The Subcommittee on Amendment of the Chemical Substance Control Regulation, the Committee on Chemical Substance Control Regulation, the Health Sciences Council, the Subcommittee on Planning of Chemical Management, the Chemical and Bio-Industry Committee, the Industrial Structure Council, and the Subcommittee for the Environmental Management of Chemicals, the Environmental Health Committee, the Central Environment Council (the meeting of the Joint Committee to Review the Chemical Substances Control Law)

Report (abstract)

December 22, 2008

II. New system of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (the Chemical Substances Control Law) to be established by 2020

1. Control of chemicals based on the WSSD goal

In the review of amendment of the current Chemical Substances Control Law, the primary concept is that considering WSSD goal. Considering precautionary approach, the control of production and use, risk control measures and information communication are attained as applied to the extent of risks in accordance with scientific risk assessment. In other words, a review of the system for the Chemical Substances Control Law should be done in order to reassess risks of chemicals that are manufactured, imported or used as chemical industrial products in Japan by 2020 and to realize risk-dependent controls by then. Based on the above concept, a system for the new Chemical Substances Control Law is reviewed on the following three issues: (1) the construction of a system for risk assessment of chemicals based on their post-marketing status; (2) an advanced pre-marketing evaluation system for new chemicals based on the risk aspect; and (3) the handling of chemicals to be controlled by strict risk control measures.

2. Construction of a system for risk assessment of chemicals based on the post-marketing status

At present, risk assessment of chemicals in food, pharmaceuticals and pesticides, etc. is carried out based on individual laws, considering the purpose and use of each. On the other hand, the current Chemical Substances Control Law functions to perform a required hazard assessment of chemicals for other use on risks via the environment[1] and implements control measures for chemicals in the

[1] The risks subject to the Chemical Substances Control Law are defined to be the potential that chemical substances, generally called as chemicals for industrial use, contaminate the environment during the steps of production and use and affect human health and/or the habitat and growth of plants and animals. The Chemical Substances Control Law

manufacturing or importing stages in accordance with their hazards and risks.

The scope of the Chemical Substances Control Law includes widely-used industrial chemical products except those for the specific uses described above. Therefore, the amounts of production or import vary, ranging from enormous to extremely minute quantities. Also, their use and releases into the environment can also occur in many different ways. Thus, in the assessment of risk, it is important to set the appropriate scope and type of exposure-related information and hazard information to collect, considering both feasibility and cost-effectiveness.

As described above, the universal goal is that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using science-based risk assessment procedures and risk management procedures, taking into account a precautionary approach. International efforts taking these factors into consideration are ongoing. We, Japan, are one of the leading countries in terms of the production of industrial chemicals and we have already streamlined our systems for chemical production. We should take positive measures to meet the international goal and collect information necessary for risk assessment and assess them considering reaching effectiveness by 2020.

In these circumstances, a desirable system is one in which the government has responsibility to implement risk assessment for control measures subject to the Chemical Substances Control Law while business institutions collect information for the assessment in principle. In addition, to promote the control of existing chemicals, a framework is required for the government to assess the extent of the risks of all chemicals already in the market and to call for the management of chemicals as needed. Based on the above concept, appropriate ways and procedures for risk assessment subject to the Chemical Substances Control Law are to initially collect exposure-related information, in particular information concerning the amount of production or import and the use of all chemicals already in the market, and subsequently collect hazard information as required. In other words, the current law system in which chemicals targeted for risk assessment are selected according to the extent of hazards should be shifted to a new system in which all chemicals in the market in principle are assessed considering potential risks.

It is recommended that the government estimate environmental exposure using information concerning the amount of production or import and the use of substances, which is routinely collected, and subsequently to implement screening assessment based on known information, and then finally to select chemicals to be assessed in priority. The government gradually obtains

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intends to prevent these risks.

additional information concerning hazards and the use of selected chemicals and then implements risk assessment. Business institutions in principle collect the relevant information (see Appendix for the detailed scheme). The system is capable of allowing chemicals, which have already been judged to have a low risk, to be reassessed when the amount of production or import or their use is changed. In such a new system with the Chemical Substances Control Law consisting of screening assessment and phased risk assessment, government and business institutions should cooperate to promote prompt and effective risk management and achieve the WSSD goal.

