

Progress in the Implementation of  
SAICM National Implementation Plan of Japan

(Provisional Translation)

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Government of Japan



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## **I. Introduction**

In order to ensure the steady implementation of Strategic Approach to International Chemicals Management (SAICM) National Implementation Plan of Japan (hereinafter referred to as the National Implementation Plan of Japan), the Inter-Ministerial Meeting on SAICM will review progress in the implementation of the National Implementation Plan of Japan and publish the results of the review, prior to the 4th session of the International Conference on Chemicals Management (ICCM4) which will be held in 2015. When reviewing the implementation progress of the National Implementation Plan of Japan, it will also collect the opinions of relevant parties as well as inviting public comments.

Based on the above-mentioned decisions, the Inter-Ministerial Meeting on SAICM compiled the results of the review of the implementation progress for the National Implementation Plan of Japan in draft report. The report was created based on the results of voluntary reviews conducted by the relevant ministries and agencies, concerning measures which have been taken from September 2012, when the National Implementation Plan of Japan was formulated, to March 2015. (For certain plan, further implementation progress is also included in the report.)

It was confirmed that efforts concerning SAICM have progressed in general since the formulation of the National Implementation Plan of Japan. However, some issues remain before the objectives set in the National Implementation Plan of Japan can be met, and therefore the report points out how the relevant parties should improve their efforts in order to resolve these issues.

The Inter-Ministerial Meeting on SAICM will make revisions to the National Implementation Plan of Japan where necessary, in response to revisions to SAICM and discussions on new issues at the ICCM, as well as revisions to relevant national plans and other environmental changes and socio-economic changes, etc. Therefore, the revision of the National Implementation Plan of Japan will be considered after ICCM4, while also taking into account what had been pointed out in the review.

## **II. How the Review of the Implementation Progress of SAICM National Implementation Plan of Japan Was Conducted**

“2. Tangible approaches” in the National Implementation Plan of Japan states the government should prioritize the following six subject areas (hereinafter referred to as “priority examination areas”), based on SAICM Global Plan of Action, discussions on “emerging policy issues” at the ICCM, etc.

1. Promotion of science-based risk assessment
2. Risk reduction throughout the whole life-cycle
3. 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

Reviews were conducted for each priority examination area shown above. However, matters included in “6. Issues to be examined in the future” were reviewed as part of other respective appropriate priority examination areas (1.-5.).

Prior to the review, the General Policy Committee of the Central Environment Council conducted the 2nd review on the progress and future issues concerning the Fourth Basic Environment Plan (it invited public comments on October 20, 2014). The Fourth Basic Environment Plan was regarded as “related national plans” in the processes of the development of the National Implementation Plan of Japan. Therefore, the review was conducted by utilizing the results of the 2nd review concerning the Fourth Basic Environment Plan, to the maximum extent possible.

### III. The Progress in Efforts for Each Priority Examination Area

This chapter explains progress in efforts made for each priority examination area.

#### **Priority Examination Area 1: The Promotion of Science-based Risk Assessment**

##### (1) The Basic Approach to Issues That Should Be Tackled

In 2002, the World Summit on Sustainable Development was held and the following international goal (WSSD2020 Goal) was agreed: “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.” In order to achieve this goal, Japan needs to collect and utilize more hazard information and exposure information, upgrade various models and methods, and accelerate risk assessment further, by taking advantage of its technical strength and through cooperation between the public and private sectors. Japan also needs to upgrade its assessment methods further, in order to minimize the risk of chemicals and products containing chemicals throughout their life cycles.

##### (2) The Status Quo and the Efforts Being Made

In order to tackle the above-mentioned issues and efficiently promote science-based risk assessment, the government is considering new methods for risk assessment as well as steadily promoting risk assessment based on existing frameworks. Therefore, the current efforts by relevant administrative institutions were reviewed concerning items a) and b) shown below.

- a) The promotion of risk assessment and the setting of target values, etc.
- b) The development and utilization of new methods in order to increase risk assessment efficiency, etc.

#### **a) The Promotion of Risk Assessment and the Setting of Target Values, etc.**

##### **The Status Quo**

As part of the efforts to promote risk assessment for chemicals, the government has implemented assessments based on the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of October 16, 1973, hereinafter referred to as the Chemical Substances Control Law (CSCL)) and the Agricultural Chemicals Regulation Law (Act No. 82 of 1948). For chemicals which cannot be covered by these assessments, the government has implemented the initial environmental risk assessment of chemicals which use documentation, the results of monitoring surveys, etc. The government also monitors exposures by setting environmental target values and upgrading quantitative assessment methods among other efforts.

Regarding general-purpose (industrial use) chemicals that are to be newly manufactured or imported, the government evaluates the hazard, etc. of substances which are reported by business operators prior to their manufacture or importation, based on the CSCL. With regard to existing chemicals which were already being manufactured or imported at the time of the enactment of the law (1973), the government implemented safety evaluations and took the necessary regulatory measures. In addition, industry and the government have cooperated with each other in the acceleration of risk assessment, through participation in the OECD HPV Chemicals Program which is an international voluntary program to obtain information on HPV (high production volume) and the implementation of a joint program among the

private and the public sectors for collecting and releasing safety information of Japan HPV existing chemical substances (commonly known as the Japan HPV Challenge Program). In 2009, the government partially revised the CSCL, through which existing chemicals became subject to the reporting of the quantities manufactured or imported, etc. from FY2011. The revision also required the government to identify Priority Assessment Chemical Substances (hereinafter referred to as PACs) through screening assessments as well as requiring business operators to submit the results of hazard tests for PACs where necessary, in order to implement detailed risk assessments. Screening assessments are conducted based on hazard information collected by the government and exposure information. The exposure information is obtained by taking into account the degradability of the chemical and the total national amount of the chemical released which was estimated based on the manufactured or imported quantities reported by business operators, etc. in the fiscal year previous of the assessment year and the shipment quantity by use (the quantities shipped two fiscal years before), among other data. In screening assessments, chemicals are classified, and those that are highly hazardous and have high exposure indicator values are determined to be equivalent to PACs. Figure 1 and Figure 2 show progress in screening assessments since FY2010. As of April 1, 2015, 177 substances have been designated as PACs.



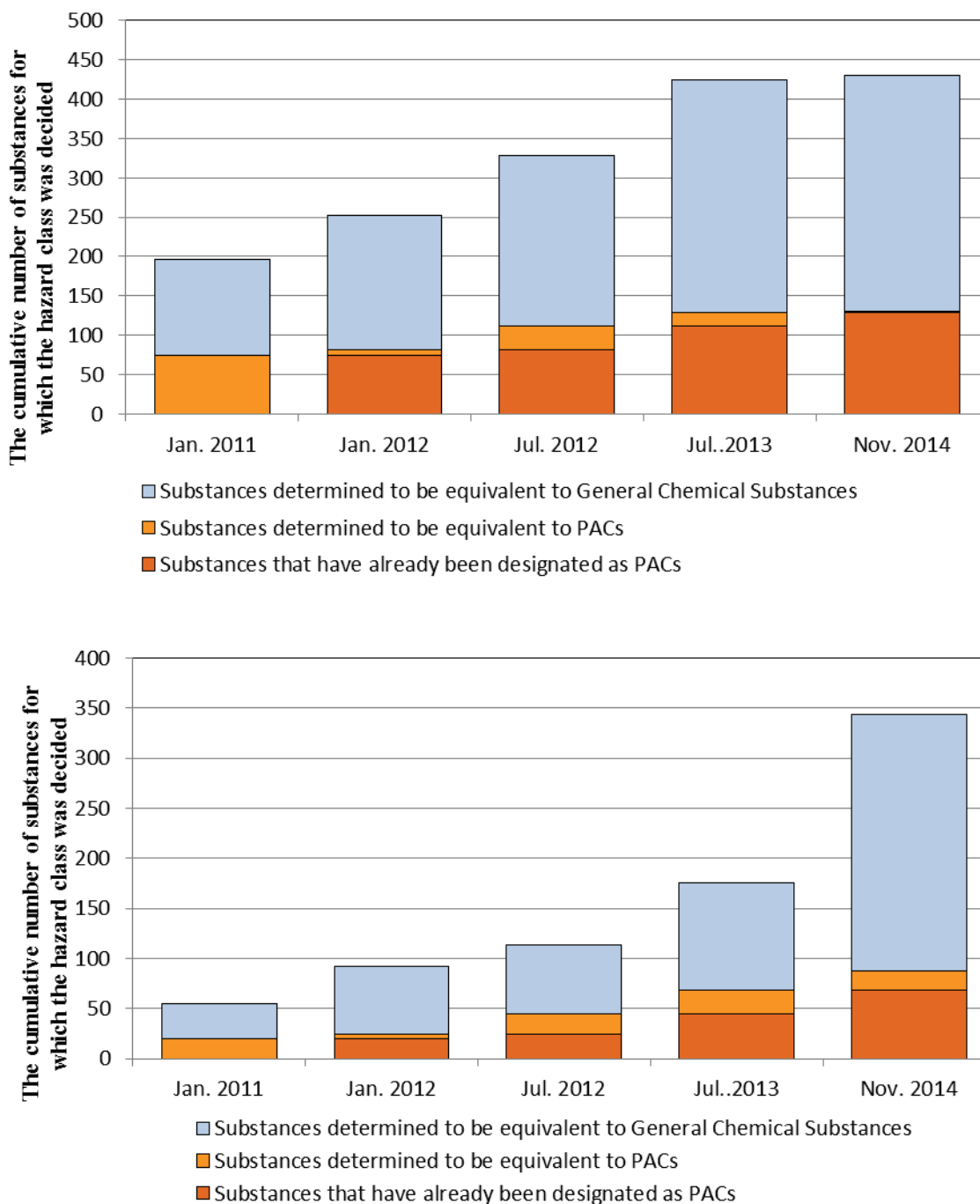
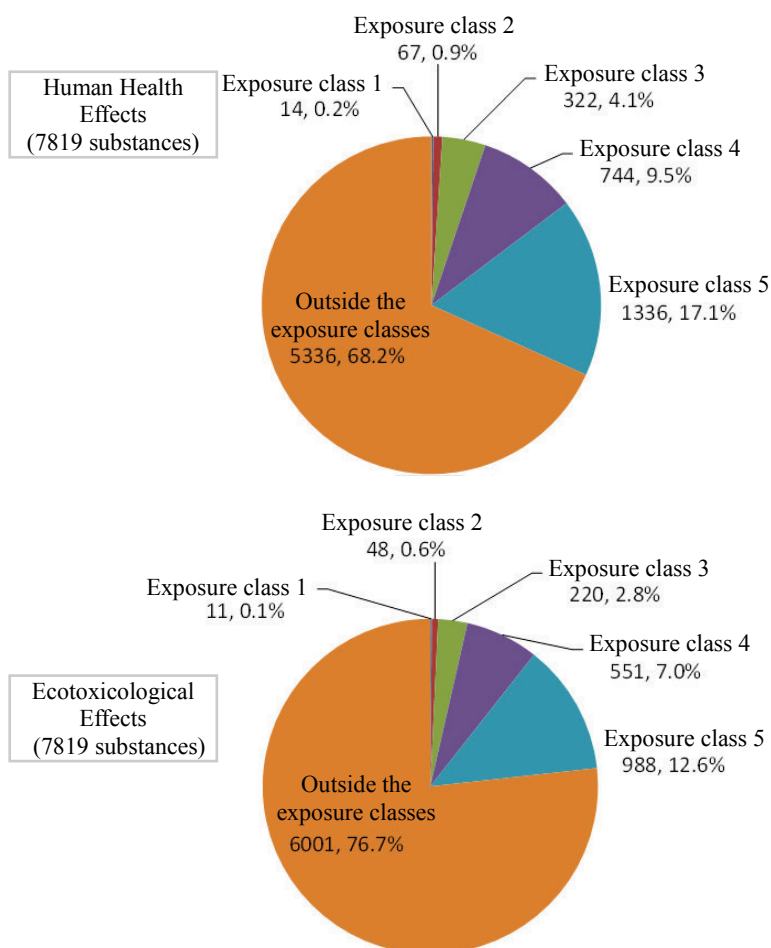


Figure 1 The Number of Substances for Which the Hazard Class Was Decided in Screening Assessments under the CSCL (until November 2014) (Top: Human Health Effects, Bottom: Ecotoxicological Effects)

Source 1): Created by the MOE based on: 2013, “How to Conduct Screening Assessments and the Results of Assessments, FY2013” (FY2013 the 4th Session of the Subcommittee on Safety Assessment of Chemicals in the Committee on Chemical Safety in the Pharmaceutical Affairs Council of the Pharmaceutical Affairs and Food Sanitation Council; FY2013 the 2nd Session of Chemical Management Measure Committee of Chemical Substance Council; the 135th Session of Session of the Chemicals Evaluation Subcommittee, Environmental Health Committee, Central Environment Council).

Source 2): Created by the MOE based on: 2014, “How to Conduct Screening Assessments and the Results of Assessments, FY2014” (FY2014 the 7th Session of the Subcommittee on Safety Assessment of Chemicals in the Committee on Chemical Safety in the Pharmaceutical Affairs Council of the Pharmaceutical Affairs and Food Sanitation Council; FY2014 the 2nd Session of Chemical Management Measure Committee of Chemical Substance Council; the 149th Session of the Chemicals Evaluation Subcommittee, Environmental Health Committee, Central Environment Council).



Exposure class	The estimated total national amount released (tons)	Exposure class	The estimated total national amount released (tons)
Class 1	> 10,000	Class 4	10 – 100
Class 2	1,000 – 10,000	Class 5	1 – 10
Class 3	100 – 1,000	Outside the classes	< 1

Figure 2 The FY2014 Results of the Screening Assessments for the Exposure Classes of Substances  
(General Chemical Substances produced/imported over 10 tons for FY2012)  
(Top: Human Health Effects, Bottom: Ecotoxicological Effects)

- Note 1. Each number indicates the number of substances which came under each class. Each percentage indicates the percentage of substances which came under each class out of the total number of substances assessed.
- Note 2. The assessment of Human Health Effects estimates total amount released in air and water and the assessment of Ecotoxicological Effects estimates total amount released in air. Each assessments are based on exposure class which made the number of the substances different.
- Note 3. Substances in exposure class 4 or higher were categorized into hazard classes. Using the priority matrix (where substances are classified into “high” priority, “medium” priority and “low” priority, based on their hazard classes and exposure classes), substances that are highly hazardous and have high exposure indicator values were identified as “high” priority and were determined to be PACs. In addition, those deemed necessary by the Three-Ministry Joint Council (based on detailed assessments by experts) were also determined to be equivalent to PACs.
- Source: Created by the Ministry of the Environment based on: 2014, “How to Conduct Screening Assessments and the Results of Assessments, FY2014” (FY2014 the 7th Session of the Subcommittee on Safety Assessment of Chemicals in the Committee on Chemical Safety in the Pharmaceutical Affairs Council of the Pharmaceutical Affairs and Food Sanitation Council; FY2014 the 2nd Session of Chemical Management Measure Committee of Chemical Substance Council; the 149th Session of Chemicals Evaluation Subcommittee, Environmental Health Committee, Central Environment Council).

With regard to agricultural chemicals, the government examines chemicals and conducts environmental risk assessments<sup>1</sup> prior to registration when business operators apply for registration, based on the Agricultural Chemicals Regulation Law. The government has been improving the methods for setting Registration Withholding Standards of Agricultural Chemicals regarding water pollution and the prevention of damage to aquatic plants and animals, and has been setting standards gradually. Figure 3 shows progress in the consideration for the setting of Registration Withholding Standards for Agricultural Chemicals regarding water pollution and the prevention of damage to aquatic plants and animals. As of March 2015, Registration Withholding Standards were decided for 277 agricultural chemicals regarding the prevention of damage to aquatic plants and animals. It was decided that standards did not need to be set for 109 agricultural chemicals because there is no risk of them escaping into water systems based on their dosage forms and their usage, among other reasons. Registration Withholding Standards were decided for 205 agricultural chemicals regarding water pollution. It was decided that standards did not need to be set for 109 agricultural chemicals, for the same reason as above.

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<sup>1</sup> Types of assessments to target chemical substances: (1) toxicity assessment to specify toxicity levels against human health and ecosystems, (2) conduct exposure assessment to estimate exposure of chemical substances against human and ecosystems, (3) comparing (1) and (2) assessments' results to assess the levels of risks

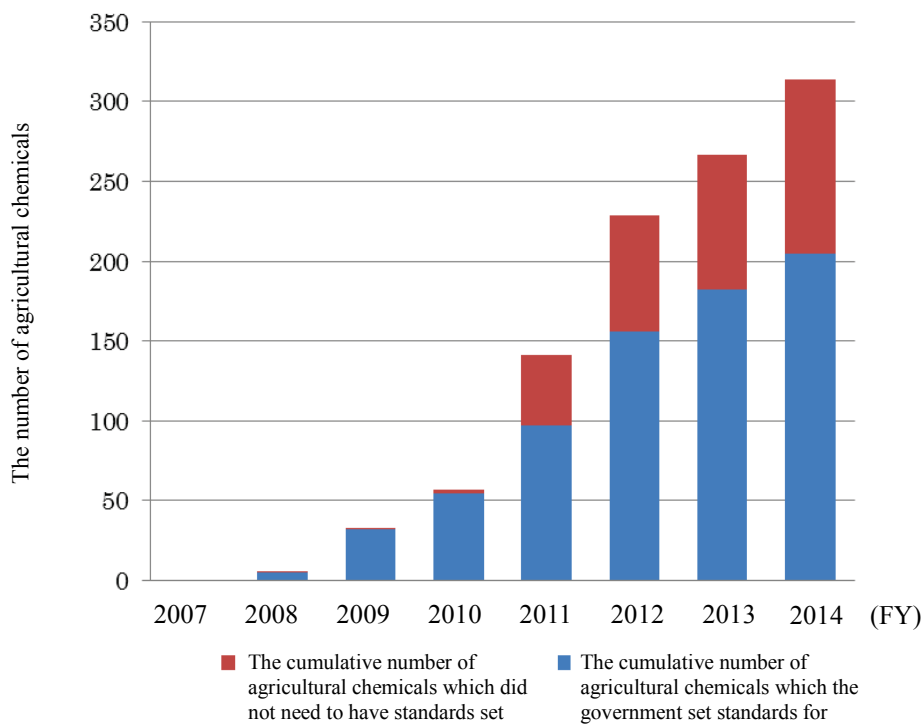
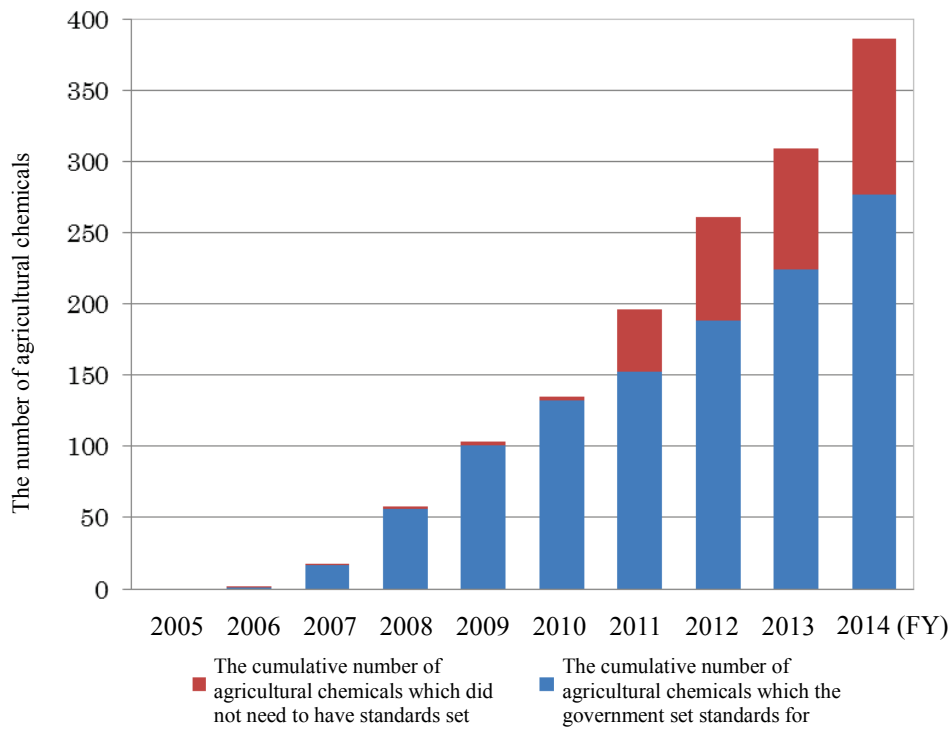


Figure 3 The cumulative number of agricultural chemicals' standards (blue bars) and ones which were set as 'not necessary to set standards' (red bars) which were decided by the government regarding the Prevention of Damage to Aquatic Plants and Animals (Top) and Water Pollution (Bottom)

Source: MOE

The government has also implemented the initial environmental risk assessment of chemicals, as the first step to screen a large number of chemicals in order to identify

substances which may have a relatively high environmental risk<sup>2</sup>, based on scientific knowledge. Figure 4 shows the number of substances assessed by the time of the 13th assessment (published in December 2014). 325 substances had been assessed by December 2014.

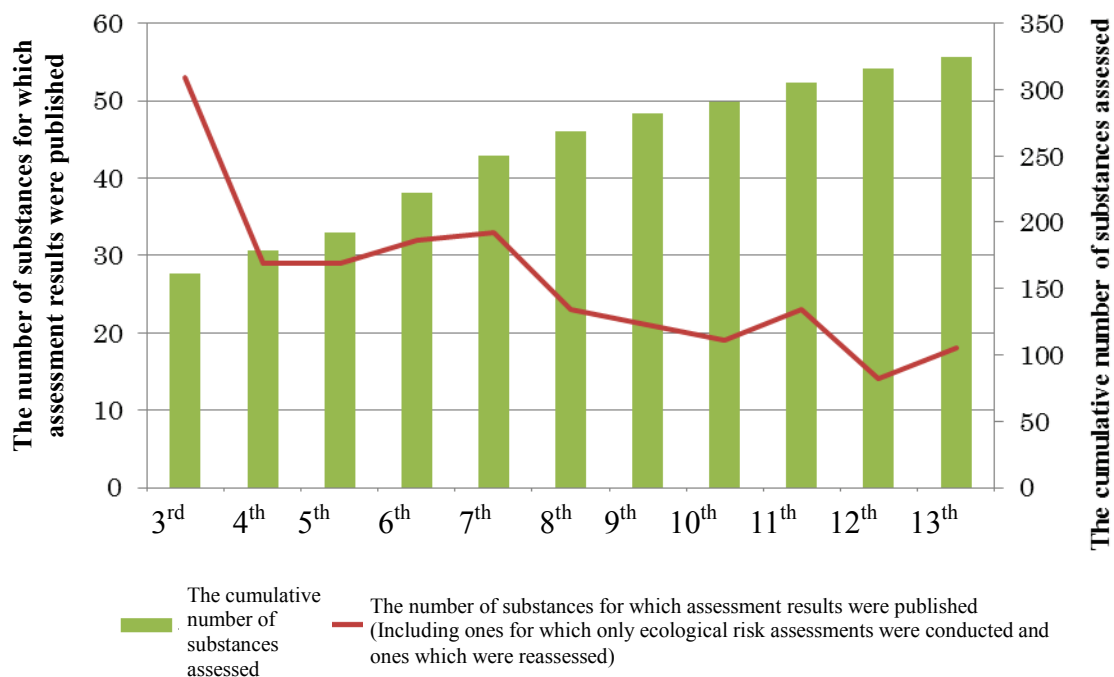


Figure 4 Changes in the Number of Substances for Which The Initial Environmental Risk Assessment of Chemicals Were Conducted

Source: The website of MOE “Information on the initial environmental risk assessment of chemicals” (<http://www.env.go.jp/chemi/risk/>)

With regard to information on exposure which is essential for risk assessment, the government has conducted various surveys monitoring, etc. including the Environmental Survey of Chemical Substances, the hazardous air pollutant monitoring survey, the water quality measurement on ambient water and ground water, and the Comprehensive Survey for the Measures on Agricultural Chemicals Remaining in the Environment. The government also worked on upgrading its concentration prediction models, etc. At the same time, the government has promoted the utilization of data on the amounts of release and other data, etc. obtained through the Pollutant Release and Transfer Register system (the PRTR system) for exposure assessment. The PRTR system was created based on the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Act No. 86 of July 13, 1999, hereinafter referred to as the Law concerning Pollutant Release and Transfer Register (PRTR Law)).

Environmental quality standards concerning air pollution have been set for 10 substances (except for dioxins) from the standpoint of protecting human health. Values that give guidelines for reducing the health risk from hazardous air pollutants in the environment (guideline values) have been set for 9 substances.

<sup>2</sup> Risk to the environment that the chemicals potentially hazardous to human health and ecosystems pose when they are released into environmental media such as the air, water and soil.

With regard to environmental quality standards concerning water pollution which are set to protect human health based on the Basic Environment Law (Act 91 of November 19, 1993), standards have been set for 27 items regarding public waters and standards have been set for 28 items regarding groundwater. These items include heavy metals, Organochlorine Compounds and agricultural chemicals. There are also “specified monitoring items” (26 items for public waters and 24 items for groundwater) for which the accumulation of knowledge should continue to be strived for, although environmental quality standards would not be set immediately, when considering the current detection levels, etc. in public waters, etc. With regard to environmental water quality standards for protecting the living environment, environmental quality standards for public waters have been set for Biochemical Oxygen Demand (BOD),<sup>3</sup> Chemical Oxygen Demand (COD),<sup>4</sup> Dissolved Oxygen (DO),<sup>5</sup> total nitrogen, total phosphorus, total zinc, etc. Of those standards, environmental quality standards have been set for 3 items for the preservation of aquatic life. There are also 6 “specified monitoring items” for the purpose of the preservation of aquatic life.

## Efforts Being Made

### <Promoting Risk Assessment>

**[The Designation of PACs Based on the CSCL and the Implementation of Risk Assessment] (The Ministry of Health, Labour and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE))**

Regarding general-purpose (industrial use) chemicals, the government conducts screening assessments for all General Chemical Substances including existing chemicals, based on the CSCL. Through screening assessments, the government will designate PACs which will be prioritized when conducting assessments to find out whether the substance has a risk of causing damage to human health, the inhabitation of flora and fauna in the living environment, etc. In order to achieve the WSSD2020 Goal, the government will conduct risk assessments to identify PACs that are deemed to have significant risk to humans or to flora and fauna in the living environment by 2020, while taking international trends into account. The government will then take the necessary regulatory measures for substances which were found to have a significant risk.

#### ◇ Screening Assessments for General Chemical Substances, etc.

The government launched screening assessments for General Chemical Substances, etc. in FY2010. The government conducts screening assessments for all chemicals including class 2 monitoring chemical substances and class 3 monitoring chemical substances specified under the former law, and designates the chemicals which cannot be determined to be non-high-risk chemicals as PACs.

In FY2012, there were 11,897 General Chemical Substances for which the sum of the quantities manufactured and imported was one ton or more. Of those substances, there were 7,699 General Chemical Substances for which the sum of the quantities manufactured and imported exceeded 10 tons. In FY2014, the government conducted screening assessments for these 7,699 General Chemical Substances. Based on estimations for

<sup>3</sup> Biochemical Oxygen Demand (BOD): The amount of oxygen required by microbes in order to decompose organic pollutants in water. A higher value indicates more severe water pollution.

<sup>4</sup> Chemical Oxygen Demand (COD): The amount of oxidizers consumed when decomposing organic pollutants in water using oxidizers. The value of the amount of oxidizers is then converted to the amount of oxygen. A higher value indicates more severe water pollution.

<sup>5</sup> Dissolved Oxygen (DO): The amount of oxygen dissolved in water. It is necessary for the inhabitation of aquatic life. A higher value indicates a better environment.

identifying exposure classes, etc., 14 substances were newly determined to be equivalent to PACs.

177 substances have been designated as PACs based on the results of the screening assessments and Risk Assessment (primary) Result II conducted in FY2014 and others, as of April 1, 2015.

◇ Risk Assessments for PACs

Based on the results of Risk Assessment I (Primary) released on July 18, 2013, the priority chemical substances of “Assessment I continuous” were designated and with the priority substances designated in 2012, there were 116 chemical substances found for which the sum of the quantities manufactured and imported exceeded 10 tons. For these 116 substances, the government conducted Risk Assessment I (Primary) by using data from FY2012 (detailed shipment quantity by use, etc.) in FY2014. The government has launched the Risk Assessment II (Primary) for 41 substances, including FY2013 results.

As the next step, with the aim of achieving the WSSD2020 Goal, the government will promote science-based risk assessment efficiently and take regulatory measures for substances which were found to have a significant risk. The government will also strive to develop new methods which contribute to the efficient promotion of risk assessment and to put them to practical use.

