Chemical Control Legislation In Japan

Outline of the 2003 Partial Amendment to the Chemical Substances Control Law

Chemical Management Policy Division
Ministry of Economy, Trade and Industry
Contents

- Background to the amendment of the Chemical Substance Control Law
- Major contents of the amendment
  - Evaluation and regulation on adverse effects on living organisms in the environment
  - Measures for persistent and high bioaccumulative existing chemical substances
  - Reform of the evaluation system for new chemical substances
  - Introduction of obligation to report the hazard information voluntarily obtained by businesses
  - Other (announcement period of substance names, stronger penalties, etc.)
About the Chemical Substances Control Law (CSCL)

- **Established in 1973**
  - Introduced hazard-based evaluation of new chemical substances
  - Restricts manufacturing, import and use of PBT
- **First Amendment in 1986**
  - Introduced risk-based regulation for persistent chemical substances with long-term toxicity
- **Second Amendment in 2003**
  - Introduced evaluation and regulation on the adverse effect on living organisms
  - Reform of the evaluation system for new chemical substances
Evaluation and regulation systems under the Former CSCL

**Existing chemical substances (Inventory)**

**New chemical substances**
- manufacture/import over 1 ton/year
- manufacture/import up to 1 ton/year
- medicine intermediate

**Prior evaluation**
- persistence, bioaccumulation, human toxicity

**Designated Chemical Substance**

**Direction to investigate toxicity**

**Class I Specified Chemical Substance**
- Hazard-based assessment
- Risk-based management

**Class II Specified Chemical Substance**

*Prior evaluation: conducted prior to the manufacture or import*
### Regulatory measures for control substances

| Class I Specified Chemical Substance | • Permission is required for manufacture and/or import (actually prohibited)  
• Any use other than that specified is prohibited  
• Import of the products (articles) specified by Cabinet Order is prohibited  
• Injunction to take measures such as recall (when the substance/product is designated, or when the law is violated) |
| Class II Specified Chemical Substance | • Mandatory reporting of planned and actual quantity manufactured/imported, use, etc.  
• If deemed necessary in terms of risk, the government issues orders to change the planned quantity manufactured/imported, etc.  
• Government provides technical guidelines and related recommendations  
• Mandatory labeling and related recommendations from government  
• Guidance and advice (where necessary to prevent environmental pollution) |
| Designated Chemical Substance | • Mandatory reporting of actual quantity manufactured/imported, use, etc.  
• Publication of the name and reported quantity of the designated chemical substance (only when more than 100 tons/year)  
• Guidance and advice (where necessary to prevent environmental pollution)  
• Government directs manufacturers and importers to investigate hazardous properties when deemed necessary in terms of risk |
Background to the amendment

Development of international and domestic efforts on chemical substance management since the last amendment of the law (1986)

(1) International
   - OECD Environmental Performance Reviews: Japan (January, 2002)
     <Recommendations>
     - Extension of the scope of regulation to protect ecosystem
     - Further improvement of the effectiveness and efficiency of chemical management
       (Many industrialized countries have been carrying out risk-based evaluation and regulation to protect human health and environment.)
   - International momentum to harmonize the evaluation systems of all countries

(2) Domestic
   - Establishment of environmental standards in Japan for water quality to protect aquatic organisms (2003)
   - Review of the standard of registration under the Pesticide Regulation Law from the viewpoint of the adverse effects on living organisms (2002)
Framework for evaluation and regulation under the Amended CSCL

Existing chemical substances

- Hazard assessment
  - Type I Monitored Chemical Substance
    - Type I Monitored Chemical Substance
      - Direction to investigate toxicity
        - Class I Specified Chemical Substance

New chemical substances

- Manufacture and import over 1 ton/y (nationwide)
- Manufacture and import up to 1 ton/y (nationwide)
- Cases defined by Cabinet Order (intermediate substance, etc.)

