Ministry of the Environment
Government of Japan

Current Situation of Chemicals Management Policy in Japan

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- Overview of Regulation on Chemicals
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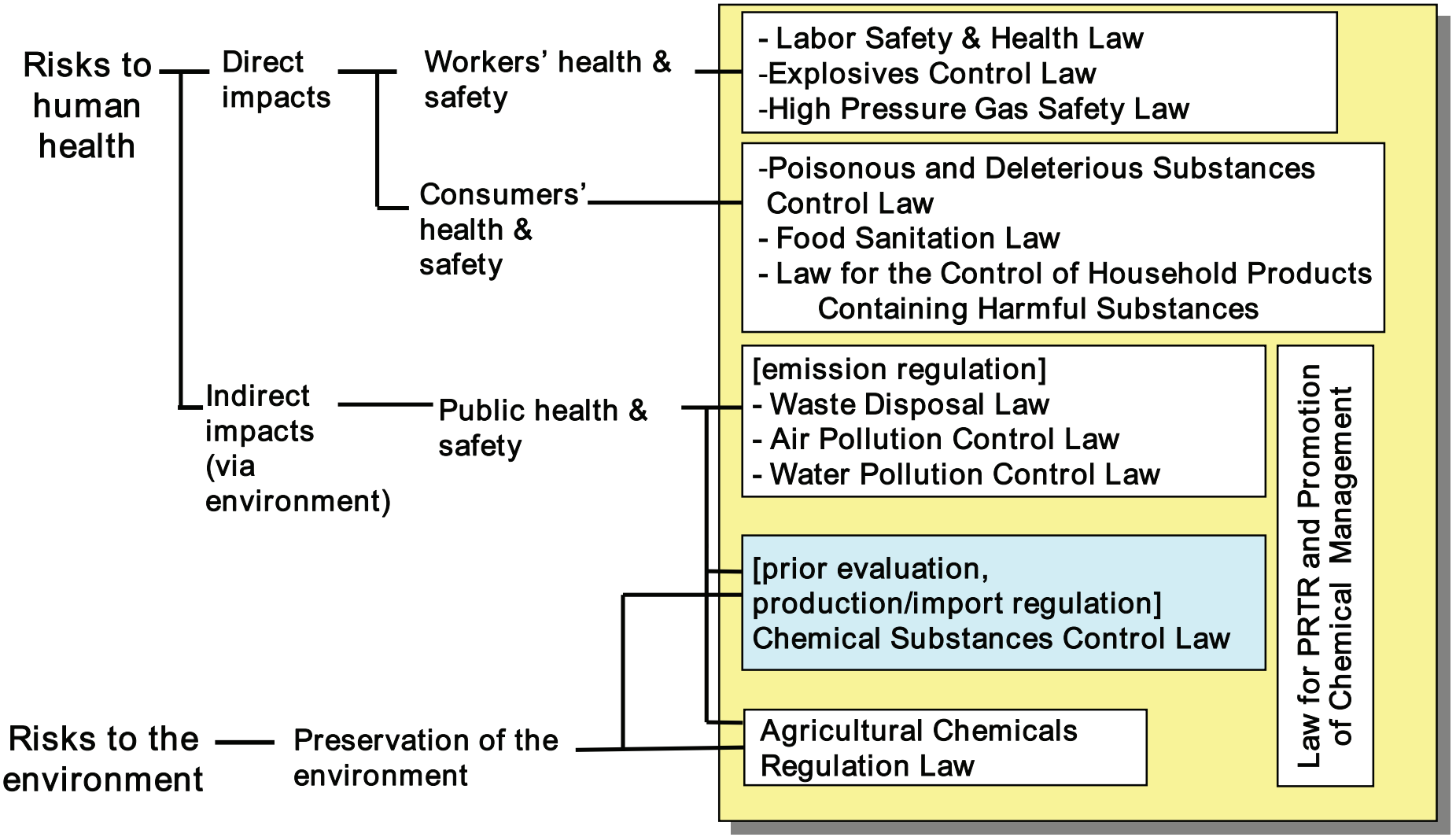
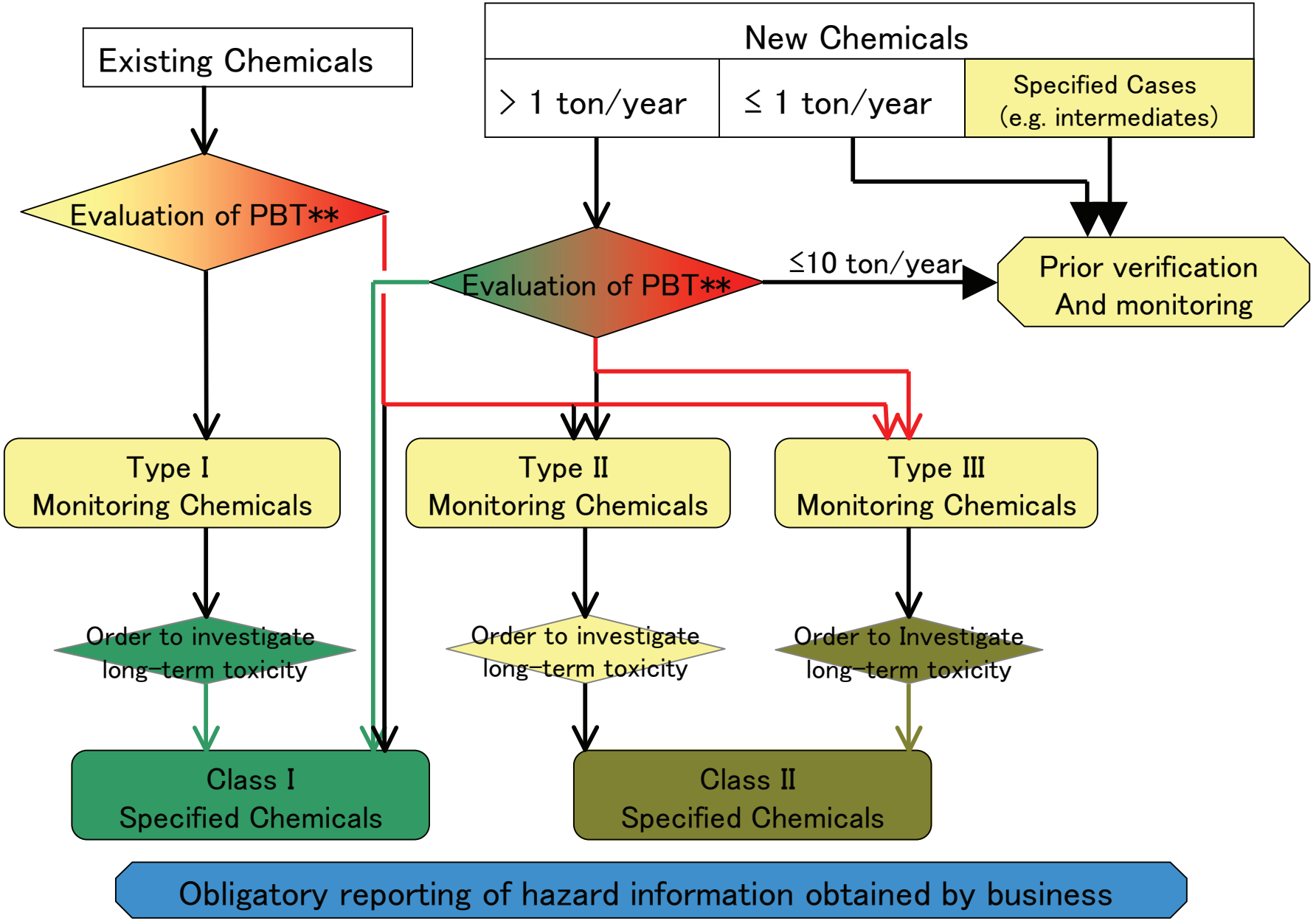
Regulation Overview



