

Chemical Regulation Policy in Japan

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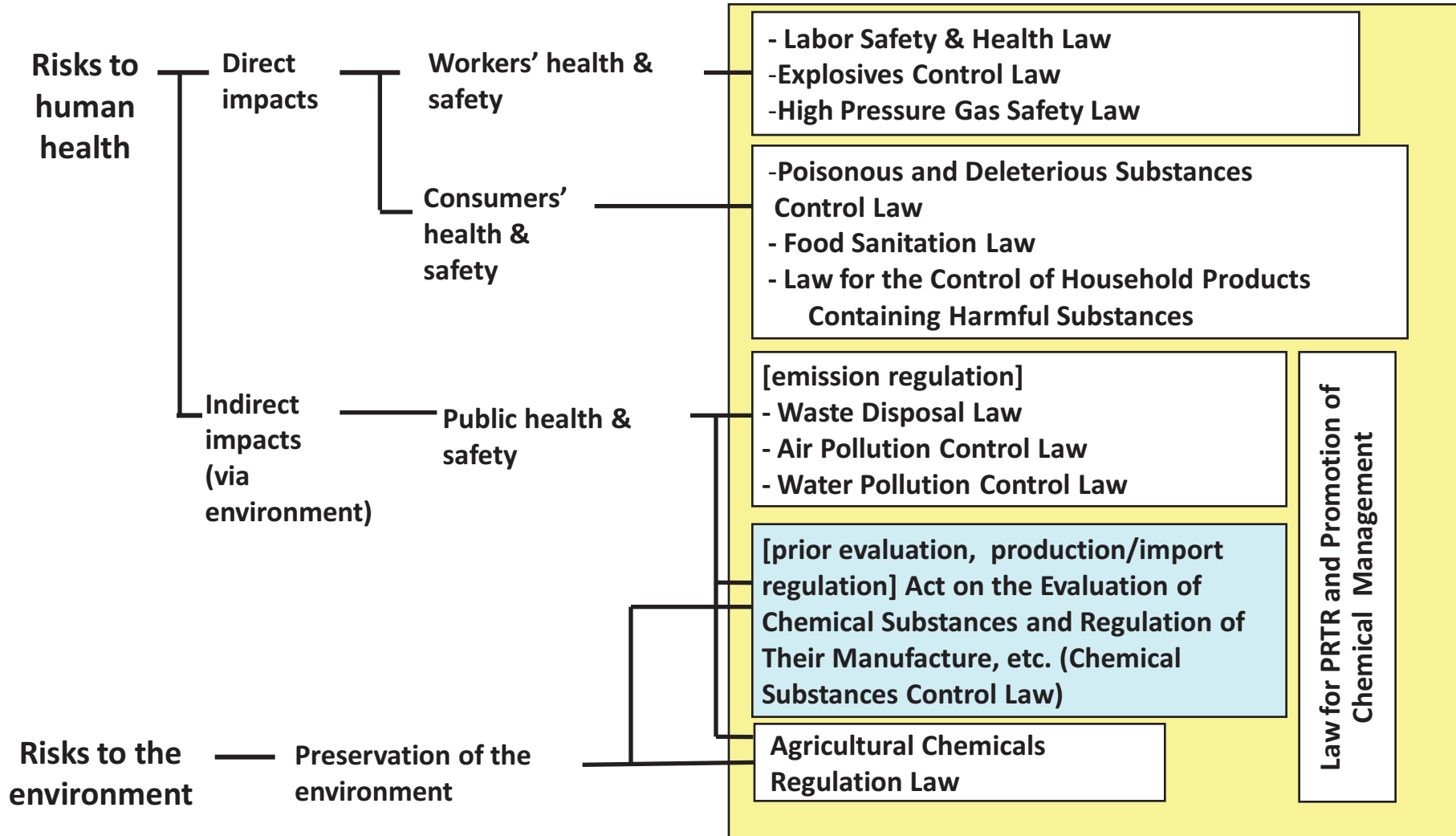
Ministry of the Environment, Japan

