

Latest progress on chemical management under CSCL in Japan

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Seminar on the Latest Trends and Development
in Chemical Management Policies
among China, Japan and Korea

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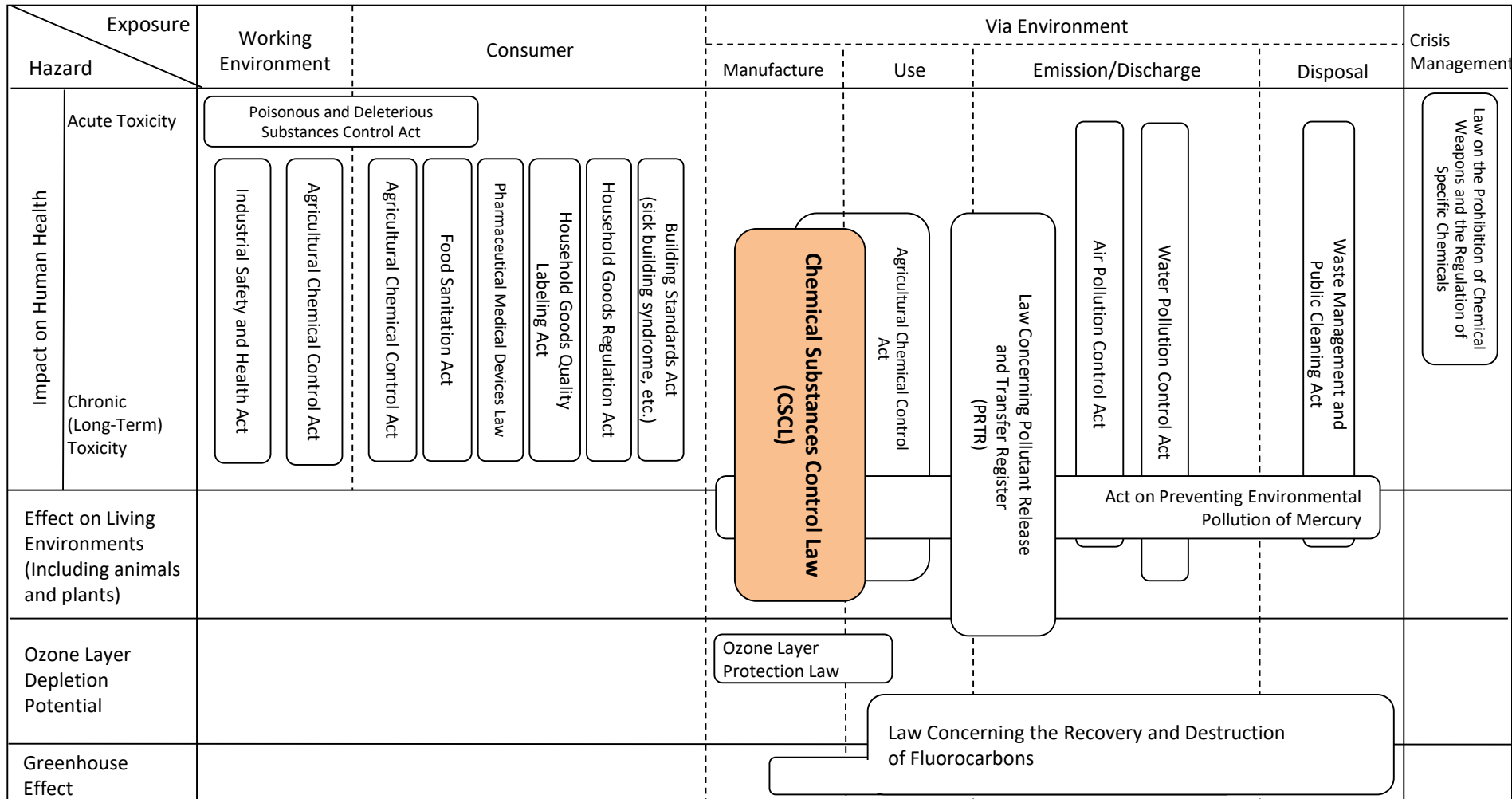
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1. Overview of Chemical Substances Control Law (CSCL)

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 impact on living environments and ecosystems.



Chemical Substances Control Law

- Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (CSCL: Chemical Substance Controls Law)
- Enacted in 1973, last revised on June 2017
- Purposes: 1. Establish a system to evaluate the properties of new chemical substances before their manufacture/import and 2. regulate their manufacture, import, and use, depending on their properties, to prevent environmental pollution caused by the chemical substances that can harm human health or damage living environment of animals and plants.