**[The Promotion of Risk Assessment concerning Agricultural Chemicals] (MOE)**

The manufacture, import, sale and use of agricultural chemicals are not allowed unless the chemicals are registered based on the stipulations in the Agricultural Chemicals Regulation Law. Prior to registration, agricultural chemicals must be inspected in order to find out whether they come under any of the items (i) to (x) of Article 3, paragraph 1 of the Agricultural Chemicals Regulation Law. Agricultural chemicals can be registered only after being assessed and determined not to pose any risks.

◇ Setting Registration Withholding Standards

Based on the stipulations of Article 3, paragraph 2 of the Agricultural Chemicals Regulation Law, the Minister of the Environment sets and announces standards (“registration withholding standards”) concerning Article 3, paragraph 1, item (iv) (persistence in crops), item (v) (persistence in soil), item (vi) (the prevention of damage to aquatic plants and animals) and item (vii) (water pollution), with the aim of preventing adverse effects on human health and aquatic plants and animals.

- With regard to the registration withholding standards concerning persistence in crops, the registration of agricultural chemicals is withheld if the methods for their use result in agricultural products, etc. which do not meet the agricultural chemical residue standards based on the Food Sanitation Law (Act 233 of 1947). With regard to registration withholding standards concerning persistence in soil, the registration of agricultural chemicals is regulated in accordance with their half-life in the soil.
- Regarding registration withholding standards concerning water pollution and the prevention of damage to aquatic plants and animals, the Agricultural Chemicals Subcommittee of the Soil and Agricultural Chemical Committee at the Central Environment Council deliberates on and steadily decides on standards for each agricultural chemical, based on the results of various toxicity tests. They also decide on the agricultural chemicals that do not require the setting of standards due to having no risk of escaping into water systems because of various reasons such as dosage forms and how they are used.

Table 1 shows the progress in the setting of registration withholding standards.

Table 1 The Setting of Registration Withholding Standards for Agricultural Chemicals

	The number of agricultural chemicals registered (1)	Standards were set			No need to set standards			The rest (1) - (2) - (3)		
		(2)	FY2012 (included in (2))	FY2013 (included in (2))	FY2014 (included in (2))	(3)	FY2012 (included in (3))		FY2013 (included in (3))	FY2014 (included in (3))
Standards for aquatic plants and animals	565	277	20	36	53	109	29	13	24	179
Standards for water pollution		205	59	26	23	109	29	12	24	251

\* The number of registered agricultural chemicals in each FY, however (1) indicates the total number of registered agricultural chemicals as of in March 2015.

As the next step, the government will take the following actions.

- To continue deliberating on agricultural chemicals without setting registration withholding standards regarding water pollution or the prevention of damage to aquatic plants and animals.
- With regard to registration withholding standards concerning persistency in soil, the Agricultural Chemicals Subcommittee of the Soil and Agricultural Chemicals Committee at the Central Environment Council deliberated on the field experiment methods for determining half-life in the soil which are stipulated in the public notice, in order to improve their universality by revising them. The subcommittee will proceed with the hearing the opinions of the Agricultural Materials Council. The government will also strive to gain the latest scientific knowledge in terms of the current assessment methods for registration withholding standards.

#### ◇ Monitoring

The government is conducting the monitoring of agricultural chemicals in order to check whether the set standards are not being exceeded in the actual environment.

- The government conducted monitoring at 7 sites nationwide (29 agricultural chemicals in total) in FY2012 and at 7 sites nationwide (18 agricultural chemicals in total) in FY2013. The government conducted monitoring at 12 sites nationwide (31 agricultural chemicals in total) in FY2014. In FY2012, no monitored values exceeded their standards. However, it was found that the monitored values exceeded their standards at 1 site and 5 sites in FY2013 and in FY2014, respectively. The government is examining the reasons for these exceeded values. The number of agricultural chemicals, with the Predicted Environment Concentration (PEC) which was estimated to be close to the standards when registration withholding standards are set, has been increasing. Therefore, the Agricultural Chemicals Subcommittee of the Soil and Agricultural Chemicals Committee at the Central Environment Council recommended that monitoring should be promoted strategically. To take this into account, the government will promote efficient monitoring by considering priorities in light of the quantities shipped as well as by developing simultaneous analysis methods for agricultural chemicals.
- With regard to registration withholding standards concerning the prevention of damage to aquatic plants and animals, before putting agricultural chemicals on the market, the



government confirms PEC, which is calculated using specific standard scenarios, do not exceed the standards prior to registration. These standards are set based on the results of three types of toxicity tests. The government will also promote surveys on the impacts on aquatic life, etc. after registration, by taking into account the differences in sensitivity between species and the spread of the agricultural chemicals.

### **[The Implementation of The Initial Environmental Risk Assessment of Chemicals] (MOE)**

The government is conducting initial assessments of environmental risk in order to prevent unfavorable effects on human health and ecosystems caused by chemical environmental pollution.

More specifically, the government looks at “environmental risk,” which means the risk to the environment that the chemicals potentially hazardous to human health and ecosystems pose when they are released into environmental media such as the air, water and soil. The government conducts initial risk assessments (screening assessments), by quantitatively examining the amount of exposure via environmental media and the toxicity of chemicals from a scientific standpoint, and by comparing the two factors. Through initial assessments, the government identifies substances that may have a relatively high environmental risk and provides the assessment results to relevant departments, etc. that need the results, thereby promoting efforts that contribute to the reduction of environmental risk.

The results of the initial assessments of environment have been compiled thirteen times so far and published as “Profiles of the Initial Environmental Risk Assessment of Chemicals” (from vol. 1 to vol. 13. A total of 325 substances have been assessed). The government published assessment results for 14 substances in FY2013 and 18 substances in FY2014

The government will take action in accordance with the results of the initial assessments, for example continuing to provide relevant departments, etc. with information on chemicals that have become “candidates for further work” as a result of the initial assessments, in order to encourage the necessary efforts. The government will also collect relevant information, conduct reassessments, etc. where necessary, for chemicals which have undergone initial assessments in the past, and publish the reassessment results as they become ready.

The government will promote initial assessments of environmental risk which focus on substances, etc. that require comprehensive chemical management, while introducing new findings by appropriately keeping track of discussions on testing methods, assessment methods and other topics taking place at OECD, etc.

### **[Risk Assessments for Chemicals in Workplaces] (MHLW)**

With regard to the labor environment, the government is conducting risk assessments regarding health impairment of workers in the labor environment using the Report of Work Exposed to Harmful Substances (launched in 2006), etc. based on the Industrial Safety and Health Act (Act 57 of 1972). Regarding the selection of subject chemicals for risk assessment, the government will consider methods to select chemicals for the assessment with the aim of promoting coordination between risk assessments and other systems, etc. In order to conduct the risk assessment properly, review meetings comprising of academic experts have held, where they will conduct evaluations based on the hazard of the chemicals and the level of workers’ exposure. If specific work processes pose particularly high risks of health impairment, regulatory measures will be taken using special ordinances based on the Industrial Safety and Health Act, in accordance with the degree of risk, etc.

- The government conducted toxicity studies and other studies needed for human health risk assessments, for the chemicals, etc. which are persistent and have other adverse properties as well as having a risk of damaging human health.
- Regarding hazard tests which are being conducted as a commissioned project, tests for two substances have been completed each year and their results have been published.
- The government created hazard assessment reports which assessed the hazard of chemicals, for 17 substances in FY2012 and 28 substances in FY2013, and 26 substances in FY2014.
- When any chemicals which have undergone risk assessments are determined to require new regulations through examinations and deliberation by experts, etc., the government makes revisions, etc. to cabinet orders and ministerial ordinances for these chemicals. In recent years, the government revised the Ordinance on Prevention of Dangers Due to Specified Chemical Substances, etc. for the following chemicals.
  - FY2012: Indium compounds, ethylbenzene, cobalt and its compounds
  - FY2013: 1,2-Dichloropropane
  - FY2014: Dimethyl-2, 2-dichlorovinyl-phosphate (DDVP), chloroform and 9 other substances

The government will continue to strive to implement effective measures in order to conduct appropriate chemical management and prevent health impairment of workers.

#### **<The Promotion of Hazard Assessments>**

##### **[The Implementation of Various Toxicity Tests, etc. Based on the CSCL] (MHLW, METI and MOE)**

Under the CSCL, the government can instruct business operators to conduct various toxicity tests, etc. in order to designate which substances will be subject to regulations concerning their manufacture, import, use, etc. of chemicals, and where necessary, the government also conducts various toxicity tests, etc. Based on this, the following tests, etc. have been carried out.

- ◇ Toxicity studies and other studies needed for human health risk assessments were conducted for chemicals, etc. which are persistent and have other adverse properties as well as having a risk of impairing human health.
- ◇ In 2013, ecotoxicity test was conducted for chemical substances without predictive formula built-in to KAshinhou Tool for Ecotoxicity (KATE) to improve its accuracy and expand its coverage due to its insufficient actual measurement value for the prediction. KATE is one of the model methods of Quantitative Structure-Activity Relationship (QSAR) used for ecotoxicity prediction measurement.
- ◇ In FY2013 and in 2014, preliminary Avian Reproduction Tests were conducted for the Monitoring Chemical Substances to verify ecotoxicity test method for Monitoring Chemical Substances technically and improve its accuracy..

##### **[Efforts by the Public and Private Sectors (the Japan HPV Challenge Program)] (MHLW, METI and MOE)**

In order to accelerate the collection of safety information on existing chemicals and to disseminate the information to the public through cooperation between industry and the government, a joint program among the private and the public sectors for collecting and releasing safety information of Japan HPV existing chemical substances (commonly known as the Japan HPV Challenge Program) was conducted from 2005 to 2013. The final report on the program was published in September 2013.

Through the voluntary efforts of business operators via the program, safety information on 67 substances (including test information) was collected. All together information on 446 substances was collected when including the overseas information collected by the government.

In addition to the information gathering activities, information on four substances was provided to the OECD/HPV program, thereby the Japan HPV Challenge Program contributed to international efforts.

#### < Promotion of Exposure Assessments >

##### [The Environmental Survey of Chemical Substances] (MOE)

In the Environmental Survey of Chemical Substances, the government conducts the following purpose-specific surveys of multimedia (water, sediment, organisms and air) in various parts of Japan, in order to ascertain the levels of chemical residue in the ambient environment.

1. A survey to check whether there is any chemical residue in the environment (initial environmental survey)
2. A survey to accurately ascertain the levels of chemical residue in the environment for chemicals whose residue in the environment has been confirmed in 1 (detailed environmental survey)
3. A survey to ascertain changes in the levels of chemical residue over time, for substances which are subject to the Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) and the potential candidate substances for POPs, as well as Specified Chemical Substances, etc. stipulated in the CSCL (monitoring survey)

#### ◇ FY2013

- Initial environmental survey  
The survey was conducted for 14 substances, at 45 sites for water and 34 sites for air.
- Detailed environmental survey  
The survey was conducted for 7 substances, at 54 sites for water, 25 sites for sediment, 13 sites for organisms and 19 sites for air.
- Monitoring survey  
The survey was conducted for 10 substances, at 48 sites for water, 63 sites for sediment, 26 sites for organisms and 37 sites for air.

The Environmental Survey of Chemical Substances has been conducted since FY1974. Survey results have been utilized as basic information, etc. for exposure assessments which are conducted in order to designate substances, etc. subject to regulations under the CSCL and the PRTR Law. The government will continue to conduct the survey for substances for which the departments in charge of regulations request the survey, as well as monitoring the levels of chemical residue in the environment for substances subject to the Stockholm Convention and other substances, as part of fact-finding efforts.

##### [The Survey of the Exposure to Chemical Compounds in Human] (MOE)

For chemicals which may affect health when they move from the environment into the human body, it is necessary to obtain basic information for environmental risk assessments and risk management, by continuously ascertaining the level of human exposure to such chemicals and their hazard through monitoring surveys. Therefore, in order to take measures to control the adverse effects of chemicals on humans, the government conducts monitoring

surveys for chemicals including dioxins using samples taken from humans (blood and urine) as well as from food.

From FY2002 to FY2010, the government conducted the “Survey on the Accumulation of Dioxins and other chemical compounds in Humans.” In FY2011, the government launched the “Survey of the Exposure to chemical compounds in Human.” From FY2011 to FY2014, the government took blood samples and urine samples from 334 residents as well as samples of their food, in a total of 12 areas (three areas each year). The government then studied the accumulation, etc. of chemicals (mainly chemicals which are highly accumulative in humans), including dioxins, fluoride compounds, Pesticide Metabolites and heavy metals. The government conducts the survey for chemicals which need to be analyzed in light of domestic and international circumstances, etc. and the government revises chemicals subject to the survey every fiscal year by listening to opinions of eminent people. The results of the survey are compiled and published as reports and pamphlets (in Japanese and in English) every fiscal year.

The survey enables us to ascertain the levels of human exposure to chemicals in Japan, based on which the government can select substances of concern, conduct risk assessments, prepare risk management measures, prevent health damage and ascertain the effectiveness of the measures. The government will carry on conducting the continual monitoring of substances which are highly accumulative in humans and other substances in blood, urine and food, thereby comprehensively analyzing the accumulation of the chemicals in humans and the changes over time as well as ascertaining the effects that the chemicals have on humans.

#### **[Ascertaining and Publishing the Amount of Release and the Amount of Waste Chemicals Transferred to Be Treated Based on the PRTR Law] (METI and MOE)**

The purpose of the PRTR Law is to promote voluntary improvement of the management of chemical substances by business operators and to prevent any impediments to the preservation of the environment. For this purpose, business operators report the amount of chemicals released into the environment and the amount of waste chemicals transferred to be treated, among other data. Chemicals subject to reporting are Class 1 Designated Chemical Substances, which are found to persistently exist in the environment over a substantially extensive area, and pose a risk of damaging human health and a risk of impeding the inhabitation or growth of animals and plants. The government then aggregates the data as well as aggregating the estimated release amounts for chemicals which are not subject to reporting, and publishes the aggregated data.

These measures have been taken since FY2001 (the ascertainment of the amounts started in FY2001 and the aggregation of data started in FY2002). Since then, the government has been aggregating the amounts of release and the amounts of waste chemicals transferred to be treated which were reported in the previous fiscal year and publishing the data along with the aggregation of the estimated amount of release for chemicals which are not subject to reporting (the “amount of release that is not required to be notified by the Government”), based on the law.

- ◇ In FY2012, the government aggregated and published the amounts ascertained in FY2011. Reports were submitted by 36,807 business establishments, the total amount of release was 174,000 tons and the total amount of waste chemicals transferred to be treated was 225,000 tons. The sum of the total amount of release and the total amount of waste chemicals transferred to be treated was 400,000 tons.
- ◇ In FY2013, the government aggregated and published the amounts ascertained in FY2012. Reports were submitted by 36,504 business establishments, the total amount of release was

162,000 tons and the total amount of waste chemicals transferred to be treated was 219,000 tons. The sum of the total amount of release and the total amount of waste chemicals transferred to be treated was 381,000 tons.

- ◇ In FY2014, the government aggregated and published the amounts ascertained in FY2013. Reports were submitted by 35,974 business establishments, the total amount of release was 160,000 tons and the total amount of waste chemicals transferred to be treated was 215,000 tons. The sum of the total amount of release and the total amount of waste chemicals transferred to be treated was 376,000 tons.
- ◇ When comparing FY2014 results with the results for the 2003 fiscal year when the current reporting requirement (the reporting of the amount handled) was introduced, the sum of the total amount of release and the total amount of waste chemicals transferred to be treated was reduced by 152,000 tons (-28.8%). When looking at the substances which continued to be designated as Class 1 Designated Chemical Substances after FY2008 revision of substances subject to reporting (“continuously designated chemical substances”), the sum of the total amount of release and the total amount of waste chemicals transferred to be treated was reduced by 170,000 tons (-33.6%). The numbers are decreasing in general over time.

These measures have been taken since FY2001 (the ascertainment of the amounts started in FY2001 and the aggregation of data started in FY2002). Since FY2008, all the data for individual business establishments have been published. The aggregation and publication of the data are being carried out steadily and the amount of release and the amount of waste chemicals transferred to be treated that were reported by business establishments are decreasing in general. The government intends to continue to carry out the aggregation and publication of relevant data steadily while also considering the possibility of revisions where necessary.

### **[Constant Monitoring of the Atmospheric Environment] (MOE)**

With regard to the atmospheric environment, prefectural governments and the municipalities designated by Cabinet Order of Air Pollution Control Act (Act 97 of 1973) are conducting the constant monitoring of air pollutants, pursuant to Article 22 of Air Pollution Control Act. The government has also been monitoring air pollutants since 1960s and compiled the results of observations all over the country and published the level of air pollution thereof.

The purposes of the measures are to monitor air pollutants in the atmospheric environment and publish the results thereof, to improve the attainment of air pollution-related environmental quality standards, etc., and to conserve the atmospheric environment. The results of air pollutant monitoring surveys conducted by the local and the governments are published on the website of MOE. The Atmospheric Environmental Regional Observation System (a.k.a. Soramame-kun) provides the information on air pollution, etc. nationwide, every hour, 24 hours a day.

The monitoring results for FY2013 are as shown below.

- Although the measured value of benzene exceeded environmental quality standard at one monitoring spot, the values of trichloroethylene, tetrachloroethylene and dichloromethane complied with environmental quality standards.

In FY2013, the government revised the standards on administrative affairs concerning the constant monitoring of air pollution which is conducted pursuant to the provision of Article 22 of Air Pollution Control Act, in order to enable the appropriate monitoring of areas around emission sources which emit large amounts of air pollutants, using PRTR data, etc.

The government also formulated “Standard Guidelines for the Environmental Monitoring of Chemicals”, in an effort to improve the efficiency of the monitoring of hazardous air pollutants in the atmospheric environment.

The government will continue to conduct the monitoring of the atmospheric environment and publish the results thereof, in cooperation with local governments, etc.

### **[Regular Observation of the Water Environment] (MOE)**

Regarding the quality of public waters, local governments, the government and the ordinance designated municipalities which are stipulated in the Water Pollution Control Act (Act 138 of 1970) measure water quality as part of regular observations, based on the stipulations in the Water Pollution Control Act and in accordance with measurement plans created by each prefectural governor every year. They conduct measurements mainly for items for which environmental quality standards regarding water pollution have been set, and the government conducts the measurement for Class A rivers which are managed by the government. The results are then published by prefectural governors.

Prefectural governors must report the measurement results to the Minister of the Environment. The MOE has developed water quality-related information systems, which it uses to compile measurement results in order to ascertain the water quality nationwide. It also publishes the results in order to contribute to the facilitation of future water environment administration.

In FY2014, the ministry published the results in “Results of the FY2013 Water Quality Survey of Public Water Areas (Announcement) <December 26, 2014>.” The results published are as shown below.

#### ◇ Items concerning health

- The environmental quality standard achievement level for 27 items was 99.2% (99.0% in the previous fiscal year).

#### ◇ Items concerning the living environment (preservation of aquatic life)

- The environmental quality standard achievement level for total zinc in category-designated water areas<sup>6</sup> (870 water areas) was 98.2% (98.6% in the previous fiscal year, for 739 water areas).
- The environmental quality standard achievement level for nonylphenol in category-designated water areas (809 water areas) was 100% (45 water areas in the previous year, the measurement started in mid FY2012).
- The environmental quality standard achievement level for Linear Alkylbenzene Sulfonic acid and its salts (LAS) in category-designated water areas (74 water areas) was 100% (the measurement started in FY2013)

The government intends to continue to receive and compile reports on the results of regular observations conducted by local governments, ordinance designated municipalities stipulated in the Water Pollution Control Act and the government, as well as to publish the results.

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<sup>6</sup> Designation of water category: For items concerning the living environment, sets of categories are created based on the water’s utilization, for rivers, lakes and sea areas, respectively. Each water area (a river, a lake or a sea area) is then put into one of the created categories.

### **[Regular Observation of Groundwater Quality] (MOE)**

Regarding groundwater quality, local governments and the ordinance designated municipalities which are stipulated in the Water Pollution Control Act measure water quality as part of regular observations, based on stipulations in the Water Pollution Control Act and in accordance with measurement plans created by local governments every year. They mainly conduct measurements for items that have already set environmental quality standards regarding groundwater pollution. The results are then published by prefectural governors.

Prefectural governors must report the measurement results to the MOE. The MOE has developed water quality-related information systems, which it uses to compile measurement results in order to ascertain the groundwater quality nationwide. It also publishes the results in order to contribute to the facilitation of future water environment administration.

In FY2014, the ministry published the results in “FY2013 Measurement Results for the Quality of Groundwater (Announcement) <February 27, 2015>.” The results published are as shown below. Based on these results, measures to control pollution (exceeding standards) are being taken.

- ◇ As a result of the survey of the general conditions in FY2013, environmental quality standards were exceeded at 5.8% of the surveyed sites (wells) (6.1% in the previous fiscal year).
- ◇ For the surveyed sites where pollution was found, surveys were conducted in areas around polluted wells in order to find out the geographical extent of the pollution. The surveys were conducted for 1,472 wells in FY2013 (1,245 wells in the previous fiscal year).
- ◇ For areas where pollution was found as a result of the surveys explained above, continual monitoring surveys were conducted. Surveys were conducted for 4,547 wells in FY2013 (4,545 wells in the previous fiscal year).

The government will continue to receive and compile reports on the results of regular observations conducted by local governments, ordinance designated municipalities stipulated in the Water Pollution Control Act and the government, as well as to publish the results.

### **[Efforts to Control Indoor Air Pollution] (MHLW)**

In order to tackle the “sick house” (indoor air pollution) problem, the MHLW has created Air Quality Guideline Values for 13 substances including formaldehyde. About 10 years have passed since the guideline values were considered and new problems, etc. have been pointed out for some of the substituted chemicals for which guideline values have not been created. In light of these facts, the government resumed the Review Meetings on the Sick House (indoor air pollution) Problem, where they discuss new Air Quality Guideline Values based on the latest findings.

- In September 2012, the government resumed the Review Meetings on the Sick House (indoor air pollution) Problem, where they are having discussions in order to set new Air Quality Guideline Values based on the latest findings, among other purposes (eight meetings have been held so far).
- In order to contribute to the discussions, the government has conducted fact-finding surveys on indoor concentrations of major chemicals in inhabited housing, in the summer and winter of FY2012 and the summer of FY2013 and FY2014.

The government will continue to have discussions on the matter at the Review Meetings on the Sick House (indoor air pollution) Problem.

**<Efforts for Setting Target Values, etc.>**

**[Surveys and Discussions Which Contribute to the Setting, Revision, etc. of Environmental Quality Standards, etc. concerning Air Pollution] (MOE)**

Environmental quality standards concerning air pollution which are set based on the Basic Environment Law, have been set for 10 substances (except for dioxins) from the standpoint of protecting human health. Values that give guidelines for reducing the health risk from hazardous air pollutants in the environment (guideline values) have been set for nine substances.

Since environmental quality standards must be reviewed continuously using appropriate science-based judgments, the government will continue to promote increasing scientific knowledge and give the necessary consideration to substances, etc. for which environmental quality standards, etc. have already been set. For substances for which environmental quality standards or guideline values (hereinafter referred to as “environmental quality standards, etc.”) have not been set, the government will collect and organize scientific findings in preparation for setting standards, etc.

In FY2012 and FY2013, the government continued to collect and organize the latest information on trends in air quality improvement policies such as the setting and revision of atmospheric environmental quality standards, etc. in various countries and at international organizations, etc. The government also continued to collect and organize information about effects on human health, with regard to substances for which environmental quality standards, etc. concerning air pollution have not been set as well as substances for which environmental quality standards, etc. have already been set. Regarding manganese and its compounds, an expert committee at the Central Environment Council launched discussions on health risk assessments for the chemicals in FY2012. The government compiled a report in March, 2014, based on which guideline values were set in April of the same year. In FY2012, an expert committee at the Central Environment Council launched discussions on assessment methods for hazard, etc. in cases where scientific knowledge on the hazardous air pollutants is limited. Based on the report compiled in March 2014, the necessary revisions were made in April of the same year.

The government will continue to collect and organize information which will contribute to the setting, etc. of environmental quality standards, etc. concerning air pollution. The government will also continue discussions on risk assessment methods as well as going ahead with the setting, etc. of environmental quality standards, etc.

**[The Revision of Environmental Quality Standards, etc. concerning Water Quality] (MOE)**

Regarding environmental quality standards which are set based on the Basic Environment Law, standards have been set for 27 items regarding the pollution of public waters with the aim of protecting human health. There are also standards regarding water pollution which aim to protect the living environment, including standards for three items which were set to preserve aquatic life. Environmental quality standards have also been set for 28 items regarding groundwater pollution.

There are also specified monitoring items, for which the accumulation of knowledge should continue to be strived for (such as the continuous monitoring of the detection levels for the chemicals in public waters, etc.), although environmental quality standards would not be set immediately, when considering the current detection levels, etc. in public waters, etc.



In addition, there are “specified items to be surveyed,” for which the accumulation of knowledge on “water environmental risk” is necessary, when considering the current detection levels in the environment and when considering their combined effects, etc. although the “water environmental risk” for each substance is relatively insignificant or unknown.

It is necessary to make appropriate science-based judgments and to make the necessary revisions continuously, concerning items that require environmental quality standards and their standards as well as specified monitoring items and their guideline values. Therefore, the government will continue to make the necessary additions and revisions. For specified items to be surveyed, the government will strive to accumulate knowledge and make revisions flexibly.

- ◇ In FY2012, it was decided that environmental quality standards would be set for nonylphenol, n-alkylbenzenesulfonic acid and its salts (alkyl C=10-14), regarding the preservation of aquatic life. In addition, three items including 4-t-octylphenol were added to specified monitoring items.
- ◇ In FY2013, the specified items to be surveyed were revised and 208 items were selected through the revision.
- ◇ In FY2014, it was decided that environmental quality standard for Trichloroethylene regarding the human health safety be revised from 0.03mg/L to 0.01mg/L.

The government will continue to make the necessary revisions based on new scientific findings.

#### **[The Revision of Soil Environmental Quality Standards, etc.] (MOE)**

The soil environmental quality standards which are set based on the Basic Environment Law, stipulate the concentrations of chemicals in the soil that should not be exceeded in order to protect human health and the living environment. Soil environmental quality standards have been set for 27 items, as the standards for determining whether the soil is contaminated or not, and as the target values when improvement measures are to be taken for contaminated soil.

The government sets soil environmental quality standards based on the idea of setting standards for items that are capable of setting standards in line with existing knowledge and various relevant standards, including environmental quality standards concerning water quality and groundwater. From FY2009 to FY2011, 1,4-dioxane and other items became subject to the creation of environmental quality standards concerning water quality and groundwater, and also changes were made to existing standards concerning water quality and groundwater. In light of these revisions, the government is revising the soil environmental quality standards.

Regarding the activities in FY2013, a report was submitted in March 2014, based on deliberations concerning the revision of soil environmental quality standards for 1,1-dichloroethylene in the Subcommittee on Soil Environmental Quality Standards of the Soil Agricultural Chemical Committee at the Central Environment Council in December 2013. Based on the report, the soil environmental quality standard for 1,1-dichloroethylene was revised in March 2014.

The government will continue to consider the revision, etc. of soil environmental quality standards and designated hazardous substances stipulated in the Soil Contamination

Countermeasures Law (Act 53 of 2002), with regard to other substances that were deliberated on in the subcommittee.

### **[Efforts to Control Indoor Air Pollution] (MHLW)**

(The content is omitted as it is the same as the content on page 19.)

b) The Development and Utilization of New Methods in Order to Increase Risk Assessment Efficiency, etc.
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#### **The Status Quo**

Regarding risk assessment methods, the following methods are being developed through international cooperation using the OECD and other frameworks: new methods including the QSAR and toxico-genomics; and new risk assessment methods which assess the environmental impacts of agricultural chemicals more accurately.

#### **Efforts Being Made**

##### **<Efforts to Increase Risk Assessment Efficiency, etc.>**

##### **[The Development and Utilization of QSAR, Toxico-genomics, etc.] (MHLW, METI and MOE)**

###### **◇ The Development of Health Effect Assessment Systems Using QSAR, etc.**

In response to the revision of the CSCL in 2009, the government needs to urgently conduct safety assessments for many chemicals which have not been assessed. Currently, the important policy issue for chemical management is to comprehensively understand the safety of chemicals by 2020, through international coordination. Therefore, the government decided to promote research for the development of efficient and highly accurate assessment methods for chemicals, including the development of predictive assessment methods such as QSAR and the categorical approach, in order to accelerate the comprehensive assessment of chemicals and contribute to international efforts for chemical management. More specifically, the government is making the following efforts.

