Latest Development of Chemical Substances Control Law in Japan

November 13th, 2014
Open Seminar on Chemicals Management Policies

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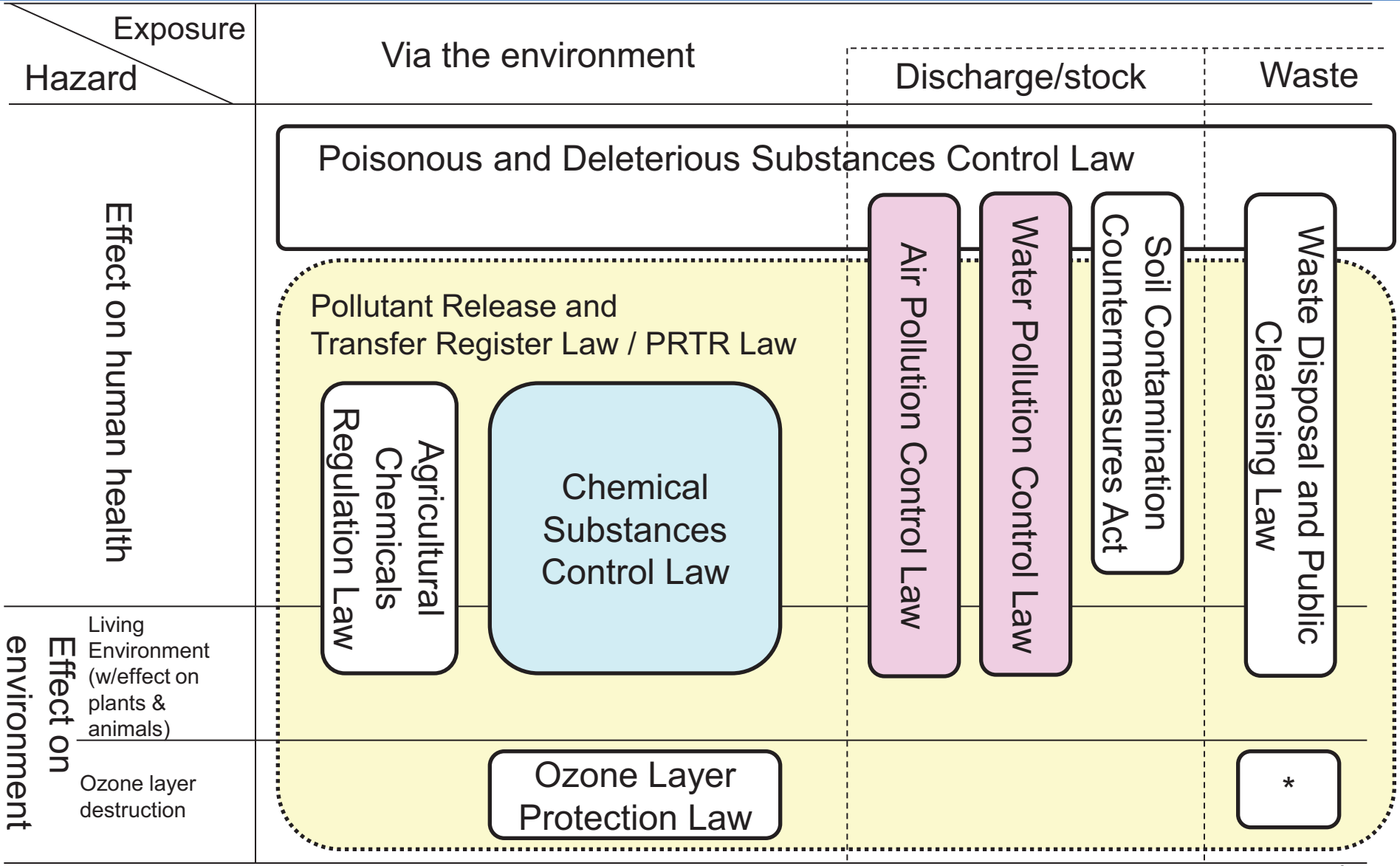
Chemical Regulations on chemical exposure via environment in Japan



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

Chemical Substances Control Law (CSCL)

<Purpose>

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

<Authority>

- Jointly authorized by three Ministries
  - Ministry of Health, Labour and Welfare (MHLW),
  - Ministry of Economy, Trade and Industry (METI), and
  - Ministry of the Environment (MOE)

<Primary Measures>

Persistence **B**ioaccumulation **T**oxicity

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

Enactment and Revision of CSCL

1973 enacted

Restriction on manufacture/import, etc. of persistent, bioaccumulative, and long-term toxic (human health) substances such as PCB-like substances.

1986 revised

Revised due to the necessity in restricting persistent and long-term toxic but are not bioaccumulative substances (such as trichloroethylene, etc.), depending on the residual status within environment.

1999 revised

Joint jurisdiction by three ministries including Ministry of the Environment to the joint jurisdiction by former Ministry of Welfare and Ministry of Ministry of International Trade and Industry, due to the reorganization of government and ministries in January, 2001.

2003 revised

Introduction of evaluation/verification system focusing on the effect on animals and plants (i.e., added ecological effect to toxicity), and evaluation system taking environmental emission into account.

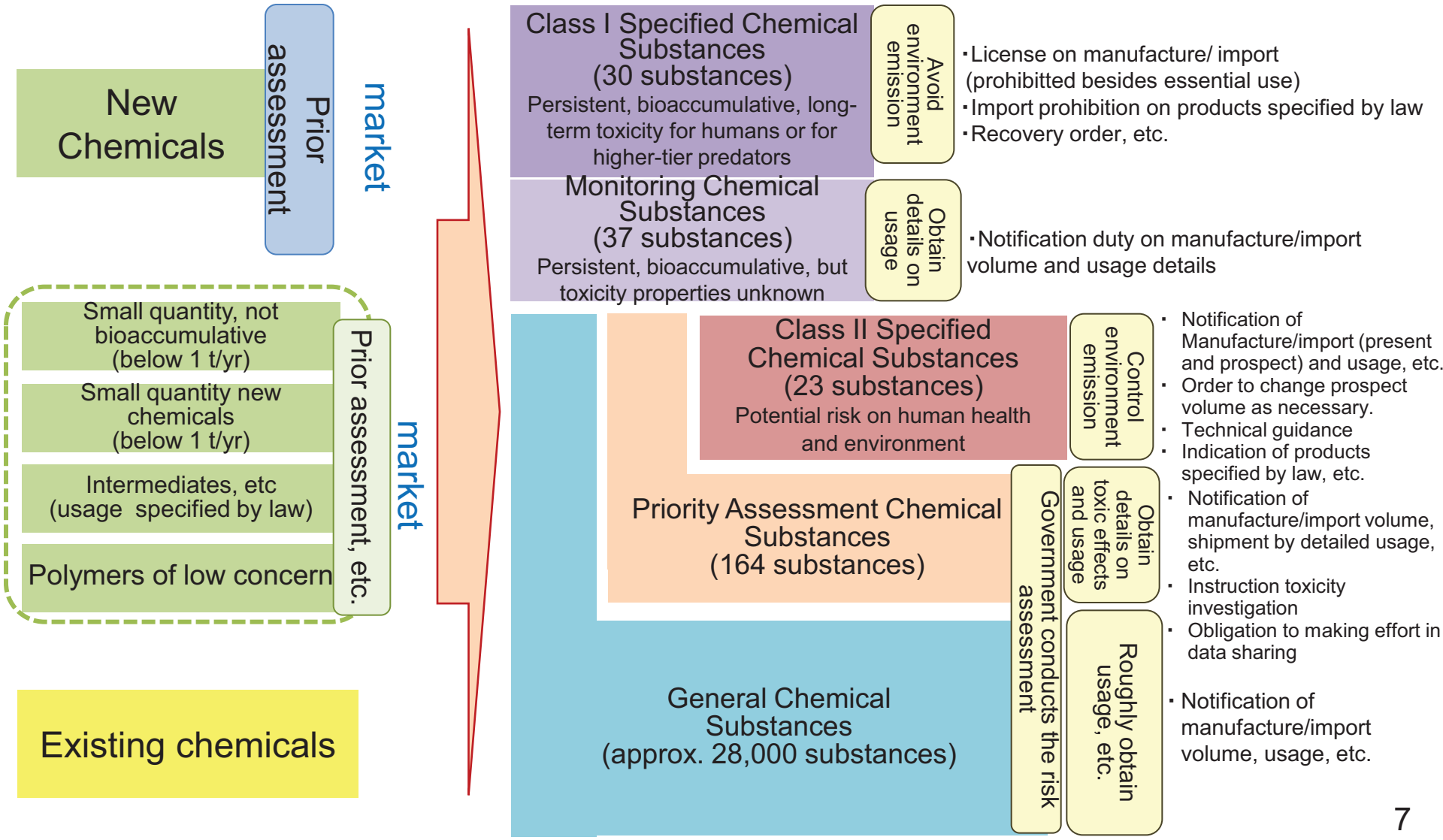
2009 revised

Fundamental revision on examination and verification system for thorough chemical substances (safety evaluation, etc. through notification obligation of manufacturing/importing entities for all chemicals including existing chemicals above certain volume, and narrowing down to Priority Assessment Chemical Substances).

Overview of CSCL

Prevent environmental contamination by chemicals through continual management before and after placing on market.

*as of October 2014



Types of Chemicals regulated under CSCL

(As of Oct. 2014)

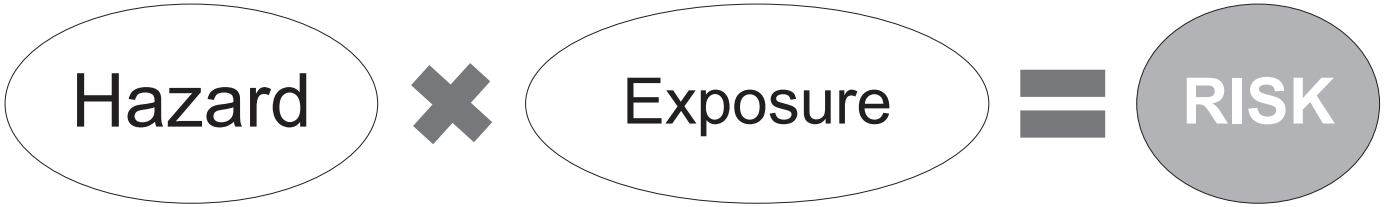
NAME	Definition	Quantity
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and toxicity (long-term toxicity for humans or predator animals at higher trophic level)	30
Class-II Specified Chemical Substances	Toxicity (long-term toxicity for humans or long-term toxicity for flora and fauna 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)*	37
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 to pose a risk *(Candidates for the Class-II Specified Chemical Substances)*	164
General Chemical Substances	Industrial chemical substances other than those above	

Chemical Substances Control Law (CSCL)

＜Approach＞

(1) Risk

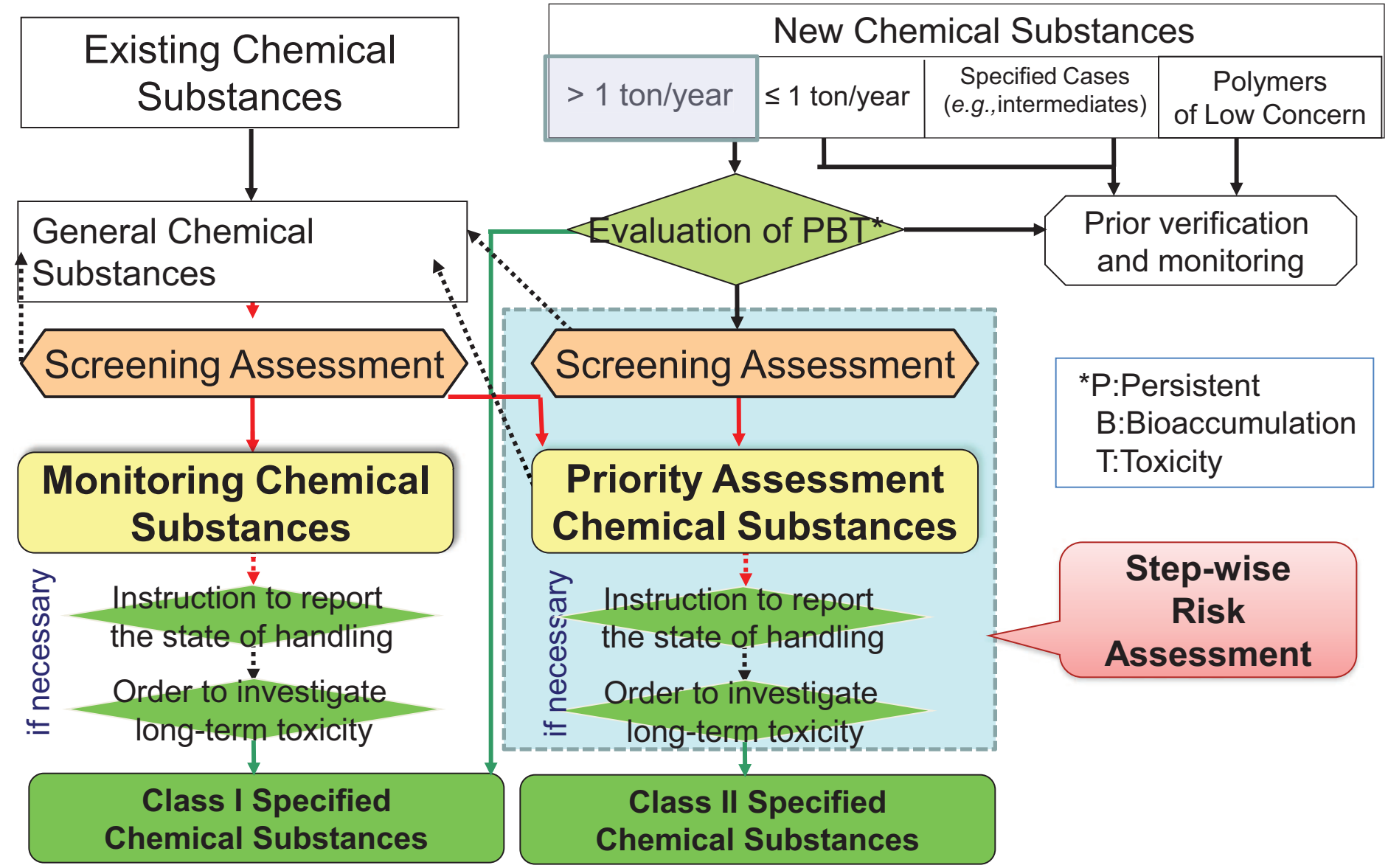
Risk of chemicals are assessed comprehensively from hazard and exposure concentration.



