

(PROVISIONAL TRANSLATION)

Rules for Enforcement of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. Associated with the Ministry of Economy, Trade, and Industry (Ministry of International Trade and Industry Ordinance of June 7, 1973)

Amended on January 19, 2004

Ministry of Economy, Trade, and Industry Ordinance No.1

This ministerial ordinance provides the rules for the enforcement of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No.117 of 1973), in accordance with the provisions of Paragraphs 1 and 2, Article 19. of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. under the control of the Ministry of International Trade and Industry.

(Terms)

Article 1. The terms used in this ordinance shall be the same as those used in the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No.117 of 1973, hereinafter referred to as “the Law”).

(Application for authorization of manufacture of Class 1 Specified Chemical Substances)

Article 2. To apply for the authorization described in Paragraph 2, Article 6 of the Law, in accordance with the provisions of Paragraph 2 of the article, the applicant shall submit an application (Form 1), together with the following documents, to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the location of the business concerned:

- 1) Drawings that show the location of the manufacturing equipment (including their relative positions with respect to other equipment), and the conditions surrounding the business premise, of the business concerned
- 2) Documents that describe the employment and allocation conditions, as well as the technical skills, of the employees
- 3) Documents that outline the method of manufacture of the chemical substance concerned

- 4) Documents that describe the production plans and the estimated volume of sales for each individual purchaser
- 5) Documents that describe the methods of storage and transportation
- 6) Copies of the articles of corporation or the act of endowment and the register, if the applicant is a corporation
- 7) Documents that show that the applicant (if the applicant is a corporation, that the corporation and its directors) does not fall under any clause of Article 8 of the Law
- 8) The most recent annual report, balance sheet, and profit and loss statement or their equivalents
- 9) Documents that explain the existence of a financial base that is robust enough to run the business properly, in addition to the aforementioned drawings and documents

(Application for permit for making structural or other changes of Class 1 Specified Chemical Substance manufacturing equipment)

Article 3. To obtain a permit for a change under Paragraph 1, Article 10 of the Law, the applicant shall submit an application (Form 2), together with the details of the proposed change, to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the location of the business concerned.

(Notification of change related to a Class 1 Specified Chemical Substance manufacturing business)

Article 4. To make notification of any change under Paragraph 2, Article 10 of the Law, the applicant shall submit a notification (Form 3) to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the location of the business concerned.

(Application for permit for import of Class 1 Specified Chemical Substances)

Article 5. To apply for the permit described in Paragraph 1, Article 11 of the Law under Paragraph 2 of the Article, the applicant shall submit an application (Form 4), together with the following documents, to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the location of the business concerned:

- 1) Documents that describe the names of the manufacturer and its country or region, the estimated date of landing, the name of the port of import, and the estimated volume of sales for each individual purchaser

- 2) Documents that describe the methods of storage and transportation
- 3) Copies of the articles of corporation or the act of endowment and the register, if the applicant is a corporation
- 4) Documents that show that the applicant (if the applicant is a corporation, that the corporation and its directors) does not fall under any Clause of Article 8 of the Law

(Notification of succession)

Article 6. To make notification of the succession of the title of a authorized manufacturer or a authorized importer under Paragraph 2, Article 16 of the Law, the applicant shall submit a notice (Form 5), together with the following documents, to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the manufacturing business concerned or to the Minister of Economy, Trade, and Industry, respectively:

- 1) The relevant document (Form 6) and a copy of the family register in the case of a person who has succeeded the title of a authorized manufacturer or licensed importer under the provision of Paragraph 1, Article 16 of the Law and has been selected as such by the universal agreement of two or more successors
- 2) The relevant document (Form 7) and a copy of the family register in the case of a person who has succeeded the title of a authorized manufacturer or licensed importer under the provision of Paragraph 1, Article 16 of the Law, but who does not fall under the proceeding paragraph
- 3) A copy of the registry of corporation in the case of a corporation that has succeeded the title of a authorized manufacturer or authorized importer through merger under Paragraph 1, Article 16 of the Law

(Records)

Article 7. With respect to the Class 1 Specified Chemical Substance concerned, the quantities manufactured and the quantities in stock at each individual business premise and the volume of sales for each individual purchaser must be entered in the records specified by Paragraph 1, Article 19 of the Law.

2. The aforementioned records must be kept at each individual business premise and be filled in with the aforementioned data for the previous month by the end of each month.
3. The records specified in the proceeding article must be kept for five years after the date of its closing.

