



Chemical Substances Control Law (CSCL)

March 2010

Chemical Safety Office, Chemical Management Policy Division,
Manufacturing Industries Bureau
Ministry of Economy, Trade and Industry



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1. The Chemical Substances Control Law: the current version

The Current Version of the Chemical Substance Control Law: Overview



[Purpose]

The purpose of this Act is to evaluate, before manufacture or import, whether or not new chemical substances have properties such as persistence, and to implement necessary regulations, in order to prevent environmental pollution caused by chemical substances that are persistent and pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna.

[Evaluation Criteria]

(1) Persistence (environmental persistence), (2) Bioaccumulation potential, (3) Toxicity for humans or flora and fauna

[Key Points]

- Notification and evaluation of new chemical substances (i.e., chemical substances that were newly manufactured or imported in or after 1973 and have not been evaluated) prior to the manufacture or import.
- Manufacture and/or import of these substances will be permitted without notification and/or evaluation upon confirmation by the government in such cases as the substance is manufactured or imported within a limited volume (the national total tonnage \leq 1 ton), and the substance is an intermediate or a closed system.
- Manufacture and/or import of these substances up to 10 tons (i.e., “low production”) will be permitted without toxicity evaluation if persistence and low bioaccumulation potential are confirmed as a result of the evaluation.
- The existing chemical substances (i.e., the chemical substances manufactured or imported in or before 1973) are to be studied and evaluated by the government.
- The chemical substance will be subject to regulation (e.g., obligation of notification on the amount to be manufactured/imported, limitation on manufacturing, import and/or use) according to its properties found in the evaluation.

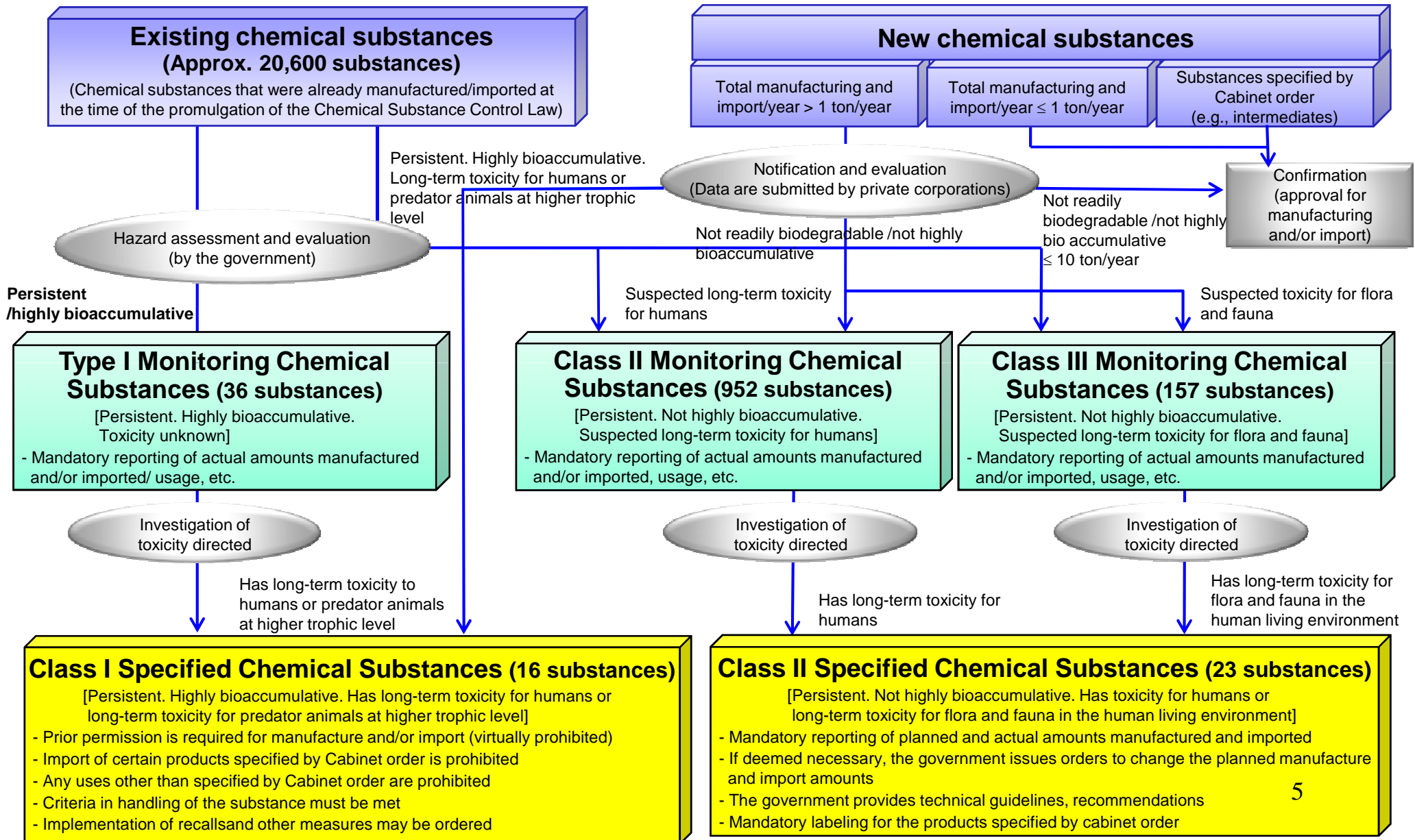
Chemical Substances Subject to the Chemical Substance Control Law



- “Chemical substances” refers to compounds that are obtained by a chemical reaction on an element or a compound.
- The chemical substances subject to the Chemical Substance Control Law are those used for general industrial chemical products. Those substances that are subject to other regulations that are equally or more stringent regulations (Poisonous and Deleterious Substances Control Act) or more specific to the usage of the substance (Food Sanitation Act) are exempted from this law.

