

Status of Chemical Management Policy in Japan

June 23, 2018

The 12th Tripartite Policy Dialogue on Chemical Management
Policy in China, Japan and Korea

Akira Nitta

Director of Chemical Evaluation Office,
Environmental Health Policy Planning and Management Division,
Environmental Health Department, Minister's Secretariat,
Ministry of the Environment

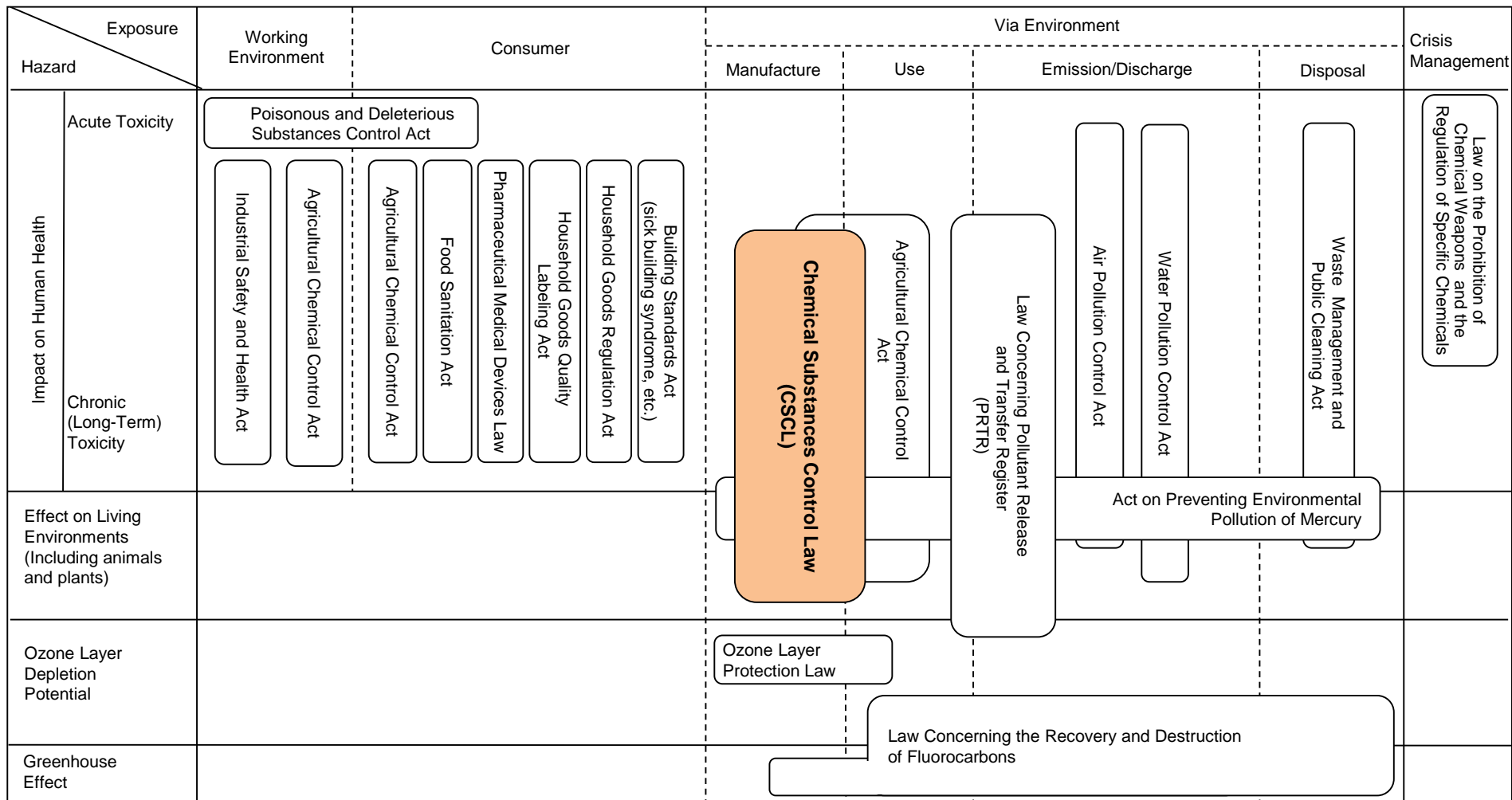
<Table of Contents>

- (1) Overview of Chemical Substances Control Law (CSCL)**
- (2) Evaluation of New Chemical Substances / Risk Assessment of Existing Chemical Substances, etc.**
- (3) Revision of CSCL**
 - **Emission factor for Exemption Rule of Small or Low volume New Chemical Substances**
 - **Criteria for Specific New Chemical Substances**

① Overview of Chemical Substances Control Law (CSCL)

Role of the Chemical Substances Control Law in Japanese Chemical Substance Control

- In Japan, chemical substances are regulated under a variety of laws according to their exposure route and life cycle stage, etc.
- The objective of CSCL is to assess any long-term toxicity to humans via the environment, and their effect on living environments and ecosystems.