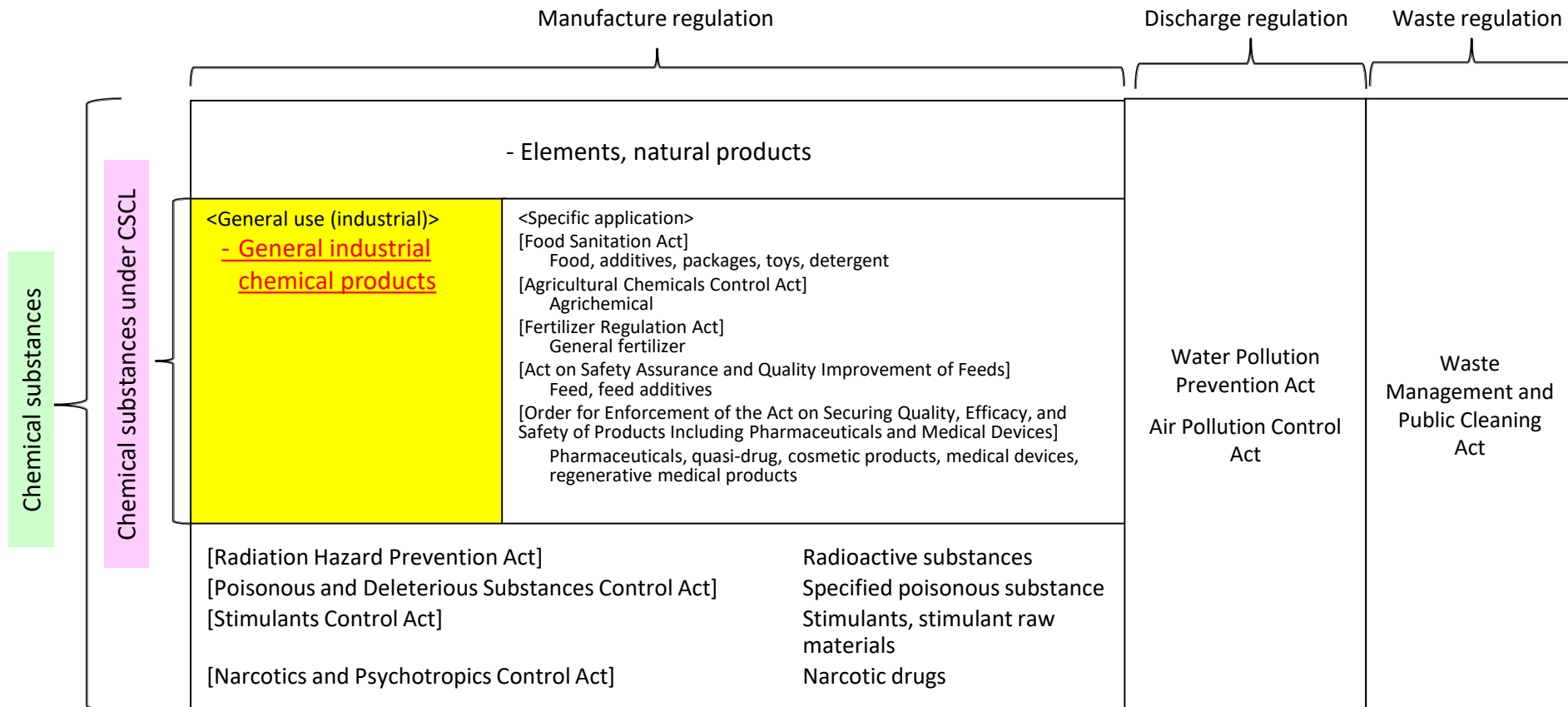
Regulates long-term toxicity to humans and impact on ecosystems through environmental exposure

- Key measures

- Reviewing new chemical substances before their launch (500 to 700 cases/year)
- Performing environmental risk assessment on chemical substances that are already on the market (approx. 28,000 substances)
- Regulates manufacture, import, and use of chemical substances depending on their properties

