

Ministerial Order on Notification Concerning the Manufacture or Import of New Chemical Substances

(Order 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 Order have the same meaning as those used in the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Act No. 117 of 1973, hereinafter referred to as the "Act").

(Notification Pertaining to the Manufacture of New Chemical Substances)

Article 2 The notification under Article 3, paragraph (1) of the Act is made by making a submission to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment, by any of the methods listed in the following items.

- (i) a method of submitting a written notification using Form No. 1 setting forth the following particulars
 - (a) name of the new chemical substance
 - (b) the structural or rational formula of the new chemical substance (if both are unclear, an outline of the manufacturing method)
 - (c) physical and chemical properties and ingredient composition of the new chemical substance
 - (d) usage of the new chemical substance
 - (e) 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
 - (f) if 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; if the new chemical substance is to be imported, the name of the country or region where such new chemical substance is manufactured
- (ii) a method of using the electronic data processing system prescribed in

Article 11

(Notification Concerning the Manufacture of a New Chemical Substance by Manufacturers in a Foreign State)

Article 3 The notification under Article 7, paragraph (1) of the Act is made by submitting to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment a written notification using Form No. 1-2 setting forth the following particulars.

- (i) name of the new chemical substance
- (ii) structural formula or rational formula of the new chemical substance (if both are unclear, an outline of the manufacturing method)
- (iii) physical and chemical properties and ingredient composition of the new chemical substance
- (iv) usage of the new chemical substance
- (v) the planned quantity to be exported every year in the three years following the commencement of the export to Japan of the new chemical substance
- (vi) if 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; if 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 a Confirmation that Notification of the Manufacture of a New Chemical Substance is not Required)

Article 4 A person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (iv) of the Act must make a request in advance to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment with regard to any new chemical substance the person intends to manufacture or import, by any of the methods listed in the following items.

(i) a method of submitting a written request using the format 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

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

(ii) a method of using the electronic data processing system prescribed in Article 11

(Report Concerning a Confirmed New Chemical Substance)

Article 5 A person who has obtained confirmation under the provisions of Article 3, paragraph (1), item (iv) of the Act, by the end of June of every fiscal year,

must submit a report 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 the relevant new chemical substance in the preceding fiscal year, by any of the methods listed in the following items; provided, however, that this does not apply if the relevant new chemical substance was not manufactured or imported in the previous year.

- (i) a method of submitting a written report using Form No. 8
- (ii) a method of using the electronic data processing system prescribed in Article 11

(Request pertaining to Confirmation of Small Production Volume New Chemical Substances)

Article 6 (1) A person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (v) of the Act must make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment with regard to any new chemical substance the person intends to manufacture or import, by any of the methods listed in the following items.

- (i) a method of submitting a written request using Form No. 9 or a copy thereof
- (ii) a method of submitting the optical disc prescribed in Article 12 (meaning an optical disc with a diameter of 120 mm that conforms to Japanese Industrial Standards X0606 and X6281 or X6241, or X6245; the same applies hereinafter)
- (iii) a method of using the electronic data processing system prescribed in Article 13

(2) The method prescribed in Article 3, paragraph (2) of the Act is the calculation method of multiplying the planned quantity to be manufactured or planned quantity to be imported to which the confirmation under the provisions of paragraph (1), item (v) of the same Article pertains for a single new chemical substance, by a coefficient specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment according to the usage of the new chemical substance.

(Request pertaining to the Confirmation of a Polymer)

Article 7 A person who intends to obtain confirmation under the provisions of Article 3, paragraph (1), item (vi) of the Act with regard to any new chemical substance the person intends to manufacture or import must make a request in advance to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment, by any of the methods listed in the following items.

- (i) a method of submitting a written request using Form No. 10 and a copy

thereof

- (ii) a method of using the electronic data processing system prescribed in Article 13

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

Article 8 The request under Article 5, paragraph (1) of the Act is made by making a submission to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment, by any of the methods listed in the following items.

- (i) a method of submitting a written request using Form No. 11 attached to a written notification using Form No. 1
- (ii) a method of using the electronic data processing system prescribed in Article 11

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

Article 9 (1) A person who intends to obtain confirmation under the provisions of Article 5, paragraph (4) of the Act must make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment with regard to any new chemical substance that the person intends to manufacture or import, by any of the methods listed in the following items.