Chemical Substances Control Law (CSCL)

- Enacted in 1973
  (two major amendments in 1986 and 2003)
- Aiming to prevent pollution of environment from PCBs and other hazardous chemicals
- Based on two pillars:
  - prior evaluation of new chemicals
  - regulation on manufacture/import and use
- Excluded: specific chemicals covered by other regulations e.g. agrochemicals, pharmaceuticals, food, fertilizer
- Three Ministries are in charge: MHLW, METI, MOE
  (*No role of local governments under CSCL)

Current (2003 Amended) CSCL



Types of chemicals regulated under CSCL

Name	Explanation	No. of substances
Class-I Specified Chemical Substances	Persistent, bioaccumulative, and hazardous (long-term human toxicity or ecotoxicity to higher predators.	16
Class-II Specified Chemical Substances	Persistent, hazardous (long-term human toxicity or ecotoxicity to living organisms), with concern for long-term existence in the environment.	23
Type-I Monitoring Chemical Substances	Persistent and bioaccumulative, but hazardous properties unknown. (Candidates for the Class-I Specified Chems.)	36
Type-II Monitoring Chemical Substances	Persistent and suspected as hazardous to human health. (Candidates for the Class-II Specified Chems.)	876
Type-III Monitoring Chemical Substances	Persistent and hazardous to living organisms. (Candidates for the Class-II Specified Chems.)	61

Note: Number of chemicals as of November 2007.

Regulation on Chemicals under CSCL

Class I Specified Chemicals	-prior permission required for manufacture and/or import (Note: Permission is prohibited virtually.) - prohibition of use unless authorized in advance - prohibition of import of products containing them - recovery of the products
Class II Specified Chemicals	- mandatory reporting of planned manufactured and/or imported amounts - subject to governmental orders that require the change of planned amounts - labelling - compliance with technical guidance provided by GOJ and/or governmental recommendation on a legal basis - compliance with guidance provided by GOJ
Monitoring Chemicals (Type I, II and III)	- mandatory reporting of manufactured and/or imported amount annually (Note: These amounts are announced publicly.) -compliance with guidance provided by GOJ -The GOJ can issue directions to investigate their hazardous properties