Prior evaluation
- Persistence, bioaccumulation, human toxicity, ecotoxicity

Type I Monitored Chemical Substance
- Direction to investigate toxicity
  - Class I Specified Chemical Substance

Type II Monitored Chemical Substance
- Direction to investigate toxicity
  - Class II Specified Chemical Substance

Type III Monitored Chemical Substance
- Direction to investigate toxicity
  - Class III Specified Chemical Substance

Prior verification
- Ex-post monitoring
  - Manufacture and import up to 10 tons/y (nationwide)

- Effects on living organisms
  - Obligation to report

Manufacturers/importers are required to report hazard information
1. Introduction of an evaluation/regulation system focused on effects on living organisms

(1) Pre-manufacturing/import evaluation on eco-toxicity taking account of
   - the framework of the pre-manufacturing/import evaluation of the former CSCL (e.g., relationship with the regulatory measures)
   - eco-toxicity test items using worldwide (OECD-MPD) (e.g., acute toxicity tests on algae, daphnia and fish)

(2) Regulation
   - Hazard-based evaluation → Monitoring measures
   - Risk-based evaluation → Quantitative management measures

- Type III Monitored Chemical Substance
- Class II Specified Chemical Substance
- Class I Specified Chemical Substance

- Evaluation by three types of tests
- Evaluation by the effects on living organisms in the living environment of human beings
- Evaluation by the effects on top predators
## Introduction of an evaluation/regulation system focused on effects on living organisms

### Test items for determination of toxicity to living organisms

| (1) Type III Monitored Chemical Substance | Algae growth inhibition test (OECD 201) 
| | Daphnia sp. acute immobilization test (OECD 202) 
| | Fish, acute toxicity test (OECD 203) |
| (2) Class I Specified Chemical Substance | Two-generation reproduction toxicity study (OECD 416) 
| | Avian reproduction test (OECD 206) |
| (3) Class II Specified Chemical Substance | Alga, growth inhibition test (OECD 201) 
| | Daphnia magna reproduction test (OECD 211) 
| | Fish, early-life stage toxicity test (OECD 210) 
| | Sediment-water chironomid toxicity test using spiked sediment (OECD 218) 
| | <limited to the case when two ministers judge it necessary, based on the status of residue in the environment> |
1. Introduction of an evaluation/regulation system focused on effects on living organisms

**Test procedures**

- The specific test procedures are provided by the Director-General notice (MHLW, METI, MOE)
- Test procedures are equivalent to the corresponding OECD test guidelines

**Good laboratory practice (GLP)**

- Standards concerning test facility and operation of GLP are provided by the Director-General notice (MHLW, METI, MOE)
- Ministry of the Environment has been added as the GLP compliance monitoring authority for eco-toxicity tests
1. Introduction of an evaluation/regulation system focused on effects on living organisms

Classification of the notice of judgment

<table>
<thead>
<tr>
<th>former</th>
<th>after the amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I specified C. S.</td>
<td>Class I Specified Chemical Substance</td>
</tr>
<tr>
<td>Designated C. S.</td>
<td>Type II Monitored Chemical Substance</td>
</tr>
<tr>
<td></td>
<td>(does not fall under Type III Monitored Chemical Substance)</td>
</tr>
<tr>
<td>Exempted from the regulation</td>
<td>Type III Monitored Chemical Substance</td>
</tr>
<tr>
<td></td>
<td>(does not fall under Type II Monitored Chemical Substance)</td>
</tr>
<tr>
<td>Impossible to determine</td>
<td>Type II and Type III Monitored Chemical Substance</td>
</tr>
<tr>
<td></td>
<td>Substance exempted from the regulation</td>
</tr>
<tr>
<td></td>
<td>Impossible to determine</td>
</tr>
</tbody>
</table>

Difference between Type II and Type III Monitored Chemical Substances

<table>
<thead>
<tr>
<th>Type II Monitored Chemical Substance (human toxicity is suspected)</th>
<th>Type III Monitored Chemical Substance (ecotoxicity has been found)</th>
</tr>
</thead>
<tbody>
<tr>
<td>When a toxicity study has proved that there is no long-term toxicity, the designation as Type II Monitored Chemical Substance is cancelled.</td>
<td>When a toxicity study has proved that there is no chronic toxicity to living organisms in the human living environment, the name of the substance is announced (designation is not cancelled, but notification of the actual quantity manufactured and imported, etc. is not required).</td>
</tr>
</tbody>
</table>
2. Measures for persistent and high bioaccumulative existing chemical substances

Background to the introduction

Existing chemical substances that are found to be persistent (P) and high bioaccumulative (B)

If they have long-term toxicity (T), they fall under Class I Specified Chemical Substances.

