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)

April 2009

I-1. Japan's Chemical Substances Control Law

- **The Chemical Substances Control Law (CSCL: *kashinhou*)** was enacted in Japan in 1973.
- In 1972, MITI made "MITI Inventory" consisting of about 20,000 chemicals that had been already manufactured or imported before CSCL was issued in Japan.
- "New Chemicals" are not listed in MITI Inventory. Pre-notification is necessary for manufacturing/import of "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 the Environment (MOE)

  (※No role of local governments under CSCL)

I-2. Existing Chemicals under CSCL

CSCL was enacted in 1973.

- The Diet passed an additional resolution that the government would 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, companies can manufacture and import high volumes of existing chemicals without pre-notification. → Concern about safety of HPV arose.

Collecting data of Japan HPV existing chemicals quickly has been 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 been contributing as well**)
  - The US started "The US HPV Challenge Program" in 1998.

- ✓ **CSCL 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 sectors 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 between the private and public sectors** was started.

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 sectors
   - Safety data of high priority (HPV) existing chemicals are collected voluntary by Sponsor companies (private sector).
2. **Releasing data through web sites**
   - The collected safety information will be publicly available.
   - It can be utilized for the self-management systems 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 <u>in 2001</u>"**

II-3. Core Target

- ✓ The government posted a list of high priority chemicals (Japan HPV: *total 645 substances*).
  ("http://www.meti.go.jp/policy/chemical_management/kasinhou/kizonpro/challenge/list0708.pdf")
- ✓ Categorized 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?

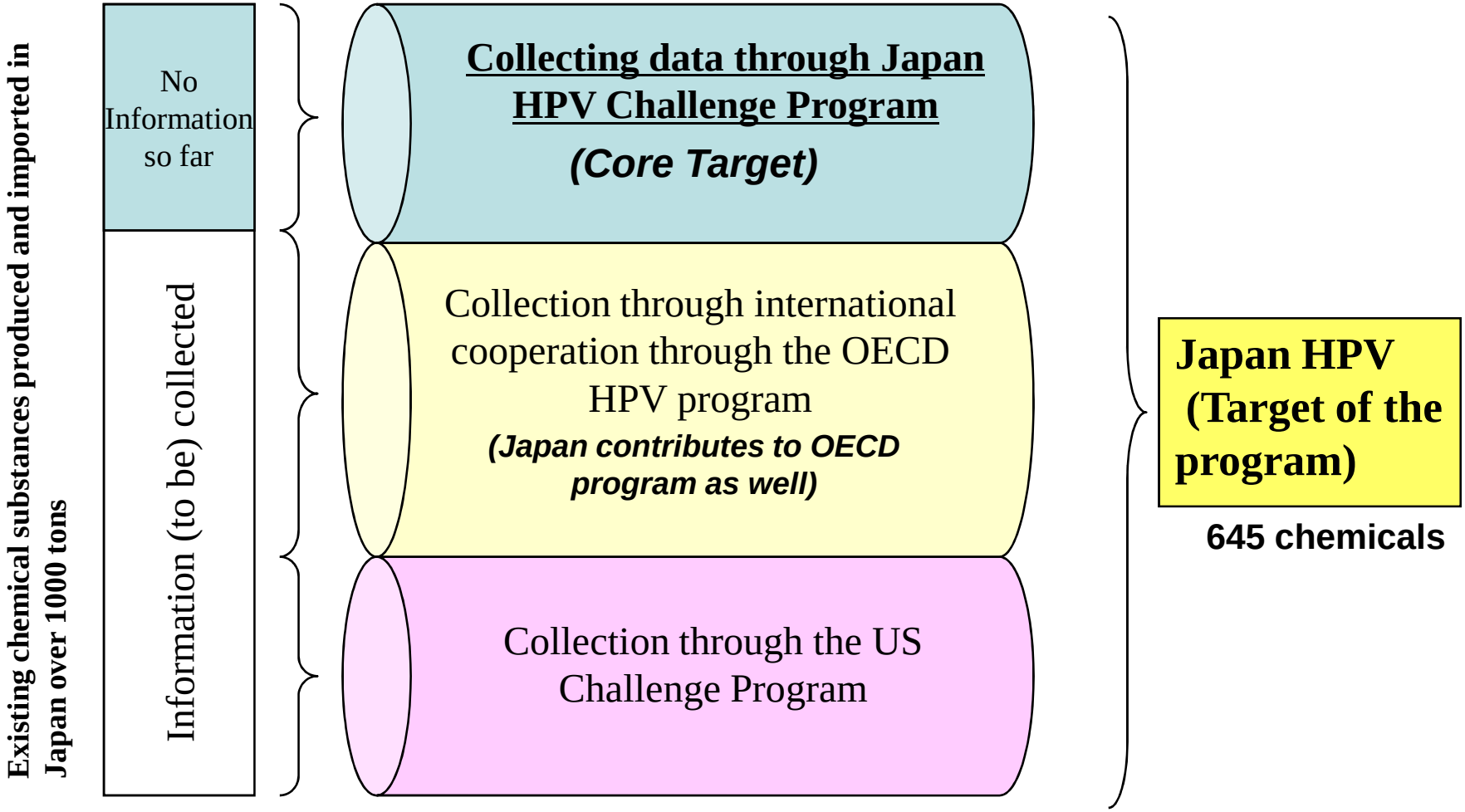
✓**OECD HPV definition: Over 1,000 tons per year**