- The government is developing comprehensive and stable assessment methods in order to achieve quicker and more accurate quantitative hazard assessment methods concerning respiratory exposure. From FY2012 to FY2014, the government examined whether or not effects on the central nervous system could be predicted using a comprehensive gene expression analysis method which uses brain samples. Xylene and p-dichlorobenzene were used in the studies.
- The government is conducting research for the development of systems which contribute to the following assessments: health effect assessments for chemicals which comprehensively analyze gene expression signatures and metabolites observed when chemicals are applied to laboratory animals, using toxico-genomics and other data analysis technologies; and health effect assessments for chemicals using QSAR. From FY2012 to FY2014, the government added data on many chemicals onto a database among other activities, with the aim of increasing the prediction accuracy of the Ames test.
- In order to upgrade hazard assessments for chemicals and to enable quick and efficient testing, the government is developing methods to obtain predictive information concerning the possibility of general toxicity and carcinogenicity of chemicals in the main organs (the liver and the kidneys) when checking the hazard of chemicals. The methods use data on genetic changes obtained from laboratory animals which were used

for toxicity tests. It is a five-year project started in FY2011. In FY2012, feasibility tests for animal testing were conducted in order to obtain and analyze genetic data. In FY2013, prototypes of toxicity determination methods were created. In FY2014, prototypes of methods were improved.

It is an essential project which greatly contributes to ensuring the safety of citizens in Japan, by providing a scientific basis for various administrative measures implemented with the aim of minimizing effects on human health when using chemicals. The government will continue to carry out the project.

◇ KAshinhou Tool for Ecotoxicity (KATE)

The MOE is conducting research and development for KATE with the National Institute for Environmental Studies. KATE predicts the median lethal concentration (LC50) for the Fish Acute Toxicity Test and the median effective concentration (EC50) for the Daphnia Acute Immobilisation Test, when the structural formulas, etc. of chemicals are entered into the system. Business operators engaged in chemical management can predict the above-mentioned concentrations for chemicals whose toxicity to ecologies is unknown, and they can utilize the results as reference information when considering the appropriate handling and management measures for the chemicals.

- The trial version (KATE Ver1.0) was released in January 2008. “KATE 2011” was released in March 2011.
- In 2013, ecotoxicity test was conducted for chemical substances without predictive formula built-in to KATE to improve its accuracy and expand its coverage due to its insufficient actual measurement value for the prediction.
- The results obtained using KATE, etc. were distributed as reference materials for the evaluation of New Chemical Substances at the Three-Ministry Joint Council.

**[Methods for Screening Assessments and Risk Assessments within the Framework of the CSCL Which Take the Whole Lifecycle into Consideration] (MHLW, METI and MOE)**

For the risk management of chemicals throughout their lifecycles, it is necessary to conduct screening assessments and risk assessments which take the whole lifecycle into consideration including the long-term use and disposal of products which contain chemicals, in addition to the manufacture, compounding and use of chemicals. For this reason, the government is conducting surveys and having discussions on the development of methods which would enable assessments that take the whole lifecycle into consideration.

**[Promotion of Risk Assessments, etc. concerning Agricultural Chemicals and Consideration for the Advancement, etc. of Assessment Methods] (MOE)**

Regarding agricultural chemicals, the government is collecting information on efforts made by other countries and efforts which are being made based on other laws and regulations, with the aim of developing new methods, etc. for risk assessments and risk management targeting organisms other than aquatic plants and animals, their populations and ecosystems. In addition, the government is conducting the following three activities.

◇ The Creation of the Manuals for Risk Assessment and Management of Agricultural Chemicals on Birds

In the past, the government had important discussions to establish risk assessment and management methods for the impacts of agricultural chemicals on terrestrial ecosystems. Based on the results of the discussions, the government created the Manuals called ‘Manuals for Risk Assessment and Management of Agricultural Chemicals on Birds’ in

2013, in order that agricultural chemical manufacturers can take voluntary measures which consider the impacts of agricultural chemicals on birds from the development stage. The assessment on agricultural chemical risk to birds is proceeded by each agricultural chemical manufacturer based on this manual.

◇ The Development of a Tool to Select Biodiversity-friendly Agricultural Chemicals and Their Utilization Methods

In the current risk assessments for agricultural chemicals, tests are conducted using fish, algae and Crustacean species. However, the current assessment methods have some concerning weaknesses from the standpoint of ecosystem conservation in Japan. For example, the *Daphnia* species used for the tests are not native ones to Japan. Therefore, the government has been developing a mesocosm experiment method which can assess the impacts of agricultural chemicals on communities endemic to local areas in Japan. By FY2013, the basic draft of experiment method was created and the development came to the stage where verification experiments can be conducted in each local area.

The government is making an effort to develop a tool which enables to select agricultural chemicals that have less impact in accordance with the type of biodiversity endemic to each local area. The government promotes the dissemination of the method after the experiment method was established.

◇ The Establishment of Risk Assessment Methods for Aquatic Ecosystems Using Statistical Methods

In the current agricultural chemical registration system, risk assessments concerning the impacts of agricultural chemicals on aquatic ecosystems are being conducted using three types of toxicity tests and standard environmental models. However, there are still some issues to be addressed in terms of the risk assessment when considering the whole ecosystems. Another challenge is to increase the accuracy of the PEC by taking into consideration biotic and abiotic conditions such as regional differences that the current standard environmental models are unable to consider. The government aims to establish better quantitative risk assessment methods for the impacts of agricultural chemicals on the whole aquatic ecosystems using statistical methods.

In FY2014, regional variations in the PEC were estimated and species sensitivity distributions were analyzed.

A method to simultaneously conduct toxicity tests for 5 species of attached algae was also developed.

The government will continue to promote efforts to establish risk assessment methods and consider how to utilize the methods in agricultural chemical risk assessments.

**[The Development of Test Methods concerning the Endocrine-disrupting Effects of Chemicals] (MOE)**

Test methods for the assessment of the endocrine-disrupting effects of chemicals are being developed through cooperation between the developed countries. Test guidelines (TG) are also being developed at the OECD.

In Japan, the government aims to develop test methods which use fish, amphibians, etc. and have them recognized as internationally standardized test methods at the OECD.

In 2009, the following two tests were included in the OECD test guidelines.

- TG229 Fish Short Term Reproduction Assay (revised in 2012)  
To assess multiple effects of chemicals on fish, including estrogenic effects and androgenic effects.
- TG231 Amphibian Metamorphosis Assay  
To assess the effects of chemicals on the hypothalamic-pituitary-thyroid (HPT) axis of amphibians.

In 2011, the following test was included in the OECD test guidelines.

- TG234 Fish Sexual Development Test  
To assess multiple effects of chemicals on fish, including estrogenic effects and anti-estrogenic effects.

The following two tests, which Japan and the US jointly submitted to the OECD, were publicized as new test guidelines in July, 2015.

- TG240 Medaka Extended One-generation Reproduction Test  
To assess the multiple effects of chemicals on reproduction of killifish, including estrogenic effects and anti-estrogenic effects.
- TG241 Larval Amphibian Growth and Development Assay  
To assess the effects of chemicals on the HPT axis, growth, etc. of amphibians.

In vitro assays have also been developed and the following two tests are to be publicized as new test guidelines in 2015.

- TG493 Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) In Vitro Assays to Detect Chemicals with ER Binding Affinity
- TG455 Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists and Antagonists

The government will continue to develop the test methods needed to assess the endocrine-disrupting effects of chemicals through cooperation with other countries, and work to have them included in the OECD test guidelines.

## **Priority Examination Area 2: Risk Reduction throughout the Whole Life-cycle**

### (1) The Basic Approach to Issues That Should Be Tackled

Through past efforts, some positive results have been produced concerning chemicals which have a particularly high risk. However, in order to achieve the WSSD2020 Goal, it is necessary to expand the scope to include a larger number of chemicals which may pose a risk, and to make various efforts more efficiently and effectively, at various stages from the manufacture and use to the release and disposal of chemicals. Therefore, the government should put more efforts into the smooth implementation of relevant laws and regulations and further encourage voluntary efforts by business operators. The government should also strengthen coordination between relevant laws, regulations and systems for environmental conservation, the protection of consumers and workers, as well as taking measures from the standpoint of those who are affected by the adverse effects of chemicals.

### (2) The Status Quo and the Efforts Being Made

In order to tackle the above-mentioned issues, the government is making efforts to reduce risk throughout the lifecycles of chemicals, by further promoting measures to reduce risk based on risk assessment results and by appropriately combining various methods, while also ensuring close coordination between relevant laws, regulations, systems and measures. More specifically, the government needs to promote the regulation of chemicals throughout their lifecycles based on various laws and regulations, from their manufacture, import and use to their release and disposal, as well as promoting lifecycle management by business operators. The government also needs to take measures to control polluted soil and hazardous chemicals manufactured in the past, as well as preparing for accidents. From these standpoints, the current efforts by the relevant administrative institutions were reviewed concerning items a), b), c) and d) shown below.

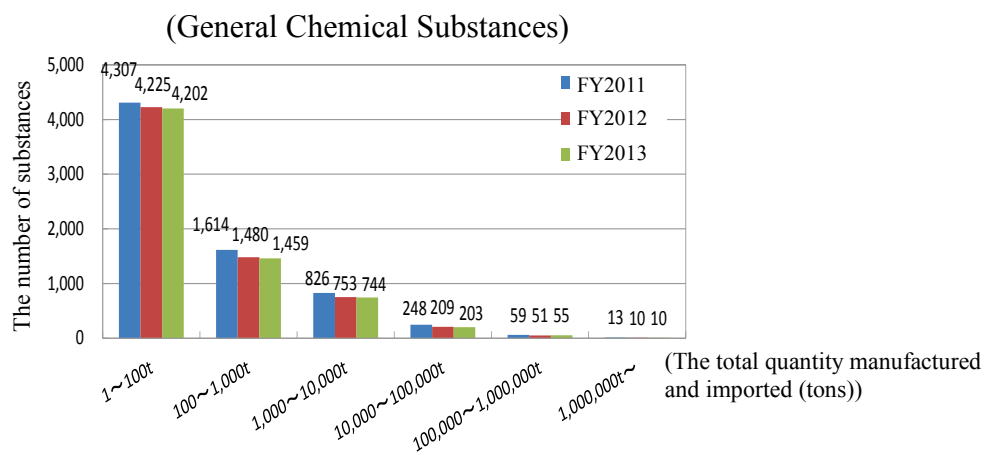
- a) The appropriate implementation of regulations at the stages of manufacture, import and use of chemicals, and the promotion of business operators' efforts
- b) The implementation of measures to control chemicals at the stages of their release into the environment, their disposal and their recycling
- c) Measures to control negative legacies including hazardous chemicals manufactured in the past, polluted soil and sediment
- d) Preparation for accidents, etc.

a) The Appropriate Implementation of Regulations at the Stages of Manufacture, Import and Use of Chemicals, and the Promotion of Business Operators' Efforts\*

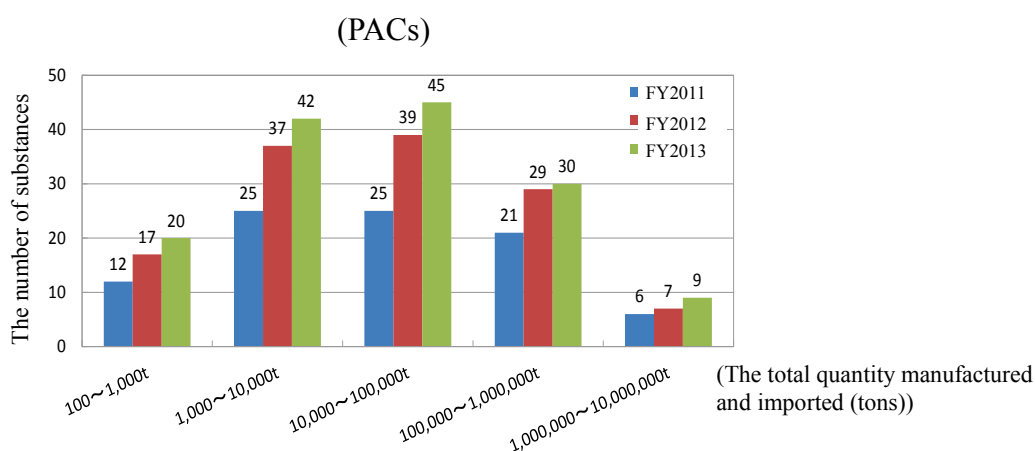
#### The Status Quo

Regarding the manufacture, import and use of general-purpose (industrial use) chemicals and agricultural chemicals, the government has been taking regulatory measures based on the CSCL and the Agricultural Chemicals Regulation Law, respectively. As mentioned before, the CSCL was partially revised in 2009 and a comprehensive management system including the management of existing chemicals was introduced in FY2011.

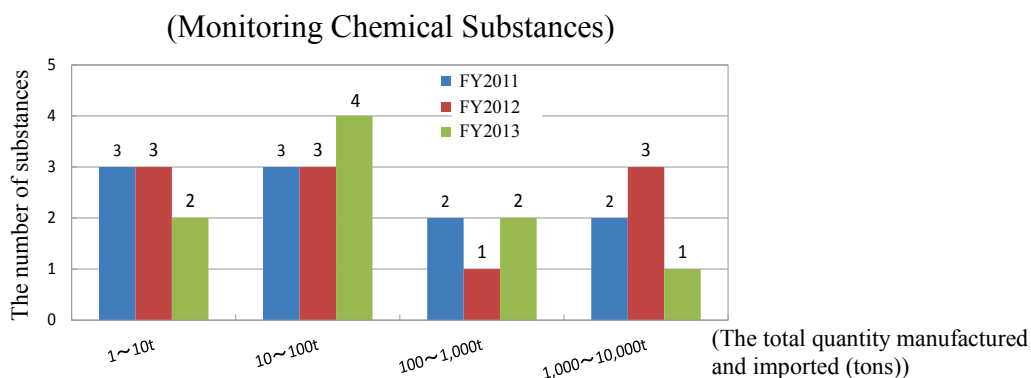
Figure 5 shows the notified numbers of chemicals categorized by the total quantity manufactured and imported, for "General Chemical Substances," "PACs" and "Monitoring Chemical Substances" which are stipulated in the CSCL. Figure 6 shows changes in the shipment quantities of agricultural chemicals stipulated in the Agricultural Chemicals Regulation Law.



Note: Business operators who manufacture or import one ton or more of a General Chemical Substance in a year are required to report the quantity. The horizontal axis of the Figure shows the total quantity calculated and the vertical axis shows the number of substances which come under each quantity class.



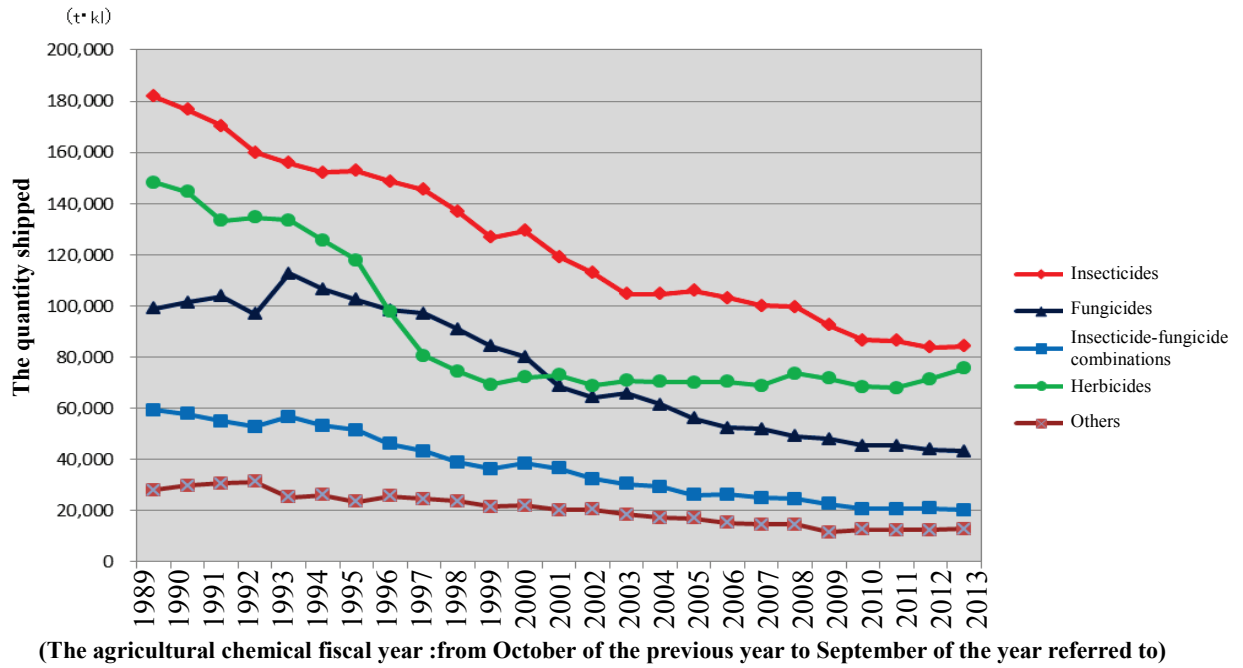
Note: Business operators who manufacture or import one ton or more of a priority chemical in a year are required to report the quantity. Every fiscal year, the government publishes the total quantities manufactured and imported for PACs whose total quantity is 100 tons or more. The horizontal axis of the Figure shows the total quantity calculated and the vertical axis shows the number of substances which come under each quantity class.



Note: Business operators who manufacture or import one kilogram or more of a Monitoring Chemical Substance in a year are required to report the quantity. Every fiscal year, the government publishes the total quantities manufactured and imported for Monitoring Chemical Substances whose total quantity is one ton or more. The horizontal axis of the Figure shows the total quantity calculated and the vertical axis shows the number of substances which come under each quantity class.

Source: Created by MOE based on data published by METI

Figure 5 The Numbers of Chemicals Categorized by the Total Quantity Manufactured and Imported, for “General Chemical Substances,” “PACs” and “Monitoring Chemical Substances” Which Are Stipulated in the CSCL



Source: The website of the Ministry of Agriculture, Forestry and Fisheries ([http://www.maff.go.jp/j/nouyaku/n\\_info/](http://www.maff.go.jp/j/nouyaku/n_info/))  
 Figure 6 Changes in the Quantities of Agricultural Chemicals Shipped (from 1989 to 2013, in the Agricultural Chemical Fiscal Year)



Figure 7 shows the number of reports regarding New Chemical Substances submitted to the government based on the CSCL. When looking at the changes over about 40 years, the number has increased over time.

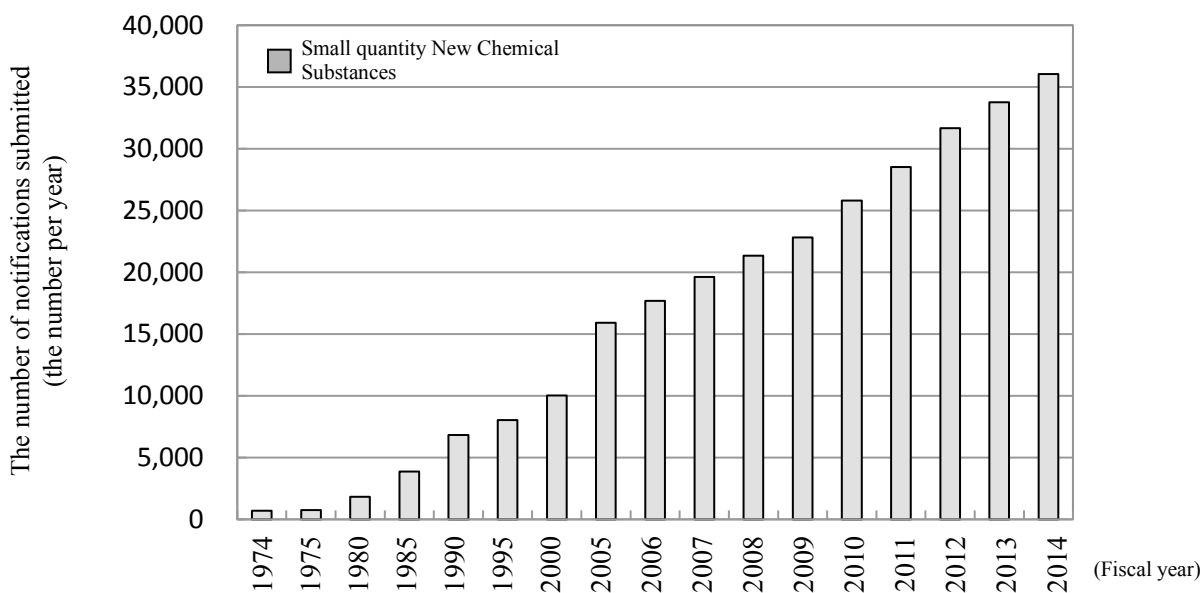
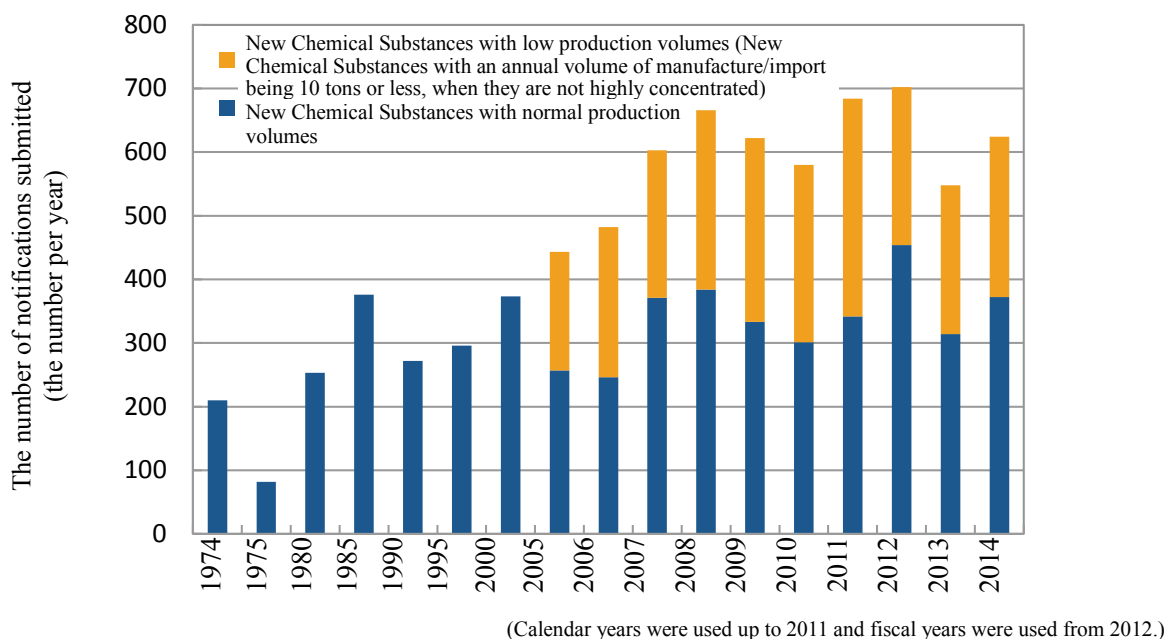


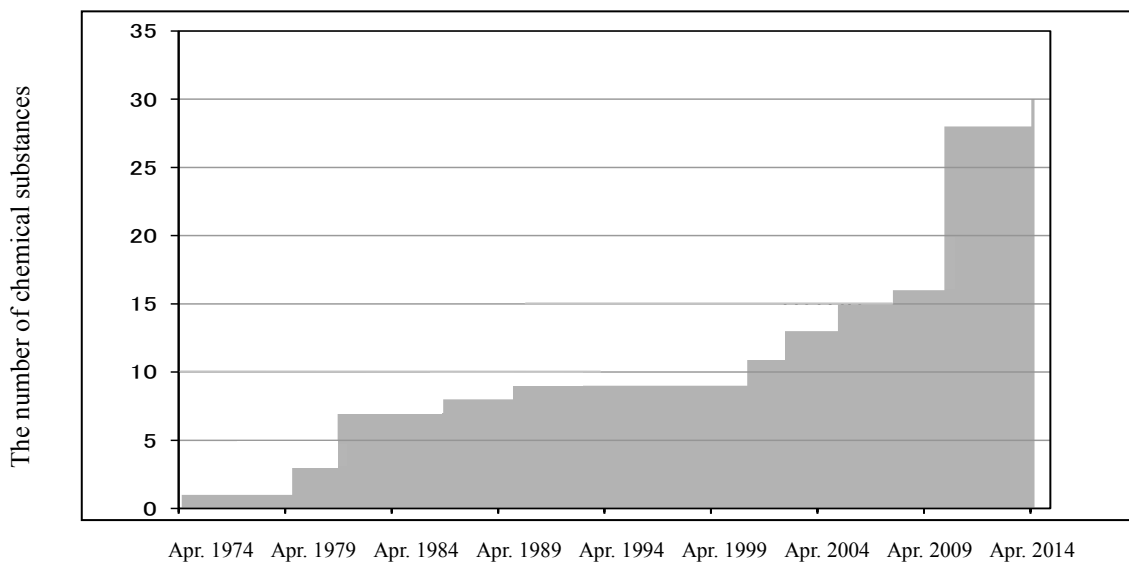
Figure 7 Changes in the Number of Notifications regarding New Chemical Substances Submitted

Note 1. New Chemical Substances with low production volumes: They are New Chemical Substances with quantities manufactured/imported nationwide in a fiscal year being 10 tons or less. They need to undergo tests to check degradability and the level of concentration.

Note 2. Small quantity New Chemical Substances: They are New Chemical Substances with quantities manufactured/imported nationwide in a fiscal year being one ton or less. The submission of hazard information, etc. for the chemicals is not required when their manufacture/import is to be reported to the government.

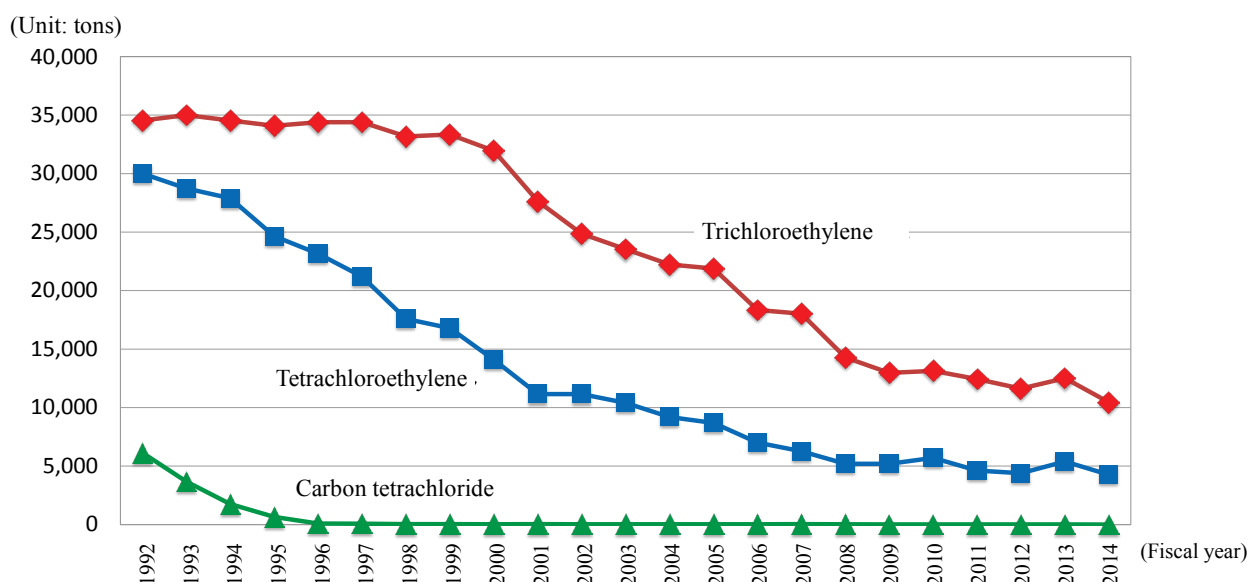
Source The website of METI ([http://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/sekou.html](http://www.meti.go.jp/policy/chemical_management/kasinhou/information/sekou.html))

Figure 8 shows changes in the number of chemicals designated as Class I Specified Chemical Substances based on the CSCL. A substance whose persistence, bioaccumulative property and long-term toxicity have been confirmed is designated as a Class I Specified Chemical Substance. Their manufacture, import and use are banned in principle. Immediately after the CSCL came into force, PCBs were designated as Class I Specified Chemical Substances. Since then, more substances were gradually added to the list and there are currently 30 Class I Specified Chemical Substances in total. A substance which has long-term toxicity and is found to have a risk because a considerable amount remains in the environment over a substantially extensive area, is designated as a Class II Specified Chemical Substance. Figure 9 shows the shipment quantities (except for shipment for export and shipment as intermediates) for trichloroethylene, tetrachloroethylene and carbon tetrachloride, which are the main Class II Specified Chemical Substances currently being manufactured or imported for purposes other than testing and research. The shipment quantities for all three chemicals are decreasing in general.



