Latest Trends on the Enforcement of Chemical Substances Control Law in Japan

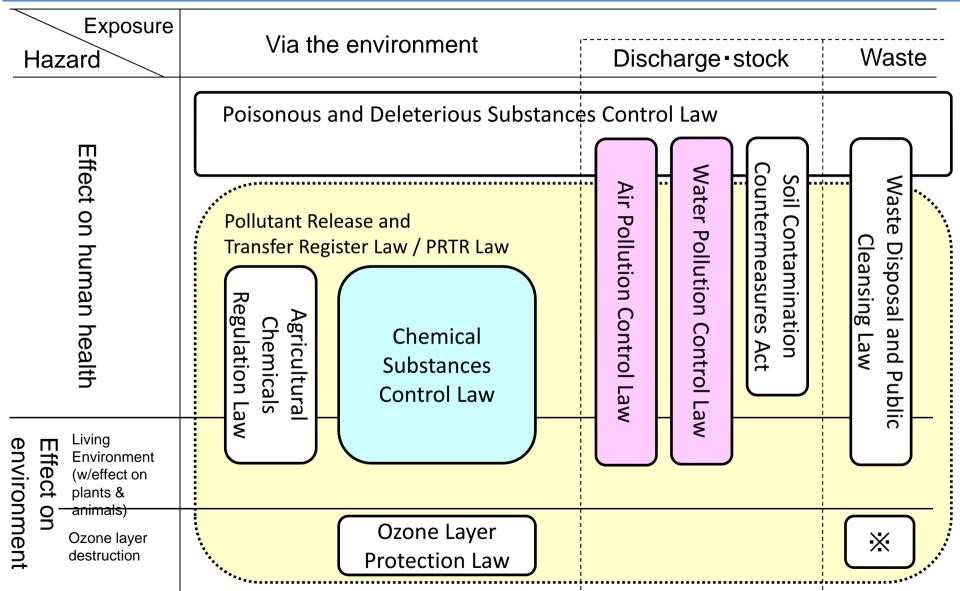
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Table of Contents

- 1. The Chemical Substances Control Law (CSCL)
- Overview
- Evaluation/ verification of new chemicals
- Risk assessment under CSCL
- Response to Class I specified chemical substances
- 2. Pollutant Release and Transfer Register Law ~PRTR~
- 3. The Strategic Approach to International Chemicals Management (SAICM)
- 4. Minamata Convention on Mercury
- Japan Environment and Children's Study (JECS)
- 6. Cooperative Enterprise with respect to Chemicals Management in Asian Countries

Implementation of the Chemical Substances Control Law (CSCL)

Chemical Regulations on chemical exposure via environment in Japan



Measures are undertaken to collect fluorocarbons from particular products under Law Concerning the Recovery and Destruction of Fluorocarbons.

Chemical Substances Control Law (CSCL)

<Purpose>

O To prevent <u>environmental pollution</u> caused by chemical substances that <u>are persistent and pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna</u>.

<Authority>

OJointly authorized by Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI), and Ministry of the Environment (MOE)

<Primary Measures>

Persistence Bioaccumulation Toxicity

- OProhibits in principle manufacturing or use of substances of PBT
- O Restricts manufacturing or use of substances of persistence and long-term toxicity and requires them to be labeled
- O Notifies the production volume of substances that could meet any of above
- Evaluates persistence, bioaccumulation, long-term toxicity, etc. of new chemical substances

Chemical Substances Control Law (CSCL)

<Approach>

(1) Risk

Risk of chemicals are assessed comprehensively from hazard and exposure concentration.

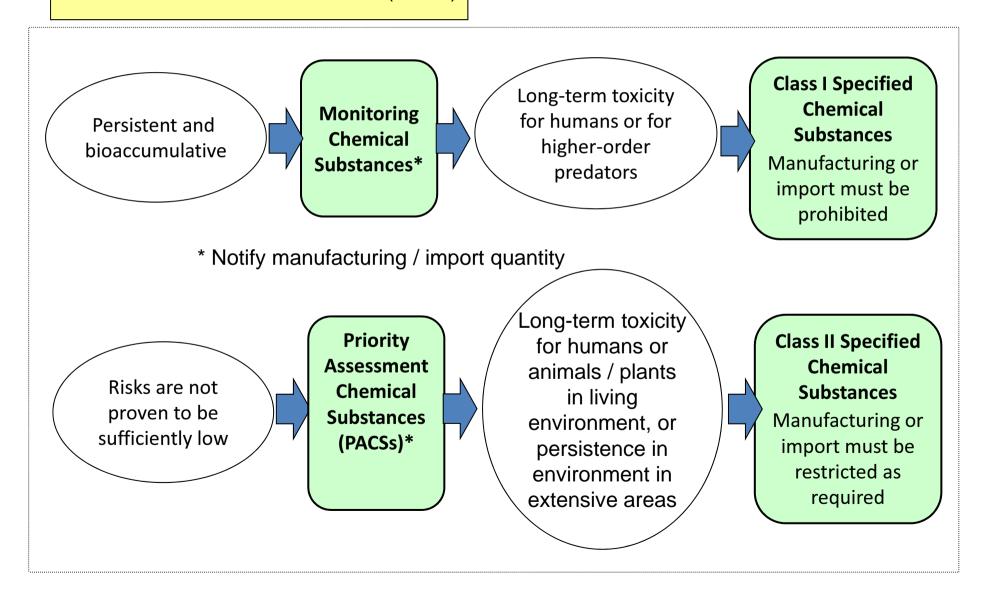


(2) Optimization of the process

A "stepwise assessment" is implemented, due to a great number of substances subject to assessment.

Chemical Substances Control Law (CSCL)

Chemical Substances Control Law(CSCL)

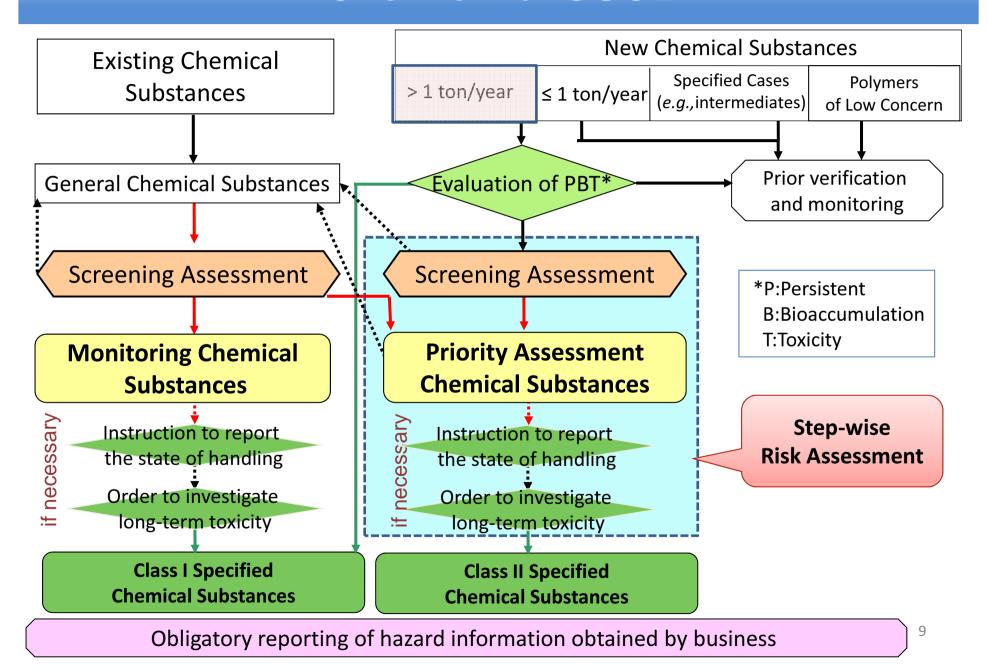


Types of Chemicals regulated under CSCL

Enforced in 2012

Name	Explanation	Quantity
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and toxicity (long-term toxicity for humans or long-term toxicity for predator animals at higher trophic level)	28
Class-II Specified Chemical Substances	Toxicity (long-term toxicity for humans or long-term toxicity for flora and fauna in the human living environment) with concern for a considerable amount of the chemical substance remaining in the environment over a substantially extensive area	23
Monitoring Chemical Substances	Persistent and bioaccumulative, but toxicity properties unknown (Candidates for the Class-I Specified Chemical Substances)	38
Priority Assessment Chemical Substances	 Not found that it is clear chemical substance does not pose long-term toxicity Considerable amount of chemical substance remains in the environment Not thought not to pose a risk 	140
General Chemical Substances	Industrial chemical substances other than those above	