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

<u>The more produced, the more important for Japanese society!</u>

Relationships between production volume and the amount detected in **<u>environmental monitoring</u>** by Ministry of the 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-1. Role of the government

1. Administer the program (selecting target chemicals, disclose progress of the program, secretariat of the 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)

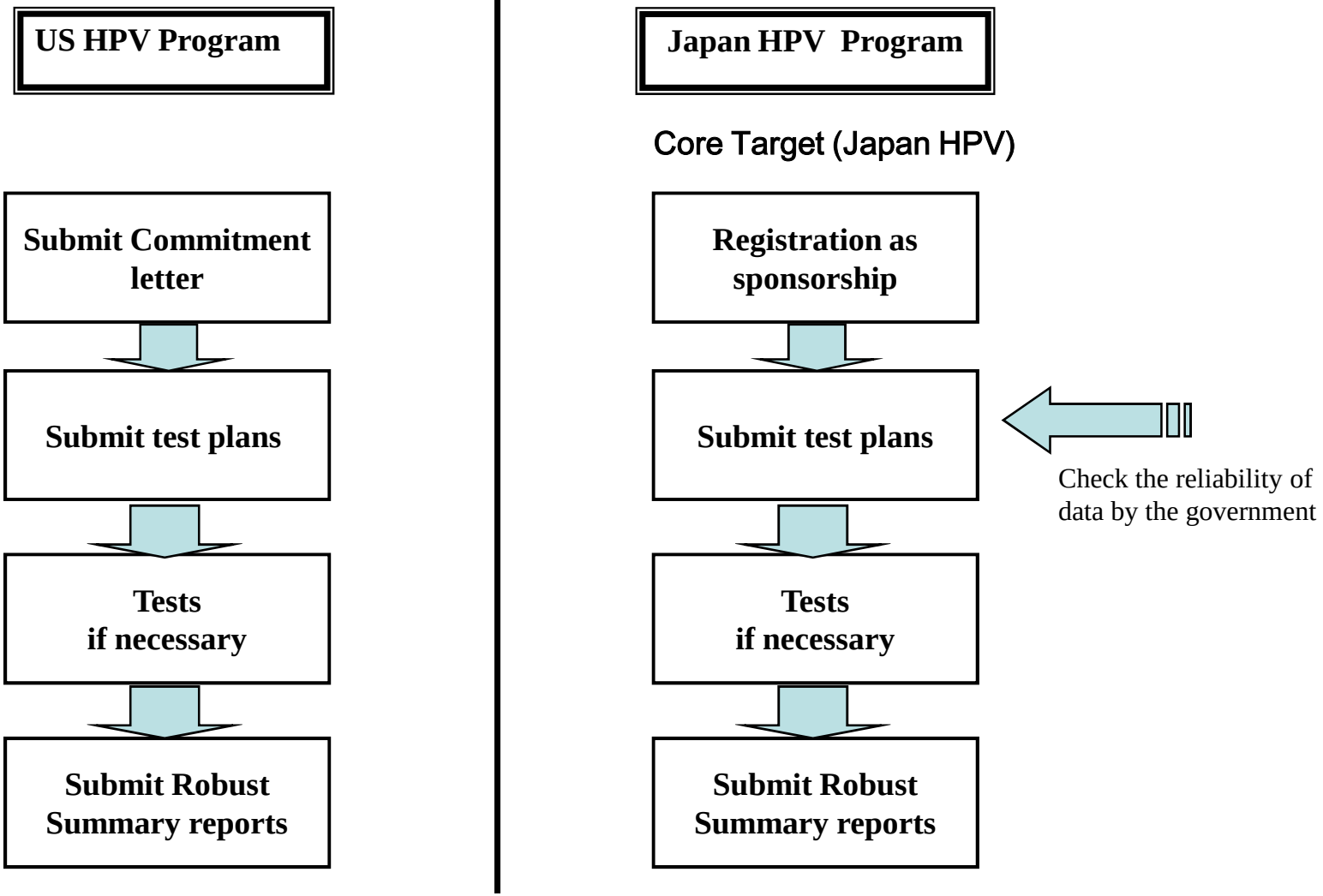
III-2. Role of the Private firms

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

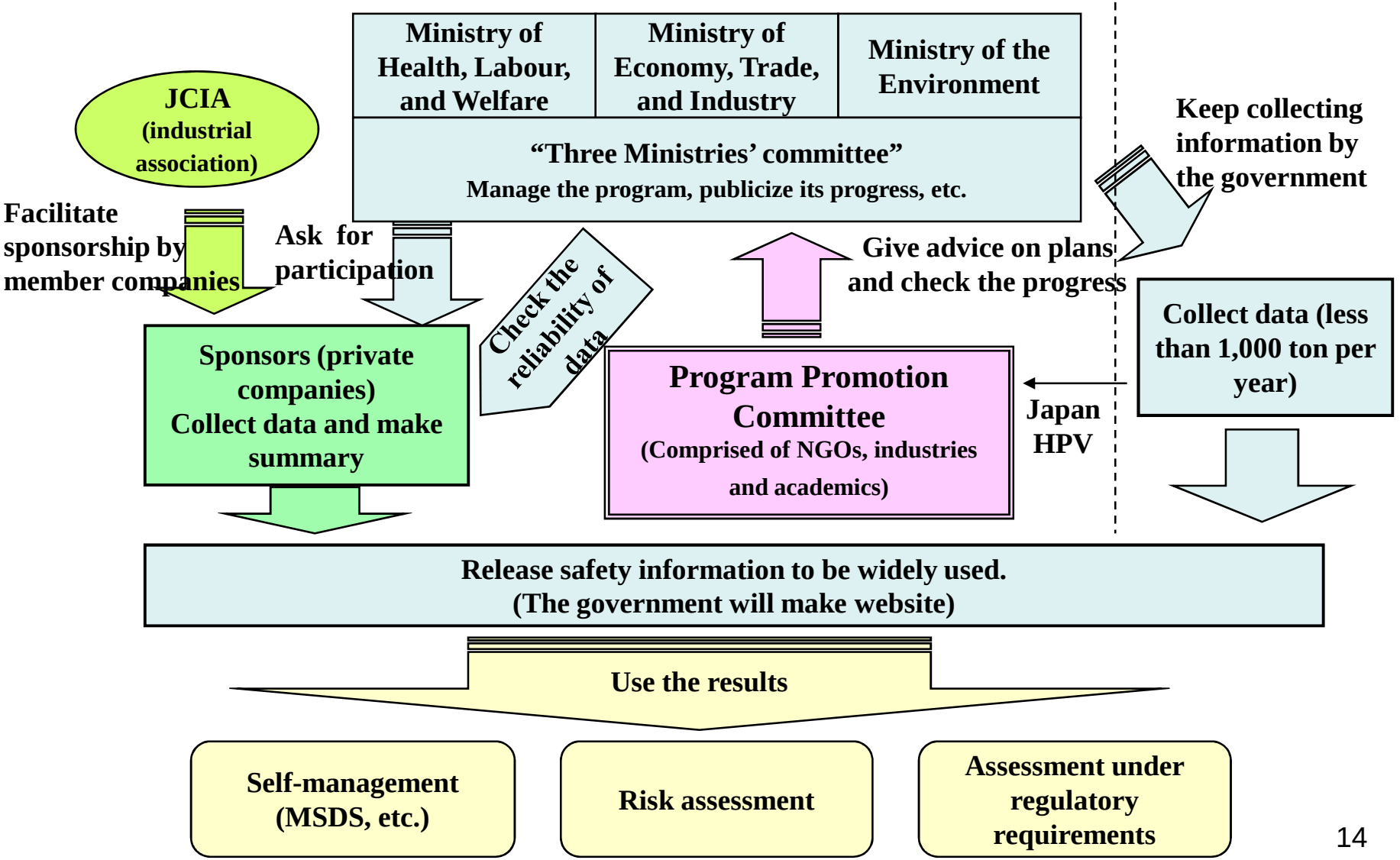
1. Identify the target chemicals
   -Japan HPV target list does not change, meaning that Japan's program does not have "no longer HPV" scheme.
   - They can use "Category approach" like US HPV Program
2. Submit **registration letter** to the government
3. Submit **test plans** to the government
4. Make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

