

Outline of the Japan HPV Challenge Program

**(A joint program among the private and the public sectors for
collecting and releasing safety information of Japan HPV existing
chemical substances)**

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I. The background of the Program

I-1. Japan's Chemical Substance Control Law

- The Chemical Substances Control Law (CSCL: *kashinhou*) was enacted in Japan in 1973.
 - In 1972, MITI made “Japan’s Existing Chemical Lists (JECL)” including about 20,000 chemicals that were already manufactured or imported before 1973 in Japan.
 - “New Chemicals” are not listed in JECL. Pre-notification is necessary to manufacture/import “New Chemicals” in Japan.
 - Three Ministries are in charge of enforcement of CSCL.
 - Ministry of Health, Labour and Welfare (MHLW)
 - Ministry of Economy, Trade and Industry (METI)
 - Ministry of Environment (MOE)
- (※No role of local government under CSCL)

I-2. Existing Chemicals under CSCL

CSCL was enacted in 1973.

- The Diet passed an additional resolution that the government will assess the safety of existing chemical substances.

(Role sharing among the government and the industry when CSCL was started)

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

Problem !!

1. Since there are huge number of existing chemicals, collecting data (test) by only the government was not advanced rapidly.
2. At the same time, the companies can manufacture and import high volumes of existing chemicals without pre-notification. → Concern about safety of HPV arose.

**Collecting Japan HPV Chemicals data
quickly was a big challenge**

I-3. History before the Program was launched

- ✓ **Worldwide approaches to existing chemicals were advanced in the 1990s.**
 - Global cooperation, led by OECD since 1992. (Japan has contributed as well)
 - The US started “The US HPV Challenge Program” in 1998.

- ✓ **CSCCL was revised in 2003.**
 - The joint council involved with the industrial circle proposed that the safety assessment of existing chemicals be conducted jointly by both the public and private sectors.
 - The Diet passed an additional resolution that the public and private sector should jointly promote systematic collection of data on existing chemical substances.

- ✓ **“Japan HPV Challenge Program” was launched in 2005.**
 - The new framework to gather safety information of existing chemicals under cooperation among the private and public sectors was started.

II. Basic Principle of the Program

II-1. Two features of the Program

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

Two features;

1. **Voluntary program** under cooperation between the private and public sector
 - Safety data of high priority (HPV) existing chemicals are collected voluntarily by the Sponsor (private sector).
2. **Releasing data through web sites** to make it widely used
 - The collected safety information will be publicly available.
 - It can be utilized for the self-management system by companies, risk assessment by researchers, and chemicals management policies by the government.

II-2. High Priority Chemicals (Target)

- ✓ Definition of High Priority Chemicals
(Target: Japan HPV)
 - 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”**

II-3. Core Target

- ✓ The government posted a list of high priority chemicals (Japan HPV: total 652 substances).
(“http://www.meti.go.jp/policy/chemical_management/kasinhou/kizonpro/challenge/list.pdf”)
- ✓ Categorize those target chemicals into three types:
Type 1: Collection finished (through OECD HPV or US HPV Program),
Type 2: Data to be collected (through OECD or US Program)
Type 3: Data not to be collected
- ✓ The type 3 is the **core target** of Japan’s program. The Japanese government asked private firms to become voluntary “Sponsors” that will gather information of Core target chemicals and make a robust summary.

