Gestión global de la seguridad de productos químicos. ¿Se aplica REACH globalmente?
2 de Febrero 2018, ICEX España Exportación e Inversiones

Chemical Substance Control Law; CSCL Japan

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1. What is Chemical Substance Control Law?

2. CSCL in Detail
   - Safety Studies
   - Risk Assessment
   - Polymer Flow Scheme

3. Summary - in comparison with REACH -
1. What is Chemical Substance Control Law?

2. CSCL in Detail
   - Safety Studies
   - Risk Assessment
   - Polymer Flow Scheme

3. Summary - in comparison with REACH-
Brief Overview of Chemical Laws in Japan

**Toxicity**
- Human Health
  - Acute
  - Chronic
  - Carcinogen

**Environment**

**Exposure**
- Work
- Consumer Use
- Via Environ.

**Pollutant Release and Transfer Register**
- Chemical Substance Control Law
  - Since 1973, Recent update in 2011 (Hazard to Risk)
- Agricultural Chemicals Control Act
- Industrial Safety and Health Law
- Food Sanitation Act
- Agricultural Chemicals Control Act
- Pharmaceuticals and Medical Devices Law
- Water Pollution Prevention Act
Purpose and Scope of CSCL

**Purpose**
To prevent environmental pollution caused by chemical substances that pose a risk of impairing human health and interfere with the inhabitation and or growth of flora and fauna.

**Scope**

**Chemical substances**
Chemical substance created through chemical reactions.

**Industrial chemicals**
Chemicals that are subject to other laws such as medicines, cosmetics and pesticides etc. are outside the scope of CSCL.

**Outline**

**New chemicals**
Notification to and evaluation by the government are required before manufacture/import.

**Existing chemicals**
Annual report of manufacture/import volume and usage is mandatory. The government conducts risk assessment based in this annual notification and may request additional toxicity information to the manufactures/importers if necessary.

*If the chemicals are already listed in CSCL inventory, no new notification is required.*

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
New Notification is necessary?

Product (Article) or Chemical Substances
- Product
- Substances

Elements or substances occurring in nature
- No

Chemical substances regulated by other regulations? (Food additive, Pesticide, Fertilizer, Medicine, Cosmetic, etc.)
- No

Chemicals with MITI (CSCL, METI) number? (Listed in CSCL inventory?)
- Yes
  - NITE CHRIP is useful to search MITI number
  - No

Research & Development use?
- No

Intermediate, Export only, Closed system, Small volume, PLC?
- Yes
  - Notification is NOT necessary with confirmation
- No

Pre-marketing notification for new chemicals needed
- No

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Overview of CSCL

The Japanese government conducts risk assessment in two phases, both before and after placing the substance on the market.

Based on the result of risk assessment, the government may take measures to control risks associated with the chemical.

New Chemicals

- > 1 ton/y
- Less than 1 ton/y
- Intermediates Export etc.
- Polymer of Low Concern (PLC)

Premarketing Notification
Evaluation

- Persistent but not bioaccumulative in 1-10 tonnage band

Premarketing Confirmation
(the substance can be placed on the market)

Class I specified Chemicals, 31 Substances
(persistent, bio-accumulative, and toxic)

Monitoring Chemicals, 37 Substances
(persistent and bio-accumulative)

Class II Specified Chemicals, 23 Substances
(toxic and high risk)

Priority Assessment Chemicals, 201 Substances

General Chemicals (+Existing chemicals), Approx. 28,000 Substances

Numbers are as of Jan. 8th 2018

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
**Evaluation / Assessment Flow**

**General chemicals (approx. 28,000)**

- **Existing Chemicals** (manufactured/imported before CSCL was published)
  - > 1 ton/y
    - Safety Study Notification
    - Evaluation
    - Screening Assessment
    - Risk is acceptable
  - Persistent and Bio-accumulative
    - Monitoring Chemicals
    - High Priority
  - Persistent, Bio-accumulative, Long term toxicity
    - Class I specified Chemicals
      - Basically ban from market, or authorization etc.
  - Long term toxicity
    - Class II Specified Chemicals
      - Restriction, notification of volume or usage, etc.

