Latest Trends on the Enforcement of Chemical Substances Control Law in Japan

Ministry of the Environment, Japan
Chemicals Evaluation Office

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1. The Chemical Substances Control Law (CSCL)
   - Overview
   - Evaluation/verification of new chemicals
   - Risk assessment under CSCL
   - Response to Class I specified chemical substances
2. Pollutant Release and Transfer Register Law ~PRTR~
3. The Strategic Approach to International Chemicals Management (SAICM)
4. Minamata Convention on Mercury
5. Japan Environment and Children’s Study (JECS)
6. Cooperative Enterprise with respect to Chemicals Management in Asian Countries
1. Implementation of the Chemical Substances Control Law (CSCL)
<table>
<thead>
<tr>
<th>Exposure Hazard</th>
<th>Via the environment</th>
<th>Discharge • stock</th>
<th>Waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poisonous and Deleterious Substances Control Law</td>
<td>Pollutant Release and Transfer Register Law / PRTR Law</td>
<td>Air Pollution Control Law</td>
<td>Water Pollution Control Law</td>
</tr>
<tr>
<td>Agricultural Chemicals Regulation Law</td>
<td>Chemical Substances Control Law</td>
<td>Ozone Layer Protection Law</td>
<td>Ozone layer destruction</td>
</tr>
</tbody>
</table>

※ Measures are undertaken to collect fluorocarbons from particular products under Law Concerning the Recovery and Destruction of Fluorocarbons.
<Purpose>
- To prevent environmental pollution caused by chemical substances that are persistent and pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna.

<Authority>
- Jointly authorized by Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI), and Ministry of the Environment (MOE)

<Primary Measures>
- **Persistence**, **Bioaccumulation**, **Toxicity**
- Prohibits in principle manufacturing or use of substances of PBT
- Restricts manufacturing or use of substances of persistence and long-term toxicity and requires them to be labeled
- Notifies the production volume of substances that could meet any of above
- Evaluates persistence, bioaccumulation, long-term toxicity, etc. of new chemical substances
<Approach>

(1) Risk

Risk of chemicals are assessed comprehensively from hazard and exposure concentration.

(2) Optimization of the process

A “stepwise assessment” is implemented, due to a great number of substances subject to assessment.
Chemical Substances Control Law (CSCL)

Chemical Substances Control Law (CSCL)

Persistent and bioaccumulative

Monitoring Chemical Substances*

Long-term toxicity for humans or for higher-order predators

Class I Specified Chemical Substances
Manufacturing or import must be prohibited

* Notify manufacturing / import quantity

Risks are not proven to be sufficiently low

Priority Assessment Chemical Substances (PACSs)*

Long-term toxicity for humans or animals / plants in living environment, or persistence in environment in extensive areas

Class II Specified Chemical Substances
Manufacturing or import must be restricted as required
<table>
<thead>
<tr>
<th>Name</th>
<th>Explanation</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class-I Specified Chemical Substances</td>
<td>Persistent, bioaccumulative, and toxicity (long-term toxicity for humans or long-term toxicity for predator animals at higher trophic level)</td>
<td>28</td>
</tr>
<tr>
<td>Class-II Specified Chemical Substances</td>
<td>Toxicity (long-term toxicity for humans or long-term toxicity for flora and fauna in the human living environment) with concern for a considerable amount of the chemical substance remaining in the environment over a substantially extensive area</td>
<td>23</td>
</tr>
<tr>
<td>Monitoring Chemical Substances</td>
<td>Persistent and bioaccumulative, but toxicity properties unknown <em>(Candidates for the Class-I Specified Chemical Substances)</em></td>
<td>38</td>
</tr>
</tbody>
</table>
| Priority Assessment Chemical Substances   | • Not found that it is clear chemical substance does not pose long-term toxicity  
• Considerable amount of chemical substance remains in the environment  
• Not thought not to pose a risk                                                                 | 140      |
| General Chemical Substances               | Industrial chemical substances other than those above                                                                                     |          |
Overview of CSCL

New Chemical Substances

- 

Existing Chemical Substances

- General Chemical Substances

<table>
<thead>
<tr>
<th>Screening Assessment</th>
<th>Monitoring Chemical Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruction to report the state of handling</td>
<td></td>
</tr>
<tr>
<td>Order to investigate long-term toxicity</td>
<td></td>
</tr>
</tbody>
</table>

- Class I Specified Chemical Substances

<table>
<thead>
<tr>
<th>Priority Assessment Chemical Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruction to report the state of handling</td>
</tr>
<tr>
<td>Order to investigate long-term toxicity</td>
</tr>
</tbody>
</table>

- Class II Specified Chemical Substances

Prior verification and monitoring

Polymers of Low Concern

Specified Cases (e.g., intermediates)

Evaluation of PBT* 

P: Persistent
B: Bioaccumulation
T: Toxicity

Obligatory reporting of hazard information obtained by business

Step-wise Risk Assessment

*If necessary
Prior evaluation and judgement is conducted to confirm whether the new chemical substances have following properties, based on report submitted by a manufacturer or importer at the time of manufacturing or importing. New chemical substances is defined as substances which have not been manufactured or imported in Japan.