(2) Optimization of the process

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

Overview of CSCL



Restriction of Manufacture/import, etc. of Chemicals substances (1)

<Specified Chemical Substances: two types>

Class-I Specified Chemical Substances

- Persistence, bioaccumulative, long-term toxicity for humans or for high-order predators
- Restriction on license of manufacture/import and usage (virtually prohibited)
- Import restriction on products designated by law
- Recovery order in case substance is designated, etc.
- Usage besides essential use (Compliance to technical standards; labelling obligation)

- 30 substances:
  Polychlorinated biphenyl
  Polychlorinated naphthalene (above three chlorines)
  Hexachlorobenzene
  Aldrin Endrin
  Dieldrin DDT (as of Oct, 2014)
  Chlordanes etc.

Restriction of Manufacture/import, etc. of Chemicals substances (2)

Class-II Specified Chemical Substances

- Long-term toxicity for humans or animals / plants in living environment
- Considerable amount remaining in the environment over a substantially extensive area
- Notification of volume of manufacture/import of present and prospect
- Order to change prospect volume when restriction on manufacture/import is necessary
- Publication of technical guidance to prevent environmental contamination, and recommendation as necessary
- Labelling obligation and compliance to technical guidance

- 23 substances:
  Trichloroethylene
  Tetrachloroethylene
  Carbon tetrachloride
  Organic tin (20 compounds)

(as of Oct, 2014)

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Evaluation/ verification of new chemicals

Prior evaluation and judgment 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.

I. Degradable: Whether or not it is easily affected chemically in natural process

II. Accumulative: Whether or not it is easily accumulated within organisms

III. Long-term toxicity to humans: Whether or not it may affect human health through continuous intake

IV. Eco-toxicity: Whether or not it will affect the habitats or growth of animals and/or plants

Exception of Notification or Evaluation for New Chemical Substances

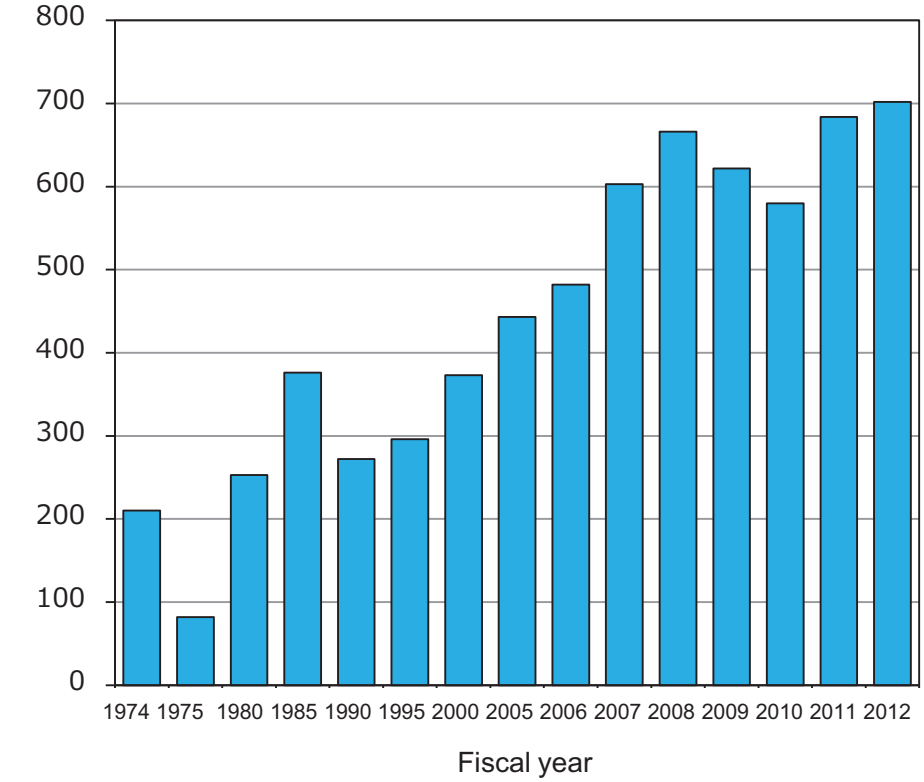
	Content
Small Quantity New Chemical Substances	Confirmed by the three ministers that the prospect national yearly manufacturing and importing volumes are below 1 ton, and are not considered to contaminate the environment and harm human health or animals and/or plants in living environment.
Intermediates, etc.*	Confirmed by the three ministers that the substances falls under such designated by the law (intermediates, closed usage, exclusively for exports) that environmental contamination by the new chemical substances is not likely to occur from the planned usage.
Polymers of Low Concern	Substances confirmed by the three ministers that the substances are polymers and do not contaminate the environment and harm human health or animals and/or plants in living environment
Low Production Volume of New Chemical Substances	Substances that may be manufactured/ imported on a condition of follow-up supervision (hearing of report and/or on-site inspection), through prior confirmation by the three ministers that the volume is below 10 tons; in a case when the new chemical substances below national yearly manufacturing and/or import volume below 10 tons are judged/notified that they are persistent but are not bioaccumulative, after specified as subject to pre-evaluation.

*Implementation of "Confirmation system of small quantity intermediates, etc. of new chemical substances" from Oct, 2014 (to p.24)

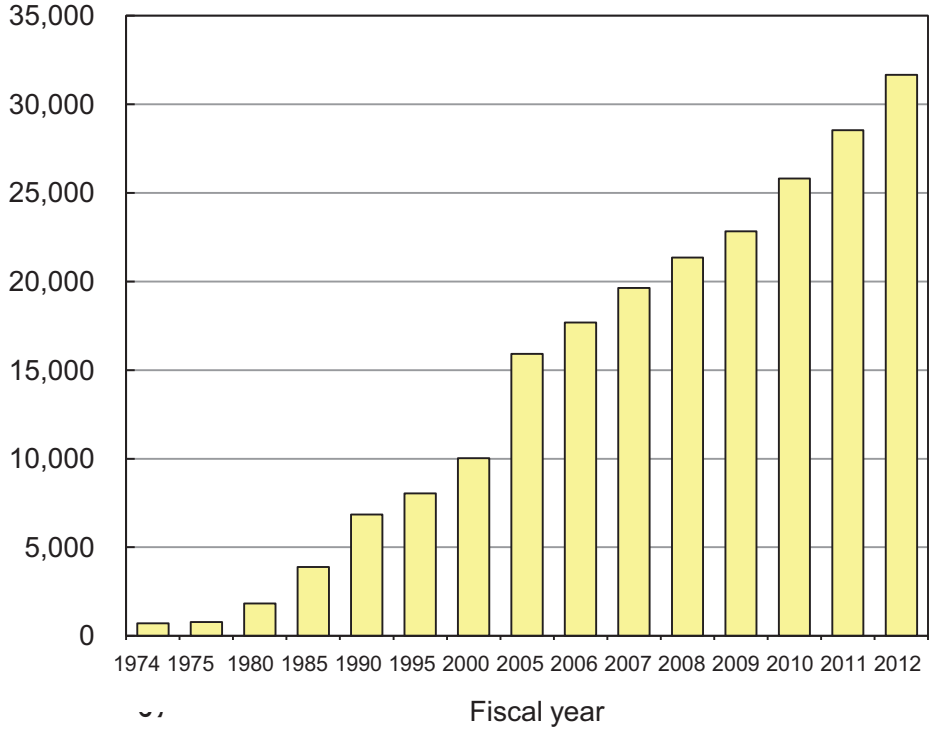
Pre-Evaluation of new chemical substances (1)

- The notification number of new chemical substances is in increasing trend. The notification number was 702 in FY 2014.
- The application number of Small Quantity New Chemical Substances was 31,672 in FY2014.

Notification number of New chemical substances



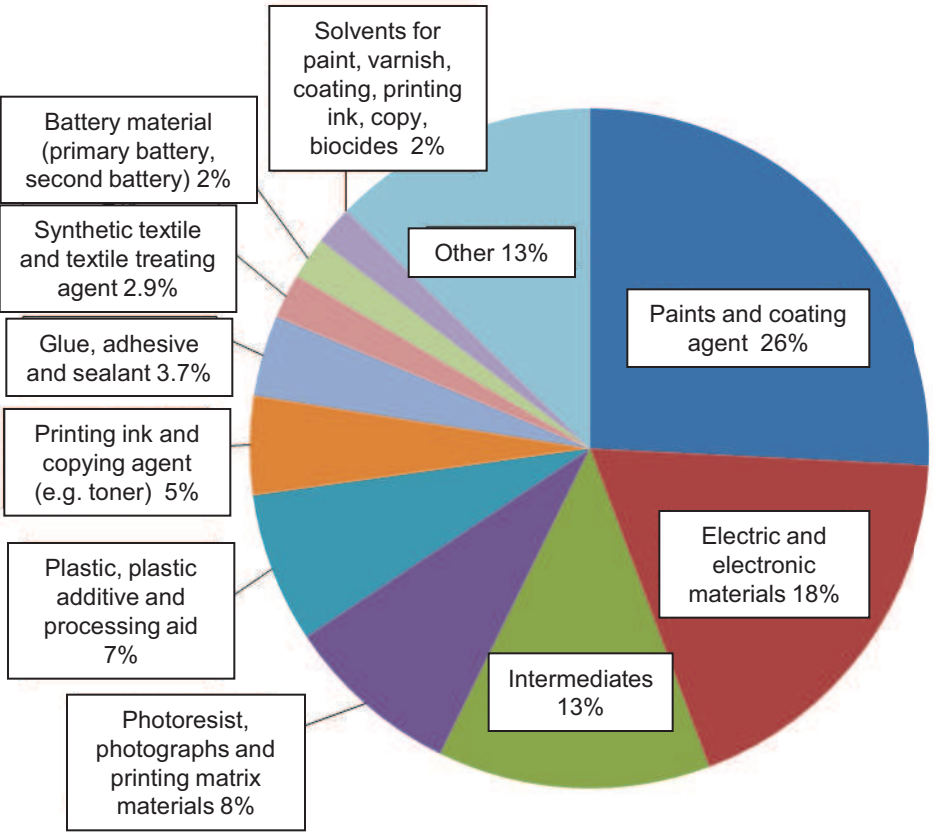
Application number of Small Quantity New Chemical Substances