**New Chemicals**

- > 1 ton/y
  - Confirmation
    - (Place on the market)
  - Persistent but not bio-accumulative
    - and 1-10 t/y
  - Pre-marketing evaluation
  - Post-marketing evaluation

- Less than 1 ton/y
  - Evaluation
  - Screening Assessment
  - Risk is acceptable

- Intermediates, Export etc.
  - Confirmation
    - (Place on the market)

- Polymer of Low Concern
  - Confirmation
    - (Place on the market)

**Priority Assessment Chemicals**

- High Priority
  - Step-wise risk assessment
    - Direction of long-term toxicity investigation
  - Risk is not acceptable

**Referred following material:** Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
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3. Summary - in comparison with REACH-
Evaluation / Assessment Flow

General chemicals (approx. 28,000)

Existing Chemicals
(manufactured/imported before CSCL was published)

New Chemicals

> 1 ton/y
Less than 1 ton/y
Intermediates, Export etc.
Polymer of Low Concern

Confirmation
(Place on the market)

Screening Assessment

Safety Study Notification
Evaluation

Screening Assessment

Pre-marketing evaluation
Post-marketing evaluation

Priority Assessment Chemicals

High Priority

Step-wise risk assessment
Direction of long-term toxicity investigation

Risk is acceptable

Risk is not acceptable

1

2

3

High Priority

Persistent and Bio-accumulative

Monitoring Chemicals

Persistent, Bio-accumulative, Long term toxicity

Class I specified Chemicals
Basically ban from market, or authorization etc.

Class II Specified Chemicals
Restriction, notification of volume or usage, etc.

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Evaluation / Assessment Flow

**New Chemicals**

- **> 1 ton/y**
  - Safety Study
  - Notification
  - Evaluation
  - Risk is acceptable
  - Persistent but not bio-accumulative
  - Less than 1 ton/y
  - Confirmation (Place on the market)
  - Intermediates, Export etc.
  - Polymer of Low Concern

**Priority Assessment Chemicals**

- **High Priority**
  - Step-wise risk assessment
  - Direction of long-term toxicity investigation

**Existing Chemicals**

- **> 1 ton / y**
  - Screening Assessment
  - High Priority

**Monitoring Chemicals**

- **Persistent and Bio-accumulative**
- **Long term toxicity**

**Class I specified Chemicals**

- Basically ban from market, or authorization etc.

**Class II Specified Chemicals**

- Restriction, notification of volume or usage, etc.

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
**Flow of Safety tests (>1 ton/y)**

1. **Biodegradation OECD TG 301C**
   - Ready (Good) Biodegradable (>60%, No metabolites remained)
     - **YES** No further tests needed
     - **NO** Remaining substance should be identified and subjected to following tests

2. **Log Pow OECD TG 107, 117**
   - **<3.5** No further tests needed
   - **≥3.5** BCF test OECD TG 305-I, II
     - **<5,000** NO (Premarketing Confirmation)
     - **≥5,000** YES

3. **BCF test OECD TG 305-I, II**
   - **<5,000** YES
   - **≥5,000** Remaining substance should be identified and subjected to following tests

4. **Long term toxicity**
   - Such as OECD TG 206, 414, 416, 417, 451, 452 are considered
     - **YES** NO
     - **NO** YES

5. **Tonnage band: 1-10 t / y?**
   - **NO** Toxicty to Human -28 days repeated dose test OECD TG 407 - Ames test OECD TG 471 - Chromosomal aberration test OECD TG 473 or 476
   - **YES** Toxicity to Human - Algal growth inhibition test OECD TG 201 - Acute daphnia immobilization test OECD TG 202 - Acute fish toxicity test OECD TG 203

6. **Eco-toxicity**
   - Algal growth inhibition test OECD TG 201
   - Acute daphnia immobilization test OECD TG 202
   - Acute fish toxicity test OECD TG 203

These results are considered for screening assessment

*If BCF value exceeds 1,000, other information such as discharge rate is considered.*

Referred following material: Procedure for New Chemicals at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Biodegradation-OECD 301C-

