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The 4th Tripartite Policy Dialogue on Chemical Management

Current Trend of Chemical Management Policy in Japan

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1. Overview of Chemical Management Policy in Japan

Regulation Overview

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law)

Regulations on Manufacturing, etc.

- Elements and natural products

- Chemical substances

**General usage
(industrial)**

**- General industrial
chemical products**

Specific usage

- Foods, additives, containers and packaging, toys and detergents
- Agricultural chemicals
- Ordinary fertilizers
- Feeds and feed additives
- Drugs, quasi-drugs, cosmetics and medical equipments

- Radioactive substances
- Specified poison
- Stimulant and raw materials for stimulants
- Narcotic

Regulations on Emissions

[Water Pollution Control] [Air Pollution Control] [Soil Contamination Countermeasures]

Regulations on Waste

[Waste Management and Public Cleansing]

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law (CSCL))

Enacted in 1973

(two major amendments in 1986 and 2003)

Aiming to prevent environmental pollution from PCBs and other hazardous chemicals

Based on two pillars:

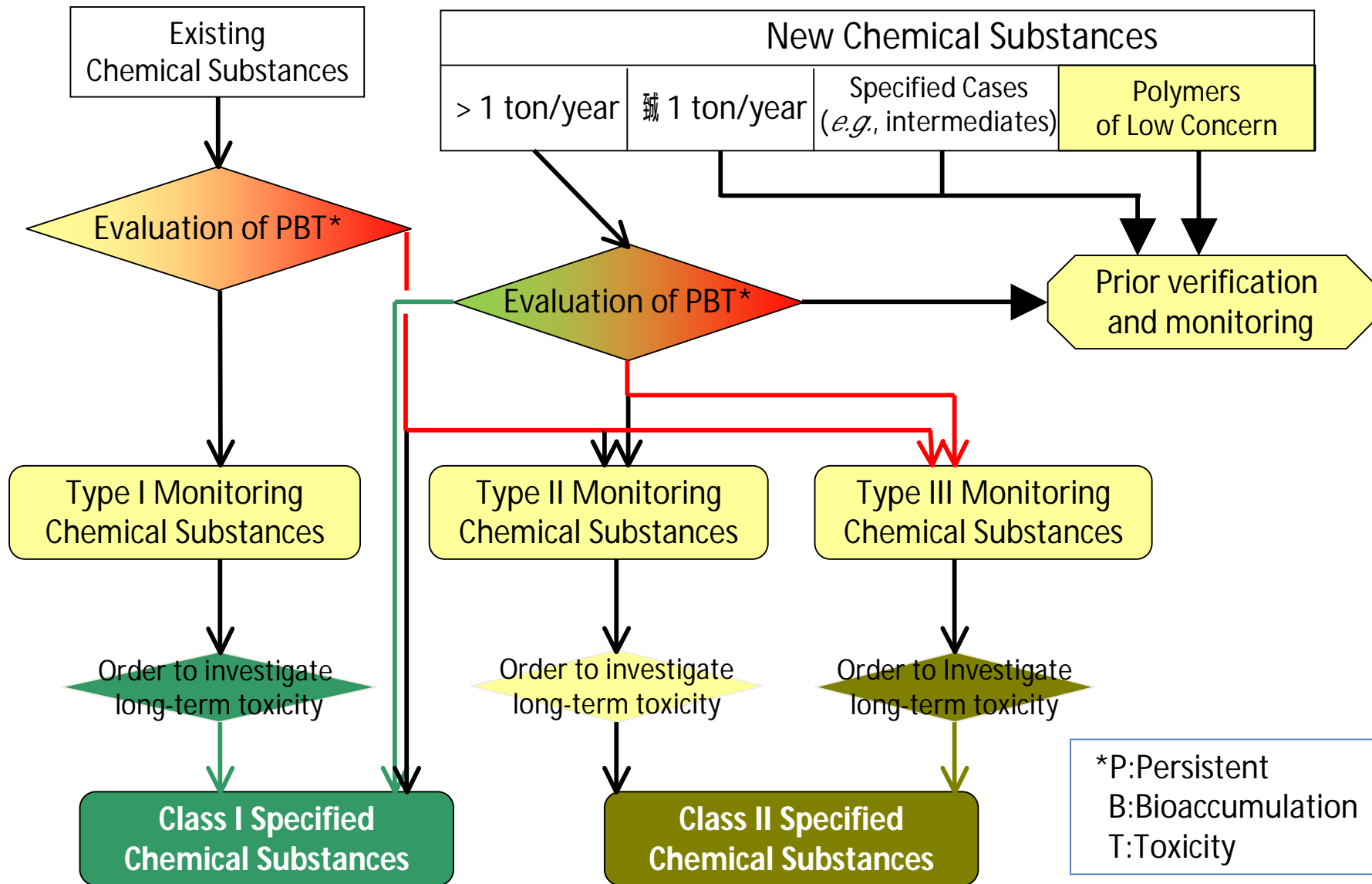
- prior evaluation of new chemicals
- regulation on manufacture/import and use