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

III-3. Flow of the Program (1)



III-4. Flow of the Program (2)



VI. Current Situation

(as of Apr. 2009)

- 112 companies and associations has already joined the program as “Sponsors”.
- 95 chemical substances has been already sponsored.
- 16 Robust study summaries were submitted by sponsors.
- Collected data will be disclosed via “J-CHECK” (http://www.safe.nite.go.jp/jcheck/)
- Interim report was compiled in August 2008.

VII. Interim report of JCP (August 2008)

(1) Program Overview

- The program made progress in terms of cooperation between the industries and government, coordinated approach with international program, unified information disclosure etc.
- Understandings and supports were expressed by industries.

(2) Future Efforts

- Government will:
  - continue recruiting sponsors considering priorities;
  - disclose information obtained by this program also in English as well as Japanese.;
  - conduct hazard assessment of those chemicals by 2012; and
  - Improve database (J-CHECK).

The list of Sponsored companies (as of June. 2008)

# of Sponsored Chemicals	Name of Sponsored Company / Organization
11	KAO CORPORATION
6	SHOWA DENKO K.K., NOF CORPORATION, Mitsubishi Corporation
5	Japan Crop Protection Association
4	ASAHI GLASS CO., LTD., Sanyo Chemical Industries, Ltd., DIC Corporation, Nippon Fine Chemical Co., Ltd., Nippon Nyukazai Co., Ltd., Mitsui Chemical Co., Ltd., ADEKA Corporation
3	ALBEMARLE JAPAN CORPORATION, IHARA CHEMICAL INDUSTRY CO., LTD., UBE INDUSTRIES. LTD., Kawaken Fine Chemicals Co., Ltd., DAICEL CHEMICAL INDUSTRIES, LTD., DAIHACHI CHEMICAL INDUSTRY CO., LTD., Mitsubishi Gas Chemical Company. Inc., Mitsubishi Shoji Foodtech Co., Ltd., Yuki Gosei Kogyo Co., Ltd.,
2	Aoki Oil Industrial Co,. Ltd., Asahi Glass Urethane Co., Ltd., KAWASAKI KASEI CHEMICALS LTD., Great Lakes Chemical Japan, San-ei Sucrochemical Co., Ltd., TOHO Chemical Industry Co., Ltd., HONSHU CHEMICAL INDUSTRIES. CO., LTD., MITSUI & CO.,LTD., MITSUBISHI RAYON CO., LTD., Meisei Chemical Works, Ltd., Lion Corpotation, RIKEN VITAMIN CO., LTD., ROQUETTE Japan K.K., API Corporation, KURARAY CO., LTD., NIPPON SHOKUBAI CO., LTD.