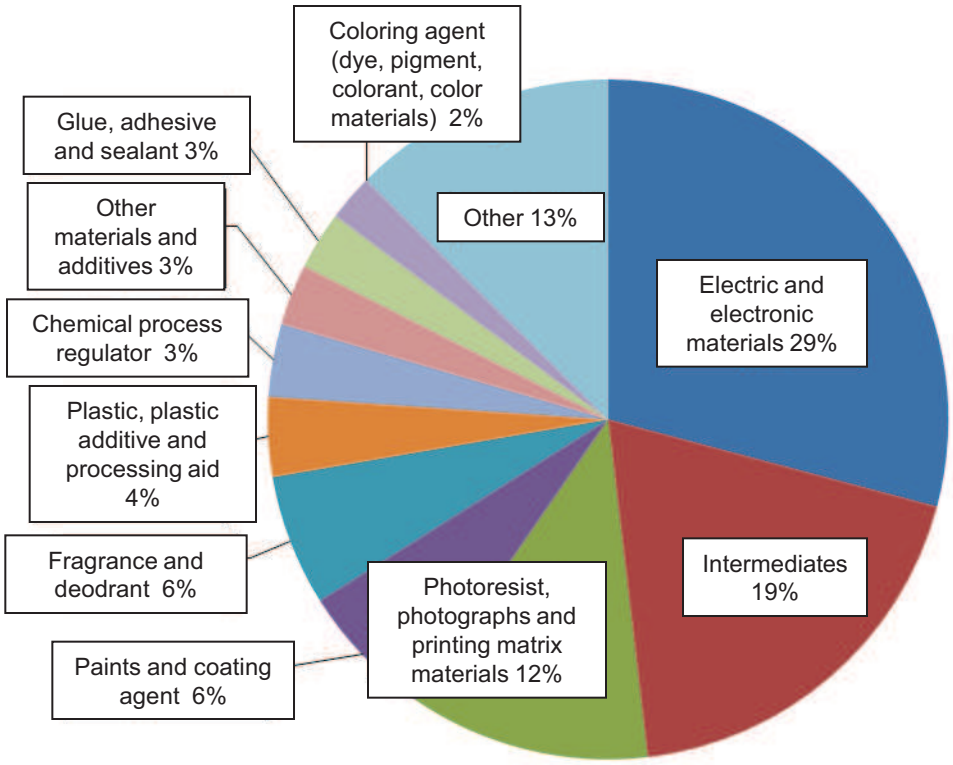
Pre-evaluation of new chemical substances (2)

- The percentage of electric/electronic materials are high in both the new chemical substances and Small Quantity New Chemical Substances.

<Usage of new chemical substances (FY2012)>

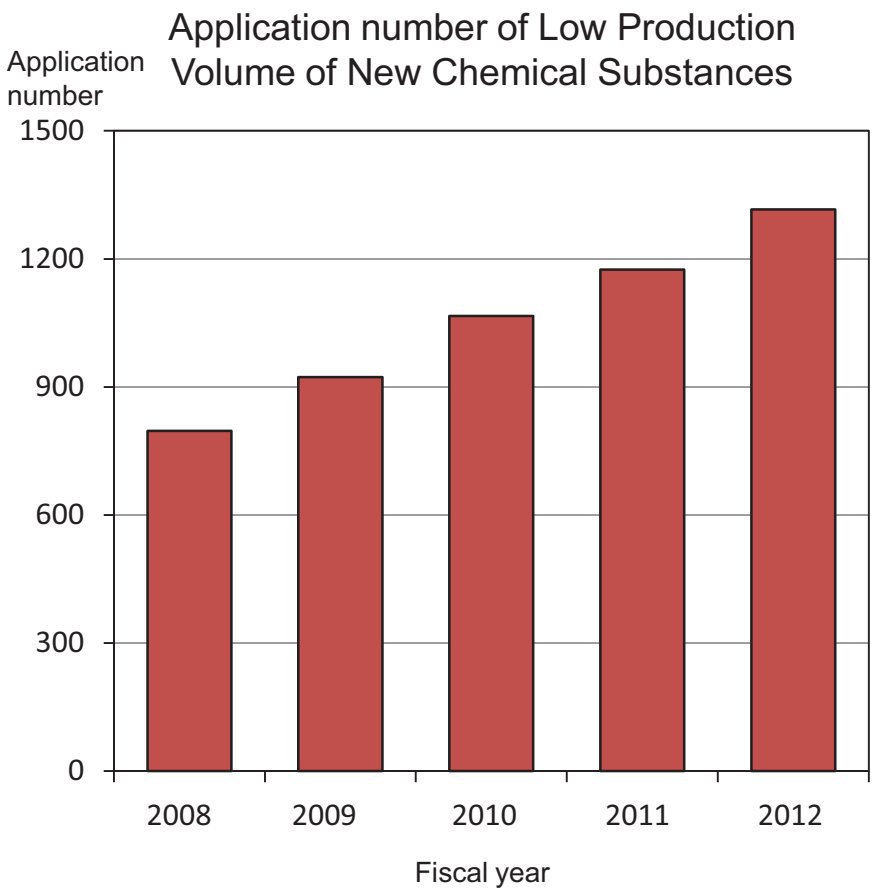


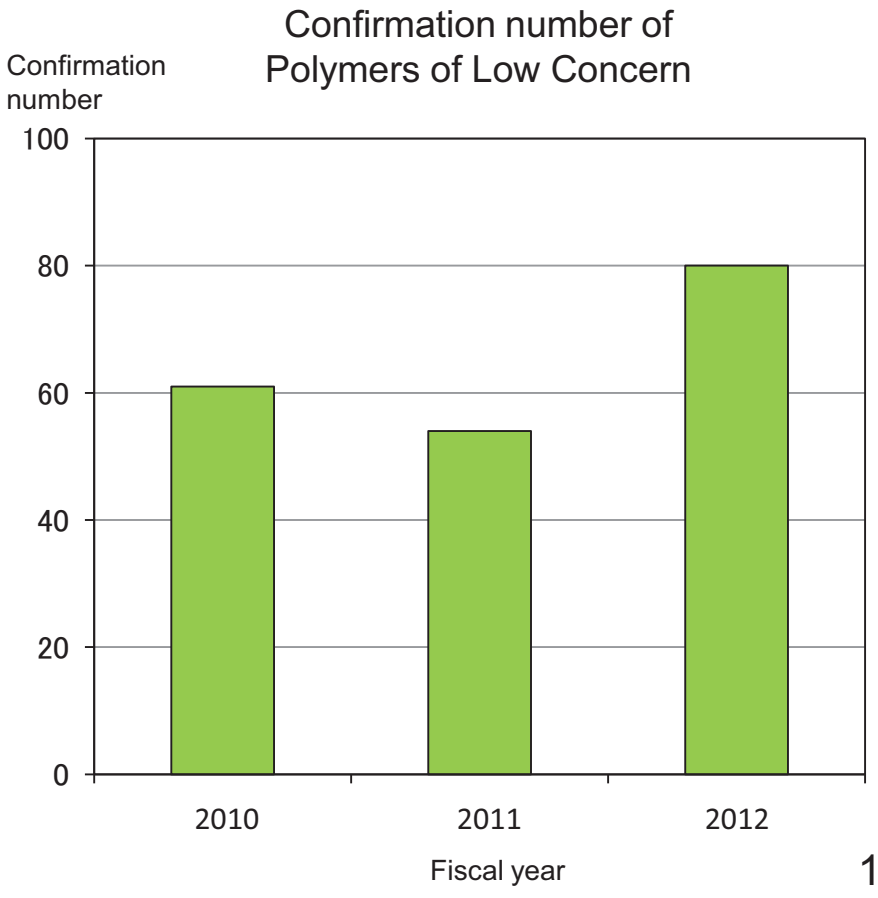
<Usage of Small Quantity New Chemical Substances (FY2012)>



Pre-evaluation of new chemical substances (3)

- The application number of Low Production Volume of New Chemical Substances is also in an increasing trend. The application number was 1,316 in FY2012.
- The confirmed number of Polymers of Low Concern, implemented from April 2010, was 80 in FY2012.

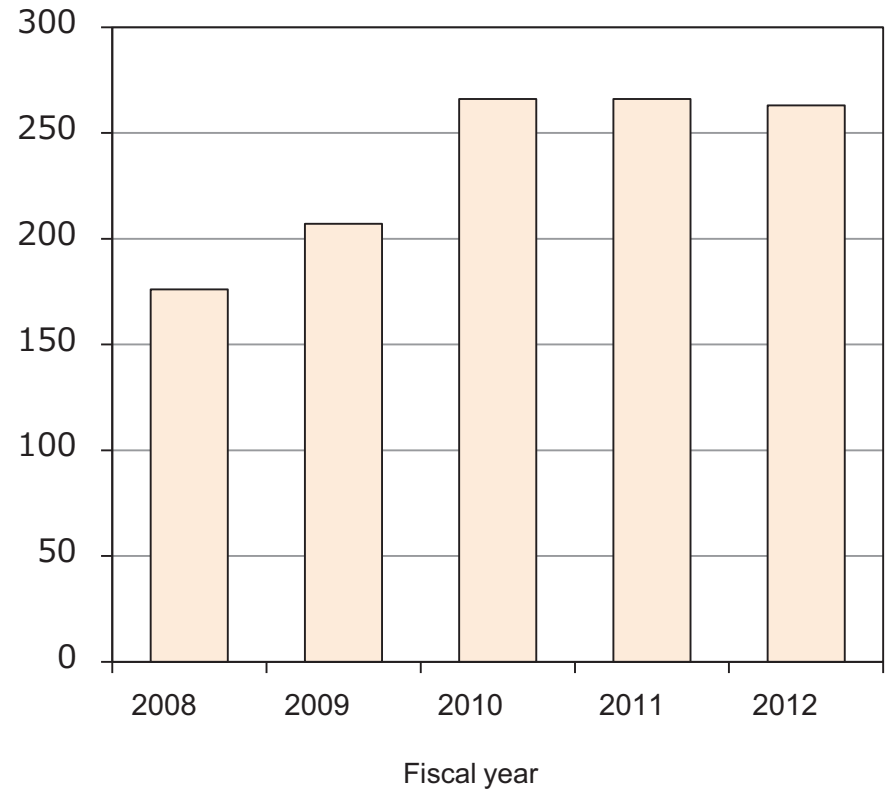




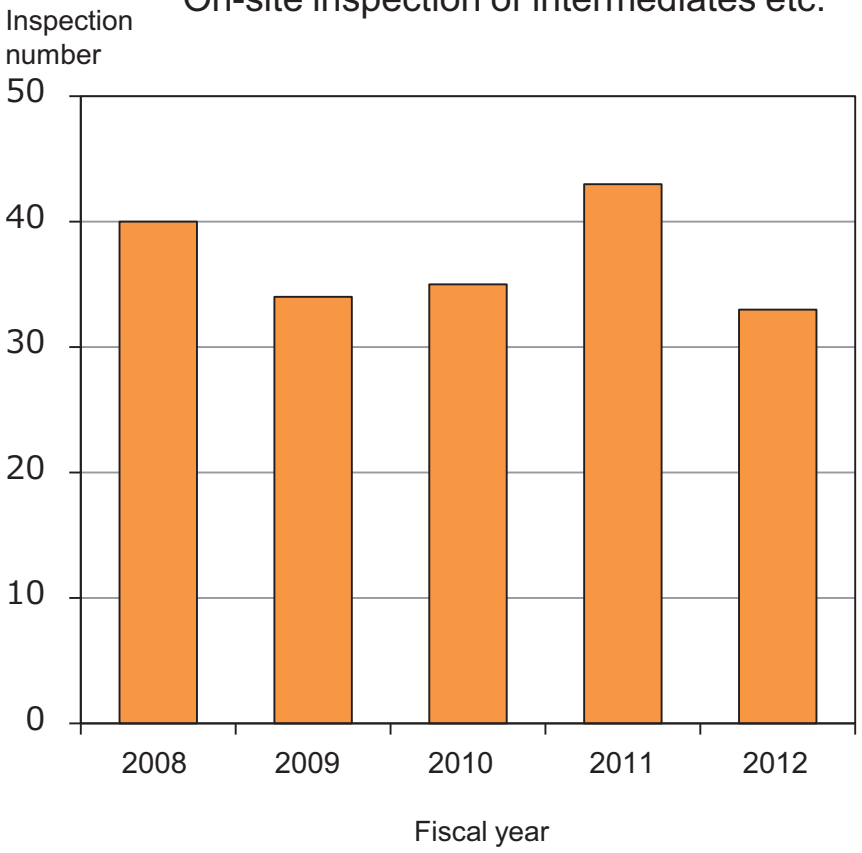
Pre-evaluation of new chemical substances (4)

- The confirmed number of intermediates etc. was 263 in FY2012.
- The number of on-site inspection at intermediate producing industries was 33 in FY2012.

Confirmed number of Intermediates etc.



On-site inspection of intermediates etc.



Confirmation system of new chemical substances of Small Quantity Intermediates etc. (1)

■ Council for Regulatory Reform

Background

- Working Group for Business Establishment, etc., a subsidiary committee to Council for Regulatory Reform established within Cabinet Office (January 23, 2013), adopted “evaluation system of new chemical substances” as one of the topics to be discussed as a subject of regulation rationalization.
- As a result of necessary consideration, reconsideration of chemical substances evaluation system was adopted in the report of Council for Regulatory Reform and in Regulatory Reform Implementation Plan.

