

**Review Results on SAICM National Implementation Plan  
of Japan**

**(March, 2020)**

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## Contents

<b>I.</b>	<b>INTRODUCTION .....</b>	<b>1</b>
<b>II.</b>	<b>HOW THE REVIEW OF SAICM NATIONAL IMPLEMENTATION PLAN OF JAPAN WAS CONDUCTED .....</b>	<b>2</b>
<b>III.</b>	<b>THE PROGRESS IN EFFORTS FOR EACH PRIORITY EXAMINATION AREA.....</b>	<b>3</b>
	<b>PRIORITY EXAMINATION AREA 1: THE PROMOTION OF SCIENCE-BASED RISK ASSESSMENT .....</b>	<b>3</b>
	(1) THE BASIC APPROACH TO ISSUES THAT W BE TACKLED .....	3
	(2) THE STATUS QUO AND THE EFFORTS BEING MADE.....	3
	a) The Promotion of Risk Assessment and the Setting of Target Values, etc. ....	3
	b) The Development and Utilization of New Methods in Order to Increase Risk Assessment Efficiency, etc. ....	23
	<b>PRIORITY EXAMINATION AREA 2: RISK REDUCTION THROUGHOUT THE WHOLE LIFE-CYCLE .....</b>	<b>28</b>
	(1) THE BASIC APPROACH TO ISSUES THAT SHOULD BE TACKLED .....	28
	(2) THE STATUS QUO AND THE EFFORTS BEING MADE.....	28
	a) The Appropriate Implementation of Regulations at the Stages of Manufacture, Import and Use of Chemicals, and the Promotion of Business Operators' Efforts*.....	28
	b) The Implementation of Measures at the Release of Chemicals into the Environment Stage, the Disposal Stage and the Recycling Stage.....	39
	c) Measures to Control Negative Legacies including Hazardous Chemicals Manufactured in the Past, Polluted Soil and Sediment .....	47
	d) Measures Taken in Cases Where Chemicals Have Been Released into the Environment via Accidents, etc. ....	52
	<b>PRIORITY EXAMINATION AREA 3: RESPONSE TO EMERGING AND UNCERTAIN ISSUES.....</b>	<b>55</b>
	(1) THE BASIC APPROACH TO ISSUES THAT SHOULD BE TACKLED .....	55
	(2) THE STATUS QUO AND THE EFFORTS BEING MADE.....	55
	<b>PRIORITY EXAMINATION AREA 4: STRENGTHENING OF SAFETY AND SECURITY .....</b>	<b>62</b>
	(1) THE BASIC APPROACH TO ISSUES THAT SHOULD BE TACKLED .....	62
	(2) THE STATUS QUO AND THE EFFORTS BEING MADE.....	62
	a) The Implementation of Various Types of Monitoring, etc. in Order to Provide the Basis for Safety and Security.....	62
	b) The Further Promotion of Risk Communication .....	68
	c) Efforts concerning Chemicals in Products .....	73
	<b>PRIORITY EXAMINATION AREA 5: THE PROMOTION OF INTERNATIONAL COOPERATION AND COORDINATION .....</b>	<b>78</b>
	(1) THE BASIC APPROACH TO ISSUES THAT SHOULD BE TACKLED .....	78
	(2) THE STATUS QUO AND THE EFFORTS BEING MADE.....	78
	a) Compliance with International Conventions and the Contribution to International Activities That Are Conducted Based on the Conventions .....	78
	b) Promoting the Development of Assessment Methods, Their International Harmonization, Data Sharing, etc.....	81
	c) Promoting the Dissemination of Information on SAICM from Japan, International Collaborative Work, Technical Support and Other Efforts .....	84
<b>IV.</b>	<b>FUTURE ACTIVITIES BASED ON THE REVIEW OF EFFORTS BEING MADE .....</b>	<b>89</b>



## **I. Introduction**

The Inter-Ministerial Meeting on Strategic Approach to International Chemicals Management (SAICM) National Implementation Plan of Japan (hereinafter referred to as the National Implementation Plan) will review progress in this plan and publish the results. When reviewing the progress of the National Implementation Plan, the government of Japan will also collect the opinions from relevant parties as well as public comments. The results of the review will be submitted to the SAICM Secretariat of United Nations Environment Programme (UNEP) before the fourth meeting of the intersessional process (hereinafter referred to as IP4) of SAICM, which is planned to be held in March 2020, and the fifth session of the International Conference on Chemicals Management (hereinafter referred to as ICCM5), which is planned to be held in October in the same year.

Based on the above decisions, the Inter-Ministerial Meeting on SAICM compiled the results of the review of the progress for the National Implementation Plan 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 was formulated, to December 2019. (For some plans, further progress is also included in the report.)

It was confirmed that almost all efforts concerning SAICM have progressed since the formulation of the National Implementation Plan of Japan. On the other hand, the objectives set in the National Implementation of Japan have some issues, and therefore the report points out how the relevant parties should improve their efforts in order to resolve these issues.

The National plans that will be replaced by the SAICM National Implementation Plan of Japan will be considered based on contents of a new international framework (Post SAICM), discussions on new issues, revisions to relevant national plans, other surrounding and socio-economic changes, and this draft's points.

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

“2. concrete 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 Action Plan of Action and discussions on “emerging policy issues” at the ICCM.

1. Promotion of science-based risk assessment
2. Risk reduction throughout the 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, “6. Issues to be examined in the future” were reviewed as part of other respective appropriate priority examination areas (1.-5.).

### 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

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, by taking advantage of its technical strength and through cooperation between the public and private sectors, Japan has strived to collect and utilize more hazard information and exposure information, upgrade various models and methods, and efficiently promote science-based risk assessment, as well as develop and practically apply new methods to do them. Japan will strive to continue those actions, and 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 Results of the Efforts

In order to tackle the above-mentioned issues and efficiently promote science-based risk assessment, the government has steadily promoted risk assessments based on the existing frameworks, and has developed new methods for risk assessment. 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**

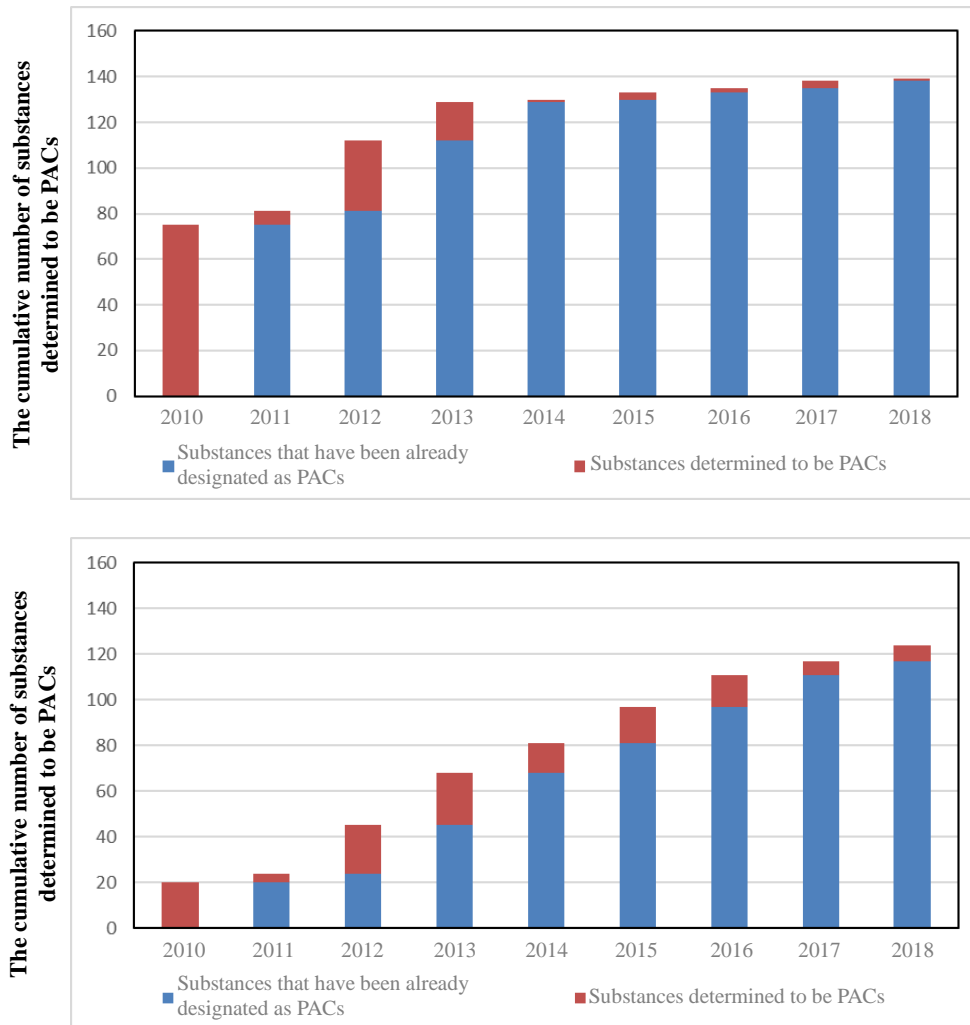
As part of the efforts to promote risk assessment for chemicals, the government has implemented assessments based on the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of October 16, 1973, hereinafter referred to as the Chemical Substances Control Law (CSCL)) and the Agricultural Chemicals Regulation Act (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, which is aimed at preventing environmental pollution by chemicals that may adversely affect human health and ecosystems. 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 FY2009, the government partially revised the CSCL in order to conduct comprehensive management of chemical substances. The revision requires the government to conduct screening assessments for General Chemical Substances, including the existing chemicals which were already being manufactured or imported at the time of enactment of the law in order to identify the chemicals which cannot be determined to be non-risk chemicals that cause damage to human health, the inhabitation of flora and fauna in the living environment, etc. via the environment, and designate them as Priority Assessment Chemical Substances (hereinafter referred to as PACs). The revision also requires the government to conduct risk assessments on the PACs by incrementally collecting information on them. 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 into the environment 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 the end of April in 2019, the number of substances designated as PACs was 223. The government has conducted step-by-step detailed risk assessments for the PACs, in which “Risk Assessment II (Primary)” for 72 PACs had been initiated by FY2018, and results of Assessment II for 32 PACs had been deliberated.

Figure 1 Changes in the Number of Substances which are determined to be equivalent to PACs in Screening Assessments under the CSCL (Limited to the deliberations until November 2018, and the quantities manufactured or imported by FY2016)

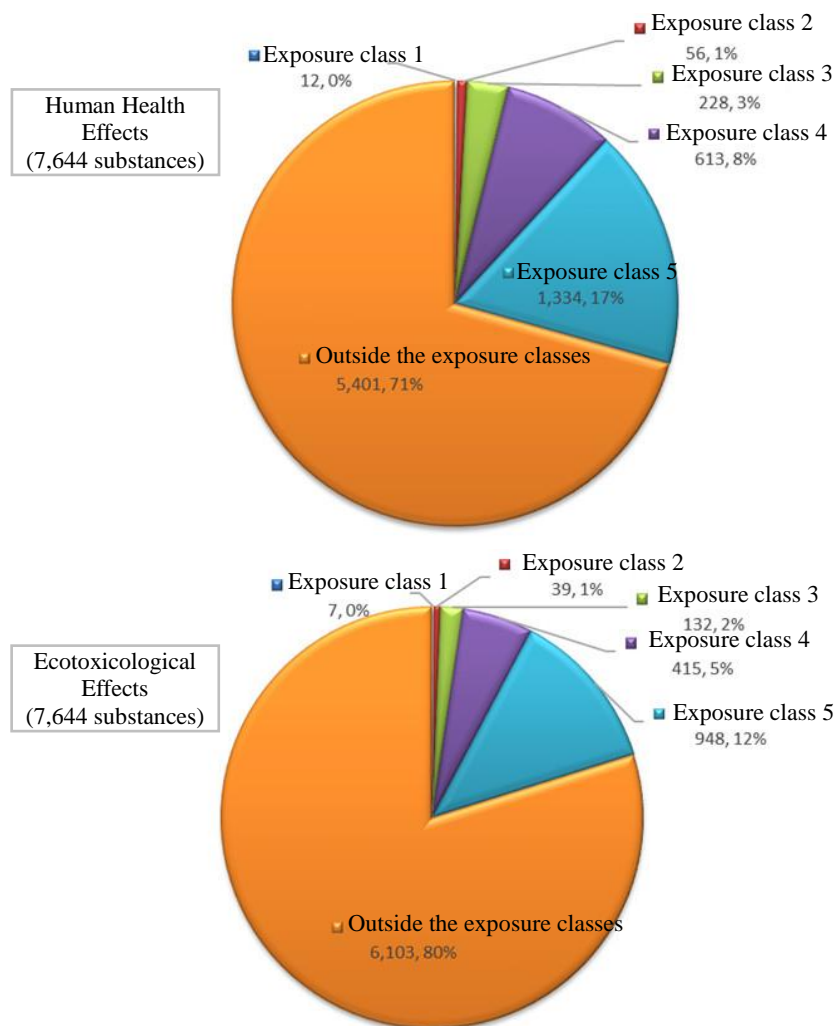
(Top: Human Health Effects, Bottom: Ecotoxicological Effects)



Source: Created by the MOE based on: “How to Conduct Screening Assessments and the Results of Assessments, FY2019” (FY2019 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; FY2019 the 4th Session of Chemical Management Measure Committee of Chemical Substance Council; the 199th Session of the Chemicals Evaluation Subcommittee, Environmental Health Committee, Central Environment Council.)



Figure 2 The FY2019 Results of the Screening Assessments for the Exposure Classes of Substances  
(General Chemical Substances produced/imported over 10 tons for FY2017)  
(Top: Human Health Effects, Bottom: Ecotoxicological Effects)



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

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.

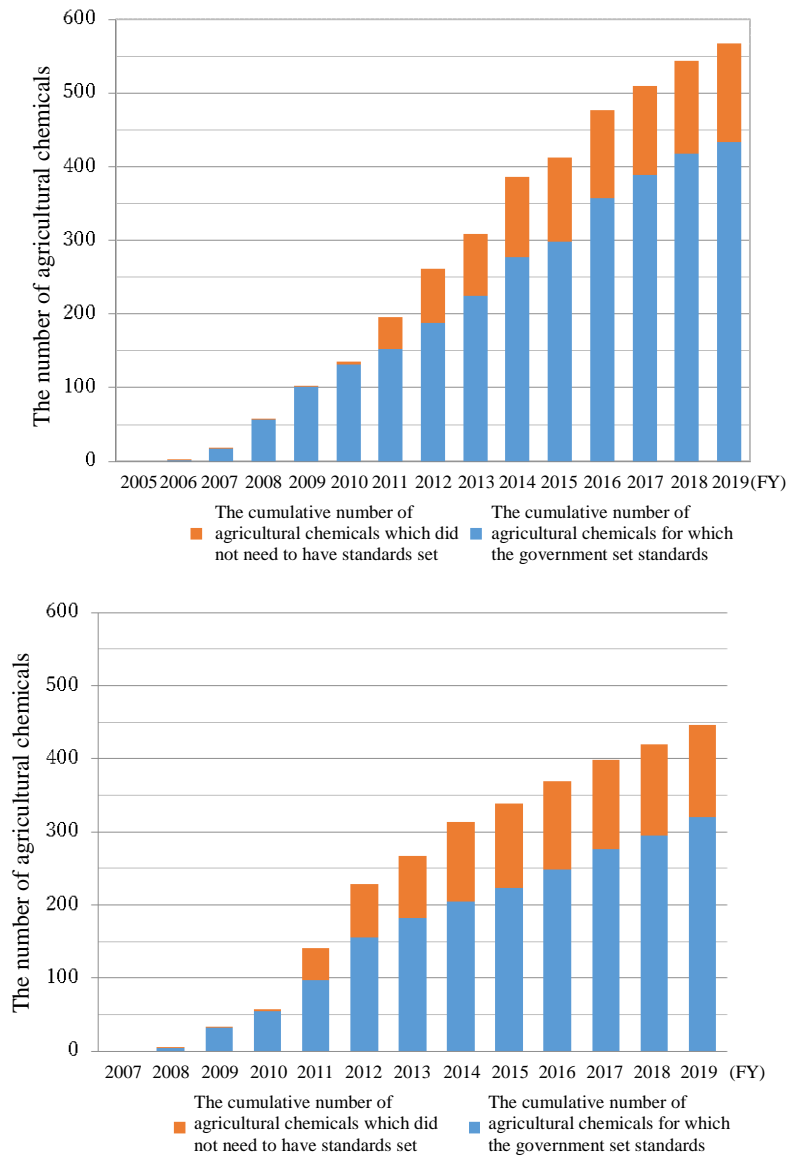
Source: Created by the Ministry of the Environment based on: “How to Conduct Screening Assessments and the Results of Assessments, FY2019” (FY2019 the 7th Session of the Subcommittee on Safety Assessment of Chemicals in the Committee on Chemical Safety in the Pharmaceutical Affairs Council of the Pharmaceutical Affairs and Food Sanitation Council; FY2019 the 4th Session of Chemical Management Measure Committee of Chemical Substance Council; the 199th 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 Act. The government has been improving the methods for setting Registration 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 for the setting of Registration Standards for Agricultural Chemicals regarding water pollution and the prevention of damage to aquatic plants and animals. As of January 2020, Registration Standards regarding the Prevention of Damage to Aquatic Plants and Animals were decided for 433 agricultural chemicals. It was decided that standards did not need to be set for 135 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 Standards regarding Water Pollution were decided for 320 agricultural chemicals. It was decided that standards did not need to be set for 126 agricultural chemicals, for the same reason as above.

