

Ministerial Ordinance on Notification, etc. of the Manufacture or Import of New Chemical Substances

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of April 15, 1974)

Final revision: Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 1 of January 11, 2005

The Ministerial Ordinance on Notification, etc. of the Manufacture or Import of New Chemical Substances shall be enacted as follows, based on paragraph (1) of Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973) and item (ii) of paragraph (1) of the Cabinet Order to Specify Cases Not Requiring Notification of the Manufacture or Import of New Chemical Substances (Cabinet Order No. 102 of 1974) under paragraph (1) of Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc., and for the purpose of implementing said Cabinet Order.

Article 1 (Terms)

The terms used in this Ministerial Ordinance shall be the same as in the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973; hereinafter referred to as the "Act").

Article 2 (Notification pertaining to Manufacture, etc. of New Chemical Substances)

The notification under paragraph (1) of Article 3 of the Act shall be made by submitting a written notification in Form 1 stating the following matters to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment:

- (i) The name of the new chemical substance
- (ii) The structural formula or the rational formula of the new chemical substance (where neither of these is known, the outline of its manufacturing process)
- (iii) The physicochemical properties and the composition of the new chemical substance
- (iv) The use of the new chemical substance
- (v) The planned quantity of manufacture or the planned quantity of import of the new chemical substance for each year during the three-year period after the commencement of its manufacture or import
- (vi) Where a person intends to manufacture a new chemical substance, the name and address of the establishment where the new chemical substance is to be manufactured; and where a person intends to import a new chemical substance, the

name of the country or region where the new chemical substance is manufactured

Article 2-2 (Notification pertaining to the Manufacture, etc. of New Chemical Substances Manufacturers, etc. in a Foreign Country)

The notification under paragraph (1) of Article 5-2 of the Act shall be made by submitting a written notification in Form 1-2 stating the following matters to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment:

- (i) The name of the new chemical substance
- (ii) The structural formula or the rational formula of the new chemical substance (where neither of these is known, its outline of the manufacturing process)
- (iii) The physicochemical properties and the composition of the new chemical substance
- (iv) The use of the new chemical substance
- (v) The planned quantity of export of the new chemical substance to Japan for each year during the three-year period after the commencement of export
- (vi) Where a person intends to manufacture a new chemical substance, the name and address of the establishment where the new chemical substance is to be manufactured; and where a person intends to export a new chemical substance, the name of the country or region where the new chemical substance is manufactured

Article 3 (Proposal pertaining to Confirmation that Notification of the Manufacture, etc., of New Chemical Substances is Not Required)

A person seeking confirmation under item (iv) of paragraph (1) of Article 3 of the Act shall, in advance and in accordance with the categories listed in the left-hand column of the following table, submit a written proposal in the form listed in the middle column of said table and a written confirmation listed in the right-hand column of said table to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.

(i) Item (i) of paragraph (1) of Article 2 of the Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Cabinet Order No. 202 of 1974; hereinafter referred to as the "Order")	Form 2	Form 3
(ii) Item (ii) of paragraph (1) of Article 2 of the Order	Form 4	Form 5
(iii) Item (iii) of paragraph (1) of Article 2 of the Order	Form 6	Form 7

Article 3-2 (Report pertaining to a New Chemical Substance for which Confirmation has been Received)

A person who has received the confirmation under item (iv) of paragraph (1) of

Article 3 of the Act shall submit a written report in Form 8 regarding the status of the handling of said new chemical substance during the preceding fiscal year, by the last day of June each fiscal year, to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment; provided, however, that this shall not apply to the case where the person did not manufacture or import said new chemical substance during the preceding fiscal year.

Article 4 (Proposal pertaining to Confirmation of Small Quantity New Chemical Substances)

(1) A person seeking confirmation under item (v) of paragraph (1) of Article 3 of the Act shall submit a written proposal in Form 9 and a copy thereof to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, during any of the periods listed in the following items each year, regarding new chemical substances expected to be manufactured or imported during the period starting on April 1 for the year associated with the period listed in item (i) below, and the period starting on the first day of the month after the month associated with each of the periods listed in items (ii) through (iv) below, until March 31 of the following year:

- (i) From January 20 through January 30
- (ii) From June 1 through June 10
- (iii) From September 1 through September 10
- (iv) From December 1 through December 10