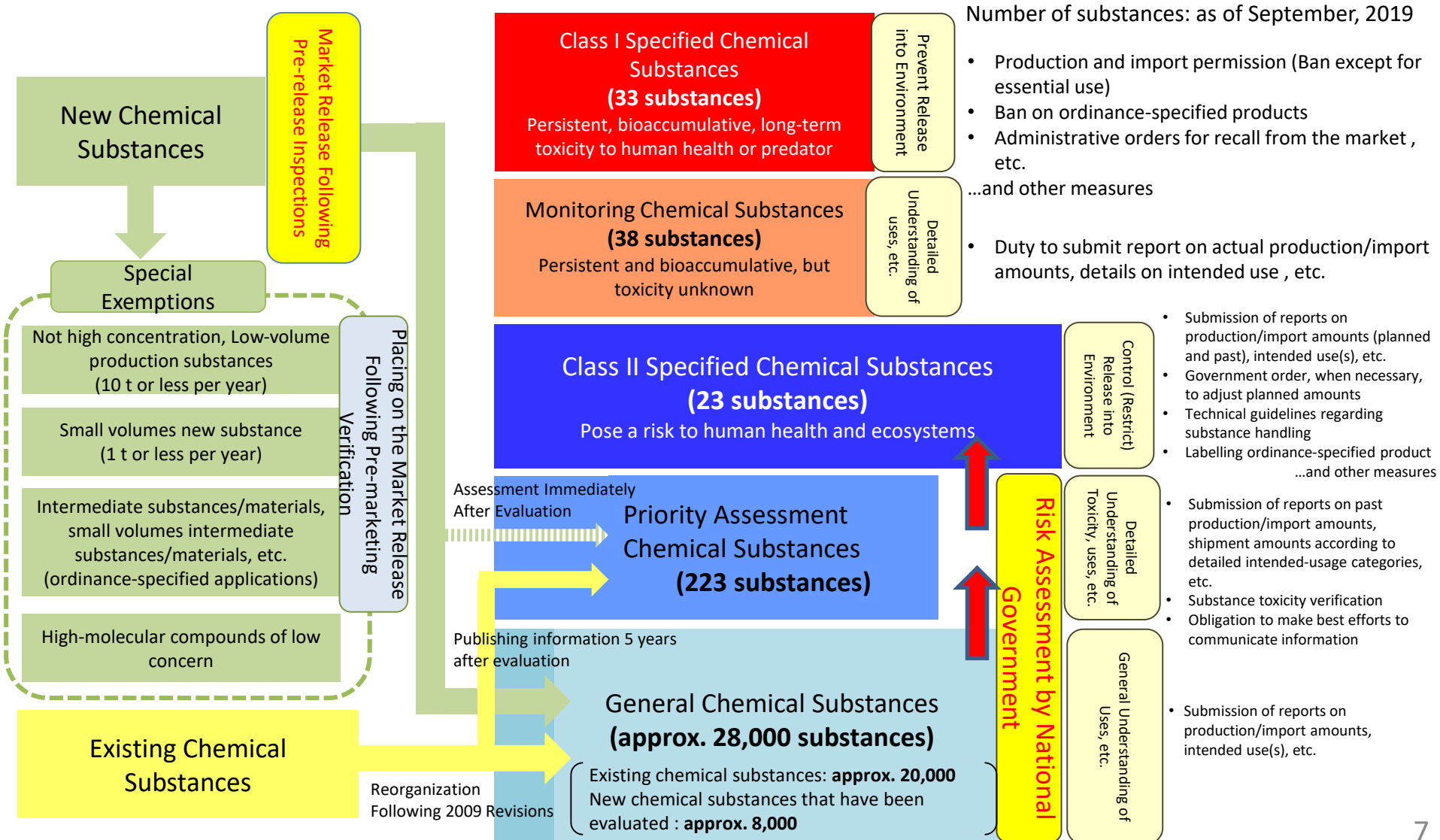
CSCL Target Substances

- Definition of chemical substances in CSCL: chemical compounds obtained by making elements or compounds react chemically.
- Chemical substances subject to CSCL: substances used for general industrial chemical products.
(Article 2 and 55)
- (*) Substances that are controlled by other regulations equivalent to or stricter than CSCL (toxic substances specified in Poisonous and Deleterious Substances Control Law, substances controlled by other regulations according to their applications (food and additives specified in the Food Sanitation Act, etc.)) are excluded.



Framework of CSCL

◆ Prevents environmental pollution by chemical substances through pre-marketing evaluation as well as continuous management after placing on the market



Class I Specified Chemical Substances

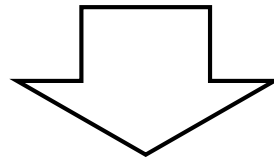
Definition

- Substances that are persistent, highly accumulated, with long-term toxicity to humans or predators of higher trophic, and specified as Class I Specified Chemical Substances by the government ordinance. 33 Substances including PCB and DDT.

