CSCL Practical Guide

Takashi Fukushima

Preface

Are you interested in the Japanese chemical market?
Through my experience as a lecturer in international conferences such as ChemCon Conference, ICCP and Chemical Watch's Regulatory Summit and many others, I have recognized that the Chemical Substance Control Law (CSCL) of Japan is considered as a kind of "black box" by global chemical producers and suppliers.
On the other hand, at least from my experience as a regulator, the regulation is very clear despite of its complexity. And such complexity is common in chemical regulations around the world. In fact, Japanese chemical companies including SMEs are dealing with CSCL successfully.
Why not oversea companies?
Why this internal vs external gap exists?
The answer is very simple. It is because of information gap due to the language barrier.
Sometime this barrier works as a trade barrier and the barrier does not protect Japanese economy as whole. As a METI official, I understood that the promotion of international trade is one of the important roles of METI, and I made substantial effort to provide English information about CSCL through my career as an official of METI and NITE.
In the real life in METI, information dissemination to the world is not the priority because of the stacked daily to-dos. My colleagues, successors are always facing difficulty to find their time to prepare English documents more than I faced.
It is true that METI and the Japanese government can use its budget to translate Japanese documents including the law itself into English but such documents are always juiceless and difficult to understand what they really means. That is why I spent my time to prepare PPT files to be presented in the attending conferences.
Unfortunately, information provided through conference presentations is somehow fragmental and the PPT files are sometime difficult to understand because of the lack of the context. It should be also noted that the audiences of such conferences are limited.
So, I decided to write this e-book to the greater audiences who are seeking practical information of CSCL to find a market of their chemicals in Japan.

I tried my best to include updated information, keep high standard of accuracy and the quality of English.
I hope this book will help all the people who need to understand CSCL.

01 October 2017, Hua Hin, Thailand

Disclaimer

CSCL has three key functions to manage industrial chemicals in Japan. This e-book covers mainly 1) new chemical notification and confirmations and 2) comprehensive assessment of general chemicals but not covers 3) management measures on class 1 and class 2 specified chemicals. Because these management measures seem to be less interesting to the majority of oversea companies.

This e-book contains information of interpretation and implementation of CSCL. This information is solely intended to provide in-depth understanding of the law and not provide advice for individual cases. Due to the nature of chemical substances, chemical properties, environmental behavior, toxicities, actual usages, emission patterns etc., of each chemical are totally different. Then, application of the law could differ. Because of this fact, it should be emphasized that the three Ministries in charge of CSCL, namely Ministry of Economy, Trade and Industry (METI), Ministry of Health, Labour and Welfare (MHLW) and Ministry of Environment (MOE) have authority to make any decision according to the law.

And in this e-book I quoted English translations of the law, Cabinet order, ministerial ordinances, notices and other documents. However, many of these source documents are not officially translated by the government. In this regard, I should emphasize that the authentic text of all quoted document is Japanese.

Lastly, to achieve the objective mentioned in the preface, this book includes my experiences, understandings and observations. Such views are my personal views and should not be considered as the views of the authorities.

Who I am?

After graduation from Chemical Department, Science Faculty, Science University of Tokyo, I joined MITI as a technical official in 1985. I experienced in chemistry related policy areas including new chemical evaluation under CSCL.
In the end of 2000, I transferred to JETRO Bangkok office as the Director of Energy and Environment Technology. At that time I launched a GHS capacity building program in cooperation with the Thai government and the Federation of Thai Industries. This program was became a template of METI's GHS capacity building program in the ASEAN region
In June 2004, I returned back to METI and assigned to the deputy director of the Chemical Management Policy Division. Since then, I involved in chemical management except 15 months assignment for the utility gas safety and 8.5 months assignment for the Basel Convention until my resignation from METI in the end of July 2017.
In the chemical management field, as the deputy director of the Chemical Management Policy Division from June 2004 to March 2008, I involved in SAICM negotiation, POPs and PIC Convention, OECD EHS programme including the establishment of WPMN.
As the program director in charge of international affairs and new chemical evaluations from June 2009 to August 2012, I was responsible for new chemical evaluation program, risk assessment scheme development, international cooperation and chemical conventions including the Minamata Convention negotiation (from INC 2 to INC 4). During this period, I involved ERIA's research projects on chemical regulation and one of the outcomes of the project is the concept of a database which promote information sharing in ASEAN and surrounding nations. The concept was realized as AJCSD.

In May 2013, I was assigned to the Deputy Director General of Chemical Management Center of NITE mainly to strengthen international activities of the center. During this period, bilateral cooperation with KCMA, Korea and SAHTECH, Taiwan started and also full operation of AJCSD started.
In May 2016, I promoted to the Director General of Chemical Management Center.
NITE is an independent institute to provide technical support for METI, and in the chemical management field, NITE support CSCL implementation such as new chemical evaluations, risk assessments, inspections, GLP and nomenclatures, and the PRTR law implementation such as totaling of environmental release and technical support for industries to comply with the law. Information service for industries is another important function of the Chemical Management Center, NITE. NITE operates well-known NITE-CHRIP and J-CHECK database to disseminate regulatory information and hazard information. NITE Chemical Management Center also supports METI to implement the Chemical Weapon Convention.
As the Director General of the Chemical Management Center, I was in charge of supervision of above activities and also involved in the latest CSCL amendment in 2017.
While working as DG and DDG in NITE, I also served as a member of program advisory committee of ChemCon and made number of presentations in the ChemCon and other conferences. I also made presentations not only to conference participants but also to the officials of authorities including USEPA, ECHA and MEP-SCC.
I moved back to METI and resigned from the government in the end of July 2017. Throughout the 32 years of government work, I directly involved in chemical management more than 14 years.

