

# **Ordinance Related to Notification, etc. Concerning the Manufacture or Import of New Chemical Substances**

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

(Terms)

Article 1 The terms used in this Ministerial Ordinance shall have the same meaning as those used 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").

(Notification Pertaining to the Manufacture, etc. of New Chemical Substances)

Article 2 The notification under Article 3, paragraph (1) of the Act shall be given by submitting to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment a completed written notice Form No. 1 setting forth the following matters.

- (i) Name of the new chemical substance
- (ii) Structural formula or rational formula of the new chemical substance  
(where both are unclear, an outline of the manufacturing method)
- (iii) Physical chemistry characteristics and ingredient composition of the new chemical substance
- (iv) Usage of the new chemical substance
- (v) The planned quantity that will be manufactured or imported every year in the three years following the commencement of the manufacture or import of the new chemical substance
- (vi) Where a new chemical substance is to be manufactured, the name and location of the place of business that is to manufacture such new chemical substance; where the new chemical substance is to be imported, the name of the country or region where such new chemical substance is manufactured.

(Notification concerning the Manufacture, etc. of a New Chemical Substance by Manufacturers in a Foreign State)

Article 2-2 Notification under Article 7, paragraph (1) of the Act shall be given by submitting to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment a completed written notice Form No. 1-2 setting forth the following matters.

- (i) Name of the new chemical substance
- (ii) Structural formula or rational formula of the new chemical substance

- (where both are unclear, an outline of the manufacturing method)
- (iii) Physical chemistry characteristics and ingredient composition of the new chemical substance
  - (iv) Usage of the new chemical substance
  - (v) The quantity planned to be exported every year in the three years following the commencement of the export to Japan of the new chemical substance
  - (vi) Where a new chemical substance is to be manufactured, the name and location of the place of business that is to manufacture such new chemical substance; where the new chemical substance is to be exported, the name of the country or region where such new chemical substance is to be manufactured

(Request pertaining to Confirmation that Notification of the Manufacture, etc. of a New Chemical Substance is not Required)

Article 3 A person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (iv) of the Act shall submit a written request in advance to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment using the form listed in the middle column and the written confirmation listed in the right-hand column, corresponding to the category listed in the left-hand column of the following Table.

(i) Article 3, paragraph (1), item (i) 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 No. 2	Form No. 3
(ii) Article 3, paragraph (1), item (ii) of the Order	Form No. 4	Form No. 5
(iii) Article 3, paragraph (1), item (iii) of the Order	Form No. 6	Form No. 7

(Report concerning Confirmed New Chemical Substance)

Article 3-2 A person who has obtained confirmation under the provisions of Article 3, paragraph (1), item (iv) of the Act shall, by the end of June of every fiscal year, submit a written report using Form No. 8 to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment concerning the status of the handling of said new chemical substance in the preceding fiscal year. However, this does not apply when said new chemical substance was not manufactured or imported in the

previous year.

(Request pertaining to Confirmation of Low Volume New Chemical Substances)

Article 4 (1) Every year, in any of the periods listed in the following items, a person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (v) of the Act shall give notice to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment by submitting written request Form No. 9 and a copy thereof for any new chemical substance he/she intends to manufacture or import during the period from April 1 of the year in which the period set forth in item (i) falls until March 31 of the following year, or for any new chemical substance he/she intends to manufacture or import during the period from the first day of the month following the relevant month in which each period set forth in item (ii) through item (iv) falls until March 31 of the following year.

(i) From January 20 to January 30

(ii) From June 1 to June 10

(iii) From September 1 to September 10

(iv) From December 1 to December 10

(2) In the cases set forth in each of 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 confirmation under Article 3, paragraph (1), item (v) of the Act for the quantities planned to be manufactured or imported that are listed in the relevant item.

(i) Where the total quantity planned for the manufacture and import of a single new chemical substance covered by a request that was made during the period specified in item (i) of the preceding paragraph exceeds 1 ton: the quantity planned for the manufacture and import of the new chemical substance covered by the request that was made during the period listed in the same item

(ii) Where the total quantity planned for the manufacture and import (including quantities planned for manufacture and import subject to confirmation under the provisions of Article 5, paragraph (4) of the Act; hereinafter the same shall apply in this paragraph) of a single new chemical substance covered by requests that were made during the periods listed in item (i) and item (ii) of the preceding paragraph exceeds 1 ton: the quantity that is planned for the manufacture and import of said new chemical substance covered by the request that was made during the period listed in item (ii) of the preceding paragraph

(iii) Where the total quantity planned for the manufacture and import of a single new chemical substance covered by requests that were made during the periods listed in items (i) through (iii) of the preceding paragraph exceeds

1 ton: the planned quantity for the manufacture and import of said new chemical substance covered by the request that was made during the period listed in item (iii) of the preceding paragraph

(iv) Where the total quantity for the planned manufacture and import of a single new chemical substance covered by requests made during the periods listed in the items of the preceding paragraph exceeds 1 ton: the planned quantity for the manufacture and import of the new chemical substance covered by the request that was made during the period listed in item (iv) of the preceding paragraph

(Request pertaining to Confirmation of a Polymer)

Article 4-2 A person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (vi) of the Act concerning a new chemical substance intended to be manufactured or imported shall give notice in advance by submitting a written request using Form No. 10 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.