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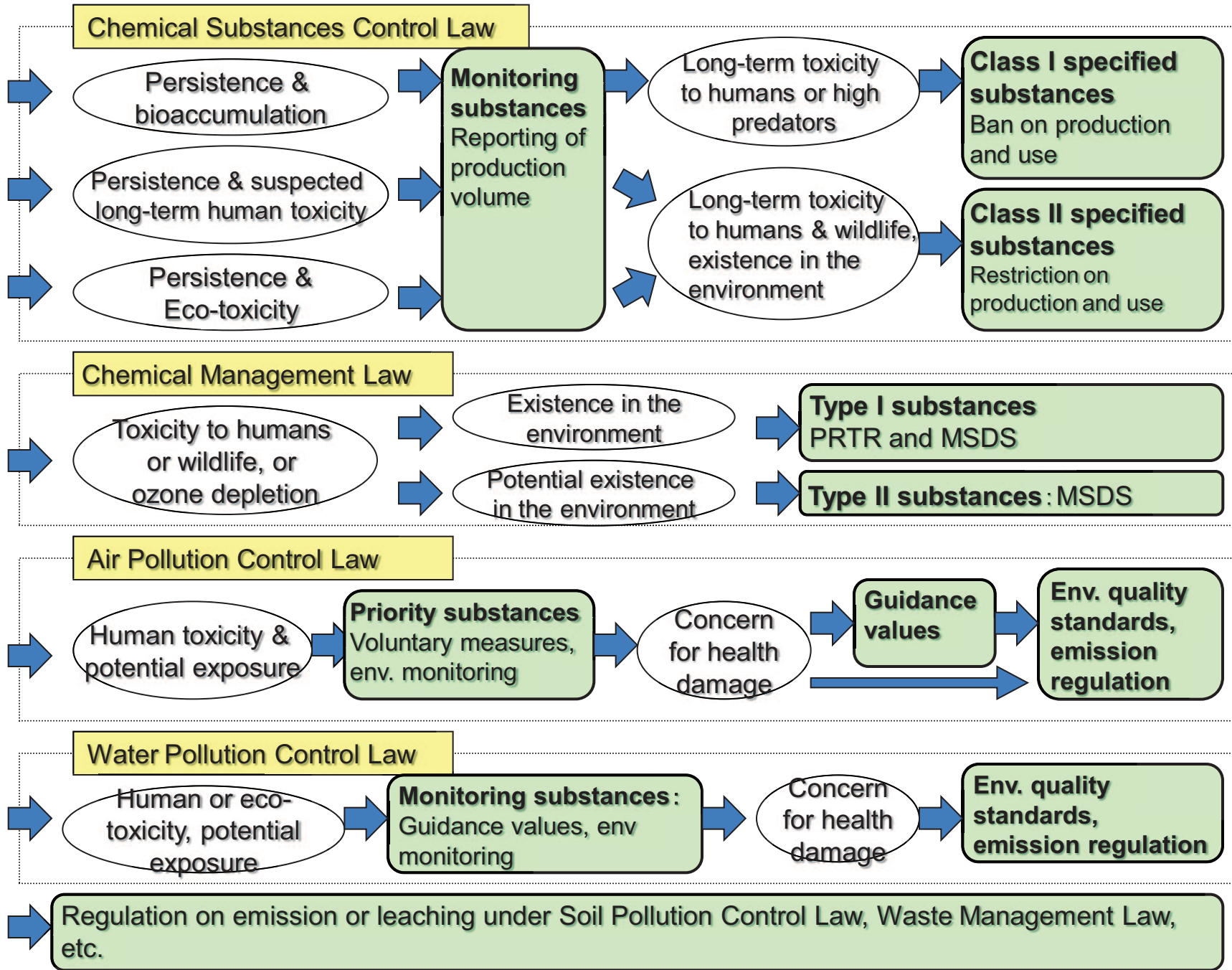
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1. Overview of Chemical Management Policy in Japan