Overview of CSCL



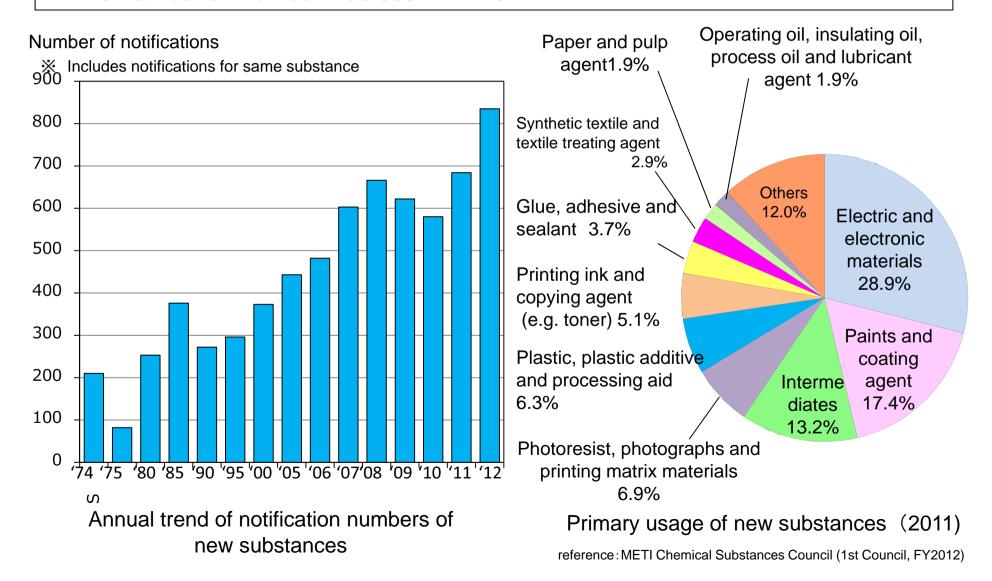
Evaluation/verification of new chemicals

<u>Prior evaluation and judgement</u> is conducted to confirm whether the new chemical substances have following properties, based on report submitted by a manufacturer or importer at the time of manufacturing or importing. New chemical substances is defined as substances which have not been manufactured or imported in Japan.

- ①Degradable: Whether or not it is easily affected chemically in natural process
- 2 Accumulative: Whether or not it is easily accumulated within organisms
- 3 Long-term toxicity to humans: Whether or not it may affect human health through continuous intake
- 4 Eco-toxicity: Whether or not it will affect the habitats or growth of animals and/or plants

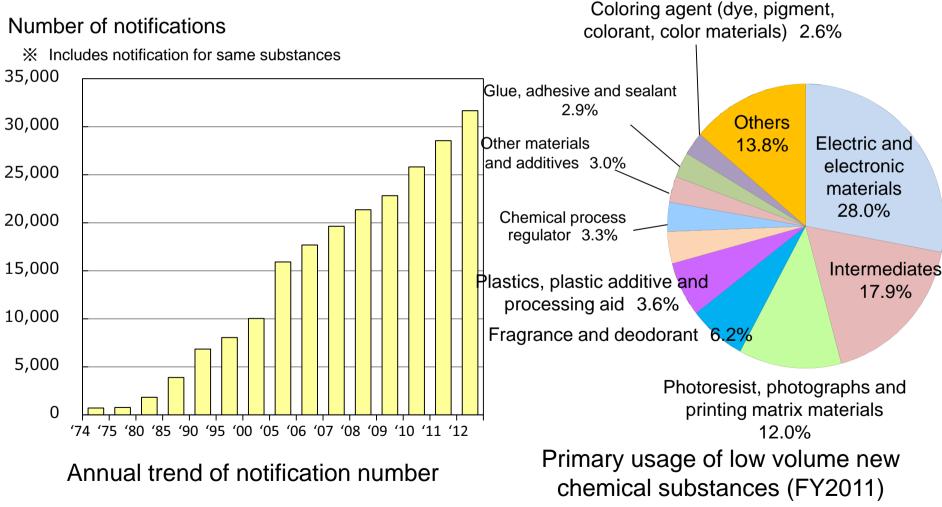
Pre-Evaluation (1) New Chemical Substances

OThe notification number of new chemical substances is in increasing trend. The notification number was 835 in FY2012.



Pre-Evaluation 2 Low Volume New Chemical Substances

O The notification number of low volume new chemical substances was 31,673 in FY2012.

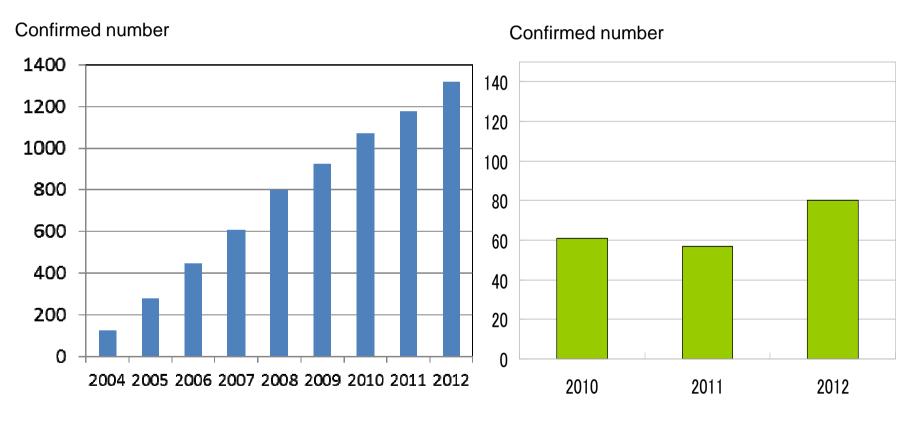


reference: METI Chemical Substances Council (1st Council, FY2012)

Pre-Evaluation 3

Low Production Volume/ Polymers of Low Concern

- O The confirmed number of new chemical substances of low production volume is also in increasing trend. The confirmed number was 1,316 in, FY2012.
- O The confirmed number of polymers of low concern, implemented from April 2010, was 80 in FY2012.



Confirmed number of new chemical substances of low production volume

Confirmed number of polymers of low concern

Step-wise Risk Assessment Based on CSCL

CSCL Chemical Inventory

Existing Chemicals + Evaluated New Chemicals

Notified Chemical Substances

Screening Assessment

Designation of PACSs

Risk Assessment (1st)

Risk Assessment (2nd)

Class II Specified Chemical Substances

Industry's role

- -Notify annual quantity of manufacture etc. (mandatory)
- Submit hazard information (voluntary)
- Notify annual quantity of manufacture etc. with detailed usage (mandatory)
- Submit requested hazard information
- Report requested for handling situations
- Conduct administratively instructed hazardous properties study (long-term toxicity tests) (mandatory upon instruction)
- -Notify planed annual quantity of manufacture etc.
- -Technical guidance for use etc.