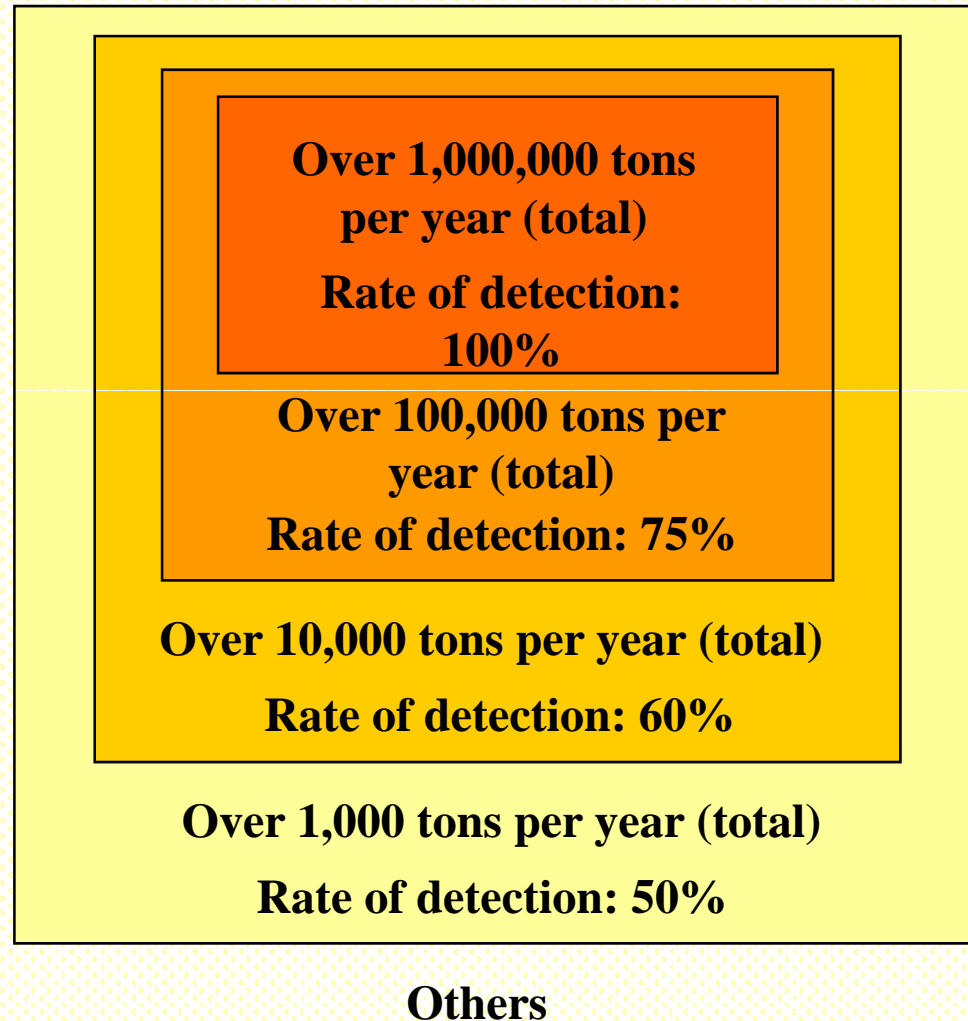
II-4. Why over 1,000 tons?

✓ OECD HPV
definition: Over 1,000
tons per year

✓ About 50 % of
chemical substances
produced and
imported total over
1,000 tons a year are
detected in
environmental
monitoring.

