1. CHEMICALS

(1) Overview of Chemical Substances Control in Japan

(i) Chemical Substances Control Law (Revised in 2009)

The Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (commonly referred to as the Chemical Substances Control Law: The Chemical Substances Control Law hereinafter, "CSCL" was enacted in 1973 with the purpose of preventing 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. Since its enactment, CSCL has undergone several revisions and when revised in 2003, a supplementary provision was added that requires the Government to review the status of enforcement of the Law after approximately five years from the enforcement. Meanwhile, the international context for chemical substances has also seen considerable changes including reaching an agreement in 2002 at the World Summit on Sustainable Development (WSSD) to minimize significant adverse effects of chemical substances on human health and the environment by 2020.

In response to these developments, the Joint Committee to Review the Chemical Substances Control Law, a council comprised of members from the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment (three ministries with jurisdiction over CSCL) started to discuss the necessity of revision of CSCL and the establishment of a new control system, etc. in January 2008. The Committee compiled and released a report in December in the same year. Based on this report, the bill to revise CSCL was adopted at a Cabinet meeting in February 2009 and submitted to the ordinary Diet session for deliberation. The revised CSCL was promulgated on May 20, 2009.

The key features of the revised CSCL are as follows:

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

1) Businesses that have manufactured or imported any chemical substances, including existing ones, in excess of the specified amounts are newly obliged to notify the quantity and other information for every fiscal year.
2) The chemical substances that have higher priority in risk assessment will be designated as “Priority Assessment Chemical Substances”, based on the content of the notifications from businesses and the existing knowledge of the hazardous properties of these substances
3) Manufacturers and importers of Priority Assessment Chemical Substances” are required as necessary to submit information on Hazardous properties and businesses handling these substances are required as necessary to report their uses.
4) The substances that raise concerns about adverse effects on humans or flora and fauna, as a result of a phased implementation of information collection and risk assessment of “Priority Assessment Chemical Substances,” will be designated as “Specified Chemical Substances” as in the current CSCL, which are subject to regulations on manufacturing and uses.
5) In addition to the “chemical substances which is persistent in the environment,” which have been the target of regulations, “chemical substances which are easily degradable in the environment” will be the target of regulations.

b) Implementation of proper chemical substances control in the distribution process

In order to prevent environmental pollution caused by “Specified Chemical Substances” and products using these substances, businesses handling them are required to adhere to certain handling standards and

obliged to indicate information necessary for trade.

c) Rationalization of evaluation and regulation systems in light of international trends

Alignment of the evaluation and regulation systems with international standards will be promoted, including reviewing regulations on "Class I Specified Chemical Substances," to permit the exceptional use of the substances regulated under the Stockholm Convention on Persistent Organic Pollutants (POPs) under more strict control.

The revised CSCL will be enforced on April 1, 2010, except for the provisions relating the notification of the quantity of chemical substances to be manufactured or imported, the designation of Priority Assessment Chemical Substances, and the abolition of the Type II and III categories of Monitoring Chemical Substances (explained in (a) above from 1) through 4). These provisions will be enforced on April 1, 2011.

(ii) Law for PRTR and Promotion of Chemical Management (Cabinet Order Revised in 2008)

The Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (hereinafter, "the Law") was enacted in 1999 with the purpose of promoting voluntary improvement of the management of chemical substances by business operators and preventing any impediments to the preservation of the environment by taking measures for the confirmation of release amounts, etc. of specific chemical substances in the environment ("PRTR system") and measures for the provision of information concerning the properties and handling of specific chemical substances by business operators ("MSDS system"). Under the Law, approximately 40,000 businesses have been reporting annually on the amount of chemical substances released and transferred from their facilities and the data of which have been compiled by the

Government for publication.

The Law provides that when 7 years have elapsed since its enforcement, the Government should review the status of enforcement and take necessary measures based on the results of the review. In pursuant to this, the joint council of the Ministry of the Environment and the Ministry of Economy, Trade and Industry conducted a review and compiled a report. Following the suggestion in the report that the method/criteria for designation of specific substances be reviewed, a council comprising of members from the Ministry of the Environment, the Ministry of Economy, Trade and Industry, and the Ministry of Health, Labour and Welfare deliberated the matter and compiled a report.