May 14, 2013 The 6th Working Group for Business Establishment (public hearing)

May 27, 2013 The 7th Working Group for Business Establishment (draft report)

June 5, 2013 Draft “Report for Regulatory Reform” Council for Regulatory Reform

June 14, 2013 Cabinet decision of “Regulatory Reform Implementation Plan”

Confirmation system of new chemical substances of Small Quantity Intermediates etc. (2)

■ Regulatory Reform Implementation Plan

Regulatory Reform Implementation Plan (June 14, 2013 Cabinet Decision)

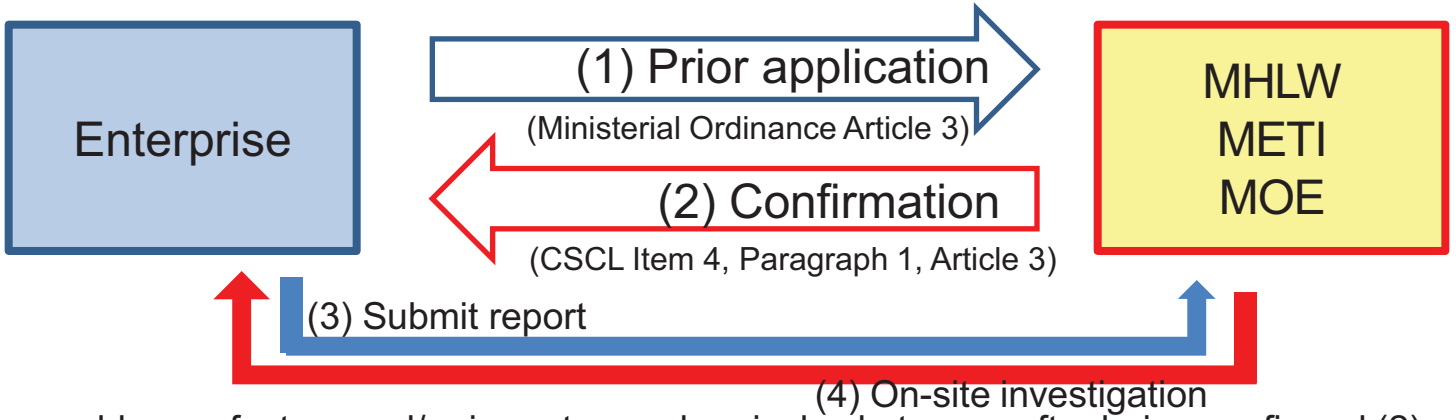
Item	Content of regulatory reform	Implementa-tion	Jurisdiction
Chemical substances evaluation reform (1) (on total volume regulation of small quantity new chemical substances confirmation system)	The confirmation system of new chemicals of small quantity is to be a system to secure predictability related to manufacture and/or import of new chemicals by industries, through ensuring the safety of human health and ecology based on scientific discussion. Thus, a discussion shall be made to reach a conclusion to confirm by per industry (enterprise) unit, taking into consideration the exemption (10 tons) of low production volume of new chemical substances.	FY 2013 Discussion/ conclusion	MHLW METI MOE
Chemical substances evaluation reform (2) (on acceptance frequency of small quantity new chemical substances confirmation system)	A discussion shall be made to reach a conclusion to increase acceptance frequency of notification for confirmation of small quantity new chemical substances, taking into consideration the situation of enterprises, from the perspective of enhancing the competitiveness of enterprises without losing business opportunity.	FY 2013 Discussion/ conclusion	MHLW METI MOE
Chemical substances evaluation reform (3) (on constructing assessment system based on usage, etc. of chemical substances)	A discussion shall be made to reach a conclusion on individual issues necessary for rationalization regarding the assessment system for new chemical substances to evaluate the effect on human health and on ecology through usage and/or exposure potential of the chemical substances, by attempting to balance the safety and optimization of cost and time required for the development of new chemical substances.	FY 2013 Discussion/ conclusion	MHLW METI MOE

Confirmation system of new chemical substances of Small Quantity Intermediates etc. (3)

■ Purpose(CSCL Item 4, Paragraph 1, Article 1)

- In accordance with Regulatory Reform Implementation Plan (Cabinet Decision, June 14, 2013), " Ministerial Ordinance to revise a part of ministerial ordinance regarding notification for manufacturing and/or importing new chemical substances" was proclaimed, and **"Confirmation system for small quantity intermediates etc. of New Chemical Substances" was newly established.** (Enacted Oct. 1st, 2014)
- For manufacturing and/or importing of new chemical substances used exclusively as **intermediates or for export**, if the annual planned manufacturing and/or importing volume per enterprise is below 1 ton, the appendix documents for application is simplified.

■ Flow diagram



Enterprises could manufacture and/or import new chemical substances after being confirmed (2) by the three ministers.

・Application accepted: as required (no expiration date)

・Documents for application: Overview of countermeasures for prevention of environmental contamination, management system, and information, etc. of users (exporter).

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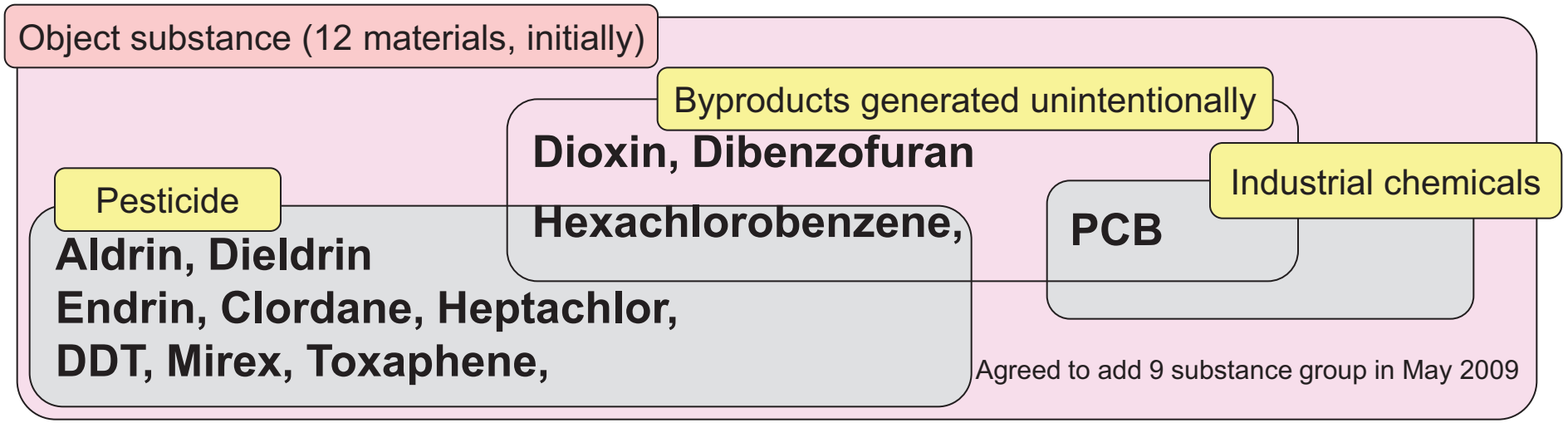
POPs Convention
(Stockholm Convention on Persistent Organic Pollutants)

POPs (Persistent Organic Pollutants)
①Toxic
②Hardly decomposable
③Accumulated
④Long-distance transferable

→ International effort is required for pollution prevention.

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

- ○Adopted 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.
- ○Professional and technical issues are discussed at Persistent Organic Pollutants Review Committee (POPRC).



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

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

- Date & Location: April 30 to May 2, 2013 at Geneva (Switzerland)
- Outcome of the meeting:
  - Listing of chemicals in Annex A to the convention (new POPs)

    -> Hexabromocyclododecane (HBCD) was listed to Annex A to the convention.
  - Assessment of alternatives to the use of PFOS, its salts, and PFOSF

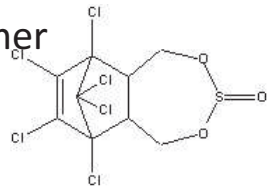
    -> Further evaluation of alternatives to PFOS, its salts, PFOSF at the POPRC.
  - Work Plan for specific exemptions and acceptable purposes

    -> Process for the evaluation of the continued need for the various acceptable purposes and specific exemptions is adopted (PFOS and Bromodiphenylether).
  - Effectiveness evaluation

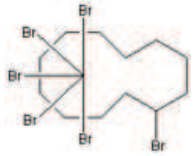
    -> Revised framework for effectiveness evaluation and the global monitoring plan for persistent organic pollutants were adopted .
- COP7：May 2015 in Geneva (Switzerland)
  - Stockholm Convention, Basel Convention, Rotterdam Convention (three COPs) will be held jointly.

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. (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)

- 2 substances above is designated as a Class I Specified Chemical Substance of CSCL, and **manufacture, import and use are prohibited**.(Enforced in May 1st 2014)*
- **Import of products in which HBCD is used** (flame-proof fabric flame curtain textiles flame-retardant treatment drug, and flame-retardant EPS beads) **are also prohibited**. (Enforced in October 1st 2014).

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

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)

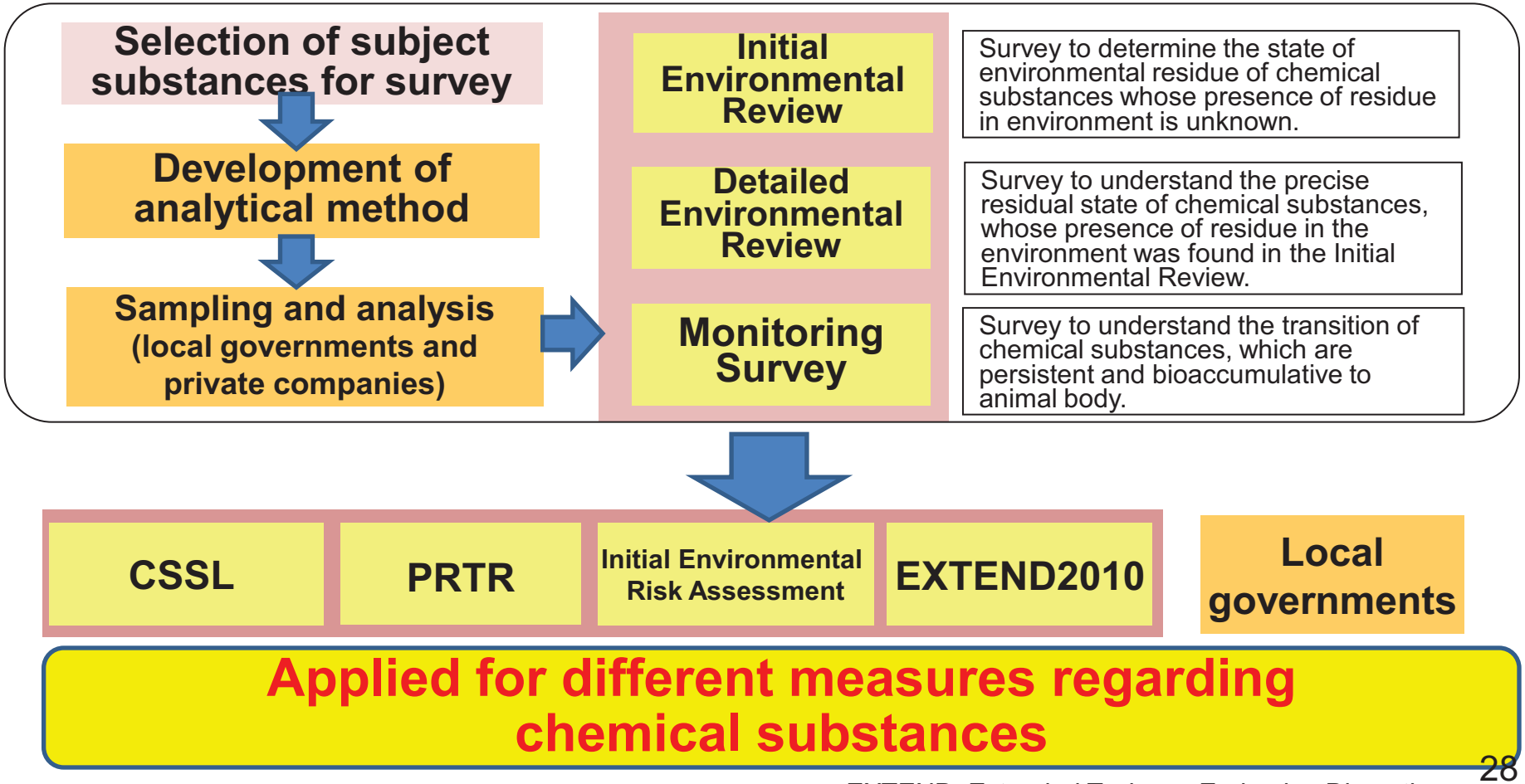
- The experts discussed about the impact of the health on consumers due to the continued use of the product in which the pigment and the impact on the ecosystem and people through the pollution of the environment has been used.
- It was concluded that risk to ecological and human health via the environment 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.

