

Outline of the 2003 Partial Amendment to the Chemical Substances Control Law

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Ministry of Economy, Trade and Industry

Ministry of Health, Labour and Welfare

Ministry of the Environment

Government of Japan

I. Background of the amendment

With the aim of preventing damage to human health caused by environmental pollution from chemical substances, Japan's 1973 Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (hereinafter "Chemical Substances Control Law") requires prior evaluation¹ of certain hazardous properties of new chemical substances intended for industrial use, and also regulates the manufacture, import and use of chemical substances that persist in the environment (i.e. persistent) and are toxic to human health if taken in continuously (i.e. having long-term toxicity to human), such as polychlorinated biphenyls (PCBs) and trichloroethylene, in ways that reflect their hazardous properties.

Meanwhile, chemical evaluations and regulations in many industrialized countries pay attention not only to effects on human health but also to those on living organisms in the environment, and take into account the potential for environmental releases of chemical substances, in evaluating new chemical substances. In January 2002, the OECD recommended that Japan should further improve effectiveness and efficiency of chemical management, and further extend the scope of regulation to include ecosystem protection.

Under these circumstances, three governmental councils (the Industrial Structure Council, the Health Sciences Council, and the Central Environment Council) reviewed current chemical evaluation and regulation system in Japan and concluded in their joint report that the government should amend the Chemical Substances Control Law to (i) introduce evaluation and regulation that could take into account the adverse effects of chemical substances on living organisms in the environment and (ii) to improve the effectiveness and efficiency of the system from the standpoint of risk management.

Based on the joint report, the government submitted the Bill for Partial Amendment to the Chemical Substances Control Law to the Diet on March 7th, 2003. The Diet passed the Bill on May 22nd, and the amended law was promulgated on May 28th, 2003.

¹ The evaluation is made before manufacture and/or import

II. Major contents of the amendment

1. Evaluation and regulation of chemical substances focused on their adverse effect on living organisms in the environment

(1) Introducing prior evaluation of ecotoxicity

Although it is at present difficult to quantitatively evaluate the adverse effects of individual chemical substances on ecosystems, it is considered possible to identify, by means of ecotoxicity tests using specific organisms, chemical substances that may have adverse effects on ecosystems.

Accordingly, ecotoxicity shall be evaluated by using these test results as part of the prior evaluation of new chemical substances under the Chemical Substances Control Law.

(2) Introducing regulations against chemical substances with certain ecotoxicity

It cannot be denied that persistent chemical substances possessing ecotoxicity may cause irreversible environmental pollution and have adverse effects on the life and growth of living organisms in the environment.

Accordingly, bearing in mind the limit of current scientific knowledge to evaluate adverse effects of chemical substances on ecosystems or living organisms in the environment, regulations have been introduced. Those include measures to promote appropriate management of chemical substances that have the potential to cause adverse effects on ecosystems, and measures to restrict manufacturing/import of chemical substances which may cause damage to flora and fauna in the human living environment.

Specifically, measures below are introduced:

a) Persistent chemical substances with certain ecotoxicity

- Introducing reporting obligation for manufacturing/ import quantities of persistent chemical substances with certain ecotoxicity , etc. (*Type III Monitoring Chemical Substances*)
- In cases it is recognized that certain chemical substances may cause damage to flora and fauna in the human living environment, compliance with technical guidelines of measures to be taken for appropriate management of chemical substances and labeling are required as *Class II Specified Chemical Substances*, and, intended quantities of manufacturing/import may be restricted, when necessary.

b) Persistent and highly bioaccumulative chemical substances with certain ecotoxicity

- Manufacturing, import and use of chemical substances that are toxic for top predators (e.g. birds or mammals) in the human living environment shall be

restricted not to be released into the environment as much as possible as *Class I Specified Chemical Substances*.

2. Measures for persistent and highly bioaccumulative existing chemical substances

Even before long-term toxicity or ecotoxicity is identified, persistent and highly bioaccumulative existing chemical substances shall be placed under legal control, according to current status of their manufacturing and use. (*Type I Monitoring Chemical Substances*)

Specifically, measures below are introduced:

- Mandatory reporting of actual quantities of manufacturing/import and uses.
- If a certain potential for risk is presented according to preliminary toxicity evaluation by the government, guidance and advice shall be given to businesses on measures for risk reduction to minimize release into the environment.
- After risk reduction measures have been taken, the manufacturers and importers are, if necessary, directed to investigate long-term toxicity. If long-term toxicity is identified, the substance shall be designated as a *Class I Specified Chemical Substance*.

3. Reforming prior evaluation system for new chemical substances taking into account their possibilities of exposure

As for new chemical substances with low possibilities of exposure through environmental pollution, flexible measures may be taken. Provided that risks are avoidable by prior verification and ex-post monitoring (e.g. on-the-spot inspection), those include (i) exemption from being the subject of prior evaluation procedures (i.e. there is no need to submit hazard data); (ii) stepwise evaluation of toxicity for chemical substances with low volume manufacturing/import.

(1) Exemptions when exposure can be controlled

Prior evaluation for new chemical substances could be exempted in the following cases where there is little or no possibility of exposure, provided the following handling methods are sure to be used.