Outline of the Preliminary Evaluation System for New Chemical Substances Under CSCL

New Chemical Substances

Regular Evaluation for New Chemical Substances

Exception Rule

Manufacture and Import volume within 10t/Year (Individual Company)

Manufacture and Import volume within 1t/Year (Individual Company)

Intermediates · Closed Applications · Export Only Items

Low Concern Polymer Compounds

Notifiers submit data on (1) degradability, (2) accumulative properties, (3) toxicity on human health and the environment

Evaluation by the Government

* Amended from production and import volumes to environmental emissions

Notifiers submit data on (1) degradability, (2) accumulative properties

Evaluation by the Government

Low Accumulation

National Pre-Confirmation

Environmental Emissions within 10t/Year (Nationwide)

Prior confirmation by the Government

* Amended from production and import volumes to environmental emissions

Environmental Emissions within 1t/Year (Nationwide)

Prior confirmation by the Government

Prior confirmation by the Government

Manufacture/Import Permitted

* Number of substances as of April 2018

<Requirement 1>
- Persistent
- High accumulation properties
- Long-term toxicity to humans or high-order predators

<Requirement 2>
- Persistent
- Suspected long-term toxicity to humans and/or toxicity to animals and plants

<Requirement 3>
- Does not fall under Requirements 1 and 2

Risk is high from the viewpoint of combined toxicity and environmental emissions

Significant long-term toxicity to humans or living environments, animals and plants

Class 1 Specified Chemical Substances (33 Substances)

- Manufacturing/import permission system (virtually prohibited)
- Prohibition on importation of ordinance-designated products
- Prohibition of use outside ordinance-designated use
- Conformity to handling standards for substances and ordinance-designated products (substance-using products)/labeling duty
- Administrative orders for recall from the market.

Priority Assessment Chemical Substances (208 Substances)

- Notification of manufacturing/import volumes, detailed use application, etc.
- For handling operators: (1) obligation to convey information, (2) guidance/advice from the country concerning the handling method, (3) reporting on the handling situation to the government

Specific General Chemical Substances
* Specific New Chemical Substances before Public Announcement

- Notification of manufacturing/import volumes, usage application.
- For handling operators: (1) obligation to convey information, (2) guidance/advice from the country concerning the handling method, (3) reporting on the handling situation to the government

General Chemical Substances (About 28,000 Substances)
* New Chemical Substances before Public Announcement

- Notification of manufacturing/import volume, usage application

Screening Assessment / Risk Assessment of General Chemical Substances etc.

General Chemical Substances (About 28,000 Substances)
 (Existing chemical substances / newly evaluated chemical substances /
specified general (new) chemical substances etc.)

Notification of Manufacturing/Import volumes (more than 1 ton/year), use application, etc. by business operators

Screening Assessment by the government

Risk is high from the viewpoint of combined toxicity and environmental emissions

Priority Assessment Chemical Substances (208 Substances)

Risk Assessment by the government

If necessary based on Risk Assessment results

Hazard Information, handling condition report request

If necessary based on Risk Assessment results

Hazard Survey Instructions

Risk to humans or living environments, animals and plants over considerably wide areas

Class II Specified Chemical Substances (23 Substances)

- Notification of manufacture, import (scheduled and actual), volumes, use application etc.
- Order for changing the planned manufacturing/import volumes as necessary
- Publication of substances and handling technical guidelines for designated products
- Labelling obligation of designated products specified by the government

* Number of substances as of May 2018

Persistent and high accumulative properties, and long-term toxicity to humans or high-order predators is unknown

Monitoring Chemical Substances (38 Substances)

- Notification of manufacturing, import volumes, detailed use application, etc.
- Obligation to communicate information to handling businesses

If necessary

Handling Condition Report Request

If necessary

Hazard Survey Instructions

Long-term toxicity to humans or high-tier predators

Class I Specified Chemical Substances (33 Substances)

- Manufacturing/import permission system (virtually prohibited)
- Prohibition of importation of ordinance-designated products
- Prohibition of use outside ordinance-designated use
- Conformity to handling standards for substances and ordinance-designated products (substance-using products)/labeling obligation
- Administrative orders for recall from the market

② Evaluation of New Chemical Substances / Risk Assessment of Existing Chemical Substances, etc.

