

**Joint Program Between the Private and Public Sectors for Collecting and
Releasing Safety Information of Existing Chemical Substances
(The Japan Challenge Program) Final Report**

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Ministry of Health, Labour and Welfare
Ministry of Economy, Trade and Industry
Ministry of the Environment

1. Outline of the Japan Challenge Program

(1) Circumstances Leading to the Start of the Japan Challenge Program

“The Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc. (Japanese Chemical Substances Control Act)” was enacted in 1973, triggered by environmental pollution problems caused by PCB. While this Act imposes on business operators a pre-marketing evaluation when they manufacture or import new chemical substances (newly registered chemical substances), chemical substances that had already been manufactured or imported before the promulgation of the Act (Existing Chemical Substances) were not subject to such evaluation. When enacting the aforementioned Act, the Diet passed an additional resolution that the government was to assess the safety of Existing Chemical Substances.

Thereafter, the government has implemented policies on the safety checking and risk assessment of Existing Chemical Substances. Since the 1990s, we have endeavored to gather safety information for High Production Volume (HPV) chemicals through international cooperation involving the Organisation for Economic Co-operation and Development (OECD) as the key player and also the relevant industry. For instance, the OECD/HPV Programme is to collect safety information of HPV Chemicals (chemicals which are produced with a production volume of 1,000 tons or more in one or more of the OECD Member countries), and to implement the initial assessment on their hazardous properties. Japan has consistently contributed to the promotion of the OECD/HPV Programme since its very beginning, and the industry has also cooperated in gathering information. The industry has also taken up activities to obtain and provide safety information under the ICCA (International Council of Chemical Association) HPV Initiative since 1998, actively contributing to the OECD/HPV Programme.

In addition, at the time of the amendment to the Japanese Chemical Substances Control Act in 2003, the joint council of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment put forward a suggestion that the safety assessment of Existing Chemical Substances should be conducted in cooperation between the public and private sectors. Accordingly, in the deliberations on the amendment bill, the Diet passed an additional resolution that the public and private sectors were to jointly promote a systematic, hazard assessment. On this basis, the “Joint Program Between the Private and Public Sectors for Collecting and Releasing Safety Information of Existing Chemical Substances (commonly known as “the Japan Challenge Program”) was launched in June 2005 as the framework to accelerate the collection of safety information of Existing Chemical Substances in cooperation between the public and private sectors and to disseminate such information to the public.

(2) Outline of the Japan Challenge Program

The Japan Challenge Program was an action to designate a number of Existing Chemical Substances as “Target Substances for Priority Information Collection” whose information was to be gathered on a priority basis, and to collect and release the safety information of these target substances. The industry and the government were to collaborate in collecting information. In relation to the safety information of substances that were not scheduled to be gathered in other overseas frameworks such as those of the OECD, we asked business operators for their voluntary, sponsoring cooperation in the Program. The sponsor companies were to collect safety information according to the SIDS (Screening Information Data Set) of the OECD and submit the information to the government. The government was to assess the reliability of the data submitted, construct a database of Existing Chemical Substances, and manage in an integrated manner the safety information regarding “Target Substances for Priority Information Collection” including the information submitted by business operators (sponsor companies), and utilize the Internet and other mediums to disseminate the information to the general public.

Specifically, 645 organic compounds were listed as Target Substances for Priority Information Collection, and among them, the government aimed to collect and release the information from abroad regarding 520 substances whose information was planned to be collected by overseas programs. For the remaining 125 substances, the private and public sectors cooperated in gathering and releasing safety information; we invited private companies and organizations from the industry to be the sponsors to gather information autonomously. We also received

sponsor registrations for six other substances which were not listed as Target Substances for Priority Information Collection.

Among the total of 651 substances (consisting of 645 Target Substances for Priority Information Collection and the six other substances for which the sponsors were registered), the information of 446 substances (approximately 70% of the total) was collected through our previous approaches, and has been or is planned to be released. In particular, the information for 67 substances was obtained through business operators' voluntary activities including the implementation of testing, and has already been made publicly available or is scheduled to be released in the near future. With the understanding and support of a great deal of business operators, we have further developed our approaches

(3) Changes in the Situation Due to the Amendment to the Japanese Chemical Substances Control Act, and the End of the Japan Challenge Program

The Japanese Chemical Substances Control Act was amended in May 2009 (fully in force from the FY2011). The Act has set all chemical substances, including Existing Chemical Substances, as the subjects of assessment under the Act, and has introduced a step-by-step risk assessment system which utilizes the shipped volumes according to usage and available hazard information. The system obliges manufactures, importers, etc. of chemical substances in a quantity of one ton or more to notify the government of the quantities for their manufacture/import/use. In the case of the shortage of required hazard information, the government may require manufactures, importers, etc. to submit the relevant hazard information, for example, through implementing testing.