As a result, the Cabinet Order was partly revised in November 2008 and the number of Class I Specified Chemical Substances, which are subject to both the PRTR system and the MSDS system and the number of Class II Specified Chemical Substances, which are subject to the MSDS system only, were increased from 354 to 462 and from 81 to 100 respectively. Furthermore, the medical industry was added among the types of industries that businesses obliged to confirm and notify the release amounts of chemical substances in the environment may engage in (23 industries had been previously specified).

The method of providing PRTR data was also reviewed. Specifically, it has been decided that the PRTR data provided by individual business facilities are disclosed by public announcement by the Government as well as being disclosed on request. The data from individual business facilities as well as national and prefectural aggregate data are disclosed on the PRTR website.

(2) ASSESSMENT OF CHEMICAL RISKS

(i) Mechanisms for systematic evaluation, classification, and

labeling of chemicals, including initiatives towards a harmonized system of classification and labeling of chemicals

(a) Implementation of GHS

Japan's inter-ministerial committee (Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, Ministry of the Environment, Ministry of Interior and Communication, Ministry of Agriculture, Forestry and Fishery, Ministry of Land, Infrastructure and Transport and Ministry of Foreign Affairs) was established in 2001, and the Purple Book of United Nations has been translated into Japanese in 2004.

Some Japanese laws have been amended to introduce GHS (pictograms, MSDS, etc) such as "Industrial Safety and Health Law", "Poisonous and Deleterious Substances Control Law" and "Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof".

One of the existing Japanese Industry Standards (JIS), JIS Z 7250 (MSDS), was revised along with GHS, and two JISs were newly drawn up, namely JIS Z7251 (labeling) and JIS Z 7252 (classification corresponding to the GHS).

(b) Classification by the Government

Some Governmental Projects are also put forward such as Classification of substances regulated by laws with the GHS Criteria (about 2,000 substances by 2008), developing "Classification Manual" & "Technical Guidance" (which were combined each other and revised as "GHS Classification Guidance for Japan's integrated Classification Manual & Technical Guidance"), "GHS Classification Guidance for chemical mixtures" and "Concept of risk assessment on consumer product exposure for GHS labeling". Classification results of substances can be found at http://www.safe.nite.go.jp/english/ghs_index.html)

(c)Comparison study of GHS classification results

Japan, China and Korea have started a comparison study among three countries on GHS classification results and labeling since 2008. The study revealed that there are some possible causes of differences of classification results such as information sources, building blocks and so on. The report of this study will be published in early 2010.

(ii) Initiatives for assessment of toxic chemicals, hazard and risk assessment, and participation in various international and regional initiatives

(a) Japan Challenge Program

Japan Challenge Program is a program to facilitate the collection and dissemination of safety information of 645 Priority Information Gathering Substances selected from among existing chemical substances as needing to collect and disseminate safety information with high priority. Information collection is to be conducted in cooperation between the public and private sectors. For the substances for which there is no plan to collect safety information through international initiatives including those led by OECD, the Government has sought sponsorship from private businesses.

The Program, launched in June 2005, has been promoted with advice from the Program Promotion Committee comprising of outside experts, etc. Among the Priority Information Gathering Substances, 532 substances have already been the target in overseas information gathering programs launched by June 2009. For the remaining 126 substances, sponsorship from private businesses has been sought and 93 of them as well as 3 substances for which sponsorship was not sought are now being investigated to obtain safety information under sponsorship of private enterprises and organizations.

In August 2009, the progress of the Program was reviewed and an

interim assessment was published.

The outline of the interim assessment is as follows:

-As a whole, the program has been making steady progress although it is a bit behind schedule. The overall framework of the program can be considered as appropriate for the purpose.
-There are still some substances left without sponsors and the safety information collection and the submission of a report have been completed for only a few substances. It was pointed out that these facts are the result of a defect in the program such as not providing enough incentives for voluntary participation in the program.
-The Government should continue the efforts to obtain sponsorship until the end of March 2009, taking into account the priority levels of each substance.
-The online database titled “J-CHECK”, which was compiled under CSCL and operated by the Government, needs improvement by enhancing the scope of information and user friendliness.
-For the substances for which safety information has been obtained through this program, the government is going to conduct hazard assessment of each chemical substance within fiscal 2012.
-Further discussion is necessary for future directions, taking into account the progress in reviewing CSCL.