		Regulations on manufacturing, etc.	Regulations on emissions	Regulations on waste		
Chemical substances	Chemical substances subject to the Chemical Substance Control Law	- Elements and natural products				
		<table border="1"> <tr> <td> General usage (industrial) - General industrial chemical products </td> <td> Specific usage [Food Sanitation Law] Foods, additives, containers and packaging, toys and detergents [Agricultural Chemicals Regulation Act] Agricultural chemicals [Fertilizers Regulation Act] Ordinary fertilizers [Act on Safety Assurance and Quality Improvement of Feeds] Feeds and feed additives [Pharmaceutical Affairs Act] Drugs, quasi-drugs, cosmetics, and medical equipments </td> </tr> </table>	General usage (industrial) - General industrial chemical products	Specific usage [Food Sanitation Law] Foods, additives, containers and packaging, toys and detergents [Agricultural Chemicals Regulation Act] Agricultural chemicals [Fertilizers Regulation Act] Ordinary fertilizers [Act on Safety Assurance and Quality Improvement of Feeds] Feeds and feed additives [Pharmaceutical Affairs Act] Drugs, quasi-drugs, cosmetics, and medical equipments	[Water Pollution Control Act] [Air Pollution Control Law] [Soil Contamination Countermeasures Act]	[Waste Management and Public Cleansing Law]
		General usage (industrial) - General industrial chemical products	Specific usage [Food Sanitation Law] Foods, additives, containers and packaging, toys and detergents [Agricultural Chemicals Regulation Act] Agricultural chemicals [Fertilizers Regulation Act] Ordinary fertilizers [Act on Safety Assurance and Quality Improvement of Feeds] Feeds and feed additives [Pharmaceutical Affairs Act] Drugs, quasi-drugs, cosmetics, and medical equipments			
[Law concerning Prevention of Radiation Hazards due to Radioisotopes, etc.] Radioactive substances [Poisonous and Deleterious Substances Control Act] Specified poison [Stimulant Drug Control Act] Stimulant and raw materials for stimulants [Narcotics and Psychotropics Control Act] Narcotic		4				

The Current Version of the Chemical Substance Control Law: the Whole Picture



Restrictions according to the Properties, etc. of Chemical Substances



- The Chemical Substance Control Law regulates the restrictions and measures according to the properties the substance (e.g., persistence, bioaccumulation, long-term toxicity for humans, and long-term toxicity for flora and fauna) and the residual conditions in the environment.

Regulatory Classification	Restrictions
<p>Class I Specified Chemical Substances (16 substances including PCBs)</p> <p>Chemical substances that are persistent, are highly bioaccumulative, and have long-term toxicity for humans or long-term toxicity for flora and fauna.</p>	<ul style="list-style-type: none"> - Prior permission is required for manufacture and/or import (virtually prohibited) - Any use other than specified by Cabinet order uses are prohibited - Import of certain products specified by Cabinet order is prohibited - Implementation of recall and other measures may be ordered (in case when the substance and/or product is specified and when the statutes are not complied with)
<p>Class II Specified Chemical Substances (23 substances including trichloroethylene)</p> <p>Chemical substances that are persistent and have toxicity for humans or long-term toxicity for flora and fauna in the human living environment</p>	<ul style="list-style-type: none"> - Mandatory reporting of planned and actual amounts manufactured and/or imported, usage, etc. - If deemed necessary, the government issues orders to change the planned manufacture and import amounts - The government provides technical guidelines, recommendations for handling - Mandatory and recommended labeling
<p>Type I Monitoring Chemical Substances (36 substances including cyclododecan)</p> <p>Existing chemical substances that are confirmed to be persistent and highly bioaccumulative</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 1 ton. - Guidelines, advice, etc. (when necessary to prevent environmental pollution) - When necessary, government directs manufacturers and importers to investigate the long-term toxicity for humans or for predator animals at higher trophic level
<p>Type II Monitoring Chemical Substances (952 substances including chloroform)</p> <p>Chemical substances that are not highly accumulative but are not readily biodegradable and suspected to have long-term toxicity</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 100 tons. - When necessary, the government directs manufacturers and importers to investigate the long-term toxicity for humans
<p>Type III Monitoring Chemical Substances (157 substances including cadmium nitrate)</p> <p>Chemical substances that are persistent and have toxicity for general flora and fauna (ecotoxicity)</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 100 tons. - When necessary, the government directs manufacturers and importers to investigate the long-term toxicity for flora and fauna in the human living environment



2. Chemical Substance Control Law: Amendment

Amendment of the Chemical Substance Control Law: Overview



The current regulations and measures are reviewed and new measures necessary to rationalize regulations are implemented to reflect international trends. The amendment is also aimed at preventing the adverse influence of harmful chemical substances on humans, flora and fauna through implementation of comprehensive chemical substance management.

Background and Needs of Amendment

1. Increased concerns for chemical substances
(to ensure safety of the public both physically and mentally)
2. Needs to achieve international goals in chemical substance management
 - To minimize the significant adverse effect of chemical substances on human health and environment by 2020 (Agreement in the Environmental Summit in 2002).
 - New regulations (REACH) are already implemented in 2007 in Europe.
 - The Chemical Substance Control Law (enactment in 1973) requires all “new chemical substances” (those manufactured or imported for the first time at the time of enactment or later) to go through prior evaluation.
 - Existing chemical substances at the time of enactment have been subject to hazard assessment by the government, but assessment has not been completed for many of these chemical substances.
3. Unconformity with international conventions
 - In an international convention (the Stockholm Convention), an agreement was made on exceptional use of certain substances that are subject to banning.
 - With the current law, provisions on exceptional use are restrictive, imposing concern that certain uses that are essential to the industries of Japan cannot be ensured.

Amendment: Overview

(1) Measures for the existing chemical substances

- Manufacturers and/or importers of all chemical substances, including existing chemical substances, will have an obligation to report the amount, etc. when manufacturing or importing more than a certain amount of the substance.
- Upon reception of the above report, the government will narrow down and prioritize the chemical substances for detailed safety assessment. The manufacturers and/or importers will be requested to submit information on the level/ type of hazard. Influences of such chemicals on human health, etc. will be evaluated and classified.
- Based on the results, manufacturing and use of the hazardous chemical substances and products containing these substances will be restricted.

(2) Ensuring conformity with international rules

- Use under strict management will be ensured when a chemical substance is newly added to the list of restriction substances in international conventions.
 - Use for semiconductors, etc.

(Reference) Related occurrences

1973 Chemical Substance Control Law enacted
2002 Agreement achieved at the Environmental Summit → 2020 Each state will complete safety assessment 8
2004 Stockholm Convention came into effect
2007 REACH came into effect (Europe) → 2018 Deadline of final registration for REACH

Shift To Risk-based Management

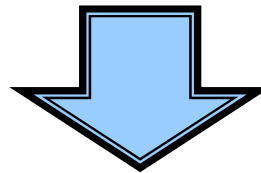


- In recent years, chemical substance management policies in the world have shown a shift from “**hazard-based management**” that only takes the intrinsic hazardous properties of chemical substances into account to “**risk-based management**” that also take emissions (exposure) to the environment into consideration.

$$\boxed{\text{Risk}} = \boxed{\text{Hazard}} \times \boxed{\text{Environmental release (exposure)}}$$

Hazard: Potential of chemical substances to impose undesired influence on humans and flora and fauna in the environment

Exposures: Amount (concentration) of chemical substances that are exposed to humans and flora and fauna



The regulation regime will be shifted from the current system that is solely based on the hazard of chemical substances to a “risk-based” system where “environmental release (exposure)” (i.e., likelihood of the chemical substance to impose influence on humans and/or flora and fauna) is additionally taken into account.