NOTE,
MITI: Ministry of International Trade and Industry. It changed to METI in the 2001 government reform.
JETRO: Japan External Trade Organization
METI: Ministry of Economy, Trade and Industry
NITE: National Institute of Technology and Evaluation
WPMN: Working Party on Manufactured Nanomaterial
ERIA: Economic Research Institute for ASEAN and East Asia

KCMA: Korea Chemicals Management Association
SAHTECH: The Safety and Health Technology Center, Taiwan
AJCSD: ASEAN Japan Chemical Safety Database
MEP-SCC: Solid Waste and Chemicals Management Center, Ministry of Environmental Protection, China

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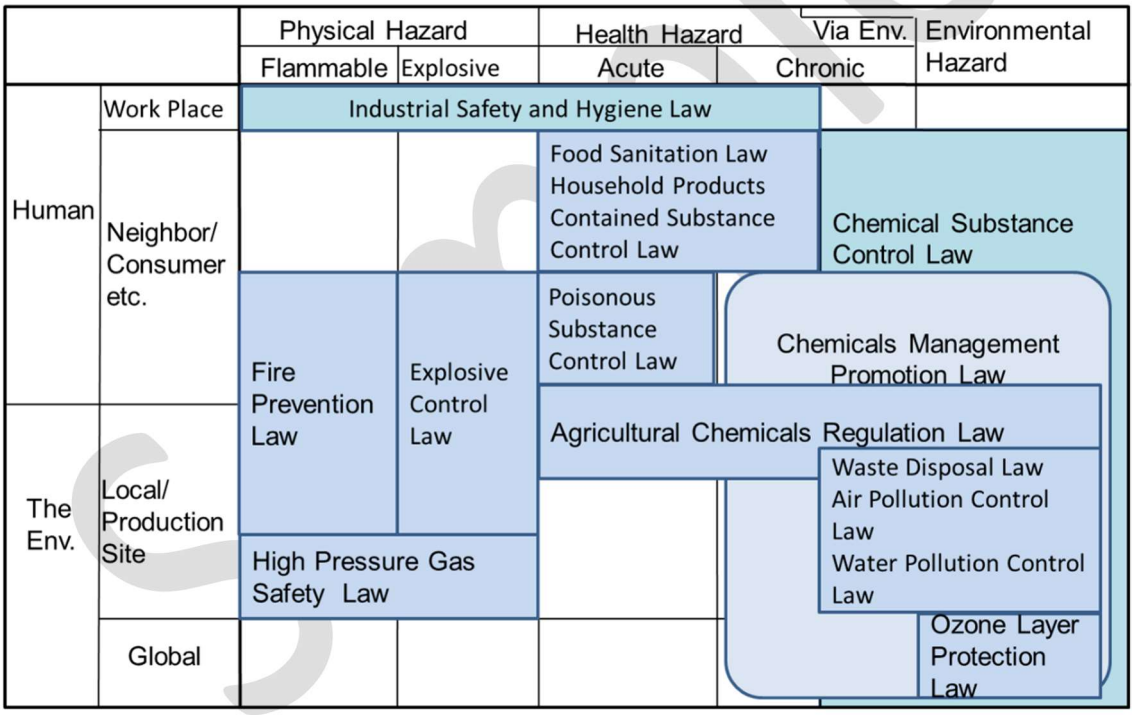
1. Regulations around chemicals in Japan

Chemicals are widely used in our daily life. And chemicals are regulated for various reasons. In Japan, like many other countries, chemicals are regulated based on its use, hazard properties and the objectives of the regulations. To understand the Chemical Substance Control Law (CSCL), a brief sketch of chemical regulation system in Japan may be useful.
Table 1 is to explain chemical regulations as whole. Top of the table indicates what chemical property is focused by each law and the left side is the target that each law is to protect. This table seems very complex, but by understanding each law, it will become clearer.

Table1: Outline of chemical regulations in Japan



Please note that the officially translated names of the legislations are sometimes very long. In this book, shorter names like “Chemical Substance Control Law” or abbreviations like “CSCL” are used instead. And official translations use the term “Act” but in this book I unified to “law” to avoid unnecessary confusion.

The followings are the examples of regulations on chemicals to be taken into humans’ body directly or indirectly, intentionally or unintentionally.

- Pharmaceutical Affairs Law,
- Food Sanitation Law

- Household Products Containing Harmful Substances Control Law

These laws regulate chemicals that the people take in intentionally or unintentionally. And these laws focus on acute and chronic toxicity to human.
The Pharmaceutical Affairs Law regulates pharmaceuticals, medical equipment and others. The Food Sanitation Law regulates food additives and packages. The Household Products Containing Harmful Substances Control Law covers all household products. It seems that those laws have clear border but sometimes the border is not so straight.
The Pharmaceutical Affairs Law regulates insecticides for sanitary insects. Other biocides including other insecticides are not regulated by the law.
The Food Sanitation Law regulates certain toys for infants and toddlers if such toys have chance to be chewed while infants and toddlers are playing with. Certain phthalates for such use are regulated by the law.
The regulation of the Household Products Containing Harmful Substances Control Law designates chemicals and household products to be regulated in a rather short list. Azo-dyes are regulated for garments by the law.

The Poisonous Substances Control Law is the law to prevent poisoning of the people. The law regulates production, import, sale and handling of poisonous and deleterious substances. Because of the nature of the law, designations and classifications under the law are based on the acute toxicity of chemicals. MHLW designate chemicals to be regulated and designation is based on the necessity of control. By this law, provision of SDS is obliged for designated chemicals.

The Agricultural Chemical Control Law sets the standards and regulates production, import, sale and use of pesticides. Due to the nature of pesticide, both human health and environmental protection are taken into account. The law mainly managed by MAFF. MOE is involved to set residue standards for pesticides.

Three laws, namely the Fire Prevention Law, the Explosive Control Law and the High Pressure Gas Safety Law are related to the physical property of chemicals. Those laws set standards for facilities and equipment based on the classification results of physical hazard property of chemicals.

Classification criteria of these laws are different from those of GHS. Thus GHS classification is not adopted by these laws.

Laws to prevent environmental pollution such as the Air Pollution Control Law and the Water Pollution Control Law are enacted after severe environmental pollution in 1960s. The Air Pollution Control Law originally focused on major air pollutants like dust, NOx and SOx. In 1990s, the law was amended to prevent scattering asbestos from building destruction sites. In 2000s, VOC regulations are introduced to prevent SPM and photochemical oxidant pollutions. The Water Pollution Control Law regulates release of waste water containing certain heavy metals and organic pollutants from specified facilities. The law also regulates pH, BOD, COD, e-coli and suspended solids. These laws are solely managed by MOE and municipalities involved in the implementation especially for the inspections.

The Chemical Management Promotion Law also relates to the environmental emission of chemicals. The law is sometimes called as the PRTR Law and obliges reporting of environmental emission and disposal of designated some 460 chemicals. The law also obliges provision of SDS of some 560 designated chemicals. The format and contents of the SDSs are defined by JIS for GHS classification and labelling. In short, the law is one of the implementation laws of GHS in Japan. The law is mainly managed by METI and MOE, and NITE support totaling of environmental release and information disseminations to the public.