^{**}Risk Assessment Scheme is under consideration in external committee of 3 Ministries

(1) Screening Assessment

【Human Health】

• Classified into hazard class by general toxicity, reproductive and developmental toxicity, mutagenicity, and carcinogenicity.

[Ecological]

Class

Exposure

•Classified into hazard class by eco-toxicological test data (algae, crustacean, fish).

Hazard Class

Class₁ Class2 Class3 Class4 اس: ال Class₁ High High High Designated as PACSs Hig Class2 High High Class3 High Medium Medium High Class4 Medium High Designated as Low Risk Class5 Medium Medium

[Physicochemical]

- Notify annual quantity of manufacture etc.
- Estimation of Total annual quantity of manufacture (every year update)

esignation of PACSs

Remain to General Chemical Substances

(Exposure class will be Update and screening every year)

1 Screening Assessment Result by Exposure Class

Evaluated substances of 7,819 (Substance over 10 t of manufacturing & import quantity, among 11,979 substances that have been reported)

In respect to hazard assessment		Human Health (number of substance)	Ecological (number of substance)	
Exposure class (Definitive value of the FY2012)	1	14	11	
	2	67	48	
	ფ	322	220	
	4	744	551	
	15	1,336	988	
	out	5,336	6,001	

O Exposure Class is attributed, by adding degradability to the National Total Discharge, which is estimated from the amount of manufacture/import notified by business entities, usage classification, and emission factor of screening assessment.

2 Collection of Hazard Information & Attribution of Hazard Class

- Toxicological information of general chemical substances are collected from 7,819 substance exceeding 10t of import and manufacturing volumes.
- Based on the "Screening assessment methods in CSCL", hazard class are attributed. Confirmation of reliability is based on the following documents.
 - · "The Reliability evaluation of hazard data on the human health effects in the CSCL"
 - · "The reliability evaluation of hazard data on the ecological effect in the CSCL"
- So far, the government has conducted information-gathering on general chemicals for screening assessment, but a call for hazard information from the business entities will be asked, further.

3 Screening Assessment Results

	2010 FY (deliberation on January 2011)		2011 FY (deliberation on January 2012)		2012 FY (deliberation on July 2012)		2013 FY (deliberation on July 2013)	
	Human Health	Ecological	Human Health	Ecological	Human Health	Ecological	Human Health	Ecological
Substance Classification of Evaluation	Type II Monitoring Chemical Substance	Type III Monitoring Chemical Substance	Chemicals		General chemical substance of all that had reported			
Exposure information	Record of 2009 FY		Record of 2010 FY		Record of 2010 FY		Record of 2011FY	
Hazard Information	Judgment basis of Type II & III Monitoring Chemical Substance		Judgment basis of OECD/HPV		Collected data that the reliability was confirmed			
Substance for evaluation	682	212	109	275	10,792		11,979	
Quantity of imports and production (over 10 t)	447	166	101	188	7,054		7,819	
Corresponding Priority	88		8	8	4	-6		40
Assessment Chemical Substances	75	20	6	4	31	21	17	23

4 Designated Priority Assessment Chemical Substances

 Designated Priority Assessment Chemical Substances are 140 (As of March 2013)

In deliberation of July 2013, 40 substances have been prepared for public notice as priority determination corresponds.

Public site for notice

(English ver.)

J-CHECK (Japan Chemicals Collaborative Knowledge Database) http://www.safe.nite.go.jp/jcheck/list7.action?category=230&request_locale=en

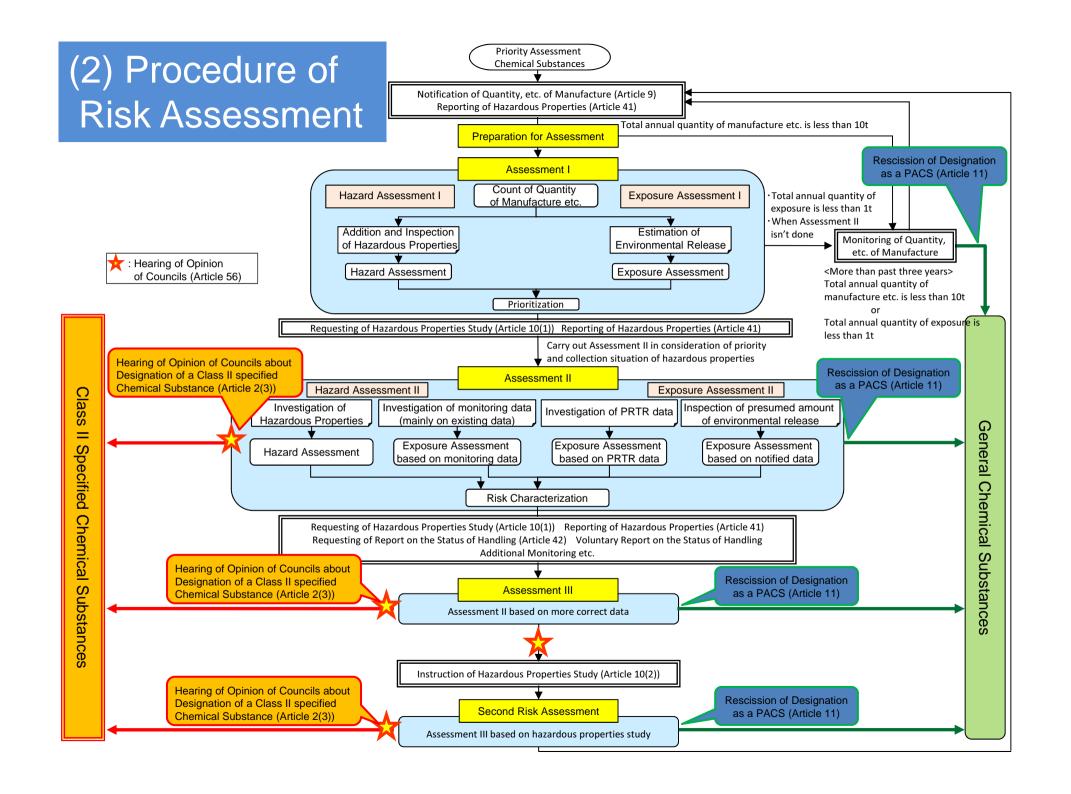
NITE CHRIP

http://www.safe.nite.go.jp/english/sougou/view/IntrmSrchYusenList_en.faces

(Japanese ver.)

Website of Chemicals Evaluation Office, MOE

http://www.env.go.jp/chemi/kagaku/kisei/yuusen.html



① Risk Assessment (1st)

Risk Assessment (1st) is composed of three stages referred as the Assessment I, II, or III.

<Assessment I >

Hazard assessment uses the same information as the screening assessment. Exposure assessment uses only the notified information of production and import volume, etc.. From these results, the priorities for implementing the Assessment II are determined.

<Assessment II >

The hazard assessment is performed by collecting additional toxicological information. The risk assessment of Exposure Assessment is performed by increasing the coverage. The recorded monitoring data and PRTR data in past is also utilized. From these data, risk assessment is carried out, and the direction of hazard investigation or the appointment to Class II Specified Chemical Substance is determined immediately. If there is no optimal decision, Assessment III is applied.

<Assessment III >

The risk assessment is conducted in detail using handling information and additional monitoring data. The necessity of direction of hazard investigation is determined.