Source: MOE

Figure 8 Changes in the Number of Chemicals Designated as Class I Specified Chemical Substances



Source: The website of the METI ([http://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/sekou.html](http://www.meti.go.jp/policy/chemical_management/kasinhou/information/sekou.html))  
 Figure 9 Changes in the Quantities of Class II Specified Chemical Substances Shipped (Except for Shipment for Export and Shipment as Intermediates)

## Efforts Being Made

### <Efforts concerning the Implementation of Regulations>

#### [The Implementation of Regulations Based on the CSCL] (MHLW, METI and MOE)

The CSCL aims to prevent chemicals which have a risk of affecting human health and ecosystems from becoming environmental pollution. It stipulates the evaluation and regulation of New Chemical Substances, continuous management measures for chemicals after they are put on market, and the regulation, etc. of chemicals in accordance with their properties, etc. After the Ordinance for the Enforcement of the CSCL was revised in March 2014, hexabromocyclododecane and endosulfan were designated as Class I Specified Chemical Substances on May 1, 2014, and their manufacture, import, etc. were banned in principle. The following activities have been conducted based on the law.

- ◇ The number of reports and requests regarding New Chemical Substances submitted
  - 602 notifications on New Chemical Substances were submitted in FY2014.
  - 36,052 notifications regarding small quantity New Chemical Substances were submitted in FY2014.
- ◇ The designation of substances to be regulated, etc. (as of April 1, 2015)
  - Class I Specified Chemical Substances: 30 (PCBs, etc.)
  - Class II Specified Chemical Substances: 23 (trichloroethylene, etc.)
  - Monitoring Chemical Substances: 37 (Tetraphenyltin, etc.)
  - PACs: 177 (phenol, benzene, etc.)

The government will continue to ensure the appropriate implementation of regulations for chemicals based on the CSCL.

**[The Implementation of Regulations, etc. Based on the Agricultural Chemicals Regulation Law] (The Ministry of Agriculture, Forestry and Fisheries (MAFF) and the MOE)**

◇ Setting Registration Withholding Standards

(The content is omitted as it is the same as the content on page 11.)

◇ Monitoring

(The content is omitted as it is the same as the content on page 12.)

◇ Setting Standards for the Use of Agricultural Chemicals and Promoting Guidance on Appropriate Use

Agricultural chemicals must control pests effectively when they are used in accordance with prescribed methods of use. In addition, agricultural chemicals must be evaluated as to whether they do not have adverse effects on human health, the environment and useful organisms, before they are registered. In order to prevent adverse effects of agricultural chemicals on human health and the environment, users must comply with the prescribed methods of use. Therefore, the government established “the Ministerial Ordinance to Provide for Standards to be Complied with by Agricultural Chemical Users” (the 2003 Ordinance of MAFF and MOE). The government requires users to comply with the standards of use, including types of crops, application rate and pre-harvest interval. The government also promotes guidance on the appropriate use of agricultural chemicals through the Campaign Against Incidents Caused by Agricultural Chemicals. In particular, the government is taking the following measures.

- Prior to registering agricultural chemicals, the government rigorously evaluates their toxicity, effects on drinking water quality and aquatic plants and animals, persistence, etc. The government also prescribes the method of use for each agricultural chemical and strives to have them complied with thoroughly. In order to prevent damage to useful organisms such as silkworms and honeybees, the government displays safety precautions with the methods of use on labels, based on the results of risk assessment.
- In order to promote the safe and appropriate use of agricultural chemicals and prevent accidents during use as well as promoting the use of more environmentally friendly agricultural chemicals, the government conducted “the Campaign Against Incidents Caused by Agricultural Chemicals” for three months (from June to August) from FY2012 to FY2014.
- In April 2013, the government revised “the Notification on Use of Agricultural Chemicals in and around Residential Areas.” (jointly issued by the director general of the relevant bureau in the MAFF and the director general of the relevant bureau in the MOE). This notification stipulates rules which agricultural chemical users should comply with when using agricultural chemicals in and around residential areas. The government aims to ensure that the drift of agricultural chemicals does not cause health damage to people including residents when agricultural chemicals are used on plants in public facilities such as parks, on roadside trees, as well as on farmland and in forests that are near residential areas. Recommended measures include: the reduction in the frequency and the amount of agricultural chemical applications through physical pest controls; the prevention of the drift of agricultural chemicals; and distributing information on the schedule of application of agricultural chemicals beforehand in consideration of residents living in the surrounding areas.
- In FY2013, the MOE revised “the Manual for the Control of Pests and Weeds in Parks, for Roadside Trees.” and is distributing the manual in order to ensure that the use of agricultural chemicals does not cause adverse effects in surrounding areas.

- The MAFF supported the following efforts through subsidy from FY2012 to FY2014: efforts to ensure the appropriate use and management of agricultural chemicals by users, and studies on drift of agricultural chemicals and agricultural chemical residues in agricultural products, as well as efforts to check the effectiveness of technologies to prevent drift.
- In order to ensure the appropriate use of agricultural chemicals on golf courses and to prevent water pollution, the MOE formulated provisional guidelines which give guidance so that the concentrations of agricultural chemicals in wastewater do not exceed the guideline values. It also conducted surveys in order to check whether agricultural chemical concentrations in wastewater exceeded the guideline values. Surveys were conducted at 24 sites nationwide in FY2012 and FY2013, and none of the sites had concentrations exceeding the guideline values.

The government will continue to carry out rigorous evaluations prior to registering agricultural chemicals, as well as promoting guidance on the appropriate use of agricultural chemicals including compliance with the standards for the use of agricultural chemicals, through the Campaign Against Incidents Caused by Agricultural Chemicals. The government will also strive to accumulate knowledge and verify the effectiveness of the current regulations on the use of agricultural chemicals, in order to check the appropriateness of the regulations.

#### **[Comprehensive Emissions Control Measures for 4 Gases including HFC] (METI and MOE)**

Private sectors take measures to control the emission of fluorocarbons, through voluntary action plan and recovery and destruction of fluorocarbons.

“Fluorocarbons Recovery and Destruction Law” (Act 64 of 2001) was revised and renamed “Act on Rational Use and Proper Management of Fluorocarbons”, which is aimed for rational use and proper management of each stage of the lifecycle of fluorocarbons. As the next step, the government will strengthen its support for the development of technologies, commercialization and popularization for non-fluorocarbon and low-GWP alternatives, through various measures including technology verification, subsidies for the introduction of technologies and dissemination and awareness-raising projects as well as steady implementation of the revised law.

#### **[Efforts Based on the Industrial Safety and Health Act] (MHLW)**

In order to prevent industrial accidents and health impairment in the workplace, the government will implement measures to prevent exposure to chemicals, etc. appropriately, based on the Industrial Safety and Health Act. The government will also promote measures to prevent workers’ exposure to asbestos during the demolition of buildings, as well as the thorough implementation of bans on the importation, etc. of products containing asbestos.

When industrial accidents caused by chemicals have occurred such as explosions and poisoning caused by chemicals, the business operators are required to report the accidents to the relevant Labour Standards Inspection Office. When serious accidents have occurred, the government conducts investigations into the accidents and takes the necessary measures such as giving guidance on how to stop violating laws and regulations and on the prevention of accidents in the future, based on the investigation results.

- Based on the results of the recently conducted mutagenicity tests, the government added chemicals which were found to be highly mutagenic to the chemicals subject to the

guidelines on exposure prevention measures. (37 chemicals in FY2012; 49 chemicals in FY2013; 69 chemicals in FY2014). As of FY2014, there are 1000 chemicals in total.)

- The government will measure the concentration of asbestos in the air at building demolition sites and debris collection sites in areas affected by the Great East Japan Earthquake, etc. (100 sites in FY2012; 85 sites in FY2013; and about 34 sites are planned for FY2014.)

The government will continue to work on the implementation of effective measures in order to manage chemicals appropriately and prevent the health impairment of workers.

#### **[Efforts Based on the Act on Control of Household Products Containing Harmful Substances] (MHLW)**

With the aim of contributing to the protection of the health of citizens, the MHLW implements regulations on household products containing harmful substances, which are needed from a public health standpoint, based on the Act on Control of Household Products Containing Harmful Substances (Act 112 of 1973).

- In April 2015, the government revised the Government Ordinance and added azo compound that have a risk of generating 24 specific aromatic amines e.g. benzin, as toxic subject to the Act on Control of Household Products Containing Harmful Substances. In July 2015, the government revised Ministerial Ordinance and designated household products that contain toxic azo dyes as well as set a standard contingent to its classification.
- When serious accidents involving products have occurred and they are assumed to have been caused by chemicals, the ministry discloses the accidents quickly and provides relevant information to consumers, in cooperation with the Consumer Affairs Agency and other relevant ministries and agencies (e.g. “The Voluntary Recall of the “Virus Protector” Has Started,” February 22, 2013.)
- Every fiscal year, the ministry publishes the results of compiling the Hospital Monitoring Reports, as well as creating pamphlets, etc. which would contribute to preventing accidents involving household products.
- Every fiscal year, local governments conduct inspections through trial purchases, etc. in order to monitor the sale, etc. of household products that do not meet control standards, as well as giving guidance when they find products which do not meet the standards.

The government will continue to conduct monitoring and give guidance based on the Act on Control of Household Products Containing Harmful Substances, and revise the chemicals subject to the law where necessary.

#### **[Efforts concerning Indoor Air Pollution] (MHLW)**

(The content is omitted as it is the same as the content on page 19.)

#### **[The Implementation of Regulations Based on the Poisonous and Deleterious Substances Control Law] (MHLW)**

The MHLW implements the necessary control of poisonous and deleterious substances from a public health standpoint, based on the Poisonous and Deleterious Substances Control Law.

- Among the useful chemicals found in daily life, chemicals which have high a risk of causing health damage mainly due to their acute toxicity are designated as poisonous substances or deleterious substances, based on the Poisonous and Deleterious

Substances Control Law (Act 303 of 1950). The law stipulates the registration system for Poisonous and Deleterious Substances Dealers, labeling on containers, etc., procedures for sale (transfer), measures to prevent theft, loss, leakage, etc., standards for transportation, disposal, etc. and so on. In cooperation with local governments, the government gives guidance, etc. to dealers and others in order to prevent the inappropriate distribution of poisonous and deleterious substances and the leakage, etc. of the substances.

Based on the Poisonous and Deleterious Substances Control Law, the government will continue to revise the substances subject to the regulations through deliberation at the Pharmaceutical Affairs and Food Sanitation Council, etc. where necessary, in light of new findings.

#### **<The Promotion of Green Procurement by the State, etc.>**

#### **[The Promotion of Green Procurement by the State, etc.] (MOE)**

Act on Promotion of Procurement of Eco-Friendly Goods and Services by the State and Other Entities (Act 100 of 2000, hereinafter referred to as the “Act on Promoting Green Purchasing”) was fully put in force in April 2001 as one of the laws aimed at achieving individual policy goals based on the Basic Act on Establishing a Sound Material-Cycle Society. It was enacted based on the idea that demand-side efforts are important in addition to supply-side efforts for recycled products, etc., in order to establish a Material-Cycle Society. The purpose of this Act is to establish a society that can develop sustainably with reduced environmental loads including chemical risk, by providing for necessary matters and for promoting a shift of demand to eco-friendly goods, etc., including the promotion of the procurement of eco-friendly goods, etc. by the State, local governments, etc., and the provision of information concerning eco-friendly goods, etc.

The State must, for the purpose of comprehensively and systematically promoting the procurement of eco-friendly goods, etc. of the State, etc., provide for a Basic Policy for promoting the procurement of eco-friendly goods, etc. (hereinafter referred to as the “Basic Policy”). In line with the Basic Policy, ministries, agencies, etc. prepare their policies for promoting the procurement of eco-friendly goods and services (hereinafter referred to as “Procurement Policies”) every fiscal year and select eco-friendly goods and services that they will procure while taking the appropriate use of the budget into account.

- Since the Law Concerning the Promotion of Procurement of Eco-Friendly Goods and Services by the State and Other Entities came into force in 2001, government ministries agencies, etc. have formulated their Procurement Policies every fiscal year and have procured designated procured goods, etc., based on the policies. The achievement rate for the procurement of designated procured goods, etc., is nearly 100%.\*

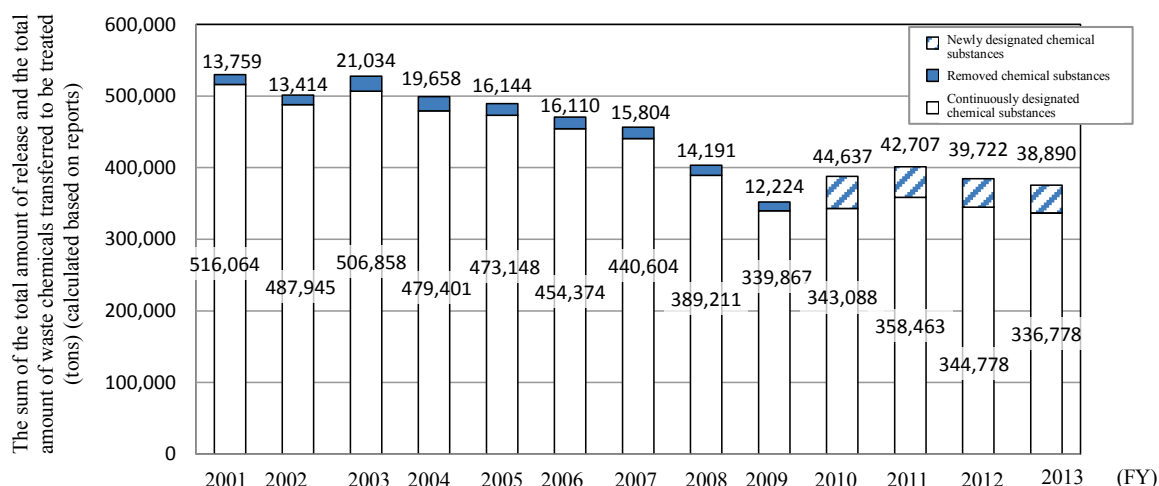
\* The calculation was done based on the results of the procurement of 199 designated procurement items (except for items for public works) by the State, etc. in FY2013. The number of designated procurement items for which the procurement rate was 95% or more: 189 items (95.0%)

It is necessary to continue to promote the procurement of designated procured goods, etc. based on the Procurement Policies formulated by ministries and agencies, etc. every fiscal year.

b) The Implementation of Measures at the Release of Chemicals into the Environment Stage, the Disposal Stage and the Recycling Stage<sup>7</sup>

The Status Quo

Regarding the release of chemicals into the environment, the PRTR system facilitated business operators' voluntary management improvements and the total amount of chemicals (subject to reporting) released is decreasing in general. The chemicals and the types of businesses, etc. subject to the PRTR system were revised in 2008, and the ascertainment of the amount of release, etc. for the revised chemicals and the types of businesses, etc. was launched in FY2010. Figure 10 shows changes in the amounts of release and the amounts of chemicals transferred to be treated which were reported based on the PRTR system, as well as the number of business establishments that submitted reports. When comparing the recent numbers with the numbers for FY2003 which is when the current reporting requirement (the reporting of the amount handled) was introduced, the sum of the total amount of release and the total amount of chemicals transferred to be treated was reduced by 152,000 tons. When looking at the substances which continued to be designated as Class 1 Designated Chemical Substances after FY2008 revision of substances subject to reporting ("continuously designated chemical substances"), the sum of the total amount of release and the total amount of chemicals transferred to be treated was reduced by 175,000 tons. The numbers are decreasing in general over time.



Source: The Overview of the PRTR Data for FY2013

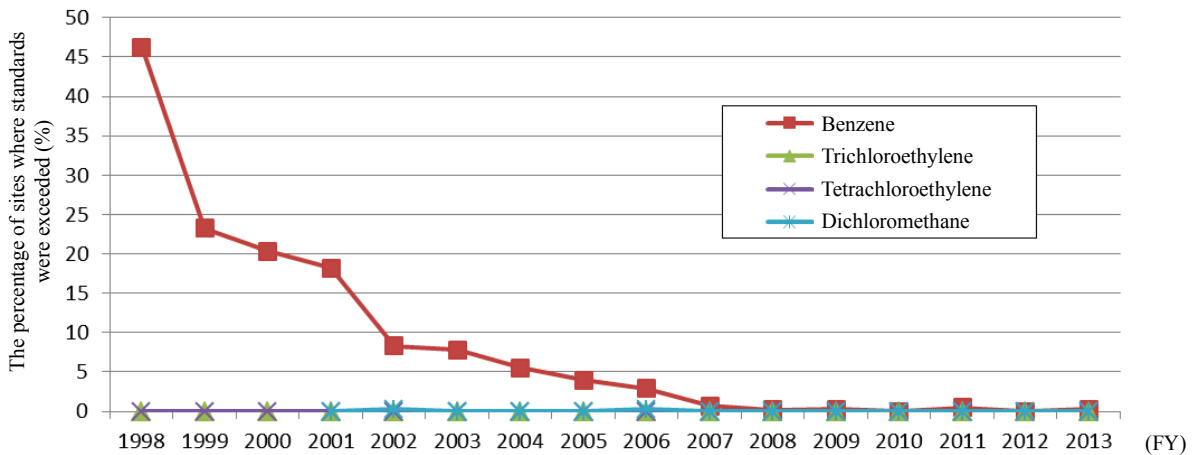
Figure 10 Changes in the Amounts of Release and the Amounts of Chemicals Transferred to Be Treated Which Were Reported Based on the PRTR System, and Changes in the Number of Reporting Business Establishments

With regard to the concentrations of pollutants in the ambient air, the government sets environmental quality standards on air pollution by benzene, etc. as well as environmental quality standards on water quality, etc. where the government is carrying out the monitoring. Figure 11 shows the percentages of monitoring spots where measured values exceeded the environmental quality standards on air pollution by benzene, etc. As the benefit of the revision of Air Pollution Control Act in 1996 to institutionalize control measures of hazardous air

<sup>7</sup>This section subjects to hazardous substances within the life cycle of electrical and electronic products which is one of the EPI topics of SAICM/ICCM.



pollutants including emissions control standards on benzene, etc., the percentage of non-attainment has decreased every year and it has been almost 0% since FY2008.

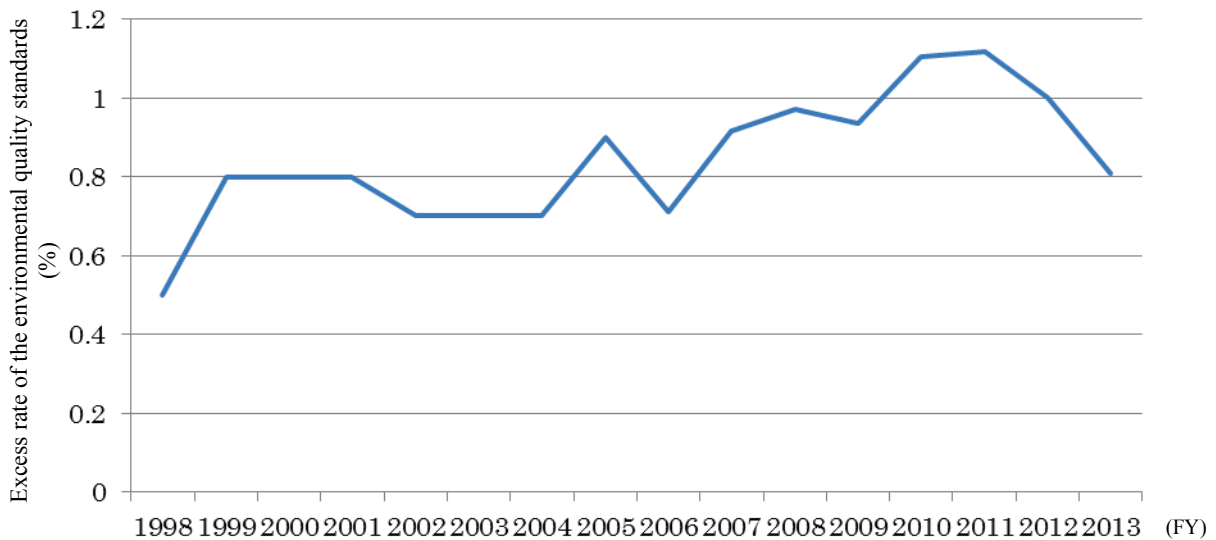


Note: They are the percentages for sites where observed values exceeded the environmental quality standards.

Source: MOE

Figure 11 Changes in the Percentages of Sites Where Observed Values Exceeded the Environmental Quality Standards regarding Benzene Air Pollution, etc.

Figure 12 shows change of the environmental standard excess situation for human health standards in the public waters regarding water pollution. The percentage has not changed significantly.



Note 1: It is the percentage of observation points where observed values exceeded the standards for human health standards.

Note 2: In FY1999, measurements were launched for nitrate nitrogen, nitrite nitrogen and fluorine and boron.

Note 3: 1,4-dioxane (One item) was added in FY2009 and the measurement for the item was launched in FY2010.

Source: MOE

Figure 12 Change of the Environmental Quality Standard Excess Situation for Human Health Standards in the Public Waters

## Efforts Being Made

### <Measures concerning the Release, Disposal and Recycling of Chemicals> [Ascertaining and Publishing the Amount of Release and the Amount of Chemicals Transferred to Be Treated Based on the PRTR Law] (METI and MOE)

(The content is omitted as it is the same as the content on page 16.)

### [Regulations, etc. Pursuant to Air Pollution Control Act] (MOE)

#### ◇ Regulations for Air Pollution Control and Other Measures

In order to promote measures for meeting the environmental quality standards on air pollutants, the government conducts surveys of the amounts of air pollutants emitted from stationary emission sources as well as surveys on the state of enforcement of Air Pollution Control Act by prefectural governments, etc. More specifically, the government is making the following efforts.

- As a fact-finding survey on the emissions of air pollutants, the government distributes questionnaires to factories and other workplaces according to the information provided by the local governments (except for local governments that conduct surveys independently). The government then publishes the results of the questionnaire surveys on the website of the MOE along with the results of surveys independently conducted by local governments (every three years).
- The government also distributes questionnaires to the local governments concerning the enforcement of Air Pollution Control Act, including notification of facilities subject to control pursuant to Air Pollution Control Act and the enforcement of administrative affairs pertaining to regulation. The government then publishes the compiled results on the website of the MOE (every fiscal year).

In future, the government intends to obtain updated information on air pollutant emissions and the situation of notification on facilities subject to control pursuant to Air Pollution Control Act, etc.

With regard to asbestos emission control, the government aims to strengthen the control measures to prevent emissions of asbestos by demolition of buildings, etc. while obtaining the updated information of air pollution by asbestos.

#### ◇ Constant Monitoring of the Atmospheric Environment

(The content is omitted as it is the same as the content on page 17.)

### [Regulations, etc. Based on the Water Pollution Control Act] (MOE)

#### ◇ The Promotion of Regulations on the Discharge of Effluent Based on the Water Pollution Control Act

Regulations based on the Water Pollution Control Act are implemented with the aim of controlling public waters pollution and groundwater pollution by regulating the discharge of water from factories and other establishments into public waters as well as regulating the seepage of polluted water into the ground, thereby protecting human health and the preserving living environment. For this purpose, the government implements regulations based on the Water Pollution Control Act.

The government set effluent standards or underground seepage water standards for 28 hazardous substances, etc. regarding effluent discharged into public waters or polluted water seeping into the groundwater level, from factories or other workplaces which have

“specified facilities” (facilities discharging polluted water or waste fluid), etc. The discharge or seepage of polluted water which does not meet the standards is prohibited.

In particular, for facilities where hazardous substances are used or stored, compliance with structural standards and regular inspections are required, in order to prevent groundwater pollution.

The government will continue to ensure that local governments give guidance to business operators who fail to comply with effluent standards, etc.

◇ Regular Observation of the Water Environment

(The content is omitted as it is the same as the content on page 18.)

◇ Regular Observation of Groundwater Quality

(The content is omitted as it is the same as the content on page 19.)

**[Measures Based on the Act on Special Measures against Dioxins] (MOE)**

In order to promote measures to reduce dioxins, the government conducts surveys of pollution based on Article 26 of the Act on Special Measures against Dioxins as well as ascertaining the emission of dioxins from emissions sources based on Article 28, etc. of the law and creating the emission inventory. Through these activities, The government checks and comprehensively examines the achievement levels for the targets set in the national reduction plan which was created based on Article 33 of the law. Regarding bromine dioxins, Article 2 of the Supplementary Provisions of the law stipulates that “the government shall promote surveys and research with regard to the process of generation, etc., and based on the results shall take the necessary measures”. Based on the stipulation, the government conducts fact-finding surveys, etc. for the emission of bromine dioxins into the environment, etc.

So far, the government has created national reduction plans and promoted the relevant measures (the first plan was created in September 2000, the second plan was created in June 2005 and the third plan was created in August 2012).

Based on reduction plan revised in August 2012, the reduction target of emission dioxins was 176g-TEQ/year. In 2013, the total emission dioxins were 127-TEQ/year that scored lower than the target level that accomplished the target goal.

Environmental pollution has been greatly reduced in recent years as can be seen in the fact that the achievement rate for the atmospheric environmental quality standards has been 100% for the past five years. The government is also conducting fact-finding surveys on emissions at facilities which are likely to emit bromine dioxins, through which the government obtains information on their concentrations, environmental dynamics, etc. The survey results, etc. have been published on the website of the MOE since FY2000.

The government will continue to promote reduction measures based on the national reduction plan, as well as accumulating knowledge on bromine dioxins, among other activities.

**[Appropriate Treatment of Waste Which Contains Hazardous Substances Based on the Waste Management and Public Cleansing Law] (MOE)**

In order to reduce the risks accompanying the disposal of chemicals, etc. whose hazard, etc. in the environment is a concern, and to prevent social problems such as disturbances to the protection of the living environment, the government promotes the appropriate treatment

of waste which may have hazardous properties, etc. More specifically, the government is making the following efforts.

- ◇ In FY2012, the government made the necessary revisions to the Manual for the Management of Infectious Waste. The government also considered the environmentally appropriate management of mercury-containing waste, including technologies to stabilize or solidify mercury-containing waste.
- ◇ In FY2013, the government conducted tests on the stabilization and solidification of mercury-containing waste, etc. and considered appropriate treatment measures for mercury-containing waste, etc.
- ◇ In FY2014, the government conducted mercury-containing waste control measures, etc. based on the Minamata Convention on Mercury.

This project aims to study and consider measures to appropriately treat waste which contains substances whose hazard is a concern, through understanding domestic and international trends as well as accumulating knowledge, among other efforts. The government needs to continue to consider measures concerning substances which require appropriate treatment measures based on accumulated knowledge, while compiling information systematically based on their characteristics.

#### **[The Appropriate Handling of Products Which Contain Substances Subject to the Stockholm Convention] (MHLW, METI and MOE)**

The chemicals which were designated to be abolished in the Stockholm Convention are designated as Class I Specified Chemical Substances based on the CSCL and their manufacture, import and use are banned in principle. The importation of ordinance-specified products that use Class I Specified Chemical Substances is also banned.

In order to minimize the amounts of Class I Specified Chemical Substances released into the environment from the products which use Class I Specified Chemical Substances, the CSCL stipulates that the government shall determine information that should be indicated on labels, with regard to technical standards for the handling of the products, measures to prevent environmental pollution, etc.

Regarding endosulfan and hexabromocyclododecane for which the decision to eliminate them was taken on the Meetings of the Conference of the Parties (COP) to the Stockholm Convention held in April 2011 and May 2013, the government revised the Order for the Enforcement of the CSCL in March 2014 and designated the two chemicals as Class I Specified Chemical Substances in May 1, 2014. The manufacture, import, etc. of the two chemicals were banned in principle. The government also added four products which use hexabromocyclododecane to the list of import-prohibited products on October 1, 2014.

Among the additional chemical substances added to the annexes of the Stockholm Convention, which was adopted at its seventh meeting of the COP in May 2015, polychlorinated naphthalenes containing two chlorine atoms and pentachlorophenol and its salts and esters are not designated as Class I Specified Chemical Substances. The government plans to designate them as Class I Specified Chemical Substances and designate products which use those chemicals for import prohibition as needed.

With regard to perfluoro (octane-1-sulfonic acid) (PFOS) and its salts for which the decision to restrict them based on the Stockholm Convention had already been taken and designated as Class I Specified Chemical Substances on April 1, 2010, the government established the following regulations.