(Electromagnetic record keeping)

Article 7-2. If the data specified in Paragraph 1 of the preceding article is to be recorded electromagnetically (using an electronic, magnetic, or other method incapable of recognition by human cognizance) so that it can be immediately displayed by means of an electronic computer or other equipment as needed, the keeping of the record may substitute for the maintenance of a record keeping that data specified in Paragraph 2, Article 19 of the Law.

2) To keep records as specified in the preceding paragraph, it is necessary to make efforts to comply with the criteria specified by the Minister of Economy, Trade, and Industry.

(Notification of the discontinuance of business)

Article 8. To give notice of the discontinuance of a business under the provisions of Paragraph 1, Article 20 of the Law, the authorized manufacturer shall submit the notice (Form 8) to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the manufacturing business concerned.

(Reporting)

Article 9. With respect to the Class 1 Specified Chemical Substances authorized under Paragraph 1, Article 6 of the Law, the authorized manufacturer shall submit a report describing the monthly quantities manufactured, monthly quantities in stock, and monthly quantities sold to each purchaser in each fiscal year within three months of the end of that year to the Minister of Economy, Trade, and Industry through the Director of the Regional Bureau of Economy, Trade, and Industry governing the manufacturing business concerned or to the Minister of Economy, Trade, and Industry.

(Submission of reports by means of flexible disks)

Article 9-2. The documents specified in the left-hand columns of the following table may be submitted on a flexible disk recording the required data in the corresponding forms specified on the right.

The application for permit under Article 2 above and the attachments specified in Clauses 2 through 9 (except Clause 6) of the Article	Form 8-3
The application for permit under Article 3 above and the attachments describing the contents of the change concerned	Form 8-4
The application for notice under Article 4 above	Form 8-5
The application for permit under Article 5 above and the attachments specified in Clauses 1, 2, and 4 of the Article	Form 8-6

The application for notice under Article 6 above	Form 8-7
The application for notice under Article 8 above	Form 8-8

2) The report specified in Article 9 above may be submitted on a flexible disk recording the required data, together with the flexible disk submission form (Form 8-2).

(Structure of flexible disk)

Article 9-3. The flexible disk referred to in the proceeding article must comply with one of the following:

- 1) A 90-mm flexible cartridge that conforms to the Japan Industrial Standards under the Industrial Standardization Law (Law No.185 of 1949) (hereinafter referred to as the Japan Industrial Standards) X6221
- 2) A 90-mm flexible cartridge that conforms to the Japan Industrial Standards X6223

(Flexible disk recording method)

Article 9-4. Flexible disk recording under Article 9-2 above shall take place according to the following methods:

- 1) Track formatting shall take place according to the method specified in the Japan Industrial Standards X6222 or the Japan Industrial Standards X6225, depending on whether the type of flexible disk to be formatted is that specified in Paragraph 1 or Paragraph 2 of Article 9-3 above, respectively.
- 2) The volume and file organizations shall comply with the Japan Industrial Standards X0605.
- 3) The character code shall comply with Annex 1 of the Japan Industrial Standards X0208.

2. The flexible disk recording specified in Article 9-2 above shall utilize the graphic characters specified in the Japan Industrial Standards X0201 and X0208 and the control characters “Return” and “Line feed” specified in the Japan Industrial Standards X0211.

(Documents to be affixed to the flexible disk)

Article 9-5. A document describing the following items must be affixed to the label area of the flexible disks specified in the Japan Industrial Standards X6221 or X6223:

- 1) The name or identification of the applicant
- 2) The date of submission

(Notification of manufactured quantities and other data relating to the Monitored

Chemical Substance)

Article 10. The following items are specified by the Ministry of Economy, Trade, and Industry Ordinance referred to in Paragraph 1 of Article 5-3, Paragraph 1 of Article 23, and Paragraph 1 of Article 25-2 of the Law, respectively:

- 1) The name of the Monitored Chemical Substance concerned
- 2) The quantities of the Monitored Chemical Substance shipped in the previous year
- 3) The name and address of the business premise that manufactured the Monitored Chemical Substance or the name of the country or region in which the Monitored Chemical Substance was manufactured, depending on whether the Monitored Chemical Substance concerned was manufactured or imported, respectively.

2. The notification under Paragraph 1 of Article 5-3, Paragraph 1 of Article 23, and Paragraph 1 of Article 25-2 of the Law shall be submitted to the Minister of Economy, Trade, and Industry using Form 9 by June 30th of each year.