* Number of substances: as of September, 2019

Description of regulation

- Approval system for manufacturing/importing Class I Specified Chemical Substances (as a general rule, manufacture/import for purposes other than for test/study and essential use are prohibited)
- Use of Class I Specified Chemical Substances for purposes other than for test/study and essential use is prohibited.
- Import of products that use the Class I Specified Chemical Substances is prohibited.
- Order to collect substances and penal rules targeting the manufacturers, importers, and users who violate the laws and regulations



**Avoid discharge of persistent,
high-accumulating, long-term toxic substances**

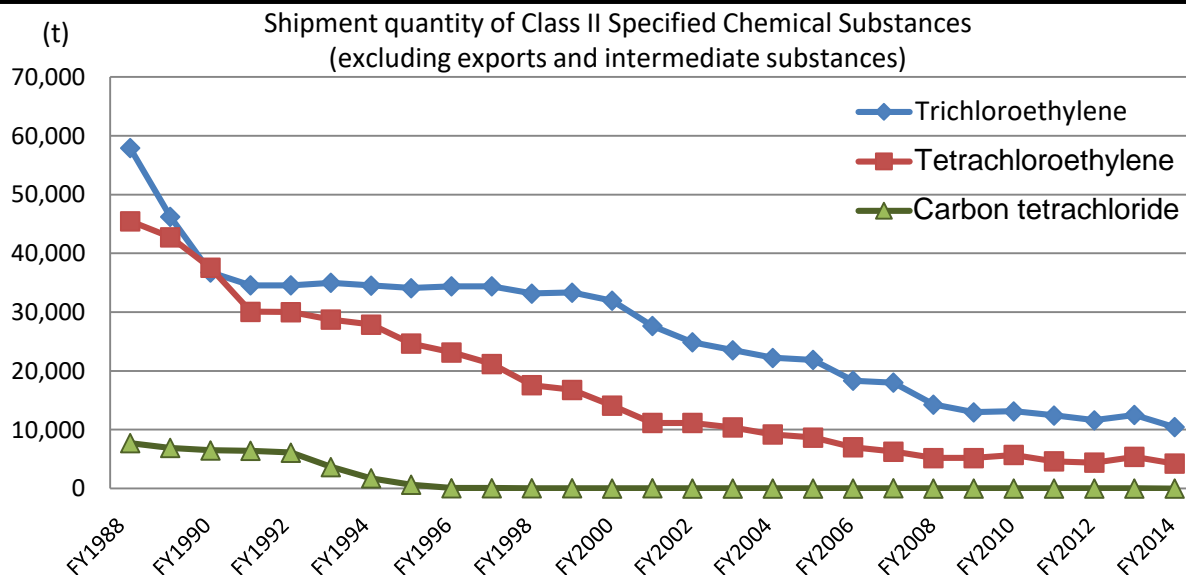
Class II Specified Chemical Substances

Definition

- Substances that can widely remain in the environment, with long-term toxicity to humans or animals/plants in the living environment and have been designated as Class II Specified Chemical Substances. 23 Substances including trichloroethylene, tetrachloroethylene, and carbon tetrachloride.
 - ⇒ Substances without accumulative property may also be regulated depending on the amount that remains in the environment.

Description of regulation

- Mandatory reporting of planned and actual amounts manufactured and imported of the Class II Specified Chemical Substances or products containing Class II Specified Chemical Substances.
- Mandatory labeling for the Class II Specified Chemical Substances and ordinance-specified products.
- If deemed necessary, government issues orders to change planned quantities, recommendation, report imposition, on-site inspection, to business operators who submit the notification. Recommendation to handling operators.
- Penal rules targeting the manufacturers/importers who violate the laws and regulations



* Class II Specified Chemical Substances other than the three substances shown on the left have no record of actual manufacturing/import quantity.

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

Test items for new chemical substances evaluation

- Tests submitted by business operators in regular evaluations for new chemical substances

	10t or above
Degradability test	○
Concentration test	○ ¹⁾
Repeated dose 28-day toxicity study in mammals	○ ¹⁾
Reverse mutation test using bacteria	○ ¹⁾
Chromosome aberration test using mammalian cultured cells	○ ¹⁾
Algal growth inhibition test	○ ¹⁾
Daphnia magna acute toxicity test	○ ¹⁾
Acute toxicity test using fish	○ ¹⁾

- 1) Test results for non-persistent substances are not required, with the exception of the degradability test.

