere. The results of these monitoring surveys have been compiled together with those monitored by the MOE.

(iii) Water Quality Measurement in Public Water Areas and Groundwater: The MOE has compiled results of the nationwide water quality survey of public water areas and groundwater implemented by the national government on the basis of the Water Pollution Control Act.

(2) Risk management

Overview of risk management

Manufacture, import and use of general-purpose (industrial) chemicals are regulated by measures stipulated by CSCL. As described above, CSCL was partially amended in 2009 to introduce a comprehensive chemical management system from FY 2011 that also includes the existing chemicals. Specifically, it introduces a mechanism whereby all businesses that manufacture or import any chemicals including existing chemicals exceeding a certain quantity are required to notify the quantity and related information every fiscal year. The government, upon receiving the notification, prioritizes the chemicals that are to be subjected to detailed safety assessment. Class I Specified Chemical Substances are prohibited from manufacture, import or use and Class II Specified Chemical Substances have restrictions relating to manufacturing or import by CSCL.

Class I Specified Chemical Substances are;

- Persistent,
- Highly bioaccumulative and
- With long-term toxicity for humans or long-term toxicity for animals at top of food chain

Class II Specified Chemical Substances are;

- Not highly bioaccumulative,
- With long-term toxicity for humans or long-term toxicity for flora and fauna in the human living environment and
- Confirmed threat of harm due to persistence in the environment

PRTR system and SDS system

PRTR system and SDS system, as stipulated by PRTR law, are in place to promote the improvement of voluntary chemicals management by businesses. These systems also help to prevent any hindrances to environmental protection. A trend in decrease in total release amount of subject chemicals notified from businesses based on the PRTR system is seen (Fig.5). The PRTR law was revised in 2008 and included revisions of subject chemicals and subject businesses specified in enforcement order for PRTR Law (enforced from FY 2011). In the SDS system, providing information of properties of the chemical and handling information when transferring the designated chemicals between businesses has been stipulated. The SDS system was amended in April 2012 to introduce GHS and it requires providing SDS for designated chemicals and obliges effort on labeling. It also requires businesses handling designated chemicals to work on improving voluntary management of chemicals according to the Japanese Industrial Standards (JIS) Z7252 (method of classification of chemicals based on GHS) and Z7253 (Hazard communication of chemicals based on GHS-Labeling and Safety Data Sheet)