- “Ministerial Ordinance to Provide for Technical Standards concerning PFOS or Its Salts and Products set forth in Items (i) to (iii) of the Paragraph on PFOS or Its Salts in the Table in Article 9 of the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc.” ( Ordinance of the MHLW, the METI and the MOE No. 4 of May 26, 2010) (Last Revised: March 31, 2011)
- “Ministerial Ordinance to Provide for Technical Standards concerning Fire Extinguishers, Fire-Extinguishing Chemicals for Fire Extinguishers, and Fire Fighting Foam Pursuant to Item (iv) of the Paragraph on PFOS or Its Salts in the Table in Article 9 of the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. as Applied by Replacing Terms Pursuant to the Provisions of Paragraph (3) of the Supplementary Provisions of Said Order for Enforcement” (Ordinance of the Ministry of Internal Affairs and Communications (MIC), MHLW, METI, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), MOE and the Ministry of Defense No. 1 of September 3, 2010) (Last Revised: March 31, 2011)
- “Matters to be Indicated with Respect to PFOS or Its Salts, or Measures, etc., for Preventing Environmental Pollution from Class I Specified Chemical Substances, to be Indicated on Containers, Packaging, or Invoices for Said Class I Specified Chemical Substances or Products that Use PFOS or Its Salts, as Stipulated in Paragraphs (1) to (4) for PFOS or Its Salts in the Table in Article 9 as Applied by Replacing Terms Pursuant to the Provisions of Paragraph (3) of the Supplementary Provisions to the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc.” (Public Notice of MHLW, METI and MOE No. 6 of March 31, 2011)

The government will continue to take appropriate measures on substances to be abolished based on the Stockholm Convention, through the implementation of the CSCL.

**[Consideration of Treatment Measures, etc. with the Aim of the Treatment of Waste Products Which Contain Substances Subject to the Stockholm Convention] (MOE)**

The government reduces the risks accompanying the disposal of waste which contains chemicals subject to regulations based on the Stockholm Convention whose hazard, etc. in the environment is a concern, in order to prevent social problems such as disturbances to the protection of the living environment, thereby establishing a safe and secure society.

In order to promote the appropriate treatment of waste which contains POPs, the government is making the following efforts.

- In FY2012, the government conducted fact-finding surveys concerning the handling of waste which contains hexabromocyclododecane (HBCD). The government also conducted verification experiments for the decomposition treatment of products containing HBCD using high-temperature incineration facilities (about 1,200°C).
- In FY2013, for waste containing HBCD, the government conducted flow surveys and verification experiments for the decomposition treatment of the waste (at two sites), as well as considering the appropriate treatment measures for the waste.
- In FY2014, the government conducted fact-finding surveys concerning the release of HBCD from final disposal sites and verification experiments for the decomposition treatment of HBCD. The government continued to consider appropriate treatment measures for waste containing HBCD, as well as conducting domestic flow surveys for candidate substances for POPs (PCN<sup>8</sup>, PCP<sup>9</sup>, DBDE<sup>10</sup> and HCBD).

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<sup>8</sup> Polychlorinated naphthalene

<sup>9</sup> Pentachlorophenol

<sup>10</sup> Decabromodiphenyl ether

**[The Control of Export and Import of Specified Hazardous Waste Based on the Basel Convention] (METI and MOE)**

In order to prevent the illegal export and import of hazardous waste, etc. and to promote the environmentally appropriate treatment of the waste, the government appropriately implements the Law for the Control of Export, Import and Others of Specified Hazardous Wastes and Other Wastes (Act No. 108 of December 16, 1992, hereinafter referred to as the Basel Law), which was enacted based on the Basel Convention. The government also strives to let all exporters, importers, etc. know the legal restrictions. Table 2 shows activities based on the Basel Law.

The government will continue to work on the appropriate implementation of the Basel Law based on the Basel Convention, and the dissemination of information on the Basel Law to all relevant parties.

Table 2 Activities Based on the Basel Law

Activities	2012	2013	2014
The number of imports approved based on the Basel Law	91	103	125
The number of exports approved based on the Basel Law	55	72	79
The number of prior consultations (the total for the MOE and the METI)	51,245	51,382	52,414
The number of sites where briefings on the Basel Law, etc. were held	9 sites nationwide	11 sites nationwide	9 sites nationwide

**[The Thorough Implementation of Extended Producer Responsibility and Further Promotion of Environmentally-friendly Designing at the Product Manufacturing Stage Based on the Home Appliance Recycling Law, the End-of-Life Vehicle Recycling Law, the Government-Certified System for Contractors of Wide Area Treatment Stipulated in the Waste Management and Public Cleansing Law, etc.] (METI and MOE)**

Based on the Law for the Recycling of Specified Kinds of Home Appliances (Act No. 97 of June 5, 1998, hereinafter referred to as the Home Appliance Recycling Law) and the Law for the Recycling of End-of-Life Vehicles (Act No. 87 of July 12, 2002, hereinafter referred to as the End-of-Life Vehicle Recycling Law), the government requires the recycling, etc. of items subject to the laws by manufacturers, etc. The government also promotes designing, etc. which makes recycling, etc. easier, through the Government-Certified System for Contractors of Wide Area Treatment stipulated in the Waste Management and Public Cleansing Law.

◇ Efforts Related to the Home Appliance Recycling Law

Based on extended producer responsibility, manufacturers, etc. are required to collect specified home appliances and recycle them into salable products. This contributes to the promotion of environmentally-friendly designing at the product manufacturing stage, including designs which take chemical management into consideration. For example, the labeling of information about flame retardants contained in products, etc. on plastic parts is being promoted with the aim of increasing the efficiency of sorting processes. In order to understand the effects of chemicals contained in specified home appliances after the appliances are spent, the MOE conducted surveys of the content, etc. of chemicals in the appliances in FY2011. The government will continue to conduct the surveys periodically.

◇ Activities Related to the End-of-Life Vehicle Recycling Law

The law requires vehicle manufacturers, etc. to collect and recycle Parts Specified for Recycling, etc. (which refer to Automobile Shredder Residue, Parts Designated for Recovery and Fluorocarbons) based on extended producer responsibility. Through the implementation of the requirement, the law promotes environmentally friendly designing at the product manufacturing stage, including designs which take chemical management into consideration.

Regarding the reduction of hazardous substances, voluntary efforts by vehicle manufacturers, etc. have progressed and produced some positive results, for example they reduced the amount of lead used per vehicle to about 100g on average. Also, some manufacturers take into consideration the ease of removing parts during dismantling, at the stage of designing vehicle structures.

Every fiscal year, the METI and the MOE ask vehicle manufacturers, etc. to report progress in their voluntary efforts to reduce the use of chemicals, at the joint meeting between the Industrial Structure Council and the Central Environment Council. In order to understand the effects of the handling of vehicles after they are spent, the MOE conducted surveys of the content, etc. of chemicals in Automobile Shredder Residue in FY2010, FY2012, and FY2014. It will continue to conduct the surveys periodically.

In FY2012, the MOE organized and published information about environmental efforts by vehicle manufacturers, etc. including environmentally friendly designing.

◇ The Waste Management and Public Cleansing Law

The Government-Certified System for Contractors of Wide Area Treatment which was created based on the Waste Management and Public Cleansing Law makes it possible for manufacturers, etc. to become involved in the recycling or treatment process for their products based on extended producer responsibility. This leads to the promotion of efficient recycling, etc. as well as the promotion of product designs which are easy to recycle or treat. Therefore, the system contributes to the thorough implementation of extended producer responsibility and the further promotion of environmentally friendly designing at the product manufacturing stage. The Government-Certified System for Contractors of Wide Area Treatment was created in 2003 based on special provisions in the Waste Management and Public Cleansing Law. Through the revision of the law in 2010, the government partially strengthened relevant regulations, for example granting the MOE authority to conduct on-site inspections and including stipulations on the procedures to change approved information in the law. Through the rigorous examination of applications, the government approves business operators who conduct regional treatment. The following shows the numbers of certification for contractors of wide area treatment given (as of the end of March 2014).

- Certification for contractors of wide area treatment of general waste: 95
- Certification for contractors of wide area treatment of industrial waste: 247

The government will continue to take the above-mentioned measures and to appropriately implement the Home Appliance Recycling Law and the End-of-Life Vehicle Recycling Law as well as the Government-Certified System for Contractors of Wide Area Treatment based on the Waste Management and Public Cleansing Law.

c) Measures to Control Negative Legacies including Hazardous Chemicals Manufactured in the Past, Polluted Soil and Sediment

The Status Quo

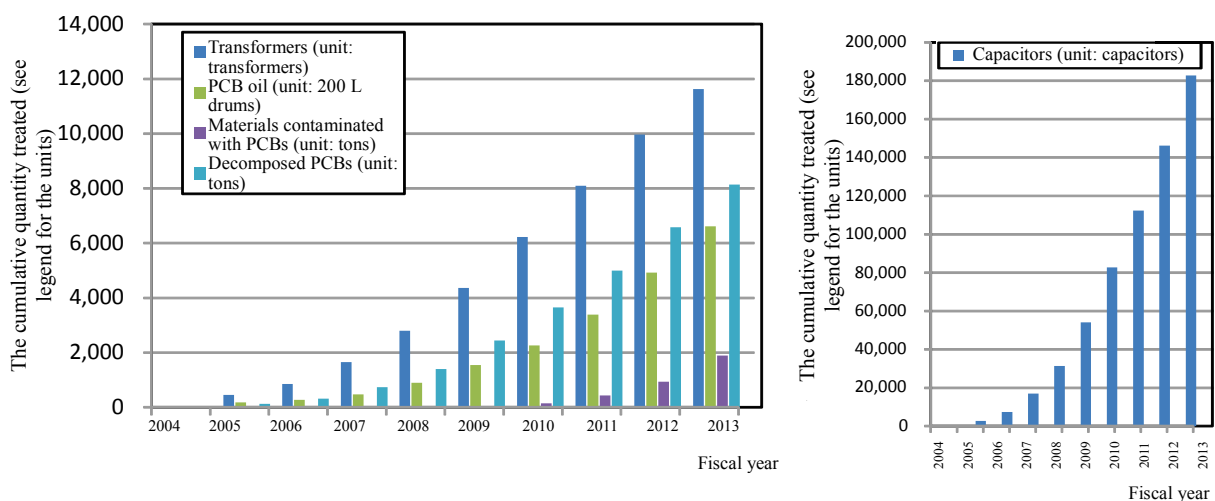
Regarding the control of negative legacies including polluted soil and hazardous chemicals manufactured in the past, their appropriate treatments, etc. are being carried out based on the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste (Act No. 65 of June 22, 2001), the Soil Contamination Countermeasures Law, etc.

With regard to polychlorinated biphenyl (PCB) waste which has been stored for a long period of time after manufacture, the import and use of PCB were virtually banned, efforts are being made to establish systems for the appropriate treatment of the waste. For example, the Japan Environmental Storage & Safety Corporation (JESCO) developed central treatment facilities and also it established the PCB Waste Disposal Fund, based on the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste which was enacted in June 2001. Figure 13 shows the progress in the treatment of PCB waste by JESCO.

JESCO launched the treatment of PCB waste using a chemical treatment method on an unprecedentedly large scale. They faced problems after the launch of the treatment and took measures to solve the problems including safety measures for workers. This made it difficult for them to complete the treatment project by the originally planned completion date (March 2016).

In 2002, after the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste came into force, small amounts of PCB were detected from some transformers and capacitors which were not supposed to contain PCB. The treatment of the equipment was launched in 2010, based on the Waste Management and Public Cleansing Law.

For the reasons explained above, in December 2012, the deadline for the treatment of PCB waste based on the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste was extended to March 31, 2027. In order to complete the treatment by the new deadline, the government revised the Basic Plan for PCB Waste Treatment and announced it in a public notice on June 6, 2014.

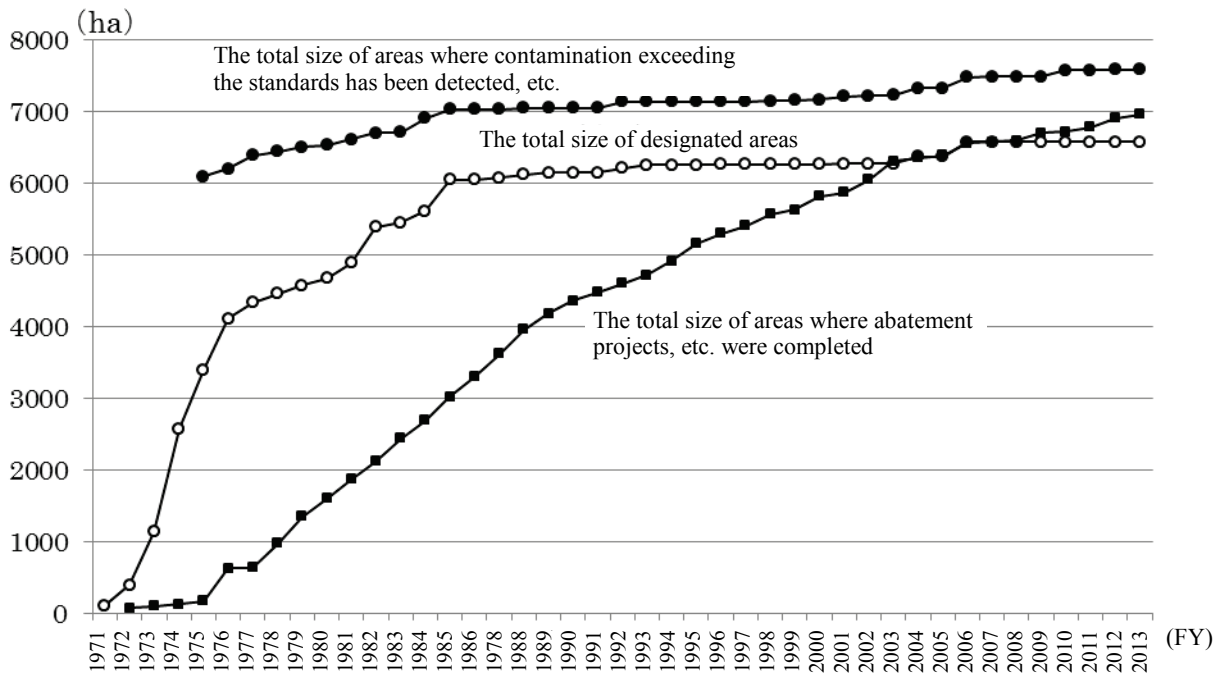


Source: JESCO(<http://www.jesconet.co.jp/business/result/pdf/H16-25result.pdf>)

Figure 13 The Cumulative Quantities of PCB Waste Treated in Each Fiscal Year



Regarding contaminated soil on agricultural land, countermeasures are being taken based on the plan to abate soil contamination of agricultural land. Figure 14 shows the progress in countermeasures to abate soil contamination on the agricultural land in designated areas. As of the end of FY2013, designated areas had been completed their countermeasures on 6,962 ha of land, which makes the plan for countermeasures progress rate 91.7%.



Source: MOE. "The Results of Detailed Surveys concerning Soil Contamination on Agricultural Land and an Outline of Countermeasures." (<http://www.env.go.jp/water/dojo/nouyo/index.html>)

Figure 14 Progress in Countermeasures to Abate Soil Contamination on Agricultural Land

## Efforts Being Made

### <Efforts to Control Negative Legacies>

#### [Efforts Based on the Soil Contamination Countermeasures Act] (The MOE)

The government conducts surveys to check the implementation of the Soil Contamination Countermeasures Act. Through the surveys, in addition to checking the implementation of the law, the government also collects and organizes information on cases of soil contamination by designated hazardous substances that have been collected by prefectural governments and the municipal governments which are designated by ordinances based on Article 64 of the law. Thereby, the government collects and publishes information on countermeasures currently being taken as well as information on soil contamination surveys. The government also compiles the information into documents that can be used for promoting future soil contamination countermeasures. Table 3 shows an outline of the survey results for the implementation of the Soil Contamination Countermeasures Act.

Table 3 An Outline of the Survey Results for the Implementation of the Soil Contamination Countermeasures Act

Measures	FY2013 survey (FY2012 results)	FY2014 survey (FY2013 results)
The number of specified facilities which use hazardous substances whose use was stopped	1,233 cases	1,080 cases
The number of reports on soil contamination survey results	243 reports	240 reports
The number of cases where survey obligations were temporarily exempted	970 cases	628 cases
The number of reports submitted for making changes to the form or nature of land	9,949 reports	10,848 reports
The number of orders issued on the survey of land which has a risk of being contaminated by designated hazardous substances	126 orders	142 orders
The number of reports on soil contamination survey results	143 reports	150 reports

Note: The surveys were conducted for departments in charge of soil contamination controls at all 47 prefectural governments and 110 (109) ordinance designated municipalities.

Source: MOE. "Surveys of the enforcement status of the Soil Contamination Countermeasures Act"

Based on the survey results for the implementation of the Soil Contamination Countermeasures Law, the government identifies problems concerning soil contamination survey methods and the methods to take countermeasures such as the removal of contamination, and considers improvement countermeasures, through examining the current methods used for soil contamination surveys and countermeasures, etc. The government also conducts surveys to examine the processing of contaminated soil, etc. in order to achieve the appropriate transportation and management of contaminated soil in an effort to promote the appropriate processing of contaminated soil.

- ◇ Through examining the current methods used for soil contamination surveys and countermeasures, etc., the government created the Guidelines on the Investigation and Countermeasure Based on the Soil Contamination Countermeasures Act (the Revised Second Edition) in 2012.
- ◇ The government created guidelines for the transportation of contaminated soil as well as for processing businesses and promotes the appropriate treatment of contaminated soil.
- ◇ The government revised the ordinances for the enforcement of the law in July 2011. Through the revisions, the government created the Special Areas with Nature Derived Contamination system, etc. through which regulations on the methods to change the form or nature of land are relaxed for some of the Areas for which Changes to Form or Nature Require Notification. The government also added special provisions on surveys of land which is deemed to have a risk of nature derived contamination.

One of the purposes of the Soil Contamination Countermeasures Law is to appropriately manage contaminated soil. Therefore, in the revision in 2009, the government clarified the measures to be taken for areas subject to regulations, through the categorization of the areas, etc. More specifically, it was decided that prefectural governors shall designate land whose soil is contaminated with designated hazardous substances and does not meet the standards as an Area which Requires Action and or an Area for which Changes to Form or Nature Require Notification, depending on whether the contamination has a risk of causing health damage. For land which is designated as an Area which Requires Action, the relevant landowner, etc. shall be instructed to take measures to prevent health damage. For land which is designated as

an Area for which Changes to Form or Nature Require Notification, measures such as the removal of contamination, etc. shall not be required. Instructions for Areas which Require Action are decided based on the levels, etc. of soil and groundwater contamination. Examples of instructions include the measurement of monitoring a groundwater quality, the containment of contamination in its current place and the removal of soil contamination (removal by excavation and purification of the current place). Therefore, the countermeasures required are not limited to the removal of contamination by excavation.

Past surveys on the implementation of the Soil Contamination Countermeasures Law found that measures equivalent to or stricter than the instructions given by prefectural governors have been taken (mainly the removal of contamination by excavation) in many cases. In addition, the survey results show that the removal of contamination and other measures have also been taken in many Areas for which Changes to Form or Nature Require Notification, where the removal of contamination and other measures are not required.

The government will continue to obtain updated information on implementation of the Soil Contamination Countermeasures Law as well as collecting and organizing information on cases of soil contamination that have been collected by prefectural governments and municipal governments which are designated by ordinances based on Article 64 of the law. Thereby, the government will continue to collect information on the measures currently being taken as well as information on soil contamination surveys.

Based on the survey results, etc., the government will consider methods for soil contamination surveys and countermeasures as well as the methods for the appropriate transportation and treatment of contaminated soil where necessary, including the consideration of issues concerning soil with nature derived contamination.

**[The Promotion of Efforts Based on the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste] (MOE)**

In order to complete the treatment of PCB waste as quickly as possible, the government promotes efforts to find any pieces of equipment containing PCBs which were not reported to prefectural or city municipal governments, among other efforts. In addition, in order to ensure that the treatment of PCB-containing equipment, which is still in use, is completed by the deadline, efforts are being made through cooperation between the relevant organizations including the MOE, JESCO, prefectural governments, city municipal governments, the METI and trade associations.

With regard to waste containing small amounts of PCBs, technical discussions for ensuring its treatment by the new deadline (March 2027) are taking place.

Table 4 shows the progress in the treatment of PCB waste.

Table 4 The Cumulative Quantity of PCB Waste (High Voltage Transformers, etc.) Treated (Units)

Activities	FY2011	FY2012	FY2013	FY2014
The cumulative quantity of PCB waste (high voltage transformers, etc.) treated (units)	120,385 units	156,202 units	194,304 units	228,124 units
The progress rate	36.5%	47.4%	56.0%	66.0%

Note 1: From the FY2010 to the FY2012, the progress rate was calculated based on the target value for the FY2016 (329,500 units).

Note 2: For the FY2013, the progress rate was calculated based on the target value for the FY2025 (347,000 units).

## **[Efforts Based on the Agricultural Land Soil Pollution Prevention Law] (MAFF and MOE)**

When soil contamination is found in an area through continuous monitoring, prefectural governor can designate the area as an Area for Countermeasures against Soil Contamination on Agricultural Land (hereinafter referred to as an Area for Countermeasures) based on the Act to Prevent Soil Contamination on Agricultural Land (Act 139 of 1970). For an area which has been designated as an Area for Countermeasures, a countermeasures plan is formulated and soil contamination countermeasures are taken.

### ◇ FY2012

- The cumulative size of areas where designated hazardous substances exceeding the standards concerning designation requirements have been detected, and areas where there is a significant risk of such contamination (hereinafter referred to as Areas Where Contamination Exceeding the Standards Has Been Detected, etc.): 7,592 ha as of the end of FY2012
- Of the 7,592 ha mentioned above, the cumulative size of areas designated as Areas for Countermeasures: 6,577 ha
- The size of areas where countermeasures plans, etc. have been completed: 6,906 ha (91.0% of the size of Areas Where Contamination Exceeding the Standards Has Been Detected, etc.)

### ◇ FY2013

- The cumulative size of Areas Where Contamination Exceeding the Standards Has Been Detected, etc.: 7,592 ha (as of the end of FY2013)
- Of the 7,592 ha mentioned above, the cumulative size of areas designated as Areas for Countermeasures: 6,577 ha
- The size of areas where countermeasures plans, etc. have been completed: 6,962 ha (91.7% of the Areas Where Contamination Exceeding the Standards Has Been Detected, etc.)

The government will continue to increase its knowledge on designated hazardous substances and other substances, as well as promoting soil contamination countermeasures including soil dressing through rural area disaster prevention and mitigation projects, etc.

## **[Progress Management for the Treatment of Agricultural Chemicals Buried in the Past] (MAFF)**

In order to manage and dispose of agricultural chemicals buried in the past, in response to requests from prefectural governments, the government provides support for the formulation of disposal plans, environmental surveys before and after the excavation and recovery and emergency measures to prevent adverse effects in the surrounding environments.

Since FY2006, the government has been supporting the efforts of prefectural governments through the subsidy.

- at 63 sites in FY2012 and at 61 sites in FY2013; and
- at 71 sites in FY2014 (on going)

The government intends to continue to support prefectural governments' efforts.

d) Measures Taken in Cases Where Chemicals Have Been Released into the Environment via Accidents, etc.

### The Status Quo

When chemicals have been released into the environment via accidents, etc., those who have established the relevant facilities are required to take emergency response measures and to report, etc. the accidents to prefectural governments, based on the Air Pollution Control Act and the Water Pollution Control Act. In 2009, the MOE formulated the “Guidelines for the Formulation of Manuals for Response Measures to Chemicals-related Accidents to Be Taken by Environment Departments of Local Governments,” in an effort to support local governments in formulating their manuals for accident responses, etc.

### Efforts Being Made

#### <Measures Taken When Chemicals Have Been Released into the Environment via Accidents, etc.>

#### [Measures Taken When Chemicals Have Been Released into the Atmosphere via Accidents, etc.] (MOE)

Article 17 of the Air Pollution Control Act stipulates measures to be taken by business operators, etc. who have established soot and smoke emitting facilities and prefectural governors when accidents occur. When chemicals have been released into the atmosphere via accidents, etc., the government will cooperate with local governments to take appropriate action so that the released chemicals will not cause damage to human health or the living environment.

#### [Reporting the Measures Taken after Accidents Based on the Water Pollution Control Act] (MOE)

Through regulating the release of effluent from factories and other establishments into public waters as well as the seepage of polluted water into the ground, the government aims to prevent the pollution of public waters and groundwater, and to protect the human health and preserve the living environment.

Those who have established specified workplaces, etc. must take emergency response measures immediately, when there is a risk of damage to human health or the living environment being caused by water containing hazardous substances, etc. that has been released into public waters or is seeping into the ground due to damage to specified facilities, etc. or any other accident. They must then report the accident and submit an outline of the measures that they have taken to the relevant prefectural governor.

When those who have established specified workplaces, etc. are found to have failed to take emergency response measures, the relevant prefectural governor can order them to take emergency response measures.

Moreover, through the revision of the Water Pollution Control Act, the reporting of the measures taken after accidents was also made compulsory when there is a risk of damage to human health or the living environment being caused by water containing hazardous substances or designated substances that has been released into public waters or is seeping into the ground due to damage to designated facilities or any other accident.

Currently, there are 56 designated substances.

◇ The following shows the results of FY2013 survey for the implementation of the Water Pollution Control Act.

- Reports submitted after accidents: 565 reports
- Orders on emergency response measures issued: 0 case

As the next step, it is necessary for prefectural governments to give appropriate guidance to business operators who have caused accidents, in order to protect the water environment.

**<Prevention of Industrial Accidents Such as Explosions and Poisoning>  
[Efforts Based on the Industrial Safety and Health Act] (MHLW)**

(The content is omitted as it is the same as the content on page 33.)

**<Other Efforts>**

**[The Project to Promote Crisis Management and Risk Management concerning the Water Environment] (MOE)**

In May 2012, there was an incident where the intake of water from the Tone River system had to be suspended. Through this experience, it was discovered that the chemicals discharged into public waters could turn into different chemicals in the water purification process, etc. and pose major risk to the management of the water environment.

In order to ensure safety and security concerning the water environment, it is necessary to take appropriate risk management measures in non-disaster times for existing hazardous substances as well as substances that could turn into hazardous chemicals in the water purification process, etc., so that water quality-related accidents can be prevented. It is also necessary to be prepared so that damage can be prevented from spreading when a water-related accident has occurred, by quickly ascertaining the causes.

In FY2013, sample analysis was conducted for river water nationwide in order to check for chemicals in the ambient environment. Samples were taken from 47 points in order to check for hexamethylenetetramine, formaldehyde and perchloric acid, and from 94 points in order to check for N,N-dimethylaniline. In addition, a fact-finding survey concerning the discharge of chemicals was conducted at five establishments which discharge a significant amount of hexamethylenetetramine into public waters or handle a large amount of hexamethylenetetramine, based on PRTR reports. Sample analysis was conducted on one sample of pre-treated effluent before discharge and on one sample of post-treated effluent before discharge, per establishments.

In FY2014, the government conducted surveys for other substances that pose a risk when released into the environment, based on the results of the survey looking for chemicals in the environment and the fact-finding survey concerning the discharge of chemicals conducted in FY2013. The government considered methods for quickly ascertaining the causes when a water quality-related accident occurs and for other risk management measures.

**[The Project for Domestic Measures concerning Oil Pollution, etc.] (MOE)**

Based on the “National Emergency Plan for Preparedness and Response to Oil Pollution Incidents, etc. (Decided on by the Cabinet in December 2006),” the map of sea areas with vulnerable coastlines (HNS-ESI Map) was created with the aim of providing information to relevant organizations, etc. when oil, noxious substance and hazardous substance spills occur. In order to provide accurate information, it is necessary to constantly update the basic data including geographic data and the distributions of animals and plants. It is also necessary to

update the hazardous and noxious substance database for the HNS-ESI Map which is used when hazardous and noxious substance spills occur, based on additions and changes to the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (IBC Code),<sup>11</sup> etc.

Therefore, the government updates the HNS-ESI Map based on the latest data and impact assessment methods, and releases the information to the public by posting it on the website, etc.

The government will continue to update the HNS-ESI Map based on the latest data and impact assessment methods, and release the information to the public by posting it on the website, etc.

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<sup>11</sup> International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code): The IBC Code provides a list of products (hazardous liquid chemicals) which were registered at the International Maritime Organization (IMO) and became possible to be internationally carried by sea in bulk. For each registered product, it provides transportation requirements for vessels that carry the product, requirements on the equipment and structure of the vessels as well as requirements concerning pollution categories. It also provides evaluation standards regarding pollution categories, transportation requirements, etc. for registered products.

## **Priority Examination Area 3: Response to Emerging and Uncertain Issues**

### (1) The Basic Approach to Issues That Should be Tackled

Regarding emerging and uncertain issues, it is important to continue to develop new methods for assessing risk more accurately, and to take measures appropriately by taking the precautionary approach from the standpoint of protecting citizens' health and the environment. In particular, there are issues for which the scientific knowledge on the risks involved is still insufficient, including: the impacts, etc. on vulnerable or sensitive groups such as children and expectant mothers being exposed to chemicals; endocrine disrupting effects of chemical substances; and the combined effects of multiple chemicals on human health or the environment. For these issues, the government needs to accelerate its risk assessment efforts.

### (2) The Status Quo and the Efforts Being Made

It was decided that the government would reduce the environmental risks posed by chemicals including the risks posed by emerging and uncertain issues, by promoting comprehensive chemical substance control measures which combine various methods, throughout the lifecycles of chemicals from their manufacture to their disposal.