Regulation Overview



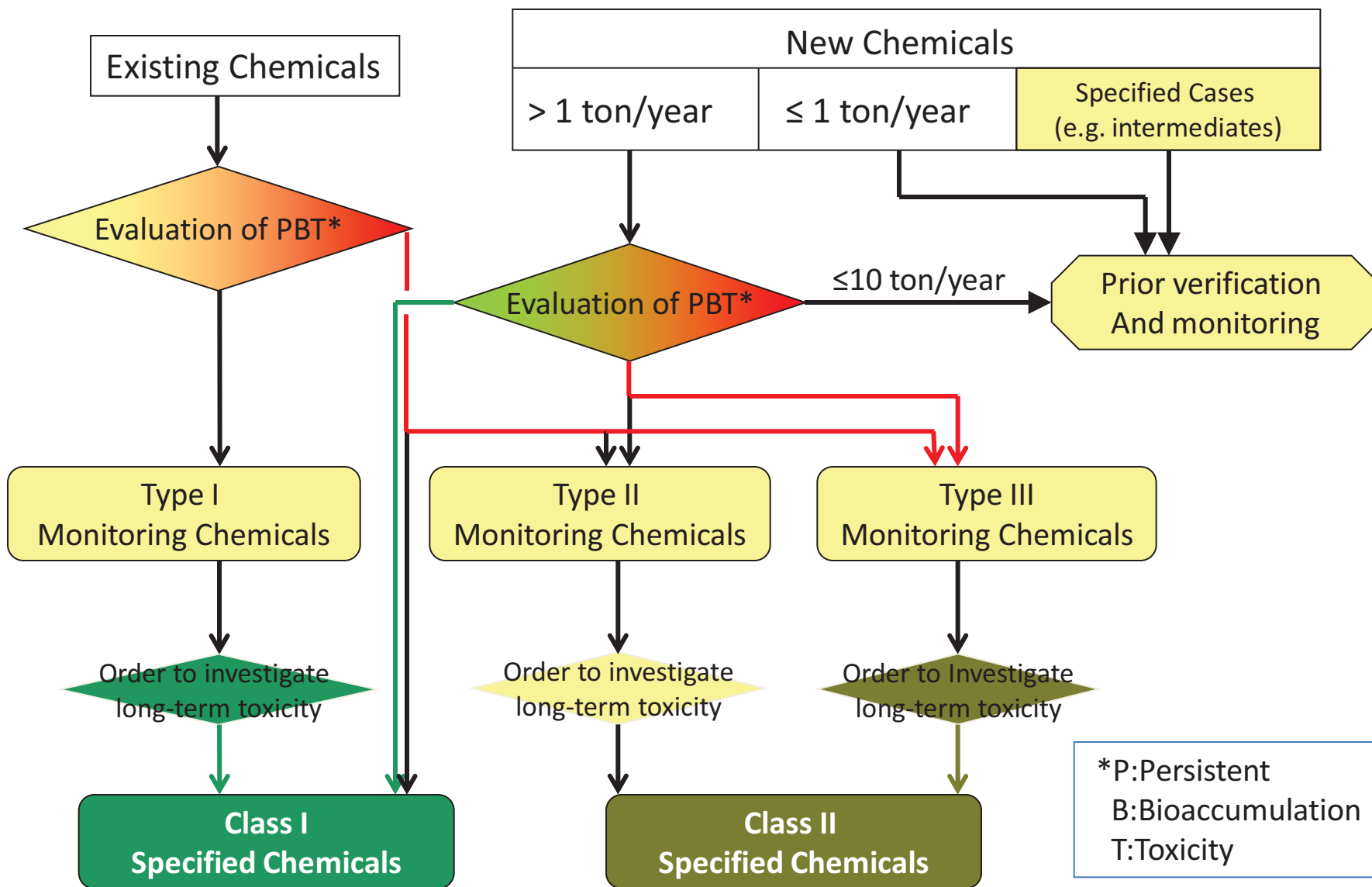
Chemicals



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

Current (2003 Amended) CSCL



Obligatory reporting of hazard information obtained by business

Types of chemical regulated under CSCL

Name	Explanation	No. of substances
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and hazardous (long-term human toxicity or ecotoxicity to higher predators).	16
Class-II Specified Chemical Substances	Persistent, hazardous (long-term human toxicity or ecotoxicity to living organisms), with concern for long-term existence in the environment.	23
Type-I Monitoring Chemical Substances	Persistent and bioaccumulative, but hazardous properties unknown. <i>(Candidates for the Class-I Specified Chems.)</i>	36
Type-II Monitoring Chemical Substances	Persistent and suspected as hazardous to human health. <i>(Candidates for the Class-II Specified Chems.)</i>	952
Type-III Monitoring Chemical Substances	Persistent and hazardous to living organisms. <i>(Candidates for the Class-II Specified Chems.)</i>	157

Note: Number of chemicals as of October 2009.

Regulation on Chemicals under CSCL

<u>Class I Specified Chemicals</u>	<ul style="list-style-type: none">-prior permission required for manufacture and/or import (Note: Permission is prohibited virtually.)- prohibition of use unless authorized in advance- prohibition of import of products containing them- recovery of the products
<u>Class II Specified Chemicals</u>	<ul style="list-style-type: none">- mandatory reporting of planned manufactured and/or imported amounts- subject to governmental orders that require the change of planned amounts- labeling- compliance with technical guideline provided by GOJ and/or governmental recommendation on a legal basis- compliance with guidance provided by GOJ
<u>Monitoring Chemicals</u> (Type I, II and III)	<ul style="list-style-type: none">- mandatory reporting of manufactured and/or imported amount annually (Note: These amounts are announced publicly.)-compliance with guidance provided by GOJ-The GOJ can instruct manufacturer/importer investigate their long-term toxicity

