

**( PROVISIONAL TRANSLATION )**

Ministerial Ordinance Concerning Notification Relating to the Manufacture or Import of New Chemical Substances (Ministerial Ordinance No.1 by the Ministry of Health and Welfare and the Ministry of International Trade and Industry, dated April 15, 1974) Amended by Ministerial Ordinance No.1 by the Ministry of Health, Labor, and Welfare, Ministry of Economy, Trade, and Industry, and Ministry of the Environment, dated January 19, 2004

Under the provisions of paragraph 1, article 3 of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No.117, 1973) and under the provisions of Clause 2, Paragraph 1 of the Cabinet Order (Cabinet Order No.102, 1974) that defines the cases where notification of the manufacture or import of new chemical substances under the provisions of Paragraph 1, Article 3 of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. , is not required, and in order to execute the said cabinet order, the Ministerial Ordinance Concerning Notification Relating to the Manufacture or Import of New Chemical Substances shall be established as follows:

(Terms)

Article 1. Terms used in this ministerial ordinance shall be in accordance with the examples of terms used in the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No.117, 1973, hereinafter referred to as the Law).

(Notification relating to manufacture, etc. of new chemical substances)

Article 2. Notification as specified in Paragraph 1, Article 3 of the law shall be made by submitting a notification using Form 1 describing the items listed in each of the following clauses to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

- 1) Name of the new chemical substance
- 2) Structural or rational formula of the new chemical substance (If neither is known, the outline of its manufacturing method)
- 3) Physical and chemical properties and component composition of the new chemical substance
- 4) Application of the new chemical substance
- 5) Planned quantity of manufacture or planned quantity of import of the new chemical substance in the three years following the commencement of its manufacture or import

6) Name and location of the business premise where the new chemical substance is manufactured (in the case of new chemical substance manufacture) or the country or region where the new chemical substance is manufactured (in the case of new chemical substance import)

Article 2-2. The notification, as specified in Paragraph 1, Article 5-2 of the Law, shall be made by submitting notification based on Form 1-2 describing the information on the items listed in each of the following clauses to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

- 1) Name of the new chemical substance
- 2) Structural or rational formula of the new chemical substance (If neither is known, the outline of its manufacturing method)
- 3) Physical and chemical properties and component composition of the new chemical substance
- 4) Intended use of the new chemical substance
- 5) Planned annual quantity of export of the new chemical substance for the three years following the start of its export to Japan
- 6) Name and address of the business premise where the new chemical substance is manufactured (in the case of new chemical substance manufacture) or country or region where the new chemical substance is manufactured

(Request concerning confirmation that a notification of manufacture, etc. of a new chemical substance is not required)

Article 3. A person seeking the authorization stipulated in the provisions of Clause 4, Paragraph 1, Article 3 of the Law shall submit an application in advance, depending on the division shown in the left column of the table shown below, to the Minister of Health, Labor, and Welfare, the Minister of the Economy, Trade, and Industry, and the Minister of the Environment by providing a request based on the form listed in the intermediate column of the said table and a confirmation sheet listed in the right column of the said table.

Clause 1, Paragraph 1, Article 2 of the Law enforcement ordinance (Cabinet Order No.202, 1974, hereinafter referred to as “the Order”) concerning Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	Form 2	Form 3
Clause 2, Paragraph 1, Article 2 of the order	Form 4	Form 5
Clause 3, Paragraph 1, Article 2 of the order	Form 6	Form 7

(Report concerning authorized new chemical substance)

Article 3-2. A person who has been confirmed under the provisions of Clause 4, Paragraph 1, Article 3 of the law shall submit a report concerning the status of handling the said chemical substance in the preceding fiscal year based on Form 8, to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment by the end of June every fiscal year. However, this shall not be applied to cases where the said new chemical substance was not manufactured or imported in the preceding fiscal year.

(Proposal concerning authorization of a small quantity new chemical substance)

Article 4. A person seeking the confirmation stipulated in the provisions of Clause 5, Paragraph 1, Article 3 of the Law shall submit a request every year to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment, within either of the following durations listed below, by providing a request using Form 9 and a copy thereof concerning a new chemical substance intended to be manufactured or imported from April 1st of the fiscal year concerned for the duration listed in Clause 1 below, and from the 1st of the next month of each duration listed in Clause 2 through 4, till March 31st of the next year of the duration concerned.