However,
- assessment of long term toxicity requires a long period of time, and
- there was no legal measure to collect the actual exposure information, etc. before completion of the assessment.

Type I Monitored Chemical Substance is thus introduced to improve the management system.

- Monitoring system similar to that of the former Designated Chemical Substances
  (i.e. reporting/publishing of actual quantity, guidance/advice for prevention of environmental pollution, direction to study hazardous properties)
- Risk-based management measures
- Applicable only to existing chemical substances
The new management measures relating to Type I Monitored Chemical Substance

Based on the assessment of existing chemical substances:
- Persistence: high
- Accumulativeness: high

Type I Monitored Chemical Substance
- Persistence: high
- Accumulativeness: high
- Public announcement of the substance name
- Reporting of actual quantity manufactured/imported and use
- Public announcement of the name and amount of the substance

None or very little
Assessment of exposure
Concern
Quantity manufactured/imported or consumption for open systems exceeds certain amount.

Preliminary toxicity assessment (on human beings and top predators)
Risk assessment based on the above data
Low concern
 Guidance/advice to reduce release into the environment (risk reduction measures)
Assessment of effect of the risk reduction measures
Low concern

Reporting of hazard information (toxicity rest data, etc) by businesses
High concern

Government directs manufacturers and importers to study hazardous effects (reporting of long-term toxicity for humans/living organisms).
Investigation and reporting

Judgment on hazardous properties
No long-term toxicity
Not designated as Class I Specified Chemical Substance
Long-term toxicity is found
Designated as Class I Specified Chemical Substance

(After direction to study)
Recommendation to limit manufacture, import and use (based on article 29 of the Law)
3. Reform of the evaluation system for new chemical substances

- Introduction of exemption of evaluation
  Manufacture/import is permitted after obtaining prior verification from three Ministers that the new chemical substance has a low possibility of causing environmental pollution due to the planned handling measures. (i.e., intermediates/substances used in closed-system/substances export only)

- Introduction of stepwise evaluation of chemical substances manufactured or imported in low quantities
  As for substances that are evaluated to be persistent but not high bioaccumulative in the process of evaluation, manufacture/import is permitted after obtaining prior verification from three Ministers that the manufacture/import amount per year (nationwide) of the substance shall be **10 tons or less.** (i.e., no obligation to submit toxicity data or eco-toxicity data)

Note: Three Ministers may order the notifiers who have received a verification to submit reports related to their business operations or to have on-site inspections by ministry personnel, if deemed necessary.
New chemical substances

Planned manufacture/import (nationwide) over 1 ton/year

Verification procedure
- Amount manufactured/imported
- Risk for human health and environment based on the existing knowledge

Not verified
- Notification of manufacture/import is required

Verified
- Manufacture/import is allowed for the year only

Ex-post monitoring

Evaluation

persistence

Persistent

Not high bioaccumulative

High bioaccumulative

Evaluation

bioaccumulative

< Toxicity test relating to humans >
- Mutagenicity test/ repeated 28-day dose toxicity study
- Alga, growth inhibition test/ daphnia acute immobilization test/ fish, acute toxicity test

< Toxicity test relating to flora and fauna >
- Not verified
- Verified

Confirmation procedure
- Amount of manufacture/import
- Risk to human health and living organisms in living environment based on existing knowledge

Manufacture/import is allowed for the year only

Ex-post monitoring

Management according to the properties of the new chemical substance, exposure
### Exemption Categories (defined by Cabinet Order)

<table>
<thead>
<tr>
<th>Category</th>
<th>Clause of Paragraph 1 of Article 2</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediates</td>
<td>Clause 1</td>
<td>Where the new chemical substance is manufactured or imported as an intermediate for another chemical substance and measures are taken to prevent environmental pollution during the process when the said intermediate is being transformed into another substance.</td>
</tr>
<tr>
<td>Use in closed system</td>
<td>Clause 2</td>
<td>Where the new chemical substance that is manufactured or imported for use employs a method that has little or no possibility of release outside the facility or the equipment and measures are taken to prevent environmental pollution throughout the process until the time of its disposal.</td>
</tr>
<tr>
<td>Substance for export only</td>
<td>Clause 3</td>
<td>Where the new chemical substance is manufactured or imported for export, the destination of the export falls under the regions specified by the ministerial ordinance (i.e. that have already established the pre-import evaluation system of new chemical substances) and measures are taken to prevent environmental pollution until its export.</td>
</tr>
</tbody>
</table>
3. Reform of the evaluation system for new chemical substances