① Degradable: Whether or not it is easily affected chemically in natural process

② Accumulative: Whether or not it is easily accumulated within organisms

③ Long-term toxicity to humans: Whether or not it may affect human health through continuous intake

④ Eco-toxicity: Whether or not it will affect the habitats or growth of animals and/or plants
The notification number of new chemical substances is in increasing trend. The notification number was 835 in FY2012.
The notification number of low volume new chemical substances was 31,673 in FY2012.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Number of Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coloring agent (dye, pigment, colorant, color materials)</td>
<td>2.6%</td>
</tr>
<tr>
<td>Glue, adhesive and sealant</td>
<td>2.9%</td>
</tr>
<tr>
<td>Other materials and additives</td>
<td>3.0%</td>
</tr>
<tr>
<td>Chemical process regulator</td>
<td>3.3%</td>
</tr>
<tr>
<td>Plastics, plastic additive and processing aid</td>
<td>3.6%</td>
</tr>
<tr>
<td>Fragrance and deodorant</td>
<td>6.2%</td>
</tr>
<tr>
<td>Photoresist, photographs and printing matrix materials</td>
<td>12.0%</td>
</tr>
<tr>
<td>Electric and electronic materials</td>
<td>28.0%</td>
</tr>
<tr>
<td>Intermediates</td>
<td>17.9%</td>
</tr>
<tr>
<td>Others</td>
<td>13.8%</td>
</tr>
<tr>
<td>Other materials</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

Annual trend of notification number

Primary usage of low volume new chemical substances (FY2011)

reference: METI Chemical Substances Council (1st Council, FY2012)
The confirmed number of new chemical substances of low production volume is also in increasing trend. The confirmed number was 1,316 in FY2012.

The confirmed number of polymers of low concern, implemented from April 2010, was 80 in FY2012.
Step-wise Risk Assessment Based on CSCL

**CSCL Chemical Inventory**
Existing Chemicals + Evaluated New Chemicals

- Notified Chemical Substances

**Screening Assessment**
- Notify annual quantity of manufacture etc. (mandatory)
- Submit hazard information (voluntary)

**Designation of PACSs**
- Notify annual quantity of manufacture etc. with detailed usage (mandatory)
- Submit requested hazard information
- Report requested for handling situations

**Risk Assessment (1st)**
- Conduct administratively instructed hazardous properties study (long-term toxicity tests) (mandatory upon instruction)

**Risk Assessment (2nd)**
- Notify planed annual quantity of manufacture etc.
- Technical guidance for use etc.

**Class II Specified Chemical Substances**

Industry’s role

**Risk Assessment Scheme is under consideration in external committee of 3 Ministries**
(1) Screening Assessment

【Human Health】
・Classified into hazard class by general toxicity, reproductive and developmental toxicity, mutagenicity, and carcinogenicity.

【Ecological】
・Classified into hazard class by eco-toxicological test data (algae, crustacean, fish).

<table>
<thead>
<tr>
<th>Exposure Class</th>
<th>Class1</th>
<th>Class2</th>
<th>Class3</th>
<th>Class4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class1</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Class2</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Class3</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Class4</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Class5</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Designation of PACSs
- Designated as PACSs
- Designated as Low Risk
- Remained to General Chemical Substances

【Physicochemical】
・Notify annual quantity of manufacture etc.
・Estimation of Total annual quantity of manufacture (every year update)
## Screening Assessment Result by Exposure Class

- **Evaluated substances of 7,819** *(Substance over 10 t of manufacturing & import quantity, among 11,979 substances that have been reported)*

<table>
<thead>
<tr>
<th>Exposure class (Definitive value of the FY2012)</th>
<th>In respect to hazard assessment</th>
<th>Human Health (number of substance)</th>
<th>Ecological (number of substance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>67</td>
<td>48</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>322</td>
<td>220</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>744</td>
<td>551</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>1,336</td>
<td>988</td>
</tr>
<tr>
<td>out</td>
<td>out</td>
<td>5,336</td>
<td>6,001</td>
</tr>
</tbody>
</table>

〇 Exposure Class is attributed, by adding degradability to the National Total Discharge, which is estimated from the amount of manufacture/import notified by business entities, usage classification, and emission factor of screening assessment.
② Collection of Hazard Information & Attribution of Hazard Class

- Toxicological information of general chemical substances are collected from 7,819 substance exceeding 10t of import and manufacturing volumes.

- Based on the “Screening assessment methods in CSCL”, hazard class are attributed. Confirmation of reliability is based on the following documents.
  - "The Reliability evaluation of hazard data on the human health effects in the CSCL"
  - "The reliability evaluation of hazard data on the ecological effect in the CSCL"

- So far, the government has conducted information-gathering on general chemicals for screening assessment, but a call for hazard information from the business entities will be asked, further.
### Screening Assessment Results

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance Classification of Evaluation</td>
<td>Human Health</td>
<td>Ecological</td>
<td>Human Health</td>
<td>Ecological</td>
</tr>
<tr>
<td></td>
<td>Type II Monitoring Chemical Substance</td>
<td>Type III Monitoring Chemical Substance</td>
<td>Part of General Chemicals</td>
<td>General chemical substance of all that had reported</td>
</tr>
<tr>
<td>Exposure information</td>
<td>Record of 2009 FY</td>
<td>Record of 2010 FY</td>
<td>Record of 2010 FY</td>
<td>Record of 2011 FY</td>
</tr>
<tr>
<td>Hazard Information</td>
<td>Judgment basis of Type II &amp; III Monitoring Chemical Substance</td>
<td>Judgment basis of OECD/HPV</td>
<td>Collected data that the reliability was confirmed</td>
<td></td>
</tr>
<tr>
<td>Substance for evaluation</td>
<td>682</td>
<td>212</td>
<td>109</td>
<td>275</td>
</tr>
<tr>
<td>Quantity of imports and production (over 10 t)</td>
<td>447</td>
<td>166</td>
<td>101</td>
<td>188</td>
</tr>
<tr>
<td>Corresponding Priority Assessment Chemical Substances</td>
<td>88</td>
<td>8</td>
<td>46</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>75</td>
<td>20</td>
<td>6</td>
<td>4</td>
</tr>
</tbody>
</table>
Designated Priority Assessment Chemical Substances

- Designated Priority Assessment Chemical Substances are 140 (As of March 2013)

In deliberation of July 2013, 40 substances have been prepared for public notice as priority determination corresponds.

