

Appendix A

Outline of the Chemical Substances Control Law

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The Chemical Substances Control Law was enacted in October 1973 as a result of the environmental pollution caused by PCB, and was enforced in April 1974. Under this Law, new chemical substances are examined before manufacture or import to determine whether or not they change chemically in nature (low biodegradability), are easily accumulated in biological organisms (high bioaccumulation) or are suspected of having toxicity to human health when consumed for a long period of time (chronic toxicity). (That is, the system of examination of new chemical substances before manufacture or import). Substances with the above properties were designated as Class 1 Specified Chemical Substances, and their manufacture, import and use, etc. were restricted. There have been 7,894 notifications for new chemical substances (as of the end of December 2002).

On the other hand, existing chemical substances have been examined for safety in principle by the government, based on the resolution of the National Diet at the time of the enactment of the Chemical Substances Control Law in 1973, and if necessary, were designated as Class 1 Specified Chemical Substances, etc. Existing chemical substances were investigated by the Ministry of Economy, Trade and Industry for biodegradability by microorganisms and bioaccumulation in fish and shellfish, by the Ministry of Health, Labour and Welfare for toxicity and the status of their persistence in the general environment, and by the MOE for effects to the ecosystem. 13 substances, PCB, HCB, PCN, aldrin, dieldrin, endrin, DDT, chlordanes, bis(tributyltin) oxide, (*N,N'*-ditolyl, *N*-tolyl-*N'*-xylyl, *N,N'*-dixylyl)-*p*-phenylene diamine, 2,4,6-tri-*tert*-butylphenol, toxaphene and mirex, have been designated as Class 1 Specified Chemical Substances (as of the end of January 2004).

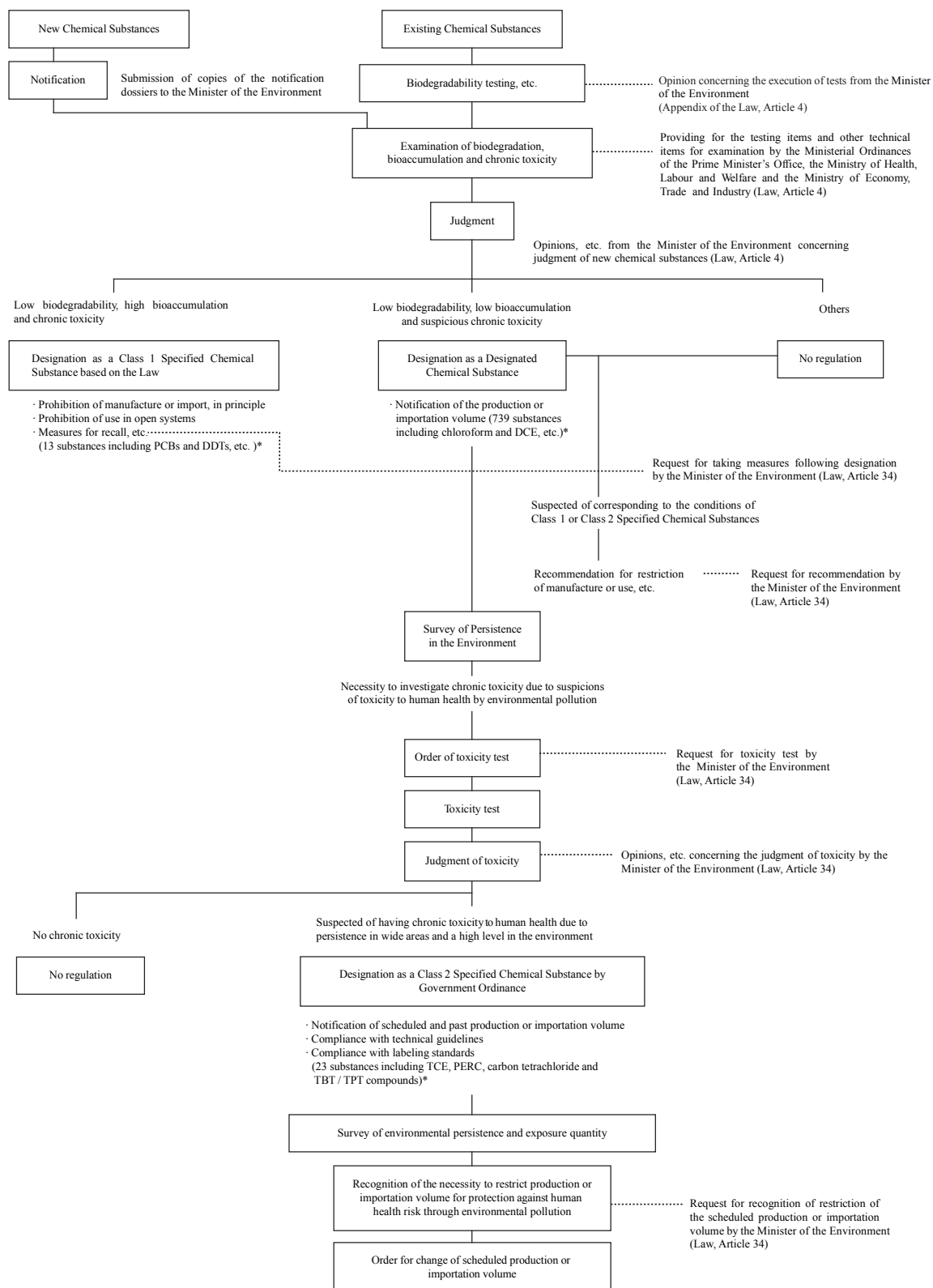
The Law was amended in May 1986 as a result of groundwater pollution by TCE, etc. and was enforced in April 1987. Since this amendment, substances with low bioaccumulation, but low biodegradability and suspicion of chronic toxicity, are designated as Designated Chemical Substances, and their production or importation volume are reported. If toxicity to human health is expected by environmental pollution caused by these Designated Chemical Substances, a governmental order of conduct and a report of toxicity test takes place for manufacturers, etc., and if toxicity is observed, these substances are to be designated as Class 2 Specified Chemical Substances and the production or importation volume etc. is regulated. So far, 739 substances including chloroform and 1,2-DCE have been designated as Designated Chemical Substances (as of the end of January 2004). Concerning Class 2 Specified Chemical Substances, 3 substances from Designated Chemical Substances, i.e. carbon tetrachloride, PERC and TCE, were designated as Class 2 Specified Substances in April 1989, which is the first time for such an occurrence. So far, 23 substances have been designated in this manner (as of the end of January 2004).