Class I Specified Chemicals

1	PCBs
2	Polychlorinated naphthalenes (only those containing more than 2 chlorine atoms in the molecule)
3	HCB
4	Aldrin
5	Dieldrin
6	Endrin
7	DDT
8	Chlordane or Heptachlor
9	Bis(tributyltin) oxide
10	N,N'-Ditolyl-p-phenylenediamine, N-Tolyl-N'-xylyl-p-henylenediamine, or N,N'-Dixylyl-p-phenylenediamine
11	2,4,6-tri-tert-butylphenol
12	Toxaphene
13	Mirex
14	kelthane or dicofol
15	hexachlorobuta-1,3-diene
16	2-(2'-Hydroxy-3',5'-di-tert-butylphenyl)benzotriazole

Note: Yellow-colored rows are POPs covered by Stockholm Convention

Recent Issue: BAT approach to By-Product HCB

- In Feb 2006, by-product HCB in TCPA (approx. 1,000–3,000 ppm) was revealed.
- Basic idea under CSCL on by-product Class I Specified Chemicals is:
  - Basically, manufacturing/importing of HCB should not be allowed even if it was unintentional by-product.
  - In case that the by-production is technically inevitable and there is no suitable alternatives, the manufacturing/import is allowed only if the amount of by-product is reduced as much as possible based on the BAT (technically and economically Best Available Techniques).

Recent Issue: BAT approach to By-Product HCB Cont'd

- In April 2006, three ministries set an Assessment Committee on the BAT Levels.
- In Nov. 2006, the first report of the Committee was published: suggesting the BAT levels as
  - 200ppm for TCPA
  - 10ppm for its derivative, Solvent Red 135
- In Apr. 2007, the second report of the Committee was published: suggesting the BAT levels as
  - 10ppm for TCPA derivatives other than SR-135 and Pigment Yellow 138
  - 10ppm for Pigment Green 36, Phthalocyanine derivatives
- The BAT levels will be incorporated into CSCL after one year (depending on the availability of low-HCB containing TCPA and pigments).

2. Risk Assessment

- Monitoring
- PRTR
- Current Risk Assessment

“Chemicals in the Environment” JMoE’ Environmental Monitoring Report

- JMoE has issued “Chemicals in the Environment” since 1974 on an annual basis.
- This environmental monitoring report presents the results of environmental surveys that JMoE has carried out in a systematic way to identify chemicals in the environment and to monitor their levels.

http://www.env.go.jp/chemi/kurohon/index.html
(in Japanese, FY2006)

http://www.env.go.jp/chemi/kurohon/en/http2005e/index.html
(in English, FY2005)

JMoE's Environmental Monitoring Program

1. The Initial Environmental Survey
2. The Advanced Environmental Survey
3. The Environmental Survey for Exposure Study
4. The Monitoring Investigation
5. The Environmental Survey for human biological samples

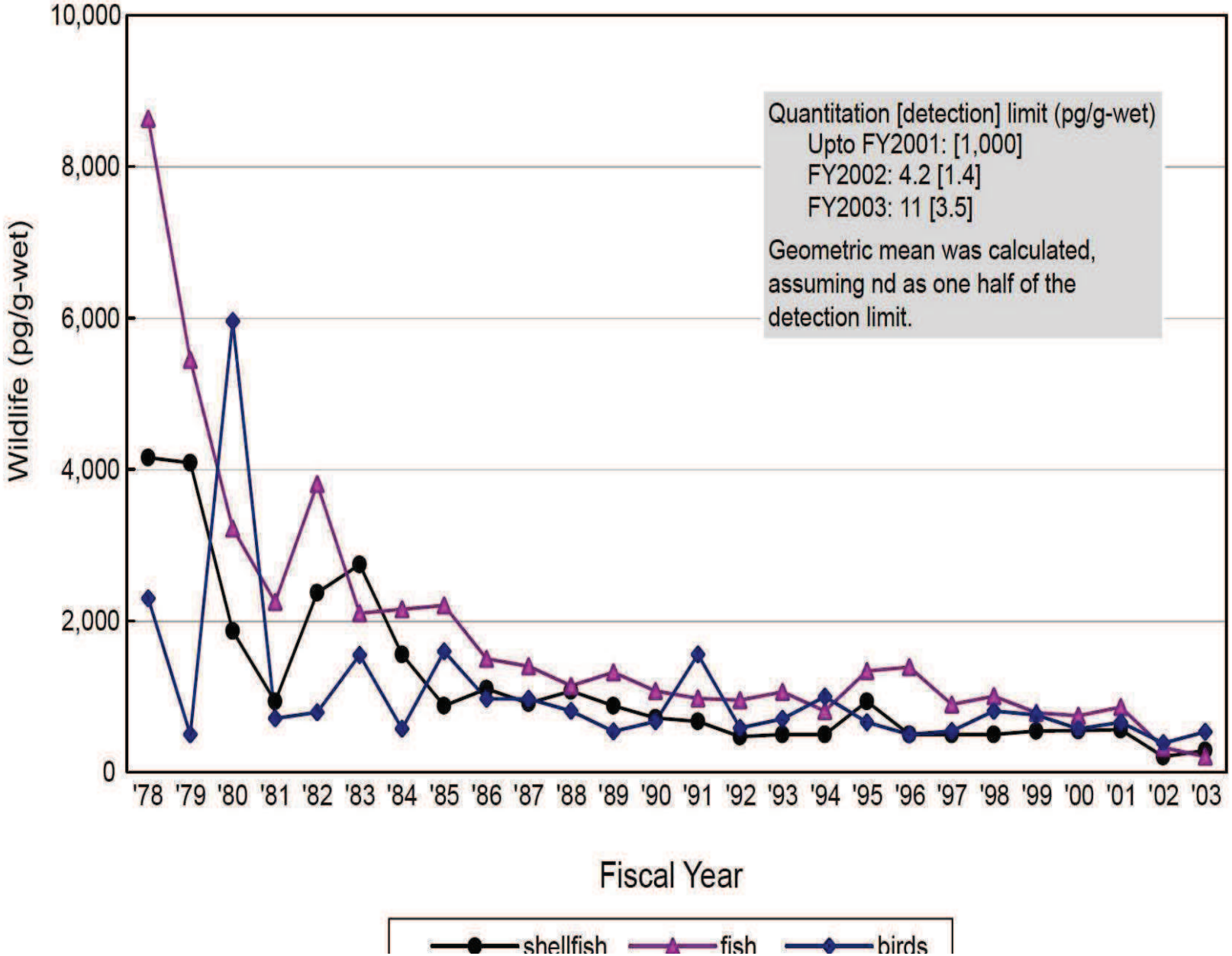
Modeling Analysis of Environmental Fate of Chemicals

