

## Amendment of the Chemical Substances Control Law

May 2009

Ministry of Economy, Trade and Industry

Ministry of Health, Labour and Welfare

Ministry of the Environment

### 1. Purpose of the amendment

- (1) In recent years, public interest in safety and security has increased, and so has public concern over chemical substances. At the global level, an agreement was reached at the World Summit on Sustainable Development to minimize adverse effects of chemicals on human health and the environment. Since then, the situation concerning control of chemical substances has changed substantially, as seen in Europe, where a new regulation on all chemical substances entered into force in 2007.
- (2) The Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter the “Chemical Substances Control Law”) has imposed strict pre-marketing evaluation of chemical substances that were introduced on the market from 1973 onward (i.e., after the enactment of the Law). On the other hand, the government, on its own, has been conducting risk assessment of chemical substances that had been in the market before the enactment of the Law (hereinafter “the existing chemical substances”) and has taken regulatory measures under the Law as needed. However, not all of the existing chemical substances have been assessed yet.
- (3) Therefore, there is a need to steadily implement risk assessment and to further enhance strict control of chemical substances in Japan by obliging manufacturers and importers of the existing chemical substances to notify the amount of chemicals they have handled in each fiscal year and by requiring them to submit toxicity information as needed. In addition, the government aims to allow related ministries to share increased amounts of information gathered under the amended Law and enforce more effective regulations on chemical

substances pursuant to relevant laws and ordinances.

- (4) Another purpose of the amendment is to eliminate international inconsistencies and construct rational evaluation and regulation systems in Japan. Although additional substances are expected to be listed under the Stockholm Convention on Persistent Organic Pollutants, corresponding provisions concerning the uses permitted exceptionally under the convention are not provided for in the Chemical Substances Control Law, which domestically implements the convention.

## 2. Summary of the amendment

### (1) Introduction of a comprehensive control system that covers the existing chemical substances

- (a) Companies that have manufactured or imported any chemical substance, including existing one, in excess of the specified amounts are newly obliged to notify quantity and other information for every fiscal year.
- (b) Chemical substances which the government identifies, from the content of their notifications and available knowledge of their hazardous properties, as having higher priority in risk assessment shall be designated as “Priority Assessment Chemical Substances.”
- (c) Manufacturers and importers of those Priority Assessment Chemical Substances may be required to submit information on hazardous properties and companies handling them may be required to report their uses.
- (d) Among the Priority Assessment Chemical Substances, substances which raise concerns about adverse effects on humans or the environment through the information gathering and the risk assessment shall be subject to regulations on manufacture and use as “Specified Chemical Substances,” as in the existing Law.
- (e) In addition to “chemical substances which is persistent in the environment”, which have been under control, “chemical substances which is not persistent in the environment” are regulated in the amended law.

### (2) Appropriate control on chemical substances in the supply chain

To prevent environmental pollution by the Specified Chemical Substances and

products containing them, the amended Law requires companies handling them to adhere to specific handling standards and obliges them to label them as needed for transactions.

(3) Rationalization of evaluation and regulation systems in light of international trends

The government eliminates international inconsistencies in its regulations, for example, by reviewing regulations on Class I Specified Chemical Substances in order to permit the exceptional use of substances that will be listed under the Stockholm Convention in the future under strict control.

3. Date of entry into force

This amendment is scheduled to enter into force in two steps.

- April 1st, 2010  
Paragraph 2. (1)(e), (2), (3) above
  
- April 1st, 2011  
Paragraph 2. (1) (a)-(d) above

# Summary of the amendment of the Chemical Substances Control Law

To minimize adverse effects of toxic chemicals on human health and environment by comprehensive control of chemical substances, the government reviews the measures for risk assessment of chemical substances and the scope of the regulated chemical substances, while taking measures to rationalize regulations in view of international trends.

## Background and necessity of the amendment

1. Increasing public interest in chemical substances (public safety and security)
2. Need to achieve international goals on chemicals management
  - There is a need to minimize adverse effects of all chemicals on human health and the environment by 2020 (agreement in the World Summit on Sustainable Development, 2002).
    - In Europe, a new regulation (REACH) entered into force in 2007.
  - Since the enactment of the Chemical Substances Control Law (in 1973), every new chemical substance has been subject to pre-marketing evaluation.
  - On the other hand, the government has been conducting safety assessment of part of the existing chemical substances (chemicals in the market before the legislation) and not all of them have been assessed yet.
3. Inconsistency with the international treaty
  - Under the international treaty (Stockholm Convention), an agreement is expected to be reached this spring to accept certain exceptional uses of the newly prohibited chemicals.
  - The existing law, which is more restrictive on exceptional uses, may fail to ensure the uses essential to Japan.

## Summary of the Amendment

### (1) Measures for existing chemical substances

- Companies that have manufactured or imported any chemical substance, including existing one, in excess of the specified amounts are newly obliged to notify applications containing quantity and other information to the government.
- Upon receipt of those applications, the government screens and prioritizes substances subject to detailed risk assessment. For these substances, the manufacturers/importers may be required to submit information on hazardous properties for government evaluation of the effects on the human health etc..
- Based on the evaluation, the government decides whether to regulate the manufacture/use of the substance and its product, etc..

### (2) Ensuring international consistency

- The government ensure that substances newly listed under the international treaty can be used under strict control.
  - Uses for semiconductors, fire fighting foam, etc.

**(For reference)** 1973 Enactment of the Chemical Substances Control Law

**Related moves**

2002	World Summit on Sustainable Development	→	2020	Completion of safety confirmation by respective countries
2004	Entry into force of the Stockholm Convention			
2007	Entry into force of REACH (Europe)	→	2018	REACH registration deadline