② Assessment I of Risk Assessment (1st)

All Priority Assessment Chemical Substances subject to assessment

- Notified information on Priority Assessment Chemical Substances under Article 9 (i) of CSCL (quantity manufactured or imported, applications, etc.)
- Information on hazardous properties used for screening assessment

Assessment I of Risk Assessment (1st)

Hazard Assessment

The Hazard Assessment Value for the endpoint subject to screening assessment is derived using the same uncertainty factor as that used in screening assessment

Exposure Assessment

Virtual emission sources by prefecture, life cycle stage and application are assumed according to a series of assumptions regarding emissions, on the basis of the quantity manufactured and delivered that has been notified by business operators

The emission factor is estimated by multiplying by detailed use class

=>

=>

Environmental concentration or human intake is estimated according to a series of assumptions concerning exposure

<Indices>

Human: Number of emission sources nationwide at possible risk and total affected area nationwide at possible risk

Ecology: Number of locations at possible risk

3 Assessment I of Risk Assessment (1st)

< Result of 2013 FY >

Prio	rity Assessment Chemical Su	bstances (Specified by FY2011)	95
,			79
	Target for Assessment I	Substance to undertake the Assessment II form 2013 FY	Total : 8 Human health : 1 Ecological : 7
	of Risk Assessment (1st)	Substance not applicable substance to the above & continually subjected to Assessment I next year	62
		Substance for Assessment I next year; production volume survey conducted for the time being (National estimate emissions below 1t)	6
	Substance for Assessment I next year time being(Nationwide total value le	2	

Ref. < Completion result of evaluation II>

Substances for Assessment II from FY2012 18 (HH: 11, Eco: 7)

Starting Substance of Assessment II of Risk Assessment (1st)

18 Substances for 2012 FY

< Human health effects (11 substances) >

- Hydrazine
- 1,3 butadiene
- Dichloromethane
 1,2 dichloropropane
- Chloro ethylene
- Ethylene oxide
- 1,2 epoxypropane
- Formaldehyde
- Acrylonitrile

Benzene

o o-toluidine

<Ecological effect (7 substances)>

- 1,3 dichloropropene
- o n-butyl acrylate
- isopropenylbenzene
- o p-dichlorobenzene
- Initiative 2,6-di-tert-butyl-4-methyl phenol
- [3-(2-ethylhexyl) propyl amine] triphenyl boron (III)
- 4,4 '- (propane-2,2-diyl) diphenol (bisphenol) A)

8 Substances for 2013 FY

< Human health effects (1 substance) >

○ N, N-dimethylformamide

<Ecological effect (7 substances)>

- Hydrazine
- Bromomethane (Methyl bromide)
- 1,2,4-Trimethylbenzene
- Naphthalene
- α-(nonyl phenyl)-ω-Hydroxy poly (oxyethylene) (also known as poly (oxyethylene) nonyl phenyl ether)
- Hydrogen peroxide
- Acrylic acid

5 Assessment II of Risk Assessment (1st)

Assessment I: Risk Assessment (1st)

OPrioritization of risk assessment utilize only the notification of production and import volume, as exposure information.



Request of handling information, Additional monitoring, etc.

Assessment III: Risk Assessment (1st)

Directions of hazard survey

Risk assessment (2nd)

Specification for Class II Specified Chemical Substances

Cancellation of specifying of Priority Assessment Chemical Substances

Hazard Assessment

Collecting additional already-known information, scrutinying individually, selecting Keystudy, and evaluating benthic organisms in addition to aquatic organisms (algae, crustaceans, fish)

Exposure Assessment

Implement exposure assessment using environmental monitoring data and the PRTR data in addition to the notification information, such as production volume

POPs Convention

(Stockholm Convention on Persistent Organic Pollutants)

POPs...

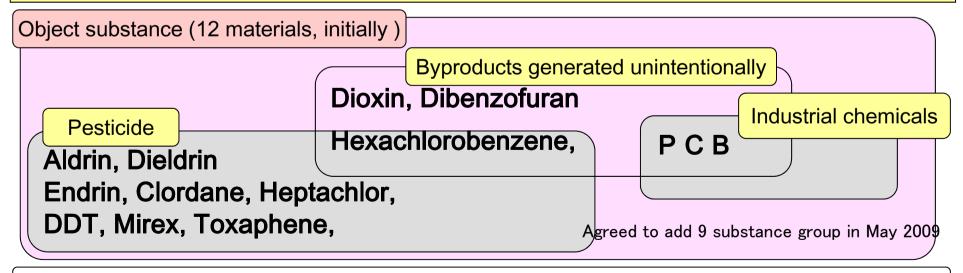
- **1**Toxic
- ②Hardly decomposable
- ③Accumulated
- 4 Long-distance transferable



International effort is required for pollution prevention.

To prevent contamination by POPs, elimination and reduction of POPs is required through international cooperation,

- OAdopted in May 2001; Japan concluded in August 2002. It entered into force in May 2004.
- The conference of the parties has been held six times so far, every two years.
- oProfessional and technical issues are discussed at Persistent Organic Pollutants Review Committee (POPRC).



Japan has developed a national implementation plan for implementing the Convention.

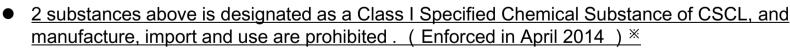
Substances that had been added to Annex A of COP5 and COP6

Matters determined in COP5

Substance	Primary use	Remarks		
Endosulfan and its isomer Pesticide		Prohibition of the manufacture, use, etc.		
	CI C	(Exception: production and use of pesticides for insect pests to in a particular crop)		

Matters determined in COP6

Substance	Primary use	Remarks
Hexabromocyclododecane, 1,2,5,6,9,10 – hexabromocyclododecane and its main isomer	Flame retardants	 Prohibition of the manufacture, use, etc. (Exception: production and use of beads method-expanded polystyrene foam and extruded polystyrene foam for construction)



 Import of products containing HBCD (flame-proof fabric flame curtain textiles flame-retardant treatment drug, and flame-retardant EPS beads) will be prohibited based on the CSCL Law (Enforced in August 2014).

* Based on Agricultural Chemicals Regulation Law, the production and sales of agricultural chemicals are already prohibited for endosulfan.

Overview of the 6th ordinary meeting of the Conference of the Parties (COP6)to the Stockholm Convention on POPs

ODate: April 30 to May 2, 2013

OLocation: Geneva (Switzerland)

OOutcome of the meeting

- Listing of chemicals in Annex A to the convention(new POPs substance)
 - →Hexabromocyclododecane (HBCD) was listed to Annex A to the convention.
- Assessment of alternatives to the use of PFOS, its salts, and PFOSF
 - →Further evaluation of alternatives to PFOS, its salts, PFOSF at the POPRC.
- Work Plan for specific exemptions and acceptable purposes
 - → Process for the evaluation of the continued need for the various acceptable purposes and specific exemptions is adopted (PFOS and Bromodiphenylether).
- Effectiveness evaluation
 - →Revised framework for effectiveness evaluation and the global monitoring plan for persistent organic pollutants were adopted .

OCOP7: May 2015 in Geneva (Switzerland)

Stockholm Convention, Basel Convention, Rotterdam Convention(three COPs)
 will be held jointly.

Outcomes of The Persistent Organic Pollutants Review Committee (POPRC-9) (Oct.14-18 2013) and Japan's responses

- Chlorinated naphthalenes (CN) and hexachlorobutadiene (HCBD):
 decides to recommend for consideration by the Conference of the Parties for listing in Annexes A and C to the convention.
- →In Japan, CN (with more than three chlorine) and HCBD are designated as Class I Specified Chemical Substances under CSCL.
- Pentachlorophenol and its salts and esters: decides to prepare a risk management evaluation that includes an analysis of possible control measures for pentachlorophenol and its salts and esters.
 - →In Japan, sales and use of PCP as an agricultural chemical is banned
- Decabromodiphenyl ether: decides to fulfill the screening criteria and prepare a risk profile to review the proposal further.
- →In Japan, Deca-BDE is designated as Class I Designated Chemical Substance.under the PRTR law.
- Dicofol: decides to place the proposal on the POPRC-10 agenda for further consideration.
- →In Japan, dicofol is designated as Class I Specified Chemical Substances under 29 CSCL.