1	Asahi Kasei Corporation, AJINOMOTO Co., Inc., Arimoto Chemical Co., Ltd., ITOCHU CHEMICAL FRONTIER Corporation, Air Water Inc., Du Pont-MGC Co., Ltd., OSAKA ORGANIC CHEMICAL INDUSTRY Ltd., OKAMURA OIL MILL, LTD., Mikuni Color Ltd., Orient Chemical Industries, Ltd., Kao-Quaker Co., KYOWA HAKKO CHEMICALS CO., LTD., Kyowa Hakko Co., Ltd., Clariant Japan K.K., CHEMIPRO KASEI KAISHA, LTD., Goi Chemical Co., Ltd., KOKYU ALCOHOL KOGYO CO., LTD., KONISHI CHEMICAL IND. CO., LTD., SAKAI CHEMICAL INDUSTRY CO., LTD., SANKO CO., LTD., SANSUI SHIKISO KOGYO CO., LTD., SANYO COLOR WORKS, LTD., SHIPRO KASEI KAISHA, LTD., JOHOKU CHEMICAL CO., LTD., Shin-Etsu Chemical Co., Ltd., Nippon Steel Chemical Co., Ltd., New Japan Chemical Co., Ltd., SUMIKA COLOR CO., LTD., Summit Pharmaceuticals International Corporation, Sumitomo Chemical Co., Ltd., DAIICHI FINE CHEMICAL CO., LTD., Dainichiseika Color & Chemicals Mfg. Co. Ltd., Taiyo Kagaku Co., Ltd., TAKEMOTO OIL & FAT Co., Ltd., TAMA CHEMICALS CO., LTD., Ciba Specialty Chemicals, TAYCA CORPORATION, Teijin Fibers Limited, DIPSOL CHEMICALS CO., LTD., DENKI KAGAKU KOGYO KABUSHIKI KAISHA , TOAGOSEI CO., LTD., Tosoh Corporation, TOYO INK MFG CO., LTD., Toray Industries, Ink, Nishiki Trading Co., Ltd., NIKKEN CHEMICAL AND SYNTHETIC INDUSTRIY CO.,LTD, NIPPOH CHEMICALS CO., LTD., NIHON EMULSION Co., Ltd., Nippon Chemical Industrial Co., Ltd., Nippon Kasei Chemical Co., Ltd., Nippon Surfactant Kogyo K. K., ZEON CORPORATION, NIPPON SODA CO., LTD., Nihon Firmenich K.K., NIHON JORYU CO., LTD., NOMA CHEMICAL INDUSTRY CO., LTD., FUSO CHEMICAL CO., LTD., Bromochem Far East Inc., MANAC INC., MARUBISHI OIL CHEMICAL CO., LTD., MITSUI FINE CHEMICAL Inc., MITSUI CHEMICALS POLYURETHANES, INC., Rhodia Japan, Ltd., WAKAYAMA SEIKA KOGYO CO., LTD., C-Chem Co., Ltd., J-PLUS Co., Ltd., Tomen Chemical Co.,Ltd., Mitsubishi Chemical Corporation, NIPPON POLYURETHANE INDUSTRY CO., LTD., The Silicone Industry Association of Japan, Japan Scientific Feeds Association

VIII. Timeline of the Program

June 2005 Launched the program
Recruiting Sponsors
Collecting Data

2008 Interim assessment of the program

-2012 Information disclosure and hazard assessment of the chemicals under this program