(Reference) WSSD: Goal for 2020



- The World Summit on Sustainable Development (WSSD) in 2002 agreed to achieve, by 2020, a situation where chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment.
- The most important key to meet the WSSD goal is a shift from “hazard-based management” that is solely based on the intrinsic hazard of chemical substances to “risk-based management” that also takes the release (exposure) of chemical substances to humans and the environment into account.

Items relevant to chemical substances

- Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes
- aiming to achieve by 2020 that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development.



In 2002, the Johannesburg Plan of Implementation was adopted as a guideline to implement the items in the Agenda 21 agreed at the World Summit on Sustainable Development.

(Reference) International Trend (Measures taken in Europe)



- In Europe, a new regulation for chemical substances, Registration, Evaluation, Authorization and Restriction of Chemical (REACH) became effective in June 2007. REACH is unique in that (1) Manufacturers and importers of all chemical substances (both new and existing substances) are obliged to register, (2) Chemical substances incorporated into an article, such as electronic and electric devices, are subject to mandatory registration, (3) The major body of risk assessment is shifted to business, and (4) Authorization is required for use, etc. of certain substances, such as carcinogenetic substances. The EU is planning to achieve the 2020 goal through the thorough implementation of risk-based management using REACH regulation.
- Obligated parties: Manufacturers or importers (including downstream users) within the EU territory, as well as agents designated by companies outside of the EU territory.
- Obligation: (1) Chemical substances (including ingredients of a preparation) must be registered at the European Chemical Agency (ECHA) with the results of safety assessment and other information. The registrars join the Substance Information Exchange Forum (SIEF) to share the assessment costs.
(2) Manufacturers and importers of articles have to notify the ECHA if their article contains a “substance of very high concern” by 0.1% (w/w) and provide information on the substance to the businesses. Chemical substances with an intended release (e.g., ink in ballpoint pens) in an article have to be registered.
(3) Use and market launch of carcinogenic, mutagenic, and reprotoxic (CMR) substances, etc. are prohibited except for the specific cases where authorization is given.
- Timeline: June 1st, 2007: Enactment (ECHA starts operation)
June 1st to December 1st, 2008: Preregistration (Extended registration deadlines below are applied after preregistration)
November 30th, 2011: Registration deadline for chemical substances manufactured and/or imported in volumes $\geq 1,000$ tons/year.
June 1st, 2011: Notification of SVHC in articles begins
May 31st, 2013: Registration deadline for all substances manufactured or imported in volumes ≥ 100
May 31st, 2018: Registration deadline for all substances manufactured or imported in volumes ≥ 10

(Reference) Detailed Timeline for REACH



Timeline for substances (registration, etc.)	Timeline for articles (notification, etc.)
<ul style="list-style-type: none"> ○ June 1st, 2008: REACH regulations start operation 	
<ul style="list-style-type: none"> ○ June 1st, 2008 to December 1st, 2008: Preregistration (registration can be extended by preregistration) 	<ul style="list-style-type: none"> ○ October 28th, 2008: Obligation to report information starts for 15 SVHC substances according to the Article 33
<ul style="list-style-type: none"> ○ By December 1st, 2008: EU member states establish penalties for infringements of REACH and report to EC 	
<ul style="list-style-type: none"> ○ Starting February 2009: Substance Information Exchange Forum (SIEF) is in operation (to discuss how to share substance safety data, etc. necessary for registration) ○ Candidate list discussed and determined ○ November 30th, 2010: Registration deadline for substances manufactured or imported in volume $\geq 1,000$ tons/year, CMR (carcinogenic, mutagenic, and reprotoxic) substances in volume ≥ 1 tons/year, and substances classified as “very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment” in volume ≥ 100 tons/year. ○ May 31st, 2013: Registration deadline for substances manufactured or imported in volume ≥ 100 tons/year but $< 1,000$ tons/year ○ May 31st, 2018: Registration deadline for substances manufactured or imported in volume ≥ 1 tons/year but < 100 tons/year 	<ul style="list-style-type: none"> ○ March 2009: Discussion and addition of SVHC substances to the list starts (public consultation starts) ○ May 31st, 2011: Notification deadline for SVHC substances (those listed 6 months earlier or before) ○ Starting June 1st, 2011: SVHC substances must be notified within 6 months after publishing on the list



◆ Preregistration Status (as of December 7th, 2008):

- Number of companies signed up through REACH-IT: **≈ 65,000 (82% consists of small and medium-sized enterprises)**
- Number of registrations: **≈ 2,600,000**
 - Germany: ≈ 820,000; UK: ≈ 440,000; France: ≈ 340,000;**
 - Poland: ≈ 190,000; Netherland: ≈ 130,000; Italy: ≈ 120,000**
- Number of substances registered: **≈ 150,000**
 - Substances without EINECS number: ≈ 26,500 (substances with CA number: ≈ 17,000)**
 - Multicomponent substance: ≈ 14,500**
 - While most SIEFs are expected to consist of 1 to 9 companies, 2 SIEFs have already been signed up by more than 5,000 companies.**
- Challenges:
 - Many cases of registration were made directly from outside the EU territory, which have been deleted.
 - Some articles and “cow”s were preregistered.
 - 3 organizations which are believed to be “Only Representative” entities made about 1,500 cases of preregistration without declaring its representation of companies located outside the EU territory.

(Reference) International Trend (Response by the U.S.)



- The U.S. has been evaluating the risk of all chemical substances launched on the market through the Toxic Substances Control Act (TSCA) and the US Challenge Program, a program to collect safety information of high production volume (HPV) chemical substances with the cooperation of the private sector. More recently, a collaborative framework was established with Canada and Mexico. With these measures, the U.S. is planning to achieve the 2020 goal.

Measures taken by the U.S.