The risk assessment of PCB as a byproduct in the organic pigments

It was identified that organic pigments contain a small amount of unintentional byproduct-PCB, on February, 2012.

PBC contents included in organic pigments (Survey of 588 items)

PCB (ppm)	<0.5	0.5-1	1-5	5-10	10-15	15-20	20-25	25-50	>50	Total
Items	359	51	89	29	13	7	10	13	17	588

^{*}Organic pigments which contain over 50ppm of PCB was found in 17 items. For these items, shipping manufacturing, and import was already stopped.

Study on environmental pollution and impact on consumer

Risk Assessment Study Group on the PCB as a by-product in the organic pigments (Mar, 2012 -- Mar, 2013)

- The experts discussed about the impact of the health on consumers due to the continued use of the product in which the pigment and the impact on the ecosystem and people through the pollution of the environment has been used.
- It was concluded that risk to ecological and human health via the environment is low except for extreme cases.
- Study on the level capable of reducing PCB, industrially and economically (Jul, 2013--)
- The level capable of reducing PCB as a by-product in organic pigments, industrially and economically, will be considered by referring to the expert opinion.

2. Pollutant Release and Transfer Register Law ~ PRTR ~

PRTR System

- O PRTR (Pollutant Release and Transfer Register) System
 - : Registration / Announcement systems of hazardous chemicals discharged amount to environment and migration amount contained in waste material.
- O It takes much time for the determination of threshold (standard value) and risk evaluation.
 - → Effectively reduce the discharge of [Gray Substance]
 - Voluntary management by business operators, information disclosure to nations and utilization by the public administration
- Preceded by U.S.A and Netherlands (Framework and main purpose are different depending on countries) → In Japan, Legislated in 1999. (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof): (Co-Jurisdiction by the MOE and METI)

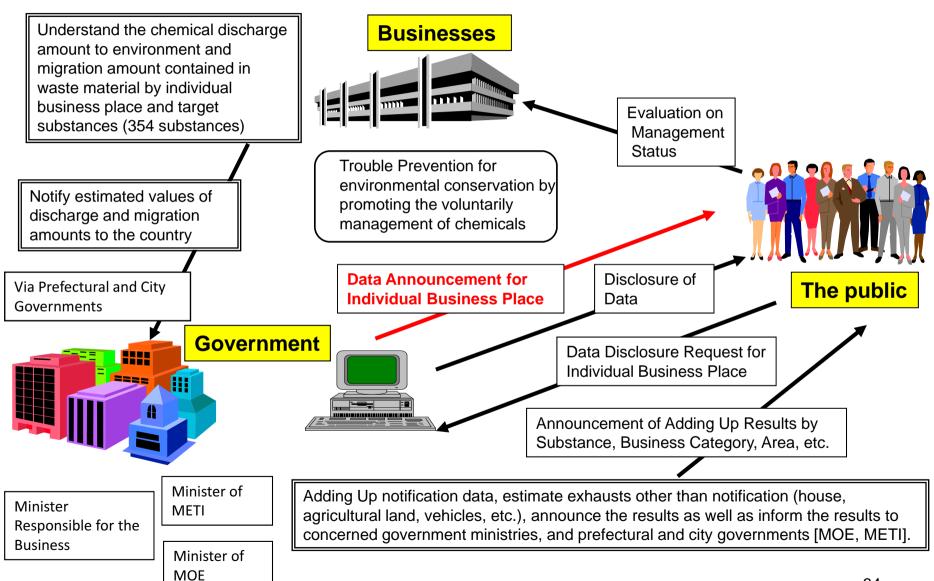
PRTR System (continued)

O PRTR System in Japan

- Purpose: Promoting the voluntarily management improvement by business operators

 Trouble Prevention for Environmental Conservation
- Target Chemicals: 354 substances \rightarrow 462 substances (started since FY2010)
- Target Business Operators: Handling Business Operators (Defined by business category / size)
- Notification of discharge amount / migration amount by the target business operators
- Estimation of discharge amount from other exhaust sources (small size business place, non-target business category, family and mobile object) by the country
 - ightarrow Adding Up and Announcement. Individual notification data has been announced since this year
- O Delivery system for MSDS (Material Safety Data Sheet) is also incorporated.

Institution of PRTR System



Trend of Notified Discharge Amount / Migration Amount, FY2003 ~ 2011

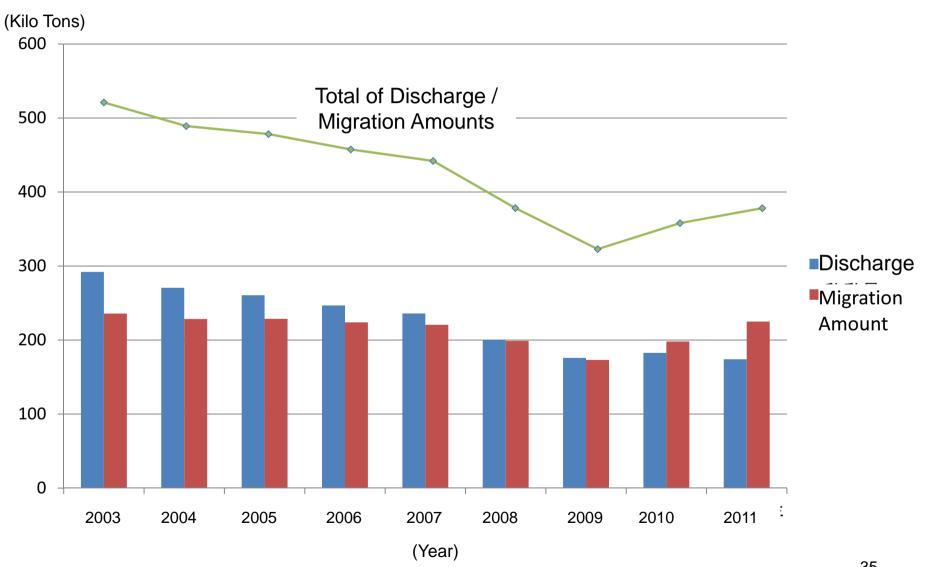
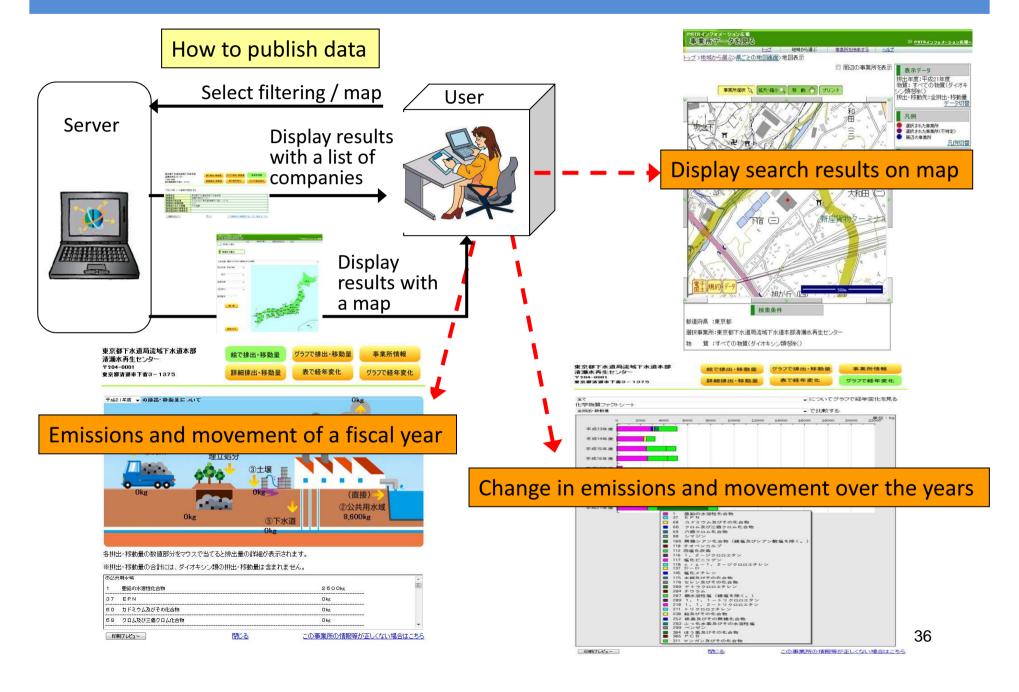