Public site for notice
( English ver. )

J-CHECK (Japan Chemicals Collaborative Knowledge Database)

NITE CHRIP

( Japanese ver. )

Website of Chemicals Evaluation Office, MOE
(2) Procedure of Risk Assessment

**Notification of Quantity, etc. of Manufacture (Article 9)**
- Total annual quantity of manufacture etc. is less than 10t

**Reporting of Hazardous Properties (Article 41)**
- Total annual quantity of exposure is less than 1t

**Priority Assessment**
- Total annual quantity of manufacture etc. is less than 10t

**Chemical Substances**
- Count of Quantity of Manufacture etc.
- Estimation of Environmental Release
- Exposure Assessment I

**Risk Assessment**
- When Assessment II isn’t done
  - Hearing of Opinion of Councils (Article 56)

**Assessment I**
- Count of Quantity of Manufacture etc.
- Estimation of Environmental Release
- Exposure Assessment I

**Assessment II**
- Count of Quantity of Manufacture etc.
- Estimation of Environmental Release
- Exposure Assessment II

**Risk Characterization**
- Investigation of Hazardous Properties
- Exposure Assessment based on monitoring data
- Investigation of PRTR data
- Inspection of presumed amount of environmental release

**Assessment III**
- Assessment II based on more correct data

**Rescission of Designation as a PACS (Article 11)**
- Total annual quantity of manufacture etc. is less than 10t
- Total annual quantity of exposure is less than 1t
- Class II Specified Chemical Substances

**Rescission of Designation as a PACS (Article 11)**
- Hearing of Opinion of Councils about Designation of a Class II specified Chemical Substance (Article 2(3))

**Instruction of Hazardous Properties Study (Article 10(2))**
- Assessment III based on hazardous properties study
Risk Assessment (1st) is composed of three stages referred as the Assessment I, II, or III.

**<Assessment I >**

Hazard assessment uses the same information as the screening assessment. Exposure assessment uses only the notified information of production and import volume, etc.. From these results, the priorities for implementing the Assessment II are determined.

**<Assessment II >**

The hazard assessment is performed by collecting additional toxicological information. The risk assessment of Exposure Assessment is performed by increasing the coverage. The recorded monitoring data and PRTR data in past is also utilized. From these data, risk assessment is carried out, and the direction of hazard investigation or the appointment to Class II Specified Chemical Substance is determined immediately. If there is no optimal decision, Assessment III is applied.

**<Assessment III >**

The risk assessment is conducted in detail using handling information and additional monitoring data. The necessity of direction of hazard investigation is determined.
Assessment I of Risk Assessment (1st)

All Priority Assessment Chemical Substances subject to assessment

- Notified information on Priority Assessment Chemical Substances under Article 9 (i) of CSCL (quantity manufactured or imported, applications, etc.)
- Information on hazardous properties used for screening assessment

Hazard Assessment

The Hazard Assessment Value for the endpoint subject to screening assessment is derived using the same uncertainty factor as that used in screening assessment.

Exposure Assessment

Virtual emission sources by prefecture, life cycle stage and application are assumed according to a series of assumptions regarding emissions, on the basis of the quantity manufactured and delivered that has been notified by business operators.

=> The emission factor is estimated by multiplying by detailed use class.

=> Environmental concentration or human intake is estimated according to a series of assumptions concerning exposure.

<Indices>
Human: Number of emission sources nationwide at possible risk and total affected area nationwide at possible risk
Ecology: Number of locations at possible risk
### ③ Assessment I of Risk Assessment (1st)

**< Result of 2013 FY >**

<table>
<thead>
<tr>
<th>Priority Assessment Chemical Substances (Specified by FY2011)</th>
<th>95</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target for Assessment I of Risk Assessment (1st)</td>
<td></td>
</tr>
<tr>
<td>Substance to undertake the Assessment II form 2013 FY</td>
<td></td>
</tr>
<tr>
<td>Human health :</td>
<td>1</td>
</tr>
<tr>
<td>Ecological :</td>
<td>7</td>
</tr>
<tr>
<td>Total : 8</td>
<td></td>
</tr>
<tr>
<td>Substance not applicable substance to the above &amp; continually subjected to Assessment I next year</td>
<td>62</td>
</tr>
<tr>
<td>Substance for Assessment I next year; production volume survey conducted for the time being (National estimate emissions below 1t)</td>
<td>6</td>
</tr>
<tr>
<td>Substance for Assessment I next year; production volume survey conducted for the time being (Nationwide total value less than 10t of production and import volume)</td>
<td>2</td>
</tr>
</tbody>
</table>

**Ref. <Completion result of evaluation II>**

| Substances for Assessment II from FY2012 | 18 ( HH: 11, Eco: 7 ) |
### Starting Substance of Assessment II of Risk Assessment (1st)