- 1) From January 20th to 30th of the same month
- 2) From June 1st to 10th of the same month
- 3) From September 1st to 10th of the same month
- 4) From December 1st to 10th of the same month

2. In the case listed in each of the following clauses, the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment shall not be allowed to confirm the planned quantity of manufacture or of import, as specified in Clause 5, Paragraph 1, Article 3 of the Law.

- 1) In the case where the total planned quantity of manufacture and import concerning the request made within period referred to in Clause 1 of the preceding paragraph concerning a new chemical substance exceeds one (1) ton, the planned quantity of manufacture or of import concerning the request made in the period referred in to the said clause concerning the said new chemical substance.
- 2) In the case where the total planned quantity of manufacture and import concerning the proposal made within periods Clauses 1 and 2 of the preceding paragraph concerning a new chemical substance exceeds one (1) ton (including the planned quantity of manufacture and of import concerning confirmation made under the provisions of Paragraph 4, Article 4-2 of the Law, hereinafter the same applies in this paragraph) the planned quantity of manufacture or import concerning the request made

in the period referred to in Clause 2 of the preceding paragraph concerning the said new chemical substance.

3) In the case where the total planned quantity of manufacture and import concerning the request made within the periods referred to in Clause 1 through 3 of the preceding paragraph concerning a new chemical substance exceeds one (1) ton, the planned quantity of manufacture or import concerning the request made in period referred to in Clause 3 of the preceding paragraph concerning the said new chemical substance.

4) In the case where the total planned quantity of manufacture and import concerning the request made within the period in each of the clauses of the preceding paragraph concerning a new chemical substance exceeds one (1) ton, the planned quantity of manufacture or import concerning the proposal made in the period referred to in Clause 4 of the preceding paragraph concerning the said new chemical substance.

(Request concerning special cases of evaluation of new chemical substances manufactured in small quantity)

Article 4-2. A request referred to in Paragraph 1, Article 4-2 of the Law shall be submitted to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment by attaching the request (Form 10) to the notification (Form 1) at the time of the notification referred to in Paragraph 1, Article 3 of the Law.

(Request concerning the confirmation of new chemical substances manufactured in small quantity)

Article 4-3. A person seeking the confirmation stipulated in Paragraph 4, Article 4-2 of the Law, who intends to manufacture or import the said new chemical substance in the fiscal year which includes the date of the notification that a new chemical substance concerning the said request falls under Clause 1, Paragraph 2 of the said article under the provisions of Paragraphs 2 or 3 of the said article (hereinafter referred to as the “notification year” and “notification date, respectively”), shall submit a request using Form 11 and a copy thereof to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

2. A person seeking the authorization stipulated in Paragraph 4, Article 4-2 of the Law, who intends to manufacture or import the said new chemical substance in the fiscal year on and after the next year of the notification year, shall submit a request annually using Form 11 and a copy thereof to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment within the period from March 1st to 10th of the same month of the preceding fiscal year of the intended manufacture or import.

3. As for the application of the provisions of the preceding paragraph for the case where the said new chemical substance is manufactured or imported in the next year of the notification year when the notification date is in March, “from March 1st to 10th of the same month,” it shall be read as “until the day exceeding 10 days from the notification date.”

4. In the following cases, the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment shall not be allowed to confirm the planned quantity of manufacture and import listed in each of the clauses concerned, as specified in Paragraph 4, Article 4-2 of the Law.

1) In the case where the total planned quantity of manufacture and import concerning the request made until the date of the request referred to in Paragraph 1 above concerning a new chemical substance (including the planned quantity of manufacture and import concerning the confirmation under the provisions of Clause 5, Paragraph 1, Article 3 of the Law, hereinafter the same applies in this paragraph) exceeds ten (10) tons, the planned quantity of manufacture or import concerning the request of Paragraph 1 concerning the said new chemical substance.

2) In the case where the total planned quantity of manufacture and import concerning the request made in the period referred to in Paragraph 2 of 1 of this article concerning a new chemical substance exceeds ten (10) tons, the planned quantity of manufacture or import concerning the proposal made in the period referred to in Paragraph 2 above concerning the said new chemical substance.