2. Recent trend on Chemical Regulations in Japan

- Amendment of the Chemical Substances
Control Law**

Amendment of CSCL

- To be reviewed after 5 years from 2003, the entry into force of Amendment of CSCL (*Supplementary Provisions Article 6*)
- Schedule of legislative review
 - Jan. 2008 Started the deliberation for CSCL on the Central Environment Council
 - ⇒ Joint deliberation with the Health Science Council and Industrial Structure Council
 - Dec. in 2008 Report on the review of CSCL from the Council To MOE
 - Feb. in 2009 Cabinet decision based on the review of CSCL
 - April in 2009 Deliberation of draft amended CSCL in the Diet was started.
 - May in 2009 Amended CSCL was published

Summary of Amended CSCL in 2009 (1)

To control chemical substances comprehensively, the government reviews measures for the risk assessment of chemical substances and scope of the regulated chemical substances, 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 this spring 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 uses essential to Japan.

Summary of Amended CSCL in 2009 (2)

(1) Measures for existing chemical substances

- Companies that have manufactured or imported any chemical substance, including existing one, in excess of the specified amounts are newly 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 these 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 ensure that substances newly listed under the international convention can be used under strict control.
 - Uses for semiconductors, fire fighting foam, etc.

Key Points of Amended CSCL in 2009 (1)

Shift to Risk-based chemical management

Risk = Hazardousness × Amount of Exposure

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

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

CURRENT CSCL

Regulations were mainly based on hazardousness of chemicals



AMENDED CSCL

Regulations will be mainly based on risks of chemicals

Key Points of Amended CSCL in 2009 (2)

- (1) 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 “Specified Chemical Substances,” which category is stipulated in the current Law.

Key Points of Amended CSCL in 2009 (2) cont'd

(1) Introduction of the framework on comprehensive control 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.

CURRENT CSCL

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



AMENDED CSCL

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 Amended CSCL in 2009 (3)

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

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

CURRENT CSCL

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



AMENDED CSCL

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

Key Points of Amended CSCL in 2009 (4)

(3) 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.

CURRENT CSCL

Class I Specified chemicals 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.



AMENDED CSCL

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

Key Points of Amended CSCL in 2009 (5)

(4) Notify 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 and enforce more effective regulations on chemical substances pursuant to relevant laws and ordinances in the future under strict control.

Schedule of the Amended CSCL

- 2010. 4. 1. Enforcement of the amended CSCL
(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 the CSCL will become effective

3. Summary of the Order for Enforcement of the Chemical Substances Control Law

Key Points of Amended the Order of CSCL (1)

1. Specified Chemicals

(1) Additional designation for Class I Specified Chemicals

12 new chemicals, which were added to the list chemicals in Annex A, B or C of the Stockholm Convention, were designated as the Class I Specified Chemicals under the CSCL.

- 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 the Articles which Import are Prohibited When Class I Specified Chemical Substances are included

14 Articles with 3 new Class I Specified Chemicals were prohibited
against their import

[PFOS or 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 Substance

- ✓ Class I Specified Chemicals should not use in principle, however the following exceptional uses would be acceptable;

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.

Articles with the Class I Specified Chemical Substance which must 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 Substance which must conform to the technical standards and labeling

- ✓ 11 Articles with 3 Class II Specified Chemicals 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.

- Notification of General Chemicals and Chemical Substances Requiring Priority Assessment should be obligated for those who manufacture and/or import chemicals more than 1 ton per year

III. Schedule (published 30 October, 2009)

- April 1st, 2009
 - Additional designation of Class I Specified Chemicals, their Essential uses and Articles with the Class II Specified Chemical Substance which must conform to the technical standards and labeling
- May 1st, 2009
 - Additional designation of the Articles which Import are Prohibited When Class I Specified Chemical Substances are included
- October 1st, 2009
 - Articles with the Class I Specified Chemical Substance must conform to the technical standards and labeling
- April 1st, 2011
 - Notification of General Chemicals and Chemical Substances requiring priority assessment

Future Challenges for Enforcement of Amended CSCL

- Evaluation methods to screen for the Chemical Substances Requiring Priority Assessment and detailed risk assessment of the Chemical Substances Requiring Priority Assessment
 - ✓ What are hazardous data needed to assess the risk?
 - ✓ How to apply the information based on QSAR and Category Approach in evaluation methods under the amended CSCL?
 - ✓ How to assess the exposure of chemicals?
- Risk assessment methods with non-persistent chemicals
 - ✓ Are other specific assessment methods needed?

Thank you for your attention!

JMoE's website

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