The most stringent test condition in OECD 301 Series

Reason 1: Test concentration and sludge

Test concentration: 100 mg/L
Inoculum concentration: 30 mg/L
Inoculum: Collect fresh samples from no fewer than 10 sites, mainly in areas where a variety of chemicals are used and discharged. From sites such as sewage treatment works, rivers, lakes, seas, sludges, etc. and mix through together
Biodegradation-Inoculum-

Sampling sites in Japan for the sludge of OECD 301C

Fresh samples
- Equally mixed
- Filtrated

Previous lot
- Equally mixed
- Filtrated
- Incubated at least 28 days with 0.1% synthetic sewage*

Sludge of OECD 301C
*Synthetic sewage: Solution with Glucose, Peptone, KH$_2$PO$_4$ (pH:7.0)

-In Japan Chemical Evaluation and Research Institute (CERI) prepares the sludge once in 2 months

From our experience, the degradation activity of the sludge is lower than the sludges from WWTP
Reason 2: Judgment criteria of ready (good) biodegradation

- In at least 2 out of 3 vessels, BOD degradation (%) must be >60%, and the average BOD degradation (%) must be >60%

  + No parent chemicals, or metabolites are remained (confirmed by HPLC or GC)

Besides of BOD and DOC, chemical analysis must be conducted to quantify the parent substance and identify and quantify metabolites.
Biodegradation - Other Methods

**OECD 302C**

Even if criteria for OECD 301C are not met, but the data suggests the biodegradation continues after 28 days (e.g. degradation curve are increasing), the judgment can be made by OECD 302C

- Test concentration: 30 mg/L
- Inoculum concentration: 100 mg/L

**OECD 301D**

If the substance is highly volatile, 301D could be conducted

- Test concentration: 2-5 mg/L
- Inoculum concentration: less than 5 ml of effluent/L

**Implementation of OECD 301F**

The discussion is still on-going including following topics

- OECD 301F should be included in CSCL?
- Protocol of OECD 301F should be modified for CSCL?
- Protocol of OECD 301C should be modified?
Bio-accumulation

Log Pow OECD TG 107, 117

- Substance with Log Pow < 3.5 can be assessed as not highly bio-accumulative (except for ionic substances)
- For ionic substances, CSCL applies Log Dow (The partition coefficient determined at pH 7)
- Substance with Log Dow < 2.5 can be assessed as not highly bio-accumulative

BCF test OECD TG 305-I,II

- Remaining degradation substances are considered for BCF study
- Implementation of OECD 305-III is under discussion
- BCF >5000: highly bio-accumulative, BCF <1000: not highly bio-accumulative
- BCF: 1000-5000: factors (distribution, discharge rate) are considered for judgment
- QSAR and Read-Across could be used but only in very limited conditions
Evaluation / Assessment Flow

General chemicals (approx. 28,000)

Existing Chemicals
(manufactured/imported before CSCL was published)

- > 1 ton / y
  - Monitoring Chemicals
    - Long term toxicity
    - Persistent, Bio-accumulative, Long term toxicity
  - Class I specified Chemicals
    - Basically ban from market, or authorization etc.
  - Class II Specified Chemicals
    - Restriction, notification of volume or usage, etc.

New Chemicals

- > 1 ton / y
  - Screening Assessment
    - High Priority
    - Persistent and Bio-accumulative
  - Step-wise risk assessment
    - Direction of long-term toxicity investigation
    - Risk is not acceptable
  - Priority Assessment Chemicals
    - Persistent but not bio-accumulative
    - and 1-10 t/y
  - Confirmation (Place on the market)

- Less than 1 ton / y
  - Safety Study Notification
    - Evaluation
      - Screening Assessment
        - High Priority
  - Intermediates, Export etc.
  - Polymer of Low Concern

- < 1 ton / y
  - Less than 1 ton / y
  - Confirmation (Place on the market)

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Risk Assessment of Chemicals

- **General chemicals (approx. 28,000)**
  - **Existing Chemicals**
    - (manufactured/imported before CSCL was published)