- ◇ In 1998, the US Challenge Program (a program to collect and make publicly available data on safety of HPV with cooperation of companies) was started.
- ◇ In 2005, the chemical industry in the U.S. voluntarily started extending its work on HPV.
- ◇ In 2007, the leaders of the U.S., Canada and Mexico agreed to develop a regional cooperation in chemical substance regulation. The U.S. Environmental Protection Agency (EPA) started publishing the evaluation results of safety information collected through the US Challenge program.
- ◇ By 2012, EPA will complete the risk evaluation of HPVs and finish the validation procedures of safety information on chemical substances in volume of at least 10 tons/year.

(Source: U.S. Environmental Protection Agency)

Key Points of Amendment of the Chemical Substance Control Law



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

- (a) Companies that manufacture or import any chemical substance, including existing substances, in excess of the specified amounts will be newly obliged to notify the quantity and use information for each fiscal year.**
- (b) Chemical substances which the government identifies, from the content of their notifications and available knowledge of their hazardous properties, as having higher priority in risk assessment will be designated as Priority Assessment Chemical Substances” (PACs)“.**
- (c) Manufacturers and importers of those PACs may be required to submit information on hazardous properties and companies handling them may be required to report their uses as necessary.**
- (d) Among the PACs that are deemed, as a result of the information gathering and the risk assessment, to raise concerns about adverse effects on humans or flora and fauna will be subject to regulations on manufacture and use as “Class Specified Chemical Substances,” as in the existing Law.**
- (e) In addition to “chemical substances that are persistent in the environment,” which have been subject to control under the current Law, “chemical substances that are not persistent in the environment” will be regulated in the amended Law.**

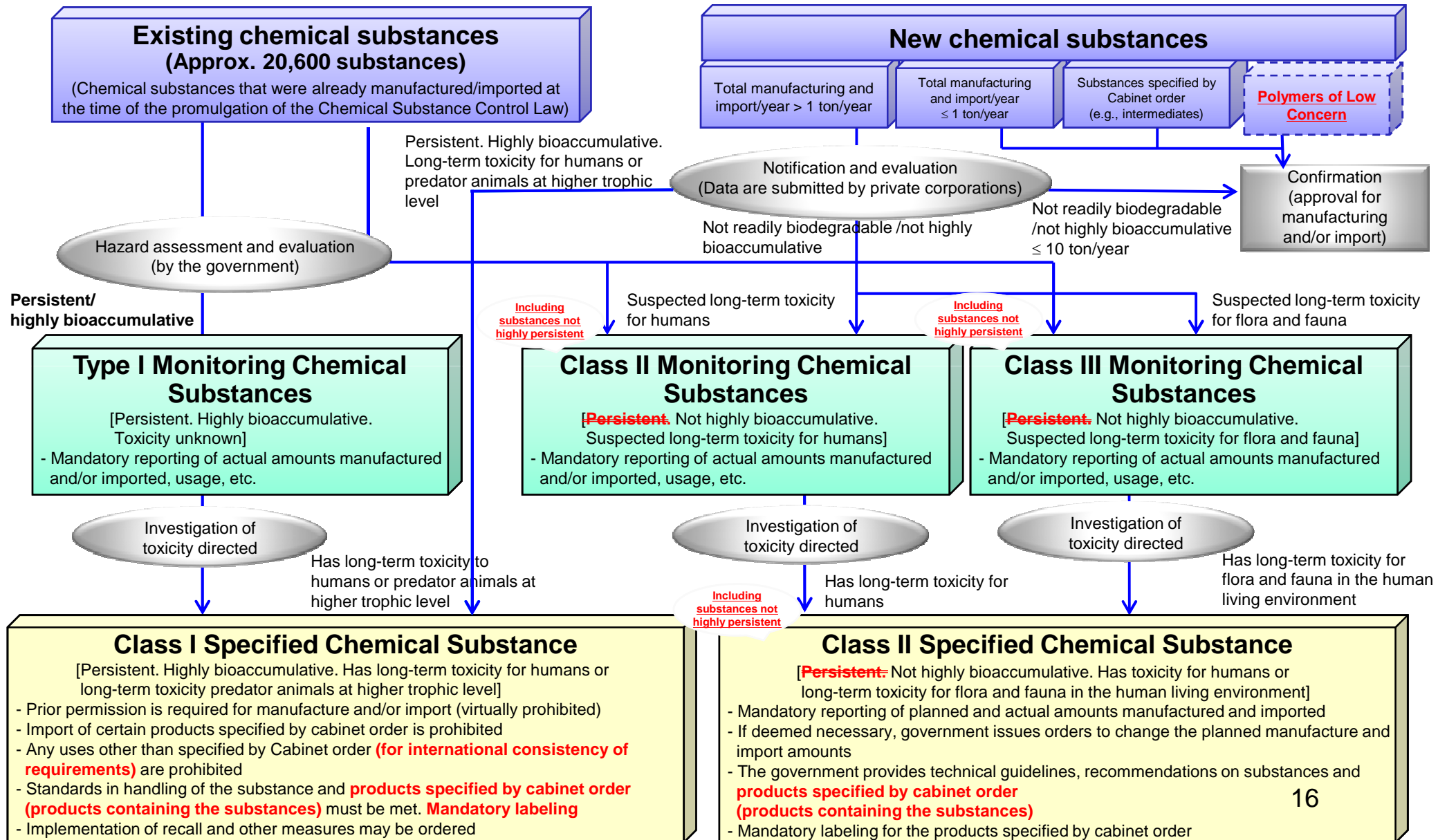
(2) Appropriate control of chemical substances in the supply chain

To prevent environmental pollution by the Specified Chemical Substances and products containing them, the amended Law will require companies handling them to adhere to specific handling standards and oblige these companies to label the products with necessary information for transactions.