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<sup>1</sup> Environmental risk assessments to target chemical substances consist of the following steps: (1) toxicity assessment to specify toxicity levels against human health and ecosystems, (2) exposure assessment to estimate exposure of chemical substances against human and ecosystems, (3) comparing the results of both assessments to assess the levels of risks

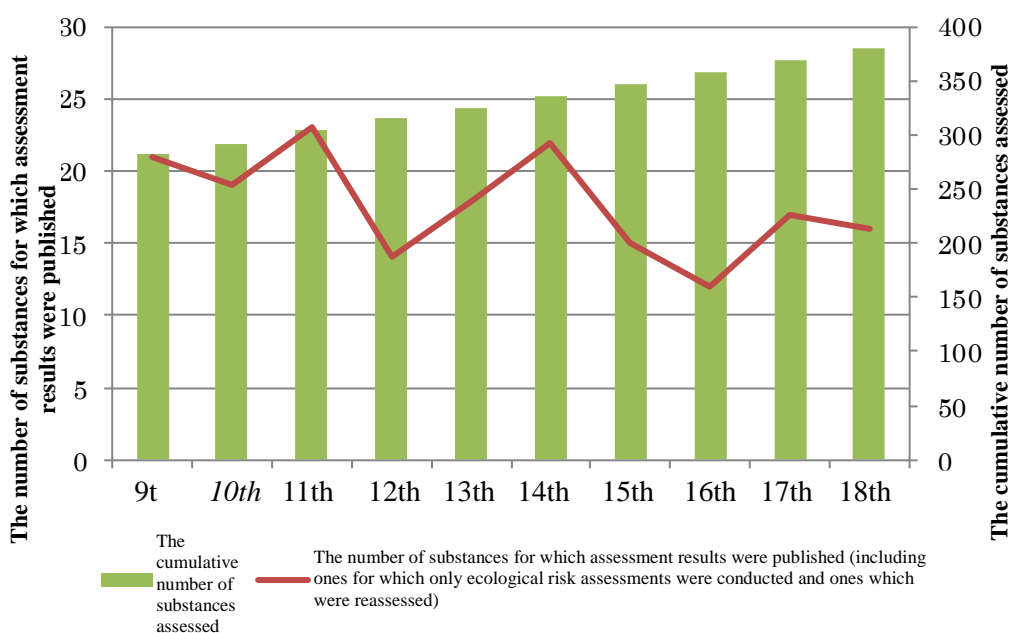
Figure 3 The cumulative number of agricultural chemicals' standards (blue bars) and ones which were set as 'not necessary to set standards' (red bars) regarding the Prevention of Damage to Aquatic Plants and Animals (Top) and Water Pollution (Bottom) (As of January 2020)



Source: "Recent administration on agricultural chemicals" (the 20th session to 31st session of the Soil and Agricultural Chemical Committee at the Central Environment Council, 2006 to 2019)

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 18th assessment (published in December 2019). 381 substances had been assessed by December 2019.

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 referred to the results of various surveys monitoring, etc. including the Environmental Survey of Chemical Substances, the hazardous air pollutant monitoring survey, the water quality measurement on public waters and ground water, and the Comprehensive Survey for the 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 “monitoring substances” (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 conservation of aquatic life. There are also 6 “monitoring substances” for the purpose of the conservation 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 FY2017, there were 11,801 General Chemical Substances for which the sum of the quantities manufactured and imported was one ton or more. Of those substances, there were 7,644 General Chemical Substances for which the sum of the quantities manufactured and imported exceeded 10 tons. In FY2019, the government conducted screening assessments for these 7,644 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., 4 substances were newly determined to be equivalent to PACs. The government again conducted screening assessments for the substances whose PAC designation had been revoked, taking into account hazard information that had been updated and scrutinized since the revoking of PAC designation, and redesignation of two substances as PACs was determined to be appropriate.

223 substances have been designated as PACs (as of April 1, 2019).

○ Risk Assessments for PACs

Risk assessments for PACs are roughly and basically classified into the following two stages according to hazard information: “Risk Assessment (Primary)” at the stage in which no data on long-term toxicity on PACs have been collected; and “Risk Assessment (Secondary)” at the stage in which data on long-term toxicity on PACs collected through the instruction of hazard study are available. “Risk Assessment (Primary)” is further classified into the following: “Assessment I,” in which an order of priority is fixed to conduct risk assessments using only reports on the quantities manufactured or imported as exposure information; “Assessment II” to determine applications and the like for requiring the reporting of information handled using the existing PRTR data and monitoring data in addition to the Assessment I data; and “Assessment III” to determine the instruction of hazard study using information handled, additional monitoring data, and the like in addition to the Assessment II data.

Based on the results of Risk Assessment I (Primary) released on March 20, 2018, the PACs of “Assessment I continuous” were designated and with the priority substances designated in FY2016, there were 152 chemical substances found for which the sum of the quantities manufactured and imported exceeded 10 tons. For these 152 substances, the government conducted Risk Assessment I (Primary) by using data from FY2016 (detailed shipment quantity by use, etc.) in FY2018. The government has launched the Risk Assessment II (Primary) for 72 substances, including FY2017 results.

As of November 2019, the Risk Assessment II (Primary) was deliberated for a cumulative total of 37 substances. Regarding another 3 substances, the designation as PACs was revoked on condition of monitoring their quantities. Although no assessment has been conducted for the remaining 32 substances, six of them are planned to be assessed after 2021 because their handling statuses need to be surveyed.

As the next step, with the aim of achieving the WSSD2020 Goal, the government will continue to 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 Act. Prior to registration, agricultural chemicals must be evaluated in order to find out whether they come under any of the items (i) to (xi) of Article 4, paragraph 1 of the Agricultural Chemicals Regulation Act. Agricultural chemicals can be registered only after being assessed and determined not to pose any risks.

○ Setting Registration Standards

Based on the stipulations of Article 4, paragraph 3 of the Agricultural Chemicals Regulation Act, the Minister of the Environment sets and announces standards (“registration standards”) concerning Article 4, paragraph 1, item (vi) (persistence in crops), item (vii) (persistence in soil), item (viii) (the prevention of damage to aquatic plants and animals) and item (ix) (water pollution), with the aim of preventing adverse effects on human health and aquatic plants and animals.

- With regard to the registration standards concerning persistence in crops, the registration of agricultural chemicals is rejected 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 Act (Act 233 of 1947). With regard to registration standards concerning persistence in soil, the registration of agricultural chemicals is regulated in accordance with their half-life in the soil.
- In order to review the official field experiment method for determining half-life to further improve the universality of the method, the registration standards concerning persistence in soil were deliberated at the Agricultural Chemicals Subcommittee of the Soil and Agricultural Chemicals Committee at the Central Environment Council. The registration standards were then revised on April 13, 2017. (Date of enforcement: October 13, 2017)
- Regarding registration standards concerning water pollution and the prevention of damage to aquatic plants and animals, the Agricultural Chemicals Subcommittee of the Soil and Agricultural Chemicals 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 for various reasons such as having no risk of escaping into water systems because of their dosage forms and how they are used. Table 1 shows the progress in the setting of these registration standards.

Table 1 The Setting of Registration Standards for Agricultural Chemicals

	The number of agricultural chemicals registered (1)	Standards were set (From FY2006 to FY2018)				No need to set standards (From FY2008 to FY2018)				Need to consider setting standards (1) - (2) - (3)
		(2)	FY2016	FY2017	FY2018	(3)	FY2016	FY2017	FY2018	
Standards for aquatic plants and animals	591	413	59	32	29	126	5	0	6	52
Standards for water pollution		295	26	27	19	124	4	2	2	172

\* The number of agricultural chemicals registered (1) indicates the total number as of the end of March 2019.

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

- To continue deliberating on agricultural chemicals without registration standards regarding water pollution or the prevention of damage to aquatic plants and animals.
- To establish risk assessment methods on birds and wild bees, following the enactment of the law Act for Partial Revision of Agricultural Chemicals Control Act (Act No. 53 of 2018) concerning which will expand the scope of risk assessment of agricultural chemicals to the flora and fauna in the living environment starting in FY2020.

## ○ Monitoring

The government is conducting the monitoring of agricultural chemicals in order to check whether the set standards are met in the actual environment.

- The government conducted monitoring at 11 sites nationwide (79 agricultural chemicals in total) in FY2016, at 4 sites nationwide (13 agricultural chemicals in total) in FY2017, and at 11 sites nationwide (19 agricultural chemicals in total) in FY2018. In each fiscal year, no monitored values exceeded their standards. Meanwhile, the number of agricultural chemicals, with the Predicted Environmental Concentration (PEC) close to the standards, has been increasing, and 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 is promoting efficient monitoring by considering priorities of monitoring in light of the quantities shipped as well as by developing simultaneous analysis methods for agricultural chemicals.
- With regard to registration standards concerning the prevention of damage to aquatic plants and animals, the government confirms that PEC, calculated using specific standard scenarios, does not exceed the standards, which are set based on the results of toxicity tests on fish, crustaceans and algae. The government, nevertheless, will also promote surveys on the impacts on aquatic life, etc. 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 18 times so far and published as “Profiles of the Initial Environmental Risk Assessment of Chemicals” (from vol. 1 to vol. 18. A total of 381 substances have been assessed). (23 substances in FY2012, 14 substances in FY2013, 18 substances in FY2014, 22 substances in FY2015, 15 substances in FY2016, 12 substances in FY2017, 17 substances in FY2018, and 16 substances in FY2019)

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 been assessed as “candidates for further work,” 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 No. 57 of 1972). If specific work processes pose particularly high risks of health impairment, regulatory measures are taken using special ordinances based on the Industrial Safety and Health Act, in accordance with the degree of risk, etc. Results of screening assessments by the CSCL has been used in order to select chemical substances as subject to the risk assessments since FY2018.

- 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.
- For use as basic data to conduct risk assessments for chemical substances in workplaces, the government created hazard assessment reports which assessed the hazard of chemicals.

(for 17 substances in FY2012, 28 substances in FY2013, 26 substances in FY2014, 25 substances in FY2015, 25 substances in FY2016, 14 substances in FY2017, and 35 substances in FY2018)

- 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. After FY2012, the government revised the Ordinance on Prevention of Hazards due to Specified Chemical Substances and other relevant ordinances. 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
  - FY2015: Naphthalene, and refractory ceramic fiber
  - FY2016: ortho-Toluidine, and antimony trioxide

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. Meanwhile, 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. Toxicity studies and other studies needed for ecotoxicological effect risk assessment were also conducted for chemicals, etc. which

are persistent and have other adverse properties as well as having a risk of impairing the inhabitation and/or growth of higher predatory animals.

- Ecotoxicity test was conducted to obtain measured values for chemical substances without predictive formula built-in to KAshinhou Tool for Ecotoxicity (KATE) to improve the accuracy and expand the coverage by KATE and category approach.

KATE is one of the model methods of Quantitative Structure-Activity Relationship (QSAR) used for ecotoxicity prediction measurement.

#### **[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 (surface water, sediment, wildlife and ambient 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)

The results for FY2017 are as follows:

##### ○ Initial environmental survey

- The survey was conducted for 15 substances, at 67 sites for water, 21 sites for sediment, and 13 sites for air.

##### ○ Detailed environmental survey

- The survey was conducted for 10 substances, at 77 sites for water, 38 sites for sediment, and 30 sites for air.

○ Monitoring survey

- The survey was conducted for 14 substances, at 47 sites for water, 62 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 using samples taken from humans (blood and urine), etc.

In the “Survey of the Exposure to chemical compounds in Humans,” which was conducted from FY2011 to FY2016, followed by the “Survey on the Accumulation of Dioxins and other chemical compounds in Humans,” which was conducted from FY2002 to FY2010, the government took blood samples and urine samples from 491 residents as well as samples of their food, in a total of 18 areas (three areas each year), and 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 conducted the survey for chemicals which need to be analyzed in light of domestic and international circumstances, etc., and revised 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. Since FY2017, the government has tested and compared various methods related to review of survey design and assurance of survey collaborators, and at the same time, analyzed chemical substances, including the biological samples that have been sampled and stored so far.

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 so on, 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 chemicals management by business operators and to prevent any impediments to the conservation 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. 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 impeding the inhabitation or growth of animals and plants. The government then collects the data as well as estimates the release amounts for chemicals which are not subject to reporting, and publishes thesedata.

These measures have been taken since FY2001 (the ascertainment of the amounts started in FY2001 and the publication of data started in FY2002). Since then, the government has been collecting 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 estimation of the 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. (Results, such as the total amount of release and the total amount of waste chemicals transferred to be treated from FY2012 to FY2018, are listed in Table 2.)

- When comparing FY2018 results with the results for the 2003 fiscal year started the current reporting requirement, the sum of the total amount of release and the total amount of waste chemicals transferred to be treated was reduced by 114,000 tons (-22.8%). Focusing on 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 141,000 tons (-29.0%). 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. The government seeks the other usage of the PRTR data. Since FY2018, the government has reviewed the PRTR Law.

Table-2 Results of the amounts of release and the amount of waste chemicals transferred to be treated based on the PRTR Law

Fiscal year of report (Fiscal year of emission)	Number of business establishments reported	Total amount of emission (thousand tons)	Total amount of waste chemicals transferred for treatment (thousand tons)	Sum (thousand tons)
FY2012 (FY2011)	31,117	175	226	402
FY2013 (FY2012)	36,940	164	222	386
FY2014 (FY2013)	36,321	161	216	377
FY2015 (FY2014)	35,874	159	225	384
FY2016 (FY2015)	35,512	155	221	376
FY2017 (FY2016)	34,795	152	225	377
FY2018 (FY2017)	34,253	152	235	387

**[Estimation of Amounts Exposed to Chemicals by Mathematical Model] (METI and MOE)**

Under the CSCL, risk assessments for scenario by emission source, exposure scenario according to application, and exposure scenario, including effects of various emission sources, are conducted using estimation models, such as PRAS-NITE, AIST-SHANEL, and G-CIEMS, based on data such as the amounts of manufacturing or import of chemical substances reported by the PTRR system or the CSCL.

The risk assessment results thus obtained are information for making a decision for comprehensive risk assessments, including comparative verification with monitoring data. They are also used as information to refine exposure information, such as information about sites that require additional monitoring.

**[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 FY2017 are as shown below.

- The values for benzene, trichloroethylene, tetrachloroethylene, and dichloromethane complied with environmental quality standards.

In FY2013, with regard to hazardous air pollutants, 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 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 Prevention Act (Act 138 of 1970) measure water quality as part of regular observations, based on the stipulations in the Water Pollution Prevention 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 FY2018, the ministry published the results in “Results of the FY2018 Water Quality Survey of Public Water Areas (Announcement) <December 24, 2019>.” 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 (conservation of aquatic life)

- The environmental quality standard achievement level for total zinc in category-designated water areas<sup>6</sup> (1,276 water areas) was 98.1% (97.8% in the previous fiscal year, for 1,234 water areas).
- The environmental quality standard achievement level for nonylphenol in category-designated water areas (1,187 water areas) was 100% (1,150 water areas in the previous year, 100%).
- The environmental quality standard achievement level for Linear Alkylbenzene Sulfonic acid and its salts (LAS) in category-designated water areas (1,132 water areas) was 99.6% (1,105 water areas, 99.7% in the previous fiscal year)

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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.

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

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

Regarding groundwater quality, local governments and the ordinance designated municipalities which are stipulated in the Water Pollution Prevention Act measure water quality as part of regular observations, based on stipulations in the Water Pollution Prevention 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 FY2017, the ministry published the results in “FY2017 Measurement Results for the Quality of Groundwater (Announcement) <December 25, 2018>.” 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 FY2017, environmental quality standards were exceeded at 5.5% 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 818 wells in FY2017 (1,064 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 4,313 wells in FY2017 (4,372 wells in the previous fiscal year).

The government will continue to compile reports on the results of regular observations conducted by local governments, ordinance designated municipalities stipulated in the Water Pollution Prevention 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 in September 2012. In January 2019, the government revised the guideline values for xylene, di-n-butyl phthalate, and di-n-ethylhexyl phthalate in line with the discussions in the meetings that had been called so far. The government will continue to have discussions to set new Air Quality Guideline Values based on the latest findings.

**<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.

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 also 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. In FY2017, an expert committee at the Central Environment Council launched discussions on the reassessment of the environment quality standard for trichloroethylene. Based on the report compiled in September 2018, the standard was revised in November 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 conserve aquatic life. Environmental quality standards have also been set for 28 items regarding groundwater pollution.

There are also monitoring substances, 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 monitoring substances 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 conservation of aquatic life. In addition, three items including 4-t-octylphenol were added to monitoring substances.
- 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 0.03 mg/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 leachate 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 FY2014, 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.

- In FY2013, the revision of soil environmental quality standard for 1,1-dichloroethylene was deliberated and the soil environmental quality standard for 1,1-dichloroethylene was revised.
- The government launched deliberation on the setting of the soil environmental quality standards for 1,4-dioxane and chloroethylene in FY2014, and set these standards in FY2015.

- In FY2018, the government deliberated the revision of the soil environmental quality standard for 1,2-dichloroethylene, and decided that cis-1,2-dichloroethylene would be collectively counted with trans-1,2-dichloroethylene as 1,2-dichloroethylene.
- In FY2019, the government is deliberating the revision of the soil environmental quality standards for cadmium and trichloroethylene.

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

(The content is omitted as it is the same as the content on page 20.)

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

#### **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 category 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.

- In order to efficiently conduct risk assessments for tens of thousands of the existing chemical species, the government is subsidized the research and development on the assessment strategy based on the advancement and practical application of in-silico approaches, such as QSAR and category approach. For example, in FY2018, with regard to Ames test QSAR, the government made efforts, such as implementation of an international challenge project with the aim of increasing prediction accuracy using a large-scale database, digitization of Ames test reports, and detailed databasing of information.
- Based on the high-accuracy toxico-genomics database and toxicity network analysis technique in the case of single exposure, the government is subsidized the research on conducting network analysis in the case of repeated exposure, developing its prediction assessment technique, and constructing a comprehensive toxicity prediction assessment system which incorporates the concept of system toxicology.