Development of Analytical Method

Environmental Specimen Bank Coop With NIES

JMoE's POPs Monitoring

Concentration of p,p'-DDT in Wildlife (shellfish, fish, birds) (geometric mean)

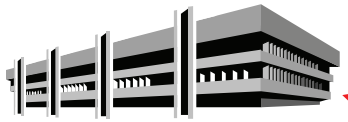


POPs Monitoring Network in East Asia

- Advocated in 2002 through the initiative of JMoE
- to respond to “effective evaluation” under the POPs Convention
- 4 technical workshops (in Dec. 2002, Dec. 2003, Oct. 2005 and Sep. 2006) held with support of many East Asian countries

Japan's Pollutant Release and Transfer Register

Report of their emissions of 354 chemicals to central government via local governments

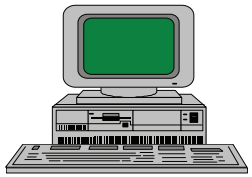


enterprises

Disclosure of data on individual emission sources

Citizens

MOE and METI

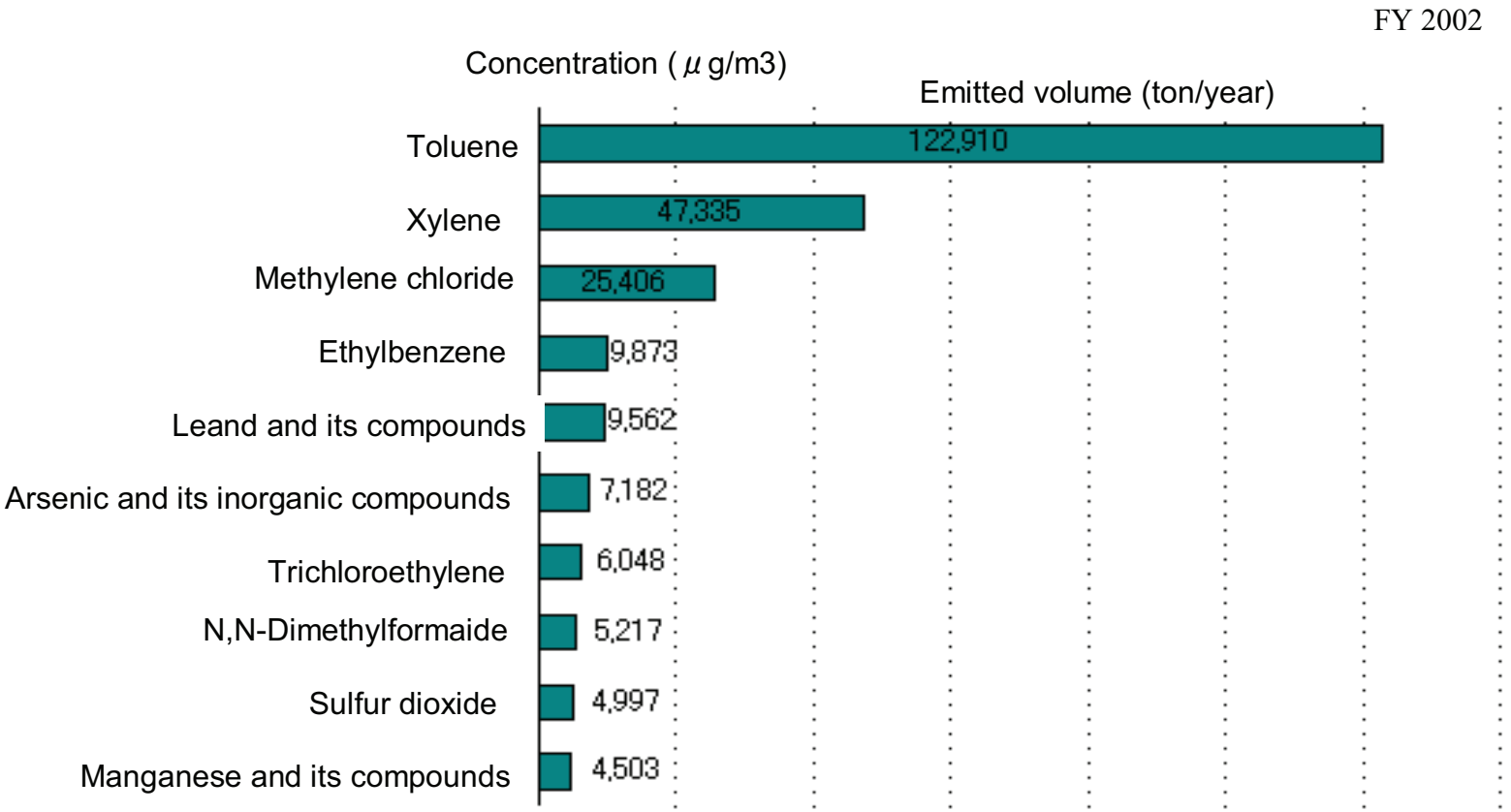


Request of data disclosure

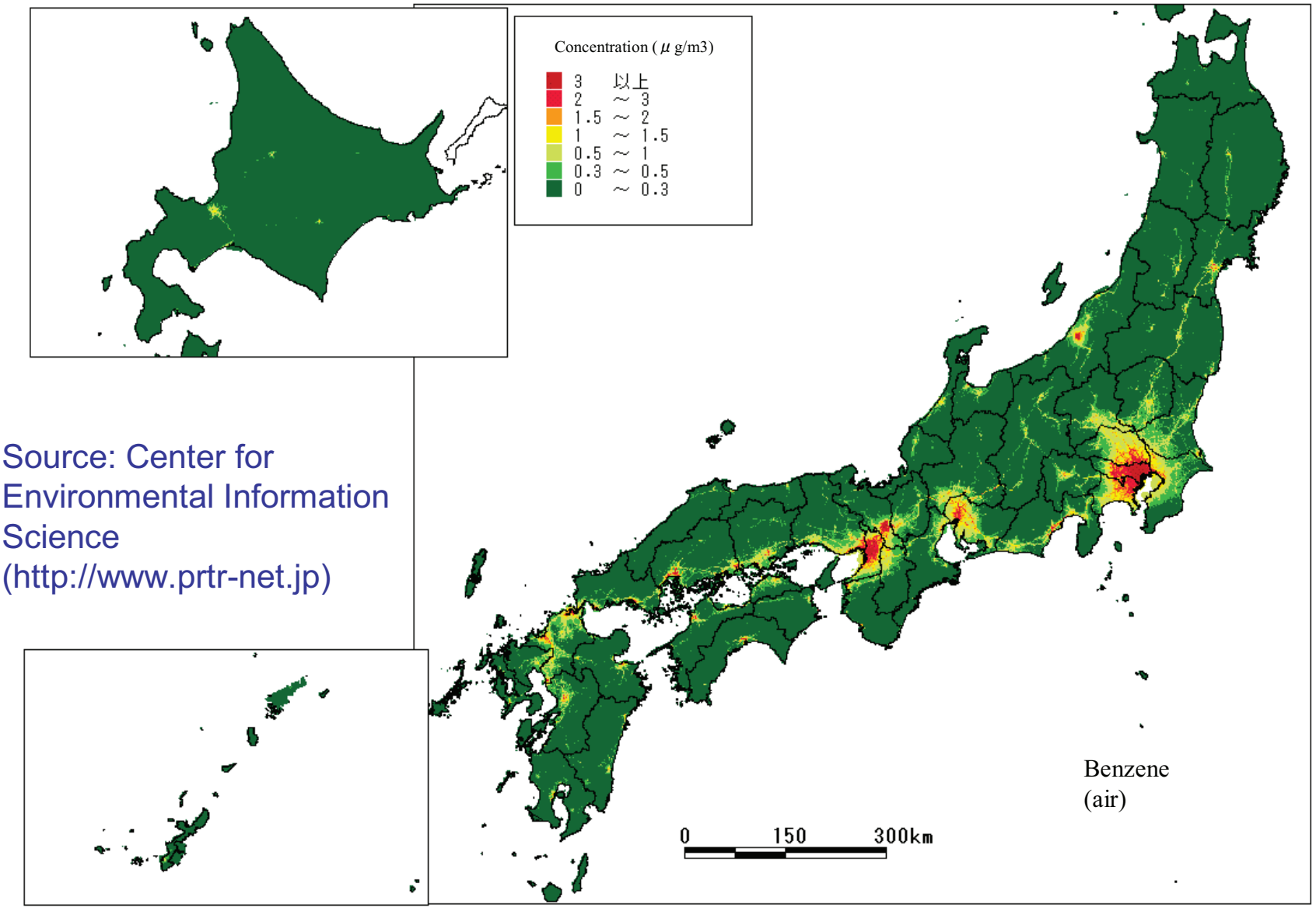
Improvement of public understanding

MOE and METI estimate emissions from non-points sources.