1) Construction of a framework for understand the exposure to post-marketing chemicals

The current Chemical Substances Control Law designates “Monitoring Chemical Substances” and demands business institutions to notify the annual amount of production or import of such chemicals and uses such data to judge whether the chemicals are designated as “Specified Chemical Substances“. This system has been working reasonably well. However, there are actually many existing chemicals in the market that are used without sufficient hazard assessment. In addition, it takes much time and cost to obtain new hazard information by the implementation of testing and there are limited institutes that can contract risk assessment studies from the government. Based on these circumstances, it is not rational to expect prompt and effective hazard information collection concerning all chemicals without exception and to implement full risk assessment.

To construct a system for more prompt and efficient risk assessment subject to the Chemical Substances Control Law considering the above viewpoints, a new system is required to oblige business institutions that manufacture or import all of the post-marketing chemicals of a certain amount or more to routinely notify the amounts to the government. Simultaneously, business institutions are also obliged to submit information of chemical usage in accordance with objective and internationally consistent classifications, in order to estimate exposure (environmental release) from the amount of production or import.

Since chemicals with serious toxicity (CMR[2], etc.) should be carefully considered in risk assessment and management, business institutions are required to optionally submit the rationale information for GHS classification if available as the reference for risk assessment and management.

2) Judgment of the priority, etc. in the implementation of risk assessment

In the next stage, the government should implement screening assessments based on

[2] Carcinogenic, mutagenic and reproduction-toxic properties.

environmental exposures using such information submitted and known information concerning hazards. Based on the results, the government should classify into chemicals that are confirmed to have sufficiently low risk and those that require further risk assessment because of no confirmation of a sufficiently low risk, and designate and publish the latter as the “Priority Assessment Chemical Substances (tentative name)”.

For the chemicals in which considerable hazard information (including CMR information) is available from the testing of existing chemicals by governmental, pre-marketing evaluations subject to the Chemical Substances Control Law, and the optional data submitted by business institutions, the government should judge also the extent of expected risks and utilize the results in selecting the “Priority Assessment Chemical Substances”. If business institutions optionally submit hazard information, etc. concerning chemicals they handle, the government can implement screening assessments with hazard information and the efforts of the business institutions that perform appropriate management can be considered better. Consequently, it is expected that the system gives the business institutions an incentive to submit the hazard data. On the other hand, existing chemicals with insufficient hazard information to which a certain exposure is expected should be designated as “Priority Assessment Chemical Substances” based on no confirmation of being of sufficiently low risk.

The “Priority Assessment Chemical Substances” should be routinely reviewed. Even the chemicals, which have already been judged to have a low risk, are reassessed when the amount of production or import or their use is changed and are able to be designated to the “Priority Assessment Chemical Substances”. In contrast, the chemicals, which are confirmed to have a sufficiently low risk by decreased environmental releases due to changes in use, etc. and/or newly obtained hazard information, are excluded from the list of the “Priority Assessment Chemical Substances”.

When a new system to oblige business institutions that manufacture or import all of the post-marketing chemicals of a certain amount or more to notify the amount and use of such chemicals to the government in this amendment is established, furthermore, a new classification of the “Priority Assessment Chemical Substances” for selecting chemicals for risk assessment is specified in this amendment, the designation system of “Type II and III Monitoring Chemical Substances” of which the amount of production or import are required to notify subject to the current the Chemical Substances Control Law should be abandoned. Of these “Type II and III Monitoring Chemical Substances”, on which considerable hazard information is already available and the amount of production or import is annually notified, those with no confirmation of being a

sufficiently low risk based on such information are designated to the “Priority Assessment Chemical Substances”. The hazard criteria used in the judgment of the current “Type II and III Monitoring Chemical Substances” are recommended to be used for the establishment of the criteria for risk assessment in the new system. On the other hand, the system for designating the “Type I Monitoring Chemical Substance” as persistent and highly bioaccumulative chemicals should be maintained because of the enhancement of information submission and management in trade as described below.