3) In the case where the total planned quantity of manufacture and import concerning the proposal made in the period referred to in Paragraphs 2 and 3 of 1 of this article concerning a new chemical substance exceeds ten (10) tons, the planned quantity of manufacture or import concerning the request made in the period referred to in Paragraph 3 of 1 of this article concerning the said new chemical substance.

(Continuation of the evaluation of new chemical substances manufactured in small quantity)

Article 4-4. The request referred to in Paragraph 7, Article 4-2 of the Law shall be made by submitting a request using Form 12 with an accompanying test record referred to in Paragraph 8 of the said article to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

(Notification, etc., by an electronic information-processing system)

Article 4-5. A person who intends to submit notification in accordance with Paragraph 1, Article 3 of the Law, to make a request in accordance with Paragraphs 1 and 7, Article 4-2 of the Law, and Article 3 of the Law, and to make a report in accordance with

Article 3-2 of the Law (hereinafter referred to as the notification, etc.), and intends to make the request using an electronic information-processing system (an electronic information-processing system connecting the electronic computer (including input/output devices, hereinafter the same applies) designated by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment, with the electronic computer related to the use of the person who intends to make a notification, etc. by telecommunication lines) in accordance with the provisions of Paragraph 1, Article 3 of the Law on the Use of Information Communication Technology in Administrative Procedures, etc. (Law No.151, 2002, hereinafter referred to as the Law on Information Communication Technology Utilization), shall input the items listed in the following clauses from the electronic computer related to the use of the person who intends to make a notification, etc. which meets with the technical standards defined by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment. However, a person who intends to make a notification, etc. may submit the documents, etc. defined to be attached under the provisions of the decree by the announcement of the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment instead of inputting items listed in clause 3.

1) Items to be recorded in the electronic notification, etc. form (a format to be used for the case notification, etc. is made using an electronic information-processing system, and of items to be described in the form that should be followed when a notification, etc. is made by a document, etc. (hereinafter referred to as the document notification, etc. form), name of the notification, etc., date of notification, etc., name of the addressee of the notification, etc., address of the person who is making the notification, etc., the name or designation of the person who is making the notification, and for the corporation, the name of the representative, and the expression of the notification, etc. can be input from the file stored in the electronic computer designated by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment)

2) Items to be described in the document notification, etc. form (excluding items listed in the preceding clause).

3) Items described or to be described in the document, etc. to be attached under the provisions of the decree when the said notification, etc. is made by the document, excluding items listed in the preceding clause.

2. A person who intends to make notification, etc. of the preceding paragraph shall include an electronic signature (as specified in Paragraph 1, Article 2 of the Law Concerning Electronic Signature and Authentication Services (Law No.102, 2000;

hereinafter the same applies) on the information about the items to be input under the provisions of the said paragraph, and shall transmit an electronic certificate (an electromagnetic record to be prepared to certify that the items used to confirm that the person who intends to make the notification, etc. and executed the electronic signature are related to the person who intends to make the said notification; hereinafter the same applies) concerning the said electronic signature together with the electronic certificate corresponding to either of the following clauses.

1) An electronic certificate prepared by a greffier under the provisions of Paragraphs 1 and 3, Article 12-2 of the Commercial Registration Law (Law No.125, 1963) (including the cases where these provisions are applied mutatis mutandis in the provisions of the other decree, hereinafter the same applies).

2) Electronic certificate specified in Paragraph 1, Article 3 of the Law Concerning Authentication Service by Local Authorities Relating to Electronic Signatures (Law No.153, 2002).

3) In addition to the items specified in the preceding paragraphs, the electronic certificate specified in the announcement by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment. (Request concerning the confirmation of new chemical substance manufactured in small quantity by an electronic information-processing system)

Article 5. A person who intends to make a request under Paragraph 1, Article 4, and intends to make a request using an electronic information-processing system under the provisions of Paragraph 1, Article 3 of the Law on Information Communication Technology Utilization shall input the items to be recorded in the request (Form 9) for the manufacture (import) of new chemical substances manufactured in small quantity. They can be input from the file stored in the electronic computer designated by the Minister of Health, Labor and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment, from the electronic computer that is related to the use of the person who intends to make a request and meets with the technical standards defined by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

Article 6. The input specified in the preceding article shall be made in accordance with the method specified in Appendix 1 of the Japanese Industrial Standards X0208 based on the Industrial Standardization Law (Law No.185, 1949) (hereinafter referred to as Japan Industrial Standards).