<table>
<thead>
<tr>
<th>18 Substances for 2012 FY</th>
<th>8 Substances for 2013 FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Human health effects (11 substances) &gt;</td>
<td>♦ Human health effects (1 substance) &gt;</td>
</tr>
<tr>
<td>○ Hydrazine</td>
<td>○ 1,3 - butadiene</td>
</tr>
<tr>
<td>○ Dichloromethane</td>
<td>○ 1,2 - dichloropropane</td>
</tr>
<tr>
<td>○ Chloro ethylene</td>
<td>○ Ethylene oxide</td>
</tr>
<tr>
<td>○ 1,2 - epoxypropane</td>
<td>○ Acrylonitrile</td>
</tr>
<tr>
<td>○ Formaldehyde</td>
<td>○ α-toluidine</td>
</tr>
<tr>
<td>○ Benzene</td>
<td></td>
</tr>
<tr>
<td>♦ Ecological effect (7 substances) &gt;</td>
<td></td>
</tr>
<tr>
<td>○ 1,3 - dichloropropene</td>
<td></td>
</tr>
<tr>
<td>○ n-butyl acrylate</td>
<td></td>
</tr>
<tr>
<td>○ isopropenylbenzene</td>
<td></td>
</tr>
<tr>
<td>○ p-dichlorobenzene</td>
<td></td>
</tr>
<tr>
<td>○ Initiative 2,6-di-tert-butyl-4-methyl phenol</td>
<td></td>
</tr>
<tr>
<td>○ [3-(2-ethylhexyl) propyl amine] triphenyl boron (III)</td>
<td></td>
</tr>
<tr>
<td>○ 4,4 '-(propane-2,2-diyil) diphenol (bisphenol A)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>♦ Ecological effect (7 substances) &gt;</td>
</tr>
<tr>
<td></td>
<td>○ Hydrazine</td>
</tr>
<tr>
<td></td>
<td>○ Bromomethane (Methyl bromide)</td>
</tr>
<tr>
<td></td>
<td>○ 1,2,4-Trimethylbenzene</td>
</tr>
<tr>
<td></td>
<td>○ Naphthalene</td>
</tr>
<tr>
<td></td>
<td>○ α-(nonyl phenyl)-ω-Hydroxy poly (oxyethylene) (also known as poly (oxyethylene) nonyl phenyl ether)</td>
</tr>
<tr>
<td></td>
<td>○ Hydrogen peroxide</td>
</tr>
<tr>
<td></td>
<td>○ Acrylic acid</td>
</tr>
</tbody>
</table>
Assessment I: Risk Assessment (1st)

Prioritization of risk assessment utilize only the notification of production and import volume, as exposure information.

Assessment II: Risk Assessment (1st)

Request of handling information, Additional monitoring, etc.

Assessment III: Risk Assessment (1st)

Directions of hazard survey

Risk assessment (2nd)

Hazard Assessment

Collecting additional already-known information, scrutinizing individually, selecting Keystudy, and evaluating benthic organisms in addition to aquatic organisms (algae, crustaceans, fish)

Exposure Assessment

Implement exposure assessment using environmental monitoring data and the PRTR data in addition to the notification information, such as production volume

Specification for Class II Specified Chemical Substances

Cancellation of specifying of Priority Assessment Chemical Substances
To prevent contamination by POPs, elimination and reduction of POPs is required through international cooperation.

- The conference of the parties has been held six times so far, every two years.
- Professional and technical issues are discussed at Persistent Organic Pollutants Review Committee (POPRC).

Object substance (12 materials, initially)

- Pesticide: Aldrin, Dieldrin, Endrin, Clordane, Heptachlor, DDT, Mirex, Toxaphene
- Industrial chemicals: Dioxin, Dibenzofuran, Hexachlorobenzene, PCP

Agreed to add 9 substance group in May 2009

Japan has developed a national implementation plan for implementing the Convention.
### Substances that had been added to Annex A of COP5 and COP6

#### Matters determined in COP5

<table>
<thead>
<tr>
<th>Substance</th>
<th>Primary use</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endosulfan and its isomer</td>
<td>Pesticide</td>
<td>• Prohibition of the manufacture, use, etc. (Exception: production and use of pesticides for insect pests to in a particular crop)</td>
</tr>
</tbody>
</table>

#### Matters determined in COP6

<table>
<thead>
<tr>
<th>Substance</th>
<th>Primary use</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexabromocyclododecane, 1,2,5,6,9,10 – hexabromocyclododecane and its main isomer</td>
<td>Flame retardants</td>
<td>• Prohibition of the manufacture, use, etc. (Exception: production and use of beads method-expanded polystyrene foam and extruded polystyrene foam for construction)</td>
</tr>
</tbody>
</table>

- 2 substances above is designated as a Class I Specified Chemical Substance of CSCL, and manufacture, import and use are prohibited. (Enforced in April 2014)
- Import of products containing HBCD (flame-proof fabric flame curtain textiles flame-retardant treatment drug, and flame-retardant EPS beads) will be prohibited based on the CSCL Law (Enforced in August 2014).

※ Based on Agricultural Chemicals Regulation Law, the production and sales of agricultural chemicals are already prohibited for endosulfan.
Overview of the 6th ordinary meeting of the Conference of the Parties (COP6) to the Stockholm Convention on POPs

Date: April 30 to May 2, 2013
Location: Geneva (Switzerland)

Outcome of the meeting
- Listing of chemicals in Annex A to the convention (new POPs substance)
  → Hexabromocyclododecane (HBCD) was listed to Annex A to the convention.
- Assessment of alternatives to the use of PFOS, its salts, and PFOSF
  → Further evaluation of alternatives to PFOS, its salts, PFOSF at the POPRC.
- Work Plan for specific exemptions and acceptable purposes
  → Process for the evaluation of the continued need for the various acceptable purposes and specific exemptions is adopted (PFOS and Bromodiphenylether).
- Effectiveness evaluation
  → Revised framework for effectiveness evaluation and the global monitoring plan for persistent organic pollutants were adopted.

COP7: May 2015 in Geneva (Switzerland)
- Stockholm Convention, Basel Convention, Rotterdam Convention (three COPs) will be held jointly.
Outcomes of The Persistent Organic Pollutants Review Committee (POPRC-9) (Oct.14-18 2013) and Japan’s responses

• Chlorinated naphthalenes (CN) and hexachlorobutadiene (HCBD): decides to recommend for consideration by the Conference of the Parties for listing in Annexes A and C to the convention.