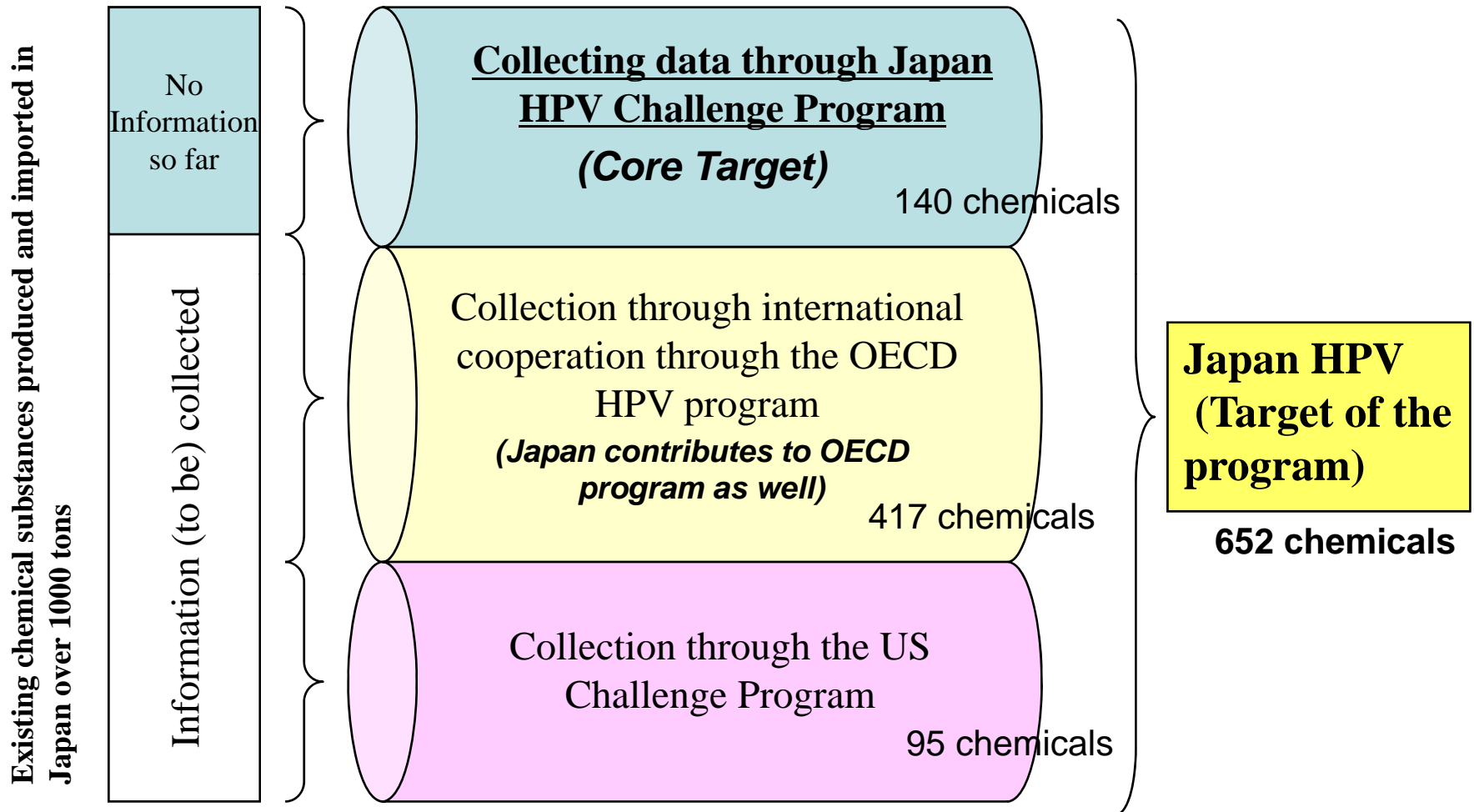


*The more produced, the
more important for
Japanese society!*



Relationships between production volume and the amount detected | 1
in environmental monitoring by Ministry of Environment

II-5. Total image of the Target chemicals



II-6. Data format

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

III. Role sharing of the Program

III-1. Role of the government

1. Administer the program (selecting target chemicals, disclose progress of the program, secretariat of promotional committee, etc.)
 2. Establish web site 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)