(Requests for Exceptions in Cases of Evaluations of Low Production Volume New Chemical Substances)

Article 4-3 A request under Article 5, paragraph (1) of the Act shall be filed by submitting written requests using Form Nos. 11 and 1 to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment when notification under Article 3, paragraph (1) of the Act is given.

(Request pertaining to Confirmation of Low Production Volume New Chemical Substance)

Article 4-4 (1) A person who intends to obtain confirmation under Article 5, paragraph (4) of the Act shall, when he/she intends to manufacture or import the relevant new chemical substance during the fiscal year (hereinafter referred to as the "notice year") that includes the day on which he/she has received notice that the new chemical substance for which he/she has made a request pursuant to the provisions of paragraph (2) or paragraph (3) of the same Article falls under paragraph (2) item (i) of the same Article (hereinafter referred to as the "notice day"), request such confirmation by submitting written request Form No. 12 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) A person who intends to obtain confirmation under Article 5, paragraph (4) of the Act shall, when he/she intends to manufacture or import the relevant new

chemical substance in or after the fiscal year that follows the year of notice, request such confirmation every year by submitting written request Form No. 12 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 the period from March 1 to March 10 of the fiscal year prior to that in which he/she intends to manufacture or import the relevant substance.

- (3) Concerning the application of the provisions of the preceding paragraph, when the manufacture or import of a new chemical substance is intended in the year following a notice year in which the notice day is in March, the expression "from March 1 to March 10" shall be deemed to be replaced with "until passage of ten days from the notice day."
- (4) In the 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 confirmation under Article 5, paragraph (4) of the Act concerning the quantity planned to be manufactured or imported listed in each of said items respectively.
- (i) Where the total quantity for the planned manufacture and import of a single new chemical substance covered by requests made up to the day of a request under paragraph (1) (including the quantity for planned manufacture and import for which there has been confirmation under the provisions of Article 3, paragraph (1), item (v) of the Act; hereinafter the same shall apply in this paragraph) exceeds 10 tons: the quantity for manufacture and import covered by the request set forth in paragraph (1)
- (ii) Where the total quantity for the planned manufacture and import of a single new chemical substance covered by requests made during the period under paragraph (2) exceeds 10 tons: the quantity for manufacture and import covered by the request made during the period set forth in paragraph (2)
- (iii) Where the total quantity for the planned manufacture and import of a single new chemical substance covered by requests made during the period under paragraph (2) and paragraph (3) exceeds 10 tons: the planned quantity of manufacture or import covered by the request made during the period set forth in paragraph (3)

(Continuation of the Evaluation of Low Production Volume New Chemical Substances)

Article 4-5 A request under Article 5, paragraph (7) of the Act shall be made by attaching the results of the tests set forth in paragraph (8) of said Article to the written request Form No. 13 and submitting them to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment.

(Notification, etc. by Electronic Data Processing System)

Article 4-6 (1) A person who intends to give notification under Article 3, paragraph (1) of the Act, make a request under Article 3 or Article 5, paragraphs (1) and (7) of the Act, and submit a report under Article 3-2 of the Act (hereinafter referred to as "notification, etc.") shall, when giving notification, etc. using electronic data processing systems (meaning electronic data processing systems which connect computers 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) with computers used by persons intending to give notification, etc. through telecommunications lines; the same shall apply hereinafter) pursuant to the provisions of Article 3, paragraph (1) of the Act on the Use of Information and Communications Technology in Administrative Procedures, etc. (Act No. 151 of 2002, hereinafter referred to as the "Act on the Use of Information and Communications Technology"), input the following matters using a computer which conforms to the technical standards prescribed by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment. However, instead of inputting the matters listed in item (iii), persons intending to give notification, etc. are not precluded from submitting, pursuant to provisions that the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment prescribe in a public notice, written documents, etc. to be attached pursuant to the provisions of laws and regulations.

- (i) Electronic notification forms (meaning forms that govern when giving notification, etc. using electronic data processing systems which are available as files on a computer designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment for the purpose of recording, among the matters to be recorded in forms that govern when notification, etc. is given via a document, etc. (hereinafter referred to as "written notification, etc."), the name of the notification, etc., the date the notification, etc. is given, the name of any other party giving the notification, etc., the domicile of the person giving the notification, etc., the name or business name of the person giving the notification, etc., the name of the representative person in the case of a juridical person, and an indication to the effect that notification, etc. is being given; the same shall apply hereinafter)
- (ii) Matters to be stated in written notification forms, etc. (except for matters listed in the previous item.)
- (iii) Matters stated in, or to be stated in, documents, etc. to be attached based