Another important law to regulate industrial chemical is the Industrial Safety and Hygiene Law (ISHL) managed by the labor part of MHLW. The origin of the law is the Labor Standards Law which established in 1946. And in 1971, certain part of the law was separated and established as an independent law. Chemical regulation by the law started in 1977 amendment of the law that was triggered by occupational diseases caused by chemicals such as Chromium (VI) and PVC monomer. And at that time, new chemical notification by ISHL has started. When chemical regulation by the law started, CSCL was already established. As the result, two new chemical notification schemes entered into force separately. This is mainly because CSCL and ISHL have totally different objective although ISHL refers

original existing chemical list of CSCL. Information provision to the workers is one of the important roles and SDS is obliged by the law. Similarly to the PRTR law, GHS is implemented by the law.
Table 2 shows the comparison of CSCL and ISHL in brief.

Table 2: Brief comparison of CSCL and ISHL

	ISHL chemical management	CSCL
Objective	Protect workers from chemical exposure	Protect people and eco-system from chemical exposure through the environment
Definition of chemicals	"chemical substance" shall be defined as an element or a compound;	"chemical substance" means a chemical compound created by causing chemical reactions to occur to elements or compounds
Control measures	Ban, permissions, control rules, guidance, labelling etc.	Ban of manufacture, import and use(class1), Control of production/import amount (class2), Technical guidelines etc.
Regulatory focus	Carcinogen	PBT chemicals

2. What is CSCL?

The official translation of the name of the Chemical Substances Control Law (CSCL) is “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” As stated in its official name, main function of CSCL is the evaluation of chemical substances, and based on the evaluation results, the government is given the authority to regulate manufacture, import and use of certain chemicals. To enable the government to evaluate chemicals, the government is given the authority to collect information.
At this point of time, CSCL has three main functions. The first one is the new chemical notification. The second is the comprehensive assessment of existing chemicals. And the last is regulation on specified chemicals such as PCB.
Before getting in to the detail directly, I would like to briefly touch the history of CSCL.

2-1 Establishment of the Law

The Japanese economy expanded rapidly between later 1950s to early 1970s. Japan’s GDP expanded to the second largest next to the United States. The growth was led by the heavy and chemical industries. During this period, the Japanese people suffered severe environmental pollutions during this period. The most famous environmental pollutions are called “Four big pollution diseases.”
The first of the four occurred in 1920s, and the others occurred in the 1950s and 1960s.
Itai-itai disease was occurred in Toyama Prefecture in 1920s. The cause of the disease was not officially specified until 1966. The cause of this disease was cadmium poisoning and the contamination came from inappropriate management of waste water from Kamioka mime.
Minamata disease was occurred in Kumamoto Prefecture in 1950s. The causative substance was accumulated methylmercury in fishes. And the substance was generated from a chemical factory. Minamata is the name of a city that the disease was first discovered and the city was chosen for the adoption of “The Minamata Convention on Mercury” which is intended to protect human health and the environment from anthropogenic emissions

and releases of mercury and mercury compounds.
Niigata Minamata Disease was found in Niigata prefecture in 1965.
Yokkaichi asthma in Mie prefecture was caused by the air pollution of sulfur dioxide in Yokkaichi area in 1961.
The 64th national diet is well known as “Environmental pollution diet” because 12 environmental pollution related laws including the Water Pollution Control Law and the Air Pollution Control Law were established or strengthened in this session. And the Environment Agency was established in January 1971. So, we can say that the basic framework of environmental management was established at this point of time.

In parallel with the discussion around “traditional” environmental pollution, PCB contamination case in 1968 triggered the discussion to manage industrial chemicals such as PCB. The PCB contamination happened in a food oil factory and many Japanese consumers who ate contaminated oil developed a disease known as “Kanemi yu-sho”. (Lately, unintentional production of dioxins in heated PCB was identified as the cause of the disease.)
When this disease was identified, production, import and use of PCB were prohibited by administrative guidance of MITI because the legal authority to control such activities of industry belonged to MITI. However, some diet members and government officials considered that the administrative guidance was not good enough because of insufficient legal stability and some limitation of the enforcement power. Thus, the Ministry of International Trade and Industry (MITI) took the lead of legislation in cooperation with the Ministry of Health and Welfare (MHW).
During the discussion of legislation, the focus was on the property of PCB and the exposure route was an issue. The Poisonous Substances Control Law already existed at that time but the law focused on rather acute toxic effect and PCB does not fulfil the criteria for designation by the law. The Food Sanitation Law can set the standard for PCB contamination in food but does not have legal power to stop the other route of exposure, especially exposure through the environment.
The other discussion was whether PCB was the only concern or not. A famous book written by Ms. Rachel Carson namely “Silent Spring” pointed out some other chemicals of concern. And MITI had recognition that

companies ware developing new chemicals day by day.
Through the discussion like this, the need of the legislation to regulate industrial chemicals was recognized by the diet members and the government officials to prevent the damage to public health. And the scope of such legislation should not be limited to PCBs or some limited number of chemicals.
In parallel with Japan, discussion of TSCA (TSCA 1972) was ongoing in the U.S.　It is quite natural that MITI officials studied the discussion of TSCA and took some ideas into the CSCL development. For the TSCA development, the need to establish a new chemical notification scheme was under discussion.
As previously mentioned, “Silent Spring” may have had some influence to the CSCL development. The Japanese translation of the book was published in 1964 and in the book, bio-accumulation of pesticides in the Clear Lake was mentioned as one of the most serious pollutions.
As the result, the original CSCL was developed as a law which focused PCB like properties, namely persistence in the environment, bio-accumulation and chronic toxicity to human being. And also the law was to be equipped a mechanism to prevent marketing of certain new chemicals which has those PBC like properties. So, the law was established as the law featured world's first new chemical notification and examination system.

2-2 The original CSCL

In October 1973, the Japanese government proclaimed the original CSCL. Under the law, the Ministry of International Trade and Industry (MITI) and the Ministry of Health and Welfare (MHW) were assigned as the authority to implement the law. At that time, the role of Environmental Agency was limited to nominal advisory role.
The original law has mainly two parts, the first was new chemical notification and evaluation and the second was restriction of specified chemicals like PCBs.
The definition of “new chemicals” is something like “chemicals not listed in the existing chemical list.” So, the first challenge to implement CSCL was to establish the existing chemical list under CSCL. This task was given to MITI by Article 2 of additional clause of the original CSCL.