Based on the decision, the government is conducting surveys and research, including: efforts to establish methods to assess the endocrine disrupting effects of chemical substances and the risks posed by nanomaterials; and surveys concerning children's health and the environment (e.g. the Japan Environment and Children's Study (JECS)). In addition to research related to above-mentioned issues, the government also promotes surveys and research on other new issues using such systems as Health and Labour Science Research and Funds for the Overall Promotion of Environmental Research.

In order to promote efforts based on the precautionary approach, the government publishes information on the above-mentioned surveys and research where necessary and in a timely manner. The government also presents measures that should be taken such as various guidelines on nanomaterials, thereby encouraging the relevant parties to take precautionary measures.

#### **The Status Quo**

In order to ensure the safety and security of citizens, it is necessary to take a precautionary attitude when taking measures for emerging and uncertain issues. Therefore, the government is making efforts to establish methods for assessing the endocrine disrupting effects of chemical substances, as well as formulating various guidelines on nanomaterials and establishing assessment methods for them. The government also conducts the JECS.

In order to respond to citizens' concerns about chemicals, the government provides information on the environmental risks posed by chemicals in an easy-to-understand manner including information about efforts to resolve emerging and uncertain issues, thereby further promoting risk communication.

With regard to the endocrine disrupting effects of chemical substances, the government has been conducting programs called SPEED '98 from 1998, ExTEND 2005 from 2005 and EXTEND 2010 from 2010, with the final goal being science-based risk assessments. Table 5 shows the progress in the consideration of risk assessments for candidate chemicals whose possible endocrine disrupting effects have been pointed out. The number of substances which underwent reliability assessments was 92 substances in total as of 2014, of which 45 substances underwent tier-one in vitro assays and 9 substances underwent tier-one bioassays.



The programs produced some results, for example, some of the test methods developed through the project was included in the OECD test guidelines (OECD TG229 Fish Short Term Reproduction Assay which uses killifish, OECD TG230 21-day Fish Assay, etc.). Based on these test methods, tier-one bioassays were conducted on 9 substances so far in order to see whether they have any effects on the endocrine system, through which some findings useful in risk assessment have been collected. As the test protocols which Japan and the United States jointly submitted to OECD were publicized in 2015, tier-two tests will be conducted to finalize the assessment of adverse effects of chemicals.

Table 5 Number of Substances Which Underwent Reliability Assessments, etc. for Endocrine-disrupting Effects

Category		ExTEND 2005				ExTEND 2010				Total
Fiscal year		2008	2009	2010	2011	2012	2013	2014		
Reliability assessment (note 1)	Selected	12	15	13	23	22	22	7	114	
	Assessment conducted	10	17	13	8	23	8	13	92	
	Potential substances for testing	7	11	7	5	13	8	12	63	
	Substances excluded from testing	3	6	6	3	10	0	1	29	
First-stage (note 2) in vitro assay (note 3)	Selected	–	–	6	11	13	5	10	45	
	Test conducted	–	–	6	11	12	6	5	40	
First-stage bioassay (note 4)	Selected	–	–	–	10	4	–	4	18	
	Test conducted	–	–	–	3	3	–	3	9	
First-stage assessment	Assessment conducted	–	–	–	–	–	–	–	–	
Second-stage (note 5) bioassay	Test conducted	–	–	–	–	–	–	–	–	
Hazard assessment	Assessment conducted	–	–	–	–	–	–	–	–	

Note 1. The government assesses the reliability of knowledge obtained through literature searches on chemicals detected in the environment, and considers what chemicals should be tested.

Note 2. At this stage, whether the chemical has any effects on the endocrine system is checked.

Note 3. The government tests whether the endocrine system reacts to the chemical, in test tubes.

Note 4. The government tests organisms to see if the chemical has any effect on the endocrine system of the organism.

Note 5. At this stage, whether the chemical is hazardous or not is checked.

Source: Document 2-5: Progress and FY 2015 Plan of Tier-One Assays for Assessment of Environmental Effects, FY2015 First Meeting of the EXTEND 2010 Sub-Committee for Actions and Effects Assessment.

## Efforts Being Made

### <The Implementation of Epidemiological Studies> [Japan Environment and Children's Study (JECS)] (MOE)

In recent years, more people have become concerned about the effects of chemicals in the environment on children's physical and mental health. Therefore, the government conducts the JECS which is a large-scale and long-term birth cohort study on 100,000 mother-child pairs. By identifying the environmental factors that affect children's health, the government aims to create appropriate risk management systems, thereby achieving a safe and secure childcare environment and contributing to measures to counteract the falling birthrate.

For three years starting from January 2011, participants in JECS were recruited 15 study areas spread. The recruiting was completed at the end of March 2014, when the registered participants reached the targeted 100,000.

In FY2014, a sub-cohort of the size of 5,000 randomly was formed within JECS on which extended environmental measurements and medical examinations have been performed.

In the sub-cohort, home visits started collecting environmental data such as indoor/outdoor air quality, noise and dwelling inspection information from FY2014. Additionally from FY2015, physical examination, neurodevelopment test and blood and urine collection and test started for the sub-cohort subjects.

In order to promote international coordination and cooperation regarding the surveys with European nations, etc. which conduct similar large-scale surveys, Japan participates in meetings of the international working group on large-scale birth cohort studies.

The recruiting of participants for the program was launched in FY2010 and the 100,000 target for registered participants was achieved.

As the next step, the government will implement Main Study and sub-cohort as well as implementing the chemical analysis of biological samples, and publish the results when they become available. The government will also continue to participate in international cooperation.

#### <The Consideration of Technologies and the Methods for Assessments>

#### [The Consideration of Risk Assessment Methods for Endocrine-disrupting Effects] (MHLW, METI and MOE)<sup>12</sup>

##### ◇ Establishing Assessment Methods for Effects on Human Health

Regarding the endocrine-disrupting effects of chemicals on human health, the government conducts surveys on the test methods for the endocrine-disrupting substances used in Japan and elsewhere, as well as developing assessment methods. As part of the efforts, the government is taking the necessary measures to have a screening method which is one of the new safety assessment method for chemicals included in the OECD guidelines. It is a method to efficiently screen chemicals that may have hormone activation properties. It uses binding assays for estrogen receptors (ER) or androgen receptors (AR) as well as reporter gene assays.

- In FY2012, the government gave technical support to other organizations in preparation for the verification of the developed test method by multiple organizations.
- In FY2013, additional tests were conducted in response to issues pointed out at the OECD expert meeting.
- In FY2014, draft guidelines were summarized for estrogen receptor binding assay and estrogen receptor reporter gene assay (antagonists), reflecting results of additional tests. The two test guidelines are to be publicized in 2015. For androgen receptors (AR) gene assay (agonists/antagonists) a necessary activities are ongoing for the preparation of the guideline.

The government will continue to take the necessary measures to have the method included in the OECD test guidelines, including the preparation of a verification report and responses to the OECD expert meetings.

##### ◇ The Establishment of Assessment Methods for Endocrine-disrupting Effects and the Implementation of the Assessments

The Fourth Basic Environment Plan (decided on by the Cabinet in April 2012) stipulates the following on the endocrine-disrupting effects of chemicals: “Regarding the endocrine-disrupting effects of chemicals, the government will accelerate the establishment of

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<sup>12</sup> This section subjects to endocrine-disrupting chemicals which is one of the EPI topics of SAICM/ICCM.

assessment methods and the implementation of assessments, while actively participating in the efforts made at the OECD, as well as conducting the necessary surveys and research and providing information to citizens.” In line with the plan, the government needs to establish assessment methods, etc.

Therefore, the government uses the Health and Labour Sciences Research Budget, etc. to implement research into endocrine-disrupting effects, in order to clarify their mechanisms and establish toxicity assessment methods, among other purposes.

The government will continue to promote research into endocrine-disrupting effects, in order to clarify their mechanisms and establish toxicity assessment methods, among other purposes.

#### ◇ The Establishment of Ecotoxicological effect Assessment Methods

In 1998, the government launched discussions on assessments for the endocrine-disrupting effects of chemicals on the environment. Currently, the government develops and improves the necessary test methods through a program called EXTEND 2010 launched in 2010, in order to establish a framework to assess the endocrine-disrupting effects of chemicals on organisms and then to conduct hazard assessments. The government is sequentially collecting the findings on substances detected in the environment and conducting tests where needed.

- In FY2012, assessments were conducted for 12 substances which had not been tested, among 43 substances selected for in vitro assays and bioassays.
- In FY2013, assessments were conducted for 6 substances which had not been tested, among 51 substances selected for in vitro assays and bioassays.
- In FY2014, assessments were conducted for 5 substances which had not been tested, among 63 substances selected for in vitro assays and bioassays.

EXTEND 2010 has produced the following results so far, including the results mentioned above. Of 100 substances the program aimed to assess, 114 substances were selected for reliability assessments, and 92 substances underwent reliability assessments. In vitro assays were conducted for 40 substances, and bioassays were conducted for 9 substances. Among long-term testing protocols that have been under development so far, test guidelines for fish and amphibian were adopted by OECD and were publicized in 2015. Development of other test methods will be continued and assessment of adverse effects will be conducted through long-term testing.

#### **[Research Budget for Assessment of the Combined Effects of Chemicals] (MOE)**

Risk assessments have been conducted for individual chemicals, but in the actual environment, it is necessary to consider the effects of combined exposure to multiple chemicals (combined effects). Therefore, some countries launched discussions on assessment methods for combined effects. The above-mentioned budget is used to collect the findings on the combined effects of chemicals and to consider countermeasures.

- ◇ In FY2012, ideas related to combined effects were assembled. The government also considered the use of the framework proposed by International Program on Chemical Safety (IPCS) of World Health Organization (WHO) when conducting ecological risk assessments. Fish combined exposure tests were conducted for two alkylphenols.
- ◇ In FY2013, applicability of the WHO/IPCS framework to environmental risk assessment were discussed in light of chemical detection levels in the environment. Combined exposure tests on algae were conducted. Items that should be included in Guidance on

Assessment of Combined Effects (preliminary draft) were discussed, as well as gathering information on status of discussions in Europe and the US.

- ◇ In FY2014, case studies were conducted to see applicability of the WHO/IPCS framework to environmental risk assessment. Studies on combined effects for human health risk assessment were also initiated.

In Western countries, interest in the combined effects of chemicals increased and they have been incorporated into regulatory frameworks, but many of the assessment methods are yet to be established. In Japan, in order to organize the basic ideas on assessment of combined effects, the government will develop a framework and prepare a guidance document. The government will also examine in detail the mechanisms causing the effects for each group of substances selected to be examined, in order to establish detailed assessment processes for their combined effects.

### **[The Consideration of Risk Assessment Methods for Nanomaterials] (MHLW, METI and MOE)<sup>13</sup>**

#### ◇ Hazard Studies, etc. for Nanomaterials

Nanomaterials are used in an increasing number of products and in various types of products. However, the necessary and sufficient data for assessing their effects on human health is yet to be collected. The safety assessment of nanomaterials is also an international issue, and at the OECD, an international cooperation program for gathering hazard information, etc. on major nanomaterials is underway. Therefore, the government is making the following efforts, while taking its international contribution into consideration.

- In order to conduct hazard studies for nanomaterials used at industrial sites, inhaled long-term cancer test has been conducted and for multi-walled carbon nanotube (1 type), test has completed in FY2014.
- The government developed hazard assessment methods for nanomaterials and products containing nanomaterials which are intentionally created and manufactured for industrial uses. Using the hazard assessment methods, the government is conducting research which contributes to the accumulation of hazard information, etc. on nanomaterials.

As the next step, the government will consider measures to prevent health impairment in workplaces in accordance with the results of the long-term carcinogenicity tests. With regard to the development of hazard assessment methods, the government will continue to promote the development of safety test methods along with the clarification of the mechanisms which produce toxicity, in order to promote the development of socially acceptable nanomaterials from a safety standpoint.

#### ◇ The Establishment of Risk Assessment Methods for Nanomaterials and the Implementation of the Assessments

The particle size and shape of nanomaterials can vary even when they are made of the same substance, and they are expected to have different hazardous properties. Therefore, the government is developing systematized safety assessment methods for nanomaterials. More specifically, the government aims to establish criteria for determining the equivalence of hazard of nanomaterials, as well as to establish low-cost and simple intratracheal instillation test methods in order to obtain preliminary hazard information.

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<sup>13</sup> This section subjects to nanotechnologies and manufactured nanomaterials which is one of the EPI topics of SAICM/ICCM.

- In FY2012, the government conducted tests related to equivalence criteria and preliminary hazard assessment technologies, using nanomaterials for which a large amount of information is available.
- In FY2013, the government compiled a draft of efficient safety assessment methods.
- In FY2014, testing on equivalence criteria of nanomaterials and initial hazard assessment technology were conducted using nanomaterials with different physiochemical properties.

◇ The Project for Considering Measures to Prevent Nanomaterials From Having an Environmental Impact

The amount of nanomaterials released into the environment is expected to increase due to the quick technological development of nanomaterials, and their adverse effects on health and the environment are being discussed in various countries as they have a strong interest in the issue. In light of the situation, the government is conducting the above-mentioned project with the aim of assessing the risks involved when nanomaterials are released into the environment.

- In FY2012, the government identified the paths through which exposure to nanomaterials occurs and formulated a verification experiment implementation plan in order to establish methods to measure the movement of nanomaterials in the ambient atmosphere. The government also conducted literature searches and gathering concerning the hazard of nanomaterials in the water environment.
- In FY2013, the government verified its methods to measure the movements of nanomaterials in the ambient atmosphere, by conducting verification experiments for establishing the methods. The government also conducted literature searches and gathering concerning the hazard of nanomaterials in the water environment, as well as conducting reliability assessments.
- In FY2014, the government verified the methods to measure movements of nanomaterials in the ambient atmosphere continuously from FY2013. The government also conducted literature searches, gathering and reliability assessments concerning the hazard of nanomaterials in the water environment, as well as conducting literature search to verify the methods to measure movements of carbon nanotube in the ambient atmosphere.

Through the implementation of studies, it is expected that knowledge on the movements of nanomaterials in the environment and their ecological toxicity (which are important issues in environmental administration) can be organized and this will provide information that can be used to determine the need for the government to take measures as part of its environmental administrative activities. At the OECD, discussions on test methods for identifying the condition of nanomaterials in water and clarifying their toxicity have started. The government will promote the utilization of the OECD's discussion results. The government will also continue to examine the environmental impact, etc. of nanomaterials in the environment as well as considering measures to control their release into the environment.

**[The Assessment of the Effects of Trace Chemicals in the Environment] (MOE)**

With regard to the health effects of trace chemicals in the environment, while patients complain about various symptoms induced by trace chemicals and the exacerbation of diseases, many of the patients' conditions and the mechanisms for the onset of the symptoms are unclear. Therefore, the government aims to clarify these conditions and mechanisms.

- ◇ In FY2012, the government collected and organized clinical data for pathophysiological and psychosomatic analysis as well as for genetic analysis.
- ◇ In FY2013, the government collected and organized clinical data for health effect assessments, and also considered objective diagnosis methods.
- ◇ In FY2014, the government collected and organized clinical data from patients who continuously claim for the symptoms.

The effects of trace chemicals are being examined from various standpoints including pathophysiological and psychosomatic standpoints, and the results show that some symptoms may be associated with chemicals and especially its smell.

#### **[Fact-finding Surveys, etc. on the Use of Insecticides, etc.] (MOE)**

Some of the agents used to control organisms such as insecticides, fungicides and herbicides are outside the scope of the Agricultural Chemicals Regulation Law, the Pharmaceutical Affairs Act (Act 145 of 1960) that ensures safety of pharmaceuticals and pharmaceutical equipments, etc., and the ingredients, etc. in these agents are not regulated. The data on these agents is insufficient in terms of the amounts manufactured, sold and used, as well as the amounts released into the environment in the process of using the agents. Therefore, the government conducts surveys for the manufacture, use, etc. of the agents which have a particularly high risk of dispersing into the environment due to how they are used.

- In FY2013, the government conducted surveys on the manufacturers and sellers of pest control agents used in daily life, etc. in order to ascertain the amount of insecticides, etc. shipped and how they are used, as well as to understand the activities of pest control businesses and voluntary management rules, etc. followed by industrial associations and others.
- In FY2014, the government organized the information surveyed in 2013 and listed product dose forms, types of pests for the use, and ingredients in the product as well as conducting survey on the manufacturers and sellers labeling information.

The government will continue to conduct surveys on the manufacture and use of insecticides, consumption amount, and product label conditions etc.

#### **[Consideration on Impacts to Water Environment by Pharmaceutical and Personal Care Products (PPCPs)] (MOE)**

Pharmaceutical waste disposals in the environment have become significant international topic and it is recommended to be registered as Emerging Policy Issue (EPI) for ICCM4. Regarding the PPCPs in the environment, the government conducted literature search and is conducting environmental survey for some chemical substances, since the existence of PPCPs in the environment is unclear. Additionally, the government will conduct risk assessment on ecotoxicological effect based on the above results.

## **Priority Examination Area 4: Strengthening of Safety and Security**

### **(1) The Basic Approach to Issues That Should Be Tackled**

In order to respond to citizens' concerns about the safety of chemicals, the government needs to provide information on the risks associated with chemicals in an easy-to-understand manner, including information on the government's measures for emerging and uncertain issues. The government should continue to promote risk communication and help citizens deepen their understanding of the risks associated with chemicals.

In order to ensure that the hazard information on chemicals adequately reaches the workers in the supply chains and eventually final consumers, it is necessary to consider how to provide the information, etc., including standardized GHS labeling and the labeling on articles, from the standpoints of the protection of workers, consumers and the environment.

### **(2) The Status Quo and the Efforts Being Made**

In order to tackle the above-mentioned issues and ensure citizens' safety and security, the government implements various environmental monitoring and publishes the results, as the information which provides the basis for ensuring their safety and security. The government also promotes risk communication based on scientific risk information, etc. In addition, the government promotes efforts to transmit information on the chemicals in products. Therefore, the current efforts by relevant administrative institutions were reviewed concerning items a), b) and c) shown below.

- a) The implementation of various types of monitoring, etc. in order to provide the basis for safety and security
- b) The further promotion of risk communication
- c) Efforts concerning chemicals in products

a) The Implementation of Various Types of Monitoring, etc. in Order to Provide the Basis for Safety and Security
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#### **The Status Quo**

Regarding efforts related to various types of monitoring, etc. which provide the basis for safety and security, the government has been implementing the following surveys, monitoring, etc., among others: the Environmental Surveys of Chemical Substances; the hazardous air pollutant monitoring surveys; the water quality measurement on ambient water and ground water; and the Comprehensive Survey for the Agricultural Chemicals Remaining in the Environment. Table 6 shows changes in the number of substances monitored in the Environmental Surveys of Chemical Substances.

The government also estimates and publishes the amount of chemicals released into the environment other than the amounts reported by business operators who are required to submit reports (hereinafter referred to as the "amount of release that is not required to be notified"), based on the PRTR Law. Table 7 shows changes in the sources of release that were included in the estimation of the amount of release that is not required to be notified.

Table 6 Changes in the Number of Substances Monitored in the Environmental Surveys of Chemical Substances

Fiscal year	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	
Media	Water	33	42	76	90	56	39	57	81	38	45	79	58	97	48	49	50	48	48	42	41	46	56
	Sediment	27	26	76	88	54	39	55	81	37	45	79	74	97	61	69	78	79	80	71	73	77	82
	Organisms	26	26	44	9	29	31	41	31	40	36	40	55	56	54	62	71	84	76	72	72	80	61
	Air	0	0	2	2	0	11	15	0	0	17	3	6	15	14	18	20	22	22	15	26	23	24
	Food	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	6	6	6	8	6
	Others (Note 1)	11	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	4	4	4	6	6
Total (Note 2)	33	33	42	78	92	77	73	108	110	67	96	116	115	128	79	87	96	101	107	100	102	102	
The number of new substances (Note 3)	33	33	34	77	79	54	32	54	74	29	42	66	57	47	30	15	16	12	3	16	19	8	
(Out of the substances above, the number of substances which continue to be monitored)	0	0	0	0	0	8	0	0	0	0	0	0	14	1	14	0	3	4	1	1	0	1	
The cumulative number of substances monitored for each fiscal year	33	33	67	144	223	277	309	363	437	466	508	574	631	678	708	723	739	751	754	770	789	797	

Fiscal year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	The cumulative number of substances monitored in each medium (Note 4)	
Media	Water	61	37	48	30	41	47	63	70	70	156	122	110	110	86	80	83	80	59	1,095 (2,572)
	Sediment	91	68	56	58	68	66	62	66	63	86	134	81	96	79	70	75	59	38	1,026 (2,764)
	Organisms	67	44	29	48	52	46	66	62	59	76	98	67	89	67	69	66	63	46	473 (2,210)
	Air	27	15	36	32	49	49	41	63	72	53	87	70	98	84	69	69	70	50	455 (1,239)
	Food	6	6	6	6	1	1	9	0	2	6	2	0	0	0	0	0	0	0	27 (80)
	Others (Note 1)	6	6	6	6	6	6	0	0	1	2	0	0	0	0	0	0	0	0	26 (92)
Total (Note 2)	107	116	85	101	95	99	98	80	93	91	171	252	128	141	110	101	93	96	1250 (Note 5) (4,040)	
The number of new substances (Note 3)	15	6	7	16	7	37	16	20	20	13	50	136	27	16	25	14	9	5		
(Out of the substances above, the number of substances which continue to be monitored)	0	0	0	8	0	20	0	0	4	0	0	15	0	0	8	2	5	0		
The cumulative number of substances monitored for each fiscal year	812	818	825	841	848	885	901	921	941	954	1,004	1,140	1,167	1,183	1,208	1,222	1,231	1,236		

(Note 1) "Others" are "rainwater" and "indoor air."

(Note 2) The total number of substances monitored in each fiscal year does not match the sum of the numbers of substances monitored in all media in the same fiscal year because some substances were monitored in multiple media.

(Note 3) "New substances" are substances which were monitored for the first time in the relevant fiscal year. The number of new substances is included in the "total" number of substances monitored.

(Note 4) The cumulative number of substances monitored in each medium does not match the sum of the numbers of substances monitored in all fiscal years because some substances were monitored in multiple years. The sum of the numbers of substances monitored in all fiscal years is shown in ( ).

(Note 5) The number "1,236" is the total number of substances monitored in the period between FY1974 to FY2012. The number does not match the sum of the numbers shown on the left because some substances were monitored in multiple media in multiple years. The sum of the numbers shown on the left is given in ( ).



Table 7 Changes in the Sources of Release That Were Included in the Estimation of the Amount of Release That Is Not Required to Be Notified

Sources of release		Fiscal year(s)				
		2001	2002	2003-2006	2007-2009	2010-2012
Releases from business establishments not subject to reporting due to the small amounts released*		X	X	X	X	X
Agricultural chemicals		X	X	X	X	X
Insecticides	Household insect repellents		X	X	X	X
	Insecticides for disinfecting		X	X	X	X
	Insecticides for nuisance insects		X	X	X	X
	Termite control agents			X	X	X
Adhesives		X	X	X	X	X
Paints		X	X	X	X	X
Antifoulants for fishing nets		X	X	X	X	X
Pharmaceuticals	Ethylene oxide		X	X	X	
	Formaldehyde	X	X	X	X	
Detergents, cosmetics, etc.	Surfactants	X	X	X	X	X
	Neutralizers, etc.	X	X	X	X	X
Insect repellents, deodorants		X	X	X	X	X
Utility engines			X	X	X	X
Cigarette smoke			X	X	X	X
Automobiles	Hot starts	X	X	X	X	X
	Additional emissions during cold starts		X	X	X	X
	Fuel evaporative emissions			X	X	X
	Air conditioning units powered by independent engines		X	X	X	X
Motorcycles	Hot starts	X	X	X	X	X
	Additional emissions during cold starts		X	X	X	X
	Fuel evaporative emissions			X	X	X
Special-purpose vehicles	Construction machinery	X	X	X	X	X
	Agricultural machinery	X	X	X	X	X
	Industrial machinery	X	X	X	X	X
Vessels	Cargo and passenger vessels, etc.	X	X	X	X	X
	Fishing vessels	X	X	X	X	X
	Pleasure boats			X	X	X
Railway vehicles	Engines	X	X	X	X	X
	Wearing of brakes, etc.		X	X	X	X
Aircraft	Engines	X	X	X	X	X
	Auxiliary power units	X	X	X	X	X
Water supply systems		X	X	X	X	X
Ozone-depleting substances		X	X	X	X	X
Dioxins		X	X	X	X	X
Low-content substances		X	X	X	X	X
Sewage treatment facilities					X	X

Note: "X" in the table indicates that an estimate was made for the relevant item.

- \* “Releases from business establishments not subject to reporting due to the small amounts released” refers to the amount released from business establishments which do not become subject to reporting due to the small amounts released, although their business types are subject to reporting. “Releases from business establishments not subject to reporting due to the small amounts released” exclude the release from the following categories: “agriculture,” “water supply systems,” “ozone-depleting substances,” “dioxins,” “low-content substances” and “sewage treatment facilities.”

## Efforts Being Made

### <Various Monitoring Efforts>

#### [The Environmental Survey of Chemical Substances] (MOE)

(The content is omitted as it is the same as the content on page 15.)

#### [The Survey of the Exposure to Chemical Compounds in Human] (MOE)

(The content is omitted as it is the same as the content on page 15.)

#### [Ascertaining and Publishing the Amount of Release and the Amount of Waste Chemicals Transferred to Be Treated Based on the PRTR Law] (METI and MOE)

(The content is omitted as it is the same as the content on page 16.)

#### [Constant Monitoring of the Atmospheric Environment] (MOE)

(The content is omitted as it is the same as the content on page 17.)

#### [Regular Observation of the Water Environment] (MOE)

(The content is omitted as it is the same as the content on page 18.)

#### [Regular Observation of Groundwater Quality] (MOE)

(The content is omitted as it is the same as the content on page 19.)

#### [The Promotion of Risk Assessment concerning Agricultural Chemicals] (MOE)

◇ Monitoring (The content is omitted as it is the same as the content on page 12.)

#### [Efforts to Control Indoor Air Pollution] (MHLW)

(The content is omitted as it is the same as the content on page 19.)

### <Efforts for the Preparation of Data, etc. on Exposure>

#### [Support for Improving the Accuracy of PRTR Notification Data] (METI and MOE)

The government is preparing the Manual for PRTR Release Estimation Methods (hereinafter referred to as the “Estimation Manual”) so that business operators can refer to it when ascertaining the amount of chemicals released into the environment, etc. in the PRTR system which was created based on the PRTR Law.

The first edition of the Estimation Manual was created in April 2001. The Estimation Manual had been revised in light of the reporting situation and the revision of the Cabinet Order on the PRTR Law in November 2008, and version 4.1 was published in March 2011. Since then, the Estimation Manual has been amended every fiscal year, based on the revisions, etc. of relevant laws and regulations. The Estimation Manual can be browsed on the websites, etc. of the MOE and the METI. On the website of the MOE, the Estimation Manual can also

be browsed using a dedicated electronic application. The government also provides the PRTR Release Estimation System which can be used on the website of the MOE since FY2004, in order to help business operators to calculate their amounts of release, etc.

Experts pointed out that the government should conduct surveys on methods used by business operators to calculate their amounts of release, etc., at the meetings of the Environmental Health Committee of the Central Environment Council, etc. The government needs to ascertain the calculation methods being used by business operators and then take improvement measures.

**[The Improvement of Accuracy in the Estimation Methods for the Amount of Release That Is Not Required to Be Notified in the PRTR System] (METI and MOE)**

Article 9 of the PRTR Law stipulates that the Minister of Economy, Trade and Industry and the Minister of the Environment shall calculate the amount of chemicals subject to the law which was released into the environment and not reported by business operators subject to the law (“the amount of release that is not required to be notified”). It also stipulates that the ministers shall publish the estimations along with the aggregation results for the amounts of release reported by business operators.

Regarding the estimations, in August 2007, an interim report was published on discussions at the joint meetings of the Subcommittee for Environmental Measures for Chemical Substances at the Environmental Health Committee of the Central Environment Council and the Fundamental Issues Subcommittee on Chemical Substance Policies within the Chemicals and Bioindustry Committee of the Industrial Structure Council. The report said, “As the estimation of the amount of release that is not required to be notified is important for risk assessment, the government should continue in its efforts to improve the accuracy of the estimations while also taking into consideration measures to enable the ascertainment of changes over time.” Therefore, the government is examining the sources of release for which estimations can be made, as well as considering what chemicals should be included in the scope of the estimations. The government is also working to improve the accuracy of estimations by revising its estimation methods including the emission factors used, based on the new information obtained every fiscal year.