(Exception of announcement of manufactured quantities, etc.)

Article 11. The quantity specified by the Ministry of Economy, Trade, and Industry Ordinance referred to by the conditional clause of Paragraph 2, Article 5 of the Law shall be one ton.

2. The quantity specified by the Ministry of Economy, Trade, and Industry Ordinance referred to by the conditional clauses of Paragraph 2 of Article 23 and Paragraph 2 of Article 25-2 of the Law shall be 100 tons.

(Persons to be instructed to conduct a study with respect to hazardous effects)

Article 12. The person specified by the Ministry of Economy, Trade, and Industry Ordinance referred to by Paragraph 1 of Article 5-4, Paragraph 1 of Article 24-1, and Paragraph 1 of Article 25-3 of the Law shall be any person who engaged in a business of manufacture or import of the Monitored Chemical Substance concerned in the three years prior to the issuance of the instructions of the hazardous study.

(Notification of planned quantities, etc. of Class 2 Specified Chemical Substances to be manufactured)

Article 13. The following items are specified by the Ministry of Economy, Trade, and Industry Ordinance referred to in Paragraph 1, Article 26 of the Law:

- 1) The name of the Class 2 Specified Chemical Substance concerned or the name of the product using the Class 2 Specified Chemical Substance concerned

2) The estimated quantities of shipment of the Class 2 Specified Chemical Substance concerned or the name of the product using the Class 2 Specified Chemical Substance concerned

3) The name and address of the business premise that manufactures the Class 2 Specified Chemical Substance or the name of the country or region in which the Class 2 Specified Chemical Substance or the product using the Class 2 Specified Chemical Substance is manufactured, depending on whether the Class 2 Specified Chemical Substance concerned is to be manufactured or the Class 2 Specified Chemical Substance concerned or the product using the Class 2 Specified Chemical Substance concerned is to be imported, respectively.

2. The notification required by Paragraph 1, Article 26 of the Law shall be submitted to the Minister of Economy, Trade, and Industry using Form 10 one month before the day on which the Class 2 Specified Chemical Substance concerned will be manufactured or imported or the product using the Class 2 specified chemical substance concerned will be imported (hereinafter referred to as “the manufacture, etc. of the Class 2 Specified Chemical Substance”) for that year.

3. With respect to the application of the provision of the preceding paragraph regarding the notification required by Paragraph 1, Article 26 of the Law in connection with the manufacture of the Class 2 Specified Chemical Substance concerned or the product using the Class 2 Specified Chemical Substance concerned in the year (hereinafter referred to as “the designated year”) containing the specified date (hereinafter referred to as “the designated date”) and in the year following the designated year (only when the designated date is in the last month or the month before the last of the year), the wording “one month before the day on which the Class 2 Specified Chemical Substance concerned will be manufactured or imported or the product using the Class 2 Specified Chemical Substance concerned will be imported (hereinafter referred to as “the manufacture, etc. of the Class 2 Specified Chemical Substance”)” in the provision of the preceding paragraph shall mean the day one month before the day on which the Class 2 Specified Chemical Substance concerned will be manufactured or imported or the product using the Class 2 Specified Chemical Substance concerned will be imported (hereinafter referred to as the manufacture, etc. of the Class 2 Specified Chemical Substance) or the day one month after the designated date for the Class 2 Specified Chemical Substance, whichever is later.

(Notification of a change in the planned manufacturing quantities of the Class 2 Specified Chemical Substance, etc.)

Article 14. To submit a notice of change under Paragraph 2, Article 26 of the Law, the notice shall be submitted to the Minister of Economy, Trade, and Industry using Form 10.

(Notification of the manufactured quantities of the Class 2 Specified Chemical Substance, etc.)

Article 15. The following items are specified by the Ministry of Economy, Trade, and Industry Ordinance referred to in Paragraph 6, Article 26 of the Law:

- 1) The name of the Class 2 Specified Chemical Substance concerned or the name of the product using the Class 2 Specified Chemical Substance concerned
- 2) The quantities shipped in the previous year of the Class 2 Specified Chemical Substance concerned or the product using the Class 2 Specified Chemical Substance concerned
- 3) The name and address of the business premise that manufactured the Class 2 Specified Chemical Substance or the name of the country or region in which the Class 2 Specified Chemical Substance or the product using the Class 2 Specified Chemical Substance was manufactured, depending on whether the Class 2 Specified Chemical Substance concerned was manufactured or the Class 2 Specified Chemical Substance concerned or the product using the Class 2 Specified Chemical Substance concerned was imported, respectively.