Excluded: specific chemicals covered by other regulations
e.g. agrochemicals, pharmaceuticals, food, fertilizers

Three Ministries are in charge: MHLW, METI, MOE

(No role of local governments under CSCL)

Current CSCL (As of April 2010)



Obligatory reporting of hazard information obtained by business

Types of chemicals regulated under CSCL

Name	Explanation	No. of substances*
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and toxicity (long-term toxicity for humans or long-term toxicity for predator animals at higher trophic level)	28
Class-II Specified Chemical Substances	Persistent , toxicity (long-term toxicity for humans or long-term toxicity for flora and fauna in the human living environment) with concern for a considerable amount of the chemical substance remaining in the environment over a substantially extensive area	23
Type-I Monitoring Chemical Substances	Persistent and bioaccumulative, but toxicity properties unknown <i>(Candidates for the Class-I Specified Chemical Substances)</i>	37
Type-II Monitoring Chemical Substances	Persistent and Suspected long-term toxicity for humans <i>(Candidates for the Class-II Specified Chemical Substances)</i>	1,070
Type-III Monitoring Chemical Substances	Persistent and Suspected toxicity for flora and fauna <i>(Candidates for the Class-II Specified Chemical Substances)</i>	277

2. Current trend of Chemical Management in Japan (1)

- Amendment to the Chemical Substances Control Law in 2009**

Summary of Amendment to CSCL in 2009 (1)

To control chemical substances comprehensively, the government reviews measures for the risk assessment of chemical substances and scope of the chemical substances regulated, while taking measures to rationalize regulations in view of international trends.

Background and necessity of the amendment

1. Increasing public interest in chemical substances
2. Need to achieve international goals on chemicals management
 - There is a need to minimize adverse effects of all chemicals on human health and the environment by 2020 (agreement in the World Summit on Sustainable Development (WSSD), 2002).
3. Inconsistency with the international convention
 - Under the Stockholm Convention, the agreement was reached to accept certain exceptional uses of the newly prohibited chemicals.
 - The existing law, which is more restrictive on exceptional uses, may fail to permit the essential uses for Japan.

Summary of Amendment to CSCL in 2009 (2)

(1) Measures for existing chemical substances

- Companies that manufacture or import any chemical substance, including existing one, in excess of the specified amounts are obliged to notify applications containing quantity and other information to the government.
- Upon receipt of those applications, the government screens and prioritizes substances subject to detailed risk assessment. The manufacturers/importers may be required to submit information on hazardous properties of substance for government evaluation.
- Based on the evaluation, the government shall decide whether to regulate the manufacture/use of the substance and its product, etc.

(2) Ensuring international consistency

- The government ensures that substances newly listed under the international convention can be used under strict control.
 - Uses for semiconductors, fire fighting foam, etc.

Key Points of Amendment in 2009 (1)

(1) Shift to Risk-based chemical management

$$\text{Risk} = \text{Hazard} \times \text{Amount of Exposure}$$

Hazard: Potential adverse effects of chemicals for human health and the environment

Amount of Exposure: Potential amount of chemicals which may expose human and ecosystem

Before the Amendment

Regulations are mainly based on hazards of chemicals



After the Amendment

Regulations shall be mainly based on risks of chemicals

Key Points of Amendment in 2009 (2)

(2) Introduction of a comprehensive control system that covers the existing chemical substances

- (a) Companies that have manufactured or imported any chemical substance, including existing one, in excess of the specified amounts are newly obliged to notify quantity and other information for every fiscal year.
- (b) Chemical substances which the government identifies from contents of the notifications and available knowledge of their hazardous properties shall be designated as "Priority Assessment Chemical Substances", which have higher priority in the risk assessment."
- (c) Manufacturers and importers of the Priority Assessment Chemical Substances are required to submit information on hazardous properties, and companies handling them are required to report their uses when necessary.
- (d) Among the Priority Assessment Chemical Substances, substances which raise concerns about adverse effects on humans or the environment through the gathered information and the risk assessment shall be subject to regulations on manufacture and use as "Class II Specified Chemical Substances", which category is stipulated in the current law.