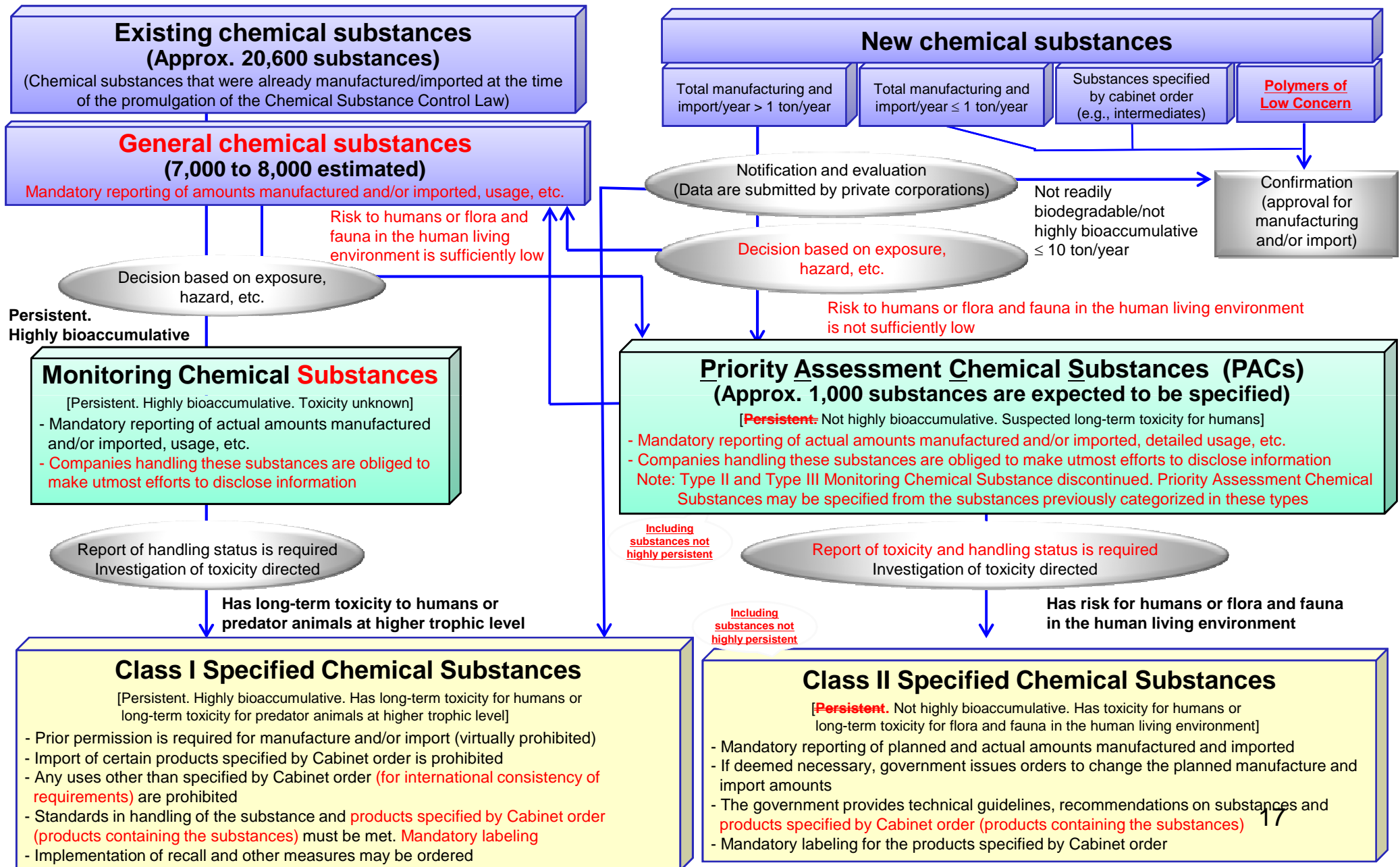
(3) Rationalization of evaluation and regulation systems in light of international trends

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

The Chemical Substance Control Law after the Amendment: the Whole Picture (First Phase)



The Chemical Substance Control Law after the Amendment: the Whole Picture (Second Phase)



Restrictions according to the Properties, etc. of Chemical Substances (after Amendment)



Regulatory Classification	Restrictions
<p>Class I Specified Chemical Substances (16 substances including PCB) Chemical substances that are persistent, are highly bioaccumulative and have long-term toxicity for humans or long-term toxicity for flora and fauna.</p> <p>→ Remain effective</p>	<ul style="list-style-type: none"> - Prior permission is required for manufacture and/or import (virtually prohibited) - Any use other than specified by Cabinet order uses are prohibited - Import of certain products specified by Cabinet order is prohibited - Implementation of recall and other measures may be ordered (in case when the substance and/or product is specified and when the statutes are not complied with)
<p>Class II Specified Chemical Substances (23 substances including trichloroethylene) Chemical substances that are persistent and have toxicity for humans or long-term toxicity for flora and fauna in the human living environment</p> <p>→ Remain effective (including not highly persistent substances)</p>	<ul style="list-style-type: none"> - Mandatory reporting of planned and actual amounts manufactured and/or imported, usage, etc. - If deemed necessary, government issues orders to change the planned manufacture and import amounts - The government provides technical guidelines, recommendations for handling - Mandatory and recommended labeling
<p>Type I Monitoring Chemical Substances (36 substances including cyclododecan) Existing chemical substances that are confirmed to be persistent and highly bioaccumulative</p> <p>→ Monitoring Chemical Substances</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 1 ton. - Guidelines, advice, etc. (when necessary to prevent environmental pollution) - When necessary, the government directs manufacturers and importers to investigate long-term toxicity for humans or for predator animals at higher trophic level
<p>Type II Monitoring Chemical Substances (952 substances including chloroform) Chemical substances that are not highly accumulative but are not readily biodegradable and suspected to have long-term toxicity</p> <p>→ Discontinued (Some substances are specified as Priority Assessment Chemical Substances)</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 100 tons. - When necessary, government directs manufacturers and importers to investigate long-term toxicity for humans
<p>Type III Monitoring Chemical Substances (157 substances including cadmium nitrate) Chemical substances that are persistent and have toxicity for general flora and fauna (ecotoxicity)</p>	<ul style="list-style-type: none"> - Mandatory reporting of actual amounts manufactured and/or imported, usage, etc. - Name of the substance and reported amounts of manufacturing and/or import is publicized by the government for the substances whose total volume is at least 100 tons. - When necessary, the government directs manufacturers and importers to investigate long-term toxicity for flora and fauna in the human living environment

Priority Assessment Chemical Substances
(Sufficiently low risk of the substance cannot be confirmed)

General Chemical Substances
(Sufficiently low risk of the substance can be confirmed)



3. Specific Items of the Amendment

(1) First Phase of Amendment



(a) Readily biodegradable substances will be included

○ While only persistent chemical substances are classified into Class II Specified Chemical Substances, Type II Monitoring Chemical Substances, and Type III Monitoring Chemical Substances under the current Law, chemical substances that are readily biodegradable will become subject to control under the amended Law.

- More stringent control of the volume of manufacture and import of these substances is needed for chemical substances even when they are readily biodegradable. This is based in a concern that these substances impose adverse effects on humans or flora and fauna if released into the environment at the amount exceeding the degradable amount in the environment.
- The 2020 Goal of the WSSD requires establishment of a system for phase-by-phase implementation of safety assessment for all chemical substances distributed in Japan.
- European countries, the U.S. and other countries in the international community do not limit their regulation of chemical substances to persistent substances. Safety is ensured through measures including restrictions on manufacture and import that are determined based on the data on toxicity and the status of environmental release of chemical substances.