Top 10 Chemicals under PRTR



Examples of Use of PRTR Data



Source: Center for Environmental Information Science (http://www.prtr-net.jp)

Risk Assessment

So far…

- Initial risk assessment project started in 1997.
- completed initial risk assessment:
  - 39 chemicals in 2002
  - 13 chemicals in 2003
  - 21 chemicals in 2004
  - 20 chemicals in 2005
  - 23 chemicals in 2006

  116 chemicals in total

From now on

-Continued work on the initial risk assessment (ca. 20 chemicals /year)
-Study on vulnerability of children's health
- Initiation of detailed risk assessment, if necessary

3. Information Collection and Sharing

- Evaluation of Existing Chemicals
- Japan HPV Challenge Program
- Multi Stakeholder Involvement

Evaluation of Existing Chemicals

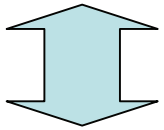
Additional resolution of the Diet in 1973 (when CSCL was adopted)

" the government would assess the safety of existing chemical substances. "

(Role sharing among the government and the industry)

	Collecting data (test)	Assessment
New Chemicals	Industry	Government
Existing Chemicals	Government	Government

.Number of Existing Chemicals : about 20,000



Number of substances evaluated (until May 2007) :

Degradation & bioaccumulation: 1525 (by METI)

Toxicity to human: 315 including (by MHLW)

Ecotoxicity: 485 including (by MOE)

Japan HPV Challenge Program

Background

- ✓ Worldwide approaches to existing chemicals were advanced in the 1990s.
  - ➢ Global cooperation, led by OECD since 1992. (Japan has been contributing as well)
  - ➢ The US started "The US HPV Challenge Program" in 1998.
- ✓ CSCL revision in 2003.
  - ➢ The Diet passed an additional resolution that "the public and private sectors should jointly promote systematic collection of data on existing chemical substances."

⇒ Launched in June 2005.

Aiming at accelerating collection and dissemination of safety data on existing chemicals through partnership between of government and industry

Features of the Program

US HPV Challenge Program is the model of Japan's Program.

Two features;

1. **Voluntary program** under cooperation between the private and public sectors
   - Safety data of high priority (HPV) existing chemicals are collected voluntary by Sponsor companies (private sector).
2. **The Collected Information will be publicly available.**
   - The collected safety information will be open to public via website.
   - It can be utilized for various purpose; self-management systems by companies, risk assessment by researchers, and chemicals management policies by the government.