Environmental Survey and Monitoring of Chemicals

- Aim: To understand the state of residual chemical substances in the general environment, basic data to promoting chemical substances countermeasures.
- Subject: Multiple media (water, sediment, air, biota, etc.)
- Survey commencement: Started from FY1974 when CSCL was first established.



EXTEND: Extended Tasks on Endocrine Disruption

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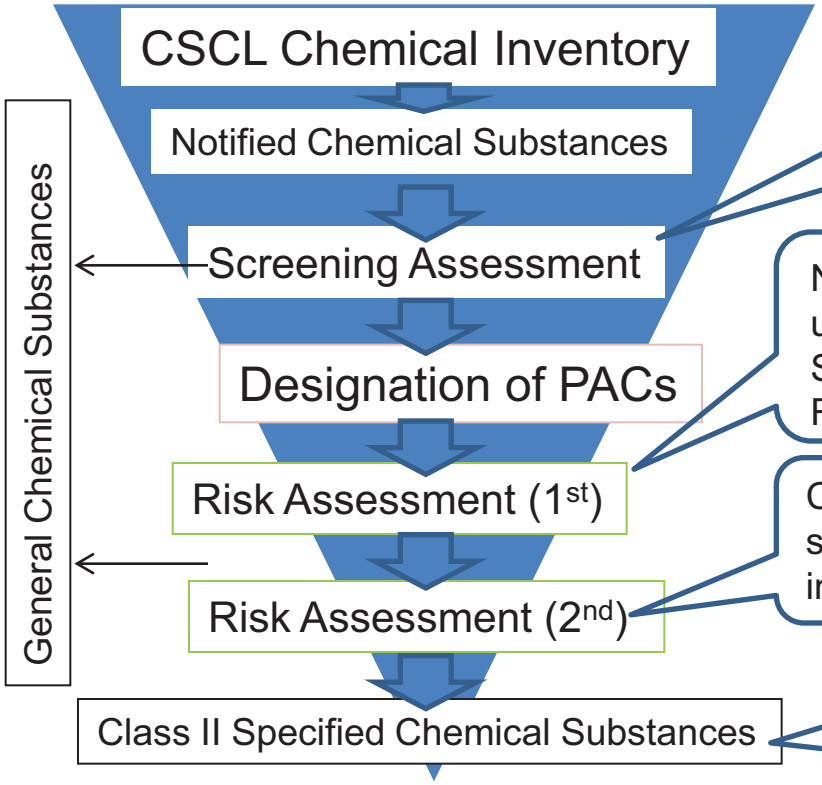
Risk Assessment under CSCL

Aim

To prevent environmental contamination by chemicals that may be harmful for human health and/or to the inhabitant or growth of animals and plants.

- Prior evaluation and regulation of new chemical substances
- Continuous management of existing substances
- Regulation by properties Persistence, Bioaccumulation, Long term toxicity

Step-wise risk assessment



＜Role of enterprises＞

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

Screening Assessment

【Human Health effect】
- Classified into hazard class by general toxicity, reproductive and developmental toxicity, mutagenicity, and carcinogenicity.

【Ecological effect】
- Classified into hazard class by eco-toxicological test data (algae, crustacean, fish).

Hazard Class

Exposure Class

	Class1	Class2	Class3	Class4
Class1	High	High	High	High
Class2	High	High	High	Medium
Class3	High	High	Medium	Medium
Class4	High	Medium	Medium	Low
Class5	Medium	Medium	Low	Low

High (Not thought to pose a risk)

Expert Judgment

Medium & Low

Designated as Low Risk

Remain to General Chemical Substances

(Exposure class will be updated and screened every year)

Designation of PACS

Exposure Class	Total Estimated Emission Volume
Class 1	over 10,000 tons
Class 2	1,000 – 10,000 tons
Class 3	100 – 1000 tons
Class 4	10 – 100 tons
Class 5	1–10 tons

【Physicochemical】
- Notify annual quantity of manufacture etc.
- Estimation of Total annual quantity of emission (updated every year)

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	Part of General 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 Assessment Chemical Substances	88		8		46		40	
	75	20	6	4	31	21	17	23

Designated Priority Assessment Chemical Substances

Designated Priority Assessment Chemical Substances are 164 (As of Oct. 2014)

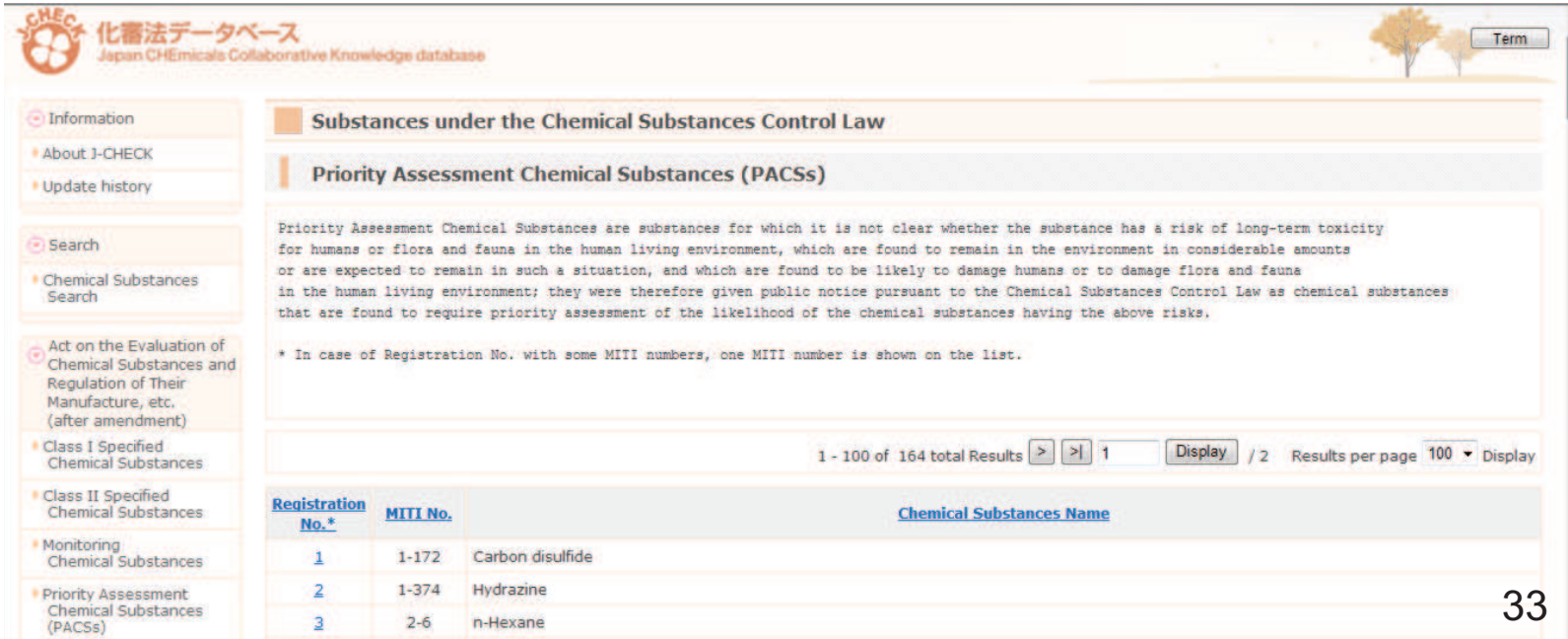
<Public site for notice (English ver.)>

J-CHECK: Japan Chemicals Collaborative Knowledge Database)

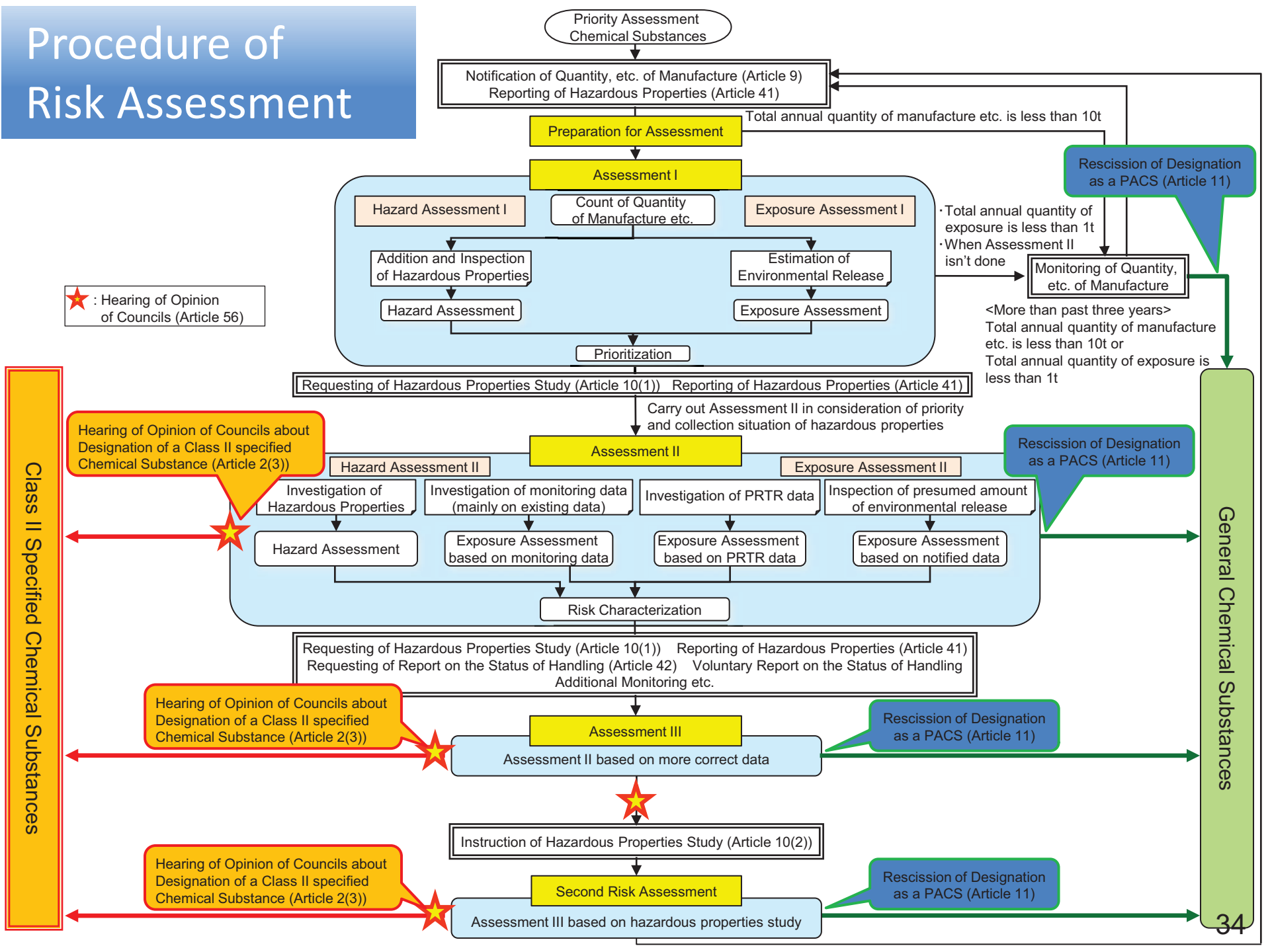
http://www.safe.nite.go.jp/jcheck/list7.action?category=230&request_locale=en

About J-CHECK:

- J-CHECK is a database developed to provide the information regarding CSCL by the authorities of the law, MHLW METI and MOE.
- J-CHECK provides the information regarding CSCL, such as the list of CSCL, chemical safety information obtained in the existing chemicals survey program, risk assessment, etc. in cooperation with eChemPortal by OECD.



Procedure of Risk Assessment



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.

