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) 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.
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 PRTR to provide 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-Labelling and Safety Data Sheet).

Fig.4 Flowchart of Japanese PRTR system

Fig.5 Annual trend of reported releases and transfers

Current status of management of chemicals
2 Major laws and regulations for chemical substances

Principal chemical-related legal system of Japan

<table>
<thead>
<tr>
<th>Hazard Exposure</th>
<th>Impact on human health</th>
<th>Impact on the environment</th>
<th>Ministry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Industrial Safety &amp; Health Act</td>
<td>Agriculture Chemicals Control Act</td>
<td>MHLW</td>
</tr>
<tr>
<td>Long-term toxicity</td>
<td>Agriculture Chemicals Control Act</td>
<td>Food Sanitation Act</td>
<td>MHLW</td>
</tr>
<tr>
<td>Environmental effects</td>
<td>Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof</td>
<td>Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.</td>
<td>MHLW</td>
</tr>
<tr>
<td>Poisonous and Deleterious Substances Control Act</td>
<td>Air Pollution Control Act</td>
<td>Water Pollution Control Act</td>
<td>MHLW</td>
</tr>
<tr>
<td>Waste</td>
<td>Act on Control of Household Products Containing Harmful Substances</td>
<td>Soil Contamination Countermeasures Act</td>
<td>MHLW</td>
</tr>
<tr>
<td>Building Standard Act</td>
<td>Waste Disposal and Cleaning Act, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Chemical related laws (in order of enactment)

<table>
<thead>
<tr>
<th>Law</th>
<th>Competent Authority</th>
<th>Subject Areas of Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Sanitation Act 1947 Act No. 233</td>
<td>MHLW</td>
<td>Food products, additives, apparatus, containers and packaging, toys, detergents</td>
</tr>
<tr>
<td>Agricultural Chemicals Control Act 1969 Act No. 82</td>
<td>MAFF, MOE</td>
<td>Agricultural chemicals</td>
</tr>
<tr>
<td>Building Standard Act 1950 Act No. 201</td>
<td>MUT</td>
<td>Substances that may cause hygiene problems in rooms (chlorpyrifos and formaldehyde)</td>
</tr>
<tr>
<td>Poisons and Deleterious Substances Control Act 1950 Act No. 303</td>
<td>MHLW</td>
<td>Specified poisonous substances, poisonous substances, deleterious substances</td>
</tr>
<tr>
<td>Pharmaceutical Affairs Act 1960 Act No. 145</td>
<td>MHLW, MAFF</td>
<td>Drugs, quasi drugs, cosmetic products and medical devices</td>
</tr>
<tr>
<td>Household Goods Quality Labeling Act 1962 Act No. 104</td>
<td>CAO, METI</td>
<td>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</td>
</tr>
<tr>
<td>Air Pollution Control Act 1968 Act No. 97</td>
<td>MOE</td>
<td>Hazardous air pollutants, etc.</td>
</tr>
<tr>
<td>Water Pollution Control Act 1970 Act No. 138</td>
<td>MOE</td>
<td>Effluent, etc.</td>
</tr>
<tr>
<td>Industrial Safety and Health Act 1972 Act No. 57</td>
<td>MHLW</td>
<td>Chemicals related to workplaces</td>
</tr>
<tr>
<td>Act on Control of Household Products Containing Harmful Substances 1973 Act No. 112</td>
<td>MHLW</td>
<td>Substances contained in household products</td>
</tr>
<tr>
<td>Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (CSCL) 1973 Act No. 117</td>
<td>MHLW, METI, MOE</td>
<td>Chemicals (however, agricultural chemicals, fertilizers, drugs and so forth that are subjected by other laws and regulations shall be exempted)</td>
</tr>
<tr>
<td>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</td>
<td>METI, MOE</td>
<td>Chemicals (including ozone-depleting substances)</td>
</tr>
<tr>
<td>Act on Special Measures against Dioxins 1999 Act No. 205</td>
<td>MOE</td>
<td>Dioxins</td>
</tr>
<tr>
<td>Soil Contamination Countermeasures Act 2002 Act No. 53</td>
<td>MOE</td>
<td>Specified hazardous substances</td>
</tr>
</tbody>
</table>

* Ministry of Agriculture, Forestry and Fisheries: MAFF
  Ministry of Health, Labour and Welfare: MHLW
  Ministry of Economy, Trade and Industry: METI
  Cabinet Office: CAO
  Ministry of the Environment: MOE

3 International cooperation in Asia related to chemicals management

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

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)