Also to promote the availability of the existing hazard information, the government should publish the existing results of governmental hazard and risk assessment of chemicals and similarly hazard information submitted by business institutions in the “Japan Challenge Program”, etc. Simultaneously to the designation of new chemicals, brief risk information data used for the pre-marketing evaluation should be published to promote the appropriate management of chemicals. It is expected that hazard information on chemicals in the market and the status of collection will be available to business institutions and the public.

3) Cooperation of business institutions to implementation of risk assessment and information gathering

For the “Priority Assessment Chemical Substances”, it is not desirable that the effects of such chemicals on human health and environment remain unassessed due to the lack of necessary hazard information, etc. The government, therefore, should implement risk assessment of the “Priority Assessment Chemical Substances” and gather hazard information and detailed information for use,[3] etc. under some legal instructions.

In that case, it is desirable to oblige manufacturers or importers to submit hazard information including items of the SIDS data (required items) from the viewpoint of international consistency. In addition, it should be also considered to oblige manufacturers or importers to submit the relevant data or other data concerning long-term toxicity if available, i.e., to enhance the obligation of hazard reporting subject to the current Chemical Substances Control Law. For exposure information including individual use, it is required to oblige users in addition to manufacturers or importers to submit such information.

Of the “Priority Assessment Chemical Substances”, those with no confirmation of sufficiently being a low risk by the risk assessment based on the above information should be assessed more

[3] The “Detailed information for use” described in this report is defined to be the information for used that is required to estimate exposure for further evaluation in progressing with the step-by-step risk assessment, and the results of risk assessment are expected to be appropriately published and identified.

accurately using long-term toxicity data. In such cases, when hazard information is insufficient, similarly to the direction of the current hazardous examination, the manufacturer or importers are obliged to collect and submit data of long-term toxicity tests.

Under the step-by-step procedures as described above, information gathering and risk assessment of chemicals in the market are implemented to avoid an undesirable status be attached to the substance due to the lack of hazard information, consequently, prompt and effective risk management can be promoted to achieve the goal by 2020.

4) Consideration of the environmental persistency of chemicals in post-marketing risk assessment

Another opinion is that even non-persistent chemicals can remain in the environment when released into the environment exceeding the degradable amount. Consequently, the possibility cannot be ruled out that environmental contamination with non-persistent chemicals has affects on human health, plants and animals. Therefore, such chemicals should be controlled by the Chemical Substances Control Law. If even new chemicals, which are to be launched in the market without a screening toxicity study due to its high degradability, are designated into the chemicals to be notified for the amount of production or import after reviewed and announced as new chemicals, such chemicals can be assessed by the above-mentioned step-by-step system for risk assessment subject to the Chemical Substances Control Law. On the other hand, there was a different opinion against the above system that degradable chemicals can be controlled by other laws at release stages and such a system should be discussed furthermore considering the background on the enactment and enforcement of the Chemical Substances Control Law.

Based on these circumstances, the government should continue to discuss whether such chemicals are controlled by the Chemical Substances Control Law or not and implement risk assessment and management of such chemicals.

5) Improvement in methods for appropriate risk assessment and provision and distribution of information

In operating the above-mentioned step-by-step system for risk assessment, to provide more accurate risk assessment, it is recommended to use PRTR data on “Class I Designated Chemical Substance (PRTR-designated substance)” subject to the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law) as well as available environmental monitoring data. In particular, based

on the fact that PRTR-designated substances have been selected considering their toxicity to humans, plants and animals and exposure through the environment, it is necessary to promote establishing the chemicals designated by both laws (the “Priority Assessment Chemical Substances” and the PRTR-designated substances) with attention to the purpose of information gathering in the Chemical Substances Control Law and the PRTR Law, and the GHS Classification. In addition, it is preferable to make the “Priority Assessment Chemical Substances” subject to environmental monitoring as much as possible.

In the discussion on the future system for the Chemical Substances Control Law, it is desirable to propose practical criteria based on scientific findings; i.e., to show which information is the rationale for judging sufficient low risk and which case is finally assessed to have a potential effect on human health, plants and animals or to be high-risk. If such criteria are presented, business institutions can recognize the extent of risks to manage on their own responsibilities and intensively collect hazard information required for the risk assessment.

