

Ministerial Ordinance Specifying Items for Tests Pertaining to New Chemical Substances and Studies Pertaining to the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances

(Ministerial Ordinance No. 3, March 31, 2010 of Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment)

Latest revision: March 30, 2018

Ministerial Ordinance No. 4, Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment

(Items Requiring Testing to Make a Determination of a New Chemical Substance)

Article 1 (1) The items to be tested and any other technical matters necessary for making a determination pertaining to a New Chemical Substance (where there is a chemical substance (including an element; the same shall apply hereinafter) recognized to be generated by a test of said New Chemical Substance under item (ii) (b), said chemical substance; the same shall apply hereinafter) pertaining to a notification under paragraphs (1) and (2) of Article 4 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter "the Act"), pursuant to paragraph (7) of Article 4 of the Act (including cases that apply mutatis mutandis under paragraph (2) of Article 7 of the Act), shall be the matters prescribed in each of the following items in accordance with the categories listed in said items..

(i) Where a determination is made pursuant to paragraph (1) of Article 4 of the Act, based on knowledge already available about a New Chemical Substance to which a notification pertains, the following matters:

- (a) knowledge relating to tests concerning physical and chemical properties
- (b) knowledge on the structural formulas
- (c) knowledge on the rational formulas
- (d) knowledge on the chemical composition
- (e) knowledge on the effects on living organisms
- (f) other knowledge considered necessary for the determination

(ii) Where a determination is made pursuant to paragraph (2) of Article 4 of the Act based on results of a test conducted for a New Chemical Substance that has been determined to fall under item (vi) of paragraph (1) of the said Article, the following matters:

- (a) As to whether it is unlikely to undergo a chemical transformation through natural processes: a biodegradation test of the chemical substance using microorganisms
- (b) As to whether it is likely bioaccumulative: a bioaccumulation test of the chemical substance in fish or shellfish or measurement test of the partition coefficient between n-octanol and water
- (c) As to whether it poses a risk of harming human health if taken in continuously: a chronic toxicity test, a test of effects on reproductive potential and future generations, a teratogenicity test, a mutagenicity test, a

carcinogenicity test, a metabolic fate test, and a pharmacological test relating to the chemical substance

(d) As to whether it poses a risk of interfering with the inhabitation and/or growth of predatory animals at higher trophic level (i.e., predator animals at higher trophic level under item (i)(b)(2) of paragraph (2) of Article 2 of the Act; the same applies in Article 6) if ingested continuously: a test of the effects of the chemical substance on the reproductive potential and future generations of mammals, and a test of the effects on avian reproduction

(2) For the determination of whether the New Chemical Substance is suspected of falling under item (i) of paragraph (3) of Article 2 of the Act (excluding the determination of whether it falls under said item), notwithstanding the provisions of (ii)(c) of the preceding paragraph, regarding whether the New Chemical Substance poses a risk of harming human health if taken in continuously, the determination shall be made based on the results of a repeated dose 28-day toxicity study using mammals, mutagenicity tests (a bacterial reverse mutation tests, and a chromosomal aberration test using cultured mammalian cells) or any other tests specified separately as equivalent to or higher than these tests by the Minister of Health, Labor and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment.

(3) For the determination of whether the New Chemical Substance falls under item (ii) (b) of paragraph (1) of Article 4 of the Act, notwithstanding the provisions of item (ii) of paragraph (1), regarding whether the New Chemical Substance poses a risk of interfering with the inhabitation and/or growth of flora and fauna, the determination shall be made based on the results of an algae growth inhibition test, a *Daphnia* acute immobilization test, and a fish acute toxicity test.

(Items Requiring Testing to Make a Determination of a specified new chemical substance)

Article 2 The items to be tested and any other technical matters necessary for determination pursuant to the provisions of Paragraph (4) of Article 4 of the Act for a new chemical substance pertaining to the notification under the provisions of Paragraph (1) of Article 3 of the Act as set forth in Paragraph (7) of Article 4 of the Act shall be the knowledge listed in Paragraph (1) Item (i) (a) through (f) of the preceding Article applied for the determination set in Paragraph (1) or Paragraph (2) of Article 4 of the Act for the relevant new chemical substance, or the results of the tests listed in the said Paragraph Item (ii) (a) through (d), the said Article Paragraph (2) or the preceding Article Paragraph (3).

(Results of Tests Pertaining to New Chemical Substances)

Article 3 For a New Chemical Substance, regarding whether it is clear that the substance is not one that is likely to pose a risk of harming human health if taken in continuously, the results of tests conducted where a designation is made pursuant to paragraph (5) of Article 2 of the Act shall be the results of tests pursuant to the provisions of paragraph (2) of the preceding Article, or the results of repeated dose 28-day toxicity tests in mammals and mutagenicity tests (a bacterial reverse mutation tests and a chromosomal aberration test using cultured mammalian cells) or any other tests specified separately as equivalent to or higher than these tests by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment.