(b) Confirmation System for Polymers of Low Concern



- Polymers of Low Concern (PLCs) will be exempted from mandatory notification of manufacture and import for new chemical substances and will become subject to confirmation based on existing knowledge.

- Polymers (macromolecular compounds made of a number of low molecular compounds bonded) that meet a certain criteria do not penetrate the plasma membrane due to their high molecular weights, imposing low effects on human health and/or growth of plants and animals as validated by the international community.

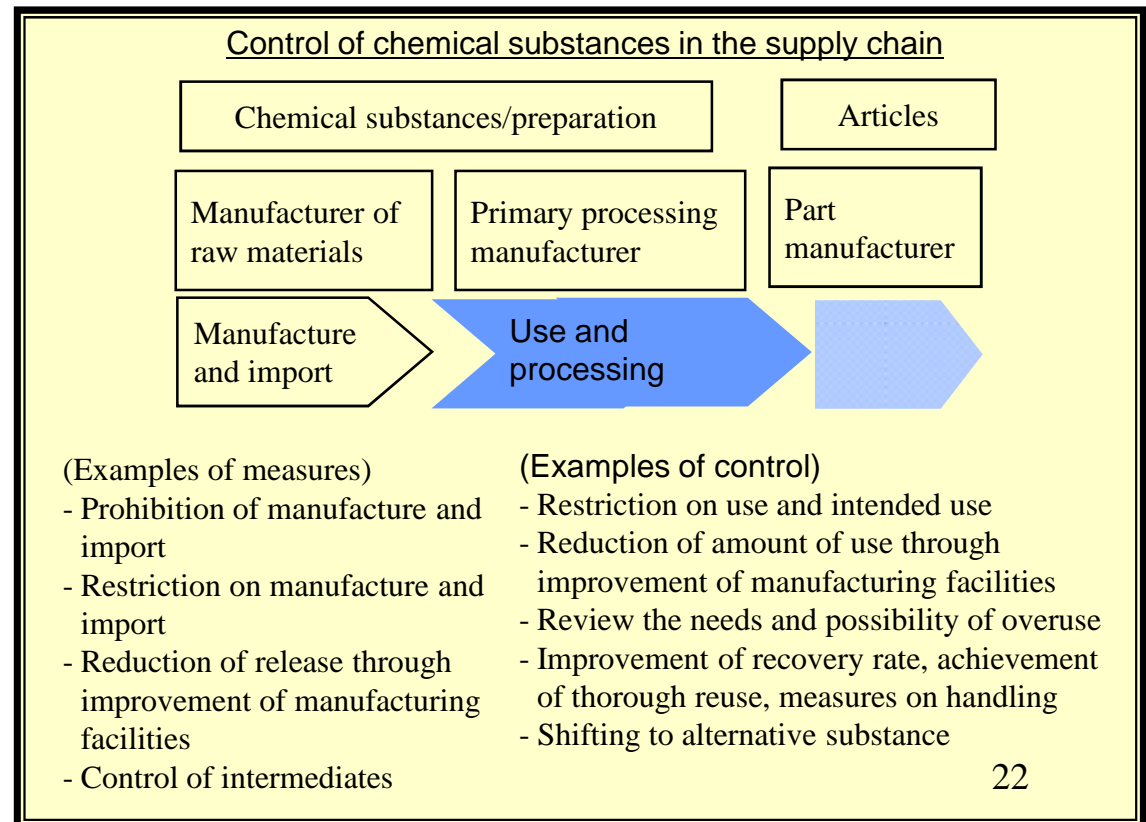
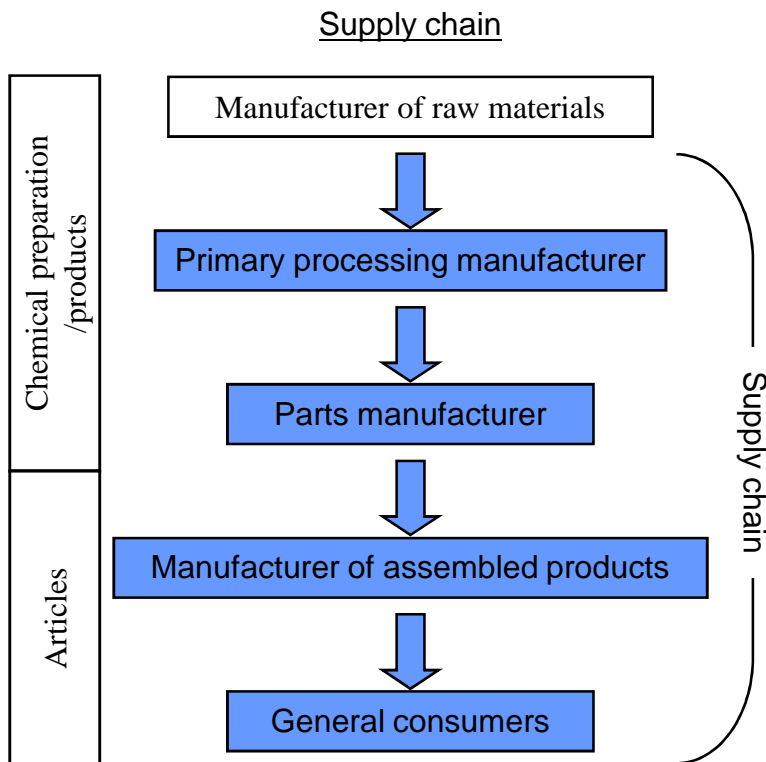
- In the light of these circumstances, mandatory notification under the Chemical Substance Control Law may be exempted for the manufacture or import of a new chemical substance if the substance is a Polymer and is confirmed by the three relevant ministers to meet the criteria for “Polymers of Low Concern” (PLCs) that are not concerned to impose adverse effects on human health, inhabitation of plants and animals in the human living environment, etc prior to those manufacture or import.

- When specified as a PLC, the manufacturer or importer may be subject to obligatory report and on-site inspection.

(c) Information Delivery in the Supply Chain



- When Type I Monitoring Chemical Substances are transferred between business entities, the entity transferring the substance is obliged to make utmost efforts to inform the recipient that the substance is specified as the Type I Monitoring Chemical Substance among other information.
- For Class II Specified Chemical Substances and Type I Monitoring Chemical Substances, the three relevant ministries and ministers may instruct the business entity handling the substance to report the status of transaction.