Simultaneously, in the system for chemical management with attention to risks, it is also essential for business institutions to surely provide chemical safety information from those upstream to those downstream in cooperation with each other. This provision of information can realize the risk assessment and management considering the effects associated with release into the environment surrounding business institutions. For efficient collection of the use of chemicals, the cooperation between downstream and upstream business institutions is important and desirable. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) stipulates the obligation that safety information on chemicals that are classified to be hazardous at a certain level or more should be provided by MSDS, etc. Considering such global trends, business institutions handling chemicals should classify such chemicals according to the GHS classification on their own responsibilities and provide the information when such chemicals are designated as hazardous chemicals at a certain level or more.

3. Advanced pre-marketing evaluation system for new chemicals based on risk aspect

The pre-marketing evaluation system for new chemicals by the Chemical Substances Control Law is a pioneer screening system worldwide to assess whether chemicals newly to be manufactured or imported are the potential substance with a persistency and high bioaccumulation similar to PCB, i.e., the “Class I Specified Chemical Substance (highly hazardous chemical)” classification, prior to launching in the market. After that, the “Class II Specified Chemical Substance” classification without high bioaccumulation was also established and potential chemicals corresponding to this

definition were also screened in the pre-marketing evaluation. This pre-marketing evaluation system has been functioning effectively to date to assess chemicals basically on hazards and prevent environmental contamination.

Then, in addition to hazard assessment, comprehensive assessment and management of all chemicals are in progress worldwide based on the amount of production and use conditions of chemicals in the market, and scientific findings of chemical properties have been accumulated.

The Chemical Substances Control Law in Japan seeks to control chemicals by measures in the manufacturing or importing stage. Therefore, hazard assessment (evaluation) of new chemicals other than those meeting certain requirements or classification is performed to judge whether to approve the launch of such chemicals. However, the pre-marketing assessment (evaluation) does not consider the extent of post-marketing risks. On the other hand, hazard assessment of existing chemicals already in the market is in progress by the government as safety inspections similar to those of the pre-marketing evaluation. However, the chemicals to be assessed are selected in accordance with the extent of post-marketing exposures based on the actual amount of production or import.

In these circumstances, to construct a system for chemical management with attention to risks under the Chemical Substances Control Law considering the international risk assessment and management system, in addition to conventional hazard assessment, risk assessment considering the extent of post-marketing exposure should be incorporated in the pre-marketing assessment (evaluation) of new chemicals. This incorporated assessment system can provide the consistency of the pre-marketing evaluation for new chemicals with a system designating the “Priority Assessment Chemical Substances” based on the screening assessment for chemicals in the market. Simultaneously, the classification of substances for assessment and the definition of substances to be assessed should be reviewed and revised as well as the introduction of new assessment methods.

1) Implementation of risk assessment in the pre-marketing evaluation

The current pre-marketing evaluation system for new chemicals obliges business institutions to collect the data to be used in the hazard assessment (degradability, bioaccumulation and long-term toxicity to humans and ecotoxicity) by the government. This is a very effective system because it promotes appropriate management of post-marketing chemicals according to the results of hazard assessment and prevents new highly hazardous chemicals from being launched in the market.

The target of this pre-marketing evaluation is new chemicals in which the amount of production or

import exceeds 1 ton/year in principle. The detailed flow of review procedures is as follows: the chemicals are first reviewed based on the results of degradability and bioaccumulation studies. Consequently, the chemicals that are confirmed to be persistent and highly bioaccumulative are considered to be a candidate of the “Class I Specified Chemical Substance” and a long-term toxicity study should be conducted to confirm the designation. Then, no new persistent and highly bioaccumulative chemicals have been notified. In cases in which chemicals are judged to be persistent but not highly bioaccumulative, their production or import of 10 tons or less is approved by prior confirmation and follow-up monitoring. When their production or import exceeds 10 tons, the chemicals are assessed based on the study results of effects on human health and the ecosystem and are judged whether to be “Type II or III Monitoring Chemical Substances”. For chemicals that are designated into the “Type II or III Monitoring Chemical Substance” category based on the results of prior confirmation, their post-marketing risk assessment and management are performed as required by the annual notification of the amount of production or import.