2. The notification under Paragraph 6, Article 26 of the Law shall be submitted to the Minister of Economy, Trade, and Industry using Form 9 by June 30th of each year.

(Certificate of sampling)

Article 15-2. In the event that personnel of the Ministry of Economy, Trade, and Industry samples a chemical substance in accordance with the provisions of Paragraphs 1 through 3 of Article 33 of the Law, or that personnel of NITE samples a chemical substance in accordance with the provision of Paragraph 5 of the article, a certificate of sampling shall be issued to the business from which the chemical substance has sampled.

(Identification Card)

Article 16. An identification card that the Minister of Economy, Trade, and Industry

requires each Ministry of Economy, Trade, and Industry personnel to carry under Paragraph 4, Article 33 of the Law shall be in conformity with Form 13.

2. An identification card that NITE requires each of its personnel to carry under Paragraph 8, Article 33 of the Law shall be in conformity with Form 14.

(Hearing of opinions)

Article 17. The hearing of opinions under Paragraph 1, Article 37 of the Law shall take place at a public hearing of opinion presided by a chairman designated by the Minister of Economy, Trade, and Industry.

2. To conduct a public hearing of opinion, the Minister of Economy, Trade, and Industry shall publicly announce and notify the subject matter, the date and place of the public hearing of opinion, and a summary of the issue in question at least fifteen days before the date of the hearing.

3. Any interested party or agent thereof who wants to advance an opinion at the hearing must notify the Minister of Economy, Trade, and Industry of his or her intention at least ten days before the hearing by submitting a document that gives an outline of the opinion and expresses that he or she has an interest in the subject matter concerned.

4. The Minister of Economy, Trade, and Industry shall select the persons allowed to express their opinions at the hearing from among those who applied for participation in the hearing, in accordance with the provision of the preceding paragraph. They will be given notice to that effect at least three days before the date of the hearing.

5. The Minister of Economy, Trade, and Industry may request academic experts, staff members of the government organizations concerned, and other appropriate persons to attend the hearing as needed.

6. At the hearing, no person is allowed to express an opinion except the demurrer, the persons designated under Paragraph 4 above or their agents, and the persons who are requested to attend the hearing, in accordance with Paragraph 5 above.

7. At the beginning of the hearing, the demurrers or their agents shall be allowed to give an outline of, and reason for, their objection.

8. In the event that a demurrer or his or her agent is absent at the hearing, the chairman may substitute the reading of the filed written opposition for the allegation under Paragraph 7 above.

9. At the hearing, the chairman may silence or order off any person who speaks beyond the scope of the subject matter or disturbs or threatens the peace and order at the hearing.

10. The agent of any demurrer or any party concerned must submit to the chairman a

document that demonstrates his or her agency.

11. In the event that the date and/or place of the hearing is changed, the chairman must notify the persons designated under Paragraph 4 above and the persons requested to attend the hearing under Paragraph 5 above of the new date and/or place of the hearing.

Article 18. Deleted

Article 19. Deleted

(Procedural exception with an electronic information-processing system)

Article 20. If the notification of Paragraph 1 of Article 5, Paragraph 1 of Article 23, Paragraph 1 of Article 25-2, or Clause 1, 2 or 6 of Article 26 of the Law which is to be made under Paragraph 1, Article 3 of the Law on the Use of Information Communication Technology for Administrative Procedures, etc. (Law No.151 of 2002), it involves an electronic information-processing system (i.e., any electronic information-processing system connecting an electronic computer including input and output units used by the Minister of Economy, Trade, and Industry and an electronic computer including input and output units used by the applicant by means of telecommunication lines). In this case, it is necessary for the applicant to submit a document (Form 17) showing his or her name, Notification Identification Code, and other required data to the Minister of Economy, Trade, and Industry in advance.

2. Upon receiving the aforementioned document, the Minister of Economy, Trade, and Industry will issue a notification code to the person who submitted the document.
3. The person who made the notification described above shall notify the Minister of Economy, Trade, and Industry when he or she makes any change in the reported items or discontinues the use of the electronic information-processing system concerned by means of Form 18 or Form 19, respectively.

Supplementary provisions

This ministry ordinance shall be put into force on June 10, 1974.

Supplementary provisions (Ministry of Economy, Trade, and Industry Ordinance No.1 dated January 19, 2004)

This ministry ordinance shall be put into force on April 1, 2004.