Discussions for revising the estimation methods and improving estimation accuracy have been taking place while utilizing the latest findings, at the “Review Meetings on the Estimation Methods for the Amount of Release from Non-point Sources for the PRTR System” (MOE) and the “Review Meetings on the Estimation Methods for the Amount of Release from Business Establishments Not Subject to Reporting Due to Their Small Amounts of Release” (METI), both of which are made up of experts. Whenever the review meetings find that new basic data and estimation methods can be used for estimations, they are used in the estimations that follow the meetings.

As the next step, the government will consider methods to estimate the amounts of release from the sources which could not be estimated before as well as the amounts of released chemicals subject to the law which could not be estimated before. The government will also work to improve the accuracy of the estimations by continuing to revise the estimation methods based on newly obtained information.

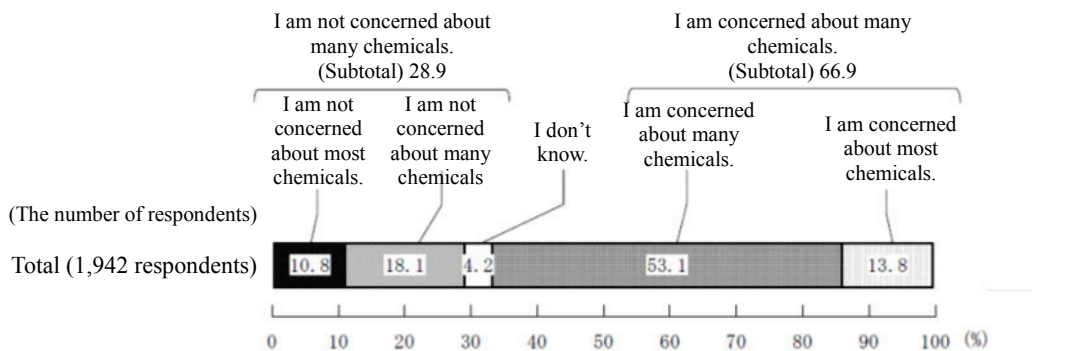
**b) The Further Promotion of Risk Communication**

**The Status Quo**

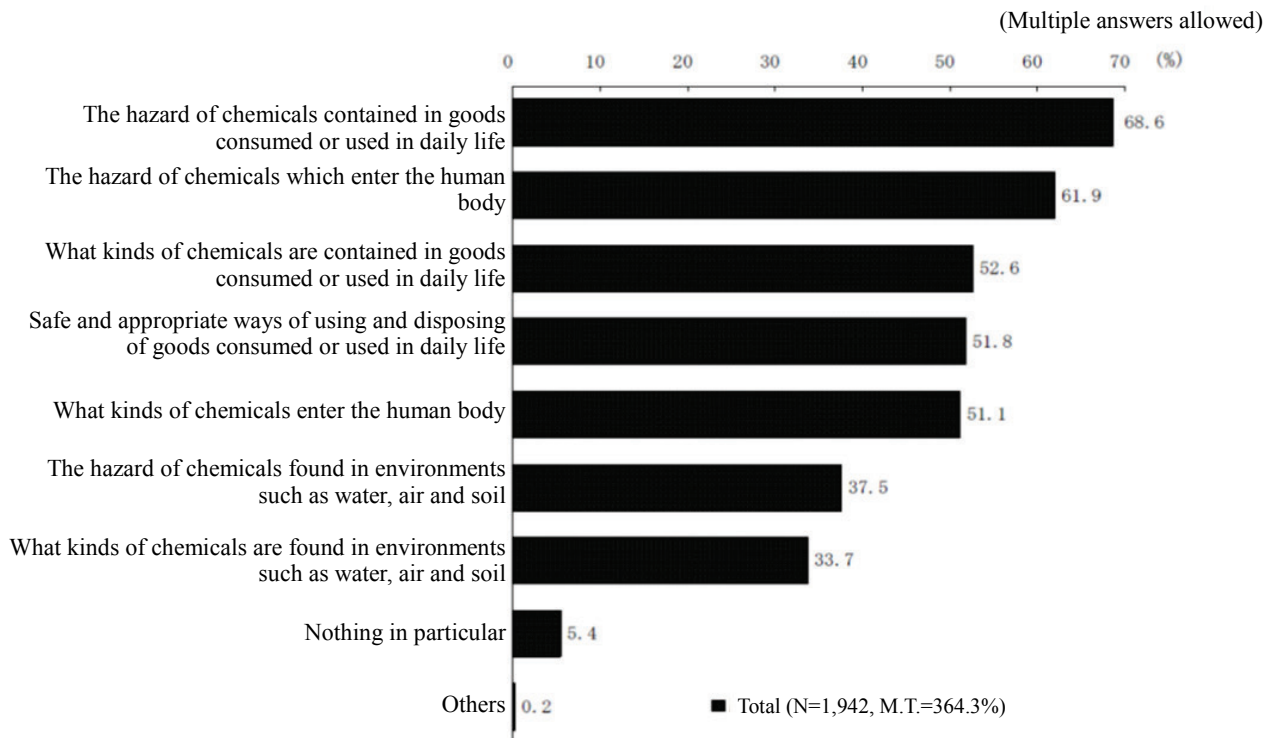
The government is working to put in place basic conditions that enable risk communication on chemicals, by providing information on databases, promoting classification and labeling, providing risk communication opportunities and developing human resources.

The government conducted the “Opinion Poll on Chemical Substances Found in Daily Life” in June 2010. With regard to people’s perception on the safety of chemicals, 28.9% of respondents answered that they are not concerned about many chemicals and 66.9% of the respondents answered that they are concerned about many chemicals. Therefore, further promotion of risk communication is needed. Figure 15 shows the overview of the results of the poll.

Figure 15 The Overview of the Results of the “Opinion Poll on Chemical Substances Found in Daily Life”



**(Perceptions of the Safety of Chemicals)**



**(Information on Chemicals That People Want to Obtain)**

Note: “I don’t know” (1.5%) was omitted from the figure

## Efforts Being Made

### <The Preparation of Information for Risk Communication> [The Preparation of Information for Risk Communication] (MOE)

The government is preparing information in order to provide information on the environmental risks associated with chemicals in an easy-to-understand manner, to further promote risk communication, and to help citizens deepen their understanding of the issue.

The government created and is updating Chemical Substances Fact Sheets where information on the hazard of chemicals and exposure to chemicals is provided in an easy-to-understand manner. Currently, information on 352 substances out of 462 substances subject to the PRTR system has been published on the MOE website.

Regarding the PRTR data collected every fiscal year, the government publishes the data via “the System for Displaying PRTR Data on Maps” available on the MOE website where individual business establishments which submit reports can be searched and their data can be viewed, rather than just publishing the aggregated data. The government updates the information on the system by adding the individual business establishments’ notification data which is collected each year.

The government creates and publishes brochures which explain the PRTR data in order to help the general public understand and utilize the PRTR data. One such brochure is “the Guidebook for Citizens to Interpret the PRTR Data.” “The Guidebook for Citizens to Interpret the PRTR Data” will be published accordingly.

The government will continue to prepare information for risk communication steadily. For the “Chemical Substances Fact Sheets” in particular, the government will update the information on substances which already have fact sheets and also collect and publish information on substances that do not have fact sheets yet.

### [The Use of Chemical Advisors to Promote Risk Communication in Local Areas] (MOE)

The government dispatches “Chemical Advisors” who clearly explain the risk information, etc. concerning chemicals which are found in daily life and also give objective information and advice on chemicals by attending venues for risk communication between citizens and business operators, etc. as neutral people. The government dispatches “Chemical Advisors” in response to requests from citizens, companies, national and local government administrative agencies, and they answer questions about “chemicals” and “the environmental risks associated with chemicals” in an easy-to-understand manner as well as providing relevant information.

Chemical Advisors have been dispatched upon request since FY2003. They were dispatched 25 times in FY2012 and 28 times in FY2013. They contribute to the promotion of risk communication in local areas, by for example serving as facilitators at risk communication opportunities, etc. organized by local governments.

The government will strive to inform more people about the Chemical Advisor system and support the promotion of risk communication in local areas since the numbers of the dispatches decreased compared with the initial stage.

**[Holding Public Symposiums on Chemical Safety Management] (Cabinet Office, MHLW, METI, MLIT, and MOE)**

The symposium has been held since 2010 to share latest knowledge from governments and research institutes with municipal governments, private sectors, and general citizen. The symposium themes were “Practical Use of Risk Assessment Survey and Challenges for the Further Usage” in FY2012, “The Latest Trend of the Chemical Substances Risk Assessment and Future Challenges” in FY2013, and “New Challenges and Background of Chemical Substances Control” in FY2014. Ministries, public sectors, private sectors, and researchers made presentations and lectures, and exchanged ideas together in these symposia. The government will further continue to hold such symposium.

**<Efforts to Transmit Information on the Chemicals in Products Including the Disclosure of Information to Consumers>**

**[Encouraging Business Operators to Utilize GHS Labeling, SDS, etc.] (MHLW)**

In order for stakeholders including citizens, workers, business operators, the government and local governments to share their knowledge about the risks posed by chemicals and deepen the trust between them while fulfilling their roles, the government created “the Workplace Safety Site” within the website of the MHLW. With the aim of promoting risk communication, various types of information are posted on the website including information on GHS model labels and SDS (safety data sheets), as well as information on risk assessments, etc. conducted by the government. The government will encourage business operators to utilize these tools further.

- The government set up a consultation desk where people can consult on chemical management methods, GHS classification, the creation of labels and SDS, etc. (the service was launched in FY2014).
- The government conducted GHS classification and created model labels and model SDS based on the classification (162 substances in FY2012; 152 substances in FY2013. Also in FY2014, it revised for 640 substances for which the issuing of SDS is required based on the Industrial Safety and Health Act).
- The government is posting the results of risk assessments and various hazard tests as well as chemical disaster cases, etc. on the Workplace Safety Site as they become available, in addition to posting GHS classification, model labels and model SDS mentioned above.

The government will continue to implement effective projects in order to promote the appropriate management of chemicals and to prevent the health impairment of workers.

**<Publishing Accident Information>**

**[Publishing Accident Information] (The Consumer Affairs Agency (CAA))**

CAA gathers consumer accident information from the relevant administrative institutions and various other sources, and provides the information to consumers. More specifically, the agency operates Accident Information Databank System where people can freely search and browse accident information. Accident information includes information on chemical accidents.

The following shows the number of accidents related to chemicals which were posted on Accident Information Databank System in each fiscal year.

- FY2012: 508 cases
- FY2013: 456 cases

- FY2014: 334cases

Note: The information is based on voluntary reports, etc. from consumers, which includes facts that are not confirmed (such as the confirmation of cause-and-effect relationships).

CAA will continue to cooperate with the relevant administrative institutions, etc. and endeavor to strengthen the collection and provision of accident information.

**[Efforts Based on the Act on Control of Household Products Containing Harmful Substances] (MHLW)**

- ◇ Disclosure of Information about Serious Accidents Involving Products That Are Assumed to Have Been Caused by Specific Chemicals  
(The content is omitted as it is the same as the content on page 34.)

**<Other Efforts>**

**[Policy Dialogue concerning Chemicals and the Environment] (MAFF, MHLW, METI and MOE)**

In March 2011, the existing Roundtable on the Environment and Industry was abolished in order to create a new venue called the “Policy Dialogue concerning Chemicals and the Environment” (hereinafter referred to as the “Policy Dialogue”), with the aim of proposing policies to ensure the safety and security of citizens concerning chemicals. The aim of the Policy Dialogue is for various parties including citizens, workers, business operators, the government, local governments and academic experts to exchange opinions about chemicals and the environment, and to make policy proposals.

At the first session in March 2011 and the second session in August 2012, the SAICM National Implementation Plan of Japan was discussed. After the plan was adopted in September 2012, individual themes were discussed in the third session in December 2012, the fourth session in January 2014 and the fifth session in August 2014. The discussion theme for each session is shown below.

- The third session of the Policy Dialogue concerning Chemicals and the Environment in December 2012: “The Basic Idea of the Precautionary Approach, etc.”
- The fourth session of the Policy Dialogue concerning Chemicals and the Environment in January 2014: “New Developments concerning Risk Assessment and Associated Challenges”
- The fifth session of the Policy Dialogue concerning Chemicals and the Environment in August 2014: “Risk Communication concerning Chemicals in Products”
- The sixth session of the Policy Dialogue concerning Chemicals and the Environment in December 2014: “Efforts being made to SAICM and how to further proceed”

As the next step, discussions should take place on the reviews, etc. of the efforts that have been made based on the SAICM National Implementation Plan of Japan with the view of achieving the WSSD2020 Goal. The government will facilitate close communication between the stakeholders relevant to chemicals as well as continuing the Policy Dialogue so that policy proposals, etc. on individual themes will be obtained.

## c) Efforts concerning Chemicals in Products<sup>14</sup>

### i. The Status Quo

In order to ensure that the hazard information on chemicals in products reaches the business operators in the supply chains and their workers adequately, it is necessary to consider standardized GHS labeling, from the standpoints of the protection of workers, consumers and the environment, as well as how to provide the information, etc., including the articles. Figure 16 shows the developments in recent years concerning the development of Japanese Industrial Standards (JIS) which are in line with the GHS, and the revision of the PRTR Law and the Industrial Safety and Health Act for encouraging the provision of SDS and labeling that comply with JIS.

Figure 17 shows changes in the numbers of hospital monitoring reports on health damage involving household products, etc. which are collected by the government as accident information on chemicals contained in products.

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<sup>14</sup> This section subjects to chemicals in products which is one of the EPI topics of SAICM/ICCM.



Figure 16 The Schedule for the Revision of JIS for the Introduction of the GHS and the Revision of the Relevant Laws

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
The PRTR Law	April 20, 2012 The revision and promulgation of the ministry ordinance and guidelines concerning the PRTR Law	June 1, 2012 First-stage enforcement	Note 1		April 1, 2015 Second-stage enforcement	Note 2		
The Industrial Safety and Health Act	January 27, 2012 The revision and promulgation of the Ordinance on Industrial Safety and Health	Put into force on April 1, 2012	Note 3					
	March 16, 2012 The revision and promulgation of the guidelines	Put into force on April 1, 2012	Note 4					
JIS Z 7252 (classification)	JIS Z 7252: 2009							
JIS Z 7250 (MSDS)	JIS Z 7250: 2005	(Abolished)			(The interim period ends) December 31, 2015			
JIS Z 7250 (MSDS)	JIS Z 7250: 2010	(Abolished)				(The interim period ends) December 31, 2016		
JIS Z 7251 (Labeling)	JIS Z 7251: 2006	(Abolished)			(The interim period ends) December 31, 2015			
JIS Z 7251 (Labeling)	JIS Z 7251: 2010	(Abolished)				(The interim period ends) December 31, 2016		
JIS Z 7253 (Information communication)	Established in March 25, 2012	Integrated JIS Z 7253: 2012						

(Note 1)

[The revision of the ministerial ordinance] (Chemicals designated in the PRTR Law)

<General> Items to be shown on SDS were increased to 16 items in line with the GHS (Article 3).

<Pure substances> Business operators are required to endeavor to create SDS in a way that complies with JIS Z 7253 (Article 4, paragraph 1).

<Pure substances> Business operators are required to endeavor to label their products in a way that complies with JIS Z 7253 (Article 5).

[The revision of the guidelines]

<General> The guidelines stipulate that business operators handling designated chemical substances, etc. should endeavor to improve their voluntary chemical management in accordance with JIS Z 7252 and Z 7253 (No. 4).

(Note 2)

[The revision of the ministerial ordinance] (Chemicals designated in the PRTR Law)

<Mixed substances> Business operators are required to endeavor to create SDS in a way that complies with JIS Z 7253 (Article 4, paragraph 1).

<Mixed substances> Business operators are required to endeavor to label their products in a way that complies with JIS Z 7253 (Article 5).

(Note 3)

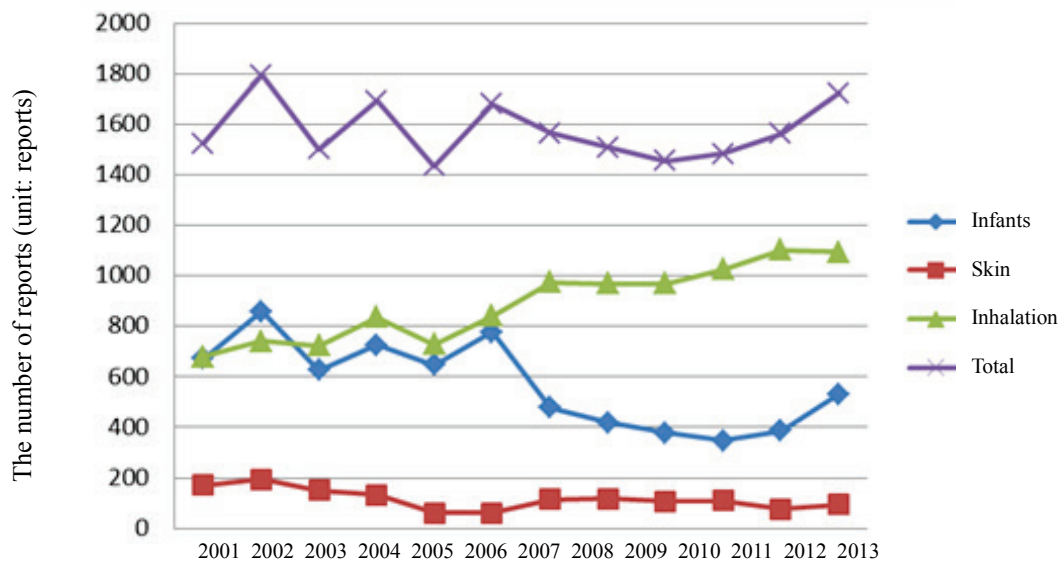
Business operators are required to endeavor to label their products, for dangerous and hazardous chemicals which are not required to have labels in the Industrial Safety and Health Act (Article 24-14).

Business operators are required to endeavor to issue SDS, for dangerous and hazardous chemicals which are not required to have SDS issued in the Industrial Safety and Health Act (Article 24-15).

(Note 4)

In order to encourage business operators to label their products and issue SDS as stipulated in the revised Ordinance on Industrial Safety and Health, the government published methods that business operators should use to let their workers know about dangerous and hazardous chemicals when the business operators have their workers handle those chemicals, for example labeling containers, etc. in a way that complies with the GHS and putting up SDS in workplaces.

Figure 17 Changes in the Numbers of Hospital Monitoring Reports on Health Damage involving Household Products, etc.



(The Numbers of Reports in Each Fiscal Year)

	FY 2011			FY 2012			FY 2013		
		No. of reports	%		No. of reports	%		No. of reports	%
1	Insecticides	252	24.6	Insecticides	296	26.9	Insecticides	265	24.2
2	Detergents (for housing and for furniture)	172	17.2	Detergents (for housing and for furniture)	175	15.9	Detergents (for housing and for furniture)	188	17.2
3	Aromatics and deodorants	105	10.3	Bleaches	127	11.5	Bleaches	116	10.6
4	Bleaches	88	8.6	Aromatics and deodorants	87	7.9	Aromatics and deodorants	74	6.8
5	Disinfectants	46	4.5	Disinfectants	44	4.0	Disinfectants	48	4.4
6	Gardening insecticides and fungicides	37	3.6	Gardening insecticides and fungicides	35	3.2	Waterproof spray	45	4.1
7	Detergents (for washing clothes and for the kitchen)	29	2.8	Insect repellents	32	2.9	Detergents (for washing clothes and for the kitchen)	41	3.7
8	Fire extinguishing agents	27	2.6	Detergents (for washing clothes and for the kitchen)	32	2.9	Fire extinguishing agents	34	3.1
9	Desiccants	22	2.1	Fire extinguishing agents	31	2.8	Repellents	28	2.6
10	Repellents	20	2.0	Repellents	24	2.2	Gardening insecticides and fungicides	25	2.3
	Total for the top 10 items	802	78.3	Total for the top 10 items	883	80.2	Total for the top 10 items	864	79.0
	Total	1,024	100.0	Total	1,101	100.0	Total	1,095	100.0

(The Numbers of Reports on Inhalation Accidents, etc. Involving Household Products in Each Fiscal Year)

## Efforts Being Made

### **<Consideration of Standardized Information Transmission and Provision Methods, etc. Used in Supply Chains concerning Chemicals in Products> [Consideration of Standardized Information Transmission and Provision Methods, etc. Used in Supply Chains concerning Chemicals in Products] (METI)**

Various regulations on chemicals that are different from Japanese legal regulations have been introduced in various countries. This creates business risk for Japanese manufacturers because huge costs are incurred when they fail to comply with the legal regulations of export destinations, including the costs of recalling products as well as the opportunity costs.

In order to comply with the regulations of export destinations, Japanese manufacturers need to ask for information on chemicals from midstream and upstream companies in their supply chains before exporting their products. Midstream and upstream companies are requested to provide information to different downstream companies in different formats, and this creates huge costs for midstream and upstream companies. In particular, many small- and medium-sized enterprises are midstream companies and they are not able to transmit information efficiently because they have difficulties in responding to requests due to a lack of personnel who have chemical management expertise and difficulties in providing information in various information transmission formats, among other reasons.

Therefore, the government aims to reduce business costs for midstream and upstream companies in particular, by establishing a system where the same format will be passed on from upstream companies through to downstream companies.

The government is considering a new information transmission scheme and ways to operate the scheme, for chemicals in products for which a standardized method has not been established in Japan, by taking global trends into account and by harmonizing the scheme with IEC62474. In this process, the government also takes into account the systems of the existing Joint Article Management Promotion-consortium (JAMP) and the now defunct Japan Green Procurement Survey Standardization Initiative (JGPSSI), as well as taking into account support for small- and medium-sized enterprises in particular (in terms of equipment for establishing the system, etc. and knowledge such as the development of operation manuals and the improvement of training).

More specifically, the government conducted a fact-finding survey mainly for small- and medium-sized enterprises in FY2012. The government also discussed a new information transmission scheme and compiled the discussion results in FY2013.

In FY2014, the government considered a more detailed scheme for information transmission based on the discussion results.

Firstly, the government will standardize domestic information transmission systems.

After the standardization of domestic information transmission systems has been achieved, the government will work to make it an internationally standardized scheme by having it certified under the IEC/ISO standards, etc. In addition, in order to make it an internationally used information transmission scheme, the government will work with the private sector to promote the use of the scheme in other countries.

**<Monitoring of Chemicals in Household Products, the Provision of Guidance on the Products, etc.>**

**[Efforts Based on the Act on Control of Household Products Containing Harmful Substances] (MHLW)**

◇ Monitoring of Chemicals in Household Products, the Provision of Guidance on the Products, etc. (The content is omitted as it is the same as the content on page 34.)

**[Efforts Based on the Household Goods Quality Labeling Act] (CAA)**

The government implements the necessary regulations on labeling based on the Household Goods Quality Labeling Act (Act No.104 of 1962), with the aim of ensuring appropriate labeling on the quality of household goods and contributing to the selection of products and the reasonable use of the products by general consumers, thereby protecting consumers. More specifically, the labeling of ingredients, directions for use, etc. on some household goods are required, and the following activities are conducted.

- Information dissemination and awareness raising via websites, guidebooks, etc. in order to promote appropriate labeling
- Revising labeling standards where necessary
- Monitoring and giving guidance on labeling stipulated in the Household Goods Quality Labeling Act, via on-site inspections, etc. by local governments (every fiscal year)

The government will continue to promote appropriate labeling based on the Household Goods Quality Labeling Act and revise labeling standards when needed.

**<Publishing Accident Information>**

**[Publishing Accident Information] (CAA)**

(The content is omitted as it is the same as the content on page 66.)

**< Publishing Accident Information>**

**[Efforts Based on the Act on Control of Household Products Containing Harmful Substances] (MHLW)**

(The content is omitted as it is the same as the content on page 34.)

**<The Promotion of Green Procurement by the Government, etc.>**

**[The Promotion of Green Procurement by the Government, etc.] (MOE)**

(The content is omitted as it is the same as the content on page 35.)

## **Priority Examination Area 5: The Promotion of International Cooperation and Coordination**

### **(1) The Basic Approach to Issues That Should Be Tackled**

In line with SAICM, the government should continue to commit itself to chemical management from an international standpoint, based on the relevant international conventions, OECD frameworks, etc. The government should also facilitate capacity development in various countries, by further strengthening cooperation with other Asian countries using our experience and technologies.

### **(2) The Status Quo and the Efforts Being Made**

In order to tackle the above-mentioned issues, it was decided that the government will make various efforts based on international conventions, as well as promoting efforts at the OECD and other international organizations, including the development of risk assessment methods for chemicals, their international harmonization and data sharing. It was also decided that the government will tap into Japanese technologies, etc. related to chemical control measures which were developed based on the lessons learned from past pollution problems including Minamata disease, in order to disseminate information to developing countries, etc. as well as providing them with technical support, etc. From these standpoints, the current efforts by the relevant administrative institutions were reviewed concerning items a), b) and c) shown below.

- a) Compliance with international conventions and the contribution to international activities that are conducted based on the conventions
- b) Promoting the development of assessment methods, their international harmonization, data sharing, etc.
- c) Promoting the dissemination of information on SAICM from Japan, international collaborative work, technical support and other efforts

#### **a) Compliance with International Conventions and the Contribution to International Activities That Are Conducted Based on the Conventions**

#### **The Status Quo**

Regarding Japan's compliance with international conventions and the contribution to international activities that are conducted based on the conventions, the government has been implementing national implementation plans that were created based on the Stockholm Convention and other conventions. The government has also been promoting coordination activities between the Basel Convention, the Rotterdam Convention and the Stockholm Convention, as part of its efforts to strengthen the coordination between international conventions. In 2010, international negotiations began with the aim of establishing a convention for preventing global environmental pollution and health damage caused by mercury. Through five Intergovernmental Negotiating Committee sessions, the Minamata Convention on Mercury was adopted in October 2013. The 6<sup>th</sup> Government Negotiating Committee was held in October 2014.

## Efforts Being Made

### <Efforts Based on International Conventions>

#### **[The Implementation of the National Implementation Plan Which Was Created Based on the Stockholm Convention] (Cabinet Office, the Ministry of Foreign Affairs (MOFA), MHLW, MAFF, METI and MOE)**

Article 7 of the Stockholm Convention stipulates that each party shall develop and endeavor to implement a plan for the implementation of its obligations under the convention. Article 5 of the convention stipulates that each party shall develop an “action plan concerning the unintentional production of substances” and subsequently implement it as part of its implementation plan. In Japan, a national implementation plan was formulated in June 2005 and the first revision took place in August 2012.

The national implementation plan includes the following measures that are required by the convention.

- Measures to reduce or eliminate releases from intentional production and use
- Measures to reduce or eliminate releases from unintentional production
- Measures to reduce or eliminate releases from stockpiles and wastes containing POPs, etc.

Chapter 4 of the national implementation plan says, “The Inter-Ministerial General Directors’ Meeting will review the national implementation plan, accommodating the periodic intervals of reporting the implementation status of the Convention decided by the Conference of the Parties at its first meeting. The Inter-Ministerial General Directors’ Meeting will publish the outcomes for comments.” The results of a review were submitted to the Secretariat of the convention in August 2012.

As the next step, the government intends to amend the national implementation plan and submit it to the Secretariat of the convention by November 2016, in response to the addition of chemical substances adopted at the Meetings of the Conference of Parties at its seventh meeting (May 2015) to the POP list, which was decided at the sixth Conference of the Parties in May 2013.

#### **[The National Residual POPs Monitoring Project] (MOE)**

The Stockholm Convention requires that the Parties shall monitor the environment at the national and international levels (Article 11), and that they shall evaluate the effectiveness of the convention using the survey results (Article 16).

Through the national residual POPs monitoring project, the government conducts monitoring surveys of air, water, sediment, organisms, etc. in Japan, in order to obtain up-to-date pollution data for 22 POPs except for dioxins and reports the results as “Chemicals and Environment” annually. The government also conducts frequent monitoring at Cape Hedo (in Okinawa) and other background air monitoring points for East Asia.

Note: The government selected Cape Hedo in Okinawa as a background air monitoring point which is not directly affected by emission sources in Japan.

In order to have them utilized for the evaluation of the effectiveness of the Stockholm Convention, compiled reports are submitted to the Secretariat of the convention periodically.

Domestic monitoring of dioxins is being conducted based on the Act on Special Measures against Dioxins.

## **<The Promotion of Activities for Enhancing Coordination between International Conventions>**

### **[Promoting Activities for Strengthening Coordination among the Basel Convention, the Rotterdam Convention and the Stockholm Convention] (MOFA, MHLW, METI and MOE)**

The Basel Convention, the Rotterdam Convention and the Stockholm Convention share the aim of preventing environmental pollution by regulating hazardous chemicals and wastes, although they regulate different substances and use different regulation methods. Therefore, cooperation and coordination among the three conventions has been enhanced, with the aim of strengthening the implementation of the conventions at the national, regional and global levels, promoting coherent policy guidance, enabling improved cost efficiencies and reduced administrative burdens, among other purposes. The areas of cooperation and coordination among the three conventions include: improving the efficiency of the conventions' secretariats and the activities of the subsidiary bodies; collaboration between regional centers; and coordination on the national-level implementation of the conventions in each party.