Accordingly, since the Act-based system to implement the risk assessment for all Existing Chemical Substances in cooperation with business operators was introduced in April 2011, progress has been made steadily as shown by the fact that 140 substances have already been designated as Priority Assessment Chemical Substances. On the basis of this situation, the Japan Challenge Program, which was to collect and release safety information of Existing Chemical Substances, was ended in FY2012, and the outcomes of the Program are to be released and utilized for the schemes of the Japanese Chemical Substances Control Act.

2. Outcomes of the Japan Challenge Program

(1) Chemical Substances whose Information Was Expected to Be Collected by Business Operators (131 Substances)

In the Japan Challenge Program, business operators were expected to collect information for 131 substances, and among these the safety information for 67 substances, including that on testing implementation, was collected through business operators' voluntary activities and published in J-CHECK (Japan Chemicals Collaborative Knowledge Database) (Note 1) (some sections of this information are to be published in the near future). For some voluntary activities of the business operators for the 67 substances, 31 consortia were formed, in which multiple companies exchanged information regarding 37 substances in cooperation with each other. Through these consortia, a greater number of companies were encouraged to join the Program. As a result, these consortia served a prominent role in increasing the number of the substances whose information was collected, as the increase in this number was associated with the rise in the number of registered sponsor companies and the rise in the number of the target substances.

Apart from the substances listed above, there are five substances for which testing has been carried out but their information is yet to be adjusted before release.

The remaining 59 substances included those (four substances) for which collection of safety information under the Japan Challenge Program was deemed to take place through the information provided from the sponsor companies to the OECD/HPV Programme, and those (seven substances) for which information submission was not considered to be necessary as the substances had been or were to be assessed through the OECD/HPV Programme, etc.

Furthermore, there were some substances for which no voluntary activity was conducted by business operators, and the reasons for this include the following: the significance of information gathering was negligible for some substances such as food additives (nine substances), as sufficient knowledge of them was already available; the domestic business was scaled down; and some substances were of low concern as they were used as an intermediate or for a closed system.

Consequently, with regard to the substances for which information was expected to be collected by business operators, the safety information, including details of testing, of approximately 60%

of such substances was gathered through voluntary activities of business operators, and became publicly available. The percentage excluded those substances due to circumstances relating to the OECD/HPV Programme, etc. or for the reasons above.

(2) Substances for which Information Was to Be Collected by the Government (520 substances)

Among the 520 substances for which information was to be obtained by the government in the Japan Challenge Program, the government collected and has released the information of 379 substances in J-CHECK (some part of the information will be released in the near future). The government was unable to collect the information of the remaining 141 substances within the framework of the Japan Challenge Program, as information collection for overseas organizations such as the OECD/HPV Programme was canceled or is incomplete.

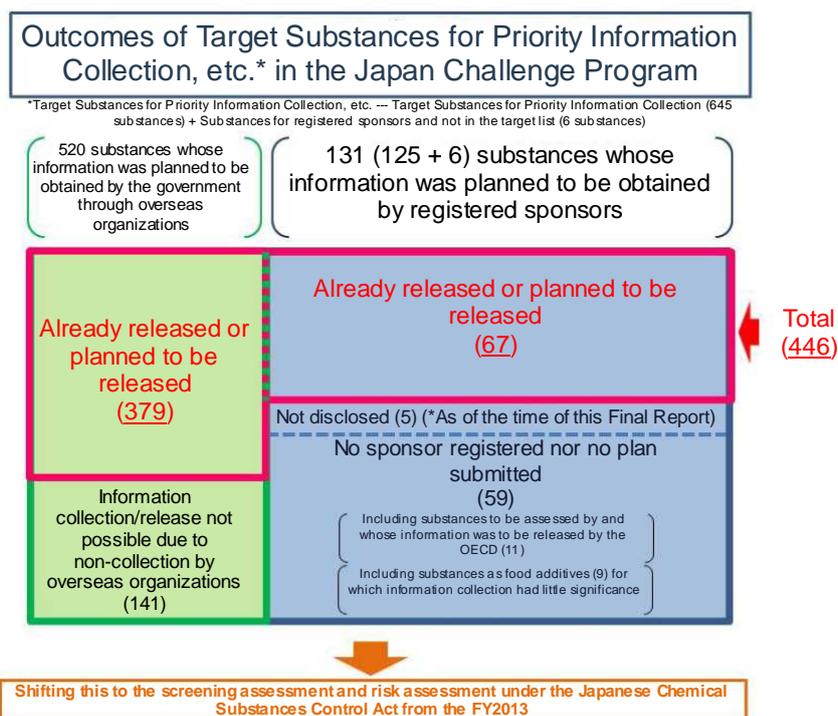


Figure Outcomes of Target Substances for Information Collection, etc.

3. Evaluation of the Japan Challenge Program, and Suggestions for Future Approaches

(1) Evaluation of the Japan Challenge Program

[1] Contributing to the Fostering of the Corporate Standard of Hazard Information Collection and Management by Business Operators

At the time the Japan Challenge Program started, the government played the main role in gathering information of Existing Chemical Substances in accordance with the Japanese Chemical Substances Control Act. However, through the planning and implementing the Japan Challenge Program that started in line with international approaches, a new system for the collaboration between the private and public sectors was introduced, in which business operators voluntarily cooperated in gathering information and testing. This accelerated the collection of safety information of chemical substances.