Key Points of Amendment in 2009 (2)

(2) Introduction of a comprehensive control system that covers the existing chemical substances

(e) In addition to “chemical substances which is persistent in the environment,” which have been under control, “chemical substances which is not persistent in the environment” are regulated in the amended law.

Before the Amendment

to prevent environmental pollution caused by chemical substances that are persistent, because such chemicals remain in the environment for a long term.



After the Amendment

Non-persistent chemicals are also regulated, because they may have adverse effect on the environment, when they are emitted more than that can be decomposed through natural processes.

Key Points of Amendment in 2009 (3)

(3) Appropriate control on chemical substances in the supply chain

To prevent environmental pollution by Class II Specified Chemical Substances and products containing those, the law requires companies handling those to adhere to specific handling standards and to label those as needed for transactions.

Before the Amendment

Companies manufacturing and importing specified chemicals are required to adhere to specific handling standards and to label those as needed for transactions.



After the Amendment

Companies handling specified chemicals and products containing those are also required to adhere to specific technical standards and to label them as needed for transactions.

Key Points of Amendment in 2009 (4)

(4) Rationalization of the framework on evaluation and regulation in light of international trends

The government eliminates international inconsistencies in its regulations, for example, by reviewing regulations on Class I Specified Chemical Substances in order to permit the exceptional use of substances that will be listed under the Stockholm Convention in the future under strict control.

Before the Amendment

Class I Specified Chemical Substances could be only used, when there is **no substitute**, and they **don't use mainly in the daily lives of consumers** and have **no risks of causing environmental pollution**.



After the Amendment

Class I Specified Chemical Substances are **permitted in case of the exceptional use** listed under the Stockholm Convention. While, **obligations to adhere to specific handling standards and label them are added**.

Key Points of Amendment in 2009 (5)

(5) Notification to related Ministers of information on chemical substances

The government aims to

- allow related Ministries to share increased amounts of information gathered under the amended law
- enforce more effective regulations on chemical substances pursuant to relevant laws and ordinances in the future under strict control