Test Items for Evaluation of New Chemical Substances

- Tests to be submitted by business operators with regular evaluation of new chemical substances

	Over 10t
Biodegradation study	○
Bioaccumulation study	○ ¹⁾
Repeated dose 28-day toxicity study in mammals	○ ¹⁾
Bacterial reverse mutation test	○ ¹⁾
Cultured mammalian cell chromosome aberration test	○ ¹⁾
Algae growth inhibition test	○ ¹⁾
Daphnia acute immobilization test	○ ¹⁾
Acute fish toxicity test	○ ¹⁾

1) Readily degradable substances require results from the degradation test only.

Status of Evaluation New Substances in FY2017

Deliberations made by the Subcommittee on Chemical Substances, Chemical Substances Committee on Safety Measures Against Chemical Substances, Pharmaceutical Affairs Commission, Pharmaceutical Affairs and Food Sanitation Council, the Evaluation Committee, Chemical Substances Council and the Subcommittee on Chemical Substance Evaluation, Environmental Health Committee, Central Environment Council, and on the basis of the degradability, accumulation, human toxicity and ecotoxicity submitted by business operators.

Date		Number of New Substances
2017	April 21	22
	May 26	21
	June 23	26
	July 28	29
	September 22	38
	October 27	31
	November 24	23
	December 22	20
2018	January 19	30
	March 23	44

Judgments on New Chemical Substances (Article 4)

Regular Evaluation and Judgments on New Chemical Substances (FY2017 Results)

No. of Reviews	No. of Judgments					
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6
284	0	10	6	34	167	0

* Regular new substances based on polymer flow schemes, as well as those subjected only to the degradation test, are also included.

- (1) Items falling under any of the items in Article 2, Paragraph 2 (Class I Specified Chemical Substances) ... **No. 1**
- (2) When persistent in the degradation test but is judged to be not highly accumulative via the accumulation test or the Pow analysis ... **No. 2 - No. 5**
 - No. 2:** Human health toxicity yes, eco-toxicity no
 - No. 3:** Human health toxicity no, eco-toxicity yes
 - No. 4:** Human health toxicity yes, eco-toxicity yes
 - No. 5:** Human health toxicity no, eco-toxicity no
- (3) When judged to be of good degradability with the degradation test ... **No. 5**
- (4) When it is unclear if it falls under No. 1 through No. 4 ... **No. 6**

Review and Judgments on Low Production Volume New Chemical Substances (below 10 tons/year nationwide) (FY2017 results)

No. of Reviews	No. of Judgments
121	121

* Low production volumes for new chemical substances based on polymer flow schemes are also included. 10