Image of the System to Display PRTR Data on Maps



Purpose of PRTR and Data Utilization Examples

Purpose of PRTR	Utilization Examples of PRTR Data (Future utilization schedule included)			
[1] Basic Data for Environmental Conservation	 Let the PRTR Discharge Amount Data to be the benchmark toward undertaking the promotion of chemical sector Use as basic data when reviewing various political measures such as system for industrial waste subject to special control, etc. 			
[2] Priority Decision for Chemicals Countermeasure by Administration	 ○ Used for the environment risk evaluation of chemicals ○ Used for the selection of target substance / target place for environment monitoring ○ Used for the risk evaluation of monitoring chemicals based on CSCL 			
[3] Promotion of voluntary management by business operators	 Provision of tools such as the estimation of environment concentration around business offices to business operators. Used as business operator instruction material at local public entities 			
[4] Provision of information to nationals and enhancement of understanding regarding chemicals	 Announce the adding up results of data and post them on the web. Prepare map information on discharge amount and estimated atmospheric concentration and post them on the web. Prepare a guidebook for citizens and chemical fact sheet in which PRTR data is utilized. 			
[5] Understanding of effect and progress status of environment countermeasure	 Understand the countermeasure situation regarding the reduction of priority undertaking substance of Air Pollution Control Act with monitoring data and PRTR data. 			

Introduction of GHS in Japan

- ➤ Promote activities including organizing liaison conferences among relevant ministries and agencies, setting the JIS standards of GHS classification methods and providing governments' classification of substances.
- Classification by governments:
- Approx. 2500 substances were classified between FY2005 and FY2011 (further classification is currently in action).
- Classification results are made available to the public:

http://www.safe.nite.go.jp/ghs/list.html (Japanese)

Systematic Revision to Introduce GHS

- Improve Japanese Industrial Standards (JIS)

 JIS Z7250 (MSDS) and Z7251 (Indication) are integrated to establish JIS Z7253, the common base of "communication" on the basis of the GHS with newly added indications in workplaces (March 25, 2012).
- Revise Ministerial Ordinance of the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
- ✓ Enlarge items listed in SDS to 16 items appropriate for the GHS (effective on: June 1, 2012 for pure substances and mixtures)
- ✓ Add a new obligation to make efforts for label indication (effective on: June 1, 2012 for pure substances; April 1, 2015 for mixtures)
- ✓ Add a new obligation to provide SDS and labels by means appropriate for the GHS (effective on: June 1, 2012 for pure substances; April 1, 2015 for mixtures)
- Revise the Ministerial Ordinance of the Industrial Safety and Health Act, etc. as well. SDS and labels compliant with relevant laws and appropriate for the GHS may be created and provided by conforming to JIS.

3. The Strategic Approach to International Chemicals Management (SAICM)

SAICM: History to Adoption

- 1992 "Agenda 21" adopted at Earth Summit (Chapter 19: Management of toxic chemicals)
- 1994 Intergovernmental forum on chemical safety established

Sep 2002 Implementation Plan on sustainable development for World Summit

- Aim 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.
- → Decide to develop the strategic approach (SAICM) for the above by 2005
- 2003 ~ 2005 Three times of preparatory meeting, Regional meetings in five regions of the world, etc.
- Feb 2006 <u>SAICM adopted at International Conference on Chemicals</u>
 Management (ICCM)

Actions to SAICM (Past and Prospect)

- May 2007 Asia-Pacific regional meeting (Bangkok)
- 2009 ICCM2

Review of SAICM implementation

- → Further chemicals management in developed countries
- → Support and fund to developing countries
- → Actions to emerging policy issues including chemicals in products, nano materials, etc.

Settle on further actions in countries and international organizations

- Nov 2009 Sep 2011: Asia-Pacific regional meeting (Beijing)
- 2009 ~ 2012 Chairmen corps meeting (multiple times)
- Nov 2011 Open-ended working group for preparation of ICCM3
- Sep 2012 ICCM3
- 2015 ICCM4

Follow-up of SAICM implementation

- 2020 ICCM5



Minimize the significant adverse effect of chemicals to health and the environment by 2020.

Japan's activities related with SAICM

O Domestic activities

- Promote a variety of individual measures (Revision of Chemical 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)
- Set up a liaison meeting at relevant Ministries and Agencies
- Place the 2020 goal and SAICM in the Basic Environment Plan
- Formulate the <u>SAICM national implementation plan</u> (11th Sep, 2012)
- Policy dialogue on chemical substances and environment

International activities

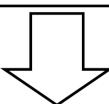
- ICCM Vice Chairperson as representative of Asia-Pacific Region
- Support Thailand and Bhutan for the Quick Start Program (in-kind QSP)
- Participate in the activities such as workshops related to emerging policy issues, etc.

SAICM National Implementation Plan (Nov.2013)

[Conventional measures and issues in chemicals management]

- Promotion of chemicals management with international viewpoint pursuant to SAICM
 - ➤ Implementation of chemicals management in each field, such as the environment (Basic Environment Plan, Law Concerning the Examination and Regulation of Manufacture, etc of Chemical Substances, Law concerning PRTR, etc.), labor safety and hygiene, and safety measures for household appliances
- ●On the other hand, measures to deal with anxiety of the citizens for the safety of chemicals, and further coordination, reinforcement, etc. in each measure of risk assessment and management are demanded.

Involvement of various stakeholders (Discussion in Policy Dialogue on Chemicals and the Environment)



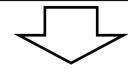
Reflection of opinions from all levels of civil society (Implementation of Public Consultation)

Development of SAICM National Implementation Plan Comprehensive strategies regarding chemical substances

(Developed by the liaison meeting among relevant Ministries and Agencies)

- Promotion of science-based risk assessment
- Risk reduction throughout whole life-cycle
- Response to emerging and uncertain issues
- Strengthening of safety and security
- Promotion of international cooperation and coordination
- Issues to be examined in the future

Review of the progress of the Plan and its announcement prior to ICCM4 to be held in 2015



Amendment, if necessary, reflecting the discussion in ICCM

Towards Achievement of WSSD2020 Goal

SAICM implementation plan of Japan 6 pillars of Actions (1)

- 6 main actions ~ Concrete action items
- Promotion of science-based risk assessment
- Risk reduction throughout whole life-cycle
- Response to emerging and uncertain issues
- (4) Strengthening of safety and security
- (5) Promotion of international cooperation and coordination
- (6) Issues to be examined in the future

(1) Promotion of science-based risk assessment

- O Promote efficiently scientific risk assessment and develop a new method and make it in practical use.
 - Take actions based on Chemical Substances Control Law, Agricultural Chemicals Regulation Act, and Industrial Safety and Health Act
 - Utilize QSAR or Category Approach

- Perform POPs and monitoring of heavy metals, etc.
- Set the environmental target, upgrade of the quantitative evaluation method for setting the environmental target, etc.