- As the project of the Health and Labour Grants-in-Aid for Scientific Research, the government subsidized the research on the improvement of prediction accuracy of Ames test by QSAR (conducted by National Institute of Health Sciences). The MHLW supported the accuracy improvement of databases by providing data on test results submitted from 1986 to 2015 in conformity with the notification system, which requires an employer that seeks to manufacture or import a new chemical substance to file a notification of the name of the new chemical substance and the result of the assessment of the potential for harm, under the Industrial Safety and Health Act.

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 trial version (KATE Ver1.0) was released in January 2008. “KATE 2011” was released in March 2011. The trial version of KATE 2017 was released in March 2018. The formal version of KATE 2017 was released. The MOE is preparing to enable KATE from the OECD QSAR Toolbox by API (Application Program Interface). Currently, when the structural formulas, etc. of chemicals are entered into the system, KATE predicts the following: The median lethal concentration for the Fish Acute Toxicity Test; the median effective concentration for the Daphnia Acute Toxicity; the median effective concentration for the Algae Acute Toxicity; no observed effect concentration for the Fish Chronic Effect; no observed effect concentration for the Daphnia Chronic Toxicity; and no observed effect concentration for the Algae Chronic Effect. Business operators engaged in chemical management can also 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.

○ Repeated Dose Toxicity Prediction System Associated with Human Health (AI-SHIPS)

In order to develop a toxicity assessment method substituted for animal testing, the METI has been conducting the research and development project called “Evaluation Technology & Development Project for Energy-saving Electronic Device Materials (Development of High-speed and Efficient Safety Assessment Technology Supporting Society’s Implementation of Functional Materials)” (commonly known as the AI-SHIPS project), which spans a period of five years, from FY2017 through FY2021. This project is aimed at not only clarification of the relationship between the structures of the existing chemical substances and their toxicity, but also development of an assessment method based on toxicology mechanism through elucidating the pathway of the onset of toxicity by conducting in vitro tests.

○ Hazard Evaluation Support System Integrated Platform (HESS)

In the METI’s contract research project “Development of Hazard Evaluation Method Using Structure-Activity Relationship Methods (FY2007 to FY2011),” the National Institute of Technology and Evaluation (NITE) and others developed “HESS,” a platform that supports read-across evaluation of repeated dose toxicity. As HESS was developed in collaboration with OECD’s QSTAR Toolbox, part of the tools and databases built-in to HESS are built in to the QSAR Toolbox, and used in the REACH regulation in Europe. HESS was released to the public on the website of NITE in June 2012, and is used by business operators for purposes such as assessments in the stage of screening chemicals under development.

○ Utilization, etc. of Bioaccumulation Predication System

With regard to bioaccumulative properties of chemical substances, there are prediction systems that are widely used around the world, such as BCFBAF (EPI SUITE) and BCS base-line model (OASIS Catalogic). Utilization of these systems is demanded for bioaccumulation assessment in the CSCL. Under these circumstances, in collaboration with NITE, the METI developed an efficient assessment method based on a combination of the above-mentioned systems and information on analogous substances with known bioaccumulative properties. This method is applied to bioaccumulation assessment for chemical substances.

The METI is considering enhanced use of QSAR in order to accelerate efficient assessment of chemical substances.

○ Utilization, etc. of degradability prediction system

With regard to degradability of chemical substances, there are prediction systems that are widely used around the world, such as BIOWIN (EPI SUITE) and Catalogic (OASIS Catalogic). Utilization of these systems is demanded for degradability assessment in the CSCL. Under these circumstances, in collaboration with NITE, the METI developed an efficient assessment method based on a combination of the above-mentioned systems and information on analogous substances with known degradability properties. This method is applied to degradability assessment for chemical substances. Shizuoka University initiated development of AI-based degradability prediction QSAR in cooperation with NITE in a contract research project initiated by the METI in FY2018.

**[Consideration of Upgrading of Toxicity Test Methods for Higher Predatory Animals]**

Under the CSCL, for the purpose of designation of Class I Specified Chemical Substances from the standpoint of biotoxicological effect, if the government determines by a preliminary assessment method that a Monitoring Chemical Substance candidate for a Class I Specified Chemical Substance is suspected of having long-term toxicity for higher predatory animals, the government can instruct business operators to conduct a hazard assessment of the chemical substance, where necessary. The government is considering preliminary toxicity assessment methods that support the government's determination for instructing hazard assessments. In FY2018, in order to establish toxicity assessment methods, the government conducted preliminary tests on long-term toxicity on birds, and verified bioaccumulative properties of chemical substances in birds by persistent or highly concentrated chemical substances.

**[Consideration of Test Methods of Difficult Substances for Ecotoxicity Test]**

The CSCL requires the government to conduct risk assessments for all chemical substances for industrial use and take necessary actions, where necessary, according to assessment results. However, insufficient progress has been made toward assessments for toxicities whose assessment methods are not established internationally, such as assessments for substances to which biotoxicological tests for aquatic plants and animals stipulated in the CSCL are inapplicable, and toxicity tests using benthic organisms. Therefore, the government is considering these assessments. Recently, the government has been conducting experimental considerations for the establishment and international standardization of a test method using Gammaridea.

**[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 concerning Agricultural Chemicals and Consideration for the Advancement of Assessment Methods] (MOE)**

Regarding agricultural chemicals, the government is collecting information on efforts made by other countries and efforts made based on other laws and regulations, with the aim of developing new methods for risk assessments and risk management targeting organisms other than aquatic plants and animals, as well as their populations and ecosystems as a whole. In addition, the government is promoting the following activities.

##### ○ The Development of a Tool to Select Biodiversity-friendly Agricultural Chemicals and Their Usage

In the current risk assessments for agricultural chemicals, tests are conducted using fish, algae, and Crustacean species, etc. 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 developed a mesocosm experiment method which can assess the impacts of agricultural chemicals on communities endemic to local areas in Japan, and formulated a manual for the risk assessment method. Since the static mesocosm experiment method described in the manual permits an ecological assessment of the impact of agricultural chemicals on biodiversity, the method is most suitable as the tool that assists in selecting the biodiversityfriendly agricultural chemicals for each area and the usage for the selected substances.

##### ○ The Establishment of Risk Assessment Methods for Aquatic Ecosystems Using Statistical Methods

In the current agricultural chemical registration system, risk assessments concerning agricultural chemicals on aquatic ecosystems are being conducted using toxicity tests and standard environmental models for aquatic lives, such as fish, algae, crustacean, etc. 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 regional differences, among others, 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.

By FY2018, regional variations in the PEC had been estimated, and species sensitivity differences for fish and hydrophytes had been analyzed.

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

#### **[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 among the developed countries, and some of them are being adopted as Test guidelines (TG) at the OECD.

Japanese government aims to develop test methods using fish, amphibians, etc. aiming at establishing internationally standardized ones at the OECD.

In 2009, the following two tests were adopted as the OECD test guidelines.

- TG229: Fish Short Term Reproduction Assay (revised in 2012)  
To assess effects of chemicals on fish, including estrogenic 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 adopted as the OECD test guidelines.

- TG234: Fish Sexual Development Test  
To assess effects of chemicals on fish, including estrogenic 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, (MEOGRT)  
To assess the effects of chemicals on reproduction of killifish, including estrogenic and anti-estrogenic effects.
- TG241: Larval Amphibian Growth and Development Assay (LAGDA)  
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 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

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.

In addition, 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, and 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 Results of the Efforts

In order to tackle the above-mentioned issues, the government has made 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 has also taken measures to control contaminated soil and hazardous chemicals manufactured in the past, as well as prepared 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, contaminated soil and sediment
- d) Preparation for accidents, etc.

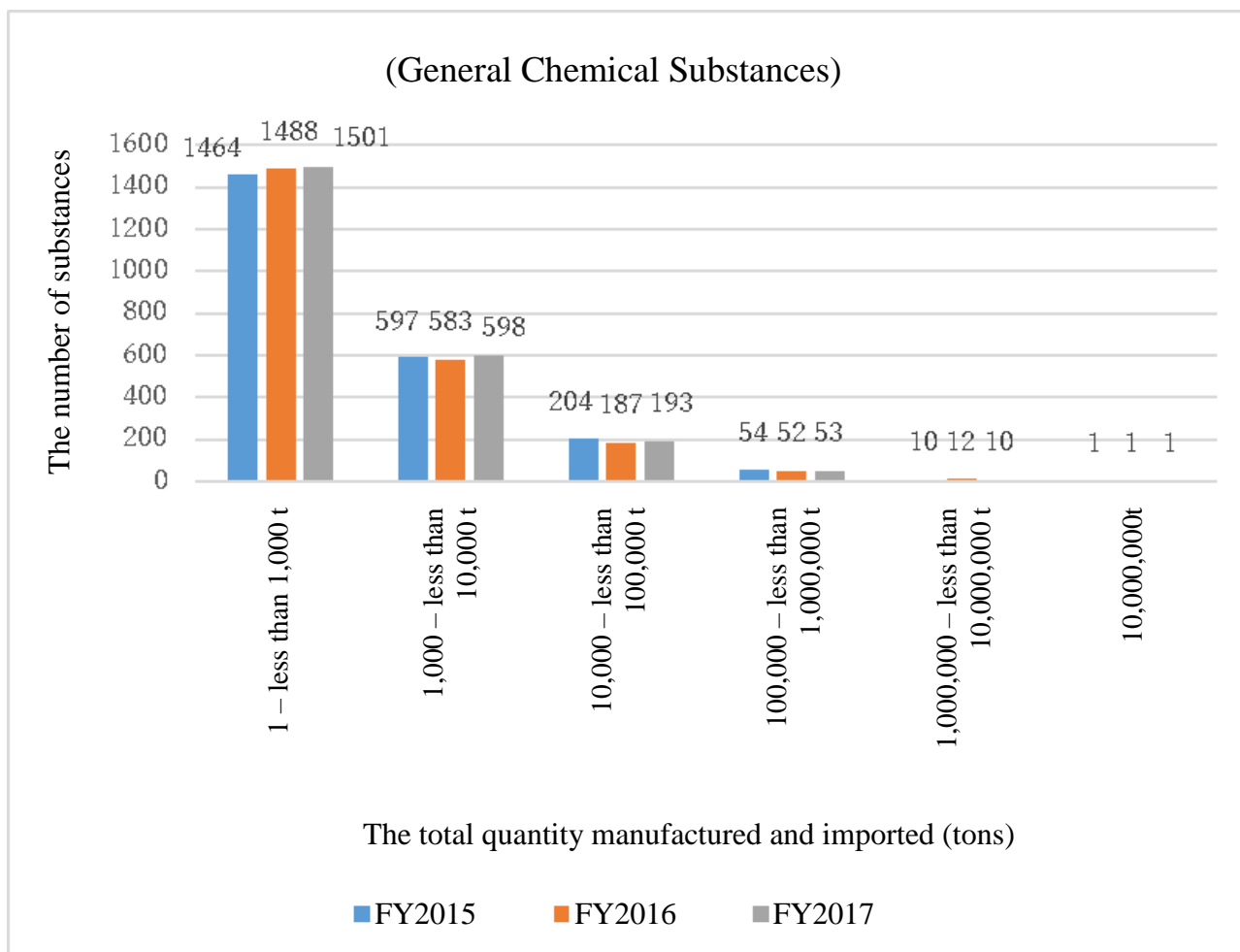
a) The Appropriate Implementation of Regulations at the Stages of Manufacture, Import and Use of Chemicals, and the Promotion of Business Operators' Efforts*
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#### **The Status Quo**

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 Act, respectively.

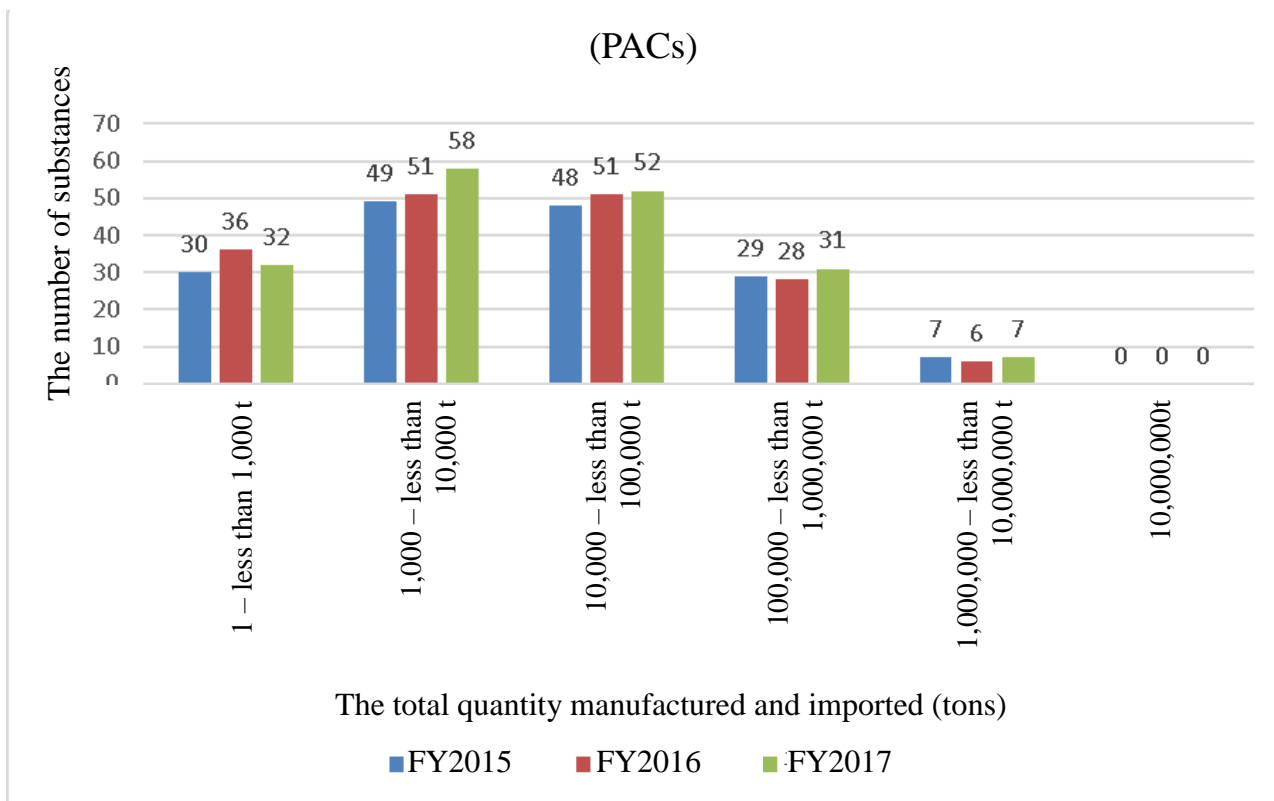
Figure 5 shows the notified numbers of chemicals categorized by the total quantity manufactured and imported, for "General Chemical Substances," "PACs" and "Monitoring Chemical Substances" which are stipulated in the CSCL. Figure 6 shows changes in the shipment quantities of agricultural chemicals stipulated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

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

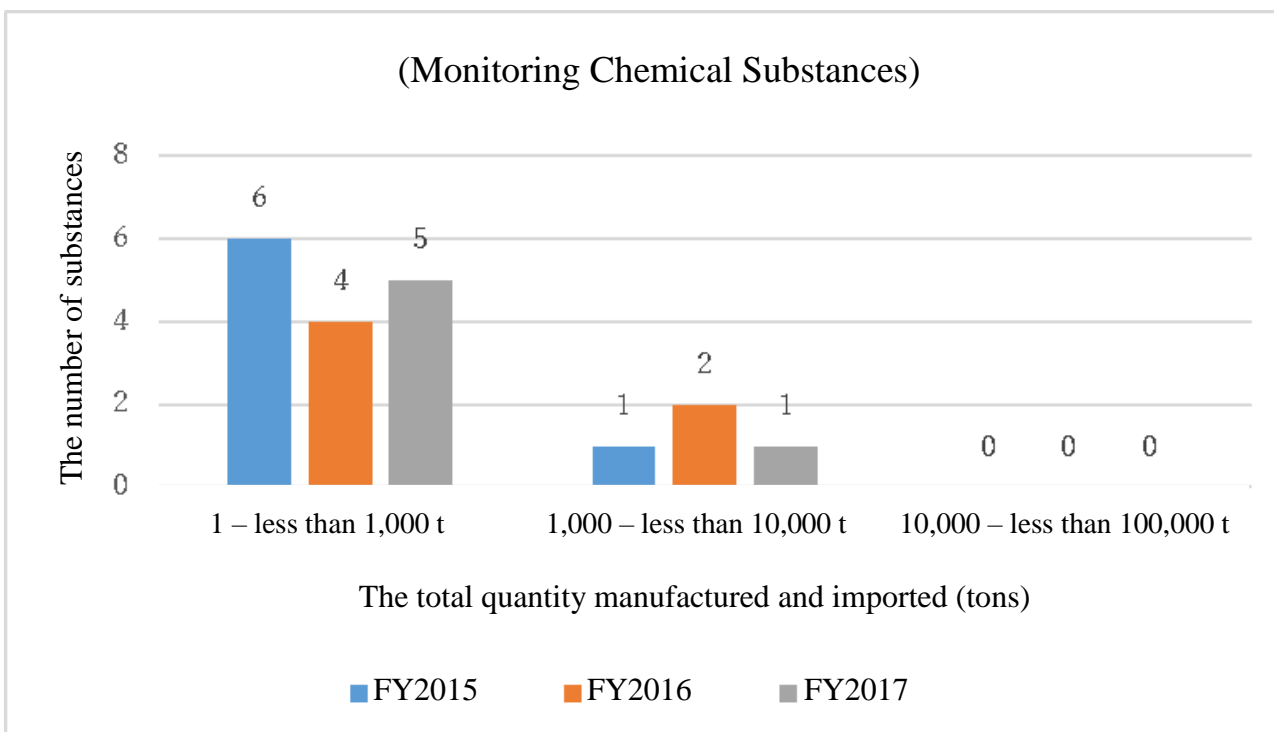


Note: Business operators who manufacture or import one ton or more of a General Chemical Substance in a year are required to report the quantity. The horizontal axis of the Figure shows the total quantity calculated and the vertical axis shows the number of substances which come under each quantity class.