(2) In cases listed in the following items, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall not issue a confirmation under item (v) of paragraph (1) of Article 3 of the Act, for the planned quantity of manufacture or the planned quantity of import listed in the respective items below:

(i) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the period set forth in item (i) of the preceding paragraph, exceeds 1 ton — the planned quantity of manufacture or the planned quantity of import of the new chemical substance for which a proposal was made during the period set forth in said item

(ii) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the periods set forth in items (i) and (ii) of the preceding paragraph (including the planned quantity of manufacture and planned quantity of import pertaining to the confirmation under paragraph (4) of Article 4-2 of the Act; hereinafter the same shall apply in this paragraph), exceeds 1 ton — the planned quantity of manufacture or the planned quantity of import of the new chemical substance for which a proposal was made during the period set forth in item (ii) of

the preceding paragraph

(iii) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the periods set forth in items (i) through (iii) of the preceding paragraph, exceeds 1 ton — the planned quantity of manufacture or the planned quantity of import of the new chemical substance for which a proposal was made during the period set forth in item (iii) of the preceding paragraph

(iv) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the periods set forth in the items of the preceding paragraph, exceeds 1 ton — the planned quantity of manufacture or the planned quantity of import of the new chemical substance for which a proposal was made during the period set forth in item (iv) of the preceding paragraph

Article 4-2 (Proposal pertaining to Exception to Evaluation of Low Production Volume of New Chemical Substances)

The proposal under paragraph (1) of Article 4-2 of the Act shall be made by submitting a written proposal in Form 10, together with a written notification in Form 1, to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, at the time of making a notification under paragraph (1) of Article 3 of the Act.

Article 4-3 (Proposal pertaining to Confirmation of Low Production Volume of New Chemical Substances)

(1) Where a person seeking confirmation under paragraph (4) of Article 4-2 of the Act intends to manufacture or import the new chemical substance during the fiscal year associated with the date on which the person received a notice stating that the new chemical substance pertaining to the proposal under paragraph (2) or paragraph (3) of said Article falls under item (i) of paragraph (2) of said Article (hereinafter such date shall be referred to as the “date of notice” and such fiscal year shall be referred to as the “fiscal year of notice”), the person shall make a proposal by submitting a written proposal in Form 11 and a copy thereof to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.

(2) Where a person seeking confirmation under paragraph (4) of Article 4-2 of the Act intends to manufacture or import the new chemical substance in and after the fiscal year following the fiscal year of notice, the person shall make a proposal by submitting a written proposal in Form 11 and a copy thereof to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, each year during the period between March 1 and March 10 of the fiscal year preceding the fiscal year of the intended manufacture or

import.

(3) With regard to the application of the provisions of the preceding paragraph in the case where the intended manufacture or import of the new chemical substance is to be during the fiscal year following the fiscal year of notice where the date of notice is in March, the term “between March 1 and March 10” shall be deemed to be replaced with “within ten days after the date of notice.”

(4) In cases listed in the following items, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall not issue a confirmation under paragraph (4) of Article 4-2 of the Act, for the planned quantity of manufacture or the planned quantity of import listed in the respective items below:

(i) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made up to the date of the proposal under paragraph (1) (including the planned quantity of manufacture and the planned quantity of import pertaining to the confirmation under item (v) of paragraph (1) of Article 3 of the Act; hereinafter the same shall apply in this paragraph) exceeds 10 tons — the planned quantity of manufacture or the planned quantity of import of the new chemical substance pertaining to the proposal under paragraph (1)

(ii) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the period set forth in paragraph (2) exceeds 10 tons — the planned quantity of manufacture and the planned quantity of import of the new chemical substance, for which a proposal was made during the period set forth in paragraph (2)

(iii) Where the total of the planned quantity of manufacture and the planned quantity of import of a new chemical substance for which a proposal was made during the periods set forth in paragraphs (2) and (3) exceeds 10 tons — the planned quantity of manufacture and the planned quantity of import of the new chemical substance, for which a proposal was made during the period set forth in paragraph (3)

Article 4-4 (Continuation of Evaluation of Low Production Volume of New Chemical Substances)

The proposal under paragraph (7) of Article 4-2 of the Act shall be made by submitting the results of the test under paragraph (8) of said Article, together with a written proposal in Form 12, to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.