(d) Measures concerning the Class I Specified Chemical Substances



- Use of Class I Specified Chemical Substances are permitted as a case of “essential use” when substitution to an alternative substance is very difficult and the substance does not impose adverse effects on human health or on the environment (mitigation of requirements).
- Labeling and other identification and compliance with the standards are imposed as obligations concerning Class I Specified Chemical Substances and products containing such substances (enhancement of management).

< Summary of the Cabinet order >

- The 12 substances, including Perfluorooctane sulfonic acid and its salt forms (Perfluorooctane sulfonate: PFOS), that were specified by the Stockholm Convention in May 2009 will be designated as the Class I Specified Chemical Substances
- For PFOS, the use for manufacture of etching agent and resist for semiconductors and use for manufacture of industrial photo films will be designated as the authorized uses (designated as “essential uses”).
- For the purpose of environmental pollution prevention, etching agent and resist for semiconductors, industrial photo films and fire-extinguishing foam, etc. containing PFOS will be designated as products for which handling business entity is obliged to meet the handling standards and to apply proper labeling.
- Products containing the 12 substances described above will be designated as import prohibited items (additives for surface treatment agents for plating, aviation hydraulic fluids, etc.).

(Reference) Stockholm Convention



- The Stockholm Convention, in order to protect human health and environment from Persistent Organic Pollutants (POPs), prohibits or restricts the manufacturing, use and international trade of chemical substances that are (1) toxic, (2) persistent, (3) bioaccumulative, and (4) having potential for long-range environmental transport.
 - In the COP4 in May 2009, twelve new substances, including PFOS, are newly designated as the substances subject to the convention.
-
- Currently, 9 substances are designated as substances for which specific measures are required.
(Annex A: Elimination; Annex B: Restriction; Annex C: Unintentional production)
(aldrin, chlordane, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, polychlorinated biphenyls, DDT, polychlorinated dibenzo-p-dioxins, and polychlorinated dibenzofurans)
 - In the Chemical Substance Control Law of Japan, these substances, except for unintentional production, are designated as the Class I Specified Chemical Substances in the Law.

(e) Measures concerning the Class II Specified Chemical Substances



- In the current Law, the government provides technical guidelines and recommendations to prevent environmental pollution for Class II Specified Chemical Substances. After the amendment, such technical guidelines and recommendations will be given for the products containing a Class II Specified Chemical Substance designated by cabinet order.
- In the current Law, labeling for the products specified by cabinet order containing Class II Specified Chemical Substances are obliged to the business entities that handle Class II Specified Chemical Substances. After the amendment, such labeling will be also mandatory for business entities that handle products containing Class II Specified Chemical Substances.

(f) Other Measures (Notification for other laws and ordinances relevant)



<Notification to relevant ministries and agencies>

- Control and management of chemical substances are subject to, in addition to the Chemical Substance Control Law, the Poisonous and Deleterious Substances Control Act, the Industrial Safety and Health Act, the Pharmaceutical Affairs Act, the Air Pollution Control Law, and the Water Pollution Control Act among others.
- In the current Chemical Substance Control Law, information on toxicity for new chemical substances can be collected before the substance is launched on the market. When new findings are obtained regarding the properties, etc. of the chemical substance based on the Chemical Substance Control Law, such findings are notified to the relevant ministries and/or agencies.

<Collection of information and on-site inspection>

- The range of collection of information and on-site inspection is extended to business entities that handle the products containing the Class I Specified Chemical Substances designated by Cabinet order.

<Guideline and advice>

- The range of guideline and advice by the government is extended to include the business entities that handle products containing the Class II Specified Chemical Substances designated by Cabinet order.

(2) Second Phase of Amendment



(a) Notification of the amount of manufacturing or import for general chemical substances

- Companies that manufacture or import 1 ton or more of chemical substances must notify the amount of manufacturing or import, use and other information for each fiscal year.
 - Notified chemical substances are assessed for their risk, and designated as a PACs (Priority Assessment Chemical Substances), if necessary.
-
- Substances exempted from mandatory notification will be limited to (1) chemical substances used for research purposes, (2) chemical substances less than 1 ton in volume, and (3) chemical substances that are known to impose low risk (e.g., water and carbon dioxide).
 - When toxicity information that has not been publicly known is obtained for substances that are subject to notification, such information must be reported to the three ministries (the Ministry of Economy, Trade and Industry; Ministry of Health, Labour and Welfare; and Ministry of the Environment).
 - Notification for the Specified Chemical Substances, the PACs, and the Monitoring Chemical Substances will be carried out according to each regulation and therefore not necessary for this regulation.

(b) Priority Assessment Chemical Substances (New Category)



- Chemical substances that are deemed as high risk are designated from those subject to notification as PACs(Priority Assessment Chemical Substances)
- Companies that manufacture or import any of the PACs at volume of 1 ton or higher are obliged to notify the amount of manufacture or import, usage and other information for each year
- Detailed risk assessment will be carried out in a stepwise manner, and, when found necessary; the substance will be designated as a Class II Specified Chemical Substance if necessary.
- When publicly unknown information is obtained, it must be notified to the three relevant ministries (“obligation to use best efforts”).
- Manufacturers, importers and users of the PACs have the following obligations, etc. as listed below.
 - (1) Manufacturers and importers:
 - Manufacturers and importers are obliged to report the amount of manufacture and/or import, as well as the usage of the substances
 - Manufacturers and importers are obliged to make best efforts to disclose information obtained through the supply chain
 - The government may request the manufacturers and importers to carry out simple toxicity tests
 - The government may instruct the manufacturers and importers to submit toxicity data
 - (2) Users:
 - Companies that use these substances are obliged to make their best efforts to notify relevant information
 - The government may request the companies to report the handling status

(c) Handling of the Monitoring Chemical Substances



- Classifications of Type II Monitoring Chemical Substances and Type III Monitoring Chemical Substances are to be discontinued after the PACs (Priority Assessment Chemical Substances) are established
 - Classification of Type I Monitoring Chemical Substances will be renamed “Monitoring Chemical Substances” and remain effective
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- Under the system of Type II Monitoring Chemical Substances, chemical substances that pose a risk of harming human health are designated and the manufacturers and importers of such substances are requested to report the amount of manufacture or import
 - Under the system of Type III Monitoring Chemical Substances, chemical substances that have a risk of imposing adverse effects on the habitats of or the growth of plants and animals are designated and the manufacturers and importers of such substances are requested to report the amount of manufacture or import
 - Classifications of Type II and Type III Monitoring Chemical Substances are to be discontinued after the new classification of the PACs is made effective under the amended Law in order to assess the toxicity of the substances to human health and flora and fauna
 - The classification of Type I Monitoring Chemical Substances, the “predecessor” of Class I Specified Chemical Substances