In April 1973, 6 months before the proclamation of the law, MITI conducted the questionnaire survey to industry organizations. A compiled list was published in the end of 1973 on the Official Gazette in order to invite additions, corrections or deletions. The due date of the invitation is in January 1974 and then revised list was published on 15th of March 1974 just before the enforcement of the law. The list contains some 20,000 of chemicals. The number of chemicals is rather small when comparing with other existing chemical list such as EINECS or TSCA inventory but sometime one MITI number covers certain range of chemicals like alkyl chains with different length, branched and not blanched. And sometimes metal salts are registered under one MITI number like "Alkali or alkaline-earth metal salt." While developing the existing chemical list, MITI merged two or more registrations into one MITI number in case that those entries were not only identical but also partially duplicate or some inclusion relation identified. And at the time of the development, MITI did not collect information of CAS numbers. That is why correspondence of MITI number and CAS number is not so good.

The objective of new chemical notification scheme under the original CSCL was to prevent PCB like chemicals. And the pathway to cause harm to the people was considered like below:

Step 1: Chemicals are released to the environment and remain in the environment

Step 2: Chemicals are accumulated into fish to the higher concentration

Step 3: People consume contaminated fishes for long period and develop disease

Although chemicals behave differently in the actual environment, data requirement of new chemical notification is based on this rather simple risk scenario.

Corresponding to the above risk scenario, evaluation of notified chemical goes through the following flow.

Step 1: Biodegradability

Regarding this step, a biodegradation test method was developed. The test method was authorized as OECD test guideline 301C and 302C. And if the test result showed that the chemical is biodegradable, such test result is

sufficient for the notification. One caution is if any degradation products are identified, the chemical is not considered biodegradable.

Step 2: Bioaccumulation
Regarding this step, a bio-accumulation test was developed. The test method is corresponding to present OECD TG 305-1 but original test method obligated 2 levels of test concentrations. If biodegradation products are identified, bioaccumulation test of the biodegradation products is to be conducted, because this test is placed as the follow-up test of biodegradation test under the law. Under the original CSCL, BCF criterion for "highly bio accumulative" was 10,000 and less than 1,000 was "not bio-accumulative." And if the test result showed that the chemical is not bio accumulative, such test result is sufficient for the notification.

Step 3: Chronic toxicity to human
In case, if the notified chemical is not biodegradable and bio accumulative, in theory, there is the possibility to complete new chemical notification. To go through the pathway, the notifier has to prove that the notified new chemical has no concern of chronic toxicity to human by providing test results including chronic toxicity, carcinogenicity etc., but such case never happened because of the testing cost.

One important thing to be mentioned here is that the government is obliged to evaluate chemicals based on available knowledge of notified chemical according to Article 4 of the law. However, in general, available knowledge of a new chemical is not enough to evaluate the chemical. According to the law, if a chemical notified without test results, the government judges that the government cannot judge based on the available information and notifies the result to the notifier. In such case, notifier is obliged to prepare test results by the law regardless of the will of the notifier to continue the notification. And the test methods are all pre-determined. This pathway is somehow troublesome both for the notifier and the government. Once this judgement was made, the notifier has no way to be released from the obligation to provide the test results and the government has to keep a book to record the status until the test results will be provided by the notifier. Because of this, actual implementation is different from the way that described in the law.

As the result, notifiers of a new chemical prepare test results as “available knowledge”, and the concept “available knowledge” and evaluation using “available knowledge” allowed a lot of flexibility for each evaluation steps such as use of “read across” and “the polymer flow scheme.”
After the evaluation of chemicals, notified chemicals are published in the Official Gazette and the existing chemical list was expanded to include those reviewed chemicals and then the list was called as the Japanese Existing and New Chemical Substances Inventory (ENCS).
Under the original law, environmental fate (biodegradation and bio accumulation) was the key endpoint for new chemical evaluation. Although legal authority to evaluate chemical property equally belonged to MITI and MHW, MITI took the mainly responsibility for the evaluation of environmental fate and new chemical evaluation scheme as whole.

Since the introduction of the law, small amount exemption was already implemented. The total amount of confirmation of a new chemical production/import was one ton nationwide per year, and the maximum amount for a company was 100kg. Other confirmation scheme was limited for intermediate for medicines.

Regarding the restriction of specified chemicals, polychlorinated biphenyl (PCB) was designated in 1974; polychlorinated naphthalene (PCN) and hexachlorobenzene were designated (HCB) in 1979; aldrin, dieldrin, endrin and DDT were in 1981; chlordane and heptachlor were in 1984. Among those specified chemicals, only PCBs are allowed to use for specified purpose. Designation of pesticides as specified chemicals does not prohibit the manufacture, import and use of these chemicals as pesticides, because such use is to be regulated by the Agricultural Chemical Control Law but the designation under CSCL prohibit the manufacture, import and use of these chemicals as industrial chemical including uses as biocide not regulated by other laws.

In 1983, CSCL was amended with other laws to ease the access to the Japanese market. In case of CSCL, newly added article, which is Article 7 in the present law, enabled foreign exporters to notify new chemicals directly. This amendment did not change the regulatory framework of CSCL. And the

number of direct notification from foreign exporters is very limited although utilization of Article 7 allows more flexibility for foreign exporters to select importers in Japan.

2-3 The 1986 amendment

The first significant amendment of CSCL was in 1986.
In early 1980s, many cases of ground water contamination by chlorinated hydrocarbons such as trichloroethylene and tetrachloroethylene were reported and became a social problem. The sources of such contamination were widely spread in various industries i.e. dry cleaning of clothes, degreasing of metals in metalworking industry, processing of semiconductors and so on. Due to the huge amount of use of chlorinated hydrocarbons in various industries, regulations on emission were not considered sufficient and the need of supply control was also discussed. Because CSCL was the only law to regulate manufacture and import of industrial chemicals, it is quite natural that the amendment was discussed.
Under the original CSCL, only PBT chemicals ware regulated but chlorinated hydrocarbons are not highly bio accumulative. Actually, measured BCFs of these chemicals are less than 100 in general. On the other hand, there must be a lot chemicals are to be classified “P”, “not B” and “T.” So, only chemical properties are not enough to define chemicals to be regulated. In this reason, new category of regulated chemicals should be defined by the risk. New regulatory category under the 1986 law, namely class 2 specified chemicals were defined using risk-based approach like “risk concern over a substantially extensive area by manufacture, import and use etc. under the CSCL.”
Newly introduced regulation on class 2 was rather moderate comparing with that of class 1 (“specified chemicals” under the original law) because they were not highly bio accumulative.
By the 1986 law, manufactures and importers of class 2 specified chemicals were obliged to submit their plan of manufacture/import amount before manufacture/import. And the government was given the authority to order to change of their plan if necessary. The government also given the authority to provide technical guidelines for users of those class 2 specified chemicals and also given the authority to give advice to the users of those chemicals.