Preliminary Evaluation and Prior Confirmation of New Chemical Substances

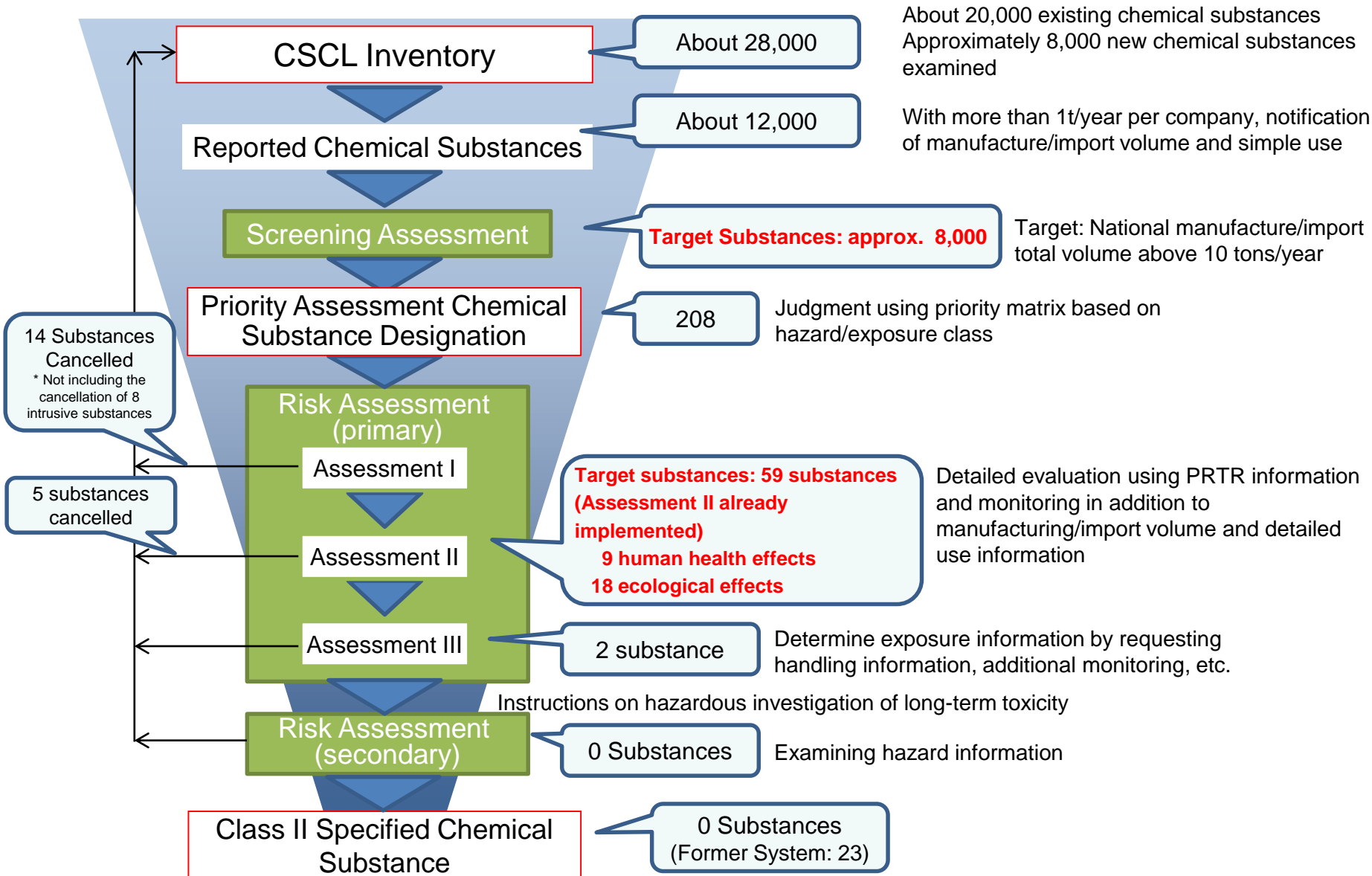
- Manufacturing and import allowed after notification of new chemical substances and regular preliminary evaluations. [new (regular)]
- Manufacturing and import can be allowed after preliminary declaration and prior confirmation without making regular notification. (special evaluation exemption scheme, notification exemption scheme) [new (low production volume), new (small amount), highly polymerized compound of low concern, intermediate substance, etc.]
- Japan's chemical industry is making a shift to the small-amount various-type approach. The system was designed in a rational manner in consideration of the small-amount various-type industry, with prevention of any environmental pollution by chemical substances as a precondition. Depending on the individual procedure differing types of information (e.g. hazardous properties) are submitted to the government body.

Procedure type	Clause	Procedure	Hazardous property data to be submitted at the time of notification	Other supporting data	Quantity upper limit	Quantity adjustment	Frequency of acceptance	Actual Number of cases in FY 2016
New (regular)	Article 3.1 of Act	Notification → Decision	Degradability, Accumulation, Human Health, Ecological Effect	Intended use, planned quantity, etc.	No	No	10 times/FY	284 cases
New (small amount)	Article 3.1.5 of Act	Declaration → Confirmation	—	Intended use planned quantity, etc.	Whole country 1 t or less	Yes	4 times/FY	35,781 cases
New (low production volume)	Article 5.1 of Act	Notification → Decision Declaration → Confirmation	Degradability, accumulation (if available, submit hazardous property data on human health, ecological effect at the time of notification)	Intended use, planned quantity, etc.	Whole country 10 t or less	Yes	Notification: 10 times/FY Declaration: As needed (renewal: 1 time/FY)	1,773 cases
Polymers of low concern	Article 3.1.6 of Act	Declaration → Confirmation	—	Molar weight, physical and chemical stability test data, etc.	No	No	As needed	45 cases
Intermediate substance, closed use, export only	Article 3.1.4 of Act	Declaration → Confirmation	—	How to handle, drawing that shows facilities and equipment.	No	No	As needed	132 cases
Small-amount intermediate substance, etc.				(Simplified)	1 t or less / 1 company	No	As needed	189 cases

CSCL Screening /Risk Assessment

* As of May 2018

Risk Assessment by Phase



Status of Risk Assessment (Primary) Assessment II for Priority Assessment Chemical Substances

- The Risk Assessment (Primary) Assessment II for Priority Assessment Chemical Substances was implemented on 3 substances in 2014, 7 in 2015, 9 in 2016 and 7 in 2017*1: a total of 26 substances (9 substances on human health impact, 18 substances on ecological impact*2) to date.
- Based on the past assessment results designations of Priority Assessment Chemical Substances were cancelled on 5 substances.