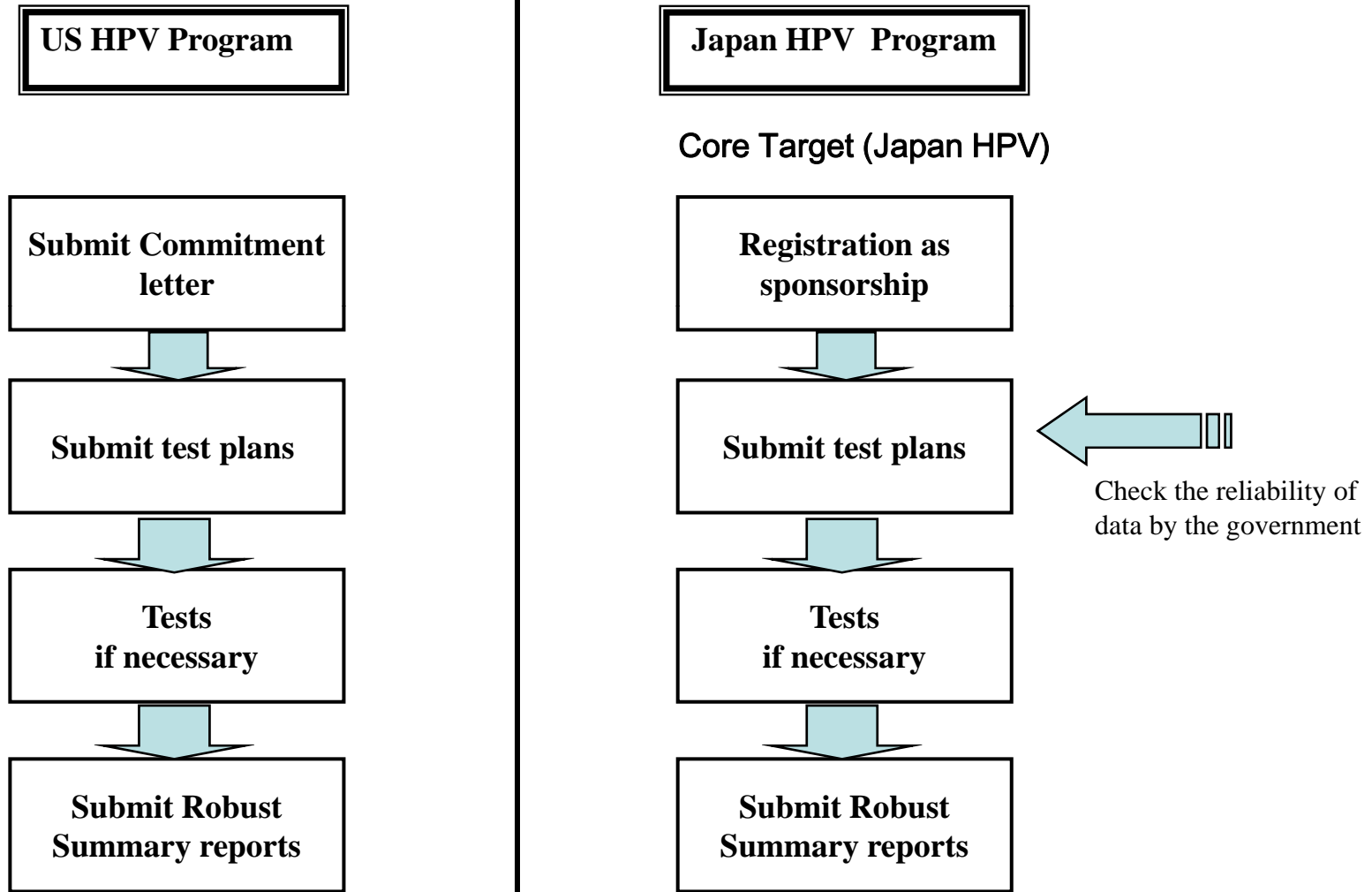
III-2. Role of the Private firms

Companies or Consortia (Sponsor) will collect data of “Core Target” – *Sponsorship is not requirement under the law*

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 gov.

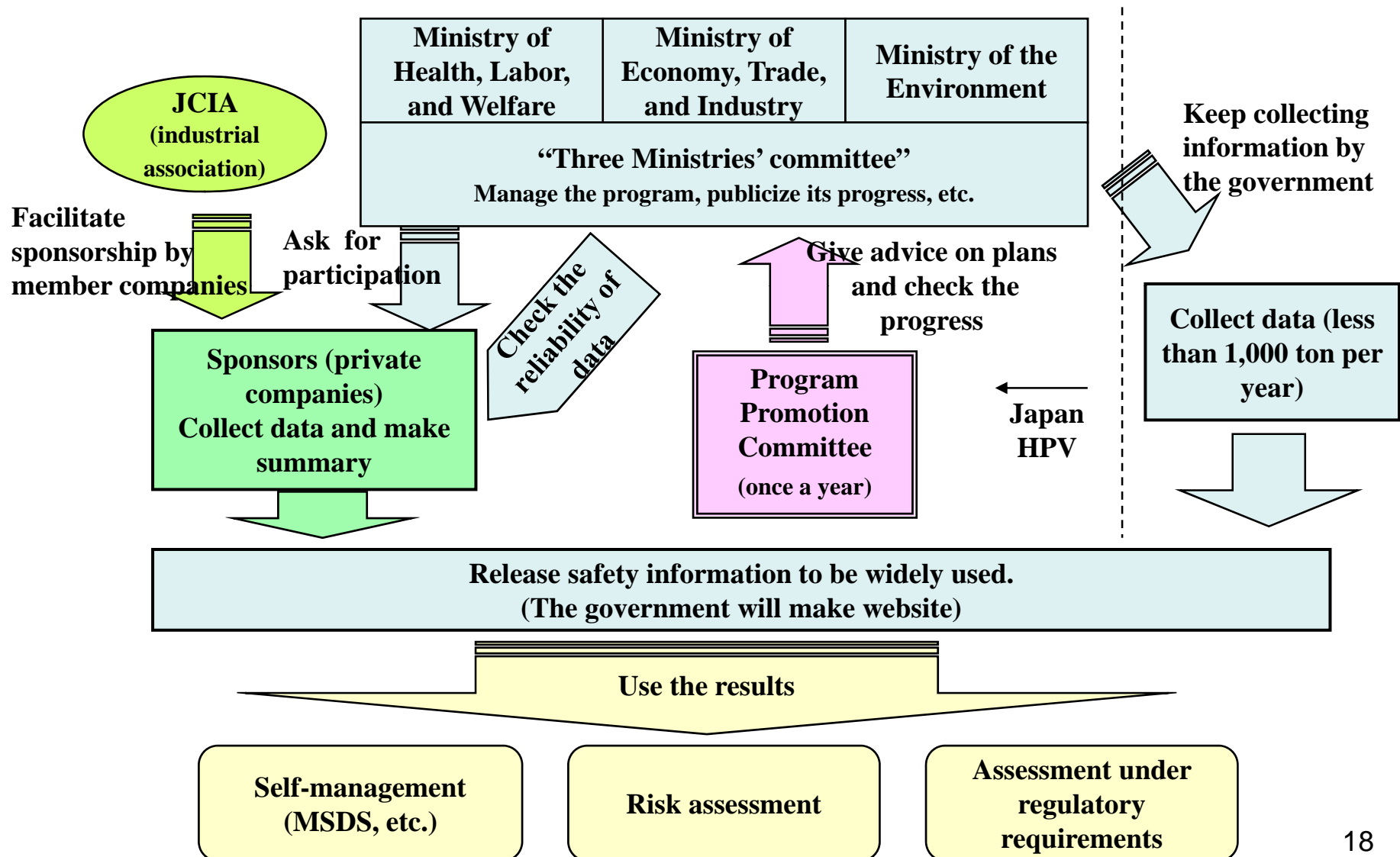
Japan Chemical Industry Association (JCIA) plays an important role to facilitate being Sponsor.