- **New Chemicals >1 ton / y**
  - > 1 ton/y

**Screening Assessment**
- No High Priority
- High Priority

**Priority Assessment Chemicals**
- Risk is acceptable
- Risk is not acceptable

**1st tiered Risk Assessment**
- Direction of long-term toxicity investigation
- Risk is not acceptable

**2nd tiered Risk Assessment**
- Risk is not acceptable

**Class II Specified Chemicals**
- Restriction, notification of volume or usage, etc.
# Risk Assessment of Chemicals

## Screening Assessment

<table>
<thead>
<tr>
<th>Exposure Class (exposure factors could be applied)</th>
<th>Strong</th>
<th>(Eco-) Toxicity (Such as PNEC mg/L)</th>
<th>Weak</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt; 10000 t/y</td>
<td>High Priority</td>
<td>High Priority</td>
</tr>
<tr>
<td>2</td>
<td>1000 – 10000 t/y</td>
<td>High Priority</td>
<td>High Priority</td>
</tr>
<tr>
<td>3</td>
<td>100 – 1000 t/y</td>
<td>High Priority</td>
<td>High Priority</td>
</tr>
<tr>
<td>4</td>
<td>10 – 100 t/y</td>
<td>High Priority</td>
<td>Middle Priority</td>
</tr>
<tr>
<td>5</td>
<td>1 – 10 t/y</td>
<td>Middle Priority</td>
<td>Middle Priority</td>
</tr>
<tr>
<td>Out of Class</td>
<td>Less than 1 t/y</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

High Priority Chemicals are categorized as “Priority Assessment Chemicals”
Risk Assessment of Chemicals

General chemicals (approx. 28,000)

Existing Chemicals
(manufactured/imported before CSCL was published)

New Chemicals >1 ton / y

> 1 ton/y

Screening Assessment

No High Priority

Priority Assessment Chemicals

201 substances
Numbers are as of Jan. 8th 2018

High Priority

1st tiered Risk Assessment

Risk is acceptable

21 substances
Numbers are as of Sep. 2017

Risk is not acceptable
Direction of long-term toxicity investigation

2nd tiered Risk Assessment

Risk is acceptable

Class II Specified Chemicals
Restriction, notification of volume or usage, etc.

Risk is not acceptable

0 substance
Numbers are as of Sep. 2017
Risk Assessment of Chemicals

General chemicals (approx. 28,000)
- Existing Chemicals (manufactured/imported before CSCL was published)
  - No High Priority
  - Risk is acceptable

New Chemicals >1 ton / y
- > 1 ton/y

Screening Assessment

Risk Assessment of Chemicals

Government leads risk assessments
- Some Concerns –Over Conservative-
  - Lack of enough monitoring data
    ⇒ Supply industry data
  - Over conservative modeling data
    ⇒ Propose multiple modeling calculation
  - Non-utilization of high tiered approach such as Species Sensitivity Distribution (SSD) and model ecosystem study
    ⇒ Propose high tiered approaches

Class II Specified Chemicals
- Restriction, notification of volume or usage, etc.

201 substances
Numbers are as of Jan. 8th 2018

21 substances
Numbers are as of Sep. 2017

0 substance
Numbers are as of Sep. 2017
Evaluation / Assessment Flow

General chemicals (approx. 28,000)

Existing Chemicals
(manufactured/imported before CSCL was published)

- > 1 ton/y
  - Risk is acceptable
    - Screening Assessment
    - High Priority
    - Persistent and Bio-accumulative

Monitoring Chemicals

- Long term toxicity
  - Persistent, Bio-accumulative, Long term toxicity

Class I specified Chemicals
Basically ban from market, or authorization etc.

New Chemicals

- > 1 ton/y
  - Safety Study Notification
  - Evaluation
  - Screening Assessment
  - High Priority
  - Persistent but not bio-accumulative and 1-10 t/y

- Less than 1 ton/y
  - Confirmation (Place on the market)

- Intermediates, Export etc.

- Polymer of Low Concern
  - Post-marketing evaluation
  - Risk is not acceptable
  - Step-wise risk assessment
  - Direction of long-term toxicity investigation
  - Persistent, Bio-accumulative, Long term toxicity

Priority Assessment Chemicals

- Class I specified Chemicals
  - Basically ban from market, or authorization etc.