*1 In addition, assessments of hazardous properties were discussed on 2 substances. *2 Including substances on which the progress with risk assessment was reported.

Date of evaluation report deliberation	Name of Substance	Assessment Viewpoint	Assessment Results (outline)	Future action
June 25, 2017	Trichloroisocyanuric acid	Ecology	- There is no exposure assessment results that give sufficient grounds for a decision on Assessment II. - Collect data on actual measurements of isocyanuric acid through environment monitoring in the future.	Assessment II to continue
November 24, 2017	Decan-1-ol	Ecology	- There is no exposure assessment results that give sufficient grounds for a decision on Assessment II. - Collect data on actual measurements of decan-1-ol through environment monitoring in the future.	Assessment II to continue
January 18, 2018	Fenobucarb	Ecology	- There is no exposure assessment results that give sufficient grounds for a decision on Assessment II. - Collect data on actual measurements of fenobucarb through environment monitoring in the future.	Assessment II
	N,N-dimethylformamide	Human Health	- On the basis of PRTR information, inform business operators with the most significant discharge amounts of their risk assessment results and encourage them to make voluntary efforts. After checking for improvement with their discharge conditions, cancel their priority.	Cancelled after efforts are confirmed
March 23, 2018	Ethylene oxide	Human Health	- Proceed to Assessment III to verify conditions with the many spots where hazardous property values exceeded the evaluation values but no PRTR registered business facilities can be identified around the area concerned. - Check how it is being handled in terms of laws and regulations.	Assessment III to continue
	Dichloroisocyanuric acid (to be reassessed after totaled with trichloroisocyanuric acid)	Ecology	- Examine chronic toxicity to fish. - Collect data on actual measurements of isocyanuric acid through environment monitoring in the future.	Assessment II to continue
	Amine oxides	Ecology	- Analyze factors contributing to uncertainty (e.g. setting of physicochemical properties, setting of discharge amount) and examine them, starting with items that can most effectively reduce uncertainty.	Assessment II to continue

- ③ Revision of CSCL**
- **Emission factor for Exemption Rule of small or low volume New Chemical Substances**
 - **Criteria for Specific New Chemical Substances**

Evaluation System for New Chemical Substances (Current System)

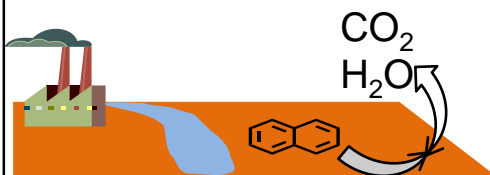
1: Regular Evaluation System

- Anyone intending to manufacture or import new chemical substances shall notify the government in advance.
- The government evaluates the properties of the newly notified chemical substance (degradability, accumulation, whether it is toxic to human health/ecology) and regulates according to the results.

Test Items for the CSCL Regular Evaluation System

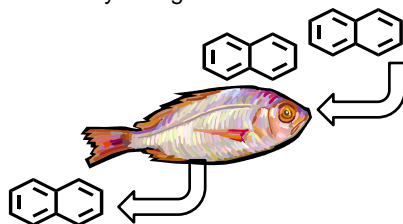
(1) Info related to degradability

Does substance degrade in natural environment?



(2) Info related to accumulativeness

Does substance accumulate easily if it enters body of organism?



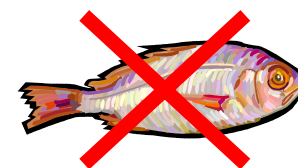
(3) Effect on Human Health

Is substance toxic to humans?



(4) Ecological Effect

Is substance toxic to living organisms?