Article 4-5 (Notification Using an Electronic Data Processing System, etc.)

Where a person intending to make a notification under paragraph (1) of Article 3 of the Act, a proposal under paragraphs (1) and (7) of Article 4-2 of the Act, a

proposal under Article 3, or a report under Article 3-2 (hereinafter collectively referred to as a “notification, etc.”) makes a notification, etc. using an electronic data processing system (which means an electronic data processing system connecting the computer designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment (including input-output devices; the same shall apply hereinafter) and a computer used by the person intending to make a notification, etc. by a telecommunications line; the same shall apply hereinafter) under paragraph (1) of Article 3 of the Act on the Utilization of Information and Communications Technology in Administrative Procedures, etc. (Act No. 151 of 2002; hereinafter referred to as the “Information and Communications Technology Utilization Act”), said person shall enter the following matters using a computer which is used by the person intending to make a notification, etc. and which conforms to the technical standards specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment; provided, however, that this shall not prevent persons intending to make a notification, etc. from submitting written documents, etc. to be attached under the provisions of laws and regulations, in lieu of entering the matters listed in item (iii):

(i) Matters that are required to be recorded in forms for electronic notification (which means forms that are required to be followed when making a notification, etc. by using an electronic data processing system and that can be obtained from files prepared on the computer designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment so as to record the title of the notification, etc., date on which the notification, etc. is made, name of the party to which the notification, etc. is made, address of the person making the notification, etc., name of the person making the notification, etc. (and in the case of a juridical person, the name of its representative person), and an indication of the intent to make the notification, etc., among matters required to be recorded when making a notification in writing, etc. (hereinafter referred to as “forms for notification in writing”); the same shall apply hereinafter)

(ii) Matters that are required to be recorded in forms for notification in writing (excluding matters listed in the preceding item)

(iii) Matters that are recorded or are required to be recorded in documents to be attached, under the provisions of laws and regulations, when making said notification, etc. in writing, excluding matters listed in the preceding items

(2) A person intending to make a notification under the preceding paragraph shall make an electronic signature (which means an electronic signature prescribed in paragraph (1) of Article 2 of the Act on Electronic Signatures and Certification Business (Act No. 102 of 2000); the same shall apply hereinafter) for the information relating to the matters to be entered under the provisions of the preceding paragraph, and shall transmit it together with an electronic certificate (which

means an electromagnetic record created to certify that the matters used to verify that the person intending to make a notification, etc. has made an electronic signature are associated with the person intending to make said notification, etc.; the same shall apply hereinafter) pertaining to said electronic signature, which falls under any of the following items:

(i) An electronic certificate prepared by a registrar under paragraphs (1) and (3) of Article 12-2 of the Commercial Registration Act (Act No. 125 of 1963) (including the case where they are applied mutatis mutandis under other laws and regulations; the same shall apply hereinafter)

(ii) An electronic certificate prescribed in paragraph (1) of Article 3 of the Act on Certification Services of Local Governments pertaining to Electronic Signatures (Act No. 153 of 2002)

(iii) In addition to what are prescribed in the preceding items, an electronic certificate specified by public notice by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment

Article 5 (Proposal using an Electronic Data Processing System pertaining to Confirmation of Small Quantity New Chemical Substances)

(1) When a person intending to make a proposal under paragraph (1) of Article 4 intends to make the proposal using an electronic data processing system pursuant to the provisions of paragraph (1) of Article 3 of the Information and Communications Technology Utilization Act, the person shall enter the following matters, using a computer which is used by the person intending to make the notification and which conforms to the technical standards specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment as specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment:

(i) Matters that are required to be recorded in forms for electronic notification

(ii) Matters that are required to be proposed under paragraph (1) of Article 4

(2) A person intending to make a notification under the preceding paragraph shall make an electronic signature for the information relating to the matters to be entered under the preceding paragraph and shall transmit it together with an electronic certificate pertaining to said electronic signature, which falls under any of the following items:

(i) An electronic certificate prepared by a registrar under paragraphs (1) and (3) of Article 12-2 of the Commercial Registration Act

(ii) An electronic certificate prescribed in paragraph (1) of Article 3 of the Act on Certification Services of Local Governments pertaining to Electronic Signatures

(iii) In addition to what are prescribed in the preceding items, an electronic certificate specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment

Article 6

(1) The entry under the preceding Article shall be made in accordance with the method prescribed in Annex 1 of the Japanese Industrial Standards (hereinafter referred to as “JIS”) X0208 based on the Industrial Standardization Act (Act No. 185 of 1949).