< Exemption of evaluation: intermediates, etc. >

Information to be submitted for prior verification request

< Example: intermediates >

(1) Entry items in a request form [Ministerial Ordinance Form 2]
- Name and structural or rational formula of the new chemical substance
- Physicochemical properties and component composition
- Planned annual amount of manufacture (import)
- Name and location of the manufacturing site (for manufacturing)
- Manufacturing country or region (for import)
- Name and address of the user of the new chemical substance
- Name and location of the use site
- Name of the chemical substance manufactured by the user
- References
3. Reform of the evaluation system for new chemical substances

<Exemption of evaluation: intermediates, etc.>

(2) Documents to be attached to the request
- Drawing that illustrates the production equipment and facility
- Document that describes the handling measure for manufacturing
- Document that describes the measures taken for the prevention of environmental pollution related to the production of the new chemical substance
- Document that describes the management system of the manufacturer (importer) that intends to manufacture (import) the substance
- Document that describes the shipment form and the measures taken to prevent the environmental pollution that can be caused by the new chemical substance during shipment
In the following exhibits, it is confirmed that the new chemical substance shall be used as an intermediate and that measures will be taken to prevent environmental pollution.

- Name, address, etc. of the user
- Location of facility where the substance will be used and stored
- Drawing that illustrates the equipment and facility for use
- Flow through which the new chemical substance is transformed into another chemical substance at the use site and the predicted amount of the new chemical substance to be released into the environment
- Measures taken to prevent environmental pollution in the course of handling the new chemical substance
- Management system of the user
- Planned annual amount of use
- Document that describes the measures taken by the manufacturer (importer) to confirm that the user is using the substance in accordance with the verification by three Ministers
3. Reform of the evaluation system for new chemical substances

<Exemption of evaluation: intermediates, etc.>

Obligation to report items relating to the verified new chemical substance after it is manufactured or imported

- The manufacturer (importer) who has obtained verification for the exemptions specified in the Cabinet Order, shall report to three ministers, by the June 30 every year.
- Their report will include the following items for the previous year for each new chemical substance verified except when there was no manufacture/import in the previous year.

  - Name of the new chemical substance
  - Date of the verification
  - Actual amount manufactured (imported)
  - Actual amount of use by the user (actual amount exported by each export destination in the case of export only)
  - If the new chemical substance was released or transferred to the outside of the facility during the process of handling, describe the overall condition.
  - If there was a slight change in the verified content, describe the changes.

- If significant changes in the matters such as the contents of measures to prevent environmental pollution occur, the manufacturer (importer) shall be required to obtain a new verification.
3. Reform of the evaluation system for new chemical substances

<A special case for low quantities of new chemical>

**Procedure of request for a special case of evaluation of low quantities of new chemical substance**

- **Request for a special case of evaluation**
  - Evaluation
- **Notice of judgment**
  - Judgment that the substance is persistent, not high bioaccumulative, and toxicity unclear
- **Request for amount verification**
  - Verification
  - Notice of verification
  - Manufacture/import is allowed

A request for a special case of evaluation (Ministerial Ordinance Form 10) shall be submitted to three ministers when submitting notification of the manufacture/import of a new chemical substance according to Article 3 of the Law.

From the next year onwards, a request for amount verification shall be submitted every year during March 1-10.
3. Reform of the evaluation system for new chemical substances

<A special case for low quantities of new chemical>

**Resumption of evaluation after manufactured/ imported**

【Paragraph 7 of Article 4-2 of the Law 】

Where a person who has received a judgment notice wants to resume the evaluation relating to the toxicity of the verified low quantities of new chemical substance, he or she may submit to three Ministers a request (Ministerial Ordinance Form 12) with the results of the toxicity test attached.

(for example, in the case where the planned amount manufactured/imported exceeds 10 tons/year)

**Continued evaluation when verification is not made**

【Paragraph 8 of Article 4-2 of the Law 】

- Where the ministers provided notice that the new chemical substance is not applicable due to its properties after evaluation
- Where they have not verified after checking the quantity
- Where they have cancelled the verification
3. Reform of the evaluation system for new chemical substances

<A special cases for low quantities of new chemical>

Request period (in relation to small quantities of new chemical substance)

In accordance with the following schedule, the planned amount of the year for which the request is made is verified in the order of request date.