The system of the Chemical Substances Control Law is displayed in Fig. 1, and within this framework MOE has the following responsibilities and authorities:

- [1] To provide testing items and other technical items for the examination of new chemical substances by the Ministerial Ordinances of the Prime Minister's Office, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry (Article 4, Clause 5).
- [2] To request necessary explanations and express opinions to the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through the examination and judgment of new chemical substances (Article 4, Clause 7).
- [3] To request that the competent minister take measures (Article 34, Clause 1) following the designation of a Class 1 Specified Chemical Substance (Article 22).
- [4] To request that the Ministers of Health, Labour and Welfare and Economy, Trade and Industry (Article 34, No. 2) order toxicity tests concerning Designated Chemical Substances (Article 24, Clause 1).
- [5] To request that the Ministers of Health, Labour and Welfare and Economy, Trade and Industry (Article 34, No. 3) recognize the necessity to restrict the manufacture, etc. of Class 2 Specified Chemical Substances (Article 26, No. 4).
- [6] To request that the competent minister (Article 34, No. 4) make the necessary recommendations concerning the restriction of the manufacture, import and use, etc. of chemical substances (Article 29) for which there is sufficient reason to suspect as Class 1 Specified Substances concerning substances other than Class 1 Specified Chemical Substances, and as Class 2 Specified Chemical Substances concerning those other than Class 2 Specified Chemical Substances.
- [7] To express opinions as to whether existing chemical substances correspond to Designated Chemical Substances, etc. when the Ministers of Health, Labour and Welfare and Economy Trade and Industry conduct toxicity tests (Supplementary Regulations, Article 4).

This law was amended (effective in April 2004) in order to introduce evaluation and regulation that could take into account the adverse effects on living organisms in the environment, and to improve the effectiveness and efficiency of the system from the standpoint of risk management.

Figure System of the Law Concerning the Examination and Manufacture, etc. of Chemical Substances



* The numbers of chemical substances are as of January 2004.