- The first simultaneous extraordinary meetings of the conferences of the parties to the Basel, Rotterdam and Stockholm conventions (ExCOPs) were held in 2010. At the meetings, decisions were made concerning the joint managerial functions of the secretariats, coordination of activities for implementation, and methods to review the synergy arrangements, among other decisions.
- At the second ExCOPs held in 2013, progress in synergies was evaluated and discussions took place on how to promote further cooperation and coordination, etc. The meetings identified actions that are recommended to be implemented by the parties, the secretariats and other institutions and stakeholders in order to further enhance cooperation and coordination among the three conventions. It was decided that an independent assessment of the synergies arrangements should be conducted by 2017. It was also stressed that the activities needed to accelerate the implementation of the three conventions at the national and regional levels should be continued.

Cooperation and coordination among the three conventions for chemicals and wastes management is a pioneer example of synergistic approach in the environmental field. This has produced some positive results such as the rational operation of the secretariats of the conventions. Through continuous cooperation and coordination among the three conventions and the consideration of cooperation and coordination with SAICM as well as future Minamata Convention on Mercury where necessary, it is expected that awareness about the importance of sound management of chemicals and wastes will increase and the implementation of each convention will be strengthened.

## **<Efforts for the Minamata Convention on Mercury>**

### **[Promoting the Implementation of the Minamata Convention on Mercury] (Cabinet Office, MOFA, the Ministry of Finance (MOF), the Ministry of Education, Culture, Sports, Science and Technology (MEXT), MHLW, MAFF, METI, MLIT, and MOE)**

In 2010, international negotiations began with the aim of establishing a convention to prevent global environmental pollution and reduce the risks to human health caused by mercury. After five sessions of Intergovernmental Negotiating Committee, the Minamata Convention on Mercury was finally adopted in October 2013. Then, the 6<sup>th</sup> Intergovernmental Negotiating Committee was held in October 2014. The convention internationally regulates mercury throughout its lifecycle, from its supply and use to its emission/release and disposal. Japan will actively contribute to future negotiations on the Minamata Convention named after

one of its cities. The government will prepare for domestic security measures with a view to the objective of the convention. The government will also actively disseminate the lessons learned of Minamata disease and implement mercury management technologies, etc., in order to achieve steady implementation of the convention based on Minamata Convention.

◇ Active Contribution to the Adoption of the Minamata Convention on Mercury

In the negotiation process of the convention, Japan has contributed to the progress of the negotiation by hosting the second session of the Intergovernmental Negotiating Committee (INC2) in 2011 and by consolidating the opinions of the Asia-Pacific region as a regional coordinator. Together with the EU and Jamaica, Japan also contributed to draft the convention text, by leading the information gathering and discussions on regulations and lists subject to the regulations on mercury-added products and manufacturing processes in which mercury or mercury compounds are used. At the INC5 held in Geneva, Switzerland in January 2013, the draft text of the convention was agreed upon, and the name of the convention was officially decided to be the Minamata Convention on Mercury based on Japan's proposal.

◇ Hosting the Diplomatic Conference of the Minamata Convention on Mercury

In response to the decision at the INC5, the Diplomatic Conference of the Minamata Convention on Mercury was held in Kumamoto City and Minamata City on October 9, 10 and 11, 2013. More than 1,000 participants attended the conference, including government officials from 139 countries and regions, including cabinet minister level representation from more than 60 countries, as well as representatives from international organizations and NGOs. The Minamata Convention on Mercury was unanimously adopted and 92 countries and regions signed the convention. Japan hosted the conference and the then Minister of the Environment Nobuteru Ishihara chaired the diplomatic conference. The Minister for Foreign Affairs Fumio Kishida signed the convention and the Final Act of the diplomatic conference.

Based on the lessons of Minamata disease, Japan's determination to prevent such human health and environmental damage has led its active participation in the negotiation process. Actually, Japan hosted the diplomatic conference and signed the convention; the fact signifies the country's support for the convention and its determination to strengthen mercury control measures to the international community. At the opening ceremony held in Minamata City, Prime Minister Shinzo Abe, in his video message, pledged assistance from Japan and called for the eradication of harm from mercury. In line with the message, the Minister for Foreign Affairs announced a total of two billion US dollars over the next three years in assistance from Japan to support pollution control measures in developing countries, in the areas of air pollution measures, water pollution measures and waste treatment. The Minister of the Environment, who chaired the diplomatic conference, announced the "MOYAI Initiative" which aims at supporting developing countries in taking mercury management measures as well as disseminating information from Minamata.

◇ Domestic Measures for the Minamata Convention on Mercury

At the national level, the government established "the Coordination Meeting for the Promotion of International Mercury Management" consisting of the ministries and agencies concerned in 2010. The government aimed to facilitate coordination, etc. between the relevant ministries and agencies on Japan's position to the intergovernmental negotiations for the establishment of a legally binding document on mercury. In response to the adoption of the Minamata Convention on Mercury in October 2013, "the Coordination Meeting for the Conclusion of the Minamata Convention on Mercury"



consisting of the ministries and agencies concerned was then established in order to facilitate and accelerate discussions for the conclusion of the convention. The discussions are underway concerning the domestic measures to implement the convention through cooperation between the relevant ministries and agencies.

On March 17, 2014, the Central Environment Council was consulted on “future mercury management measures based on the Minamata Convention on Mercury” and the topic was discussed in the Environmental Health Committee, the Air Quality, Noise and Vibration Committee and the Sound Material-Cycle Society Committee. On May 23, 2014, the Working Group for Policy Development was established within the Chemical Policy Subcommittee in the Manufacturing Industry Committee of the Industrial System Council, in order to discuss measures to ensure the domestic implementation of the Minamata Convention on Mercury. As the scope of the convention includes various fields, it was decided that the emission of mercury into the air would be discussed at the Subcommittee for Measures to Control Mercury Emissions into the Air within the Air Quality, Noise and Vibration Committee, and the appropriate management of mercury waste would be discussed in the Expert Committee for the Consideration of the Appropriate Management of Mercury Waste within the Sound Material-Cycle Society Committee. It was also decided that other issues would be discussed at joint meetings of the Working Group for Policy Development in the Chemical Policy Subcommittee within the Manufacturing Industry Committee of the Industrial System Council and the Subcommittee for the Consideration of Measures for the Minamata Convention on Mercury within the Environmental Health Committee of the Central Environment Council. Discussions began in May 2014 and reports were summarized between December 2014 and February 2015.

Based on the reports, The Act on preventing Environmental Pollution on Mercury and the amendment of the Air Pollution Control Act were endorsed by the cabinet and submitted to the 189th Diet. Both acts were passed at the Diet session and promulgated in June 2015.

UNEP (the Interim Secretariat of the convention) expects that the convention will be entered into force in the period between 2015 and 2017. The Japanese government will continue to discuss domestic measures in preparation for the ratification of the convention and develop the relevant legislation.

Based on the national implementation plan, measures to prevent environmental pollution by Mercury will proceed comprehensively and systematically.

b) Promoting the Development of Assessment Methods, Their International Harmonization, Data Sharing, etc.
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#### The Status Quo

Various efforts are being made in order to promote the development of assessment methods, their international harmonization, data sharing, etc. New risk assessment methods are being developed because efficient and highly accurate risk assessment methods are required in order to facilitate risk assessments based on the CSCL.

The development, revision, etc. of OECD Test Guidelines and the OECD Principles of Good Laboratory Practice (OECD GLP Principles) are currently ongoing at the OECD. The OECD Test Guidelines aim to standardize test methods for chemicals and the OECD GLP Principles are used to set standards which should be met by facilities conducting tests. Efforts

are being made in Japan to achieve international harmonization by for example setting forth test methods, etc. that comply with the guidelines and principles.

The integration and analysis of data are also ongoing regarding the Japan Environment and Children's Study (JECS), etc. by taking into account the harmonization of the data with the results of surveys conducted by other countries.

## Efforts Being Made

### <The Development, etc. of Assessment Methods>

#### [The Development of Assessment Methods, Their International Harmonization, Data Sharing, etc. Based on the CSCL and Using OECD and Other International Frameworks] (MHLW, METI and MOE)

##### ◇ The Development of Risk Assessment Methods

New risk assessment methods are being developed such as the Quantitative Structure-Activity Relationship (QSAR) and toxico-genomics through international cooperation using the OECD and other frameworks. The MHLW implemented research from FY2012 to FY2014 using the Health and Labour Sciences Research Budget and other budgets. The aim is to put the QSAR and the categorical approach into practical use for the assessment of the risks chemicals pose to human health, as well as to include in the OECD guidelines the test methods for human health risk assessments which are required for the manufacture, etc. of New Chemical Substances based on the CSCL. The MOE is conducting research and development for KATE with the National Institute for Environmental Studies. The system is used to predict the ecological toxicity of chemicals. The trial version (KATE Ver1.0) was released in January 2008 and KATE 2011 was released in March 2011.

The government will continue to conduct the above-mentioned research in order to enable efficient risk assessments for evaluations that are conducted based on the CSCL.

##### ◇ The International Harmonization of Test Methods, etc. for Chemicals in Line with the OECD Test Guidelines and the OECD-GLP Principles

The government set methods for degradation tests, bioaccumulation tests and toxicity tests that comply with the OECD Test Guidelines as well as setting standards (GLP Standards) for test facilities which comply with the OECD-GLP Principles. The aim is to ensure the credibility of test data for New Chemical Substances, etc. and to enable exchanges of data between countries, based on the CSCL.

- “Test Methods concerning New Chemical Substances etc.” (Notice by the Director General of the Pharmaceutical and Food Safety Bureau 0331 No. 7; Notice by the Director General of the Manufacturing Industries Bureau No. 5 of March 29, 2011; Notice by the Policy Planning Division in the Environmental Health Department of the Environmental Policy Bureau No. 110331009 of March 31, 2011)
- “Standards for Test Facilities Used for Tests concerning New Chemical Substances and Others” (Notice by the Director General of the Pharmaceutical and Food Safety Bureau 0331 No. 8; Notice by the Director General of the Manufacturing Industries Bureau No. 6 of March 29, 2011; Notice by the Policy Planning Division in the Environmental Health Department of the Environmental Policy Bureau No. 110331010 of March 31, 2011)

The government conducts the screening of documents and inspections of test facilities when applicants want to have their compliance with the GLP Standards confirmed. The MHLW checks compliance with the GLP Standards for test facilities used to conduct tests

on toxicity, etc. Compliance at 31 test facilities has been confirmed as of March 2015. The METI checks compliance with the GLP Standards for the test facilities used to conduct degradation tests and bioconcentration tests, etc. Compliance at a total of eight test facilities (for degradation tests and bioconcentration tests, etc.) has been confirmed as of March 2015. The MOE checks compliance with the GLP Standards for the test facilities used to conduct ecological toxicity tests. Compliance at nine test facilities has been confirmed as of March 2015.

The government developed a database (commonly known as J-CHECK) through which the government publishes information on the evaluation of New Chemical Substances and chemical safety information. The government also shares information with relevant countries by creating an English website of J-CHECK and linking it with a global portal site (eChemPortal) operated by the OECD.

The government will continue to revise test methods where necessary, for degradation tests, bioaccumulation tests and toxicity tests which are conducted based on the CSCL, in light of the formulation and revision of the OECD Test Guidelines. The government will also promote the international harmonization of testing methods and testing facilities by checking the testing facilities for compliance with the GLP Standards. The government will also provide information to citizens, business operators, etc. in an easy-to-understand manner by appropriately utilizing the database.

#### **[The Development, etc. of Assessment Methods to Be Included in the OECD Test Guidelines] (METI)**

The OECD prepares and publishes the standard test methods used to check for risks posed by chemicals (test guidelines).

These test methods are widely used for various tests in OECD countries.

The METI is working to develop new simple chemical safety assessment methods and to have them included in the OECD test guidelines.

For the following test methods, research and development has been completed and Round Robin Tests are being conducted at multiple test laboratories with a view to including them in the OECD test guidelines.

◇ An in vitro carcinogenicity test (a transformation test method using Bhas42 cells)

The draft guidance document was submitted to the OECD and expected to be declassified as a new guidance document within 2015.

◇ A test method for endocrine-disrupting substances which uses binding assays for estrogen receptors (ER) or androgen receptors (AR) as well as reporter gene assays

Additional tests were conducted in response to issues pointed out at the OECD expert meeting. Other necessary activities are ongoing including the preparation of a verification report and responses to the OECD expert meetings.

In FY2014, draft guidelines were summarized for estrogen receptor binding assay and estrogen receptor reporter gene assay (antagonists), reflecting results of additional tests. The two test guidelines are to be publicized in 2015. For androgen receptors (AR) gene assay (agonists/antagonists) a necessary activities are ongoing for the preparation of the guideline.

**[The Development of Test Methods concerning the Endocrine-disrupting Effects of Chemicals] (MOE)**

(The content is omitted as it is the same as the content on page 24.)

**<Coordination of JECS with Surveys in Other Countries>  
[Japan Environment and Children's Study (JECS)] (MOE)**

◇ The Integration of Data with Other Similar Studies such as Large-scale Cohort Studies in Other Countries and the Analysis of the Data

(The content is omitted as it is the same as the content on page 53.)

<b>c) Promoting the Dissemination of Information on SAICM from Japan, International Collaborative Work, Technical Support and Other Efforts</b>
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i. **The Status Quo**

Regarding the promotion of the dissemination of information on SAICM from Japan, international collaborative work, technical support and other efforts, the government is making continuous efforts on information dissemination and sharing, including policy dialogues on chemical management in Asia and capacity building courses on chemical control measures. The government is also continuously making efforts on technology transfer and capacity building through technical cooperation projects which use bilateral cooperation frameworks as well as through the POPs Monitoring Project in East Asian Countries, among other projects.

In light of the adoption of the Minamata Convention on Mercury in October 2013, Japan is expected to contribute to the following activities: the promotion of the relevant international cooperation; support for developing countries; the measurement of mercury and the prediction of its concentration at the international level; as well as the promotion of international mercury control measures.

ii. **Efforts Being Made**

**<The Dissemination and Sharing of Information and Technical Support>  
[Policy Dialogues, etc. in Asia] (METI and MOE)**

“The promotion of information exchanges on policies and regulations concerning chemical management” was agreed upon at the Eighth Tripartite Environment Ministers Meeting (TEMM 8) held in December 2006. In response to the decision, the MOE has held “the Tripartite Policy Dialogue on Chemicals Management in China, Japan and Korea” every year since FY2007, with the aim of promoting information exchanges on policies and regulations concerning chemicals management in Japan, China and Korea.

The MOE has held “Workshop for Capacity Building on Chemicals Management in Asian Countries” every year since FY2011 to promote the capacity of chemicals management and to strengthen the capacity of chemicals management of government officials in Asia.

The METI signed the Memorandum of cooperation (MOC) with Thailand on August 30, 2012 and with Vietnam on July 15, 2012 in order to strengthen a risk-based chemical management system, by establishing Policy Dialogue on Chemical Management and implementing technical cooperation. With Vietnam, a second term of MOC was signed in July 3, 2015. Based on the MOCs, the METI is providing necessary information for system development and supporting capacity building to government officials and the industry in

Thailand and Vietnam with the cooperation of Japanese industry. The METI has also held “the Policy Dialogue on Chemical Management in Japan and Thailand” as well as “the Policy Dialogue on Chemical Management in Japan and Vietnam”, every year since 2012.

In addition, the government is gathering and sharing information on chemical control measures overseas via “the Network for Strategic Response to International Chemical Management” (<http://www.chemical-net.info/eng/index.html>), by disseminating information on the website and holding seminars, in order to strengthen the Japanese response to overseas trends in chemical control measures that have effects on economic activities in Japan. The Network for Strategic Response to International Chemical Management is managed by the chemical industry, corporate users of chemicals, relevant ministries and agencies, etc.

“The Eighth Tripartite Policy Dialogue on Chemicals Management in China, Japan and Korea” was held in Jeju Island in November 2014, and three countries exchanged views in regard to chemicals management policy in each country and exchanged information about the measurement of international trend of chemicals management and the conditions regarding ratification of the Minamata Convention on Mercury. It was agreed that the three countries will exchange information regarding the method of risk evaluation of existing chemicals and its result and the approach to ratify the Minamata Convention on Mercury in the next dialogue. A tripartite expert meeting was also held along with the Policy Dialogue and it was agreed that experts from the three countries will exchange information on cooperative research on acute fish toxicity test and non-animal test methods, such as QSAR.

Since 2011, MOE has been conducting workshops for capacity building to promote the capacity of chemicals management and to strengthen the capacity of chemicals management of government officials. “First Workshop on Environmental Chemical Risk/Pollution and Challenge in Indonesia” was held in Jakarta, Indonesia in February 2015 and “Fourth Workshop on Environmental Chemical Risk/Pollution and Challenge in Vietnam” was held in Hanoi, Vietnam in March 2015. In the workshops the countries exchanged view and information regarding chemicals management policies including evaluation and regulation of chemical substances and PRTR systems. It was confirmed that Japan will continue to cooperate with Indonesia and Vietnam on the improvement of chemicals management of the two countries.

The government will continue to hold policy dialogues and workshops for capacity building on chemicals management in Asia. Through these efforts, the government aims to coordinate and harmonize chemical evaluation and regulation systems in China, Japan and Korea as well as to promote capacity building for chemicals management in Asia, thereby contributing to achieving appropriate chemicals management in Asia.

#### **[Efforts through Official Development Assistance (ODA)] (MOFA)**

The Japan International Cooperation Agency (JICA) is conducting projects for the appropriate management of chemicals and waste in various parts of the world, as technical cooperation projects using bilateral cooperation frameworks.

Examples of JICA’s projects related to the appropriate management of chemicals include the following: (1) the International Training Course on Persistent Organic Pollutants of the Stockholm Convention (Brazil, 2011-2016); (2) the Development of Basic Schemes for PRTR System in Kingdom of Thailand (2011-2016); (3) Disseminations Agricultural Chemical Residue Analysis Techniques to Promote Environmental Protection (China, 2009-

2012); (4) the Project of Capacity Building for Analysis and Reduction Measures of Persistent Organic Pollutants in Serbia (2014-2017); and (5) the Project for Strengthening Chemicals Management in Vietnam (2015-2018). As issue-specific training, JICA also conducts training projects with the themes of “Risk Management and Residue Analysis of Chemicals for Environmental Safety” and “Chemical Management Policy: Reflecting International Discussion (from 2016, the theme will be “Chemical Management in the ASEAN”)” and “Capacity Building for the ratification of Minamata Convention on Mercury”. Examples of JICA’s projects related to the appropriate treatment, etc. of waste containing hazardous substances include the following: (1) Strengthening the Capacity for Solid Waste Management in Ulaanbaatar City (Mongolia, 2009-2012); and (2) Development of an Integrated Solution related to Industrial Waste Management in the Industrial Pole of Manaus (Brazil, 2009-2010).

As the next step, it is important to conduct projects which aim to develop systems where chemical management can be carried out while building the capacity of national chemicals-related institutions in the partner countries, because technical control measures for sources of release alone would be reactive and inadequate.

### **[The POPs Monitoring Project in East Asian Countries] (MOE)**

The Stockholm Convention requires that the Parties shall monitor the environment at the national and international levels (Article 11), and that they shall evaluate the effectiveness of the convention using the survey results (Article 16).

The POPs Monitoring Project in East Asian Countries sets background air monitoring points in East Asia as well as collecting and analyzing air samples, while also achieving technology transfer and capacity building. Workshops by inviting personnel in charge of the POPs monitoring in East Asian countries and experts from international organizations were held, in order to share and analyze data for the evaluation of the effectiveness of the convention, among other activities.

The project compiled a report on the POPs monitoring results in the Asia-Pacific region including Japan. Subsequently, the report to the Regional Organization Group (ROG), which was established at the Conference of the Parties to the Stockholm Convention in September 2014 in order to evaluate the effectiveness of the convention, was submitted.

The government will continue to conduct the above-mentioned activities in order to implement the Stockholm Convention appropriately.

### **[Facilitating the Early Entry into Force of the Minamata Convention on Mercury] (MOE)**

#### **◇ The Promotion of International Cooperation and Support for Developing Countries**

The ratification of the Minamata Convention on Mercury by 50 countries is needed before the convention enters into force. The ratification of the convention by more countries (particularly developing countries) is essential for the effective implementation of the convention. Therefore, Japan pledged the assistance to developing countries for the interim period (until the convention enters into force) at the INC5 held in January 2013 in order to support their preparations for the ratification of the convention. The government then contributed 1.75 million dollars to UNEP (which serves as the interim secretariat of the convention) by March 2015 to fulfil the pledge. Japan also supports the ratification of the convention by developing countries with its own training materials which aid the development of legislations and capacity building in preparation for the ratification and

implementation of the convention. MOEJ is cooperating with a new JICA training program called “Capacity Building for Ratification of Minamata Convention on Mercury” in 2014.

It is important to transfer Japan’s advanced mercury management technologies to emerging economies (particularly industrial countries and countries which use a large amount of mercury) to reduce the anthropogenic release of mercury. From this purpose, the Japan conducts feasibility studies to explore Japanese mercury management technologies and methods to other countries. In addition to the training materials which aid the development of legislations and capacity building in preparation for the ratification and implementation of the convention, training programs are also conducted.

The government will continue to support developing countries’ capacity building as well as promoting Japanese mercury control technologies to other countries.

◇ Promoting the Mercury Monitoring and Modeling at Global Level

Economies in the Asia-Pacific region are growing rapidly. Emissions of mercury from the region into the atmosphere account for a large portion of the global emissions, which may affect Japan. In order to contribute to international negotiations on the Minamata Convention on Mercury and the consideration of mercury management measures in the region, the government selected Cape Hedo in Okinawa as a background air monitoring station in FY2007 which is not directly affected by emissions in Japan. The government then started monitoring for the atmospheric mercury concentration (the background concentration), etc. The government also uses long-distance diffusion, transport and accumulation models in order to estimate environmental mercury concentrations and mercury emissions in the Asia-Pacific region, as well as predicting the effectiveness of emissions reduction measures (the reduction of mercury inflow to Japan, etc.).

The survey results have been published every year since FY2010, when it was confirmed its credibility based on the accumulated data. The data obtained so far have always been below the national guideline value for atmospheric mercury concentrations.

Another background air monitoring has started in Oga City in Akita in FY2014 in addition to Cape Hedo in Okinawa.

◇ Contributing to the Promotion of International Mercury Management Measures through the UNEP Global Mercury Partnership, etc.

The UNEP Global Mercury Partnership was launched in response to the resolution at the UNEP Governing Council session in 2005, as an effort to promote the voluntary reduction of the release of mercury by governments, NGOs, companies, etc. Various activities are currently conducted including pilot projects, awareness raising activities and the creation of guidance documents, in eight partnership areas including mercury waste management, mercury releases from the cement industry and reducing mercury in artisanal and small-scale gold mining.

Japan serves as the partnership lead in the area of mercury waste management. The government has been actively contributing to the mercury waste management partnership, by for example: holding the mercury waste management partnership area meeting in the Philippines in 2013; and leading the formulation of a document which compiled good practices for mercury waste management as a reference material that can be used by developing countries, etc. when they treat mercury waste. The government will continue to contribute to international mercury management measures via the partnership program in line with the discussions in the INC sessions, etc.

## IV. Future Activities Based on the Review of Efforts Being Made

It is important to steadily implement science-based risk assessment and risk reduction throughout the whole lifecycle while taking international trends into consideration such as the activities at the ICCM and the OECD, in order to achieve the WSSD2020 Goal which is the goal of SAICM National Implementation Plan of Japan. More specifically, it is necessary to endeavor to develop systems which facilitate the operation of the CSCL, the PRTR Law, etc. as well as continuing to make efforts to respond to emerging and uncertain issues based on the precautionary approach.

In order to encourage other relevant parties to take appropriate actions for risk reduction in addition to the government's efforts, it is necessary to promote the development of systems, etc. for sharing chemical information between the relevant parties, and implement proper information sharing with consumers, as well as to raise awareness and build trust through the further promotion of risk communication.

Regarding efforts for international cooperation and coordination, it is important to steadily promote domestic measures, etc. based on international conventions. It is also important for Japan to actively promote international efforts by for example contributing to discussions at the international conferences of the ICCM, the OECD, etc. as well as providing support for the early entry into force of the Minamata Convention on Mercury and supporting the promotion of chemical control measures in Asia.

Based on the above-mentioned approach, the Japanese government will take the following specific measures.

### <The Promotion of Science-based Risk Assessment>

◇ The government will continue to smoothly implement screening assessments for General Chemical Substances, etc. and risk assessments for PACs based on the CSCL, as well as checking the progress and conducting progress management appropriately at joint councils of the relevant ministries. As the appropriate operation of the CSCL requires the smooth implementation of ecotoxicological effect studies, the government will continue to develop and improve the systems for supplying the test organisms used for the studies, including birds and the benthic organisms required for detailed risk assessments, etc.

◇ The supplementary provisions of 2009 revision of the CSCL stipulate that the law shall be reviewed five years after the revision enters into force. The stipulations in the law will therefore be reviewed where necessary through close cooperation between the relevant ministries and agencies while taking into account progress in the implementation of the law.

In FY2015, the government plans to establish review meetings for preliminary review, consideration and summarization of issues regarding the situation in the enforcement of the CSCL.

◇ Regarding the development and utilization of new assessment methods such as the QSAR and toxico-genomics, the government will actively participate in the efforts made by the OECD including Adverse Outcome Pathways (AOPs<sup>15</sup>) which are being considered in other countries. The government will also utilize the outcomes of the efforts and continue to strongly push forward domestic efforts to develop and utilize these new assessment methods in Japan.

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<sup>15</sup> An Adverse Outcome Pathway (AOP): An analytical construct that describes a sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect. (Source: <http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>)



#### <Risk Reduction throughout the Whole Life-cycle>

- ◇ The government will promote chemical risk control measures effectively and comprehensively through close cooperation and coordination between the relevant parties. More specifically, the government will study and consider methods which enable risk assessments that take into account the whole lifecycle through cooperation between the relevant ministries, agencies and organizations. The government will aim to put them to practical use as well as efficiently utilizing various monitoring programs, etc. From the standpoint of further reducing environmental risk throughout the whole lifecycle of chemicals, from their manufacture to disposal, the government will aim to achieve seamless chemical management from their use to disposal. The government will also improve coordination with efforts being made by other relevant parties using the Policy Dialogue concerning Chemicals and the Environment and other opportunities.
- ◇ In order to complete the treatment of PCB waste as quickly as possible, the government will continue to promote efforts to find any pieces of equipment containing PCBs which have not been reported to prefectural or city municipal governments, among other efforts. The government will also strengthen cooperation between the relevant organizations including the MOE, JESCO, prefectural governments, city municipal governments, the METI and trade associations.

#### <Response to Emerging and Uncertain Issues>

- ◇ In order to promote risk assessments for the endocrine-disrupting effects of chemicals, the government will complete test methods that are currently under development as quickly as possible. The government will accelerate risk assessments in order to pave the way for future risk management.
- ◇ Regarding the combined effects of chemicals, the government will consider how it should evaluate the combined effects of chemicals as part of the environmental administrative activities by focusing on the similarities in the structures of substances and identical action mechanisms, while keeping track of trends in Western countries.
- ◇ Regarding nanomaterials, the government will deepen the knowledge on measurement methods for nanomaterials in the environment. The government will continue to consider how they should be handled in light of their effects on human health and ecosystems.
- ◇ Regarding the assessment of the effects of trace chemicals in the environment, the detailed mechanisms for the onset of the relevant symptoms are unclear. Therefore, an effective way forward would be to organize the findings obtained so far, summarize the types of disorders and establish diagnostic methods. The government will consider them while taking their feasibility, etc. into account.

#### <Strengthening of Safety and Security>

- ◇ The government will continue to hold the Policy Dialogue concerning Chemicals and the Environment and exchange opinions with participants with the aim of building consensus among the stakeholders and make policy proposals that ensure citizens' safety and security.
- ◇ It is essential that every participant should share the information regarding the toxicity of chemical substances and other for the appropriate management.

#### <The Promotion of International Cooperation and Coordination>

- ◇ The government will steadily develop domestic legislation for the ratification of the Minamata Convention on Mercury. In this process, the government will create a comprehensive mercury

control system in light of the fact that the convention contains a wide range of stipulations throughout the lifecycle of mercury from the mining of mercury and mercury compounds to their disposal. The government will also endeavor to introduce Japan's excellent mercury control technologies to other countries and contribute to the promotion of mercury control measures at the global level as a country which has experienced the Minamata disease.

Progress in the Implementation of  
SAICM National Implementation Plan of Japan

(Provisional Translation)

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