→ In Japan, CN (with more than three chlorine) and HCBD are designated as Class I Specified Chemical Substances under CSCL.

• Pentachlorophenol and its salts and esters: decides to prepare a risk management evaluation that includes an analysis of possible control measures for pentachlorophenol and its salts and esters.

→ In Japan, sales and use of PCP as an agricultural chemical is banned.

• Decabromodiphenyl ether: decides to fulfill the screening criteria and prepare a risk profile to review the proposal further.

→ In Japan, Deca-BDE is designated as Class I Designated Chemical Substance under the PRTR law.

• Dicofol: decides to place the proposal on the POPRC-10 agenda for further consideration.

→ In Japan, dicofol is designated as Class I Specified Chemical Substances under CSCL.
It was identified that organic pigments contain a small amount of unintentional byproduct-PCB, on February, 2012.

- PCB contents included in organic pigments (Survey of 588 items)

<table>
<thead>
<tr>
<th>PCB (ppm)</th>
<th>&lt;0.5</th>
<th>0.5-1</th>
<th>1-5</th>
<th>5-10</th>
<th>10-15</th>
<th>15-20</th>
<th>20-25</th>
<th>25-50</th>
<th>&gt;50</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items</td>
<td>359</td>
<td>51</td>
<td>89</td>
<td>29</td>
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*Organic pigments which contain over 50ppm of PCB was found in 17 items. For these items, shipping manufacturing, and import was already stopped.

- Study on environmental pollution and impact on consumer

Risk Assessment Study Group on the PCB as a by-product in the organic pigments (Mar, 2012 -- Mar, 2013)

- The experts discussed about the impact of the health on consumers due to the continued use of the product in which the pigment and the impact on the ecosystem and people through the pollution of the environment has been used.
- It was concluded that risk to ecological and human health via the environment is low except for extreme cases.

- Study on the level capable of reducing PCB, industrially and economically (Jul, 2013--)

- The level capable of reducing PCB as a by-product in organic pigments, industrially and economically, will be considered by referring to the expert opinion.
2. Pollutant Release and Transfer Register Law  ~ PRTR  ~
PRTR System

- PRTR (Pollutant Release and Transfer Register) System
  - Registration / Announcement systems of hazardous chemicals discharged amount to environment and migration amount contained in waste material.

- It takes much time for the determination of threshold (standard value) and risk evaluation.
  - Effectively reduce the discharge of [Gray Substance]
  - Voluntary management by business operators, information disclosure to nations and utilization by the public administration

- Preceded by U.S.A and Netherlands (Framework and main purpose are different depending on countries) → In Japan, Legislated in 1999. (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof): (Co-Jurisdiction by the MOE and METI)
PRTR System in Japan
- Purpose: Promoting the voluntarily management improvement by business operators
- Trouble Prevention for Environmental Conservation
- Target Chemicals: 354 substances → 462 substances (started since FY2010)
- Target Business Operators: Handling Business Operators (Defined by business category / size)
  - Notification of discharge amount / migration amount by the target business operators
  - Estimation of discharge amount from other exhaust sources (small size business place, non-target business category, family and mobile object) by the country
    → Adding Up and Announcement. Individual notification data has been announced since this year

Delivery system for MSDS (Material Safety Data Sheet) is also incorporated.
Institution of PRTR System

**Businesses**

Understand the chemical discharge amount to environment and migration amount contained in waste material by individual business place and target substances (354 substances)

Notify estimated values of discharge and migration amounts to the country

**Government**

Via Prefectural and City Governments

**The public**

Data Announcement for Individual Business Place

Disclosure of Data

Data Disclosure Request for Individual Business Place

Announcement of Adding Up Results by Substance, Business Category, Area, etc.

Adding Up notification data, estimate exhausts other than notification (house, agricultural land, vehicles, etc.), announce the results as well as inform the results to concerned government ministries, and prefectural and city governments [MOE, METI].

**Minister Responsible for the Business**

Minister of METI

Minister of MOE
Trend of Notified Discharge Amount / Migration Amount, FY2003 ~ 2011

Total of Discharge / Migration Amounts

(Kilo Tons)

Discharge
Migration Amount

Year
2003 2004 2005 2006 2007 2008 2009 2010 2011
How to publish data

Server

Select filtering / map

Display results with a list of companies

User

Display results with a map

Display search results on map

Emissions and movement of a fiscal year

Change in emissions and movement over the years
## Purpose of PRTR and Data Utilization Examples

<table>
<thead>
<tr>
<th>Purpose of PRTR</th>
<th>Utilization Examples of PRTR Data (Future utilization schedule included)</th>
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</table>
| [1] Basic Data for Environmental Conservation | ○ Let the PRTR Discharge Amount Data to be the benchmark toward undertaking the promotion of chemical sector  
○ Use as basic data when reviewing various political measures such as system for industrial waste subject to special control, etc. |
| [2] Priority Decision for Chemicals Countermeasure by Administration | ○ Used for the environment risk evaluation of chemicals  
○ Used for the selection of target substance / target place for environment monitoring  
○ Used for the risk evaluation of monitoring chemicals based on CSCL |
| [3] Promotion of voluntary management by business operators | ○ Provision of tools such as the estimation of environment concentration around business offices to business operators.  
○ Used as business operator instruction material at local public entities |
| [4] Provision of information to nationals and enhancement of understanding regarding chemicals | ○ Announce the adding up results of data and post them on the web.  
○ Prepare map information on discharge amount and estimated atmospheric concentration and post them on the web.  
○ Prepare a guidebook for citizens and chemical fact sheet in which PRTR data is utilized. |
| [5] Understanding of effect and progress status of environment countermeasure | ○ Understand the countermeasure situation regarding the reduction of priority undertaking substance of Air Pollution Control Act with monitoring data and PRTR data. |
Promote activities including organizing liaison conferences among relevant ministries and agencies, setting the JIS standards of GHS classification methods and providing governments’ classification of substances.