Schedule of the Enforcement

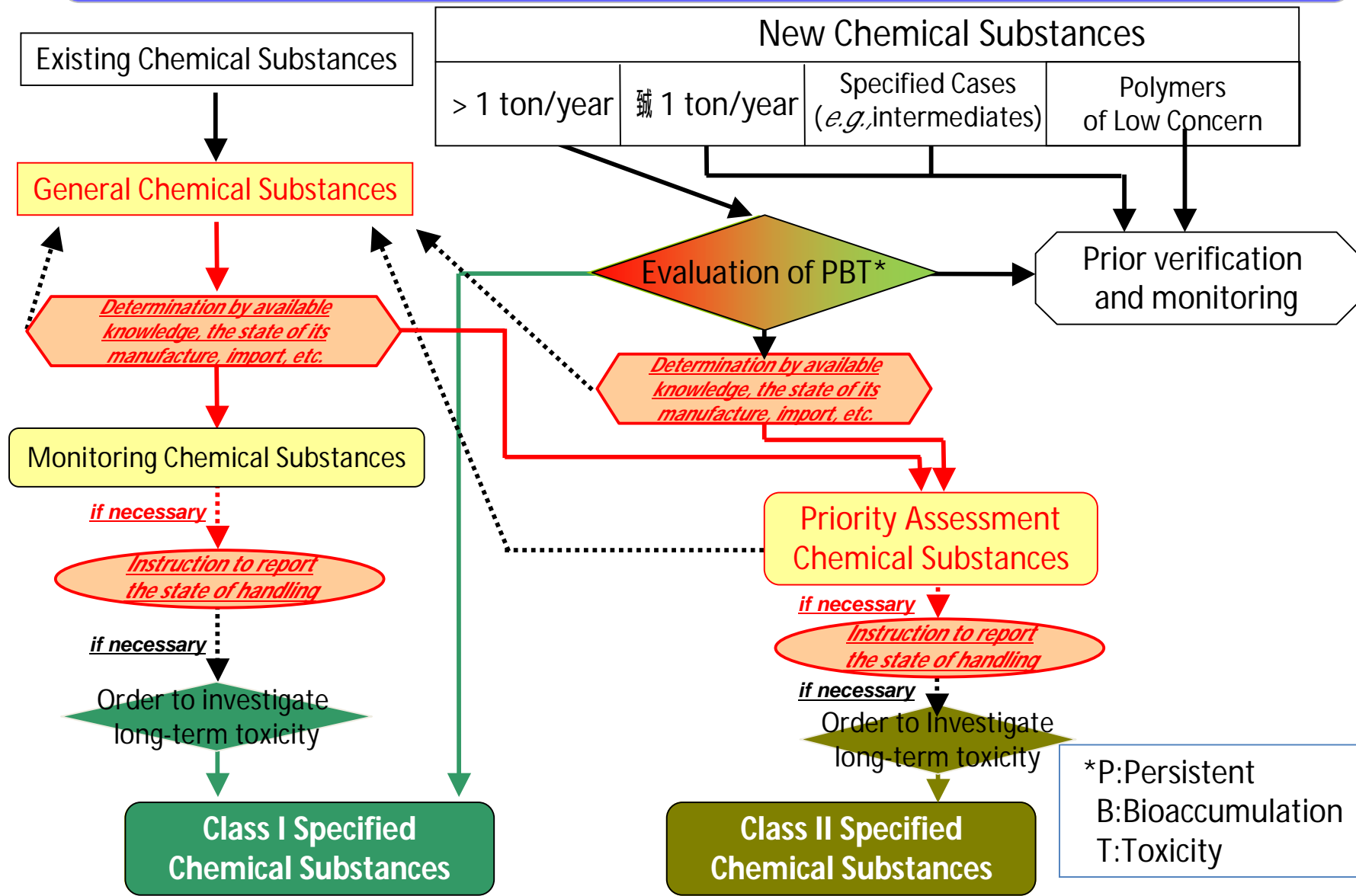
2009.5.20 Promulgation

2010. 4. 1. Enforcement

(Except obligation to notify quantity and other information for any chemicals and designation of the Priority Assessment Chemical Substances, etc.)

2011. 4. 1. The unenforced regulations under CSCL will become effective

CSCCL amended (April 1, 2011 ~)



*P: Persistent
B: Bioaccumulation
T: Toxicity

Obligatory reporting of hazard information obtained by business

Types of chemicals regulated under CSCL (April 1, 2011 ~)

Name	Explanation
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and toxicity (long-term toxicity for humans or long-term toxicity for predator animals at higher trophic level)
Class-II Specified Chemical Substances	Toxicity (long-term toxicity for humans or long-term toxicity for flora and fauna in the human living environment) with concern for a considerable amount of the chemical substance remaining in the environment over a substantially extensive area
Monitoring Chemical Substances	Persistent and bioaccumulative, but toxicity properties unknown <i>(Candidates for the Class-I Specified Chemical Substances)</i>
Priority Assessment Chemical Substances	<ul style="list-style-type: none"> · Not found that it is clear chemical substance does not pose long-term toxicity · Considerable amount of chemical substance remains in the environment · Not thought not to pose a risk
Existing Chemical Substances	Chemical substances that were already manufactured/imported at the time of the promulgation of Chemical Substance Control Law (in 1973)
General Chemical Substances	Sufficiently low risk of the substance can be confirmed

3. Current trend of Chemical Management in Japan (2)

- Amendment to the Order for Enforcement of the Chemical Substances Control Law in 2009**

Key Points of Amendment in 2009

1. Specified Chemical Substances

(1) Additional designation for Class I Specified Chemical Substances

12 new chemicals, added to the list chemicals in Annex A, B or C of the Stockholm Convention, were designated the Class I Specified Chemical Substances under CSCL (*Enforced in April 1, 2010*)

- Perfluorooctane-1- sulfonic acid (PFOS) or its salts
- Perfluorooctane-1- sulfonyl fluoride (PFOSF)
- Pentachlorobenzene
- 1-alpha,2-alpha,3-beta,4-alpha,5-beta,6-beta-Hexachlorocyclohexane (alpha-Hexachlorocyclohexane)
- 1-alpha,2-beta,3-alpha,4-beta,5-alpha,6-beta-Hexachlorocyclohexane (beta-Hexachlorocyclohexane)
- 1-alpha,2-alpha,3-beta,4-alpha,5-alpha,6-beta-Hexachlorocyclohexane (gamma-1,2,3,4,5,6-Hexachlorocyclohexane or Lindane)
- Decachloropentacyclo[5.3.0.0^{2,6}.0^{3,9}.0^{4,8}]decan-5-one (Chlordecone)
- Hexabromobiphenyl
- Tetrabromophenoxybenzene (Tetrabromodiphenyl ether)
- Pentabromobiphenyl (Pentabromodiphenyl ether)
- Hexabromophenoxybenzene (Hexabromodiphenyl ether)
- Heptabromophenoxybenzene (Heptabromodiphenyl ether)