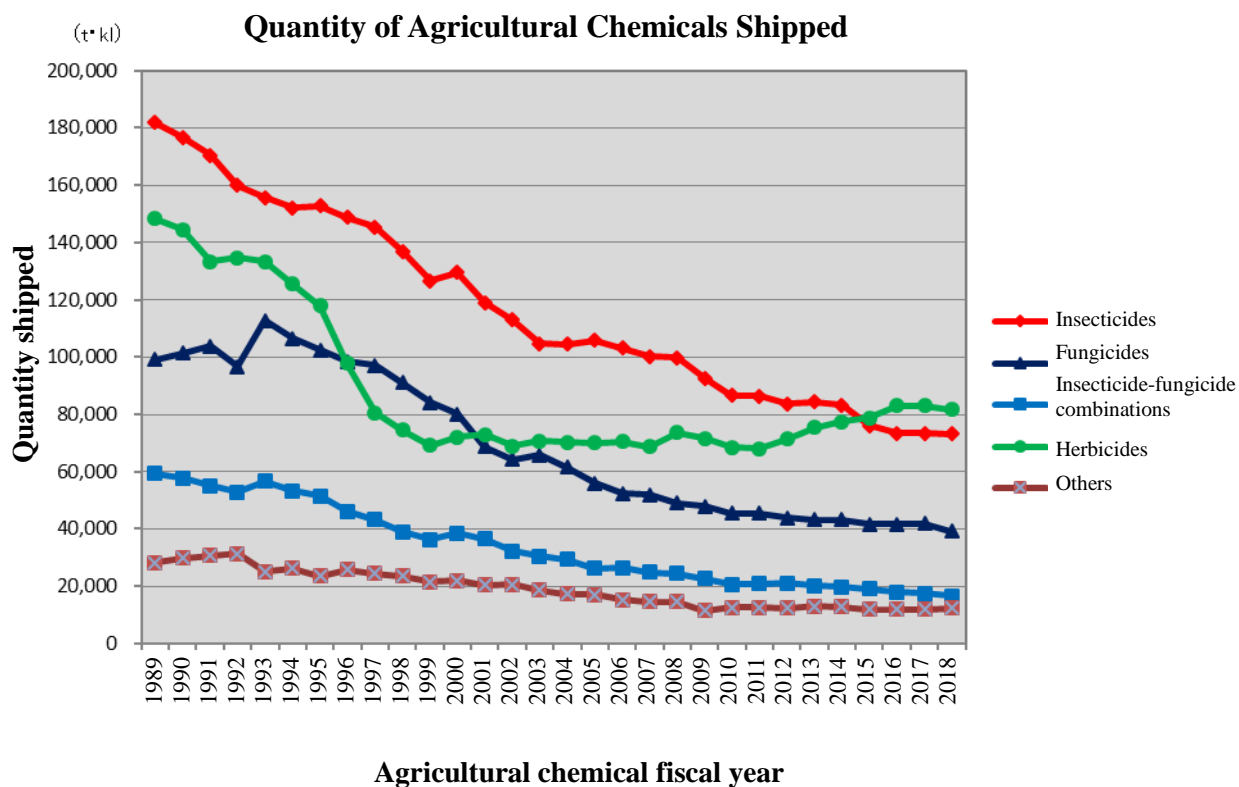
Note: Business operators who manufacture or import one ton or more of a priority chemical in a year are required to report the quantity. Every fiscal year, the government publishes the total quantities manufactured and imported for PACs whose total quantity is 100 tons or more. The horizontal axis of 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  
[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/volume\\_index.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/information/volume_index.html)

Figure 6 Changes in the Quantities of Agricultural Chemicals Shipped (from 1989 to 2018, in the Agricultural Chemical Fiscal Year)



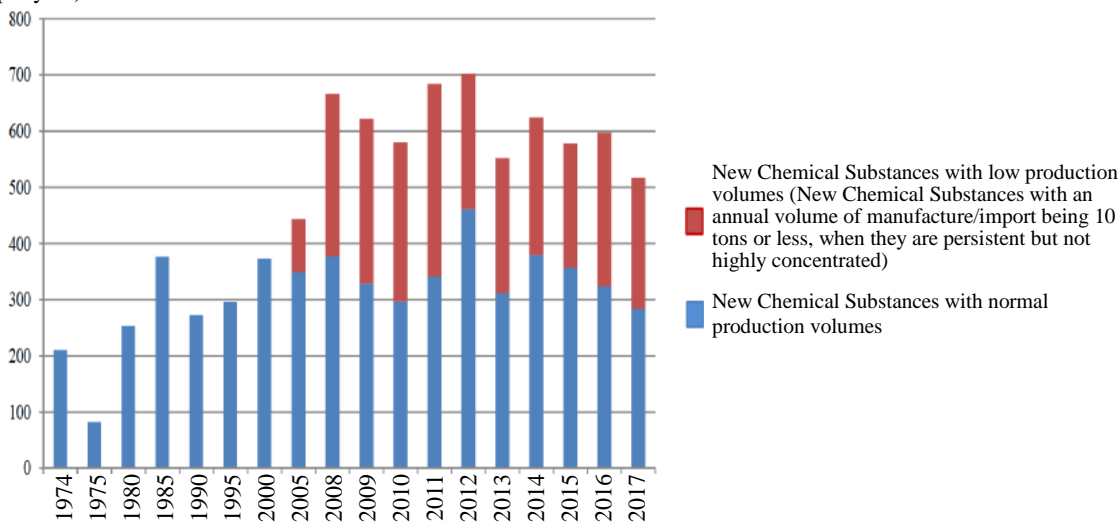
Agricultural Chemical Fiscal Year: October of the previous year to September of the current year

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 7 shows the number of reports regarding New Chemical Substances submitted to the government based on the CSCL. Figure 8 shows changes in the number of Small-quantity 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

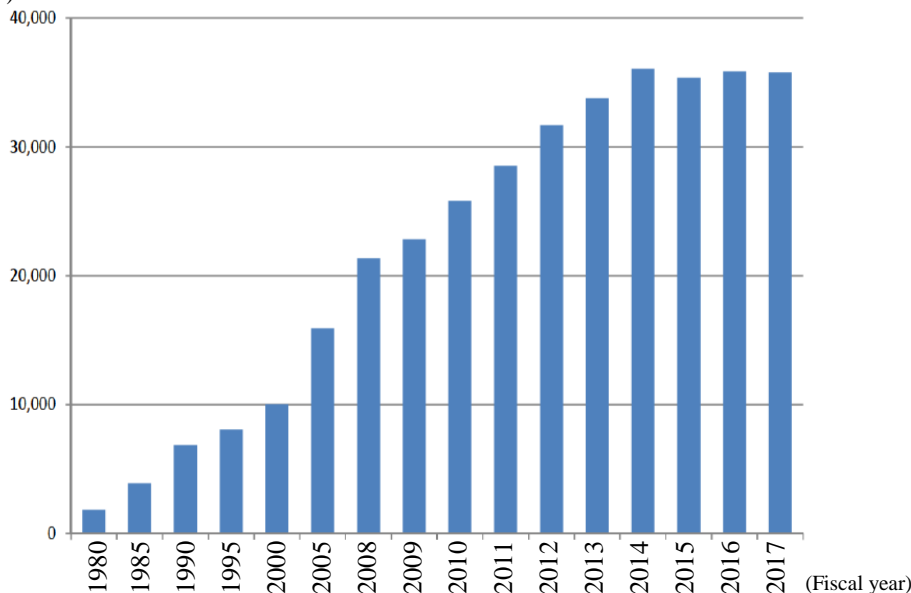
The number of notifications submitted  
(the number per year)



(Calendar years were used up to 2011 and fiscal years were used from 2012.)

Figure 8 Changes in the Number of Notifications regarding Small-quantity New Chemical Substances reported

The number of notifications submitted  
(the number per year)



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.

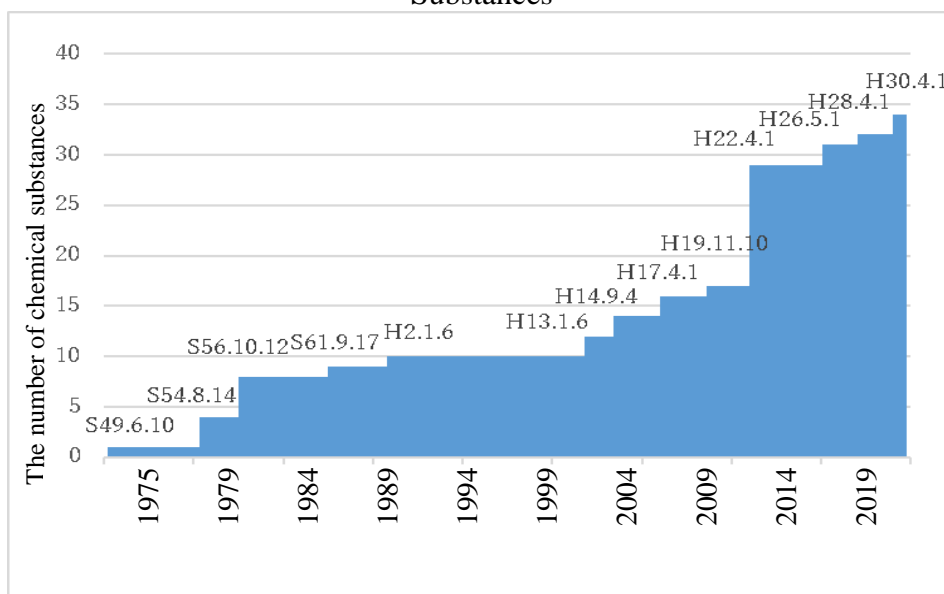
Note 2. Small quantity New Chemical Substances: They are New Chemical Substances with quantities manufactured/imported nationwide in a fiscal year being one ton or less. The submission of hazard information, etc. for the chemicals is not required when their manufacture/import is to be reported to the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

Source The website of METI

([https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/information/sekou/sekou\\_h29.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/information/sekou/sekou_h29.pdf))

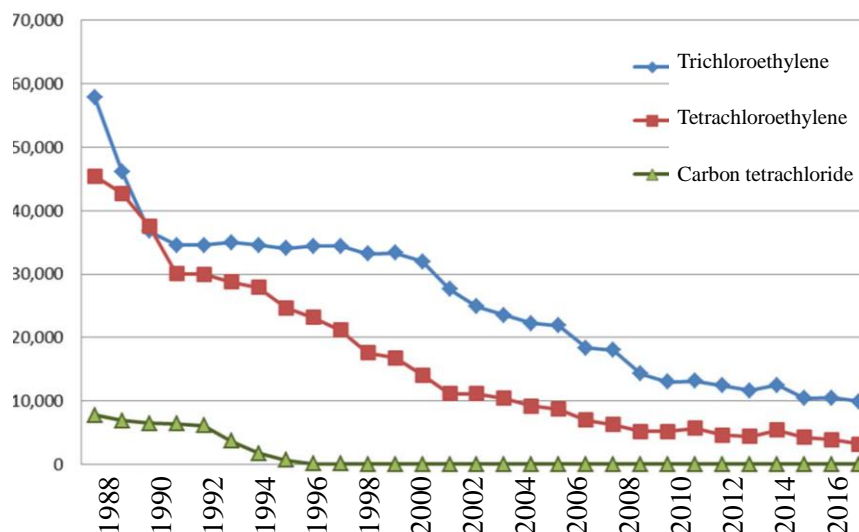
Figure 9 shows the designation statuses of Class I Specified Chemical Substances based on the CSCL. A substance whose persistence, bioaccumulative property and long-term toxicity have been confirmed is designated as a Class I Specified Chemical Substance. Their manufacture, import and use are banned 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 33 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 10 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.

Figure 9 Changes in the Number of Chemicals Designated as Class I Specified Chemical Substances



Source: MOE

Figure 10 Changes in the Quantities of Class II Specified Chemical Substances Shipped (Except for Shipment for Export and Shipment as Intermediates)



Source: The website of the METI  
[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/information/sekou/sekou\\_h29.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/information/sekou/sekou_h29.pdf)

**<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., The CSCL was partially revised in FY2009, and a comprehensive management system including the management of the existing chemical substances has been introduced since FY2011. In the revision of FY2017, the upper limits of the national amounts stipulated in the system for exceptions in cases of evaluations of small-quantity or low-production volume New Chemical Substances were revised, and control on highly toxic chemical substances among General Chemical Substances was tightened. The following activities have been conducted based on the law.

- The number of reports and requests regarding New Chemical Substances submitted
  - 555 notifications on New Chemical Substances were submitted in FY2018.
  - 36,304 notifications regarding small quantity New Chemical Substances were submitted in FY2018.
- The designation of substances to be regulated, etc. (as of April 1, 2019)
  - Class I Specified Chemical Substances: 33 (PCBs, etc.)
  - Class II Specified Chemical Substances: 23 (trichloroethylene, etc.)
  - Monitoring Chemical Substances: 38 (Tetraphenyltin, etc.)
  - PACs: 223 (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 Act] (The Ministry of Agriculture, Forestry and Fisheries (MAFF) and the MOE)**

- Setting Registration Standards  
(The content is omitted as it is the same as the content on pages 11 to 12.)
- Monitoring  
(The content is omitted as it is the same as the content on pages 13.)
- 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 FY2018, in order to further enhance the safety of agricultural chemicals, the Agricultural Chemicals Regulation Act was revised, through which the system for re-evaluation of the safety of agricultural chemicals was introduced, and the examination on the safety of agricultural chemicals was improved, among others. 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, safety precautions with the methods of use are displayed 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 conducts “the Campaign Against Incidents Caused by Agricultural Chemicals” for three months (from June to August) every year.
- In April 2013, the government revised “the Notification on Use of Agricultural Chemicals in and around Residential Areas.” (jointly issued by the director generals of the MAFF and 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 March FY2018, the MOE revised “the Manual for the Control of Pests and Weeds for Park and 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: 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 and damage to aquatic plants and animals, the MOE formulated guideline values for water pollution and guideline values for aquatic plants and animals and gives guidance so that the concentrations of agricultural chemicals in discharged water do not exceed these values. It also conducts surveys in order to check whether the actual agricultural chemical concentrations in discharged water exceed the guideline values. Surveys were conducted at 1,481 sites nationwide in FY2018, and five samples had concentrations exceeding the guideline values for aquatic plants and animals. Therefore, the government informed golf course stakeholders anew about the guidelines, and gave a warning notice to all prefectures to urge them to pay more attention to the use of agricultural chemicals on golf courses.

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 Fluorinated gases (HFCs, PFCs, SF<sub>6</sub> and NF<sub>3</sub>) (METI and MOE)**

With regard to measures against fluorocarbons, in response to the adoption of the Kigali Amendment on the Montreal Protocol in FY2016, the Japanese government revised the Act on the Protection of the Ozone Layer through the Control of Specified Substances and Other Measures (Act No. 53 of 1988, hereinafter referred to as the “Ozone Layer Protection Law”) in FY2018. Since enforcement of the Ozone Layer Protection Law in January 2019, the amounts of HFCs have decreased in a phased manner by regulating the manufacture and import of HFCs in Japan.

The Act on Rational Use and Proper Management of Fluorocarbons (Act No. 64 of 2001 hereinafter referred to as “Fluorocarbons Emission Restraining Law”), which aims for rational use and proper management of each stage of the lifecycle of fluorocarbons, was revised in June 2019 in order to improve the recovery rates of fluorocarbons when refrigerators and air conditioners for business use are discarded.

As the next step, the government will strive to steadily implement the Ozone Layer Protection Law and the Fluorocarbons Emission Restraining Law. It also will take measures, such as the technological development of next-generation refrigerants and refrigeration air-conditioning systems and projects to support the introduction of equipment using non-fluorocarbon refrigerants, through which development, commercialization, and spread of natural refrigerants with extremely low global warming potentials (GWPs) are promoted. Based on this, the government will take efficient and effective measures for emissions control of fluorinated gases.

**[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 investigation committee meeting is also conducted by experts to improve and strengthen measures to prevent workers’ exposure to asbestos during the demolition of buildings. In addition, the government will make utmost efforts to ensure the 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. It also takes the necessary measures including the promotion of exposure prevention measures according to the dangerous and hazardous risks, etc.

The government will continue to work on the implementation of effective measures in order to manage chemicals appropriately and prevent explosion accidents and 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. benzidine, 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. The system was reformed in FY2019 to start the operation of “Monitoring system on Health effect cases related with chemical substances.” This is aimed at ensuring of the safety of users of household articles through collection of hazard information on the chemicals included in household articles where necessary, and minute investigation of the collected information in cooperation with specialists to consider how to handle the chemicals.
- 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 20.)

### **[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 Business Operators, 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 Poisonous and Deleterious



Substances Business Operators 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.

**[Measures based on Act on Preventing Environmental Pollution of Mercury] (METI and MOE)**

The government appropriately enforces the Act on Preventing Environmental Pollution of Mercury (Act No. 42 of 2015, hereinafter referred to as the “Mercury Pollution Prevention Act”) in order to ensure precise and smooth implementation of the Minamata Convention on Mercury to prevent environmental pollution of mercury.

The Mercury Pollution Prevention Acts prohibits acts, such as mining of mercury, manufacturing of specified mercury-using products, utilization of mercury, etc. in the specified manufacturing processes, and collection of gold by means using mercury, etc. Concerning storage of mercury, etc. and management of mercury-containing recyclable resources, the Act also stipulates that the standards are set and that measures are taken, such as submission of reports. In FY2018, the government compiled the reports submitted on the storage of mercury, etc. and the management of mercury-containing recyclable resources, and published their results.