Status of Evaluation for New Substances in FY2018

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
2018	April 20	19
	May 18	27
	June 15	22
	July 13	29
	September 21	51
	October 19	28
	November 16	25
	December 21	21
2019	January 18	31
	March 22	31

Judgments on New Chemical Substances (Article 4)

Regular Evaluation and Judgments on New Chemical Substances (FY2018 Results)

No. of Reviews	No. of Judgments					
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6
176	0	9	6	31	130	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
116	116

* Low production volumes for new chemical substances based on polymer flow schemes are also included. 13

Preliminary Evaluation and Prior Confirmation of New Chemical Substances

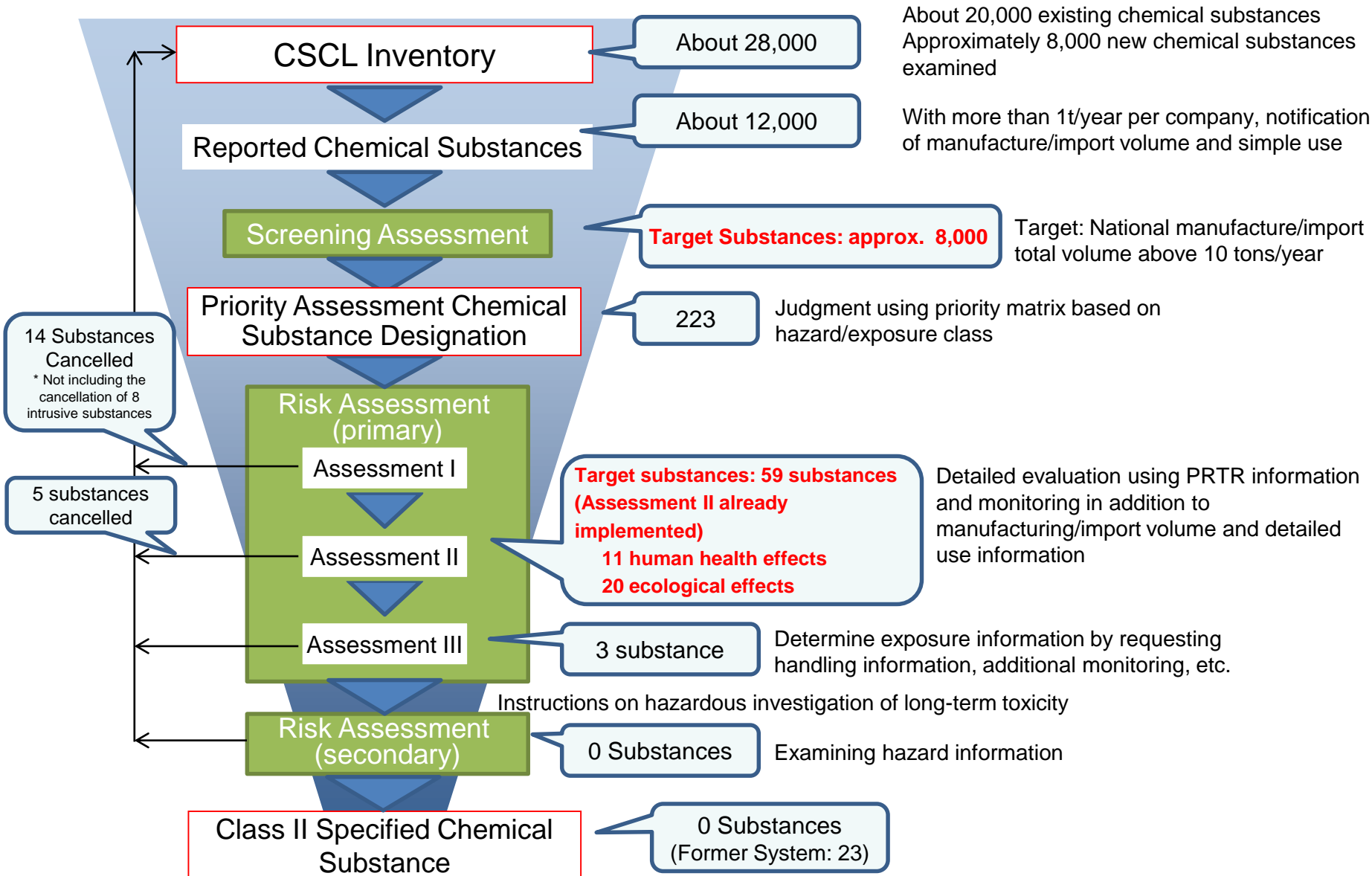
- Japanese chemical industry is shifting its marketing style to producing small lots of many products. Following this trend, the special exemption system and notification exemption system were established as rational systems that consider high-variation/ low-volume production while requiring that chemical pollution be prevented.
- Information that needs to be submitted to the administration varies, depending on the procedure.
- Business operators who were checked under the special exemption system must accept report imposition and on-site inspection, as necessary.