(b) Contribution to the OECD Activities

OECD has been developing guidelines for testing chemical substances since 1981. Japan has been an active participant in the program, contributing by providing scientific knowledge required in revising the guidelines and by sending experts to participate in related meetings. The finalized guidelines have been effectively utilized where appropriate, including being adopted into national laws, etc.

In Japan, the Ministry of the Environment published a guideline

("Guidelines for preventing the environmental impact of manufactured nanomaterials") for preventing adverse effect by manufactured nanomaterials in March 2009. The Ministry of Economy, Trade and Industry (METI) also published a report of The Expert Meeting on Safety Measures for Nanomaterial Manufactures etc. in March 2009. The Ministry of Health, Labour and Welfare notified on Measures for Prevention of Exposure etc. to Nano materials and published a report of the Expert Meeting on Safety Measures for Manufactured Nanomaterials in March, 2009. Japan has also been contributing to OECD's work on manufactured nanomaterials by, for example, presenting the outline of the Guidelines and the English version of the expert meeting report in a joint meeting of OECD Chemicals Committee, and also participating in the sponsorship programme to test representative manufactured nanomaterials organised by OECD Working Party on Manufactured Nanomaterials

Japan plans to continue its efforts in contributing to OECD's activities, including the program for developing test guidelines for screening endocrine-disrupting chemicals and the efforts toward issues related to nanomaterials.

(c) Initial Risk Assessment

In order to prevent adverse effect on human health and the ecosystem caused by chemical substances emitted into the environment, including the water, air, soil, etc., through human activities, it is necessary to quantitatively assess the risk of these chemical substances.

In the light of this, the Ministry of the Environment has been conducting environmental risk assessments to screen out the substances that could have adverse effect on human health or the ecosystem. The initial risk assessment has been performed from the standpoint of not overlooking the harmful effect, based on their hazard information and the data obtained from environmental monitoring.

About 20 to 30 substances that are potentially hazardous to human health or the ecosystem are selected and assessed annually. By September 2009, the assessment results on 250 substances have been published. For those which are potential candidates for further assessment, considerations will be made for the necessity of such further assessment with a view to implement regulations on these substances.

(iii) Strategies for exposure assessment and environmental monitoring and improvement in procedures for using toxicological and epidemiological data to predict and estimate the effects of chemicals on human health and the environment

In fiscal 1974, the Environmental Survey and Monitoring of Chemicals were launched with the purpose of grasping the persistence of existing chemical substances in the general environment. This survey has been incorporated into a broader framework of the Comprehensive Survey of Chemical Substances on Environmental Safety launched in fiscal 1979 for the target substances selected from among the Priority List (a list of chemical substances on which surveys are to be conducted with high priority). This comprehensive survey framework has been expanded with other related surveys such as Wildlife Monitoring, Follow-up Survey of the Status of Pollution by Unintentionally Formed Chemical Substances, Monitoring of Surface Water and Bottom Sediment and The Investigation and Survey of Designated Chemical Substances, etc.

In the meantime, a drastic review of the survey method based on the Priority List has been conducted in order to be able to respond more quickly and more appropriately to the changes in the situation surrounding the issues related to chemical substances in the environment, including the effectuation of the POPs Convention, as well as to the current political issues. As a result of the review, a new survey method has been adopted, where the target substances are selected on

request from various policy making divisions of the Government so that the survey results can be utilized in formulating policies and measures relating chemical substances in the environment. The new survey framework, titled the Environmental Survey and Monitoring of Chemicals, was also launched in 2002, which is comprised of three surveys with different purposes: the Initial Environmental Survey, the Environmental Survey for Exposure Study, and the Environmental Monitoring.