Despite high costs on the part of business operators, a large number of companies understood and supported the main purpose of the Japan Challenge Program, completed long-term activities such as testing as the Program sponsors, obtained the safety information of more than 60 substances at their own expense, and managed to release the information; this fact should be highly appreciated. Furthermore, these implementation processes fostered their recognition that it is a corporate standard for companies involved in the globalization of the chemical industry that, on their own initiative, they embark on the collection, management and release of hazard information. This should be regarded as a huge contribution of the Japan Challenge Program to chemical substance management.

[2] Acceleration of the Collection and Release of Safety Information of Existing Chemical Substances through the “Cooperation Between the Private and Public Sectors”

One of the features of the Japan Challenge Program was that it aimed to accelerate the collection and release of safety information, which had been previously conducted by the government alone, under the cooperation between the public and private sectors.

With support from business operators, we managed to gather the safety information of 446 substances, which accounted for approximately 70% of the total 645 substances originally designated as the Target Substances for Priority Information Collection and the six substances for which sponsors were registered. This safety information, along with the details and results of

the Program activities, was published in J-CHECK and the homepages of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment. In this manner, the Japan Challenge Program made firm progress in the collection and release of safety information of Existing Chemical Substances in Japan.

The information is expected to be utilized for the appropriate management of chemical substances of business operators through the use of the SDS (Safety Data Sheet), and for information for consumers, etc.

(2) Suggestions for and Issues in Future Approaches

[1] The Modality of the Provision of Information of Chemical Substances

As the Japan Challenge Program came to an end in FY2012, the risk assessment of Existing Chemical Substances proceeds in accordance with the Japanese Chemical Substances Control Act. On the basis of the fact that cooperation between the private and public sectors was effective in the Japan Challenge Program, business operators are expected to actively gather safety information where they are short of it, to implement testing if necessary, and to share their information with relevant parties including the government. They are also expected to enrich the risk assessment and safety information of Existing Chemical Substances, etc., and to release information, while enhancing their cooperation with the government. The industry has already started tackling these issues under the GPS/JIPS¹.

On the other hand, one issue arising from the Program was the difficulty in providing information on the safety of chemical substances. In the Program, not only the information gathered by the government but also that gathered by business operators were, in principle, to be made publicly available upon confirmation of reliability by the government. Moreover, the internationally used SIDS items were adopted to ensure the comprehensiveness and accuracy of information provision. From this, we consider that the database of the safety information of Existing Chemical Substances fulfilled its role. Meanwhile, it was pointed out that people not specializing in the relevant chemical field, such as general consumers, and those people engaging in different chemical fields found it difficult to understand the information.

¹ GPS/JIPS (Global Product Strategy/Japan Initiative of Product Stewardship)

The JIPS is regarded as a specific implementation in Japan of the GPS set forward by the ICCA. It is a new voluntary activity conducted by the Japan Chemical Industry Association (JCIA) since 2009 for chemical management, and is to manage chemical products in the supply-chain and to release this information to the public.

Safety information for chemical substances is required to be utilized in the appropriate chemical management by people who handle chemical substances up to those substances for general consumers in the supply-chain and who possess correct understanding of the information. As international distribution continues to expand, some people hold the view that the international standardization of information service using the SDS should be set forward. At the same time, there is difficulty in uniformly providing appropriate information to people with different knowledge/experience, expertise or needs. The modality of the provision of hazard information of chemical substances remains an issue in the future management of chemicals.

[2] Importance of Further Active Responses to Globalization

As economic activities are increasingly globalized, the cross-border trade of chemicals has also kept expanding and led to the situation where the same chemical substances are available all over the world. On this basis, as seen from the case of the OECD/HPV Programme, it is important to effectively make progress in the collection of safety information of chemical substances through sharing the roles involved among relevant countries in cooperation.

In the beginning of the Japan Challenge Program, the Program took account of the situation abroad. For instance, chemical substances to be assessed by organizations such as the OECD were excluded from the list of the chemical substances on which business operators were requested to cooperate. Furthermore, efforts have been made for the release of information to other countries; the English version of the J-CHECK homepage was created, and the J-CHECK is connected with the eChemPortal, which is a portal site of the OECD regarding information on chemical substances. Meanwhile, some of the business operators registered as the Japan Challenge Program sponsors experienced problems in submitting data under the Program due to their agreements on data use with consortia based on the REACH of the EU. This led to the realization that international cooperation is of essential importance.

In order to carry forward the collection and release of safety information of chemical substances in a more effective way, Japan considers it important to base itself on its experiences of the Japan Challenge Program, take account of approaches around the world for an appropriate management of chemical substances, enhance its cooperation with international organizations and other countries, and release information abroad, in accordance with the WSSD 2020 goal.