Fig.5 Annual trend of reported releases and transfers

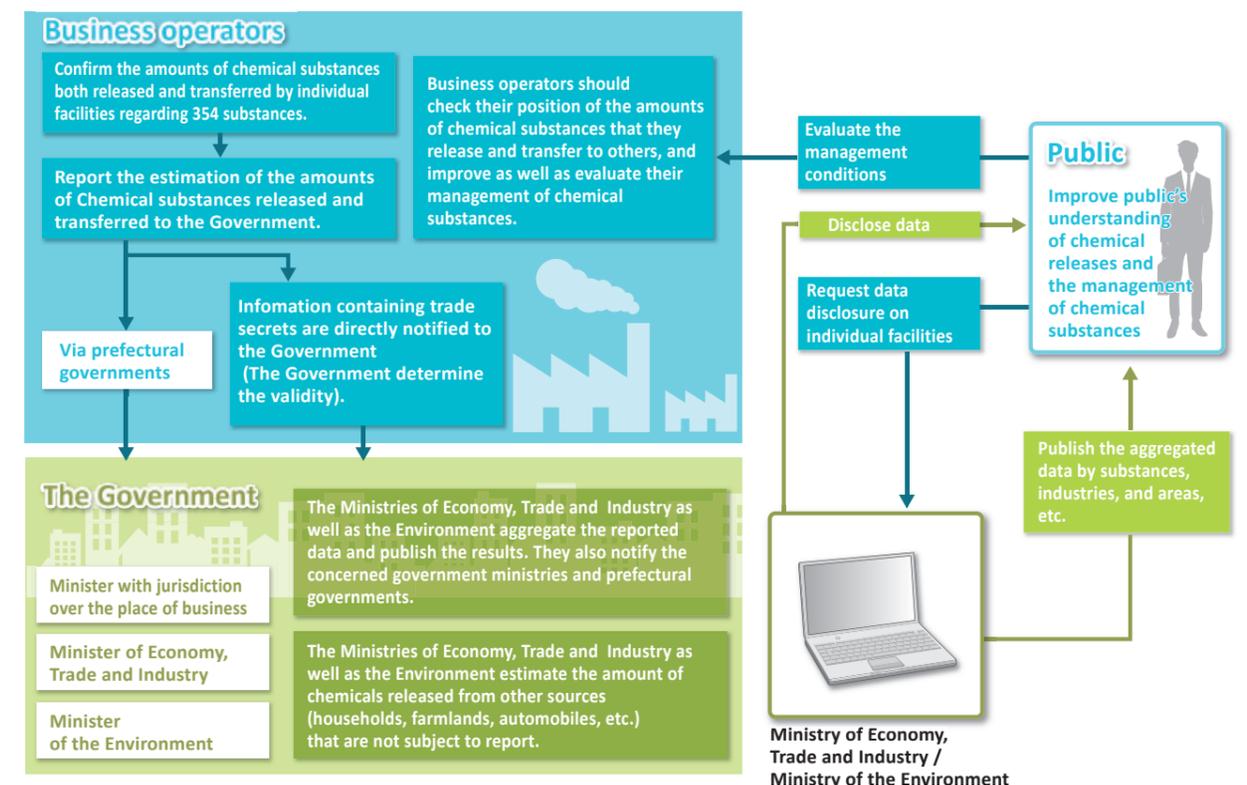


Fig.4 Flowchart of Japanese PRTR system

2 Major laws and regulations for chemical substances

3 International cooperation in Asia related to chemicals management

Principal chemical-related legal system of Japan

Hazard Exposure	Impact on human health		Impact on the environment
	Acute toxicity	Long-term toxicity	Effects on the living environment (including animals and plants)
Work environment	Poisonous and Deleterious Substances Control Act	Industrial Safety and Health Act Agricultural Chemicals Control Act	
Consumers		Agricultural Chemicals Control Act Food Sanitation Act Pharmaceutical Affairs Act Household Goods Quality Labeling Act Act on Control of Household Products Containing Harmful Substances Building Standard Act	
Via environmental effects		Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Agricultural Chemicals Control Act Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	
Pollution by emissions and stocks	Poisonous and Deleterious Substances Control Act	Air Pollution Control Act Water Pollution Control Act Soil Contamination Countermeasures Act	
Waste		Waste Disposal and Cleaning Act, and others	

Chemical related laws (in order of enactment)

Law	Competent Authority*	Subject Areas of Regulation
Food Sanitation Act 1947 Act No. 233	MHLW	Food products, additives, apparatus, containers and packaging, toys, detergents
Agricultural Chemicals Control Act 1948 Act No. 82	MAFF MOE	Agricultural chemicals
Building Standard Act 1950 Act No. 201	MLIT	Substances that may cause hygiene problems in rooms (chlorpyrifos and formaldehyde)
Poisonous and Deleterious Substances Control Act 1950 Act No. 303	MHLW	Specified poisonous substances, poisonous substances, deleterious substances
Pharmaceutical Affairs Act 1960 Act No. 145	MHLW MAFF	Drugs, quasi drugs, cosmetic products and medical devices
Household Goods Quality Labeling Act 1962 Act No. 104	CAO METI	Textile products, plastic goods, electrical appliances and apparatuses, and miscellaneous manufactured goods used by general consumers in their daily lives which are extremely difficult for general consumers to discern the quality of at the time of purchase
Air Pollution Control Act 1968 Act No. 97	MOE	Hazardous air pollutants, etc.
Waste Disposal and Cleansing Act 1970 Act No. 137	MOE	Wastes
Water Pollution Control Act 1970 Act No. 138	MOE	Effluent, etc.
Industrial Safety and Health Act 1972 Act No. 57	MHLW	Chemicals related to workplaces
Act on Control of Household Products Containing Harmful Substances 1973 Act No. 112	MHLW	Substances contained in household products
Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (CSCL) 1973 Act No. 117	MHLW METI MOE	Chemicals (However, agricultural chemicals, fertilizers, drugs and so forth that are subjected by other laws and regulations shall be exempted.)
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law) 1999 Act No. 86	METI MOE	Chemicals (including ozone-depleting substances)
Act on Special Measures against Dioxins 1999 Act No. 105	MOE	Dioxins
Soil Contamination Countermeasures Act 2002 Act No. 53	MOE	Specified hazardous substances

* Ministry of Agriculture, Forestry and Fisheries : MAFF
Ministry of Health, Labour and Welfare : MHLW

Ministry of Land, Infrastructure, Transport and Tourism : MLIT
Ministry of Economy, Trade and Industry: METI

Cabinet Office : CAO
Ministry of the Environment :MOE

Workshop for Capacity Building on Chemicals Management in Asian Countries

The workshop has been held since 2012 to promote the capacity of chemicals management and to strengthen the capacity of chemicals management of government officials and experts in charge of intergovernmental cooperation on chemicals management in Asian countries.

Major agendas are as follows;

- Current status and challenges on chemicals management and environmental management in Asian countries
- Knowledge and experience of Japan on chemicals management
- Risk assessment methods of chemical substances



2nd Workshop on Environmental Chemical Risk/ Pollution and Challenge in Vietnam

Workshop on Environmental Monitoring of Persistent Organic Pollutants (POPs) in East Asian Countries

The Workshop has been held annually to build up a framework of monitoring system in East Asian Countries and to continuously collect POPs monitoring data to contribute to the effectiveness evaluation of Stockholm Convention on POPs.

Tripartite Policy Dialogue on Chemicals Management in China, Japan and Korea

The Tripartite Policy Dialogue has been held to discuss the future challenges of environmentally sound chemicals management faced by the three countries in Northeast Asia (the People's Republic of China, Japan, and the Republic of Korea) and to explore collaboration possibilities among those three countries.

Network for Strategic Response on International Chemical Management

MOE established the Network for Strategic Response on International Chemical Management on July 26, 2007. Activities of the network include the followings related to chemicals management:

- Sharing information and strengthening cooperation between countries,
- Organizing seminars which invite speakers from overseas and
- Delivering columns, mails and magazines.

Documents of the seminars including a seminar held as part of the Tripartite Policy Dialogue are available on the following website.(<http://www.chemical-net.info/eng/index.html>)