

(PROVISIONAL TRANSLATION)

Ministerial ordinance to designate the items, etc. of tests and the items of studies to be conducted in connection with the Type I Monitored Chemical Substance and Type II Monitored Chemical Substance related to a new chemical substance

(Ordinance No.1 of the General Administrative Agency of the Cabinet, Ministry of Health and Welfare and Ministry of International Trade and Industry, July 13, 1974)

Amended on: November 21, 2003

(Ministry of Health, Labor, and Welfare, Ministry of Economy, Trade, and Industry, and Ministry of Environment)

Article 1. Judgment, as stipulated in Paragraph 1, Article 1 and Paragraph 2, Article 4-2 of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as “the Law”), shall be made on the basis of knowledge already in possession regarding the structural formula, rational formula, component composition, physical and chemical properties on living organisms, etc.

Article 2. Judgment, as stipulated in Paragraph 2, Article 4 of the Law (including the corresponding application according to Paragraph 2, Article 2) shall be made according to the results of a variety of tests (as listed below) conducted on a new chemical substance that is found to be applicable to Clause 6, Paragraph 1, Article 4 of the Law (or on a chemical substance (including an element) that is considered to have been generated as the result of the test performed according to Clause 1 above, if any. This applies to any clause of this article.). This procedure shall apply to subsequent cases:

1) A degradation test on the chemical substance using microbes, etc. to determine whether the substance is not easily degradable by natural reactions.

2) A concentration test in the body of fish or shellfish or a measurement test of the distribution coefficient between 1-octanol and water to determine whether the substance tends to easily accumulate in the bodies of living organisms.

3) A chronic toxicity test, a test concerning the sustainability of the effects on reproduction or on offspring, a teratogenicity test, a mutagenicity test, a carcinogenicity test, a biotransformation test, or a pharmacological test.

4) If the substance is to be ingested continually, a test concerning the suspected impacts on the reproductive ability of mammal and on the subsequent future generations and a test of the impacts on the reproductive ability of the bird shall be conducted to check whether the substance has a potential to adversely affect the life or growth and development of animals at the top of the food chain (the term refers to the animals at the top of the food chain as stipulated in Clause 1, b (ii), Paragraph 2, Article 2 of the Law, which shall apply to the same term hereafter).

2. For the judgment of whether the new chemical substance is suspected to be applicable to Clause 1, Article 2-3 of the Law (excluding the judgment of whether the substance is applicable to the same item of the article), judgment of whether the substance is harmful to human health, if it is to

be ingested continually, shall be made on the results of the reverse mutation test using a 28-day repeated dose toxicity study, a bacteria test, and a mutagenicity test using a chromosomal aberration test with the cultured cells of mammals, regardless of the stipulation of Clause 3 of the preceding paragraph.

3. For the judgment of whether the new chemical substance is applicable to any Clause of Paragraph 6, Article 2 of the Law, judgment of whether the substance has any adverse effects on the growth and development of fauna and flora shall be made on the basis of a growth inhibition test on seaweed, an acute toxicity swimming inhibition test on water fleas, and an acute toxicity test on fish, despite the stipulation of Clause 4, Paragraph 4 of the article.

Article 2-2. The results of tests to be performed for the designation, as stipulated in Paragraph 5 of Article 2 of the Law according to the provision of Paragraph 8, of the same Article of the Law, on whether or not the chemical substance is harmful to human health if ingested continuously, shall be the performance of the tests defined in Paragraph 2 of the preceding article, or the results of tests designated by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment as equivalent or higher to the tests listed above.

Article 2-3. The judgment under Paragraph 3, Article 4-2 of the Law shall be made on the results of the following tests on a new chemical substance determined to be applicable to Paragraph 3, Article 2 (or chemical substances recognized to have resulted from the test performed according to Clause 1 of the paragraph (including elements, which applies to the same instance hereafter):

- 1) A degradation test on the chemical substance utilizing microbes, etc. to determine whether the substance is easily degradable by natural reactions
- 2) A concentration test in the body of fish or shellfish or a measurement test of the distribution coefficient between 1-octanol and water to determine whether the substance tends to easily accumulate in the bodies of living organisms

Article 2-4. The toxicity test according to Paragraph 1, Article 5-4 of the Law:

- 1) A chronic toxicity test, a test concerning the sustainability of the effects on reproductive ability and on offspring, a teratogenicity test, a mutagenicity test, a carcinogenicity test, a biotransformation test, or a pharmacological test shall be conducted to determine whether the substance is harmful to human health if it is to be ingested continuously.
- 2) If the chemical substance is to be ingested continually, a test concerning the suspected impacts on the reproduction of mammals and on offspring and a test of the impacts on the reproductive ability of a bird shall be conducted to determine whether the substance has the potential to adversely affect the life or growth and development of animals at the top of the food chain.

Article 3. According to Paragraph 1, Article 24 of the Law, a study on toxicity shall include a chronic toxicity test, a test regarding the sustainability of the effects on reproductive ability and on offspring, a teratogenicity test, a mutagenicity test, a carcinogenicity test, a biotransformation test, or a pharmacological test.

Article 4. The tests specified in the specifications of Article 2 to Article 2-3 must be performed in test facilities that are equipped with the necessary facilities, equipment, and personnel in order to ensure the reliability of test results that are recognized as having being appropriately managed.

2. The stipulation of the preceding paragraph shall be applied to tests to be conducted for the purpose of acquiring necessary knowledge specified in Article 1 and for the study specified in Article 2-4 and the preceding Article.

Supplementary Provision

This order shall be enforced from the date of promulgation.

Supplementary Provision (Ordinance No.3 of the Ministry of Health, Labor, and Welfare, the Ministry of Economy, Trade, and Industry, and the Ministry of the Environment)

This Ministerial Ordinance shall be enforced on April 1, 2004.