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
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
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 emission 10 t or less	Yes	Notification: 10 times/FY Declaration: As needed
New (small amount)	Article 3.1.5 of Act	Declaration → Confirmation	—	Intended use planned quantity, etc.	Whole country emission 1 t or less	Yes	10 times/FY (4 times/FY by post/via reception desk)
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
Intermediate substance, etc.	Article 3.1.4 of Act	Declaration → Confirmation	—	How to handle, drawing that shows facilities and equipment, etc.	No	No	As needed
Small-amount intermediate substance, etc.				(Simplified)	1 t or less / 1 company	No	As needed

CSCL Screening /Risk Assessment

* As of September 2019

Risk Assessment by Phase



Risk Assessment (primary) Assessment II of Priority Assessment Chemical Substances

○ Risk Assessment (primary) Assessment II for Priority Assessment Chemical Substances was performed on 3 substances in 2014, 7 substances in 2015, 9 substances in 2016, 7 substances in 2017*¹, and 6 substances in 2018. To date, a total of 36 substances has been assessed (including assessment of 12 substances for human health impact, 25*² substances for ecological impact, 1 substance for both human health and ecological impacts).

○ Five substances have been removed from Priority Assessment Chemical Substances based on the performed assessments.

*1 Two substances were deliberated for assessment of other hazardous properties. *2 Including substances of which risk assessment progress were reported.

Assessment deliberation date	Substance name	Assessment aspect	Assessment result (overview)	Action to be taken
2017.6.25	Trichloroisocyanuric acid	Ecological effect	<ul style="list-style-type: none"> - Exposure assessment results obtained so far are not enough as grounds for evaluating Assessment II. - Collect actual measurement data of isocyanuric acid by environmental monitoring. 	Continue Assessment II
2017.11.24	Decan-1-ol	Ecological effect	<ul style="list-style-type: none"> - Exposure assessment results obtained so far are not enough as grounds for evaluating Assessment II. - Collect actual measurement data of decan-1-ol by environmental monitoring. 	Continue Assessment II
2018.1.18	Fenobcarb	Ecological effect	<ul style="list-style-type: none"> - Exposure assessment results obtained so far are not enough as grounds for evaluating Assessment II. - Collect actual measurement data of fenobcarb by environmental monitoring. 	Continue Assessment II
	N,N-dimethylformamide	Human health effect	<ul style="list-style-type: none"> - Inform major discharging business operators (based on PRTR information) of risk assessment results, encourage them to voluntarily improve the situation, confirm that discharge amount is reduced, and then remove it from the Priority Assessment Chemical Substances. 	Remove after confirming improvement
2018.3.23	Ethylene oxide	Human health effect	<ul style="list-style-type: none"> - Proceed to Assessment III and check the conditions of the multiple locations where no PRTR notification business operators are identified nearby or in the surrounding area of the monitoring points that marked hazardous property assessment values higher than the criterion. - Check how the substance is regulated by other laws and regulations. 	Assessment III
	Sodium dichloroisocyanurate (re-assessed together with Trichloroisocyanuric acid)	Ecological effect	<ul style="list-style-type: none"> - Examine chronic toxicity to fish. - Collect actual measurement data of isocyanuric acid by environmental monitoring. 	Continue Assessment II
	Amine oxide	Ecological effect	<ul style="list-style-type: none"> - Analyze uncertainty factors (definition of physicochemical properties, allowable discharge amount, etc.) and examine items that can be effectively applied limit uncertainty. 	Continue Assessment II

Risk Assessment (primary) Assessment II of Priority Assessment Chemical Substances