(adjustment of the amount is done by the total of small quantities of new chemical substance and low quantities of new chemical substance)

In the first year, requests for low quantities of new chemical substances are received every month

From the second year on: Request period for low quantities new
4. Obligation to report the hazard information voluntarily obtained by businesses

Background

- Implementation of similar systems in Western countries (safety net of the evaluation system)
- Progress of the voluntary action to collect hazard information by businesses (e.g., HPV, etc.)

Hazardous information obtained by businesses should be utilized for operation of the CSCL. (Example: evaluation of a new chemical substance, assessment of existing chemical substance, etc.)

- Introducing obligation to report certain hazard information relating to the substances that have been manufactured or imported by the businesses (Fine of up to 200,000 yen for businesses that failed to submit a report or submitted a false report.)

- Upon receiving the report, the government is obligated to take the necessary measures (e.g., designating some Monitored Chemical Substances) based on the report and other knowledge. 【Article 31-2 of the Law】
4. Obligation to report the hazard information voluntarily obtained by businesses

1. Persons/substance subject to reporting
   manufacturer/importer of the following chemical substances
   - Type I, II, and III Monitored Chemical Substance
   - Class II Specified Chemical Substance
   - Substances that have been announced to be exempt from the regulation
   - Small quantities (up to 1 ton/year) of new chemical substance
   - Low quantities (up to 10 tons/year) of new chemical substance
   - Existing chemical substances

2. Hazard Information subject to reporting
   the following properties that are related to test items of evaluation and hazard study of the CSCL (where tests have been conducted or equivalent knowledge has been obtained)
   - Persistence
   - High bioaccumulativeness
   - Human toxicity
   - Eco-toxicity

Concrete standards of hazardous properties are specified in joint Ministerial Ordinance and related notice

However, exempted is any information that is in the public domain such as that included in major scientific journals and test data published by the government.
5. Other

(1) Amendment of the public announcement period after evaluation is completed

Provisions on the public announcement period of the name of the new chemical substance are partially amended to avoid significant competitive disadvantage to the first notifier (i.e., the notifier who bore the test expense).

<table>
<thead>
<tr>
<th>Former system</th>
<th>Substance exempt from regulation</th>
<th>Designated chemical substance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Publicly announced “without delay” after the notice of the judgment</td>
<td>Publicly announced “without delay” after the notice of the judgment</td>
</tr>
<tr>
<td>After the amendment</td>
<td>Substance exempt from regulation</td>
<td>Type II and Type III Monitored Chemical Substances</td>
</tr>
<tr>
<td></td>
<td>Publicly not announced for 5 years after the notice of the judgment</td>
<td>Publicly announced “without delay” after the notice of the judgment</td>
</tr>
</tbody>
</table>
5. Other

(2) Strengthening of penalties

Introduction of heavy penalties for corporations

Considering similar laws, heavy penalties are applied to especially serious breaches of duty from the viewpoint of the prevention of environmental pollution.

< Examples >

<table>
<thead>
<tr>
<th>Violation</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation in the manufacture/import/use of Class I Specified Chemical Substance</td>
<td>Maximum of 100 million yen</td>
</tr>
<tr>
<td>Violation of the restriction of the manufacture/import of new chemical substance</td>
<td>Maximum of 50 million yen</td>
</tr>
</tbody>
</table>
5. Other

(3) Strengthening of orders for measures regarding Class I Specified Chemical Substance

- Where any chemical substance has been designated as a Class I Specified Chemical Substance and the three Ministers deem that measures are particularly necessary in order to prevent the spread of environmental pollution by Class I Specified Chemical Substances, they can order measures such as recall of the chemical substance or products (articles) in which the chemical substance is used. 【Article 22 of the CSCL】

- The amendment allows such implementation in the following cases:

  (1) New product (article) which uses the substance that has already been designated as a Class I Specified Chemical Substance is added to the list of import prohibition
  (2) There is a violation of the regulations for Class I Specified Chemical Substance
      (regulation of manufacture/import, import regulation of products in which the substance is used, regulation of use)
Thank you