The government will continue to take appropriate measures to lead the measures against mercury in the world.

**<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 No.100 of May 31,2000, hereinafter referred to as the “Act on Promoting Green Procurement”) 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.

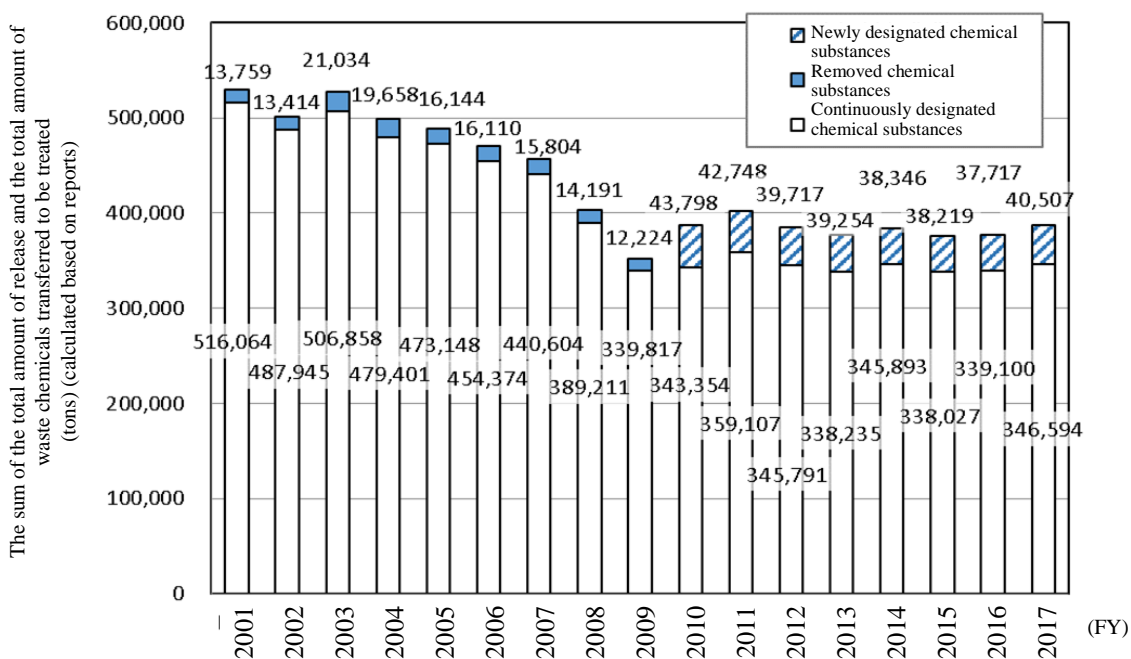
The State must, for the purpose of comprehensively and systematically promoting the procurement of eco-friendly goods, etc. of the State, independent administrative agencies, etc., provide for a Basic Policy on promoting Green procurement of eco-friendly goods, etc. (hereinafter referred to as the “Basic Policy”). In line with the Basic Policy, all agencies, such as the State and independent administrative agencies, prepare their policies for promoting the procurement of eco-friendly goods and services every fiscal year and publish procurement results to promote steady implementation of eco-friendly goods, etc.

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

The Status Quo

Regarding the release of chemicals into the environment, the PRTR system improved business operators' voluntary chemicals management and the total amount of chemicals (subject to reporting) released is decreasing. The PRTR system were revised in 2008. In that time, the target of the chemicals and the type of businesses at PRTR system was changed. This revision was launched in FY2010. From FY2018, the amendment of the PRTR system is under consideration. Figure 11 shows that the transition of the amounts of release and the amounts of chemicals transferred which were reported based on the PRTR system. 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 141,000 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 160,000 tons. The amount of chemicals tend to decline over time.

Figure 11 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

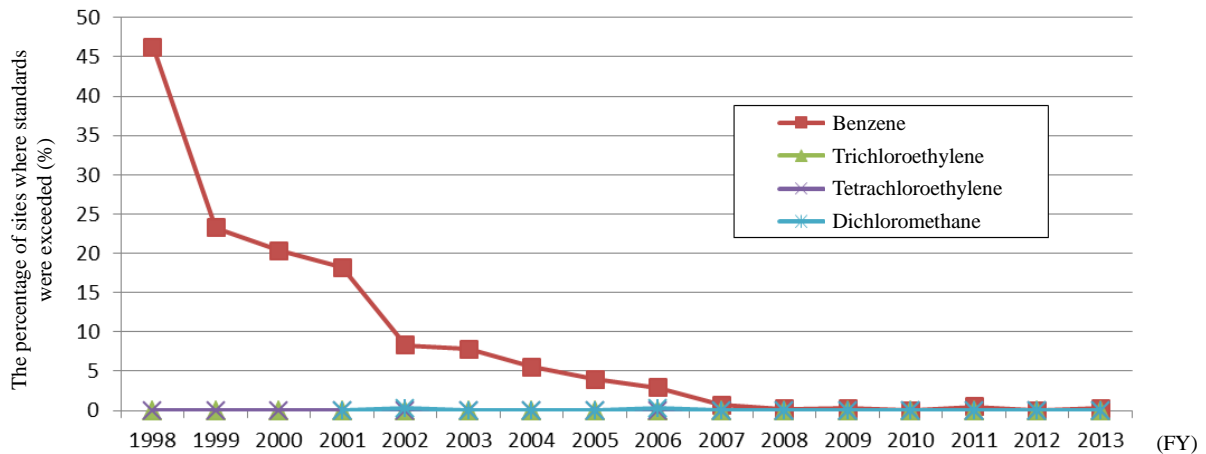


Source: The Overview of the PRTR Data for FY2017

<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.

With regard to the concentrations of pollutants in the 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 12 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 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.

Figure 12 Changes in the Percentages of Sites Where Observed Values Exceeded the Environmental Quality Standards regarding Benzene Air Pollution, etc.

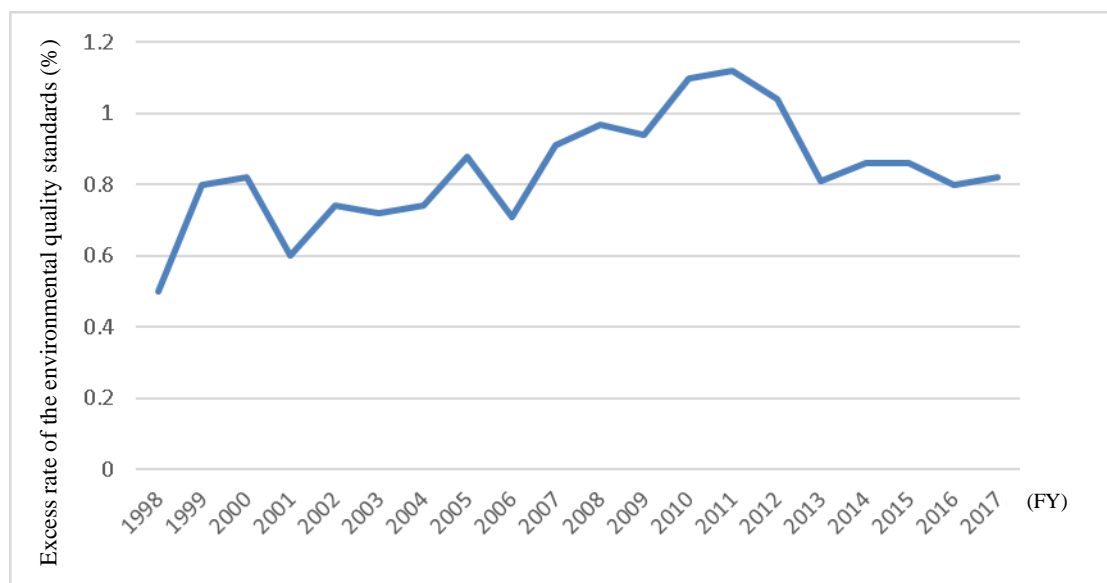


Note: They are the percentages for sites where observed values exceeded the environmental quality standards.

Source: MOE

Figure 13 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.

Figure 13 Change of the Environmental Quality Standard Excess Situation for Human Health Standards in the Public Waters



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

## 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 to 18.)

### [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 will continue to strive 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.

#### ○ Constant Monitoring of the Atmospheric Environment

(The content is omitted as it is the same as the content on page 18 to 19.)

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

#### ○ The Promotion of Regulations on the Discharge of Effluent Based on the Water Pollution Prevention Act

Regulations based on the Water Pollution Prevention 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 Prevention 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 pages 19 to 20.)

○ Regular Observation of Groundwater Quality

(The content is omitted as it is the same as the content on pages 21.)

**[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 (Act No. 105 of 1999) 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 FY2017 the total emission dioxins were 103g-TEQ/year that scored lower than the target level that accomplished the target goal.

Environmental pollution has been greatly reduced as can be seen in the fact that the achievement rate for the atmospheric environmental quality standards has been 100% for the past 10 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 major efforts.

○ Efforts on mercury-containing waste

In order to prevent global-scale pollution of mercury, the Minamata Convention on Mercury was adopted and ratified in August 2017. In response to this, the government revised the Order for the Enforcement of the Waste Management and Public Cleansing Law, through which mercury-containing waste and mercury-containing waste, etc. were designated as specially controlled waste and they are required to be treated after they are purified, sulfurized, and solidified. In addition, mercury-using waste products are designated as mercury-using product industrial waste, and certain treatment standards for them were established.

With regard to long-term management of waste metal mercury, the government conducted technical studies. It also prepared “Manual for Collecting Mercury Blood Pressure Monitors, etc. Put in Dead Storage at Medical Institutions” to promote the collection of mercury blood pressure monitors, etc. owned by the relevant bodies, such as the Japan Medical Association. Furthermore, the government prepared “Guidelines for Mercury Waste” to assure the appropriate treatment of mercury waste.

○ Efforts on Communication under the Waste Treatment System

The Waste Management and Public Cleansing Law stipulates that when entrusting treatment of industrial waste to an industrial waste disposer, a discharge undertaker must convey information necessary for waste treatment so that the trustee can treat the industrial waste appropriately. Nevertheless, accidents, etc. have occurred by improper treatment arising from lack of communication. Therefore, from FY2017 to FY2018, the government considered the clarification of information, etc. to be conveyed by dischargers to disposers.

○ Efforts on Infectious Waste

The government made appropriate and necessary revisions to the “Manual for the Management of Infectious Waste based on the Waste Management and Public Cleansing Law,” which was created for the purpose of ensuring the appropriate treatment of infectious waste.

**[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.

The 8th Meeting of the Conference of the Parties to the Stockholm Convention held in FY2017 decided that the following substances were newly eliminated: Polychlorinated linear-chain paraffin (limited to those whose a number of carbons of 10 to 13 and whose chlorine

content is over 48% in total weight; hereinafter referred to as “polychlorinated linear-chain paraffin); and 1,1'-oxybis (2,3,4,5,6-pentabromobenzene) (also known as and hereinafter referred to as decabromodiphenylether). In response to this, the government revised the Order for the Enforcement of the CSCL in February 2018, and designated the two chemicals as Class I Specified Chemical Substances on April 1, 2018. The manufacture, import, etc. of the two chemicals were banned in principle. The government also added six products which use decabromodiphenylether and six products which use polychlorinated linear-chain paraffin to the list of import-prohibited products on October 1, 2018. Among the additional chemical substances added to the annexes of the Stockholm Convention, which was adopted at the ninth meeting of the COP held from the end of April through the beginning of May in 2019, *o,p'*-Dicofol, perfluorooctanoate (PFOA) and its salts, and PFOA-related compounds 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.

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 promotes the appropriate treatment of waste which contains chemicals subject to regulations based on the Stockholm Convention whose hazard, etc. in the environment is a concern, 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.

- The government conducted verification experiments for the decomposition of waste which contains HBCD,<sup>8</sup> as well as surveyed the statuses of release from the final disposal sites. Based on the results of the surveys conducted, etc., the government also considered the appropriate treatment measures for HBCD-containing waste.
- The government conducted domestic flow surveys for chlorine-based preparations (PCP,<sup>9</sup> PCN,<sup>10</sup> and HCB<sup>11</sup>), and strives to ascertain products which contain such substances, etc. It also conducted verification experiments for the decomposition of chlorine-based preparations and considered the appropriate treatment measures for waste which contain chlorine-based preparations.
- Since FY2016, based on the results of the above-mentioned surveys and considerations, the government has conducted considerations for the institutionalization of waste which contains POPs, and conducted considerations for the analysis method of POPs in exhaust gas or effluent generated with waste treatment.

#### **[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

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<sup>8</sup> HBCD: Hexabromocyclododecane

<sup>9</sup> PCP: Pentachlorophenol

<sup>10</sup> PCN: Polychlorinated naphthalene

<sup>11</sup> HCB: Hexachlorobutadiene

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 3 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 3 Activities Based on the Basel Law

Activity	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
The number of imports approved based on the Basel Law	91	103	125	167	266	139	125
The number of exports approved based on the Basel Law	55	72	79	97	104	105	16
The number of prior consultations (total for the MOE and the METI)	51,245	51,382	52,414	49,733	49,580	43,710	37,972
The number of sites where briefings on the Basel Law, etc. were held	9	11	9	11	9	Not conducted	11

\* The number of import approval cases based on Basel Convention is compiled per calendar year (January through December)

**[Measures based on Act on Preventing Environmental Pollution of Mercury] (METI and MOE)**

(The content is omitted as it is the same as the content on pages 38.)

**[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, FY2014, FY2016, and FY2018. It will continue to conduct the surveys periodically.

In FY2012 and FY2015, the MOE organized and published information about environmental efforts by vehicle manufacturers, etc. including environmentally friendly designing.

○ The Government-Certified System for Contractors of Wide Area Treatment based on 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 2019).

- Certification for contractors of wide area treatment of general waste: 68
- Certification for contractors of wide area treatment of industrial waste: 280

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, and Contaminated Soil, etc.

### The Status Quo

Regarding the control of negative legacies including contaminated 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 (Act No. 53 of 2002), etc.

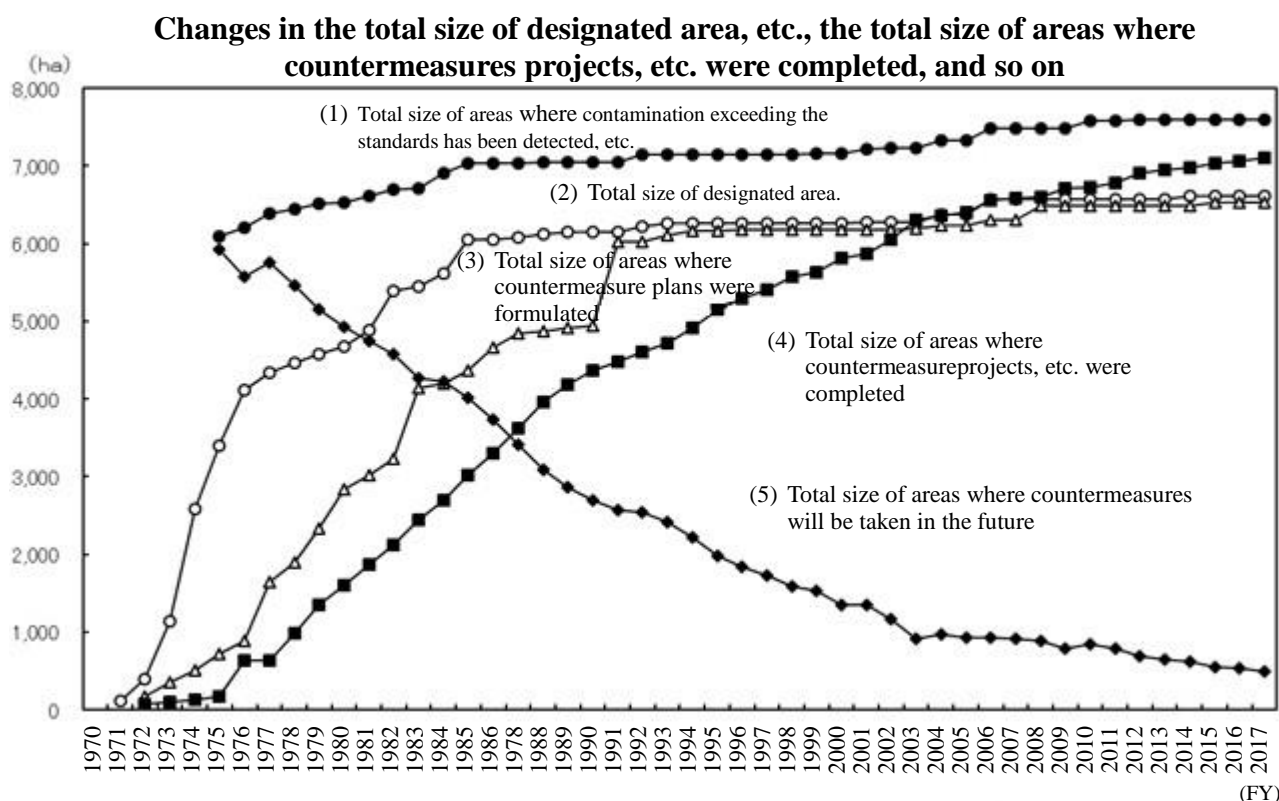
With regard to polychlorinated biphenyl (PCB) waste which has been stored for a long period of time after manufacture, the import and use of PCB were virtually banned, efforts are being made to establish systems for the appropriate treatment of the waste. For example, the Japan Environmental Storage & 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.

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). Therefore, the government revised the Basic Plan for PCB Waste Treatment to extend each facility's deadline for treating PCB (the planned treatment completion deadline). The government gave the local governments that own their facilities pledges, such as no reextension of the deadline.