Result of Assessment I

- Risk Assessment (1st) has been conducted three times. Among 140 substances designated as Priority Assessment Chemical Substances by FY 2012, Risk Assessment (1st) was conducted on 116 substances, exceeding the total national manufacture/import volume of 10 tons. Risk Assessment (2nd) is conducted on 18 substances in FY 2012, 8 substances in FY 2013, and 16 substances in FY 2014

Date/number of target substances	Jul. 2012	Jul. 2013	**Jul. 2014**
Priority Assessment Chemical Substances*1	87	95	**140**
Assessment I of Risk Assessment (1st)	86	79	**116**
Substances to undertake Assessment II (Human health) (Ecological)	**18** **(11)** **(7)**	**8** **(1)** **(7)**	**16** **(3)** **(13)**
Substances not applicable to the above and will continually be subjected to Assessment I next year	63	62	**97**
National estimate emissions below 1t (Production volume survey conducted for the time being*2, and Assessment I will be conducted next year) (Cancellation of designation as Priority Assessment Chemical Substances)	5 (-) (-)	6 (-) (-)	**7** **(3)** **(4)**
National total manufacture/import volume below 10 t (Production volume survey conducted for the time being*2, and Assessment I will be conducted next year) (Rescission of designation as Priority Assessment Chemical Substances)	1 (-) (-)	2 (-) (-)	**5** **(4)** **(1)**

*1・・・Target substances for July 2012 assessment were designated substances of Apr. 2011 (of which one substance was cancelled in Jan. 2012). Target substances for July 2013 assessment were substances designated by FY 2011. For June 2014 assessment, the target substances were substances designated by FY 2012.

*2・・・Rescission of designation as Priority Assessment Chemical Substances for substances below national total manufacture/import volume of 10 t or national estimate emissions below 1 t , according to Article 11 of CSCL.

Starting Substance of Assessment II

18 Substances for 2012 FY

< Human health effects (11 substances) >

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

<Ecological effect (7 substances)>

- 1,3 - dichloropropene
- n-butyl acrylate
- isopropenylbenzene*
- 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 2013FY

< 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

* Substances subject to the evaluation/ discussion at the Joint Council by three ministries, held on June 27, 2014.

(4) Starting Substance of Assessment II (cont.)

FY 2014 16 substances

＜Human health effect (33substances)＞

- Carbon disulfide
- Aniline
- 4, 4’-Diamino-3, 3’-dichlorodiphenylmethane (also known as “4, 4’-methylenebis(2-chloroaniline)”)

＜Ecological effect (13 substances)＞

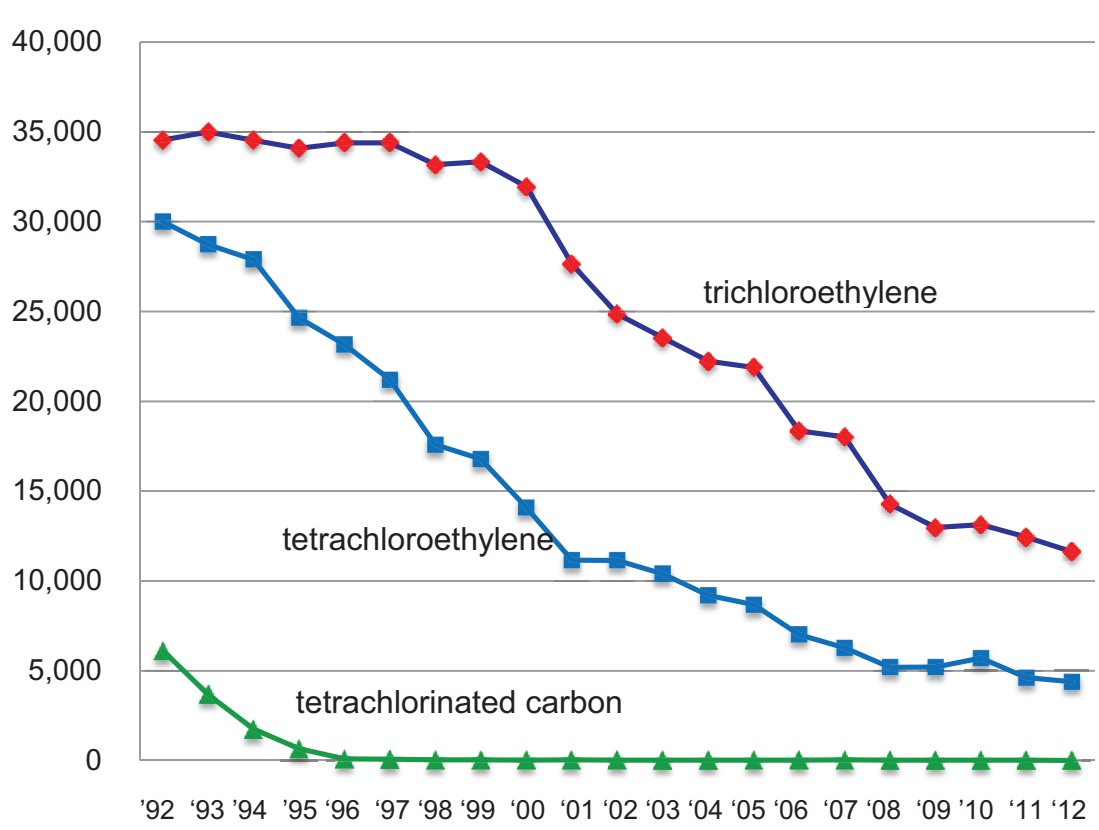
- Tetraethylthiuram disulfide (also known as “disulfiram”)
- Bis(N, N-dimethyldithiocarbamic acid)N, N’-ethylenebis (thiocarbamoyl thiozinc) (also known as “polycarbamate)
- N, N-dimethylpropane-1, 3-diyldiamine
- N, N-dimethyldodecylamine＝N-oxide
- 1-Dodecanol
- Trisodium＝2, 2′, 2″-nitrilotriacetate
- 2-[(3-dodecaneaminopropane-1-yl)(dimethyl)ammonium]acetate
- Xylene
- Benzyl benzoate
- (R)-4-isopropenyl-1-methylcyclohex-1-ene (also known as “d-limonene”)
- 1, 3, 5-Trichloro-1, 3, 5-triazinan-2, 4, 6-trione
- (T-4)-bis[2-(thioxo-*k*S)-pyridine-1(2H)-olato-*k*O]zinc(Ⅱ)
- Benzenesulfonic acid, sodium salt (limited to linear alkane with carbons 10 to 14)

Class-II Specified Chemical Substances

- The Class-II Specified Chemical Substances that are manufactured and/or imported for usage other than research purposes are trichloroethylene (TCE), tetrachloroethylene (PCE), and tetrachlorinated carbon (CCl_4). However, the shipment quantity (besides export and for intermediates) are in a decreasing trend.

Trend in shipment quantity of principal Class-II Specified Chemical Substances (besides export and for intermediates)

Yr.	TCE	PCE	CCl4
1988	57,922	45,483	7,736
1989	46,201	42,760	6,904
1990	36,762	37,554	6,492
1991	34,546	30,059	6,420
1992	34,546	30,009	6,127
1993	35,002	28,727	3,681
1994	34,541	27,892	1,747
1995	34,084	24,648	658
1996	34,396	23,159	89
1997	34,394	21,200	70
1998	33,179	17,585	37
1999	33,340	16,787	44
2000	31,952	14,089	27
2001	27,634	11,153	37
2002	24,863	11,148	29
2003	23,537	10,397	22
2004	22,233	9,191	22
2005	21,889	8,683	30
2006	18,351	7,013	27
2007	18,020	6,270	40
2008	14,284	5,198	20
2009	12,971	5,200	16
2010	13,142	5,703	17
2011	12,437	4,618	18
2012	11,628	4,391	15



unit: ton

Reporting of hazard information

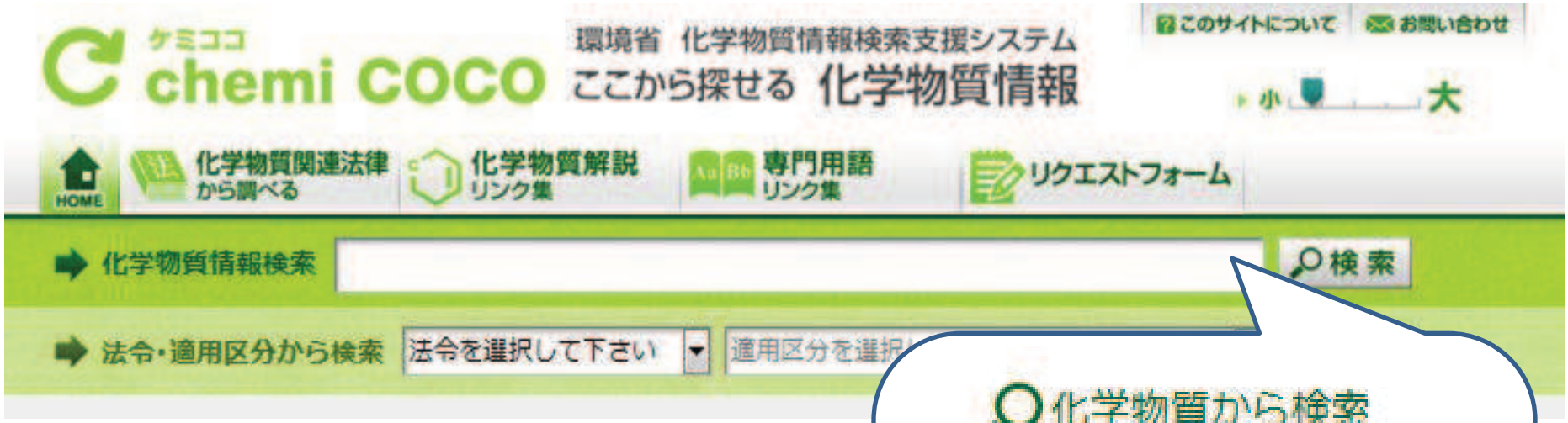
- The manufacturer and/or importer of chemical substances are obliged to report when hazard such as toxicity is observed for humans and animals/plants at a certain degree by tests required for assessments of CSCL. (Article 41)

<Reporting number of hazard information>

	FY 2010	FY 2011	FY 2012
Degradation	74	101	88
Accumulation	3	3	5
Physical chemical properties	6	4	10
Human toxicity	90	79	113
Ecotoxicity	48	37	51
Total	221	224	267

Chemicoco: Chemical Information Retrieval Support System

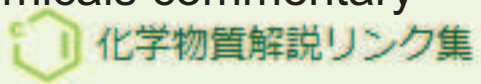
Chemicoco is a search tool for chemicals information.(Japanese only)
Users can access directly to reliable chemical information of appx. 2200 substances.

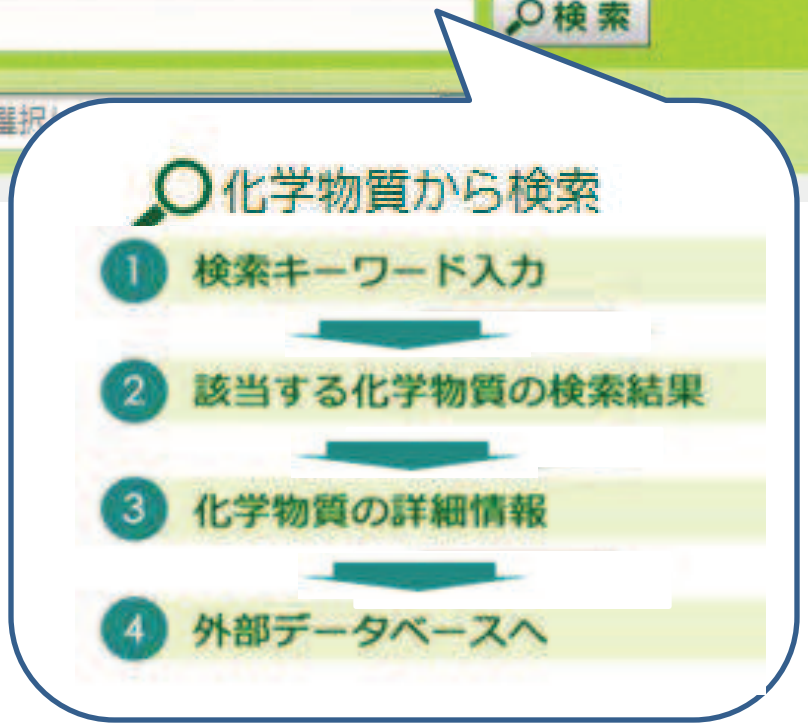


Search from
related Laws and how to use

Lists for outside data base

Links for Chemicals commentary





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

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PRTR System

◆ PRTR (Pollutant Release and Transfer Register) System

: Registration / Announcement systems of hazardous chemicals discharged amount to environment and migration amount contained in waste material.

◆ 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)

◆ PRTR System in Japan

- Purpose:
  - Promoting the voluntarily management improvement by business operators
  - Preventive measures for Environmental Conservation
- Target Chemicals: 354 substances -> 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
  -> Adding Up and Announcement. Individual notification data has been announced since FY2008.

◆ Delivery system for SDS (Safety Data Sheet) is also incorporated.