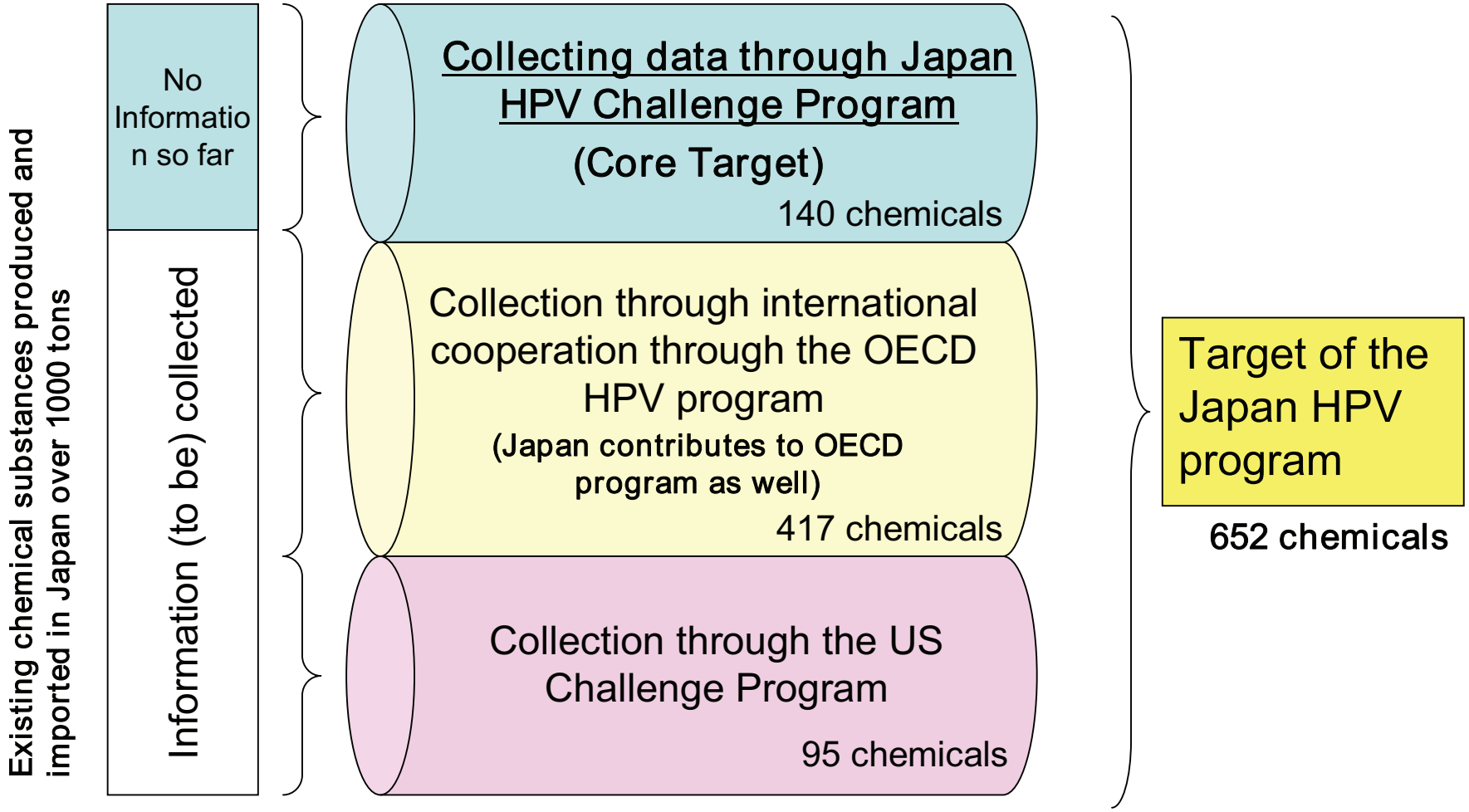
Targeted chemicals

- Organic chemicals (except for Polymers)
- Identify chemical substances based on the CAS number. (not Japan's CSCL number)
- HPV : over total 1,000 tons per year (in Japan)

(Based on METI's "survey of import/manufacturing volume of chemical substances in 2001")

<u>About 650 substances are the target of the Program</u>

Targeted chemicals (Cont'd)



Japan Challenge Program : Role of the GOJ

1. Administer the program (selecting target chemicals, disclose progress of the program, secretariat of the promotional committee, etc.)
2. Establish website to release the collected data publicly
3. Check the reliability of data submitted by the Sponsor
   (METI: Physicochemical properties, Environmental fate and Pathways, MOE: Ecotoxicity Tests, MHLW: Human Health Effects)

* Keep getting data of existing chemicals that are manufactured and imported less than total 1,000 tons per year

(Role sharing among three Ministries in terms of collecting data of non-HPV existing chemicals)

METI	Biodegradation, Bioaccumulation, Physicochemical properties
MOE	Acute toxicity to fish, Acute toxicity to aquatic invertebrates, Toxicity to aquatic plants
MHLW	Repeated dose toxicity, Genetic Toxicity (effects on the gene and chromosome)

Japan Challenge Program : Role of Industry

Companies or Consortia (Sponsor) will collect data of "Core Target" – Sponsorship is voluntary basis

1. Identify the target chemicals
   -Japan HPV target list does not change, meaning that Japan's program does not have "no longer HPV" scheme.
   - They can use "Category approach" like US HPV Program
2. Submit **registration letter** to the government
3. Submit **test plans** to the government
4. Make test if necessary and submit **Robust Summary** to the government