(2) Addition of Articles containing Class I Specified Chemical Substances for Import-prohibited Items

14 Articles with 3 new Class I Specified Chemical Substances were prohibited against their import (*Enforced in May 1, 2010*)

[PFOS and its salts]

- Aviation hydraulic fluids
- Spinning oil
- Etching agent for processing of metal
- Etching agent for semi-conductor production (exclude the compound-semi-conductor which makes it possible for the radio equipment to send and receive an equal to or more than 3 MHz frequency electric wave)
- Surface preparation agent or its preparation additives for metal plating
- Anti-reflective coating for semi-conductor production
- Abrading agent
- Fire extinguisher, fire-extinguishing chemical for fire extinguisher and fire fighting foam
- Insect baits (limited to insecticides for control of termites or ants)
- Photographic paper

[Tetrabromodiphenyl ether and Pentabromodiphenyl ether]

- Paints
- Adhesives

(3) Essential Uses of Class I Specified Chemical Substances

✓ Class I Specified Chemical Substances should not be used in principle; however, the following exceptional uses shall be acceptable (*Enforced in April 1, 2010*)

Essential Uses of Class I Specified Chemical Substances

[PFOS or its salt]

- Production of etching agent (limited to ceramic filter or the compound-semi-conductor which makes it possible for the radio equipment to send and receive an equal to or more than 3 MHz frequency electric wave)
- Production of photo-resist for semi-conductor
- Production of photographic film for industry

✓ Those who use Class I Specified Chemical Substances in their articles shall follow the technical standards and implement labeling to prevent the environmental pollution (*Enforced in October 1, 2010*)

Articles with the Class I Specified Chemical Substances which shall conform to the technical standards and labeling

[PFOS or its salt]

- Production of etching agent (limited to ceramic filter or the compound-semi-conductor which makes it possible for the radio equipment to send and receive an equal to or more than 3 MHz frequency electric wave)
- Photo-resist for semi-conductor
- Photographic film for industry
- fire extinguisher, fire-extinguishing chemical for fire extinguisher and fire fighting foam (for the time being)

(4) Designation of Articles with the Class II Specified Chemical Substances which must conform to the technical standards and labeling

- ✓ 11 Articles with 3 Class II Specified Chemical Substances were designated to impose new obligations of technical standards and labeling

[Trichloroethylene]

- Adhesives (excluding those of animal and botanical origin)
- Paints (excluding water-based paints)
- Metalworking fluids
- Cleaning agents

[Tetrachloroethylene]

- Vulcanized agents
- Adhesives (excluding those of animal and botanical origin)
- Paints (excluding water-based paints)
- Cleaning agents
- Finishing agents for textile goods

[Tributyltin compounds]

- Antiseptics and fungicides
- Paints (limited to those used to prevent shellfishes, algae, and other living organisms in water from adhering to surfaces)

II. Measures Concerning General Chemical Substances, etc.

- The minimum amount of manufacture or import of General Chemical Substances and Priority Assessment Chemical Substances subject to notification is set as 1 ton/year/company

III. Schedule (Date of Promulgation: October 30, 2009)

- April 1, 2010
Additional designation of Class I Specified Chemical Substances, their Essential uses and Articles with the Class II Specified Chemical Substance which shall conform to the technical standards and labeling
- May 1, 2010
Additional designation of the Articles containing Class I Specified Chemical Substances for import-prohibited items
- October 1, 2010
Articles with the Class I Specified Chemical Substances shall conform to the technical standards and labeling
- April 1, 2011
Notification of General Chemical Substances and Chemical Substances requiring Priority Assessment

Future Challenges for Enforcement of CSCL Amended

- ✓ Establish overall road map of assessment
- ✓ Review (if changes are introduced, or periodically)
- **Screening assessment** to prioritize substances subject to detailed assessment
 - ✓ Collect hazard information
 - ✓ Identify hazards and patterns of exposure
- **Detailed risk assessment** to decide whether further measures need to be introduced
 - ✓ Analyze risk in detail
 - ✓ Stepwise approach to improve the accuracy and efficiency of assessment

Comprehensive Management System for Chemical Substances

Thank you for your kind attention!

MOEJ's website

(English)

<http://www.env.go.jp/en/>

(中文)

<http://www.env.go.jp/cn/>

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<http://www.env.go.jp/kr/>