In these circumstances, to place the importance on assessment of the “Priority Assessment Chemical Substances” considering risks, the government should also assess new chemicals by screening based on the expected post-marketing amount of production or import and use in addition to the data concerning degradability and bioaccumulation, and hazard information such as screening toxicity information, which are subject to the current system. Consequently, the government should designate those substances with no confirmation of sufficiently low risk based on such information to the “Priority Assessment Chemical Substances” and assess them in a fashion similar to post-marketing chemicals considered to be risks.

In judging whether new chemicals correspond to the “Priority Assessment Chemical Substances”, the same criteria as those for post-marketing chemicals should be applied and the amount of production or import and use should be obtained from the schedule information described in the application form.

2) Disclosure of chemical names after pre-marketing evaluation

Under the current Chemical Substances Control Law, when the results of hazard assessment for new chemicals are disclosed, such chemicals are represented by their IUPAC name[4] following pre-marketing evaluation (without delay for regulated substances, and 5 years after for others). Such chemicals are treated similarly to existing chemicals. Once the detailed name such as the IUPAC

[4] It is a name given by the International Union of Pure and Applied Chemistry (IUPAC), which is an international academic organization of chemists and was established in 1919. The IUPAC nomenclature, a systematic nomenclature of organic compounds was established in 1973 and later revised in 1993.

name has been disclosed, the structures of such chemicals are easily specified and the same chemicals can be manufactured by others. Consequently, the disclosure of the detailed name of new chemicals after the evaluation can be harmful for the applicant business. For example, in the United States, the generic name in which a part of the structure is concealed is allowed, and the name is announced with consideration in many countries.

To prevent duplicate applications of new chemicals, it is necessary to disclose the chemical name that accurately identifies the substance such as the IUPAC name. On the other hand, to prevent replication by late manufacturers and guard the interests of the developer, it is required to consider the method of disclosure by a name from which chemicals cannot be completely identified (e.g. a generic name). It was pointed out that the correspondence of chemicals with their hazard information should be definitive and other information on similar chemicals should be easily linked in order to utilize hazard information on chemicals for not only safety control but also QSAR development.

Guarding the interests of the developer can be achieved by an effective system of intellectual property protection and an appropriate interval before the disclosure of the name. On the other hand, the extent of negative effects of the disclosure of a detailed name should be continuously assessed and discussed considering practical conditions although it is required to remain internationally consistent with maintaining the competitive edge.

3) Active utilization of QSAR and category approach

The QSAR is a model by which the chemical structure or physiochemical properties are quantitatively correlated with biological activity (toxicity). The category of chemicals indicates groups of chemicals with similar physicochemical and toxic properties (or properties with certain regularity) due to structural similarity. The category approach is a method that uses the existing test results of some of chemicals included in a category, so that the results of untested chemicals are assumed. Both of them are positively used in Europe and the United States etc., where reduction of animal testing is requested.

These methods will be utilized to the extent possible, in light of seeking effectiveness in cost and period for testing and international request to cut animal testing. The accuracy of assessment by QSAR and the category approach strongly depends on the extent of accumulation of hazard data of similar chemicals, therefore, it is generally considered that these methods are reasonable to use for the hazard assessment of existing chemicals. On the other hand, these methods are effectively used in screenings in the stage of developing new chemicals; therefore, it is possible to complement the

test results (data) by combining them with other methods such as the use of the OECD QSAR tool box[5]. In addition, it is important to develop animal testing alternatives including QSAR.

4) Pre-marketing evaluation of new chemicals with possible low risks due to small quantities

For chemicals with a small quantity of production or import, as with the systems of other countries, such chemicals are not targeted for risk assessment or management by the government, but are under the control of business institutions. The reasons are probably the low adverse effects of environmental contamination due to the small amounts involved and less expectation that many business institutions simultaneously use such chemicals.