Chemical substances to be used as intermediates;

Chemical substances to be used for process in which the possibilities of environmental release is extremely low, such as in closed systems;

Chemical substances for export only (provided the prior evaluation system is well-established in the country of destination)

(2) Stepwise evaluation of chemical substances with low volume manufacturing/ import

New chemical substances with total amount of domestic manufacturing/import quantities equal or less than 1 ton per year continue to be exempted from prior evaluation procedures.

New chemical substances with total amount of domestic manufacturing/import quantities equal or less than 10 ton could be manufactured or imported without obligatory submission of toxicity data, if the chemical substances are judged persistent but not highly bioaccumulative, and considered not to present significant risk to human health and living organisms in the environment according to the evaluation based on the information already-known, because there is very little possibility of polluting the environment in a wide area by those chemical substances.

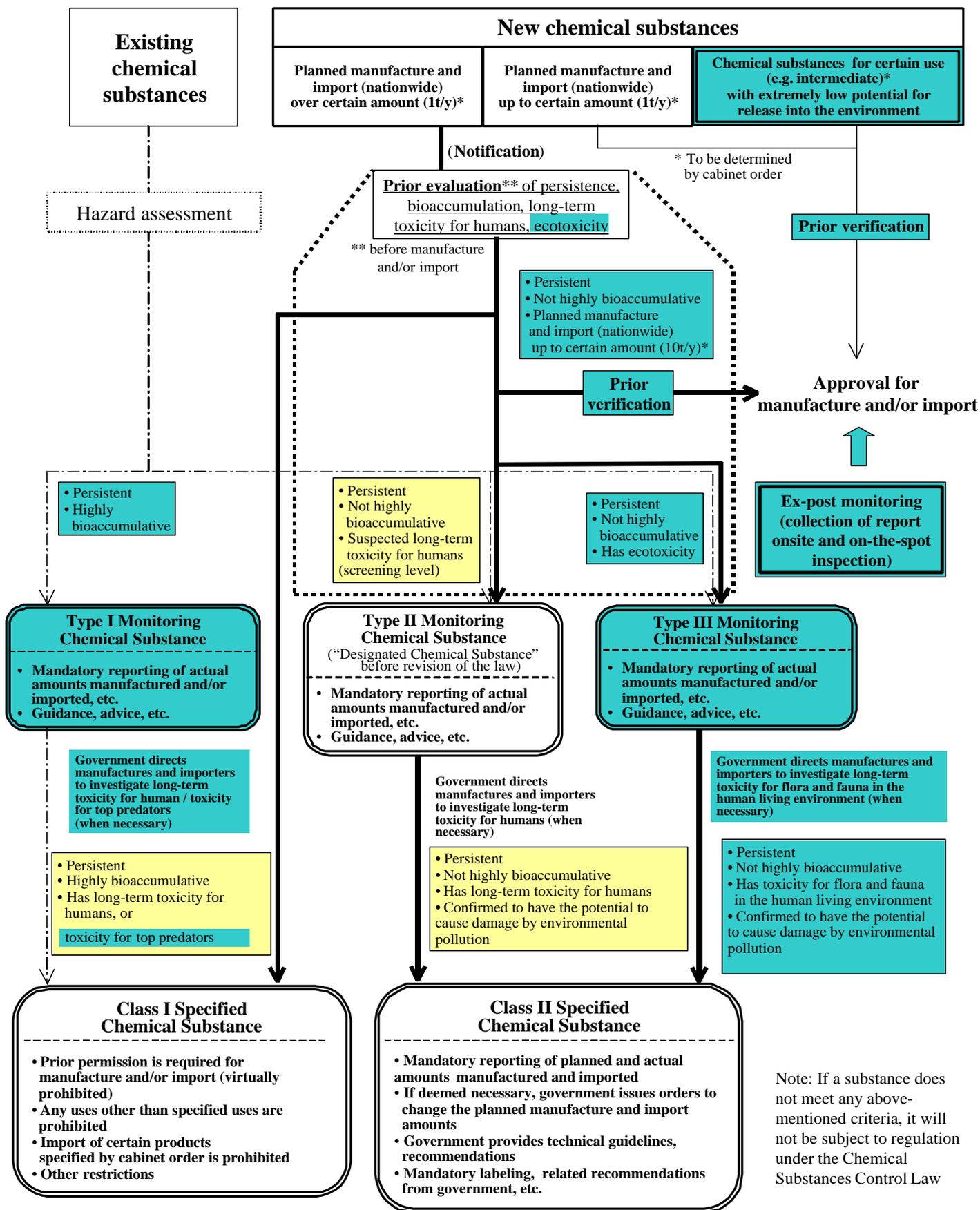
4. Introducing obligatory reporting system for hazard information voluntarily obtained by businesses

In order to utilize hazard data for reviewing evaluation on new chemical substances and to promote evaluation of existing chemical substances by the government, obligatory reporting system is introduced. Under the system, the manufacturers and importers are required to submit self-obtained information indicating that chemical substances they handle possess a hazard listed in the evaluation items under the Chemical Substances Control Law.

III. Schedule for enforcement of the amended law

The amended Chemical Substances Control Law will come into force on the day determined by cabinet order, which shall be no later than one year after the promulgation of the law (May 28th, 2003).

New Framework for evaluation and regulation of chemical substances in Japan under amended Chemical Substances Control Law



Manufacturers and importers of chemical substances are required to report voluntarily-obtained hazard information of the substances

(Current revisions to the law are marked with)