2. The input specified in the preceding article shall be made using the graphic characters specified in the Japanese Industrial Standards X0201 and X0208; and “Return” and

“Line feed” among the control characters specified in the Japanese Industrial Standards X0211.

(Special cases concerning the confirmation of new chemical substances manufactured in small quantity by an electronic information-processing system)

Article 7. A person who intends to make a request based on Paragraph 1, Article 4, and intends to use the Internet for this request using an electronic information-processing system under the provisions of Paragraph 1, Article 3 of the Law on Information Communication Technology Utilization, notwithstanding the provisions of Article 5, may, under the provisions stipulated by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment, input the following items from the electronic computer that is related to the use of the person who intends to make a request and meets with the technical standards defined by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

1) Items to be recorded in the electronic notification form

2) Items deemed to be requested under the provisions of Paragraph 1, Article 4

2. A person who intends to make a request referred to in the preceding paragraphs shall include their electronic signature on the information about items to be input under the provisions of the said paragraphs, and shall transmit it together with an electronic certificate that relates to the said electronic signature and falls under either of the following clauses:

1) An electronic certificate prepared by a greffier under the provisions of Paragraphs 1 and 3, Article 12-1 of the Commercial Registration Law

2) An electronic certificate defined in Paragraph 1, Article 3 of the Law Relating to Authentication Service by Local Authorities Engaged in Electronic Signature

3) In addition to those defined in the preceding paragraphs, the electronic certificate must be in accordance with provisions stipulated by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment.

(Measures for identifying name, etc.)

Article 8. The measures for identifying the name or designation stipulated in Paragraph 4, Article 3 of the Law on Information Communication Technology Utilization involves procedures including an electronic signature on the information recorded in the electronic notification form and to transmit an electronic certificate referred to in each of the clauses, in Paragraph 2, Article 4-5, and Paragraph 2 of the preceding article together with the said request.



(Applicant's Code)

Article 9. A person who intends to make a request under the provisions of Article 5 or Paragraph 1, Article 7 shall submit a document using Form 13 which states the applicant's confirmation code and other necessary matters to the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment prior to applying the request.

2. Upon receiving the document stated in the preceding paragraph, the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment shall grant an applicant's code to the person who submitted the said document.

3. The person who has made a request referred to in Paragraph 1 above, when the matter(s) requested are altered or the use of the applicant's code is discontinued, shall without delay notify the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment based on Form 14 or 15, respectively.

Supplementary provisions

1. This ministerial ordinance shall be enforced from April 16, 1974.

2. As for the enforcement of Article 4 in the fiscal year that includes the enforcement date of this ordinance, "from the 1st of the next month of the period referred to in each of the clauses concerned" shall read as "from May 16th for the period referred to in Clause 1, and from the 1st of the next month of the period referred to in each of the clauses concerned for the period referred to in Clauses 2 and 3," and "from March 1st to 10th of the same month" referred to in Clause 1 of the same paragraph shall read as "from April 16<sup>th</sup> to 25th of the same month," and "one (1) ton" in both of the clauses in Paragraph 2 of the same article shall read as "875 kg."

Supplementary provisions (Ministerial ordinance No.1 by the Minister of Health, Labor, and Welfare, the Minister of Economy, Trade, and Industry, and the Minister of the Environment dated January 19, 2004)

1. This ministerial ordinance shall be enforced from April 1st, 2004.

2. As for the enforcement of the provision of Clause 1, Paragraph 1, Article 4 of the Ministerial Ordinance Relating to the Notification, etc. Concerning the Manufacture or Import of a New Chemical Substance after amendment for the case seeking confirmation under the provision of Clause 5, Paragraph 1, Article 3 of the Law in the fiscal year that includes the date of this cabinet order, "January 20th" in the said clause shall be read as "February 20<sup>th</sup>," and "the 30th of the same month" shall be read as "the

1st of the following month.”