Trichloroethylene, tetrachloroethylene and tetrachloromethane were designated as class 2 specified chemicals in March 1989.
In parallel with the groundwater contamination by chlorinated hydrocarbons, sea water contamination by organic tin compounds was also found especially in the Seto Inland Sea and other bays like the Tokyo bay. These compounds were used as fishing nets antifouling agents and ship-bottom paints. Domestic uses of these tributyltin and triphenyltin compounds have already faded out at that time although no regulation was introduced. So, the Japanese government decided to use CSCL to prevent the re-marketing of thirteen tributyltin and triphenyltin compounds. As the first batch of regulation, seven triphenyltin compounds were designated as class 2 specified chemical in December 1989.
In case of tributyltin compounds, the situation was a bit tricky, because as the test result obtained through the Existing Chemicals Survey Program indicated that tributyltin oxide (TBTO) was highly bio accumulative. TBTO was designated as class 1 specified chemicals on the same day of the designation of seven triphenyltin compounds. And MITI continued the review of other tributyltin compounds. The test results were between 1,000 and 10,000, and the government designated thirteen tributyltin compounds as class2 in September 1990. Because at that time criteria for highly bio-accumulative was 10,000.

This expansion of regulatory scope led the expansion of the simple risk scenario mentioned in “2-2 The original CSCL” to include direct exposure to persistent chemicals in the environment.
Due to this expansion of risk scenario, new chemical notification scheme was also changed. Before the amendment, evidence of biodegradability or not bio accumulative when not biodegradable was sufficient for new chemical notification. But after the amendment, “not bio accumulative when not biodegradable” could fit the hazard criteria of class 2. From this point of view, review of potential of chronic toxicity was required at the time of new chemical notification. The question was how the potential of chronic toxicity of a new chemical could be reviewed in a cost effective manner.
Under the original law, test methods to review chronic toxicity were already listed by MHW. But those test methods including carcinogenicity test were extremely expensive and then not suitable for new chemical notification if

the notified chemicals are not highly bio-accumulative.
On this particular point, an OECD decision provided great help to consider suitable dataset. The decision was “Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals (8 December 1982)” called OECD MPD.
Among various test items included in the OECD MPD, the Japanese government decided to introduce repeated dose toxicity (28days) test and mutagenicity tests as screening dataset for chronic toxicity for humans. And then new category as a candidate class of class 2 specified chemicals was introduced. The class was called “designated chemicals”.
Under 1986 law, the role of MHW became more important for the evaluation of screening test results. At the early stage of implementation of the amended law, judgement criteria for designated chemicals were not clear and the decisions of MHW heavily relied on experts’ judgement. Because of this, not so often but rarely, councils under ministries have made deferent judgements on the same chemical and took time to reach agreement.

It should be noted that sometime strengthening and relaxation of a regulation happens at the same time. In the 1986 amendment, the upper limit for small amount exemption of a manufacturer / importer was expanded from 100kg to 1 ton although the nationwide cap amount remained the same. Because of this, possibility of quantity adjustment of small amount confirmation was increased.

2-4. The 2003 amendment

The second significant amendment of CSCL was in 2003.
This amendment was triggered by OECD environmental policy review which was published in 2002. In the sectorial review on chemicals, OECD stated in the recommendation section that “further improve the effectiveness and efficiency of chemical management and further extend the scope of regulation to include ecosystem protection” and in the section specific for the authorization of new chemicals for production and import, the report stated that “The scope of regulation in Japanese chemical management should be further extended to include ecosystem protection.”

Taking OECD's recommendation into account, definition of class 1 and class 2 specified chemicals were expanded to protect ecosystem. As for class 1, adverse chronic effect to higher trophic animal was added to adverse chronic effect to human. As for class 2, adverse chronic effect to animals and plants in the living environment was also added.
No chemical was newly designated as class 1 or class 2 because of this amendment but some of already designated class 1 and class 2 considered to fulfill these added criteria.

Similar to the 1986 amendment, required data for new chemical notification was expanded to include screening level eco-toxicity listed in OECD MPD. This change also affected to the candidate classes. Before this amendment, candidate chemicals of class 1 did not designated by the law although MITI (and later METI) has published bioaccumulation test results which identify highly bio-accumulative chemicals. Such chemicals were designated as type 1 monitoring chemicals by the 2003 law. Former designated chemicals were re-named to type 2 monitoring chemicals and the criteria of this category of chemicals remained the same. Another candidate class for class 2 specified was introduced as type 3 monitoring chemicals and the criteria for this class was eco-toxicity concern.

The characteristics of these candidate classes is summarized in table 3 below:

Table 3 Characteristics of monitoring chemicals under the 2003 amendment

category	biodegradation	bioaccumulation	toxicity to human	eco-toxicity
Type 1	not biodegradable	bio-accumulative	Uncertain	
Type 2	not biodegradable	not bio-accumulative	concerned	-
Type 3	not biodegradable	not bio-accumulative	-	concerned

Because of these characteristics, designation as type 2 and designation as type 3 on one notified chemical happened at the constant frequency.

In the 2003 amendment, relaxations were also included.
The most important relaxation in the 2003 amendment was the introduction of low volume exemption. Newly introduced low volume exemption enabled

industries to produce/import chemicals up to 10 tons per year nationwide, if the chemical is not biodegradable and not bio accumulative. This scheme is, from the view of legislation technique, to allow production/import under specified condition on the half-way of new chemical evaluation. Equal to ordinal new chemical notifications, producer/importer has to notify under Article 3. And under Article 4, the Japanese government makes a judgement whether the notified chemical is eligible to the low volume exemption and notifies the judgement result to the producer/importer. Then, the producer/importer applies for confirmation of the allowable volume under Article 5 of the law.
Because the upper limit (10ton) is for nationwide, the intended volume of production / import may not be allowed if other producer / importer who also notified the chemical under Article 3 applied for the confirmation of the same chemical.
Other areas of relaxations are for intermediates, closed-system and export only. For these chemicals, producers/importers are required confirmation by the government. To apply for the confirmation, producers/importers are required to submit information that the chemicals are not likely to cause environmental pollutions

In the 2003 amendment, Article 6 of the additional clause set a rule of 5 year review. This obligation is not specific to CSCL. The Japanese government adopted a policy that all legislation shall be reviewed after 5 year implementation.