2: Exemption Rule for small or low volume new chemical substances

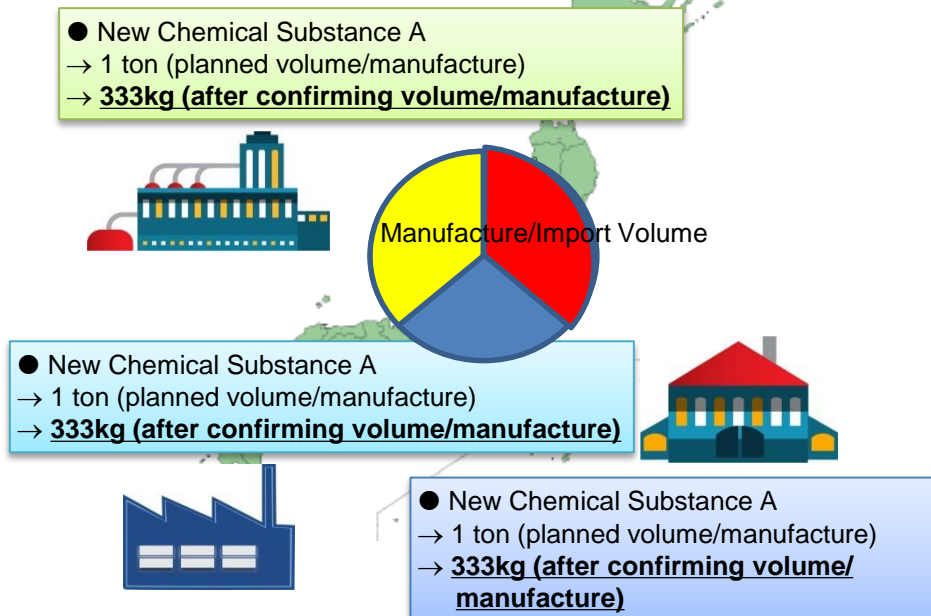
- In regards to new chemical substances whose manufacturing/import volume is below a specific amount, and as a special measure, some or all of the above-mentioned evaluations will be exempt, and manufacturing and importing can be carried out after confirming the volume.
- A similar special evaluation exception scheme exists in Europe and the United States, but due to the existence of original domestic gross amount regulations in Japan, adjustment of the confirmation volume by the government may occasionally take place.

	Hazardous Items Requiring Evaluation	Individual Company's Maximum Volume	Nationwide Maximum Volume
Small Volumes New Chemical Substances	None	1 ton (Manufacture/ Import Amount)	1 ton (Manufacture/ Import Amount)
Low Volumes New Chemical Substances	Degradability/Accumulativeness (No Toxicity Required)	10 tons (Manufacture/ Import Amount)	10 tons (Manufacture/ Import Amount)

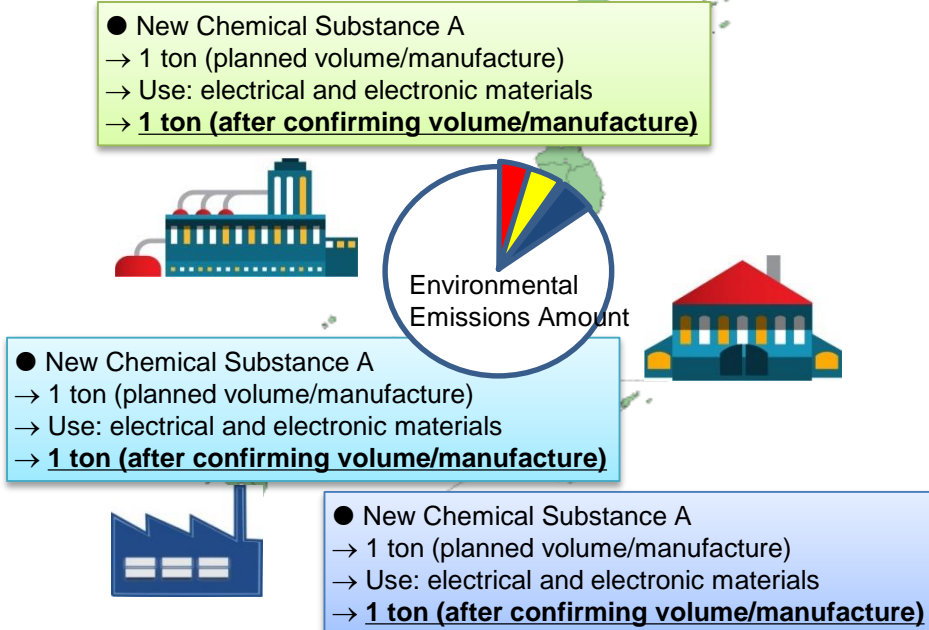
Proposed Review of the Exemption Rule

- Utilize the "emission factor" for individual usage, and review it as a more rational regulatory system on the premise of ensuring safety.
- Specifically, change the domestic gross amount regulation of the special evaluation exemption scheme from the manufacture/import volume to environmental emissions (manufacture/import volume multiplied by the emission factor for individual usage).
- Entry in force: January 1, 2019

Before Change: Domestic Gross System (Manufactured/Imported Volume)



After Change: Domestic Gross System (Environmental Emissions)



- With an emission factor of 0.0012 for electric and electronic materials the volume of production is 1 ton, the environmental discharge amounts to 1.2 kg, and the total discharge of the three companies is 3.6 kg, so there is no need to adjust the quantity.