(2) Risk reduction throughout whole life-cycle

- O Further promote the risk reduction measures based on the results of the risk assessment
- O Risk reduction in the whole life-cycle of chemicals and a proper combination of various means
- Actions based on Chemical Substances Control Law, Industrial Safety and Health Act, and Act on Control of Household Products Containing Harmful Substances
- Measures against the environmental emission

- Operation of the PRTR system
- Actions related to the products recycling or the disposal stage, etc. Actions for accidents and disasters, etc.

Action Items (2)

(3) Response to emerging and uncertain issues

- O Right actions for the unsolved problems including the following problems that require the efforts based on the thought of preventive measures
- O Actions considering the influence of the exposure to chemicals on the health of the group who are vulnerable or have great sensitivity to chemicals.
- Ecology children survey

- Actions for endocrine disruption of chemicals
- Study on the complex influence of chemicals
- Actions for nanomaterials
- Research for the influence of the minimum amount of chemicals on human health

(4) Strengthening of safety and security

- O Continual performance of various monitoring, etc. as a basis for ensuring safety and security on chemicals
- Conduct various environmental surveys and monitoring
- Further promotion of risk communication
- Promotion of taking actions for chemicals in products

Action Items (3)

(5) Promotion of international cooperation and coordination

- O Management of chemicals in line with SAICM from the global aspect in collaboration among the relevant Ministries and Agencies and contribution to the international performance of SAICM
 - Promote actions based on POPs (Stockholm convention on Persistent Organic Pollutants)
 - Participate in OECD, etc.
 - Collaborate globally on the Ecology and Children survey.
 - Cooperation with the regions in Asia.

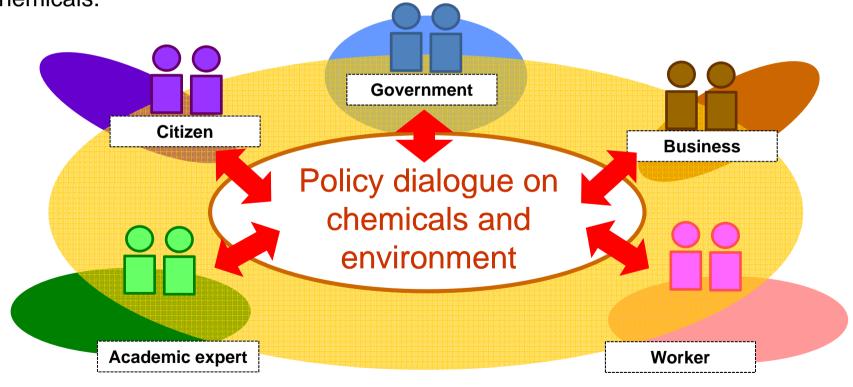
(6) Issues to be examined in the future

- O With regards to the various topics we take its emergency and social requirement into consideration, in light of the discussions in "Policy Dialogue on Chemicals and Environment" where various entities participate and exchange their opinions, examine them in their priority levels, and promptly implement it once it becomes possible for that.
 - Actions for emerging policy issues of SAICM (chemicals in products, nanomaterials, e-waste, lead in paints)
 - Actions for the so-called "sick-house" issues
 - Biocide

Policy Dialogue on Chemicals and Environment

 All relevant sectors and stakeholders should be involved in the decision-making processes to ensure transparency and accountability.

O Policy dialogue was set up in March 2012 as a site where the relevant entities exchange opinions on chemicals and environment for consensus formation. It aims at making policy proposals for securing the people's safety and security against the chemicals.



continue discussions on progress of the SAICM implementation plan.

Chemicoco: Chemical Information Retrieval Support System

Chemicoco is a search tool for chemicals information. (Japanese only)
Users can access directry to reliable chemical information! app.2200 substances linled.



URL: http://www.chemicoco.go.jp/

Manufactured Nanomaterials

MOEJ's activities

- Publication of MOEJ's guidelines for preventing environmental impacts from manufactured nanomaterials (MNs) (March 2009)
- Projects for attempts to verify the validity of current control measures (FY 2009-2010)
- Refocused to hazard identification and monitoring of MNs in the environment (FY 2011-)
 - Evaluation of existing studies on ecotoxicity of MNs
 - Development of methodology for measurement of MNs aiming at monitoring MNs in the environment

Association with activities by OECD

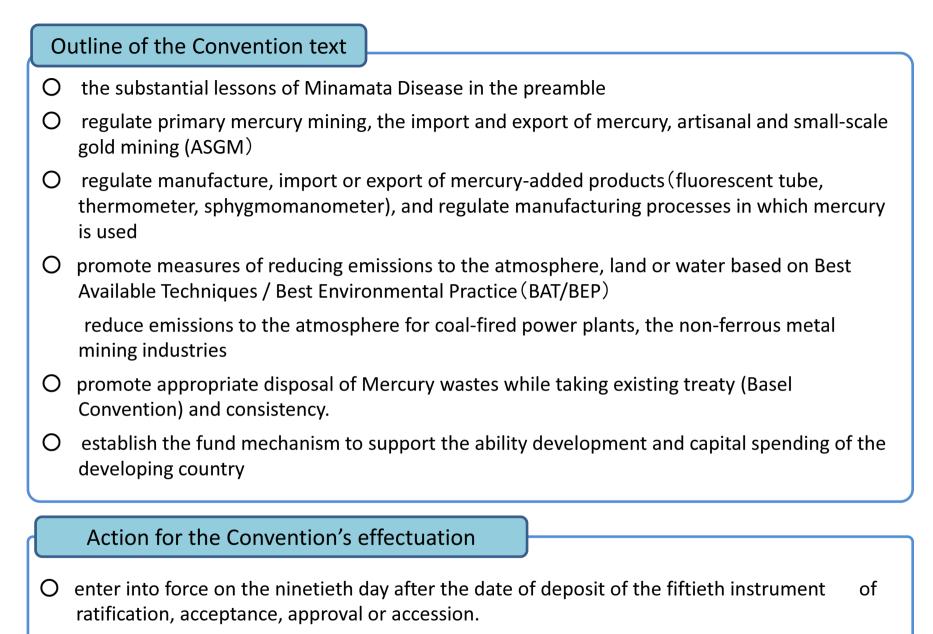
 Participation into discussion under the Working Party on Manufactured Nanomaterials (WPMN) of OECD programme

4. Minamata Convention on Mercury

Minamata Convention on Mercury

Process to adoption

- O UNEP started its program for Global Mercury Assessment and Management in 2001
- O February 2009, UNEP GC Decision 25 agreed to commence Negotiations in 2010 and aim at the adoption of the Convention by 2013
- O June 2010, Intergovernmental Negotiating Committee(INC1) was held, and held five times of INC until 2013
- O January 2013, agreed upon the "Minamata Convention on Mercury" texts in INC5
- October 2013, The Conference of Plenipotentiaries on the Minamata Convention was held in minamata and kumamoto
 - > more than 1000 people including about 60 ministers and other governmental representatives from 139 countries and area
 - ➤ adopt Minamata Convention on Mercury unanimously and start a signature. 92 countries and area signs the Convention .



hold the first Conference of the Parties (COP1) within one year.
 The UNEP secretariat mentioned aiming at the Convention's effectuation of 2016, in the Conference of Plenipotentiaries

5. Japan Environment and Children's Study (JECS)

Japan Environment and Children's Study(JECS)

Core Hypothesis · · · Chemical exposure during the fetal and infant stages adversely effects children's health and development.