- Class II Specified Chemicals
  - Restriction, notification of volume or usage, etc.

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Registration of Polymers

- Registration through Polymer Flow Scheme (PFS) may be possible
- If the criteria of Polymers of Low Concern (PLC) is met, the process can be shortened

<table>
<thead>
<tr>
<th>Assessment by experts (in the Chemical Councils)</th>
<th>Polymers that pass PFS</th>
<th>Polymers meeting PLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time of government procedure</th>
<th>Long (approx. 2-4 months)</th>
<th>Short (about 1 month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed in the Inventory</td>
<td>Listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

- Polymer definition in CSCL
  - Molecules are characterized by the sequence of one or more types of monomer units
  - The weight % of molecules containing three monomer units or above is 50% of the total weight or more
  - The weight % of any molecule of the same molecular weight is less than 50% of the total weight
  - NAMW (Number Average of Molecular Weight) is 1000 or more

Referred following material: Outline of the CSCL at following URL <http://www.meti.go.jp/policy/chemical_management/english/cscl/about.html>
Polymer Flow Scheme (PFS)

1. Stable in neutral, acid and alkaline water
   - Yes
   - No

   2. Soluble in water and 4 organic solvents
      - Yes (at least one solvent)
      - No

   3. Contain metals
      - Yes
      - No
      - Except for Na, Mg, K, Ca (and show cationic function)

   4. Oligomer (MW <1000): less than 1%
      - Yes
      - No

   5. Contain Ae, Se
      - Yes
      - No

   6. NAMW : \( \geq 10000 \)
      - Yes
      - No

   7. Contain listed functional groups*
      - Yes
      - No

Confirmation as PLC

Eco-toxicity Studies
- Could be requested for water soluble polymers with functional groups of concerns

Regular Registration

Registration through PFS

* C-C double or triple bond, C-N double or triple bond, Aziridyl group, Amino Group, Epoxy group, Sulfonic acid group, Hydrazino group, Phenolic hydroxyl group, Fluorine
Topics

1. What is Chemical Substance Control Law?

2. CSCL in Detail
   - Safety Studies
   - Risk Assessment
   - Polymer Flow Scheme

3. Summary - in comparison with REACH-
## Summary – in comparison with REACH –

<table>
<thead>
<tr>
<th></th>
<th>CSCL, Japan</th>
<th>REACH, EU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start</strong></td>
<td>1973, recent update in 2011</td>
<td>2007 (came into force)</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>Environment and Human Health (long-term) via environmental exposure</td>
<td>Workers, Consumers and Environment</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>New chemicals (mainly &gt;1 t/y)</td>
<td>New and existing chemicals (&gt;1 t/y)</td>
</tr>
<tr>
<td></td>
<td>No new notification required if the chemicals are already in the inventory</td>
<td>Registration required even if the same substances are already registered</td>
</tr>
<tr>
<td><strong>Number of Studies</strong></td>
<td>1-10 t/y: 1-2, &gt;10 t/y: 1-8</td>
<td>1-10 t/y: approx. 20, &gt;10 t/y: &gt;20</td>
</tr>
<tr>
<td></td>
<td>Depending on the biodegradation result and tonnage</td>
<td>Depending on the tonnage and substance properties etc.</td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td>Pre-market (Risk assessment in post-market)</td>
<td>Post-market (random)</td>
</tr>
<tr>
<td></td>
<td>(Risk assessment in post-market)</td>
<td>(IT automatic check in pre-market)</td>
</tr>
<tr>
<td><strong>Risk Assessment</strong></td>
<td>All chemicals* (new and existing), tiered approach, leaded by authority</td>
<td>&gt;10 t/y and classified substances, conducted by registrants</td>
</tr>
<tr>
<td><strong>Polymers</strong></td>
<td>Could be registered thought PFS</td>
<td>Exempted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Monomers have to be registered)</td>
</tr>
</tbody>
</table>

*Except for the candidates for Monitoring, or Class I specified Chemicals

** The definition varies in each regulation
Thank you for your kind attention!!