(Knowledge Pertaining to a New Chemical Substance Subject to Exception to Evaluation)

Article 4 (1) The determination under paragraph (2) of Article 5 of the Act shall be made based on already available knowledge about a New Chemical Substance to which a notification pertains, relating to the structural formula, rational formula, chemical composition, physical and chemical properties, and effects on living organisms.

(2) The determination prescribed under paragraph (3) of Article 5 of the Act for a New Chemical Substance determined to fall under item (iii) of paragraph (2) of said Article shall be made based on the results of tests which are listed in the following items and shall be conducted.

- (i) As to whether it is unlikely to undergo chemical transformation through natural processes: a biodegradation test of the chemical substance using microorganisms
- (ii) As to whether it is likely bioaccumulative: a bioaccumulation test of the chemical substance in fish or shellfish or measurement test of the partition coefficient between n-octanol and water

(Tests Pertaining to a Priority Assessment Chemical Substance)

Article 5 Tests relating to properties of a Priority Assessment Chemical Substance pursuant to paragraph (1) of Article 10 of the Act and prescribed by an Ordinance of the Ministry of Health, Labour and Welfare, of the Ministry of Economy, Trade and Industry, and of the Ministry of the Environment, shall be as follows:

- (i) Tests relating to physical and chemical properties
- (ii) As to whether it is unlikely to undergo chemical transformation through natural processes: a biodegradation test of the chemical substance using microorganisms
- (iii) As to whether it is likely bioaccumulative: a bioaccumulation test of the chemical substance in fish or shellfish or measurement test of the partition coefficient between n-octanol and water
- (iv) As to whether it poses a risk of harming human health: a repeated dose 28-day toxicity test using mammals, and mutagenicity tests (a bacterial reverse mutation tests and a chromosomal aberration test using cultured mammalian cells), and tests prescribed separately by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment as being equivalent or superior.
- (v) As to whether it poses a risk of interfering with the inhabitation and/or growth of flora and fauna in the human living environment (this means flora and fauna in the human living environment pursuant to item (i)(b)(2) of paragraph (2) of Article 2 of the Act; the same applies in the following Article): an algae growth inhibition test, a *Daphnia* acute immobilization test, and a fish acute toxicity test

(Studies Pertaining to Hazardous Properties of a Priority Assessment Chemical Substance)

Article 6 The studies of hazardous properties prescribed by an Ordinance of the Ministry

of Health, Labour and Welfare, of the Ministry of Economy, Trade and Industry, and of the Ministry of the Environment pursuant to paragraph (2) of Article 10 of the Act shall be as follows:

- (i) As to whether it poses a risk of harming human health if ingested continuously: studies on chronic toxicity, effects on reproductive potential and future generations, teratogenicity, mutagenicity, carcinogenicity, metabolic fate, or pharmacological characteristics of the chemical substance

As to whether it poses a risk of interfering with the inhabitation and/or growth of flora and fauna in the human living environment if the flora and fauna ingest or are exposed to it continuously: studies relating to effects on algae growth, effects on *Daphnia* reproduction, effects on the population and/or growth of fish at the early life stage, and other effects on the growth and/or population of flora and fauna in the human living environment when the Minister of Economy, Trade and Industry and Minister of the Environment find it particularly necessary in view of the status of a Priority Assessment Chemical Substance remaining in the environment.

(Studies Pertaining to Hazardous Properties of a Monitoring Chemical Substance)

Article 7 The studies of hazardous properties prescribed by an Ordinance of the Ministry of Health, Labour and Welfare, of the Ministry of Economy, Trade and Industry, and of the Ministry of the Environment pursuant to paragraph (1) of Article 14 of the Act shall be as follows:

- (i) As to whether it poses a risk of harming human health if ingested continuously: studies relating to chronic toxicity, effects on reproductive potential and future generations, teratogenicity, mutagenicity, carcinogenicity, metabolic fate, or pharmacological characteristics of the chemical substance
- (ii) As to whether it poses a risk of interfering with the inhabitation and/or growth of higher trophic level predator animals if ingested continuously: studies on the effects on the reproductive potential and future generations of mammals, or of the effects on avian reproduction

(Test Facilities, etc.)

Article 8 (1) The tests prescribed under Articles 1 through 5 shall be conducted at the test facilities, etc. that possess the facilities, equipment and personnel, etc. necessary to ensure the reliability of the test results, and have been confirmed as being appropriately managed and operated.

(2) The provisions of the preceding paragraph shall apply *mutatis mutandis* to the tests conducted in order to obtain knowledge under item (i) of paragraph (1) of Article 1 and paragraph (1) of Article 4, and to the tests for the studies under Article 6 and the preceding Article.

Supplementary Provision

This ministerial ordinance shall enter into force on April 1, 2011.