With the quantity of chemical substances currently distributed in Japan reaching several tens of thousands, in order to grasp the actual status of chemical substances in and their effect on the environment and to sequentially detect slight changes in ambient concentration, continuous improvements in analysis methods/survey frameworks are necessary and appropriate accuracy control needs to be ensured. It is also necessary to collect samples that enable accurate grasping of the actual condition in the environment. In considering the addition of the target substances for monitoring, it is necessary to continue the efforts to find the best and most appropriate balance between survey costs and the amount/quality of information to be obtained from the survey, noting the POPs Convention requirements as well as keeping an eye on the development of analysis methods by taking into consideration the property of each chemical substance and on the collection of appropriate samples.

One remaining issue is how to pass down the long-accumulated knowledge and skills of experienced and highly capable officials in major survey/assessment-conducting entities as their mass retirement approaches close.

(3) SOUND MANAGEMENT OF TOXIX CHEMICALS

(i) Progress within the larger framework of Strategic Approach to International Chemicals Management (SAICM)

(a) Internal Policies

Japan's Inter-ministerial committee has been arranged. The member ministries are Ministry of the Environment, Cabinet Office, Ministry of Foreign Affaires, Ministry of Finance, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labor, and Welfare, Ministry of Agriculture, Forestry, and Fisheries, Ministry of Economy, Trade, and Industry, and Ministry of Land, Infrastructure, Transport, and Tourism.

The Third Environmental Basic Plan (Cabinet decision in April 2006, based on the Basic Environmental Law) incorporated the SAICM objectives.

The information on SAICM itself and its implementation in other countries has been distributed through several channels e.g. national seminars for public on SAICM.

(b) International Policies

Japan had served as the Focal Point of Asia Pacific Region until May 2009 and has served as the Vice Chair of International Conference on Chemicals Management (ICCM) until 2012.

Japan's Ministry of the Environment has sponsored the SAICM regional meeting in Asia Pacific region held in 2007. Ministry of the Environment has also bilaterally supported Thailand and Bhutan to facilitate the implementation of SAICM in their countries under the Quick Start Program. Due to these activities, Japan received silver prize at the second session of International Conference on Chemicals Management.

(ii) Policy measures to phase out chemicals that pose unreasonable and unmanageable risk to human health and human environment, such as, for example, ozone-depleting substances

The Fourth Meeting of the Conference of the Parties of the Stockholm Convention (COP4) was held in May 2009, where delegates reached a decision to list nine substance groups (12 substances) in Annexes of the Convention. In order to ensure compliance with this decision, the Japan is to implement necessary measures under CSCL and other laws.

It was concluded at the joint council of the Ministry of Health, Labour

and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment held in June 2009 that in order to secure international consistency, it is appropriate to designate the nine substance groups (12 substances) as Class I Specified Chemical Substances under CSCL and prohibit, in principle, their manufacturing and import. In the council held in July 2009, a conclusion was reached that it is appropriate to take measures enabling the use of perfluorooctane sulfonate acid (PFOS) and its salt, which is among the nine substance groups (12 substances) (Table 1), for specific purposes such as those related to semiconductors, etc.(Table 2).
In the future, the Order for Enforcement of CSCL will be revised based on the results of deliberation in these councils and through necessary procedures, including inviting public comments. After the nine substance groups (12 substances) are additionally designated as Class I Specified Chemical Substances, necessary measures will be formulated for manufacturing, importing and using of these substances.

(iii) Policies aimed at reducing the risks posed by lead, mercury and cadmium and other harmful heavy metals, including through a review of relevant studies, such as, for example, the United Nations Environment Programme global assessment of mercury and its compounds

In response to the UNEP (United Nations Environmental Programme) Mercury Programme launched in 2001 and the UNEP Lead and Cadmium Activities launched in 2005, Japan has been addressing the issues of mercury and other harmful heavy metals.

As for mercury, specific activities have been being conducted including surveys to clarify the material flows and emission inventory of Japan and the continuous monitoring on the atmospheric mercury levels in Japan. The results of the surveys and monitoring have been submitted to UNEP, which contribute to UNEP initiatives such as the Global Atmospheric

Mercury Assessment (UNEP 2008), etc.

Japan has also been providing its knowledge on lead and cadmium to UNEP, which has been included in such documents as “Reviews of scientific information on lead” (UNEP 2008) and “Reviews of scientific information on cadmium” (UNEP 2008).