Institution of PRTR System

Understand the chemical discharge amount to environment and migration amount contained in waste material by individual business place and target substances (354 substances)

Businesses

Evaluation on Management Status

Trouble Prevention for environmental conservation by promoting the voluntarily management of chemicals

Notify estimated values of discharge and migration amounts to the country

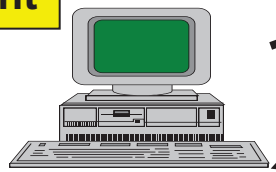
Via Prefectural and City Governments

Data Announcement for Individual Business Place

Disclosure of Data

The public

Government



Data Disclosure Request for Individual Business Place

Announcement of Adding Up Results by Substance, Business Category, Area, etc.

Adding Up notification data, estimate exhausts other than notification (house, agricultural land, vehicles, etc.), announce the results as well as inform the results to concerned government ministries, and prefectural and city governments [MOE, METI].

Minister Responsible for the Business

Minister of METI

Minister of MOE

FY2005-2014 Transition of Release and Transfer

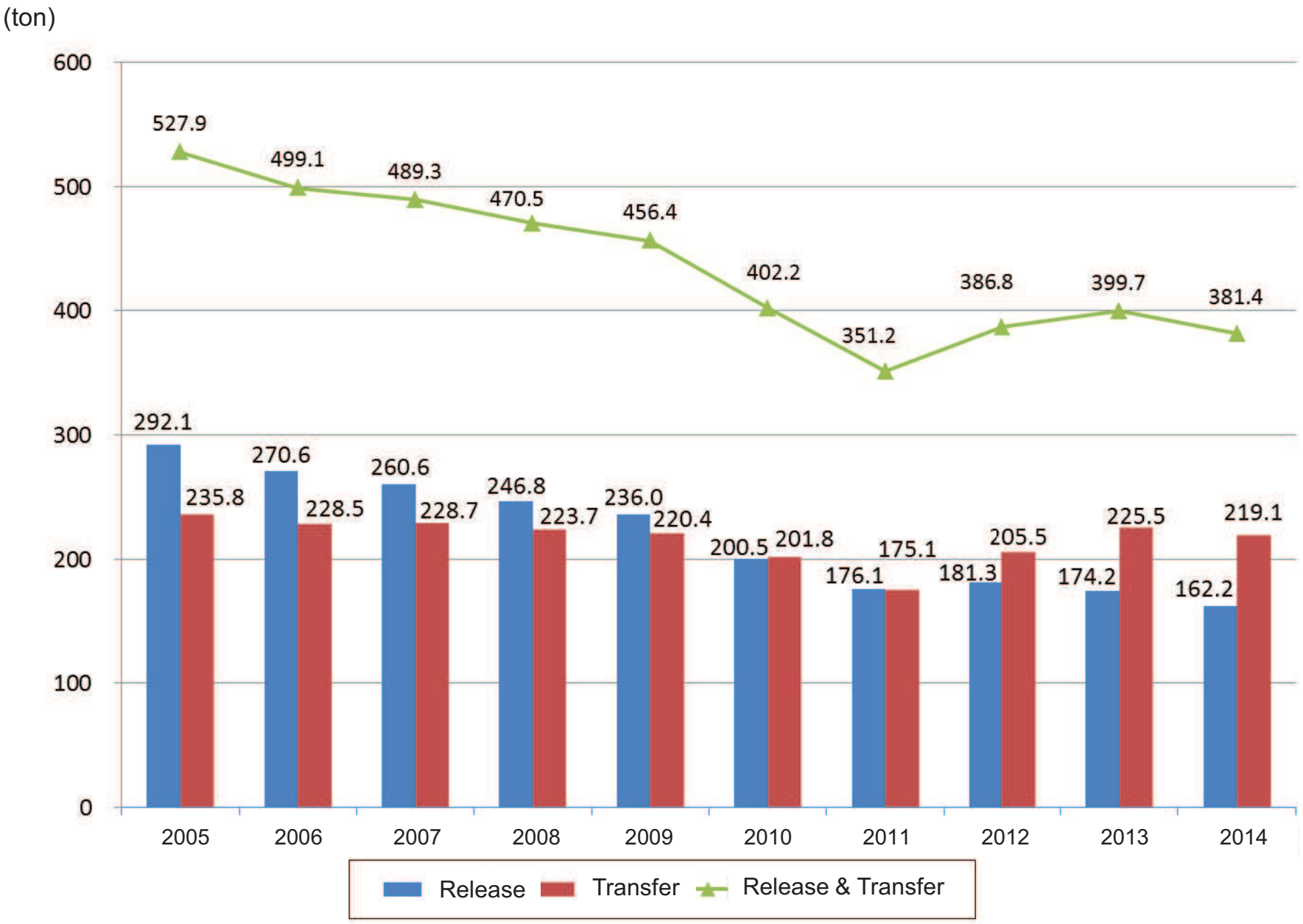


Image of the System to Display PRTR Data on Maps

How to publish data

Server

Select filtering / map

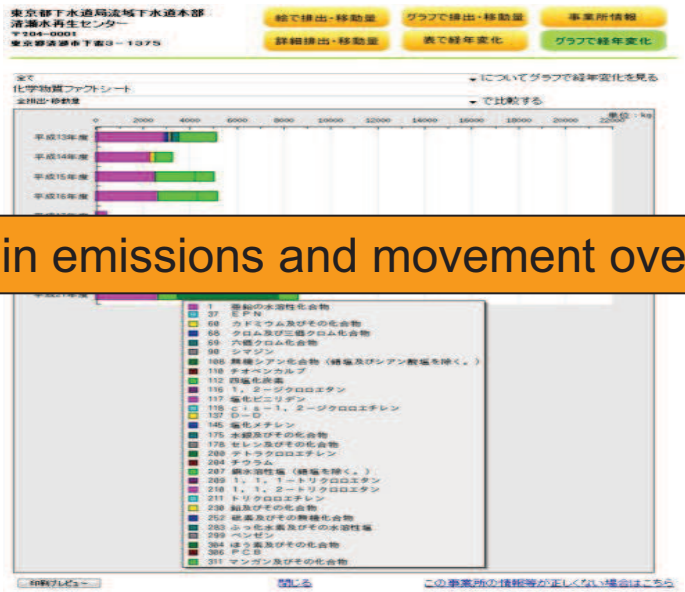
Display results with a list of companies

User

Display results with a map

Display search results on map

Emissions and movement of a fiscal year



Change in emissions and movement over the ye

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.

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SAICM: History to Adoption

- 1992 "Agenda 21" adopted at UNCED (the 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 SAICM adopted at International Conference on Chemicals 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, nanomaterials, etc.

- Nov 2009 Sep 2011: Asia-Pacific regional meeting (Beijing)
- Sep 2012 ICCM3 (Nairobi)

  Review of SAICM implementation
  - Establish guidance for 2020 goal
  - Support and fund to developing countries
  - Add endocrine disrupting chemicals to action to emerging policy issues

- Mar 2013 Asia-Pacific regional meeting (Geneva)
- Sep – Oct 2015 ICCM4
- 2020 ICCM5

} Follow-up of SAICM implementation

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

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

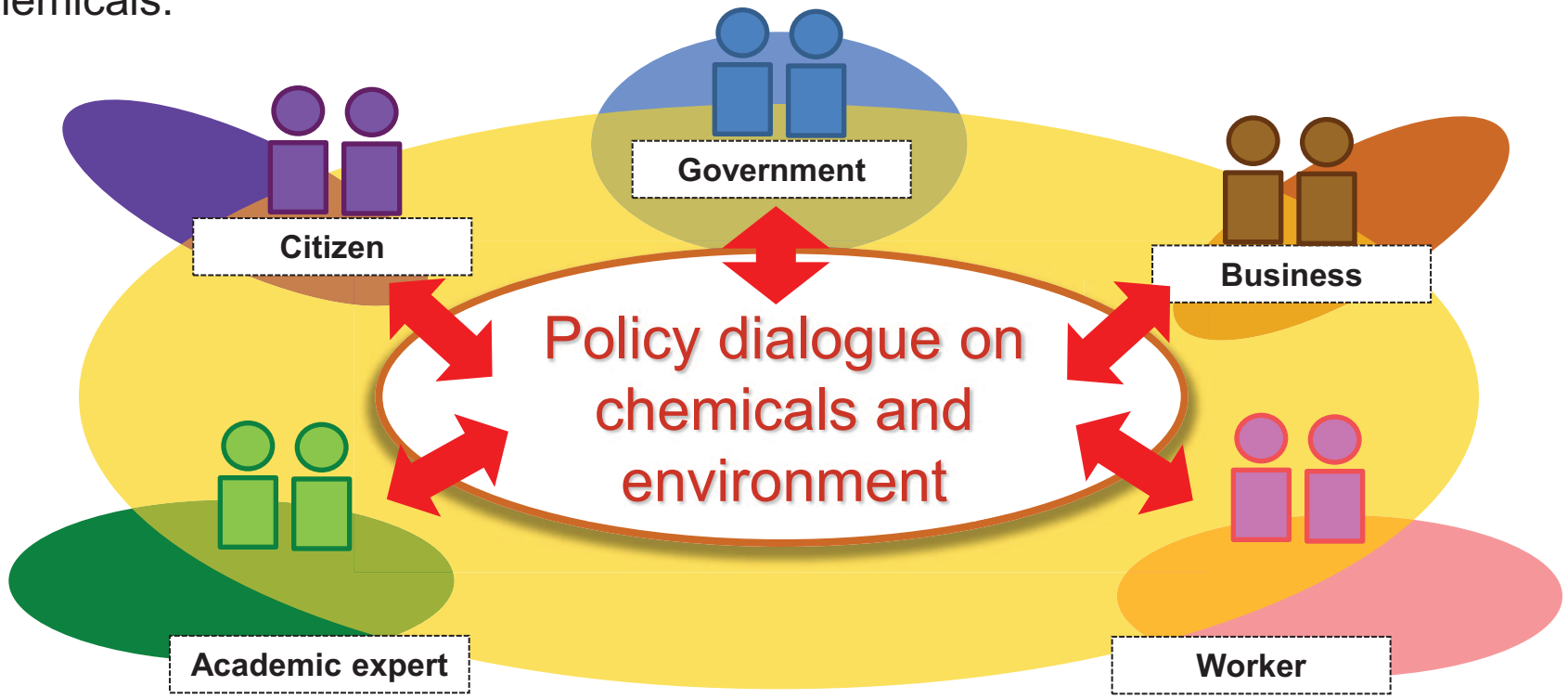
Review of the progress of the Plan and its announcement prior to ICCM4 to be held in 2015

Amendment, if necessary, reflecting the discussion in ICCM

Towards Achievement of WSSD2020 Goal

Policy Dialogue on Chemicals and Environment

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

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Minamata Convention on Mercury (1)

Process to adoption

- UNEP started its program for Global Mercury Assessment and Management in 2001.
- February 2009, UNEP GC Decision 25 agreed to commence Negotiations in 2010 and aim at the adoption of the Convention by 2013.
- June 2010, Intergovernmental Negotiating Committee (INC1) was held, and held five times of INC until 2013.
- 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 City and Kumamoto City.**
  - More than 1000 people including about 60 ministers and other governmental representatives from 139 countries and area.
  - Signed by 125 countries, agreed by 6 countries (USA, Uruguay, Gabon, Djibouti, Monaco), as of 9th October, 2014.

Minamata Convention on Mercury (2)

Outline of the Convention text

- Substantial lessons of Minamata Disease in the preamble.
- Regulate primary mercury mining, the import and export of mercury, and artisanal and small-scale gold mining (ASGM).
- Regulate manufacture, import or export of mercury-added products (fluorescent tube, thermometer, sphygmomanometer), and regulate manufacturing processes in which mercury is used.
- Promote measures of reducing emissions to the atmosphere, land or water based on Best Available Techniques / Best Environmental Practice (BAT/BEP).
- Promote appropriate disposal of Mercury wastes while taking existing treaty (Basel Convention) and consistency.
- Establish the fund mechanism to support capacity building and capital spending of the developing countries.
- Will go into effect 90 days after fifty countries approve ratification.

Minamata Convention on Mercury (3)

Status towards Conclusion of Convention

- UNEP secretariat stated at diplomatic conference to set the goal for effectivation of Convention in 2016.
- As a country experiencing Minamata Disease, we are now drafting a relating law to submit to the Diet in the first half of year 2015, for early conclusion of the Convention.
- Submitted “Countermeasures on Mercury in response to the Minamata Convention” to Environmental Committee.

  -> Started review in three subcommittes/ advisory committees mentioned below.
  - Environmental Health Committee- Subcommittee on mercury countermeasures in response to Minamata Convention
  - Atmosphere/ Noise and Vibration committee- Subcommittee on mercury countermeasures on atmospheric emission
  - Environment and Sound Material-Cycle Society Committee- Advisory committee on appropriate countermeasures of mercury waste

  -> Will compile plans by the end of the year and aim to submit draft law in the first half of the year 2015.