<Expected Result>

- ✓ Utilizing emission factors that take into account its use, the volume adjustment will decrease, and the production and import volume would increase.
- ✓ The uncertainty due to volume adjustment is eliminated, and business predictability will improve.

Emission Factor for Exemption Rule for small and low volume (draft)

Use Number (#)	Use Classification	Emission factor for Exemption Rule for small and low volume			
		Total	Manufacturing phase – usage phase	Long-term usage phase	Disposal phase
101	Intermediate material	0.004	0.004	0	0
102	Paint, varnish, coating agent, ink, copying, biocide solvent	0.9	0.9	0	0.001
103	Bonding agent, adhesive agent, sealing material solvent	0.9	0.9	0	0.0007
104	Metal cleaning solvent	0.8	0.8	0	0.001
105	Cleaning washing solvent	0.8	0.8	0	0.002
106	Other washing solvents	0.8	0.8	0	0.002
107	industrial solvent	0.4	0.4	0	0.006
108	Aerosol solvent, physical foaming agent	1	1	0	0
109	Other solvents	1	1	0	0
110	Chemical process regulator	0.02	0.008	0	0.01
111	Colorant (dye, pigment, coloring matter, coloring material)	0.01	0.002	0.00004	0.01
112	Water-based detergent 1	0.07	0.06	0	0.009
113	Water-based detergent 2	1	1	0	0
114	Wax (for floors, vehicles, leather, etc.)	1	1	0	0
115	Paint, coating agent	0.01	0.01	0	0.004
116	Ink, copying chemical (toner, etc.)	0.1	0.01	0	0.09


Emission Factor for Exemption Rule for small and low volume (draft)


Use Number (#)	Use Classification	Emission factor for Exemption Rule for Small and Low Volume			
		Total	Manufacturing phase – usage phase	Long-term usage phase	Disposal phase
117	Anti-fouling agent for ship bottom paint, anti-fouling agent for fishing nets	0.9	0.005	0.9	0.0009
118	Biocide 1 [ones that are contained in and shipped as part of a molded product]	0.04	0.03	0.0007	0.008
119	Biocide 2 [ones that are used in a manufacturing process and not contained in molded products] <<industrial use>>	0.2	0.2	0	0.009
120	Biocide 3 <<household use, professional use>>	0.4	0.4	0	0.01
121	Powders, chemical foaming agent, solid fuel	0.02	0.02	0	0
122	Air freshener, deodorizer	1	1	0	0
123	Bonding agent, adhesive agent, sealing material	0.02	0.01	0	0.01
124	Resist material, photographic material, printing plate material	0.05	0.04	0	0.01
125	Synthetic fabric, fiber treating agent	0.2	0.1	0.09	0.03
126	Paper/pulp chemical	0.1	0.01	0	0.09
127	Plastic, plastic additive, plastic processing aid	0.03	0.009	0.003	0.01
128	Synthetic rubber, rubber additive, rubber processing aid	0.06	0.005	0.04	0.02
129	Leather treating agent	0.02	0.01	0	0.01
130	Glass, enamel, cement	0.03	0.01	0	0.02
131	Ceramic ware, refractories, fine ceramics	0.1	0.04	0	0.06
132	Grinding stones, abrading agent, friction agent, solid lubricant	0.1	0.07	0	0.07

Emission Factor for Exemption Rule for small and low volume (draft)

Use Number (#)	Use Classification	Emission factor for Exemption Rule for Small and Low Volume			
		Total	Manufacturing phase – usage phase	Long-term usage phase	Disposal phase
133	Metal manufacturing/processing material	0.1	0.1	0	0.02
134	Surface treatment agent	0.1	0.07	0	0.05
135	Welding material, soldering material, sealing and cutting material	0.03	0.01	0	0.02
136	Hydraulic oil, insulating oil, lubricating oil (engine oil, bearing oil, compressor oil, grease, etc.)	0.02	0.009	0	0.007
137	Metal processing oil, Anti-rust oil	0.03	0.02	0	0.007
138	Electric/electronic material	0.01	0.006	0	0.007
139	Battery material (primary cell, secondary cell)	0.03	0.005	0	0.03
140	Water treatment agent	0.05	0.03	0	0.02
141	Drying agent, adsorptive agent	0.09	0.08	0	0.009
142	Heat medium	0.08	0.07	0	0.01
143	Anti-freezing solution	0.08	0.07	0	0.007
144	Construction material, construction material additive substance	0.3	0.3	0	0.03
145	Atomizing agent, landfill pre-treatment chemical (snow melting agent, soil conditioner, extinguishing agent, etc.)	1	1	0	0
146	Separation and refinement processing agent	0.1	0.1	0	0.009
147	Fuel, fuel additive	0.004	0.004	0	0
199	For export	0.001	0.001	0	0