Assessment deliberation date	Substance name	Assessment aspect	Assessment result (overview)	Action to be taken
2018.7.13	Benzyl benzoate	Ecological effect	<ul style="list-style-type: none"> - Exposure assessment results obtained so far are not enough as grounds for evaluating Assessment II. - Collect actual measurement data by environmental monitoring. 	Continue Assessment II
2018.7.13 2018.9.21	Aniline	Human health effect	<ul style="list-style-type: none"> - The currently estimated exposure concentrations of Aniline are low enough to conclude that the substance in the environment will not harm human health. - Aniline will remain Priority Assessment Chemical Substance since it remains subject to Risk Assessment (primary) Assessment I in terms of ecological impact. 	Continue Assessment I
	Acrylic acid	Ecological effect	Identify the operators that discharge the substance most based on PRTR information and inform them of the state of risk assessment. Meanwhile, because there is uncertainty in the sources and environmental monitoring, proceed to Risk Assessment (primary) Assessment III to understand actual discharge states and collect measurement data through environmental monitoring to examine necessary measures.	Assessment III
2018.9.21	Carbon disulfide	Human health effect / ecological effect	<ul style="list-style-type: none"> - Inform major discharging business operators (based on PRTR information) of risk assessment results, encourage them to voluntarily improve the situation, confirm that discharge amount is reduced, and then remove it from the Priority Assessment Chemical Substances. 	Cancel after confirming efforts
2019.1.18	Piperazine	Human health effect	<ul style="list-style-type: none"> - In September 2018, carbon bisulfide was determined to be readily degradable, based on the obtained knowledge. Accordingly, there are no grounds for specifying PDK as Priority Assessment Chemical Substance. As a result of performing a screening assessment afresh by using the hazard class for piperazine, a variation that contains no carbon bisulfide, and the exposure class for PDK, it was confirmed that the substance still falls under the "high" priority group. - Perform Risk Assessment (primary) Assessment I, with consideration of the actual state of the use, discharge, and degradation. 	Continue Assessment I
	Stearamide	Ecological effect	<ul style="list-style-type: none"> - The currently estimated exposure concentrations are low enough to conclude that the substance in the environment will not harm the inhabitation and growth of animals and plants in the living environment, in the greater area. - Exposure assessment results obtained so far are not enough as grounds for evaluating Assessment II. - Organize, examine and re-evaluate the risk assessment methods for substances with surface active action (handling of physicochemical property data on environmental behavior, environmental concentration estimation methods, risk assessment method for benthos, etc.). At the same time, through environmental monitoring, collect actual measurement data of the areas with relatively high, estimated environmental concentrations of the substance. 	Continue Assessment II

Risk Assessment (primary) Assessment II of Priority Assessment Chemical Substances

Assessment deliberation date	Substance name	Assessment aspect	Assessment result (overview)	Action to be taken
2019.3.23	Triphenylboron	Ecological effect	<ul style="list-style-type: none"> - A detailed information document on the physicochemical properties (draft) and hazard assessment report on ecological impact (draft) were deliberated and approved. - The assessment method for fishing net antifoulant was approved. It was decided that the Risk Assessment (primary) Assessment II will be continued. 	Continue Assessment II
	Copper pyrithione	Ecological effect	<ul style="list-style-type: none"> - Considering that the substance is known to promptly degrade in the environment, producing alteration products, risk assessment was performed on the alteration products (POSA and PSA) as well as the parent substance (copper pyrithione). - Risk estimation was performed because the substance is not covered by PRTR and thus its CSCL-based discharge amount cannot be obtained and there is no environmental monitoring data. Currently, estimated PEC is an estimation using a discharge amount estimated from CSCL notification information. The substance readily degrades in water, with uncertainty in its behavior in the environment. Also, no actual measurement concentration of the substance has been obtained through environmental monitoring. Therefore, the substance has various uncertainties. With the information we currently have, we cannot determine whether it is harming the inhabitation and growth of animals and plants in the living environment. - For the reason above, we will study the uncertainty factors that require additional research while performing re-assessment considering how problems of the exposure assessment method for anti-fouling paint scenarios are dealt with. 	Continue Assessment II
	Nonylphenol	Ecological effect	<ul style="list-style-type: none"> - The 3 ministries are discussing what parameter should be used as key data in performing risk assessment from the viewpoint of ecology. It will be examined in a deliberation council in July again. 	To be determined

3. Response to the POPs Convention

Response to the POPs Convention (additional Class I substances)

■ Stockholm Convention on Persistent Organic Pollutants (POPs Convention)

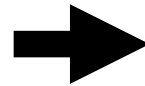
■ To prevent **Persistent Organic Pollutants (POPs)** pollution, each nation **eliminates and reduces the pollutants in cooperation with other nations**.

Adopted in May 2001. Japan acceded to it in August 2002 and it entered into force in May 2004.

- Conference of the Parties (COP) is held once every 2 years. It has been held 9 times.
- Specialized/technical issues are deliberated by the POPs Review Committee (POPRC) under COP.