Before the 2003 amendment, the Japanese government reform was happened in 2001. This government reform had some influence to CSCL. The name of MITI changed to METI (Ministry of Economy, Trade and Industry) and MHW was merged with MOL (Ministry of Labour) then changed its name to MHLW (Ministry of Health, Labour and Welfare). The Environmental Agency was upgraded to MOE (Ministry of the Environment) and given the concrete authority in the implementation of CSCL.

2-5 The 2009 amendment

In the 1986 amendment and the 2003 amendment, the scope of regulated

chemicals was expended and the data set for new chemical notification was also expanded.
The focus of the 2009 amendment was different.
The focus of the 2009 amendment is to strengthen management of existing chemicals.
When the Japanese Diet passed the original law, a supplementary resolution was adopted. In the resolution, the role to evaluate existing chemicals was solely assigned to the Japanese government. Based on the supplementary resolution, the Japanese government mobilized substantial amount of budget to conduct testing and many test results became available to the public. However, testing is costly and the number of existing chemicals is very large. As the result, the number of tested chemical is not sufficient.
The situation in the world was somehow similar to the situation in Japan. OECD made a Council Decision in 1987, and in the decision, member countries decided to establish or strengthen national programmes to systematically investigate existing chemicals. In 1991, OECD adopted another Council Decision to investigate high production existing chemicals in a co-operative way. The Japanese government contributed to the programme through its existing program.
In the supplementary resolution to the 2003 law, the role sharing for evaluating existing chemical was changed from the original law. In the supplementary resolution to the 2003 law, the Japanese diet urged systematical progress of hazard assessment through public-private cooperation and acceleration through international cooperation.
To accelerate evaluation of existing chemicals, the Japanese government launched the "Japan Challenge Program" which was corresponding to the U.S. HPV Challenge Program. The program achieved good progress but had some limitations.
In parallel with voluntary approach taken in the U.S. and Japan, discussion of EU REACH was on-going since publish of EU white paper 2001. EU REACH was adopted in the end of 2006 and entered into force in the middle of 2007. And EU REACH obliged registration of all chemicals in the market.

As described in "2-4 The 2003 amendment," 5 year review was required and the three Ministries established joint review council in January 2008. The joint council published a report in the end of 2008 and the following 3 issues

were pointed out.
1) Establish a public-private coordination framework to enable to prioritize chemicals to be assessed among all chemicals in the market and step-wise information collection of chemical hazard and exposure of such prioritized chemicals.
2) In addition to the present hazard based evaluation of notified new chemical, conduct risk based evaluation of new chemical.
3) Continue strict management and appropriate risk reduction of class 1 specified chemicals, monitoring chemicals and class 2 specified chemicals taking international trend into account.
Based on the report, the three Ministries jointly prepared draft legislation and submitted to the 171st diet in 2009.

The most significant change under the 2009 amendment was the introduction of comprehensive assessment of "general chemicals." The term "general chemicals" is newly introduced to CSCL to cover existing chemicals plus reviewed new chemicals minus regulated chemicals. The law obliges manufactures and importers to report production/import volume and use categories. The government conducts screening based on the reported information and available knowledge and then designates priority chemicals as "Priority Assessment Chemical Substance (PAC)." After the designation of PACs, the manufactures and the importers of PACs are obliged to report production/import volume, detail use categories and distributions. Based on such information, the government conducts several steps of risk assessment and request additional information if necessary. If the assessment result indicates risk concern over a substantially extensive area by manufacture, import and use etc. under the CSCL, the government designates the chemical as class 2 specified chemical. By the 2009 amendment, the process to investigate all existing chemicals was established under CSCL.
At the same time, criteria of class 2 were changed. Under the 1996 and the 2003 law, "not biodegradable" was one of the criteria of class 2. But under the 2009 law, such condition is not applied to class 2 anymore. Because biodegradability of a chemical does not ensure that the chemical does not cause risk concern
Establishing the comprehensive assessment scheme was also affected to the candidate class of class 2 specified chemicals under the 2003 law, namely

type 2 monitoring chemicals and type 3 monitoring chemicals. These 2 classes were abolished by the 2009 amendment.
This amendment was focused on post-marketing management of chemicals and did not change new chemical notification. However, method and meaning of evaluations of notified new chemicals have changed slightly.
Under the previous laws, new chemical evaluations were solely based on chemical properties, i.e. biodegradability, bio-accumulation and screening toxicity (human health and eco-toxicity). Under the 2009 law, notified new chemical is reviewed from the risk perspective. The government conducts screening assessment of notified new chemicals using the same procedure of screening of general chemicals as described in chapter "6-2-1 Annual reporting of general chemicals and screening". Regarding screening of notified new chemicals, it should be noted that the government uses expected production/import amount for screening instead of actual produced / imported volume. It means an ambitious business plan may incur unexpected designation to a PAC if the hazard class of the notified chemical is high.
Because of the need to conduct screening, meaning of toxicity data evaluation have changed. Under the 2003 law, toxicity data was used to determine whether the notified chemical fulfills the criteria of type 2 / type 3 monitoring chemicals. On the other hand, under the 2009 law, toxicity date of a notified chemical is used to determine hazard class of the chemical and the determined hazard class will be used not only at the pre-marketing evaluation but also for post-marketing management.
It should be noted that under the previous laws, some notified new chemicals were designated as type 2 / type 3 monitoring chemical immediately and marketing of those chemicals faced difficulties because of such designations. This kind of situations was eliminated under the 2009 law.
The introduction of comprehensive assessment was entered into force in 2011 as the second phase implementation of the 2009 amendment.

