

## Outline of the Chemical Substances Control Law

The Chemical Substances Control Law (formally, "Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances") was enacted in October, 1973, as a result of the environmental pollution caused by PCB, and was enforced in April, 1974. With this Law, new chemical substances are examined before manufacture or import whether they do not change chemically in nature (low biodegradability), are easily accumulated in biological organisms (high bioaccumulation) and have the suspicions of toxicity to human health when taken 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 6,876 notifications for new chemical substances (5,136 for manufacture and 1,740 for import) and 5,349 (4,083 for manufacture and 1,266 for import) have been examined and recognized as safe (as of the end of December, 1998).

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 the 1973, and if necessary, they are designated as a Class 1 Specified Chemical Substances etc..

Existing Chemical Substances were investigated their biodegradability by microorganisms and bioaccumulation in fishes and shellfishes by the Ministry of International Trade and Industry, their toxicity by the Ministry of Health and Welfare and the situation of their persistence in the general environment and effects to ecosystem by the Environment Agency. So far, the 11 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 and 2,4,6-tri-tert-butylphenol have been designated as Class 1 Specified Chemical Substances (as of the end of December, 2000).

The Law was amended in May, 1986, as a result of ground water pollution by trichloroethylene 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, governmental order of conduct and 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. are regulated. So far, 616 substances including chloroform and 1,2-dichloroethane have been designated as Designated Chemical Substances (as of the end of February, 2002). Concerning Class 2 Specified Chemical Substances, 3 substances i.e., carbon tetrachloride, tetrachloroethylene and trichloroethylene were designated as Class 2 Specified Substances for the first time from Designated Chemical Substances in April, 1989, and so far 23 substances have been designated as above (as of the end

of October, 1999).

The system of the Chemical Substances Control Law has been indicated in Figure 1, and in this framework the Environment Agency has the following responsibilities and authorities.

- ① To provide for 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 and Welfare and the Ministry of International Trade and Industry (Article 4 Clause 5).
- ② To request for necessary explanation and express opinions to the Minister of Health and Welfare and the Minister of International Trade and Industry by the examination and judgment of new chemical substances (Article 4 Clause 7)
- ③ To request to the competent minister to take measures (Article 34 Clause 1) following the designation of a Class 1 Specified Chemical Substance (Article 22)
- ④ To request to the Ministers of Health and Welfare and International Trade and Industry (Article 34 No. 2) to order toxicity test concerning Designated Chemical Substances (Article 24 Clause 1)
- ⑤ To request to the Ministers of Health and Welfare and International Trade and Industry (Article 34 No.3) to recognize the necessity to restrict the manufacture etc. of Class 2 Specified Chemical Substances (Article 26 No. 4)
- ⑥ To request to the competent minister (Article 34 No. 4) to make the necessary recommendations concerning the restriction of the manufacture, import and use etc. of chemical substances (Article 29) when 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 whether existing chemical substances correspond to Designated Chemical Substances etc. when the Ministers of Health and Welfare and International Trade and Industry conduct toxicity tests (Supplementary Regulations Article 4)