POPs (Persistent Organic Pollutantss)

- =
1. Toxic,
 2. Persistent,
 3. Bio-accumulative, and
 4. long-range transporting substances



Requires international preventative efforts

Overview of COP9

○ Date: Mon, April 29 – Fri, May 10, 2019, Place: Geneva (Switzerland)

○ Results

- Target substances were added. Following POPRC's recommendations, the following was decided:

→ **Dicofol**: added to Annex A

Perfluorooctanoic acid PFOA, its salts and PFOA-related compounds: added to Annex A

- Acceptable purposes and individual exemption for the substances that had been previously added to Annex were re-examined.
- Effectiveness evaluation of the Convention.

COP9 New Target Substances under POPs Convention

Substance name	Main use	Description of main regulations
Dicofol	Pesticide	- Prohibition of manufacture/use (Annex A) (no provision to exclude particular uses)
Perfluorooctanoic acid PFOA, its salts and PFOA-related compounds	Fluorine-containing polymer processing aid, surfactant, foam, etc.	- Prohibition of manufacture/use (Annex A) (the following uses are excluded in the provisions.)* <ul style="list-style-type: none"> — Photolithography or etching process in semiconductor manufacturing — Photo coating applied to the film — Oil/water repellent fiber products to protect workers — Invasive/implantable medical devices — The form used with the (mobile/fixed) systems that are placed to reduce steam from liquid fuel and prevent fires caused by liquid fuel. — <u>Use of perfluorooctyl iodide (PFOI) for manufacturing perfluorooctane bromide (PFOB) for manufacturing pharmaceuticals</u> — Manufacture of polytetrafluoroethylene (PTFE) and polyVinylidene difluoride (PVDF) for the following products: <ul style="list-style-type: none"> - High-performance anti-corrosion gas filter membranes, water processing membranes, membranes for medical fibers - Industrial dump heat exchanger - Industrial sealing material that can prevent leakage of volatile organic compounds and PM 2.5 particles — Manufacture of fluorinated ethylene propylene (FEP) for manufacturing high-voltage transmission wire and cable — Manufacture of fluoroelastomer for manufacturing O-rings, V-belts, and plastic accessories used for car interior

*1 Provisions on individual exclusions become void 5 years from their effective dates.
 Japan will examine whether those uses should be excluded in Japan or not.

Response to POPs Convention within Japan

CSCL is one of the laws and regulations that guarantee Japan's adherence to the POPs Convention. Thus, each of the following POPs specified in the convention needs to be deliberated by Subcommittee on Chemical Substance Evaluation and **necessary actions must be taken by CSCL** (revision of cabinet / ministerial orders):

- Dicofol
- Perfluorooctanoic acid PFOA, its salts and PFOA-related compounds

[Considerations towards national actions]

- ❑ Specify the substances as CSCL Class I Specified Chemical Substances (i.e., substances that are persistent, highly-accumulative, and toxic to human or high-level predator animals on a long-term basis) (regulatory measure 1.)
- ❑ Also, consider taking the regulatory measures 2. to 5. below, based on the actual state of manufacture within the country, import, and use of the substances, cases in other countries, environmental risk assessment results within the country, etc.

Regulatory measures:

1. Limit manufacture/import permission and use (CSCL Article 17 and 22)
2. Limit import of products containing Class I Specified Chemical Substances (CSCL Article 24)
3. Use of the substances for exceptionally allowable purposes (essential use) (CSCL Article 25)
4. Obligation to comply with technical criteria (CSCL Article 28)
5. Order to collect the substances following their designation as Class I Specified Chemical Substance (CSCL Article 34)

Central Environment Council's 1st report (August 2019)

The following chemical substances, which were additionally included in the scope of POPs Convention, **should be specified as Class I Specified Chemical Substances under CSCL:**

- Dicofol
- Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

Central Environment Council's 2nd report (October 2019)

The following measures should be taken along with the designation of the substances as Class I Specified Chemical Substances:

- Limit the import of products that contain Class I Specified Chemical Substances (CSCL Article 24)
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
Products: floor wax, etc.
- Permit use for exceptionally acceptable purposes (essential use) (CSCL Article 25)
PFOA-related compounds
Purposes: use of perfluorooctyl iodide (PFOI) for manufacturing perfluorooctane bromide (PFOB) for manufacturing pharmaceuticals
- Obligation to comply with technical standards (CSCL Article 28)
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
Products: fire extinguishers, fire-extinguishing chemical for fire extinguishers, fire extinguishing foam

→ The order for CSCL enforcement, etc. will be revised after public comments, etc.