The Confirmation System for Small Amounts of New Chemicals by the Chemical Substances Control Law also has been functioning appropriately in Japan based on a similar viewpoint. However, this system cannot deny the use of the same substances by multiple business institutions and in cases in which applications are submitted by multiple business institutions, the government has to confirm that the total amount to be used domestically is 1 ton or less. Generally, new chemicals that are manufactured or imported in small amounts are often sophisticated products specific to limited uses; therefore, excluding some exceptions, there is almost no possibility that many business institutions submit applications for the same substance. The data for the 2007 fiscal year shows that approximately 15,000 substances were notified for confirmation as small amounts of new chemicals and more than 80% of them were submitted by one business institution alone. For duplicated cases, more than 97% of them were submitted by up to three business institutions and more than 99% by up to five business institutions. Based on the mean amount per business institution of 300 kg to 500 kg at present, almost the entire small amount of new chemicals is expected to be around 1 ton/year.

From the viewpoint of advanced chemical management according to the extent of concerns about risks even small amounts of new chemicals are required for business institutions to voluntarily manage them while promoting international consistency of the system. Therefore, in the Exception to Evaluation for Small Amount of New Chemicals, it should in principle confirm such chemicals per the unit of business institution (up to 1 ton/year/institution) while the system keeps consistent with special measures for new chemicals that are produced in small amounts. However, in cases of duplicated applications by multiple business institutions, to maintain the current risk level as an

[5] The QSAR tool box is a software packaging various QSAR models provided by many member countries, the category classification, inventory of chemical compounds, and the actual data of physicochemical properties and hazards, providing a function to estimate toxic values of chemical substances. This tool box is produced for the Use by the government and chemistry-related business institutions and the product (ver. 1.0) has been published in March 2008.

appropriate safety net, the application of small amounts of new chemicals with a high possibility of risk concerns should not be permitted after judging the possibility of risk based on domestic amounts and existing findings such as QSAR, etc. In addition, the government should conduct on-site inspections to make follow-up confirmation.

5) Establishment of the confirmation system of polymers of low concern (PLCs)

It is generally considered that polymers, which have a high molecular weight and cannot pass through cell membranes, are of low concern. Therefore, REACH excludes all polymers from regulation (registration) at present (some monomers alone are registered.) The United States, Canada and Australia adopt common criteria for polymers of low concern (PLCs) as substances exempted from notification of new chemicals, based on mean molecular weight, the volume of contained low-molecular substance and functional groups.

For PLCs, from the viewpoint of international harmonization concerning the criteria for polymers of low concern (PLC criteria) and the review system, if business institutions submit the application for confirmation of new chemicals corresponding to the PLC criteria with required data and the government makes confirmation, the evaluation based on hazard data obtained from tests should not be required. Similarly to the Exception to Evaluation for Small Amounts of New Chemicals, the government should consider the necessity of follow-up confirmation such as on-site inspections to confirm that polymers actually manufactured correspond to the PLC criteria. On the other hand, the Polymer Flow Scheme is a simple test method for polymers difficult to conduct studies on subject to the review in the Chemical Substances Control Law, and has been confirmed to have some role. Therefore, also after establishment of PLC Confirmation System, this method should function as a test method for polymers other than PLC.

4. Handling of chemicals targeted for strict risk control measures

Substances targeted for strict risk control measures should continue to be treated by strict control measures considering international trends, and for chemicals judged as high risk by risk assessment, risk-reducing measures including the restriction of manufacture or import, appropriate handling, and secure communication of safety information should be given.

1) International harmonization of “Class I Specified Chemical Substance”

The Chemical Substances Control Law designates high-risk chemicals with persistence, high

bioaccumulation and long-term toxicity as “Class I Specified Chemical Substances” and has been strictly restricting their manufacturing and use in principle. Such chemicals in which risk control is substantially difficult will continue to be controlled by strict measures.

On the other hand, the Stockholm Convention on Persistent Organic Pollutants (POPs convention) was concluded to regulate highly hazardous chemicals and Japan is also a signatory country. Therefore, when new chemicals are added to the POPs convention, it is necessary to set control measures by the Chemical Substances Control Law. The POPs convention promotes the assessment of candidate chemicals to be added and the additional substances are expected to be decided at the Conference of Parties of United Nations Conventions, although uses that cannot be replaced are to be exceptions allowed under certain conditions. In the Chemical Substances Control Law, “Class I Specified Chemical Substances” are extremely limited in their use, i.e., their use is actually prohibited. However, considering this trend and from the view point of international harmonization in control, it is necessary to review the use limitation of “Class I Specified Chemical Substances”. To be specific, uses that cannot be replaced and are included in those internationally permitted by the POPs convention (essential use) etc. should be permitted also by the Chemical Substances Control Law under certain conditions such as strict control over releases into the environment. However, even if chemicals are permitted as essential use, the replacement and reduction of them by business institutions should be pledged.