These efforts have been reviewed by convening an investigative committee of experts and the inter-ministerial committee for addressing the issues of heavy metals, etc.

In recent years, Japan as the country having the experience of Minamata disease has been making an active contribution to international discussions on mercury. For example, Japan served for the Bureau as a representative of the Asia-Pacific region at UNEP Ad Hoc Open-ended Working Group on Mercury, an international forum to discuss on international actions including a legal binding instrument on mercury. Japan also has been serving the lead country in the waste management area of UNEP Global Mercury Partnership.

(iv) Initiatives to reduce overdependence on the use of agricultural chemicals

Japan has been promoting sustainable agriculture, which aims to reduce environmental impact of agricultural chemicals and chemical fertilizers.

Table 1: Substances that are considered appropriate for addition to Class 1 Specified Chemical Substances

Substance	**Purposes**
1. Perfluorooctane sulfonate acid (PFOS) and its salts	Water repellent, Lipid repellent, Surfactant
2. Perfluorooctane sulfonyl fluoride (PFOSF)	Starting material for PFOS
3. Pentachlorobenzene	Agricultural chemicals, Byproduct
4. r-1, c-2, t-3, c-4, t-5, t-6-hexachlorocyclohexane (Alpha hexachlorocyclohexane)	Byproduct of substance 6
5. r-1, t-2, c-3, t-4, c-5, t-6-hexachlorocyclohexane (Beta hexachlorocyclohexane)	Byproduct of substance 6
6. r-1, c-2, t-3, c-4, c-5, t-6-hexachlorocyclohexane (Gamma-hexachlorocyclohexane)	Agricultural chemicals, Pesticides
7. Decachloropentacyclo [5.3.0.0.0.0] decan-5-one (Chlordecone)	Agricultural chemicals, Pesticides
8. Hexabromobiphenyl	Flame retardants
9. Tetrabromo(phenoxybenzene) (Tetrabromodiphenyl ether)	Flame retardants
10. Pentabromo(phenoxybenzene)(Pentabromodiphenyl ether)	Flame retardants
11. Hexabromo(phenoxybenzene)(Hexabromodiphenyl	Flame retardants

ether)	
12. Heptabromo(phenoxybenzene)(Heptabromodiphenyl ether)	Flame retardants

* In the Annexes to the Stockholm Convention on POPs, the total of 9 substances were determined to be added to the lists, considering No.1 and 2 as one, No. 9 and 10 as one, and No. 11 and 12 as one.

Table 2: Measures that will become necessary in consequence of the addition of Class I Specified Chemical Substances

Products that are prohibited from import when Class I Specified Substance is used

Class I Specified Chemical Substance	Products*
PFOS and its Salt	Aviation hydraulic fluid
	Treating agent for yarn
	Etching agents for compound metals and semiconductors (excluding high-frequency compound semiconductors that enable radio devices to transmit/receive the frequency of 3 MHz or over);
	Surface treatment agents or additives/adjustment agents for metal plating
	Anti-reflective coating for semiconductors
	Abrasive compound
	Fire extinguishers and fire-extinguishing fluid/foam
	Insecticide (Restricted only to termite and ant control products)
	Printing paper
Tetrabromodiphenyl ether	Paints
	Adhesive agents

Pentabromodiphenyl ether	Paints
	Adhesive agents

Purposes for which Class I Specified Chemical Substance can be used

Class I Specified Chemical Substance	Purposes*
PFOS and its Salt	Manufacturing of etching agents (Restricted only to agents for piezoelectric filters or for compound semiconductors that enable radio devices to transmit/receive the frequency of 3 MHz or over)
	Manufacturing of semiconductor resists
	Manufacturing of photographic films for industrial use

Products that are subject to the technical guideline when Class I Specified Chemical Substance is used

Class I Specified Chemical Substance	Products
PFOS and its Salt	Etching agents (Restricted only to agents for piezoelectric filters or for compound semiconductors that enable radio devices to transmit/receive the frequency of 3 MHz or over)
	Semiconductor resists
	Photographic films for industrial use
	Fire extinguishers and fire-extinguishing fluid/foam

* Applicable only for the time being