Another important change under the 2009 amendment is further harmonization to international agreement and global practice.
CSCL is one of the implementation laws of the Stockholm Convention on POPs. Under the convention, "PFOS and its salts, SFOSF" and other eight chemicals were listed in the Annexes of the convention in 2009. And "PFOS

and its salts, SFOFS" is in Annex B (restriction) of the Convention. It meant that certain essential uses are allowed under the convention.
Unlike to the other eight chemicals, PFOS is a "living" chemical and being used in various industries like semi-conductor production. So, PFOS is allowed to be produced and used for specified essential use under the Convention.
POPs criteria under the Convention and PBT criteria under CSCL is almost identical. And to regulate PFOS in Japan, PFOS should be designated as class 1 specified chemical by CSCL. On the other hand, management measure of class 1 specified chemicals was simply banning under previous CSCL. Because of this, the government established a mechanism including the introduction of the concept of "essential use" and relating technical guidelines to allow continuation of production, import, export and use of PFOS.
Another area for international harmonization is on polymers. Under the previous laws, the Japanese government adopted the "Polymer Flow Scheme (PFS)" to evaluate polymers. The scheme requires several test results but not costly comparing with the preparation of ordinary dataset (biodegradation, bio-accumulation, screening toxicity (human health and eco-toxicity)). However, in other developed countries like U.S., certain polymers are exempted from their new chemical notification schemes. This was why the Japanese government decided to introduce low concern polymer exemption.
These changes were implemented in 2010 as the first phase implementation of the 2009 amendment.

2-6 The 2017 amendment

As Article 6 of the additional clause obliges review of implementation status of the 2009 law after 5 year implementation, Review Committee on execution status of CSCL committee was established in August 2015 to review and discuss the execution status, in advance of the discussion in the related councils.
The date and discussion points were summarized in table 4

Table 4: Dates and discussion points of the CSCL review committee (fy2015)

Date	Discussion point
31-Aug-15	Establishment of the review committee.
	CSCL execution status and issues to be discussed.
16-Oct-15	Progress of risk assessment of existing chemicals toward the WSSD 2020 goal.
4-Dec-15	New chemical evaluation and confirmations.
24-Dec-15	CSCL chemical management measures and activities
8-Feb-16	Reporting of the review committee.

Through the series of meeting, many points were discussed including acceleration of risk assessment, utilization of QSARs, interpretation of WSSD 2020 goal etc. and many points discussed could be achieved without amending the law itself. However, relatively minor points were identified as matters to be solved through the amendment of the law.

One issue was further relaxations of small and low volume exemptions and the other is the management measures of extremely hazardous new chemical substances.

Small and low volume exemptions were unique comparing with corresponding exemption schemes in other countries because the volume was managed nationwide production and import. It was like a “quota system” and if the quota of a chemical was already used in a certain fiscal year, newcomers are not allowed to produce/import the chemical within the fiscal year. Even in the first application period (every January for the next fiscal year), planned volume of production/import is not allowed if other producers/importers applied for the confirmation of the same chemical at the same time and the total planned volume exceeded 1 ton (or 10 ton for low volume exemption). In such case, companies share the 1 ton (or 10 ton) according to the confirmed volume by the authorities. This quantity adjustment system has been criticized by industries because this system reduced the predictability and then companies may lose business opportunities.

The other point was something like a backlash against the 2009 amendment. Under the 2009 amendment, regulatory classes namely type 2 monitoring chemicals and type 3 monitoring chemicals were abolished because new candidate category of class 2 specified chemicals were introduced as priority

assessment chemicals. As the result, some experts argued that the function to warn industries about hazardous property of notified new chemicals declined.
Based on such discussion, METI and MOE decided to launch council process. METI has Industrial Structure Council and MOE has Central Environment Council as the bodies to provide policy advice to the Ministers. A joint meeting of a working group and a subcommittee under each council was assigned for further discussion and had meetings to develop concrete policy. Dates and discussion points are summarized in table 5.

Table 5: Dates and discussion points of the joint meeting (fy2016)

Date	Discussion point
26-Sept-2016	CSCL implementation status and schedule of discussion
28-Nov-2016	Further rationalization of exemptions from new chemical notification Management measures of extremely hazardous new chemical substances
27-Dec-2016	Reporting of "direction of future chemical management measures"

Through the discussion of the joint meeting, the following conclusions were agreed.

Regarding further rationalization of exemptions from new chemical notification, nationwide upper limit of exemptions was discussed. And they concluded that the present cap "nationwide manufacture and import amount" is to be changed to "nationwide environmental release" on the assumption that the safety of human health and ecosystem is ensured.
Change of nationwide upper limit from "manufacture and import volume" to "environmental emission" contributes to enhance predictability of individual business plans by declining the number of cases of quantity adjustment while ensuring appropriate level of protection of human health and the environment by applying use categories and emission factors assigned to each use category.
The outline of this amendment appears in table 6.

Table 6: 2017 CSCL amendment outline of exemptions

Volume limit under CSCL 2009

Exemptions	Volume limit per company	Volume Limit nationwide
Small amount	1 ton/year (manufacture and import)	1 ton/year (manufacture and import)
Low volume	10 ton/year (manufacture and import)	10 ton/year (manufacture and import)

Volume limit under CSCL 2017 amendment

Exemptions	Volume limit per company	Volume Limit nationwide
Small amount	1 ton/year (manufacture and import)	1 ton/year (**release to the environment**)
Low volume	10 ton/year (manufacture and import)	10 ton/year (**release to the environment**)

Use categories and emission factors are already developed for screening and risk assessment purpose. However, these emission factors will not be directly applied to these exemptions. Because through the discussion in the Diet, uncertainties on emission factors were pointed out and the government was asked to carefully apply these emission factors to estimate nationwide environmental release. The new exemption scheme will enter into force from 2019 fiscal year by cabinet order and application for confirmation will likely start January 2019. So, emission factor table and detail implementation rules are expected to be established by the end of FY 2018.

One of significant issue relating implementation is supplementary document to be attached to the application. For these exemptions, no attachment was required so far. However, because of significantly increased importance of the use information, supplemental document to demonstrate appropriateness of claimed use category will be required. Detail rule for such supplementary documentation is also now under consideration and public consultation is expected.

Another significant point is the application period for small amount exemptions. Since the establishment of the law, application to small amount exemption is limited to only four times in a year. To allow more flexibility to the industries, application period is expected to be increased to ten times a year.

As the result, under this amendment, the authorities are required to estimate total environmental emission of a chemical in a short period. To enable this, SMILES code or some other information to identify chemical is to be required in the application format. For certain category of chemicals such as UVSBs, such information may not be applicable and the application scope of such information will also be published.