Classification by governments:
- Approx. 2500 substances were classified between FY2005 and FY2011 (further classification is currently in action).
- Classification results are made available to the public:
Systematic Revision to Introduce GHS

- Improve Japanese Industrial Standards (JIS)
  JIS Z7250 (MSDS) and Z7251 (Indication) are integrated to establish JIS Z7253, the common base of “communication” on the basis of the GHS with newly added indications in workplaces (March 25, 2012).

- Revise Ministerial Ordinance of the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
  - Enlarge items listed in SDS to 16 items appropriate for the GHS (effective on: June 1, 2012 for pure substances and mixtures)
  - Add a new obligation to make efforts for label indication (effective on: June 1, 2012 for pure substances; April 1, 2015 for mixtures)
  - Add a new obligation to provide SDS and labels by means appropriate for the GHS (effective on: June 1, 2012 for pure substances; April 1, 2015 for mixtures)

- Revise the Ministerial Ordinance of the Industrial Safety and Health Act, etc. as well. SDS and labels compliant with relevant laws and appropriate for the GHS may be created and provided by conforming to JIS.
3. The Strategic Approach to International Chemicals Management (SAICM)
**SAICM: History to Adoption**

- **1992**  “Agenda 21” adopted at Earth Summit
  (Chapter 19: Management of toxic chemicals)

- **1994**  Intergovernmental forum on chemical safety established

- **Sep 2002**  **Implementation Plan on sustainable development for World Summit**
  - Aim to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach.
  → Decide to develop the strategic approach (SAICM) for the above by 2005

- **2003 ~ 2005**  Three times of preparatory meeting, Regional meetings in five regions of the world, etc.

- **Feb 2006**  **SAICM adopted** at International Conference on Chemicals Management (ICCM)
Actions to SAICM (Past and Prospect)

- May 2007  Asia-Pacific regional meeting (Bangkok)
- 2009  ICCM2
  **Review of SAICM implementation**
  → Further chemicals management in developed countries
  → Support and fund to developing countries
  → Actions to emerging policy issues including chemicals in products, nano materials, etc.

- Nov 2009  Sep 2011: Asia-Pacific regional meeting (Beijing)
- 2009 ~ 2012  Chairmen corps meeting (multiple times)
- Nov 2011  Open-ended working group for preparation of ICCM3
- Sep 2012  ICCM3
- 2015  ICCM4
- 2020  ICCM5

Settle on further actions in countries and international organizations

Minimize the significant adverse effect of chemicals to health and the environment by 2020.
Japan’s activities related with SAICM

○ Domestic activities
  • Promote a variety of individual measures (Revision of Chemical Substances Control Law and Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof)
  • Set up a liaison meeting at relevant Ministries and Agencies
  • Place the 2020 goal and SAICM in the Basic Environment Plan
  • Formulate the SAICM national implementation plan (11th Sep, 2012)
  • Policy dialogue on chemical substances and environment

○ International activities
  • ICCM Vice Chairperson as representative of Asia-Pacific Region
  • Support Thailand and Bhutan for the Quick Start Program (in-kind QSP)
  • Participate in the activities such as workshops related to emerging policy issues, etc.
SAICM National Implementation Plan (Nov. 2013)

[Conventional measures and issues in chemicals management]
- Promotion of chemicals management with international viewpoint pursuant to SAICM
  - Implementation of chemicals management in each field, such as the environment (Basic Environment Plan, Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances, Law concerning PRTR, etc.), labor safety and hygiene, and safety measures for household appliances
- On the other hand, measures to deal with anxiety of the citizens for the safety of chemicals, and further coordination, reinforcement, etc. in each measure of risk assessment and management are demanded.

Involvement of various stakeholders (Discussion in Policy Dialogue on Chemicals and the Environment)

Reflection of opinions from all levels of civil society (Implementation of Public Consultation)

Development of SAICM National Implementation Plan
&lt;Comprehensive strategies regarding chemical substances&gt;
(Developed by the liaison meeting among relevant Ministries and Agencies)

- Promotion of science-based risk assessment
- Risk reduction throughout whole life-cycle
- Response to emerging and uncertain issues
- Strengthening of safety and security
- Promotion of international cooperation and coordination
- Issues to be examined in the future

Review of the progress of the Plan and its announcement prior to ICCM4 to be held in 2015

Amendment, if necessary, reflecting the discussion in ICCM

Towards Achievement of WSSD2020 Goal
SAICM implementation plan of Japan
6 pillars of Actions (1)

○ 6 main actions ~ Concrete action items
(1) Promotion of science-based risk assessment
(2) Risk reduction throughout whole life-cycle
(3) Response to emerging and uncertain issues
(4) Strengthening of safety and security
(5) Promotion of international cooperation and coordination
(6) Issues to be examined in the future

(1) Promotion of science-based risk assessment

○ Promote efficiently scientific risk assessment and develop a new method and make it in practical use.
  - Take actions based on Chemical Substances Control Law, Agricultural Chemicals Regulation Act, and Industrial Safety and Health Act
  - Utilize QSAR or Category Approach
  - Set the environmental target, upgrade of the quantitative evaluation method for setting the environmental target, etc.
  - Perform POPs and monitoring of heavy metals, etc.