If essential use is permitted, “Class I Specified Chemical Substances” can be distributed in specific markets in the future. Therefore, the obligation to inform is required to be introduced in order to surely provide information concerning safety and appropriate management from upstream to downstream. In addition, products containing “Class I Specified Chemical Substances” should be strictly managed by appropriate information provision to customers from business institutions.

2) Encouraging information provision on “Type I Monitoring Chemical Substances”

“Type I Monitoring Chemical Substances” are persistent and highly bioaccumulative; however, their long-term toxicity to humans or top predators remains unknown. If “Type I Monitoring Chemical Substances” have long-term toxicity to humans or top predators, their environmental contamination can damage humans, plants and animals, therefore, their exposure status is monitored by the notification of the amount of production or import as preventive measures. In addition, when it is required to judge whether such chemicals correspond to “Class I Specified Chemical Substances” because they are expected to contaminate the environment, they are controlled by a system in which business institutions are obliged to perform a hazard study on long-term toxicity to

humans or top predators considering the circumstances of production, import and use.

As described above, “Type I Monitoring Chemical Substances” have long-term toxicity to humans or top predators and their environmental contamination can damage humans, plants and animals. Therefore, it is desirable to prevent environmental contamination by minimizing their releases into the environment but not restricting their production, etc. However, the current Chemical Substances Control Law does not establish a system of information communication related to dealing with “Type I Monitoring Chemical Substances” between business institutions. Consequently, business institutions can release chemicals into the environment without realizing that such chemicals are “Type I Monitoring Chemical Substances”.

Therefore, to promote voluntary control by business institutions and prevent environmental contamination by “Type I Monitoring Chemical Substances”, a system should be introduced that in handling “Type I Monitoring Chemical Substances”, business institutions provide information on the chemicals, including the fact that such chemicals are “Type I Monitoring Chemical Substances” and their handling requirements. Similarly, in handling products that include “Type I Monitoring Chemical Substances” and that can be released into the environment, similar information provision should be laid on business institutions in order to minimize releases of “Type I Monitoring Chemical Substances” into the environment.

3) Risk reduction measures of chemicals of high-risk concern

The current law designates high-risk chemicals as “Class II Specified Chemical Substances” whose production, import and use are controlled. For the production or import of “Class II Specified Chemical Substances”, the system obliges business institutions to notify the expected amount of production or import every year and can demand them to change the expected amount to prevent damage to humans, plants and animals by environmental contamination of such chemicals.

Based on the results of the above-mentioned step-by-step risk assessment, it is recommended that chemicals that are assessed to be high-risk are designated as “Class II Specified Chemical Substances” and risk-reducing measures including the restriction of manufacture or import, appropriate handling, and secure communication of safety information are given. In addition, for products including “Class II Specified Chemical Substances”, if such products are judged to be high-risk based on the form or status of the relevant substances released into the environment, such products should be under risk control measures similar to those for “Class II Specified Chemical Substances”.

For “Class II Specified Chemical Substances”, the current law has already obliged business institutions to label preventive measures for environmental contamination on “Class II Specified Chemical Substances” and relevant products, which imposes strict management on business institutions. To secure the control of high-risk chemicals everywhere in Japan, measures for secure information communication should continue to be given including the current labeling system.

There is an opinion that a similar duty of information communication to those for “Class II Specified Chemical Substances” should be introduced to the “Priority Assessment Chemical Substances”, which are to be introduced by this amendment of the system, in order to improve the risk control of chemicals across the country. Another opinion is that the “Priority Assessment Chemical Substances” is defined as chemicals that require further risk assessment because they offer no confirmation of sufficiently low risk. Therefore, it is difficult to implement appropriate risk control measures based on the condition that business institutions have not obtained results of risk assessment and that the number of the relevant chemicals is expected to be considerable. Based on these circumstances, the government should continue to review whether to introduce the duty of information communication to “Priority Assessment Chemical Substances” and implement them as required.