- on the provisions of laws and regulations when said notification, etc. is given via a document, etc., except for matters listed in the previous item
- (2) A person who intends to give notification, etc. under the preceding paragraph shall affix an electronic signature to the information input pursuant to the provisions of said paragraph (meaning an electronic signature provided under Article 2, paragraph (1) of the Act on Electronic Signatures and Certification Business (Act No. 102 of 2000); the same shall apply hereinafter) and shall transmit it with an electronic certificate (meaning an electromagnetic record prepared in order to verify that the person who intends to give the notification, etc. is the person who affixed the electronic signature; the same shall apply hereinafter) pertaining to said electronic signature and which falls under any of the following items.
- (i) An electronic certificate prepared by a registrar based on the provisions of Article 12-2, paragraphs (1) and (3) of the Commercial Registration Act (Act No. 125 of 1963) (including cases where these provisions are applied mutatis mutandis pursuant to other laws and regulations; the same shall apply hereinafter)
  - (ii) An electronic certificate prescribed under Article 3, paragraph (1) of the Act on Certification Business of Local Governments in Relation to Electronic Signatures (Act No. 153 of 2002)
  - (iii) In addition to what is provided in the preceding item, 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 in a public notice

(Requests in connection with Confirmation of Low Volume New Chemical Substances, etc. by Means of an Electronic Data Processing System)

- Article 5 (1) A person who intends to make the request under Article 4, paragraph (1) or Article 4-2, when making the request using an electronic data processing system pursuant to the provisions of Article 3, paragraph (1) of the Act on the Use of Information and Communications Technology, shall enter the following matters as provided for by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment using a computer which shall conform to the technical standards prescribed by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment.
- (i) Matters to be recorded in electronic notification, etc. forms.
  - (ii) Matters for which notice is to be given pursuant to the provisions of Article 4, paragraph (1) or Article 4-2
- (2) A person who intends to make the request under the preceding paragraph shall affix an electronic signature to the information input pursuant to the

provisions of the preceding paragraph and shall transmit it along with an electronic certificate in connection with said electronic signature and falls under any of the following items.

- (i) An electronic certificate prepared by a registrar based on the provisions of Article 12-2, paragraphs (1) and (3) of the Commercial Registration Act
- (ii) An electronic certificate prescribed under Article 3, paragraph (1) of the Act on Certification Business of Local Governments in Relation to Electronic Signatures
- (iii) In addition to what is provided for 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 inputting under the preceding Article shall follow the form prescribed in the Japanese Industrial Standards (hereinafter referred to as "Japanese Industrial Standards") Annex 1 X0208 based on the Industrial Standardization Act (Act No. 185 of 1949).

(2) The inputting under the preceding Article shall use "carriage return" and "line feed" among the graphic characters prescribed in the Japanese Industrial Standards X0201 and X0208 and control characters prescribed under the Japanese Industrial Standard X0211.

(Measures to Clarify Names, etc.)

Article 7 Measures to clarify names or business names under Article 3, paragraph (4) of the Act on the Use of Information and Communications Technology means affixing electronic signatures to information recorded in electronic notification, etc. forms and transmitting the electronic certificate listed in the items under Article 4-6, paragraph (2) and the items under Article 5, paragraph (2) along with said request.

(Requestor Code)

- Article 8 (1) A person who intends to submit a request under the provisions of Article 5, paragraph (1) to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment shall submit a document using Form No. 14 stating the person's confirmation code and other necessary matters
- (2) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment shall grant a requestor code to a person who submits the document prescribed under the preceding paragraph after receiving said document.
- (3) A person who has submitted a request under paragraph (1) shall, in the event



of a change in the request or if the use of the requestor code ceases, notify the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment, without delay, by means of Form No. 15 or Form No. 16, respectively.

#### **Supplementary Provisions**

- (1) This Ministerial Ordinance shall come into effect as of April 16, 1974.
- (2) Concerning the application of the provisions of Article 4 in a fiscal year that includes the day of enforcement of this Ministerial Ordinance, "from the first day of the month following the relevant month in which each period set forth in the relevant item falls" in paragraph (1) of the same Article shall be deemed to be replaced with "from May 16 for the period listed in item (i), and for from the first day of the month following the relevant month in which the periods set forth in item (ii) and item (iii) fall"; "from March 1 to March 10" in item (i) of the same paragraph shall be deemed to be replaced with "from April 16 to April 25"; and "1 ton" in each item of paragraph (2) of the same Article shall be deemed to be replaced with "875 kilograms."

#### **Supplementary Provisions [Ordinance of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment No. 1 of January 19, 2004]**

- (1) This Ministerial Ordinance shall come into effect as of April 1, 2004.
- (2) Concerning the application of the provisions of Article 4, paragraph (1), item (i) of the Ordinance related to Notification, etc. concerning Manufacture or Import of New Chemical Substances after revision in the case where confirmation is sought under the provisions of Article 3, paragraph (1), item (v) of the Act in the fiscal year that includes the day of enforcement of this Ministerial Ordinance, "January 20" in said item shall be deemed to be replaced with "February 20", and "January 30" shall be deemed to be replaced with "the first day of the following month".

#### **Supplementary Provisions [Ordinance of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment No. 1 of January 11, 2005]**

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

#### **Supplementary Provisions [Ordinance of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the**

**Ministry of the Environment No. 1 of February 1, 2010]**

This Ministerial Ordinance shall come into effect as of April 1, 2010; provided, however, that the provisions of Article 2 shall come into effect as of April 1, 2011.