(2) The entry under the preceding Article shall be made by using graphic letters prescribed in JIS X0201 and X0208, and by using the “RETURN” and “LINE FEED” from the control letters prescribed in JIS X0211.

Article 7 (Measure to Clarify Names, etc.)

The measure to clarify the name under paragraph (4) of Article 3 of the Information and Communications Technology Utilization Act shall mean to make an electronic signature for the information recorded in forms for electronic notification and transmit it together with an electronic certificate listed in the items of paragraph (2) of Article 4-5 and the items of paragraph (2) of Article 5.

Article 8 (Proposer Code)

(1) A person intending to make a proposal under paragraph (1) of Article 5 shall submit, in advance, a document in Form 13 stating the proposer confirmation code and other necessary matters to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.

(2) On receiving a document set forth in the preceding paragraph, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall issue a proposer code to the person who submitted the document.

(3) For any changes to the matters proposed, or for the termination of use of the proposer code, the person who made the proposal under paragraph (1) shall notify to that effect to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, without delay, using Form 14 or Form 15, respectively.

Supplementary Provisions

(1) This Ministerial Ordinance shall come into effect as from April 16, 1974.

(2) With regard to the application of the provisions of Article 4 during the fiscal year associated with the date of enforcement of this Ministerial Ordinance, the term “starting on the first day of the month after the month associated with each of the periods listed in the items below” in paragraph (1) of said Article shall be deemed to be replaced with “starting on May 16 for the period listed in item (i) below and starting on the first day of the month after the month associated with each of the periods listed in items (ii) and (iii),” the term “From March 1 through March 10” in

item (i) of said paragraph shall be deemed to be replaced with “From April 16 through April 25,” and the term “1 ton” in the items of paragraph (2) of said Article shall be deemed to be replaced with “875 kilograms.”

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 2 of June 7, 1974)

This Ministerial Ordinance shall come into effect as from June 10, 1974.

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of July 30, 1983)

This Ministerial Ordinance shall come into effect as from the date of enforcement of the Act for Partial Revision of the Related Acts for the Smooth Acquisition of Type Approval, etc. by Foreign Business Operators (August 1, 1983).

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of January 10, 1987)

This Ministerial Ordinance shall come into effect as from March 1, 1987.

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of February 2, 1990)

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

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of March 26, 1997)

This Ministerial Ordinance shall come into effect as from the day of promulgation; provided, however, that the provisions for revising Forms 1 and 1-2 shall come into effect as from June 1, 1997, and the provisions for revising Form 3 shall come into effect as from January 1, 1998.

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 1 of March 30, 1998)

This Ministerial Ordinance shall come into effect as from December 1, 1998.

Supplementary Provisions

(Ordinance of the Ministry of Health and Welfare and Ministry of International Trade and Industry No. 3 of November 29, 2000)

This Ministerial Ordinance shall come into effect as from January 6, 2001; provided, however, that the provisions for revising Forms 1 through 3 (excluding the part to revise the term “Minister of Health and Welfare Minister of International Trade and Industry” to “Minister of Health, Labour and Welfare Minister of Economy, Trade and Industry Minister of the Environment” and the part to revise the term “paragraph (1) of Article 3” to “Article 3”) shall come into effect as from the

day of promulgation.

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 March 30, 2001)

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

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 1 of February 3, 2003)

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

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 2 of April 30, 2003)

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

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 1 of January 19, 2004)

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

(2) With regard to the application of the provisions of item (i) of paragraph (1) of Article 4 of the revised Ministerial Ordinance on Notification, etc. of the Manufacture or Import of New Chemical Substances in the case where a person seeking confirmation under item (v) of paragraph (1) of Article 3 of the Act in the fiscal year associated with the date of enforcement of this Ministerial Ordinance, the terms “January 20” and “January 30” in said item shall be deemed to be replaced with “February 20” and “the first day of the next month,” respectively.

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 1 of January 11, 2005)

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