III-3. Flow of the Program (1)



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III-4. Flow of the Program (2)



VI. Present and Future of the Program

VI-1. Current Situation

(as of Nov. 2006)

- 62 companies and 3 associations already joined the program as “Sponsors”
- 12 Consortiums are formulated.
- 77 substances (of 140) are 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.

The list of Sponsored companies (as of Nov. 2006)

# of Sponsored Chemicals	Name of Sponsored Company / Organization
8	KAO CORPORATION
6	SHOWA DENKO K.K.
5	NOF CORPORATION, Mitsubishi Corporation, Japan Crop Protection Association,
4	Sanyo Chemical Industries, Ltd., DAICEL CHEMICAL INDUSTRIES, LTD., Dainippon Ink and Chemicals Incorporated, DAIHACHI CHEMICAL INDUSTRY CO., LTD., NIPPON NYUKAZAI CO., LTD., Mitsui Chemical Co., Ltd.,
3	ASAHI GLASS CO., LTD., ADEKA CORPORATION, Kawaken Fine Chemicals Co., Ltd., NIPPON FINE CHEMICAL CO., LTD., Mitsubishi Gas Chemical Company. Inc., YUKI GOSEI KOGYO co., ltd.,
2	UBE INDUSTRIES. LTD., HONSHU CHEMICAL INDUSTRIES. CO., LTD., MITSUI & CO., LTD., MITSUBISHI RAYON CO., LTD., LION CORPORATION,
1	Asahi Kasei Corporation, Arimoto Chemical Co., Ltd., ALBEMARLE JAPAN CORPORATION, API Corporation, Du Pont-MGC Co., Ltd., Orient Chemical Industries, Ltd., Kao-Quaker Co., KAWASAKI KASEI CHEMICALS LTD., KYOWA HAKKO CHEMICALS CO., LTD., Clariant Japan K.K., KURARAY CO., LTD., Chemtura Japan Limited., CHEMICAL KASEI KAISHA, LTD., Goi Chemical Co., Ltd., KONISHI CHEMICAL IND. CO., LTD., SANSUI SHIKISO KOGYO CO., LTD., SANYO COLOR WORKS, LTD., SHIPRO KASEI KAISHA, LTD., JOHOKU CHEMICAL CO., LTD., New Japan Chemical Co., Ltd., SUMIKA COLOR CO., LTD., SUMITOMO CHEMICAL CO., LTD., Dainichiseika Color & Chemicals Mfg. Co. Ltd., Ciba Specialty Chemicals, TAYCA CORPORATION, DENKA, TOSOH, TOYO INK MFG CO., LTD., Toray Industries, Ink, Nishiki Trading Co., Ltd., NIPPOH CHEMICALS CO., LTD., NIPPON SHOKUBAI CO., LTD., NIHON JYORYU KOGYO CO., LTD., ZEON CORPORATION, NIPPON SODA CO., LTD., NOMA KAGAKU, MIKUNI COLOR, RIKEN VITAMIN CO., LTD., Rhodia Japan, Ltd., WAKAYAMA SEIKA KOGYO CO., LTD., SILICONE industry Association of Japan, Japan Scientific feeds Association

VI-2. Timeline of the Program

This program is still at an early stage compared to US HPV Challenge Program.

June 2005 Launched the program

Recruiting Sponsor

Collecting Data

2008 *Interim assessment of this program*

2009 Revise CSCL?



Important!

Thank you!!

--End--

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