Necessity to review Chemical Substance Management regarding high toxicity

- In recent years, and in regard to the new chemical substances review, occasionally, there are chemical substances that pose a serious risk when released into the environment due to high toxicity to human health and the habitat of animals and plants, while emissions are extremely small.
- 

- However, even with such chemical substances, if emission to the environment is small, it does not correspond to the Priority Assessment Chemical Substances to which certain regulatory measures are imposed, and as a general chemical substance, there is only a notification obligation for the manufacture/import volume, making it impossible to take sufficient measures under the current CSCL.
- 

- It is therefore necessary to take measures to encourage businesses to handle appropriate chemical substances that are highly toxic in thereby avoiding any accidental discharge.

Proposed Review of Chemical Substances with High Toxicity

In order to call attention to businesses dealing with highly toxic chemical substances, we will establish jurisdiction, such as the obligation of business operators to communicate information, and provide national guidance and advice to business operators.

* To be enforced from: April 1, 2018

<Image Diagram>

Notification

Notify the business operator about the highly toxic chemical substance

Administration



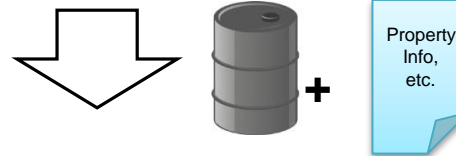
Report on Handling Info

The minister in charge may request any business operator handling highly toxic chemical substances to report on the handling situation.

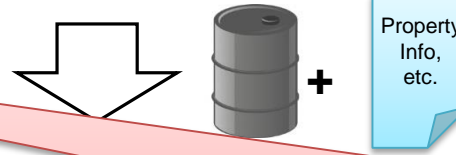
Duty to Communicate Info

Duty to communicate the info that it is a highly toxic chemical substance

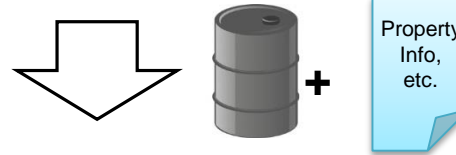
Reporting Business Operator



Primary Downstream Operator



Secondary Downstream Operator



3rd Downstream Operator

Guidance & Advice

Guidance and advice on the handling method for highly toxic chemical substances, according to the actual situation of the business concerned

* For example, in order to prevent any environmental pollution instructions and advice are provided with information such as improvement measures for the management method along the supply chain.

* For example, a business operator handling a highly toxic chemical substance should keep records on the state of delivery and stock status of the chemical substance in advance, in the form of a document, and for a certain period of time, so that it can respond when asked for reports.

Judgment Criteria for Specific New Chemical Substances

- When a chemical substance is so highly toxic that once discharged into the environment, and even if only in very small quantities, it will be continuously taken in by humans, etc. in and around the discharged area and may cause damage to human health and the flora and fauna in human living environments. The specific new chemical substances scheme is intended to advise business operators on the handling of such substances appropriately so that they will not be accidentally discharged into the environment.
- Judgment criteria for specific new chemical substances was made available to the public in April 13, 2018.

Judgment Criteria for Specific New Chemical Substances

- Any substance that meets any of the following conditions is considered to be a specific new chemical substance.
- Toxicity to human health
 - Any of the toxic property assessment values derived from the following tests being 0.0005mg/kg/day or less: (1) Bacterial reverse mutation test (2) Chromosome aberration test using mammalian cultivated cells or mouse lymphoma TK test (3) Repeated dose 28-day toxicity study, repeated dose 90-day toxicity study or combined repeated dose toxicity study with reproduction/developmental toxicity test in mammals (4) reproductive and developmental toxicity studies
 - Either of the following tests shows highly positive results while the other one positive abnormality: (1) Bacterial reverse mutation test (2) Chromosome aberration test using mammalian cultivated cells or mouse lymphoma TK test
- Ecotoxicity
 - PNECs calculated in principle from the algae growth inhibition test, daphnia acute immobilization test, and fish acute toxicity test, being 3×10^{-4} mg/L or less in three types of chronic toxicity test, 3×10^{-5} mg/L or less in two types of chronic toxicity test and one type of acute toxicity test, or 3×10^{-5} mg/L or less in one type of chronic toxicity test and two types of acute toxicity test.