4. Order for Enforcement of the Amended Chemical Substance Control Law

Order for Enforcement of the Amended Chemical Substance Control Law: Overview

1. Items related to Specified Chemical Substances

(1) Addition of new substances to Class I Specified Chemical Substances

- 12 substances subject to the Stockholm Convention are designated as substances to be added to the class

(2) Addition of products containing a Class I Specified Chemical Substance for import prohibited items

- Products that contain a Class I Specified Chemical Substance and cause environmental pollution are prohibited for import (12 products containing 3 substances, including PFOS, are designated)

(3) Designation of certain Class I Specified Chemical Substances for an exceptional usage (essential use)

- When a certain substance classified in the Class I Specified Chemical Substance is essential for the manufacturing of a product, the use of such substance may be permitted as an exception if technical standards and labeling obligations are met (3 Usages are designated for PFOS. (Use of foam distinguisher agents is not designated as a usage essential for manufacturing but technical standards and mandatory labeling are imposed on their use.)

(4) Designation of products containing Class II Specified Chemical Substances

- Compliance with the technical guidelines are newly imposed on the products containing a Class II Specified Chemical Substance
- Handling companies of products containing a Class II Specified Chemical Substance are obliged to conduct mandatory labeling (8 products containing 3 substances are designated)

2. Notification of general chemical substances, etc.

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

Reference: Dates of enforcement (Date of promulgation: October 30th, 2009)

- April 1st, 2010: → Class I Specified Chemical Substances are to be added. Essential uses are to be added. Products containing Class II Specified Chemical Substances are to be designated
- May 1st, 2010: → Import of prohibited products are to be added
- October 1st, 2010: → Obligation to meet the standards and mandatory labeling for products containing a Class I Specified Chemical Substance
- April 1st, 2011: → Notification of general chemical substances and Priority Assessment Chemical Substances

(Reference (1)) Order for Enforcement of the Amended Chemical Substance Control Law

1. Class I Specified Chemical Substances

- (1) Perfluorooctane sulfonate (PFOS) or its salts
- (2) Erfluorooctane sulfonyl fluoride (PFOSF)
- (3) Pentachlorobenzene
- (4) r-1, c-2, t-3, c-4, t-5, t-6- hexachlorocyclohexane (i.e., α -hexachlorocyclohexane)
- (5) r-1, t-2, c-3, t-4, c-5, t-6- hexachlorocyclohexane (i.e., β -hexachlorocyclohexane)
- (6) r-1, c-2, t-3, c-4, c-5, t-6- hexachlorocyclohexane (i.e., γ -hexachlorocyclohexane)
- (7) Decachloropentacyclo [5. 3. 0. 0^{2,6}. 0^{3,9}, 0^{4,8}] decane-5-one (i.e., chlordecone)
- (8) Hexabromobiphenyl
- (9) Tetrabromo (phenoxybenzene) (i.e., tetrabromodiphenyl ether)
- (10) Pentabromo (phenoxybenzene) (i.e., pentabromodiphenyl ether)
- (11) Hexabromo (phenoxybenzene) (i.e., hexabromodiphenyl ether)
- (12) Heptabromo (phenoxybenzene) (i.e., heptabromodiphenyl ether)

2. Import prohibited products

<PFOS or its salts>

- (1) Aviation hydraulic fluids
- (2) Treating agents for yarn
- (3) Etching agents for metal processing
- (4) Etching agents for semiconductors (excluding high-frequency compound semiconductors to allow radio equipment to transmit waves of 3 megahertz or higher)
- (5) Surface treating agents for metal plating or additives to prepare the agents
- (6) Anti-reflective coatings for semiconductors
- (7) Abrasive compounds
- (8) Fire extinguishers, agents for fire extinguishers, and fire-extinguishing foam
- (9) Insecticides for termites and termite repellents
- (10) Printing paper

<Tetrabromodiphenyl ether, pentabromodiphenyl ether>

- (1) Paints
- (2) Adhesives

(Reference (2)) Order for Enforcement of the Amended Chemical Substance Control Law

3. Essential uses of Class I Specified Chemical Substances

<PFOS or its salts>

- (1) Manufacture of etching agents for semiconductors (limited to voltage filters and high-frequency compound semiconductors to allow radio equipment to transmit waves of 3 megahertz or higher)
- (2) Manufacture of semiconductor resists
- (3) Manufacture of photo films for industrial purposes

4. Products containing a Class I Specified Chemical Substance that is subject to obligation to meet technical standards and mandatory labeling

<PFOS or its salts>

- (1) Etching agents for semiconductors (limited to voltage filters and high-frequency compound semiconductors to allow radio equipment to transmit waves of 3 megahertz or higher.)
- (2) Semiconductor resists
- (3) Photo films for industrial purposes
- (4) Fire extinguishers, agents for fire extinguishers, and fire-extinguishing foam

5. Products containing a Class II Specified Chemical Substance that is subject to obligation to meet technical standards and mandatory labeling

<Trichloroethylene>

- (1) Adhesives (excluding adhesives of animal or plant origins)
- (2) Paints (excluding water-based paints)
- (3) Metal processing oil
- (4) Detergents

<Tetrachloroethylene>

- (1) Vulcanizing agents
- (2) Adhesives (excluding adhesives of animal or plant origins)
- (3) Paints (excluding water-based paints)
- (4) Detergents
- (5) Finishing/processing agents for fiber products

<Tributyltine compounds>

- (1) Antiseptic agents and anti-mold agents
- (2) Paints (limited to paints used to prevent live growth of crustaceans, algae and other aquatic life on the hulls)

Useful URLs for the Information on the Chemical Substance Control Law

<Ministry of Economy, Trade and Industry>

http://www.meti.go.jp/policy/chemical_management/index.html

<Ministry of the Environment>

<http://www.env.go.jp/chemi/kagaku/index.html>

<Ministry of Health, Labour and Welfare>

<http://www.nihs.go.jp/mhlw/chemical/kashin/kashin.html>

<Public Comment (Ministry of Economy, Trade and Industry)>

<http://www.meti.go.jp/feedback/index.html>



Thank you.