In order to ensure the treatment by the above-mentioned deadlines, the government revised the Law concerning Special Measures for Promotion of Proper Treatment of PCB Waste in FY2016, through which new actions are taken, such as the requirement of treatment during the treatment period (one year before the planned treatment completion deadlines).

Regarding contaminated soil on agricultural land, countermeasures are being taken based on the plan for countermeasures against soil contamination on agricultural land. Figure 14 shows the progress in countermeasures against soil contamination on the agricultural land in designated areas. As of the end of FY2017, designated areas had been completed their countermeasures on 7,100 ha of land, which makes the plan for countermeasures progress rate 93.5%.

Figure 14 Progress in Countermeasures against Soil Contamination on Agricultural Land



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>)

## Efforts Being Made

### <Efforts to Control Negative Legacies>

#### [Efforts Based on the Soil Contamination Countermeasures Act] (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 Act. 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 4 shows an outline of the recent survey results for the implementation of the Soil Contamination Countermeasures Act.

Table 4 An Outline of the Recent Survey Results for the Implementation of the Soil Contamination Countermeasures Act

Measures	FY2017 survey (FY2016 results)	FY2018 survey (FY2017 results)
The number of specified facilities which use hazardous substances whose use was stopped	1,204 cases	1,076 cases
The number of reports on soil contamination survey results	284 reports	290 reports
The number of cases where survey obligations were temporarily exempted	650 cases	573cases
The number of reports submitted for making changes to the form or nature of land	10,946 reports	10,741 reports
The number of orders issued on the survey of land which has a risk of being contaminated by designated hazardous substances	118 orders	154 orders
The number of reports on oil contamination survey results	119 reports	170 reports

Note: The surveys were conducted for departments in charge of soil contamination controls at all 47 prefectural governments and 111 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 Act, the government has been conducting the appropriate management of environmental risk through identifying problems concerning soil contamination survey methods and the methods to take countermeasures such as the removal of contamination, and considering improvement countermeasures, through the examination project of methods for soil contamination surveys and countermeasures, etc. The government also conducts the survey project 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.

- The government revised the ordinances for the enforcement of the Act in July 2011. Through the revisions, the government created some systems including the Special Areas with Nature Derived Contamination among the Areas for which Changes to Form or Nature Require Notification, where the regulations on the methods to change the form or nature of land are relaxed. By the revision of the ordinances, the government also added special provisions on surveys of land which is deemed to have a risk of nature derived contamination.
- In order to promote the appropriate management of soil contamination, it was necessary to increase the opportunities for conducting soil contamination survey. It was also necessary to take measures, such as the improvement of the system for orders on emergency response measures for decontamination by the prefectural governors concerned, the formulation of rules of tightening the standard for approving the business for contaminated soil treatment, the formulation of rules for approving succession of the business, and the formulation of rules for a person that operates specified facilities that use harmful substances to cooperate in soil contamination survey. For these purposes, the government partially revised the Soil Contamination Countermeasure Law in FY2017, and enforced the revised law in April 2019 after the revision of the cabinet order and ministerial ordinances.
- Through the examination project of the methods for soil contamination surveys, countermeasures, etc., the government created the “Guidelines on the Investigation and Countermeasure Based on the Soil Contamination Countermeasures Act (the Revised 3rd Edition)” in FY2019 based on the above-mentioned revision of the Act.

- Through the survey project to examine the processing of contaminated soil, etc., the government created “Guidelines for Transportation of Contaminated Soil (Revised 4th Edition),” and “Guidelines for Processing Business of Contaminated Soil (Revised 4th Edition)” based on the above-mentioned revision of the Act in FY2019.

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 by designated hazardous substances and does not conform to 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 create a plan for decontamination, etc. that includes measures, etc. for decontamination, etc., and submit the plan to the governor concerned. For land which is designated as an Area for which Changes to Form or Nature Require Notification, measures such as the removal of contamination shall not be required. Instructions for Areas which Require Action are decided based on the levels, etc. of soil and groundwater contamination.

The government will continue to obtain updated information on implementation of the Soil Contamination Countermeasures Act 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 Act. 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.

**[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 MOE is engaged in activities of support for prefectural or city municipal governments pertaining to investigation for finding any pieces of equipment which were not reported to prefectural or city municipal governments, as well as activities pertaining to raising awareness for storage operators. 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, detoxification treatment certification, technical discussions etc., for ensuring its treatment by the new deadline (March 2027) stipulated by Law Concerning Special Measures against PCB Waste are taking place.

Table 5 shows the progress in the treatment of high-concentration PCB waste.

Table 5 The Cumulative Quantity of High-concentration PCB Waste (Transformers, Capacitors, etc.) Treated (Units) (( ) indicates progress rate %)

	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
	120,385 units	156,202 units	194,304 units	228,124 units	256,273 units	283,371 units	312,867 units	337,056 Units
	36.5%	47.4%	56.0%	66.0%	73.9%	81.7%	90.2%	97.1%

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

**[Efforts Based on the Act to Prevent Soil Contamination on Agricultural Land] (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.

○ Status of FY2016

- 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 FY2016
- Of the 7,592 ha mentioned above, the cumulative size of areas designated as Areas for Countermeasures: 6,609 ha
- The size of areas where countermeasures plans, etc. have been completed: 7,055 ha (92.9% of the size of Areas Where Contamination Exceeding the Standards Has Been Detected, etc.)

○ Status of FY2017

- The cumulative size of Areas Where Contamination Exceeding the Standards Has Been Detected, etc.: 7,592 ha (as of the end of FY2017)
- Of the 7,592 ha mentioned above, the cumulative size of areas designated as Areas for Countermeasures: 6,609 ha
- The size of areas where countermeasures plans, etc. have been completed: 7,100 ha (93.5% 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 grant for consumption and safety measures.

- Provided at 53 sites in FY2018
- To be provided at 52 sites in FY2019

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 Prevention 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. Furthermore, in the "Next Step for Environmental Measures for Chemicals (Report)" compiled by the Central Environment Council in June 2019, the use and sharing of existing PRTR information for disasters are specified. As the next step, the government will plan to consider necessary measures and position them in the Chemical Substance Management Guidelines.

#### 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 Prevention 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 conserve 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.

Furthermore, 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.

On December 18, 2019, a request was issued to the prefectural governors, etc., regarding "Thorough measures for water pollution accidents caused by natural disasters."

- The following shows the results of FY2017 survey on the enforcement of the Water Pollution Prevention Act.
  - Reports submitted after accidents: 520 reports
  - Orders on emergency response measures issued: 0 case

As the next step, it is necessary for prefectural governments to continue providing 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 36.)

**<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.

From FY 2013 to FY 2015, sample analysis of river water nationwide and survey of actual discharge conditions from business establishments were conducted to grasp the existence state in the general environment, and in FY 2016, the evaluation and compilation of the results of these water quality surveys were performed. From FY 2017 to FY 2018, interviews were conducted at the business sites targeted for the survey, and the usage status of the target substances was investigated, and in June 2018, the findings thus obtained from the survey were compiled and notified to local governments.

**[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>12</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.

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<sup>12</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

Regarding emerging and uncertain issues, it is important to continue to develop new methods for assessing risk more adequately, and to take measures appropriately by taking the precautionary approach from the standpoint of protecting public 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 chemicals; 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 Results of the Efforts

In the SAICM national implementation plan, the government would reduce the environmental risks posed by chemicals including those by emerging and uncertain issues, through promotion of comprehensive chemicals control measures which combine various methods, throughout the lifecycles of chemicals from their manufacture to their disposal.

Based on the decision, the government has been conducting surveys and research, including: efforts to establish methods to assess the endocrine disrupting effects of chemicals 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 has also been promoting surveys and research on other new issues using such systems as Health and Labour Science Research and The Environment Research and Technology Development Fund.

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

### **The Status Quo**

In order to ensure the safety and security of citizens, it is necessary to take a precautionary approach when taking measures for emerging and uncertain issues. Therefore, the government is making efforts to establish methods for assessing the endocrine disrupting effects of chemicals, 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 public 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. Environmental risk assessment is currently being conducted for nonylphenol, which has undergone the Tier 2 *in vivo* test.

With regard to the endocrine disrupting effects of chemicals, the government has been conducting programs called SPEED '98 from 1998, EXTEND 2005 from 2005, EXTEND 2010 from 2010, and EXTEND 2016 from 2016, with the final goal being science-based risk assessments. Table 6 shows the progress of the program aiming at conducting risk assessments for candidate chemicals which were considered to have potential of endocrine

disrupting effects. The number of substances which underwent reliability assessments was 175 in total as of 2018, of which 89 underwent Tier 1e *in vitro* assays, 20 underwent Tier 1 *in vivo* assays, and four Tier 2 *in vivo* test. Environmental risk assessment is currently being conducted for nonylphenol, for which the Tier 2 *in vivo* test was conducted. In addition, several test methods developed in this program (OECD TG240: Medaka Extended One Generation Reproduction Test (MEOGRT), OECD TG241: Larval Amphibian Growth and Development Assay (LAGDA), etc.) have been adopted as OECD test guidelines.

Table 6 Number of Substances Which Underwent Reliability Assessments, etc. for Endocrine-disrupting Effects

Category		ExTEND 2005			EXTEND 2010			
Fiscal year		2008	2009	2010	2011	2012	2013	2014
Reliability assessment (note 1)	Selected	12	15	13	23	22	22	7
	Conducted	10	17	13	8	23	8	13
	Candidates for testing	7	11	7	5	13	8	12
	Substances not for testing	3	6	6	3	10	0	1
Tier 1 (note 2) in vitro assay (note 3)	Selected	–	–	6	11	13	5	10
	Conducted	–	–	6	11	12	6	5
Tier 1 <i>in vivo</i> assay (note 4)	Selected	–	–	–	10	4	–	4
	Conducted	–	–	–	3	3	–	3
Tier 1 assessment	Conducted	–	–	–	–	–	–	–
Tier 2 (note 5) <i>in vivo</i> test	Conducted	–	–	–	–	–	–	–
Hazard assessment	Conducted	–	–	–	–	–	–	–

Category		EXTEND 2010	EXTEND 2016			TOTAL
Fiscal year		2015	2016	2017	2018	
Reliability assessment (note 1)	Selected	18	25	18	9	184
	Conducted	30	9	30	16	177
	Candidates for testing	22	9	20	15	129
	Substances not for testing	8	0	10	1	48
Tier 1 (note 2) in vitro assay (note 3)	Selected	22	23	20	15	125
	Conducted	9	17	17	6	89
Tier 1 <i>in vivo</i> assay (note 4)	Selected	7	4	12	2	43
	Conducted	6	1	2	2	20
Tier 1 assessment	Conducted	–	12	2	3	17
Tier 2 (note 5) <i>in vivo</i> test	Selected	1	2	2	0	5
	Conducted	1	1	2		4
Hazard assessment	Conducted	–	–	1	0	1

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 examined.

Note 3. The government tests whether the endocrine system reacts to the chemical, as “test-tubes experiments”.

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 has adverse effect or not is checked.

### <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 at 15 unit centers nationwide. The recruitment was completed at the end of March 2014, when the registered participants reached the targeted 100,000. Since 2014, follow-up surveys of newly born children have been in full swing, and chemical analysis of biological samples has been carried out. In addition to the follow-up survey, a detailed survey (conducted on about 5,000 people extracted from among the 100,000 national surveys) has been conducted, in which collection of environmental samples, health surveys/biological sampling by physicians, and mental development surveys are being conducted.

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

As the next step, the government will further promote the return of research results to society, such as presentation of academic papers and dissemination of information to the public. 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>13</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 has contributed to the establishment of the OECD test guideline for 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.

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

The Fifth Basic Environment Plan (decided on by the Cabinet in April 2018) stipulates the following on the endocrine-disrupting effects of chemicals: "Regarding the endocrine-disrupting effects of chemicals, the government will accelerate the establishment of assessment methods and the implementation of assessments, and take necessary measures for risk management based on the results. In addition, while actively participating in the

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<sup>13</sup> This section subjects to endocrine-disrupting chemicals which is one of the EPI topics of SAICM/ICCM.

efforts made at the OECD, the government will consider the development of new assessment methods and provide 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 initiated studies for assessment of endocrine-disrupting effects of chemicals on the environment. Currently, the government develops and improves the necessary test methods through a program EXTEND 2016 launched in 2016, 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 existing knowledge on substances detected in the environment and conducting tests where needed.

By FY2018, a total of 184 substances were selected as the substances to be studied, and 130 substances were concluded to be "substances that could be tested for endocrine disrupting effects," of which 89 were tested *in vitro*. Furthermore, Tier 1 *in vivo* assay was performed on 20 substances, and Tier 2 *in vivo* test was performed on 4 substances. Among the long-term test methods that have been under development for a long time, the Medaka Extended One Generation Reproduction Test (MEOGRT) and the Larval Amphibian Growth and Development Test (LAGDA), which are test methods for fish and amphibians, were adopted as test guidelines by the OECD in September 2015. As the next step, 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). Internationally, progress has been made in recent years in various countries on the combined effects of chemicals. For example, in some parts of the United States and Europe, the combined effects of chemicals are being examined in screening, regulation, and evaluation of chemicals. In addition, WHO proposed a framework for considering the assessment of combined exposure to multiple of chemicals, and OECD and others are also conducting related technical studies.

In Japan, too, it is necessary to accumulate knowledge on the assessment of combined effects as soon as possible and to take appropriate measures. Therefore, the existing studies and findings were collected and basic concepts have been organized to establish a framework for combined effect assessment and to draft guidance, and detailed studies were conducted on the mechanism of action for respective group of substances to be examined so that the WHO/IPCS framework could be used in risk assessment practices in Japan.

- In FY2017, case studies were conducted based on the concept of the WHO/IPCS framework, and an ecotoxicity test was conducted by combining substances that are considered to have a significant contribution to toxicity to fish, daphnia, and algae.

- In FY2018, case studies were conducted mainly for polycyclic aromatic hydrocarbons and acrylates, taking into account the uncertainties of the combined effect assessment based on the examination of FY2017. In addition, as in FY2017, ecotoxicity tests were conducted by combining substances that are considered to have a significant contribution to toxicity to fish, daphnia, and algae.

**[The Consideration of Risk Assessment Methods for Nanomaterials] (MHLW, METI and MOE)<sup>14</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, a long-term carcinogenicity test by inhalation has been conducted, and for multi-walled carbon nanotube (one type), a test was completed in FY2014. In addition, a long-term carcinogenicity test of titanium oxide (nanoparticles, anatase type) by inhalation was started in FY 2016, and as of December 2019, the test results have been compiled.
- 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.

Based on the results of the above long-term carcinogenicity test, multi-walled carbon nanotubes, which were found to be carcinogenic in animals, were subject to the “Guidelines for Preventing Health Problem Caused by Chemicals” in March 2016 from the perspective of preventing health problem in workplaces, and it was made known to business operators that they should take measures to prevent health problems. 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>14</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.
- In FY2015, the assessment method was established by collecting the results obtained so far.

○ 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 there are concerns in other countries that nanomaterials will have an adverse effect on human health and the environment. Therefore, the establishment of a test method for evaluation of toxicity of nanomaterials to human health and the environment, accumulation of knowledge on the dynamics of the environment and living organisms, and the establishment of a method for evaluation of environmental risk based on the characteristics of the nano-sized particles have been issues.

Therefore, through this project, (1) establishment of measurement technology for nanomaterials in the environment, (2) understanding of the behavior of nanomaterials in the environment, and (3) examination of ecotoxicity of nanomaterials have been conducted.

- In FY2018, following on from FY2017, based on the results obtained so far, the government conducted a demonstration experiment to establish a method for measuring the behavior of nanomaterials (carbon nanotubes) in the ambient air, and verified the measurement method, also collecting the necessary information for verification.
- The government continues to collect information on the ecotoxicity of nanomaterials and their environmental fate. Furthermore, since the OECD has started studies on test methods to obtain toxicity of nanomaterials to aquatic organisms, the government will participate in the discussion and consider the utilization of the results in Japan.

**[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 argue 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. The MOE conducted surveys on these issues.

- 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.
- In FY2015, the government compiled the results of the surveys and research and compiled them as the "Report on Research and Investigations on the Health Effects of Trace Chemicals in the Environment in FY2015."

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 Act, 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 Pharmaceuticals and Personal Care Products (PPCPs)] (MOE)**

Pharmaceuticals discharged into the environment are receiving international attention as an Emerging Policy Issue (EPI) in SAICM. The MOE organized existing knowledge on Pharmaceutical and PPCPs<sup>15</sup> in the environment, including pharmaceuticals, narrowed down the substances to be examined, and grasped the existence of chemicals in the environment through the “Environmental Survey and Monitoring of Chemicals” and promoted environmental risk assessment by the "Initial Environmental Risk Assessment of Chemicals." At the same time, we started ecotoxicity tests to compensate for the lack of knowledge, and examined the appropriate environmental risk assessment methods based on the characteristics of pharmaceuticals and the like.

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<sup>15</sup> PPCPs: Pharmaceutical and Personal Care Products



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

### (1) The Basic Approach to Issues

In addition to conducting various monitoring operations as a basis for ensuring the safety of chemicals and leading to the security of the people, stakeholders, including the people, workers, businesses, and the government, must share understanding of the risks of chemicals, including information on the status of responses to unexplained problems, further promote risk communication while fulfilling their respective roles, and raise public understanding.

