

Ministerial Ordinance Specifying Items Concerning the Testing of New Chemical Substances and the Study of the Hazardous Properties of Type I Monitoring Chemical Substances and Type II Monitoring Chemical Substances

(Ordinance of the Prime Minister's Office, Ministry of Health and Welfare, and Ministry of International Trade and Industry No. 1 of July 13, 1974)

Final revision: Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 3 of November 21, 2003

The order specifying items of the testing of new chemical substances shall be enacted as follows, pursuant to the provisions of paragraph (4) of Article 4 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973).

Article 1

The determination under paragraph (1) of Article 4 (including the case where it is applied mutatis mutandis under paragraph (2) of Article 5-2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the "Act")) and paragraph (2) of Article 4-2 of the Act shall be made based on the existing knowledge concerning the structural formula, rational formula, composition, physicochemical properties, and effects on living organisms of the chemical substances pertaining to the notification.

Article 2

(1) The determination under paragraph (2) of Article 4 of the Act (including the case where it is applied mutatis mutandis under paragraph (2) of Article 5-2 of the Act) shall be made based on the results of any of the following tests which have been conducted with regard to the new chemical substance determined to fall under item (vi) of paragraph (1) of Article 4 of the Act (including any chemical substances (including elements; the same shall apply hereinafter) found to have been generated as a result of the test set forth in item (i); hereinafter the same shall apply in this Article):

(i) Biodegradability test of the chemical substance using microorganisms to determine whether the chemical substance is unlikely to undergo chemical transformation through natural processes

(ii) Bioconcentration test of the chemical substance in fish or shellfish or measurement of the partition coefficient between 1-octanol and water to determine whether the chemical substance is likely to accumulate in organisms

(iii) Chronic toxicity studies, reproduction/developmental toxicity test, prenatal developmental toxicity study, mutagenicity test, carcinogenicity studies,

toxicokinetics and pharmacology studies to determine whether the chemical substance has the potential to be hazardous to human health if ingested continuously

(iv) Test of the effects of the chemical substance on the reproductive functions and future generations of mammals, and avian reproduction test, to determine whether the chemical substance has the potential to impair the inhabitation and/or growth of animals at the top of the food chain (which means the animals at the top of the food chain as prescribed in (b)-2. of item (i) of paragraph (2) of Article 2 of the Act; the same shall apply hereinafter) if ingested continuously

(2) Notwithstanding the provision of item (iii) of the preceding paragraph, in the case of making a determination as to whether the new chemical substance is likely to fall under item (i) of paragraph (3) of Article 2 of the Act (excluding a determination as to whether the new chemical substance falls under said item), the determination shall be made based on the test results of repeated dose 28-day toxicity study in rodents and mutagenicity tests through bacterial reverse mutation test and in vitro mammalian chromosomal aberration test to determine whether the new chemical substance has the potential to be hazardous to human health if ingested continuously.

(3) Notwithstanding the provision of item (iv) of paragraph (1), in the case of making a determination as to whether the new chemical substance is likely to fall under any of the items of paragraph (6) of Article 2 of the Act, the determination shall be made based on the results of test on alga, growth inhibition test, daphnia acute immobilization test, and fish, acute toxicity test, to determine whether the new chemical substance has the potential to impair the inhabitation and/or growth of flora and fauna.

Article 2-2

The results of the test conducted for the designation under paragraph (5) of Article 2 of the Act, under the provisions of paragraph (8) of said Article, to determine whether the new chemical substance has the potential to be hazardous to human health if ingested continuously, shall be deemed to be the results of the test prescribed in paragraph (2) of the preceding Article, or the results of a test separately specified as being equivalent or better by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.

Article 2-3

For any new chemical substance determined to fall under item (iii) of paragraph (2) of Article 4-2 of the Act (or any chemical substances (including elements; the same shall apply hereinafter) found to have been generated as a result of the test set forth in item (i)), the determination under paragraph (3) of said Article shall be

based on the results of the test listed in the following items:

(i) Biodegradability test of the chemical substance using microorganisms to determine whether the chemical substance is unlikely to undergo chemical transformation through natural processes

(ii) Bioconcentration test of the chemical substance in fish or shellfish or measurement of the partition coefficient between 1-octanol and water to determine whether the chemical substance is likely to accumulate in organisms

Article 2-4

The study of hazardous properties under paragraph (1) of Article 5-4 of the Act shall be as follows:

(i) Chronic toxicity studies, reproduction/developmental toxicity test, prenatal developmental toxicity study, mutagenicity test, carcinogenicity studies, toxicokinetics and pharmacology studies to determine whether the chemical substance has the potential to be hazardous to human health if ingested continuously

(ii) Test of the effects of the chemical substance on the reproductive functions and future generations of mammals, or avian reproduction test, to determine whether the chemical substance has the potential to impair the inhabitation and/or growth of animals at the top of the food chain if ingested continuously

Article 3

The study of the hazardous properties under paragraph (1) of Article 24 of the Act shall include chronic toxicity studies, reproduction/developmental toxicity test, prenatal developmental toxicity study, mutagenicity test, carcinogenicity studies, toxicokinetics, or pharmacology studies.

Article 4

(1) The tests under Article 2 through Article 2-3 shall be conducted at any authorized testing facilities that have the facilities, equipment, and personnel, etc. necessary to ensure the reliability of the test results and that are managed properly.

(2) The provision of the preceding paragraph shall apply *mutatis mutandis* to tests conducted to obtain knowledge under Article 1 and those conducted for the study under Article 2-4 and the preceding Article.

Supplementary Provisions

This order shall come into effect as from the day of promulgation.

Supplementary Provisions

(Ordinance of the Prime Minister's Office, Ministry of Health and Welfare, and Ministry of International Trade and Industry No. 1 of March 31, 1984)

This Ordinance shall come into effect as from the day of promulgation.

Supplementary Provisions

(Ordinance of the Prime Minister's Office, Ministry of Health and Welfare, and Ministry of International Trade and Industry No. 1 of December 1, 1986)

This order shall come into effect as from the date of enforcement of the Act on the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.(Act No. 44 of 1986) (April 1, 1987).

Supplementary Provisions

(Ordinance of the Prime Minister's Office, Ministry of Health and Welfare, and Ministry of International Trade and Industry No. 1 of August 14, 2000)

This order shall come into effect as from the date of enforcement of the Act on the Partial Revision of the Cabinet Act (Act No. 88 of 1999) (January 6, 2001).

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 3 of November 21, 2003)

This Ordinance shall come into effect as from April 1, 2004.