Method · Target : Birth cohort study, 100,000 subjects.

Term: 16 years (recruitment 3 years, data collection 13 years) possibly longer.

Funding: 3.1 billion yen (\$ 31 million) in FY 2010

4.6 billion yen (\$ 46 million) in FY 2011

6.1 billion yen (\$ 61 million) in FY 2012

6.1 billion yen (\$ 61 million) in FY 2013

Prospective Results :

- (1) Identify environmental factors impacting children's health and development.
- (2) Develop better risk management specifically addressing children's health.
- (3) Ensure a sound environment where future generations lives.
- (4) Promote children's environmental health studies.



Chemical exposure during the fetal and infant stages adversely effects children's health and development.

(Exposure)

Chemicals in the Environment

POPs (dioxins, PCBs, organofluoric compounds, flame retardants, etc.), heavy metals (mercury, lead, arsenic, cadmium, etc.), endocrine disruptors (bisphenol A, etc.), agrichemicals, VOC (benzene, etc.), etc.

Genetics

Socioeconomics

Lifestyle

(Effect)

Physical Development:

Low birth weight, development after birth, etc.

Congenital Anomalies:

Hypospadias, cryptochidism, cleft lops, cleft palate, spina bifida, etc.

Sexual Differentiation:

Sex ratio, genital development impairment, sexual differentiation of the brain, etc.

Psychoneuro developments:

Autism, learning disorders, AHDH (attention-deficit hyperactivity disorder), etc.

Compromised Immune System:

Pediatric allergies, atopic eczema, asthma, etc.

Endocrine / Metabolic Abnormalities:

Lowered glucose tolerance, obesity, etc

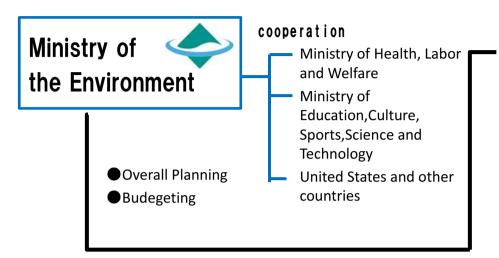
Research Flow

Enrollment 100,000 pregnant women

Informed consent Early Pregnancy Questionnaire Long-term Storage Collect mother's blood and urine Mid to late (Specimen Bank) samples pregnancy Evaluate at health condition of baby **Measure Chemical** at birth **Substances** Collect cord blood samples At birth Collect parent's blood samples and mother's hair Collect baby's dried blood sample **Analyze Results** Collect breast milk 1 month old Collect baby's hair 6 months to Questionnaire (every 6 months) **Statistical Analysis** 12 years old Environmental measurements

Identify environmental factors affecting children's health

Organization





Local Governments

cooperation

- Outreach to increase citizens awareness and participation
- Assist recruitment through the Mother-Child Health Handbook
- Provide administrative data based on applicable laws



Cooperating Local
Medical Institutions
(Hospitals and Clinics)

 Register study participants (expectant mothers) and collect biological specimens at the request of the regional centers.



National Center(National Institute for Environment Studies)

- Implementation body
- Data systems management,
 specimen storage, and accuracy control
- Support and oversight of Unit Centers



Medical Support Center (National Center for Child Health and Development)

- Providing medical support
- Support protocol writing relating to the outcome measurement
- Guidance and support for health care professionals involved in the study



Regional Centers (15 locations nationwide)

- Recruit study participants and conduct follow-up until 13 years old
- Collect biological specimens and implement questionnaire program
- Communicate with participants through individual consultation services

6. Cooperative Enterprise with respect to Chemicals Management in Asian Countries

日中韓化学物質政策ダイアローグ

O2006, December

In 8th Tripatite Environmental Ministries Meeting among Japan, China, Korea Upon receiving the agreement on "promotion of information exchange on policiec and regulations on chemical management.

O2007,

The First Tripartite Policy Dialogue on Chemicals Management among China, Japan, and Korea

Purpos:

- Different situation in three countries should be recognized;
- Long-term co-operation should be set up based on common interests; and
- Co-operative activities should include the elements of capacity building, collaboration and efforts for harmonization

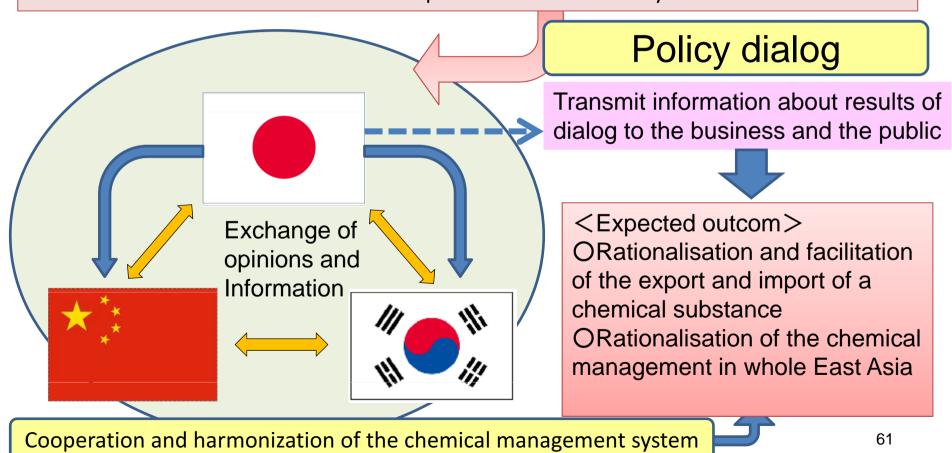
The 7th Dialogue has been held since Fiscal year 2007.

H19	H20	H21	H22	H23	H24	H25
JAPAN	KOREA	CHINA	JAPAN	KOREA	CHINA	JAPAN
(Tokyo)	(Seoul)	(Beijing)	(Tokyo)	(Jeju)	(Hangzhou)	(Kyoto)

For the harmonization of the chemical substance policy among China, Japan and Korea

We has been a dialog about chemical management with China and Korea which are closely related to Japan about chemical management.

The export and import of the chemical substance are performed frequently with in the East Asia area (Mainly, China, Japan and Korea). Especially, proper management of the chemical substance within East Asia is important for each country.



Training Seminar in Asia (Viet Nam) for Enhancing the Ability of Handling Chemicals

[Summary]

Purpose:

To promote an improvement of a capacity of chemical management and to strengthen chemical management in Asia.

Major agendas:

- Current status and problems of environmental pollution in Viet Nam
- Knowledge and experience of Japan on chemicals management
- Risk assessment methods of chemical substances



Place: Hanoi, Viet Nam

Date: 1 st, 16th February, 2012 / 2 nd, 7th March, 2013

Participants: Departments of Ministry of Natural Resources and Environment, Department of Natural Resources and Environment from local governments, etc. Approximately 30 people

Project for the Development of Basic Schemes for PRTR System in Kingdom of ¶hailand

Project by: JICA, MONRE, MOI

Place: Kingdom of Thailand Rayong province

Term: 2011~2014

Contents: the Development of Basic

Schemes for PRTR System





プロジェクトのホームページ:

The Network for strategic Response to International Chemical Managemant

Purpose

The Network for strategic Response to International Chemical Management was established on July 26, 2007. All organisation can participate in the network as long as it arranges to network's objectives.

Activities

Osharing of information and strengthening of cooperation. Hold a seminars was consisted of lectures from administrator from overseas, column, mail magazine.

Participants

OAs od October 2nd, 2013 Number of organizations:313



Thank you for your attention.