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 Results of the Efforts

In order to tackle the above-mentioned issues and ensure citizens' safety and security, the government implemented various environmental monitoring and publishes the results, as the information which provides the basis for ensuring their safety and security. The government also promoted risk communication based on scientific risk information, etc. In addition, the government promoted 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) Implementation of various types of monitoring, etc. in order to provide the basis for safety and security
- b) Further promotion of risk communication
- c) Efforts concerning chemicals in products

a) 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 and Monitoring of Chemical Substances; the hazardous air pollutant monitoring surveys; the water quality survey of public water and ground water; and the Comprehensive Survey for the Agricultural Chemicals Remaining in the Environment. Table 7 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 8 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 7 Changes in the Number of Substances Monitored in the Environmental Surveys of Chemical Substances

Fiscal year	Media						Total number of substances <sup>(Note 2)</sup>		The cumulative number of substances monitored	
	Water	Sediment	Sediment	Air	Food	Others <sup>(Note 1)</sup>	Number of new substances <sup>(Note 3)</sup>	continue to be monitored		
1974	33	27	26	0	0	11	33	33	0	33
1975	42	26	26	0	0	15	42	34	0	67
1976	76	76	44	2	0	0	78	77	0	144
1977	90	88	9	2	0	0	92	79	0	223
1978	56	54	29	0	0	0	77	54	8	277
1979	39	39	31	11	0	0	73	32	0	309
1980	57	55	41	15	0	0	108	54	0	363
1981	81	81	31	0	0	0	110	74	0	437
1982	38	37	40	0	0	0	67	29	0	466
1983	45	45	36	17	0	0	96	42	0	508
1984	79	79	40	3	0	0	116	66	0	574
1985	58	74	55	6	0	0	115	57	14	631
1986	97	97	56	15	0	0	128	47	1	678
1987	48	61	54	14	0	0	79	30	14	708
1988	49	69	62	18	0	0	87	15	0	723
1989	50	78	71	20	0	0	96	16	3	739
1990	48	79	84	22	3	3	101	12	4	751
1991	48	80	76	22	6	4	107	3	1	754
1992	42	71	72	15	6	4	100	16	1	770
1993	41	73	72	26	6	4	102	19	0	789
1994	46	77	80	23	8	6	102	8	1	797
1995	56	82	61	24	6	6	107	15	0	812
1996	61	91	67	27	6	6	116	6	0	818
1997	37	68	44	15	6	6	85	7	0	825
1998	48	56	29	36	6	6	101	16	8	841
1999	30	58	48	32	6	6	95	7	0	848
2000	41	68	52	49	1	6	99	37	20	885
2001	47	66	46	49	1	6	98	16	0	901
2002	63	62	66	41	9	0	80	20	0	921
2003	70	66	62	63	0	0	93	20	4	941
2004	70	63	59	72	2	1	91	13	0	954
2005	156	86	76	53	6	2	171	50	0	1,004
2006	122	134	98	87	2	0	252	136	15	1,140
2007	110	81	67	70	0	0	128	27	0	1,167
2008	110	96	89	98	0	0	141	16	0	1,183
2009	86	79	67	84	0	0	110	25	8	1,208
2010	80	70	69	69	0	0	101	14	2	1,222
2011	83	75	66	69	0	0	93	9	5	1,231
2012	80	59	63	70	0	0	96	5	0	1,236
2013	59	38	46	50	0	0	74	14	0	1,250
2014	153	58	57	75	0	0	178	74	0	1,324
2015	69	53	68	71	0	0	103	9	0	1,333
2016	81	61	80	82	0	0	120	21	8	1,354
2017	185	68	62	69	0	0	208	55	1	1,409
The cumulative number of substances monitored <sup>(Note 4)</sup>	1,287 (3,060)	1,035 (3,004)	483 (2,477)	486 (1,536)	27 (80)	26 (92)	1,409 (4,649)	/		
The cumulative number of substances detected <sup>(Note 5)</sup>	536	484	298	342	21	13	839			
The detection ratio <sup>(Note 6)</sup>	42%	47%	62%	70%	78%	50%	60%			

(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) "Number of new substances" are the number of substances that were monitored for the first time in the relevant fiscal year out of the number of substances listed in the "Total number of substances" column.

- (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 the total number of surveyed substances is the total number of substances monitored in each medium or all media in the period between 1974 and 2017, and have been monitored over multiple years. The sum of the numbers of substances monitored in all fiscal years is shown in ( ).
- (Note 5) “839” is the number of substances detected from some media as a result of the survey.
- (Note 6) The detection ratio is the ratio of the cumulative total of detected substances to the cumulative total of surveyed substances.

Table 8 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	2010-2016	2017
Releases from business establishments not subject to reporting due to the small amounts released*		X	X	X	X	X	X
Agricultural chemicals		X	X	X	X	X	X
Insecticides	Household insect repellents		X	X	X	X	X
	Insecticides for disinfecting		X	X	X	X	X
	Insecticides for nuisance insects		X	X	X	X	X
	Termite control agents			X	X	X	X
Adhesives		X	X	X	X	X	X
Paints		X	X	X	X	X	X
Antifoulants for fishing nets		X	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	X
	Neutralizers, etc.	X	X	X	X	X	X
Insect repellents, deodorants		X	X	X	X	X	X
Utility engines			X	X	X	X	X
Cigarette smoke			X	X	X	X	X
Automobiles	Hot starts	X	X	X	X	X	X
	Additional emissions during cold starts		X	X	X	X	X
	Fuel evaporative emissions			X	X	X	X
	Air conditioning units powered by independent engines		X	X	X	X	X
Motorcycles	Hot starts	X	X	X	X	X	X
	Additional emissions during cold starts		X	X	X	X	X
	Fuel evaporative emissions			X	X	X	X
Special-purpose vehicles	Construction machinery	X	X	X	X	X	X
	Agricultural machinery	X	X	X	X	X	X
	Industrial machinery	X	X	X	X	X	X
Vessels	Cargo and passenger vessels, etc.	X	X	X	X	X	X
	Fishing vessels	X	X	X	X	X	X
	Pleasure boats			X	X	X	X
Railway vehicles	Engines	X	X	X	X	X	X
	Wearing of brakes, etc.		X	X	X	X	X
Aircraft	Engines	X	X	X	X	X	X
	Auxiliary power units	X	X	X	X	X	X
Water supply systems		X	X	X	X	X	X
Ozone-depleting substances		X	X	X	X	X	X
Dioxins		X	X	X	X	X	X
Low-content substances		X	X	X	X	X	X

Sewage treatment facilities				X	X	X
General waste treatment facilities						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," "sewage treatment facilities," and "general waste 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 pages 15 to 16.)

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

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

#### [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 to 18.)

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

(The content is omitted as it is the same as the content on page 18 to 19.)

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

(The content is omitted as it is the same as the content on pages 19 to 20.)

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

(The content is omitted as it is the same as the content on pages 21.)

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

○ Monitoring (The content is omitted as it is the same as the content on pages 11 to 12.)

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

(The content is omitted as it is the same as the content on page 20.)

### <Efforts for the Development of Data on Exposure>

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

The government is developing the Manual for PRTR Release Calculation Methods (hereinafter referred to as the “Calculation Manual”) so that business operators can refer to it when ascertaining the amount of chemicals released into the environment, in the PRTR system.

The first edition of the Calculation Manual was created in April 2001. The Calculation Manual has been revised every fiscal year in light of the reporting situation, the revision of the Cabinet Order on the PRTR Law in November 2008 and the revision of relevant laws and regulation, and was organized as version 4.2 as of December 2019. Since then, the Calculation Manual has been amended every fiscal year. The Calculation Manual can be browsed on the websites of the MOE and the METI. On the website of the MOE, the Calculation Manual can also be browsed using a dedicated electronic application. The government also provides the PRTR Release Calculation 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.

Experts pointed out that the government should conduct surveys on methods used by business operators to calculate their amounts of release, at the meetings of the Environmental Health Committee of the Central Environment Council. 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 estimate 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 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 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 to enable the ascertainment of transition.” Therefore, the government is examining the release sources for which estimations can be made, as well as considering the scope of the estimations. The government is also working to improve the accuracy of estimations by revising its estimation methods including the emission coefficients used, based on the new information obtained every fiscal year.

The government has two meetings consists of experts. These are 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). Two meetings discuss on revising the estimation methods and improving estimation accuracy have been taking place while utilizing the latest findings. 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. In March 2019, the new estimated results of unreported emissions of the target chemicals released from municipal solid waste treatment facilities.

As the next step, the government will continue to 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 continue to work to improve the accuracy of the estimations and to revise the estimation methods based on newly obtained information.

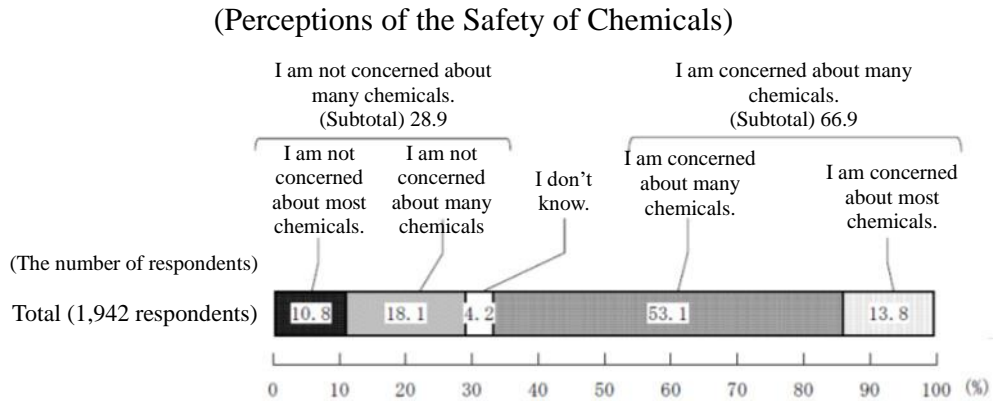
**b) The Further Promotion of Risk Communication**

**The Status Quo**

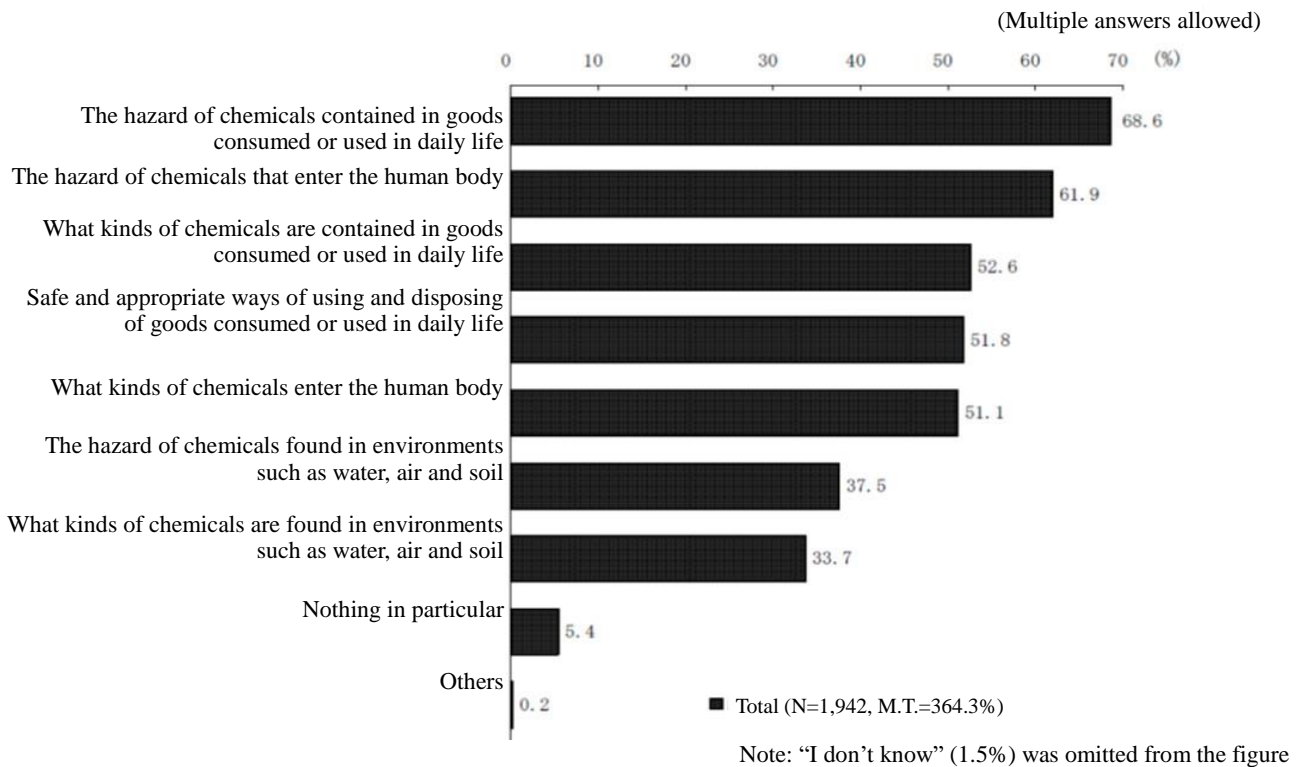
The government is working to put in place basic conditions that enable risk communication on chemicals, by providing information on databases, promoting classification and labeling, providing risk communication opportunities and developing human resources.

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



(Information on Chemicals That People Want to Obtain)



## 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 “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 are 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. In addition, we will try to issue a "Citizen's Guidebook for Understanding PRTR Data" in a timely manner.

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

The MOE has dispatched Chemical Advisors who are human resources to provide objective information and advice on chemicals at the request of citizens, companies, and governments since 2003. The Chemical Advisors provide information from a neutral standpoint to citizens and businesses, such as acting as a facilitator in risk communication conducted by local governments to contribute to the promotion of risk communication in the region. (25 times in 2012; 28 times in 2013; 27 times in 2014; 24 times in 2015; 23 times in 2016; 17 times in 2017; 20 times in 2018)

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 2007 to share latest information in terms of risk assessment and management of new chemicals from governments and research institutes with municipal governments, private sectors, and general citizen.

The symposium themes were "Risk assessment of multiple chemicals" in FY2015, "New development of chemical substance safety management" in FY2016, "New direction of risk management for diverse chemical substance groups" in FY2017, "Direction of unsteady chemical substance risk assessment and management" in FY2018, and "Utilization of methods and tools for chemical substance assessment and management" in 2019. Ministries, public sectors, private sectors, and researchers made presentations and lectures, and exchanged ideas together in these symposiums.

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, NITE)**

In order for stakeholders including citizens, workers, business operators, the government and national institutes 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 and “GHS-related information” within the website of the NITE. With the aim of promoting risk communication, various types of information are posted on the website including information on GHS classification results conducted by the governments, GHS aligned sample labels, and Safety Data Sheets (SDSs), as well as information on risk assessments, etc. conducted by the government. The government will encourage business operators to utilize these tools further.

- Results of GHS classification conducted by the government 4,258 substances in total (disclosed up to FY2018)
- Based on the results of the examinations by experts, the government implemented amendments to the Enforcement Order of the Industrial Safety and Health Act (Cabinet Order No. 318 of 1972), and added labels and SDS mandatory substances based on the Industrial Safety and Health Act (27 substances enforced in March 2017; 10 substances enforced in July in 2018).
- 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; 149 substances in FY2014; 151 substances in FY2015; 150 substances in FY2016; 150 substances in FY2017; 163 substances in FY2018).
- 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.
- NITE, in cooperation with the Ministry of Economy, Trade and Industry and related industrial associations, has created the risk assessment guidance of consumer products for GHS labeling and a tool to estimate the exposure of chemicals in consumer products, and released them from April 2008.

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 through the “Accident Information Databank System” where people can freely search and browse accident information, including accident information on chemicals. CAA will continue to work on collecting and disseminating accident information in cooperation with related government agencies.

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

(508 cases in FY2012; 456 cases in FY2013; 334 cases in FY2014; 229 cases in FY2015; 295 cases in FY2016; 279 cases in FY2017; 205 cases in FY2018)

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

#### [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 pages 34 - 35.)

### <Other Efforts>

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

In March 2011, the existing “Roundtable on Chemicals and the Environment” 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 SAICM National Implementation Plan of Japan was adopted in September 2012, individual themes were discussed in the sessions shown below. In the 13th session, the results of discussions from the viewpoint of improving literacy (comprehension) in relation to chemicals were compiled and disclosed as "Towards an Improvement in Understanding of Chemicals and Environmental Risks and Approaches to them."

The outline of the Policy Dialogue held since 2012 is shown in Table 9.

Table 9 The outline of the Policy Dialogue held since 2012

Session	Date	Main Agenda
3rd	December 2012	✓ The Basic Idea of the Precautionary Approach, etc.
4th	January 2014	✓ New Developments concerning Risk Assessment and Associated Challenges
5th	August 2014	✓ Risk Communication concerning Chemicals in Products
6th	December 2014	✓ Efforts being made toward SAICM and how to proceed further
7th	May 2015	✓ Efforts being made toward SAICM and how to proceed further
8th	September 2015	✓ Report on compilation of inspection report for the SAICM National Implementation Plan of Japan
9th	December 2015	✓ Results of the 4th International Conference on Chemicals Management (ICCM4)
10th	July 2016	✓ Discussions for future proceedings and policy proposals
11th	January 2017	<ul style="list-style-type: none"> <li>✓ Discussions for Policy Proposals</li> <li>➤ Summary of previous discussions in the “ Policy Dialogue concerning Chemicals and the Environment”</li> <li>➤ Education on chemicals</li> </ul>
12th	August 2017	<ul style="list-style-type: none"> <li>✓ Discussions for Policy Proposals</li> <li>➤ Common Understanding of Policy Dialogue Members on Chemical Substance Management</li> <li>➤ Aiming to improve literacy (understanding) on chemicals (arrangement of issues)</li> </ul>
13th	January 2018	✓ Summary of common understanding in previous discussions "Towards an Improvement in Understanding of Chemicals and Environmental Risks and Approaches to them (draft)"
14th	September 2018	<ul style="list-style-type: none"> <li>✓ Special Lecture "History of Life and the History of Chemicals" (Professor Emeritus Naotake Kato, Kyoto University)</li> <li>✓ Recent trends and future developments in SAICM</li> </ul>
15th	September 2019	✓ Information sharing related to the response of chemicals in the event of a disaster or accident - Introduction of good examples

At the 16th policy Dialogue in January 2020, discussions will be held on the reviews, etc. of the efforts of the SAICM National Implementation Plan of Japan. Based on the contents of the new international framework for chemical management from 2020, which will be formulated in ICCM5, 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>16</sup>

#### The Status Quo

In order to ensure that the hazard information on chemicals in products is provided adequately throughout the supply chains, efforts are being made to provide information, including SDS, labeling, and molded products based on standardized GHS labeling. Specifically, the government has implemented 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. These trends are shown in Figure 16.