(2) Risk reduction throughout whole life-cycle

○ Further promote the risk reduction measures based on the results of the risk assessment
○ Risk reduction in the whole life-cycle of chemicals and a proper combination of various means
  - Actions based on Chemical Substances Control Law, Industrial Safety and Health Act, and Act on Control of Household Products Containing Harmful Substances
  - Measures against the environmental emission
  - Actions related to the products recycling or the disposal stage, etc.
  - Operation of the PRTR system
  - Actions for accidents and disasters, etc.
Action Items (2)

(3) Response to emerging and uncertain issues

- Right actions for the unsolved problems including the following problems that require the efforts based on the thought of preventive measures
- Actions considering the influence of the exposure to chemicals on the health of the group who are vulnerable or have great sensitivity to chemicals.
  - Ecology children survey
  - Study on the complex influence of chemicals
  - Research for the influence of the minimum amount of chemicals on human health
  - Actions for endocrine disruption of chemicals
  - Actions for nanomaterials

(4) Strengthening of safety and security

- Continual performance of various monitoring, etc. as a basis for ensuring safety and security on chemicals
  - Conduct various environmental surveys and monitoring
  - Further promotion of risk communication
  - Promotion of taking actions for chemicals in products
(5) Promotion of international cooperation and coordination

- Management of chemicals in line with SAICM from the global aspect in collaboration among the relevant Ministries and Agencies and contribution to the international performance of SAICM
- Promote actions based on POPs (Stockholm convention on Persistent Organic Pollutants)
- Participate in OECD, etc.
- Collaborate globally on the Ecology and Children survey.
- Cooperation with the regions in Asia.

(6) Issues to be examined in the future

- With regards to the various topics we take its emergency and social requirement into consideration, in light of the discussions in “Policy Dialogue on Chemicals and Environment” where various entities participate and exchange their opinions, examine them in their priority levels, and promptly implement it once it becomes possible for that.
- Actions for emerging policy issues of SAICM (chemicals in products, nanomaterials, e-waste, lead in paints)
- Actions for the so-called “sick-house” issues
- Biocide
All relevant sectors and stakeholders should be involved in the decision-making processes to ensure transparency and accountability.

Policy dialogue was set up in March 2012 as a site where the relevant entities exchange opinions on chemicals and environment for consensus formation. It aims at making policy proposals for securing the people’s safety and security against the chemicals.

continue discussions on progress of the SAICM implementation plan.
Chemicoco: Chemical Information Retrieval Support System

Chemicoco is a search tool for chemicals information. (Japanese only)
Users can access directly to reliable chemical information! 2200 substances linked.

Search from
related Laws and how to use

Lists for outside database

Links for Chemicals commentary

URL: http://www.chemicoco.go.jp/
Manufactured Nanomaterials

• MOEJ’s activities
  – Publication of MOEJ’s guidelines for preventing environmental impacts from manufactured nanomaterials (MNs) (March 2009)
  – Projects for attempts to verify the validity of current control measures (FY 2009-2010)
  – Refocused to hazard identification and monitoring of MNs in the environment (FY 2011-)
    • Evaluation of existing studies on ecotoxicity of MNs
    • Development of methodology for measurement of MNs aiming at monitoring MNs in the environment

• Association with activities by OECD
  – Participation into discussion under the Working Party on Manufactured Nanomaterials (WPMN) of OECD programme
4. Minamata Convention on Mercury
**Minamata Convention on Mercury**

**Process to adoption**

- UNEP started its program for Global Mercury Assessment and Management in 2001
- February 2009, UNEP GC Decision 25 agreed to commence Negotiations in 2010 and aim at the adoption of the Convention by 2013
- June 2010, Intergovernmental Negotiating Committee (INC1) was held, and held five times of INC until 2013
- January 2013, agreed upon the “Minamata Convention on Mercury” texts in INC5
- **October 2013, The Conference of Plenipotentiaries on the Minamata Convention was held in minamata and kumamoto**
  - more than 1000 people including about 60 ministers and other governmental representatives from 139 countries and area
  - adopt Minamata Convention on Mercury unanimously and start a signature. 92 countries and area signs the Convention.
Outline of the Convention text

- the substantial lessons of Minamata Disease in the preamble
- regulate primary mercury mining, the import and export of mercury, artisanal and small-scale gold mining (ASGM)
- regulate manufacture, import or export of mercury-added products (fluorescent tube, thermometer, sphygmomanometer), and regulate manufacturing processes in which mercury is used
- promote measures of reducing emissions to the atmosphere, land or water based on Best Available Techniques / Best Environmental Practice (BAT/BEP)
- reduce emissions to the atmosphere for coal-fired power plants, the non-ferrous metal mining industries
- promote appropriate disposal of Mercury wastes while taking existing treaty (Basel Convention) and consistency.
- establish the fund mechanism to support the ability development and capital spending of the developing country

Action for the Convention’s effectuation

- enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession.
- hold the first Conference of the Parties (COP1) within one year.
- The UNEP secretariat mentioned aiming at the Convention’s effectuation of 2016, in the Conference of Plenipotentiaries
5. Japan Environment and Children’s Study (JECS)
Core Hypothesis: Chemical exposure during the fetal and infant stages adversely affects children’s health and development.

Method • Target: Birth cohort study, 100,000 subjects.

Term: 16 years (recruitment 3 years, data collection 13 years) possibly longer.

Funding:
- 3.1 billion yen ($31 million) in FY 2010
- 4.6 billion yen ($46 million) in FY 2011
- 6.1 billion yen ($61 million) in FY 2012
- 6.1 billion yen ($61 million) in FY 2013

Prospective Results:
(1) Identify environmental factors impacting children’s health and development.
(2) Develop better risk management specifically addressing children’s health.
(3) Ensure a sound environment where future generations live.
(4) Promote children’s environmental health studies.
Chemical exposure during the fetal and infant stages adversely affects children’s health and development.