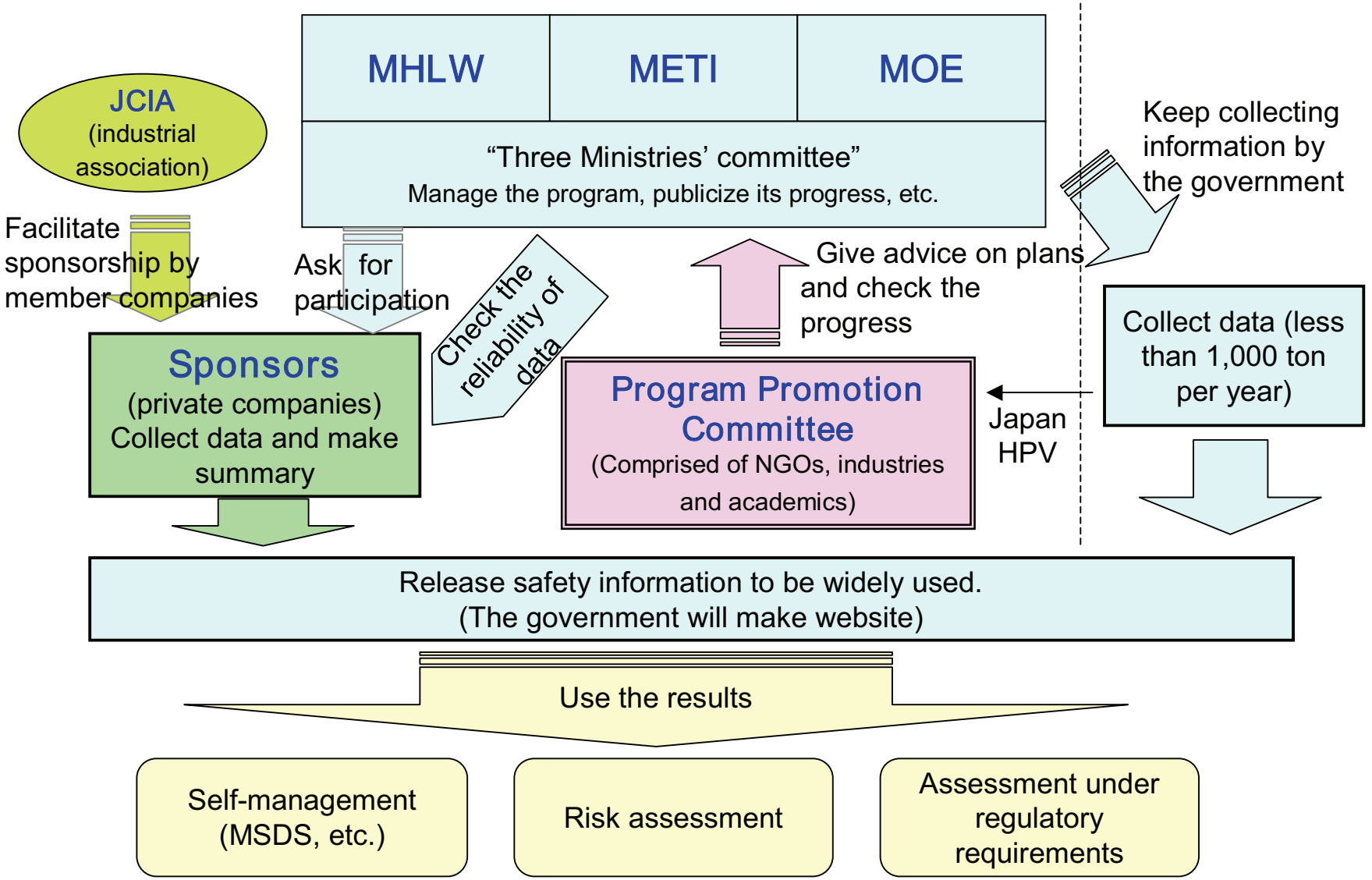
Japan Chemical Industry Association (JCIA) plays an important role to facilitate Sponsorship.

Data format for collection

Screening Information Data Set (SIDS):

- **Physicochemical properties**: Melting point, Boiling point, Relative density, Vapor pressure, Partition coefficient, Water solubility, Dissociation constant
- **Environmental fate and Pathways**: Photodegradability, Stability in water, Biodegradability, Transmigration and distribution
- **Ecotoxicity Tests**: Acute toxicity to fish, Acute toxicity to aquatic invertebrates, Toxicity to aquatic plants
- **Human Health Effects**: Acute toxicity, Repeated dose toxicity, Genetic Toxicity (effects on the gene and chromosome), Reproductive toxicity

Program Flow



Current Situation

(as of May 2007)

- 74 companies and 3 associations has already joined the program as “Sponsors” (including 19 consortiums)
- 16 categories has been formulated.
- Approx. 80 substances (of 140) has been already sponsored.
- Sponsor companies are making test plan now. (No data publicly available yet)

How to deal with Orphan candidates might be the big issue soon.

Multi Stakeholders Involvement

Chemicals and the Environment Round Table (CERT)

- ✓ 21 meetings since 2001
- ✓ Member: NGOs, Industry Associations, Governments (national and local authorities)

- ✓ Missions:
  1. to gather a variety of opinions from the public by using the Internet and having local meetings;
  2. to promote information sharing and mutual understanding for reducing environmental risks through dialogue among NGOs, industry and government; and
  3. to disseminate, to citizens, industry and government, information on the discussions and mutual understanding made at the meetings.

4. Challenges and Future Efforts

- Review & Revision of CSCL etc.
- Cooperation among China, Japan and Korea

Review & Revision of CSCL etc.

2006 Apr. The 3rd Basic Environment Plan

Dec.

- Interim Report by the Subcommittee of Industrial Structure Council
- 1st Meeting of Subcommittee of Central Environment Council

2007 Aug. Interim report by Joint Session

2008 Interim Assessment of Japan HPV Challenge Program

2009 Review and Revision of CSCL

Cooperation among China, Japan and Korea

December 2006

◆TEMM8 (Tripartite Environmental Ministers Meeting) was held in Beijing and three ministers agreed to proceed with information exchange regarding policies and regulations on chemicals management

March 2007

◆1st International Workshop and Working-level Meeting at Hayama

- ✓ http://www.env.go.jp/en/chemi/temm.html
- ✓ http://ncis.nier.go.kr/temm_cmp/index.html

November 2007

◆Tripartite Policy Dialogue on Chemicals Management

December 2007

◆TEMM9 will be held at Toyama

Summary

✓ Risk Management

- based on CSCL for human health and the environment

✓ Risk Assessment

- supported by relevant activities: environmental monitoring and PRTR

✓ Information Collection and Sharing

- existing chemicals has become a big issue, like in other countries
- measures in cooperation with citizens, industry, and government

✓ Future

- review process of legal scheme has started
- policy dialogue among China, Japan and Korea

Thank you!