Figure 17 shows changes in the numbers of reported accidents, collected and compiled by the government, into the "Health damage accidents caused by chemicals contained in household products" reports.

<sup>16</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	FY2019	
Domestic Laws and Regulations	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				
	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								
Domestic Standards	JIS Z 7252 (Classification)			JIS Z 7252: 2014 Revision (Provisional period: May 24, 2020)						May 25, 2019 JIS Z 7252: 2019 revision (GHS Ver. 6)	
	JIS Z 7250 (MSDS)	JIS Z 7250: 2010 Revision	(Abolished: Provisional period ended December 31, 2016)								
	JIS Z 7251 (Labeling)	JIS Z 7251: 2010 Revision	(Abolished: Provisional period ended December 31, 2016)								
	JIS Z 7253 (Information communication)	Established in March 25, 2012	Integrated	JIS Z 7253: 2012 (Provision period: May 24, 2022)							May 25, 2019 JIS Z 7253: 2019 revision (GHS Ver. 6)

(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).
- 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)

<Products containing designated chemicals at least at the specified content>

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

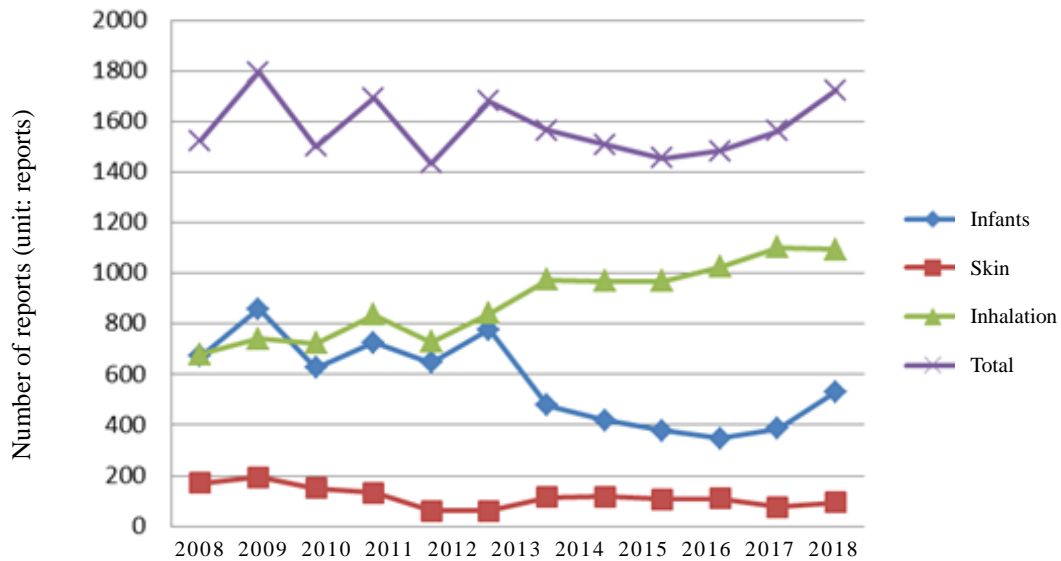
Business operators are required to endeavor to issue SDS, for dangerous and hazardous chemicals which are not required to have SDS issued in the Industrial Safety and Health Act (Article 24-15).

(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)



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

	FY 2016			FY 2017			FY 2018		
	Household goods, etc.	No. of reports	%	Household goods, etc.	No. of reports	%	Household goods, etc.	No. of reports	%
1	Detergents (for housing and for furniture)	269	22.4	Detergents (for housing and for furniture)	269	20.7	Detergents (for housing and for furniture)	266	20.6
2	Insecticides	276	22.0	Insecticides	255	19.6	Insecticides	248	19.2
3	Bleaches	123	9.8	Bleaches	146	11.2	Bleaches	119	9.2
4	Aromatics and deodorants	90	7.2	Waterproof spray	98	7.6	Waterproof spray	92	7.1
5	Disinfectants	59	4.7	Aromatics and deodorants	69	5.3	Disinfectants	89	6.9
6	Waterproof spray	55	4.4	Disinfectants	58	4.5	Detergents (for washing clothes and for the kitchen)	67	5.2
7	Detergents (for washing clothes and for the kitchen)	53	4.2	Gardening insecticides and fungicides	55	4.2	Aromatics and deodorants	65	5.0
8	Gardening insecticides and fungicides	44	3.5	Detergents (for washing clothes and for the kitchen)	31	2.4	Gardening insecticides and fungicides	42	3.2
9	Repellents	30	2.4	Herbicide	23	1.8	Repellents	39	3.0
10	Desiccants	22	1.8	Fire extinguishing agents	22	1.7	Herbicide	21	1.6
	Total for the top 10 items	1,046	83.3	Total for the top 10 items	1,026	79.0	Total for the top 10 items	1,048	81.0
	Total	1,256	100.0	Total	1,101	100.0	Total	1,294	100.0

## 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. Specifically, in addition to the regulation on chemicals contained in environmentally friendly products, such as the EU RoHS Directive, etc., the regulation on chemicals contained for chemicals themselves, such as the EU REACH Regulation, has been expanded. In addition, similar regulations have been introduced in Asian and other countries, and responding to these regulations has become an issue for businesses involved in manufacturing in the supply chain.

In today's manufacturing, international division of labor is progressing, and various products are manufactured through a globally expanding supply chain and sold to countries throughout the world. Businesses are not only required to respond to regulations that directly affect their products, but are also required to indirectly respond to regulations related to the supply chain that supplies their products, including information required to determine compliance with laws and regulations in the destination country of the final product. Thus, regulatory compliance of products manufactured by the division of labor in the supply chain is heavily dependent on information transmitted between companies.

The Ministry of Economy, Trade and Industry has studied the transmission of chemicals in products for which a standardized method has not been established in Japan, and developed a new information transmission scheme, "chemSHERPA," which is aligned with IEC62474, keeping an eye on global trends, and taking into account both the existing Joint Article Management Promotion-consortium (JAMP) and the former Japan Green Procurement Survey Standardization Initiative (JGPSSI). In cooperation with JAMP, which has been the operating organization of chemSHERPA since 2016, the Ministry is promoting activities for domestic dissemination and ensuring compatibility with other schemes outside Japan as necessary.

#### **[Examination for minimizing environmental risks throughout the life cycle] (MOE)**

In order to conduct more detailed risk assessments of the entire life cycle of manufacturing, importing, using, recycling, and disposing of chemicals, the Ministry of the Environment is developing a method to understand the flow and stock throughout the life cycle of chemicals by utilizing big data related to chemicals, including information on production and import quantities and usage of chemicals, and industrial statistics of products using chemicals, PRTR information, and monitoring data.

### **<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 pages 37.)

**[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 72.)

**< 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 pages 37.)

**<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 38.)



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

### (1) The Basic Approach to Issues

Until now, the government has been working on domestic chemical management from an international perspective in line with SAICM, and has contributed to the international implementation of SAICM by complying with international treaties related to chemical substance control measures. In line with the new international framework for chemical substance management after 2020 expected to be formulated in ICCM5, the government should continue to commit itself to chemical management from an international standpoint, based on the relevant international conventions, OECD frameworks. The government should also facilitate capacity development in various countries, by further strengthening cooperation with other Asian countries using its experience and technologies.

### (2) The Results of the Efforts

In order to tackle the above-mentioned issues, the government has made 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. The government has tapped into Japanese technologies related to chemical substance control measures, 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 addition, to prevent global environmental pollution and health damage caused by mercury, the Minamata Convention on Mercury was adopted at a diplomatic conference held in Kumamoto City and Minamata City in October 2013 and entered into force in August 2017, having contributed to domestic mercury control and the steady implementation of the Convention.

## 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 and the second revision in October 2016.

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 review results were submitted to the Secretariat of the convention in August FY2012 and FY2016, respectively.

As the next step, the government intends to amend the national implementation plan and submit it to the Secretariat of the convention by the end of December 2020, in response to the addition to the POP list of chemicals adopted at the Meetings of the Conference of Parties at its eighth (May 2017) and ninth (May 2020) meetings.

#### [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 ambient air, surface water, sediment, wildlife, etc. in Japan, in order to obtain up-to-date pollution data for 30 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.
- At the third ExCOPs held in 2017, the activities and issues of each of the three conventions were confirmed. Through the progress of the synergies among the three conventions, it was confirmed that the rational operation of the convention secretariat and the joint implementation of technical assistance activities have been progressing.
- At the fourth ExCOPs held in 2019, an amendment was adopted to add dirty plastic to the wastes controlled by the Basel Convention. This amendment, which was implemented by a joint proposal with the participation of Japan, was a significant achievement for promoting environmental measures including the marine plastic waste problem, which has attracted international attention in recent years. Furthermore, it was also agreed to establish a mechanism to comply with the Rotterdam Convention, which had been pending for many years.

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 a new international framework for chemical substance management after 2020, in place of SAICM, as well as the 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, and the Minamata Convention on Mercury was finally adopted in October 2013 and entered into force on August 16, 2017. The convention internationally regulates mercury throughout its lifecycle, from its supply and use to its emission/release and disposal. In November 2019, the Third meeting of the Conference of the Parties to the Minamata Convention on Mercury (COP3) was held. Japan will continue to contribute to domestic measures against mercury and to the steady implementation of the Convention, bearing the name of Japan's place.

#### ○ 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.

Japan hosted the Diplomatic Conference of the Minamata Convention on Mercury in Kumamoto City and Minamata City on October 9 through 11, 2013, and the Minamata Convention was adopted at the meeting. 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; this signifies to the international community the country's support for the convention and its determination to strengthen mercury control measures.

#### ○ Efforts to implement the Minamata Convention on Mercury

As part of the "MOYAI Initiative," which supports developing countries on mercury control and disseminates information from Minamata, Japan is implementing initiatives to accelerate mercury countermeasures by supporting developing countries in terms of networking of information and efforts of Japan and related countries as well as survey and evaluation of the current situation of each country utilizing Japan's experience, including monitoring. Furthermore, Japan will support developing countries in strengthening their measures against mercury through international development of Japan's advanced mercury countermeasure technology and know-how.

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. In the review and risk assessment of the CSCL, evaluation methods for difficult-to-evaluate substances are being examined and evaluation methods based on international trends and accumulation of knowledge are being reviewed.

The OECD Test Guidelines and the OECD Principles of Good Laboratory Practice (OECD GLP Principles) have been established 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 that comply with the guidelines and principles and conducting inspections of test facilities. Furthermore, Japan contributes to the improvement and harmonization of international management of chemicals, such as taking a leading role in considering the development and renewal of test methods and the like.

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

## 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 category 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 Ver. 1.0) was released in January 2008 and KATE 2011 was released in March 2011. Furthermore, the trial version of KATE 2017 was released in March 2018, and the official version of KATE 2017 was released in January 2019.

The MOE is also working on preparations to make KATE available from the OECD QSAR Toolbox using the API (Application Program Interface) function.

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 28 test facilities has been confirmed as of March 2019. 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 six test facilities (for degradation tests and bioconcentration tests, etc.) has been confirmed as of March 2019. 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 2019.

The government developed a database (commonly known as J-CHECK) through which the government publishes information on the evaluation of New Chemicals 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.

Degradability assessment and accumulation assessment under the CSCL have problems such as the lack of use of data based on a number of internationally recognized test methods. Accordingly, in light of international trends, and in order to make the criteria for degradability and accumulation in the CSCL more scientifically relevant, the government is examining the ideal form and the direction to be evaluated for degradability and accumulation in the CSCL.

#### **[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 include them in the OECD test guidelines.

○ Hand1 Luc EST assay (in vitro test for reproductive and developmental toxicity)

This is a test method to evaluate reproductive and developmental toxicity by monitoring the expression level of Hand1 gene with luciferase during the process of differentiation of ES cells into cardiomyocytes, and the OECD is considering the creation of test guidelines.

○ 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

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) 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 26 to 27.)

**[Consideration of Upgrading of Toxicity Test Methods for Higher Predatory Animals]**

(The content is omitted as it is the same as the content on page 25.)

**[Consideration of Test Methods of Difficult Substances for Ecotoxicity Test]**

(The content is omitted as it is the same as the content on pages 25.)

**<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 57.)

**c) Promoting the Dissemination of Information on SAICM from Japan, International Collaborative Work, Technical Support and Other Efforts**

**The Status Quo**

As for promoting the information dissemination 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.

#### 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 “13th Japan-China-Korea Policy Dialogue on Chemicals Management” was held in Fukuoka City in October, 2019, and information and opinions were exchanged on the latest trends and future directions of chemical substance management policies, responses to international trends in chemical substance management, and the status of responses to the latest issues in each country. Prior to the dialogue, a Japan-China-Korea expert meeting was held to exchange information on technical methods for risk assessment. In order to harmonize the methods of conducting ecotoxicity tests, comparative results of chronic fish toxicity tests conducted in various countries as a joint research effort between Japan, China, and South Korea were reported, and the results were confirmed. The three countries have agreed to work toward formulating a "Policy Dialogue Tripartite Action Plan" on chemicals management in Japan, China, and South Korea from 2020.

In addition, the MOE has been conducting training for government officials since FY2011 to promote the improvement of chemical substance control measures in each country in the Asian region. In November 2020, the “5th Seminar on the Promotion of Capacity Development for Chemical Substance Control Measures in Asia (Indonesia)” was held in Jakarta, Indonesia. Participants exchanged opinions and information on chemical substance management policies such as the examination and regulation system for chemicals and the PRTR system, and confirmed that they would continue to cooperate to improve chemical substance management in both countries. In March 2020 (scheduled), the “8th Seminar on the Promotion of Capacity Development for Chemical Substance Control Measures in Asia” will be held in Vietnam.

The Ministry of the Environment will continuously hold policy dialogues on chemical management in Asia and seminars on promotion of capacity development for chemical substance control measures in Asia and thus will promote cooperation and harmonization of the chemical substance examination and regulation system with the three countries of Japan, China, and South Korea, promote the capacity development for chemical substance control measures in the Asian region, and strive to realize appropriate chemical substance control measures.

The METI supports the establishment and operation of a risk-based chemical substance management system, by establishing Policy Dialogue on Chemical Management and implementing technical cooperation. The METI signed the Memorandum of cooperation (MOC) on the Second Phase Cooperation with the Ministry of Industry and Commerce of Vietnam on July 3, 2015 and with the Ministry of Industry of Thailand on December 22, 2015, respectively (resulting from the first MOCs signed by both countries in 2012). Based on the MOCs, the METI is providing necessary information for system development and support of



human resources development to government officials and the private sector of partner countries in cooperation with Japanese industry and NITE. The METI has also held the Policy Dialogue to strengthen chemical substance management every year since 2012.

In addition, the government is gathering and sharing information on chemical substance 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 Ministry of Economy, Trade and Industry (METI) has developed the ASEAN-Japan Chemical Safety Database (AJCSD) using the framework of the ASEAN Economic Ministers and Minister of Economy, Trade and Industry of Japan Consultations - Economic and Industrial Cooperation Committee (AMEICC). In April 2016, full-scale operation started, having NITE as the operator. This tool will increase transparency by sharing and disclosing regulatory information in Japan and the ASEAN region, and reduce compliance risks related to chemical safety, and is expected to contribute to harmonization of regulatory systems in the future.

#### **[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) 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) Project of Capacity Building for Analysis and Reduction Measures of Persistent Organic Pollutants in Serbia (2014-2017); and (4) Project for Strengthening Chemicals Management in Vietnam (2015-2018). As Knowledge Co-Creation Program, 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 has been changed ‘Capacity Building for Ratification of the Minamata Convention on Mercury’),” “Capacity Building for ratification of the Minamata Convention on Mercury,” and “Promotion of appropriate treatment technology for the treatment and disposal of hazardous waste. Examples of JICA’s projects related to the appropriate treatment, etc. of waste containing hazardous substances include the following: (1) Project for Formulation of Western Province Solid Waste Management Master Plan (2019-2022); (2) The Project for development of mechanism for household E-waste management in Malaysia (2015-2018); and (3) Project for E-waste Reverse Logistics Improvement (2014-2017).

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 contribute to the appropriate implementation of the Stockholm Convention by continuing our work for the next submission by 2020.

### **[Efforts on Mercury] (MOE)**

#### ○ 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 meetings regularly; 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. In addition, since 2017, the government has been conducting joint research in the chlor-alkali field, led by the US Environmental Protection Agency (USEPA). The government will continue to contribute to international mercury management measures via the partnership program.

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

In order 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, and aiming at achieving the WSSD2020 Goal which is the goal of SAICM National Implementation Plan of Japan, the government has been endeavoring to develop systems that 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, the government has been promoting the development of systems 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. The government has been actively promoting 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 and consider a national plan based on the new international framework for chemical substance management after 2020, which is scheduled to be formulated in ICCM5.

### <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 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.
- The supplementary provisions of 2017 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.
- 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>17</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.

### <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

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<sup>17</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>)

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 MOE will continue to provide support for prefectural or city municipal governments pertaining to investigation for finding any pieces of equipment which has not been reported, as well as for activities pertaining to raising awareness for storage operators. The government will also strengthen cooperation between the relevant organizations including the MOE, JESCO, prefectural governments, city municipal governments, the METI, and the 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 making 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>

- For the strengthening of chemical management in emerging countries and elsewhere, and international cooperation in chemical management, the government will continue to promote actions, including sharing of experiments, etc. regarding chemical control in Japan.
- 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.