**Chemicals in the Environment**
- POPs (dioxins, PCBs, organofluoric compounds, flame retardants, etc.),
- Heavy metals (mercury, lead, arsenic, cadmium, etc.),
- Endocrine disruptors (bisphenol A, etc.),
- Agrichemicals, VOC (benzene, etc.), etc.

**Physical Development**:
- Low birth weight, development after birth, etc.

**Congenital Anomalies**:
- Hypospadias, cryptochidism, cleft lops, cleft palate, spina bifida, etc.

**Sexual Differentiation**:
- Sex ratio, genital development impairment, sexual differentiation of the brain, etc.

**Psychoneuro developments**:
- Autism, learning disorders, ADHD (attention-deficit hyperactivity disorder), etc.

**Compromised Immune System**:
- Pediatric allergies, atopic eczema, asthma, etc.

**Endocrine / Metabolic Abnormalities**:
- Lowered glucose tolerance, obesity, etc.
Research Flow

Enrollment 100,000 pregnant women

Early Pregnancy

- Informed consent
- Questionnaire
- Collect mother’s blood and urine samples

Mid to late pregnancy

- Evaluate at health condition of baby at birth
- Collect cord blood samples
- Collect parent’s blood samples and mother’s hair
- Collect baby’s dried blood sample

At birth

- Collect breast milk
- Collect baby’s hair

1 month old

- Questionnaire (every 6 months)
- Environmental measurements

6 months to 12 years old

- Measure Chemical Substances
- Collect breast milk
- Collect baby’s hair

Statistical Analysis

Identify environmental factors affecting children’s health
Organization

**Ministry of the Environment**
- Overall Planning
- Budgeting

**Cooperation**
- Ministry of Health, Labor and Welfare
- Ministry of Education, Culture, Sports, Science and Technology
- United States and other countries

**Local Governments**
- Outreach to increase citizens awareness and participation
- Assist recruitment through the Mother-Child Health Handbook
- Provide administrative data based on applicable laws

**Cooperating Local Medical Institutions (Hospitals and Clinics)**
- Register study participants (expectant mothers) and collect biological specimens at the request of the regional centers.

**National Center (National Institute for Environment Studies)**
- Implementation body
- Data systems management, specimen storage, and accuracy control
- Support and oversight of Unit Centers

**Medical Support Center (National Center for Child Health and Development)**
- Providing medical support
- Support protocol writing relating to the outcome measurement
- Guidance and support for health care professionals involved in the study

**Regional Centers (15 locations nationwide)**
- Recruit study participants and conduct follow-up until 13 years old
- Collect biological specimens and implement questionnaire program
- Communicate with participants through individual consultation services
6. Cooperative Enterprise with respect to Chemicals Management in Asian Countries
In 8th Tripartite Environmental Ministries Meeting among Japan, China, Korea

Upon receiving the agreement on “promotion of information exchange on policies and regulations on chemical management.

The First Tripartite Policy Dialogue on Chemicals Management among China, Japan, and Korea

Purpose:
- Different situation in three countries should be recognized;
- Long-term co-operation should be set up based on common interests; and
- Co-operative activities should include the elements of capacity building, collaboration and efforts for harmonization

The 7th Dialogue has been held since Fiscal year 2007.

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<tr>
<td>Japan (Tokyo)</td>
<td>Korea (Seoul)</td>
<td>China (Beijing)</td>
<td>Japan (Tokyo)</td>
<td>Korea (Jeju)</td>
<td>China (Hangzhou)</td>
<td>Japan (Kyoto)</td>
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For the harmonization of the chemical substance policy among China, Japan and Korea

We have been a dialog about chemical management with China and Korea which are closely related to Japan about chemical management.

The export and import of the chemical substance are performed frequently within the East Asia area (Mainly, China, Japan and Korea). Especially, proper management of the chemical substance within East Asia is important for each country.

Policy dialog

- Transmit information about results of dialog to the business and the public

〈Expected outcome〉

- Rationalisation and facilitation of the export and import of a chemical substance
- Rationalisation of the chemical management in whole East Asia

Cooperation and harmonization of the chemical management system
Training Seminar in Asia (Viet Nam) for Enhancing the Ability of Handling Chemicals

【Summary】

Purpose:
To promote an improvement of a capacity of chemical management and to strengthen chemical management in Asia.

Major agendas:
- Current status and problems of environmental pollution in Viet Nam
- Knowledge and experience of Japan on chemicals management
- Risk assessment methods of chemical substances

Place: Hanoi, Viet Nam

Date: 1st, 16th February, 2012 / 2nd, 7th March, 2013

Participants: Departments of Ministry of Natural Resources and Environment, Department of Natural Resources and Environment from local governments, etc. Approximately 30 people
Project for the Development of Basic Schemes for PRTR System in Kingdom of Thailand

Project by: JICA, MONRE, MOI
Place: Kingdom of Thailand Rayong province
Term: 2011 ~ 2014
Contents: the Development of Basic Schemes for PRTR System

The Network for strategic Response to International Chemical Management

**Purpose**

The Network for strategic Response to International Chemical Management was established on July 26, 2007. All organisations can participate in the network as long as it arranges to network’s objectives.

**Activities**

- Sharing of information and strengthening of cooperation.
  - Hold seminars consisted of lectures from administrators from overseas, columns, and mail magazines.

**Participants**

- As of October 2nd, 2013
  - Number of organisations: 313
Thank you for your attention.