- (i) a method of submitting a written request using Form No. 12 and a copy thereof
 - (ii) a method of submitting the optical disc prescribed in Article 12
 - (iii) a method of using the electronic data processing system prescribed in Article 13
- (2) The method prescribed in Article 5, paragraph (5) of the Act is the calculation method of multiplying the planned quantity to be manufactured or planned quantity to be imported to which the confirmation under the provisions of paragraph (1), item (vi) of the same Article pertains for a single new chemical substance, by a coefficient specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment according to the usage of the new chemical substance.

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

Article 10 The request under Article 5, paragraph (7) of the Act is made by making a submission to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment,

by any of the methods listed in the following items.

- (i) a method of submitting a written request using Form No. 13 with the results of the tests under Article 5, paragraph (8) of the Act attached thereto
- (ii) a method of using the electronic data processing system prescribed in Article 11

(Notification by an Electronic Data Processing System)

Article 11 (1) A person who intends to give a notification under Article 3, paragraph (1) of the Act, a request under Article 5, paragraphs (1) and (7) of the Act, make a request under Article 4, and submit a report under Article 5 (hereinafter referred to as "notification, etc.") must, when giving notification, etc. using an electronic data processing system (meaning an electronic data processing system which connects 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 applies hereinafter) with computers used by persons intending to give a notification, etc. through telecommunications lines; the same applies hereinafter) pursuant to the provisions of Article 3, paragraph (1) of the Act on the Use of Information and Communications Technology in Administrative Procedures (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; provided, however, that 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 the forms to be used when giving a notification, etc. using an electronic data processing system 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 address 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

- corporation, and an indication to the effect that notification, etc. is being given; the same applies 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 the relevant notification, etc. is given via a document, etc., except for matters listed in the previous item
- (2) A person who intends to give a notification, etc. under the preceding paragraph must affix an electronic signature to the inputted information pursuant to the provisions of the same 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 applies hereinafter) and 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 applies hereinafter) pertaining to the relevant 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 applies 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) Beyond what is provided for 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

(Request Pertaining to Confirmation of Small Production Volume New Chemical Substances Using an Optical Disc)

Article 12 A person who intends to make a request by the method prescribed in Article 6, paragraph (1), item (ii) or Article 9, paragraph (1), item (ii) must submit an optical disc in which the matters to be stated in a written request using Form No. 9 or Form No. 12 are recorded, and an optical disc submission slip using Form No. 14.

(Requests in connection with Confirmation of Small Production Volume New Chemical Substances Using an Electronic Data Processing System)

Article 13 A person who intends to make a request under Article 6, paragraph

(1), Article 7 or Article 9, paragraph (1), 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, must 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 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.

(i) matters to be recorded in an electronic notification, etc. forms.

(ii) matters to be included in the request pursuant to the provisions of Article 6, paragraph (1), Article 7 or Article 9, paragraph (1)

(iii) the requestor code granted pursuant to the provisions of Article 16, paragraph (2)

Article 14 (1) The person inputting the matters referred to in the preceding Article must follow the format 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 person inputting the matters referred to in the preceding Article must 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)

Article 15 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 11, paragraph (2) along with the relevant request, or inputting the matters specified in Article 13, item (iii).

(Requestor Code)

Article 16 (1) A person who intends to make a request under the provisions of Article 13 must make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment in advance by submitting a document using Form No. 15 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 grants a requestor code to a person who submits the document prescribed under the preceding paragraph

after receiving the relevant document.

- (3) A person who has made a request under paragraph (1), in the event of a change in the request or discontinuation of the use of the requestor code, must 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. 16 or Form No. 17, respectively.

Supplementary Provisions

- (1) This Ministerial Order comes 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 Order, "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 is 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 is deemed to be replaced with "from April 16 to April 25"; and "1 ton" in each item of paragraph (2) of the same Article is deemed to be replaced with "875 kilograms."

Supplementary Provisions [Order 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 Order comes into effect as of April 1, 2004.
- (2) Concerning the application of the provisions of Article 4, paragraph (1), item (i) of the Order related to Notification concerning the Manufacture or Import of New Chemical Substances after amendment in the case when 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 Order, "January 20" in the relevant item is deemed to be replaced with "February 20", and "January 30" is deemed to be replaced with "the first day of the following month".

Supplementary Provisions [Order 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 Order comes into effect as of the day of promulgation.

Supplementary Provisions [Order 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 Order comes into effect as of April 1, 2010; provided, however, that the provisions of Article 2 come into effect as of April 1, 2011.

Supplementary Provisions [Order of the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment No. 5 of July 31, 2018]

This Ministerial Order comes into effect as of January 1, 2019.