Action for the Convention’s effectuation

- Contributed 1.6 million dollars to UNEP, the provisional secretariat of Minamata Convention in March, 2014.
- Plan to conduct supporting project for capacity building in developing countries.
- Conduct a Survey for deployment of our high technology on mercury countermeasure to developing countries.

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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 :

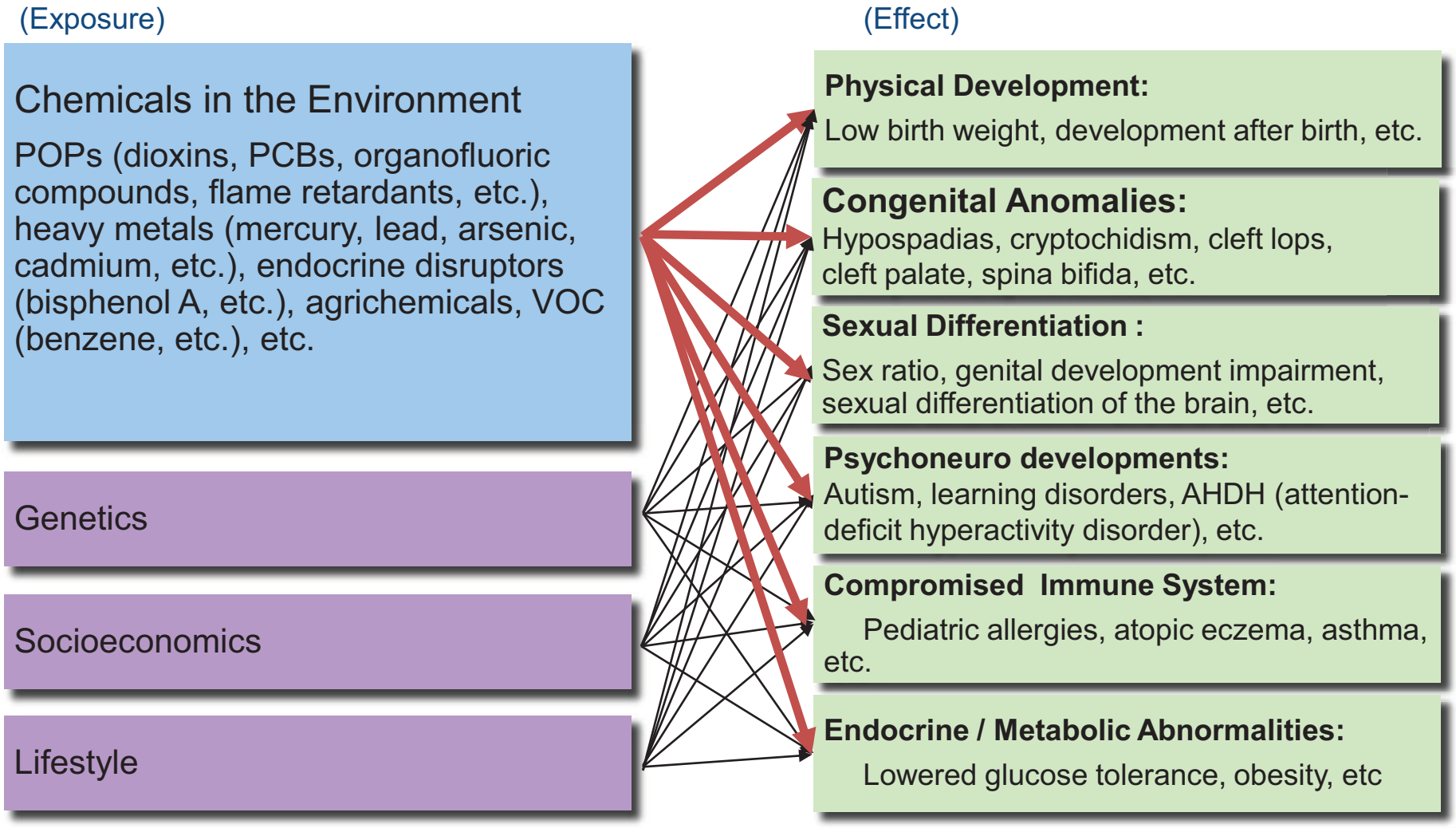
(1) Identify environmental factors impacting children's health and development.

(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.



Research Flow

Enrollment 100,000 pregnant women

Early Pregnancy
Mid to late pregnancy
- ・Informed consent
- ・Questionnaire
- ・Collect mother's blood and urine samples

At birth
- ・Evaluate health condition of baby at birth
- ・Collect cord blood samples
- ・Collect parent's blood samples and mother's hair
- ・Collect baby's dried blood sample

1 month old
- ・Collect breast milk
- ・Collect baby's hair *2

6 months to 12 years old
- ・Questionnaire (every 6 months)
- ・Interviews (every few yrs.) *1
- ・Environmental measurements *1

Long-term Storage (Specimen Bank)

Measure Chemical Substances

Analyze Results

Statistical Analysis

Identify environmental factors affecting children's health

*1 for a part of subjects *2 small cuts using scissors

Organization

Ministry of the Environment

cooperation

- Ministry of Health, Labor and Welfare
- Ministry of Education,Culture, Sports,Science and Technology
- United States and other countries

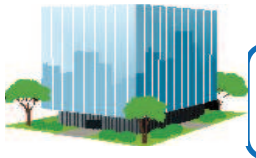
- ●Overall Planning
- ●Budegeting

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

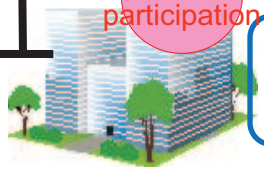


Local Governments

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

cooperation

Call fo participation



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

Cooperating Local Medical Institutions (Hospitals and Clinics)

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

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Workshop on Environmental Chemical Risk/ Pollution and Challenge in Asia

【Summary】

Purpose:

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

Agenda:

- Current status and issues of environmental pollution in Vietnam
- Knowledge and experience of Japan on chemicals management
- Risk assessment methods of chemical substances

Place: Hanoi, Vietnam

Date: 1st, 16th February, 2012
2nd, 7th March, 2013
3rd, 21st January, 2014

Participants:

MONRE (Ministry of Natural Resources and Environment),
DONRE (Natural Resources and Environment from local gov.),
MOIT (Ministry of Industry and Trade),
VINACHEMIA, etc.

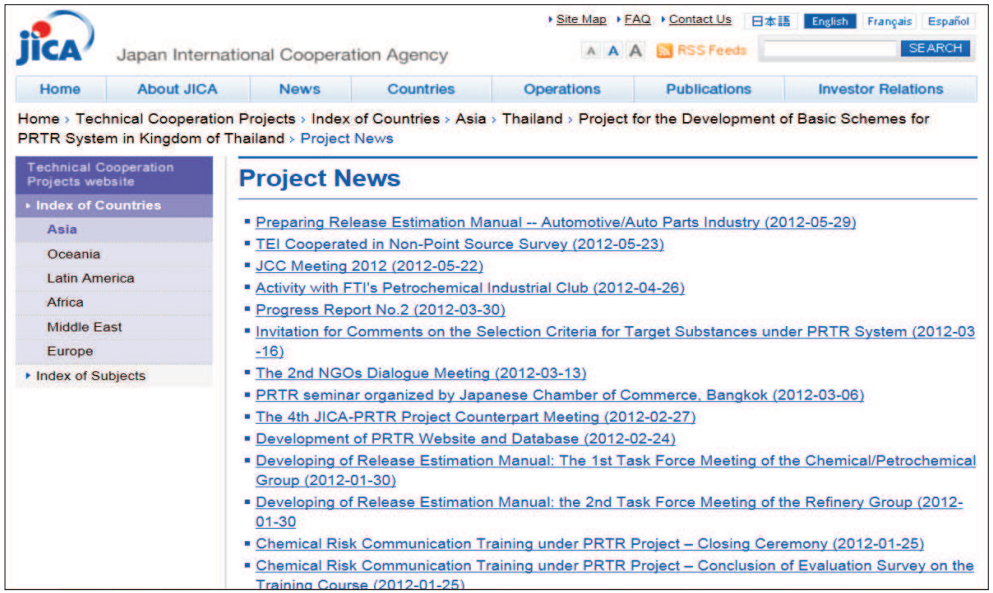
Project for the Development of Basic Schemes for PRTR System in Kingdom of Thailand

Project by: **JICA, MONRE, MOI**

Place: **Kingdom of Thailand Rayong province**

Term: **2011 - 2014**

Contents: the Development of Basic Schemes for PRTR System



PROJECT Website:

http://www.jica.go.jp/project/english/thailand/013/index.html

The Network for Strategic Response to International Chemical Management

Purpose

The Network for Strategic Response to International Chemical Management was established on July 26, 2007. All organization can participate in the network as long as they agree with the terms of network's objectives.

Activities

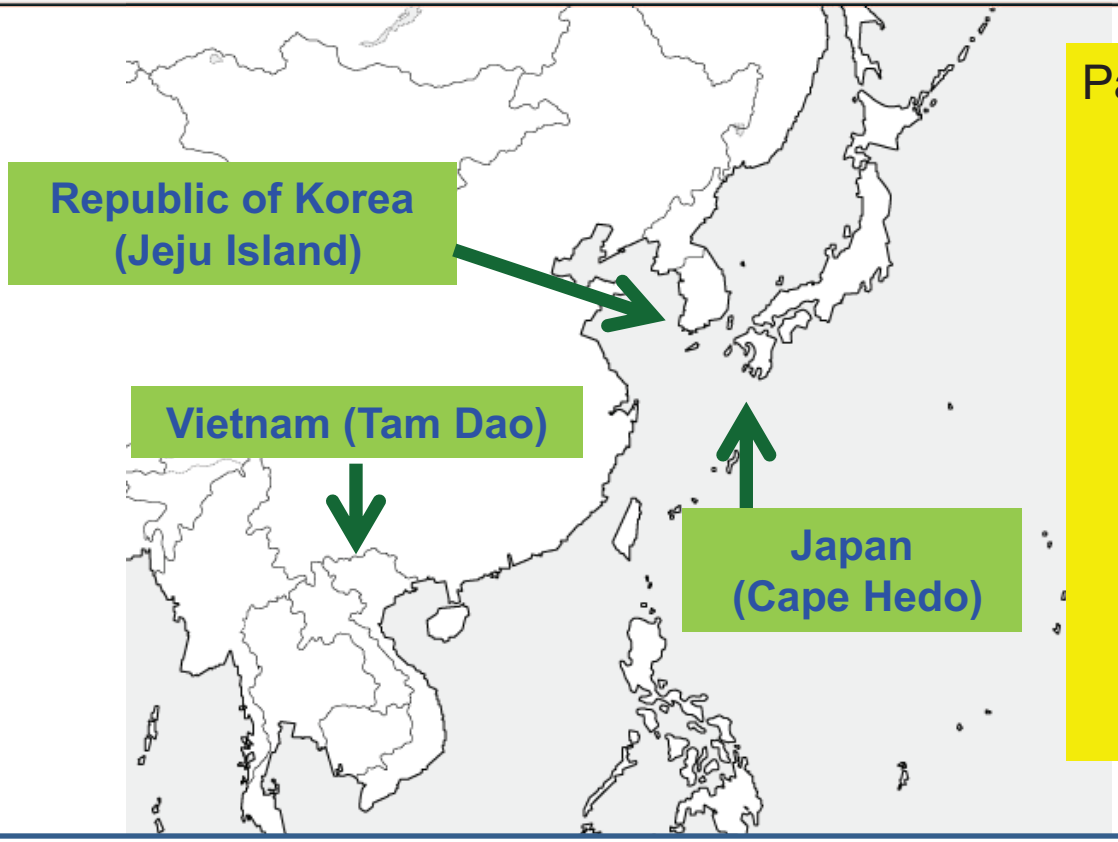
- Sharing of information and strengthening of cooperation.
- Hold seminars consisting of lectures and presentation from administrator from overseas, column, mail magazine, etc.

Participants

- As of October 2nd, 2014
  Number of organizations: 315

POPs Monitoring Project in East Asia

Started in FY 2002 in response to Stockholm Convention on Persisting Organic Pollutants (POPs).
Purpose：To establish monitoring system and collect monitoring data continuously in East Asia
[1] Collect and analyze environmental samples in East Asian Countries
[2] Hold workshops for monitoring data quality check, information exchange, etc.



Participating countries
- Cambodia
- Indonesia
- Japan
- Lao PDR
- Malaysia
- Mongolia
- Philippines
- Republic of Korea
- Singapore
- Thailand
- Vietnam

Besides frequent monitoring at above three focal survey sites, corroborative support monitoring was conducted, and provided important information for the effectiveness evaluation to the Stockholm Convention as a Monitoring Report in Asia-Pacific Regions.

Thank you for your attention.