Regarding extremely hazardous new chemical substances, several measures were identified by the amendment law. It includes notification to notifiers about the judgement result that the chemical substance is classified as highly hazardous, public announcement of the judgement results by the three Ministers when the name of the notified chemical is published, requiring notifiers to provide information to their downstream users, and provision of guidance and advice to manufacturers where necessary.
This amendment is not a substantial change because in case of severely hazardous new chemical substances, the joint evaluation council provides advises to the notifiers to share their evaluation results to downstream users. So, this amendment intended to provide legal bases to already implemented practices. However, evaluation results are to be published when the names of notified new chemicals. It implies that more open decision making is required to evaluate a chemical as extremely hazardous. So, it is expected that the evaluation criteria is clarified in the evaluation criteria.
According to this amendment, a new category named "Specified new chemicals" is defined. However, this new category is a sub-category of new chemicals. That is why, the same 5-year publication rule is to be applied.
There are several opportunities that the government get information that an existing chemical is extremely hazardous. The government collect information of hazard property in the process of screening and risk assessment. Based on such information, the name of the existing chemical is to be published as "Specified general chemical" and the manufactures and importers of the chemicals are obliged the same obligation of the notifier of specified new chemicals.
This amendment will enter into force April 1st 2018.
Implementation will be one fiscal year earlier to exemptions because required preparation is limited compared to the amendment of exemptions.
Evaluation criteria of "extremely hazardous" will be published.

3. Legal structure and outline of present CSCL

Before going to the details of the CSCL implementation, it may be useful to look at the law itself and its supporting documents.

3-1 Structure of the law

The law consists of 8 chapters and title of each chapter is as follows:

- Chapter 1: General rule
- Chapter 2: New chemical evaluation
- Chapter 3: Reporting of general chemicals
- Chapter 4: Measures on priority assessment chemical substances
- Chapter 5: Regulations etc. on class 1 specified chemicals
  - Section 1: Measures on monitoring chemicals
  - Section 2: Regulations on class 1 specified chemicals
- Chapter 6: Regulations on class 2 specified chemicals
- Chapter 7: Miscellaneous rules
- Chapter 8: Penalties

Chapter 1 has 2 articles. Article 1 defines objective of the law and Article 2 clarifies definitions of chemical category. By Article 1, the characteristics of CSCL is defined that the objective of the law is to protect human health and the environment from chemical pollution in the environment. Article 2 defines “chemical substance” and each category under CSCL.

Chapter 2 has 5 articles. Article 3 is on new chemical notification and exemptions, Article 4 is on new chemical evaluation, and Article 5 is on low volume exemption. Article 6 is restriction of new chemical production / import, Article 7 is new chemical notification from over sea exporter to Japan.

Chapter 3 has only Article 8 which describes reporting rule of general chemicals.

Chapter 4 has 4 Articles. Article 9 is on reporting rule of PACs, Article 10 is on investigation of hazard property etc. of PAC. Article 11 is on rescinding of PAC designation. Article 12 is information provision to users.

Chapter 5, Section 1 has 4 articles these describe reporting obligation, investigation of hazard properties, descending of designation and information provision relating monitoring chemicals.

Chapter 5, Section 2 has 18 articles these describe regulations on class 1 specified chemicals.
Chapter 6 has 3 articles. Article 35 is submission of manufacture/import plan, Article 36 is on technical guidance, Article 37 is on labeling etc.
Chapter 7 has 19 articles including recommendation and advise by ministers (Article 38, 39), reporting of hazard information (Article 41), Levy report (Article 43), inspections (Article 44), ministers in charge (Article 53), relation to other laws (Article 55) and opinion of councils (Article 56).
Chapter 8 has 7 articles on penalties against the violation of the law.

CSCL has additional clauses. The most important article is Article 2 of additional clause to the original law as mentioned in "2-2 the original law" that is about existing chemical list. In additional clauses, dates of enforcement and transitional measures are included.

3-2 Supporting documents under the law

To implement a law, the law itself is not enough. Under the law, layers of supporting documents are prepared to implement the law.
The layer just under the law is the cabinet orders that require authorization by the cabinet as whole. Entrustment to a cabinet order is clearly stated in the law. In general, a cabinet order describes important information that is expected to be amended without amending the law itself.
The second layer is ministerial ordinances that require authorization by the designated Minister(s). It means the content of the ministerial ordinance is solely belongs to the authority of the designated ministry(ies). Entrustment to a ministerial ordinance is also stated in the law.
Publication on the Official Gazette is the most official method to disseminate information to the public. In this sense, laws, cabinet orders and ministerial ordinances are always published on the Official Gazette. Other than these documents, the Official Gazette is used to inform chemicals lists, guidance documents and so on. In general, such publications are required in the law itself and relevant article is quoted when such information is published.
Notices and announcements are also used for to inform technical details and operational matters etc. In general, provisions of such information are not obliged to the government by the law. Director Generals, division directors,

office directors etc. can issue such notices/announcements. Notices and announcements could be issued not only to the industries but also to other authorities to inform technical and operational matters of the law.

In case of CSCL, information provides through cabinet order, ministerial ordinances, publication on the Official Gazette and notices / announcement is summarized in table 7 below.

Table 7 Supporting documents of the law and its contents (outline)

Category	Contents
Cabinet Order	Regulated Chemicals (Class 1 & Class 2 specified Chemicals) etc.
Ministerial Ordinance	Notification format etc.
Publication on the Official Gazette	Chemical lists (Existing chemical inventory, Evaluated chemicals, PACs) Guidance (Test method, Technical guidance etc.)
Notice/Announcement	Implementation rule, evaluation criteria etc.

3-3 Cabinet orders

Under the CSCL, one important cabinet order "Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc." exists.
The order has been amended several times especially for the addition of class 1 specified chemicals. The latest amendment was in March 2016 to add HBCD and pentachlorophenol and its salt, ester.
The order consists of 13 articles. And main articles are as follows:

Article 1: List of Class 1 Specified Chemicals
Article 2: List of Class 2 Specified Chemicals
Article 3: Case of exemptions (Intermediates, Closed system, Export only), Volume limit of Small Amount Exceptions
Article 4: Volume limit of Low Volume Exception
Article 5 : Threshold amount for annual reporting of general chemical
Article 6: Threshold amount for annual reporting of priority assessment chemical
Article 7: Prohibited products to import when containing Class 1
Article 8: Essential use of Class 1