

Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.

(Ordinance of the Ministry of International Trade and Industry No. 40 of June 7, 1974)

Final revision: Ordinance of the Ministry of Economy, Trade and Industry No. 14 of March 4, 2005

The Ministry of International Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. shall be enacted as follows, based on paragraphs (1) and (2) of Article 19 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973).

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 (Application for Permission to Manufacture Class I Specified Chemical Substances)

A person intending to apply for permission under paragraph (1) of Article 6 of the Act, pursuant to the provisions of paragraph (2) of said Article, shall submit a written application in Form 1, together with the following documents, to the Minister of Economy, Trade and Industry, through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business:

- (i) Drawings indicating the positions of manufacturing equipment (including positions relative to other equipment) and the areas surrounding the place of business
- (ii) A document explaining the employment situation and allocation of employees and their technical abilities
- (iii) A document showing an outline of the manufacturing method
- (iv) A document containing production plans and expected quantity of sales for each major customer
- (v) A document explaining the method of storage and method of transport
- (vi) Where the applicant is a juridical person, its articles of incorporation, articles of endowment, and a certificate of the registered matters
- (vii) A document explaining that the applicant (where the applicant is a juridical person, the juridical person itself and the officers who conduct its business) does not

fall under any items of Article 8 of the Act

(viii) A business report, balance sheet, and profit or loss statement, or other documents equivalent thereto, for the most recent business year

(ix) In addition to what are listed in the preceding item, a document explaining that the applicant possesses an adequate fiscal basis to ensure proper business operations

Article 3 (Application for Permission to Change Structure, etc. of Equipment for Manufacturing Class I Specified Chemical Substances)

A person seeking permission for changes under paragraph (1) of Article 10 of the Act shall submit a written application in Form 2, together with a description of the changes, to the Minister of Economy, Trade and Industry, through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business.

Article 4 (Notification of Changes Concerning the Business of Manufacturing Class I Specified Chemical Substances)

A person intending to notify changes under paragraph (2) of Article 10 of the Act shall submit a written notification in Form 3 to the Minister of Economy, Trade and Industry through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business.

Article 5 (Application for Permission to Import Class I Specified Chemical Substances)

A person intending to apply for permission under paragraph (1) of Article 11 of the Act, pursuant to the provisions of paragraph (2) of said Article, shall submit a written application in Form 4, together with the following documents, to the Minister of Economy, Trade and Industry:

(i) A document containing the name of the manufacturing establishment and country or area where the manufacturing establishment is located, the scheduled date of landing in Japan, the name of the port of importation, and the expected quantity of sales for each major customer

(ii) A document explaining the method of storage and method of transport

(iii) Where the applicant is a juridical person, its articles of incorporation, articles of endowment, and a certificate of the registered matters

(iv) A document explaining that the applicant (where the applicant is a juridical person, the juridical person itself and the officers who conduct its business) does not fall under any items of Article 8 of the Act

Article 6 (Notification of Succession)

A person intending to notify his/her succession to the status of permitted

manufacturer or permitted importer under paragraph (2) of Article 16 of the Act shall submit a written notification in Form 5, together with the following documents. A person succeeding to the status of a permitted manufacturer shall submit said written notification and documents to the Minister of Economy, Trade and Industry, through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business pertaining to said succession, and a person succeeding to the status of permitted importer shall submit said written notification and documents to the Minister of Economy, Trade and Industry.

(i) Regarding an heir who has succeeded to the status of permitted manufacturer or permitted importer under paragraph (1) of Article 16 of the Act, and who has been selected by unanimous consent where there are two or more heirs, a document in Form 6 and a copy of the family register

(ii) Regarding an heir other than the person set forth in the preceding item, who has succeeded to the status of permitted manufacturer or permitted importer under paragraph (1) of Article 16 of the Act, a document in Form 7 and a copy of the family register

(iii) Regarding a juridical person who has succeeded to the status of permitted manufacturer or permitted importer through a merger under paragraph (1) of Article 16 of the Act, a certificate of the registered matters of the juridical person

Article 7 (Books)

(1) The books set forth in paragraph (1) of Article 19 of the Act shall record the quantity of manufacture, quantity of stock, and quantity of sales for each customer, for each Class I Specified Chemical Substance and each place of business.

(2) The books set forth in the preceding paragraph shall be prepared for each place of business, and the recording of the matters prescribed in the preceding paragraph during the preceding month shall be completed before the end of each month.

(3) The books set forth in paragraph (1) shall be preserved for five years from the date of closing.

Article 7-2 (Preservation Using Electromagnetic Means)

(1) When the matters listed in paragraph (1) of the preceding Article are recorded by using electromagnetic means (which means electronic means, magnetic means or other means that are imperceptible by humans) and are preserved in a way that allows the immediate display of said records by using computers or other equipment when required, the said preservation of records may act as a substitute for the preservation of books containing said matters prescribed in paragraph (2) of Article 19 of the Act.

(2) In the case of preserving records pursuant to the provisions of the preceding paragraph, efforts shall be made to meet the standards specified by the Minister of

Economy, Trade and Industry.

Article 8 (Notification of Abolition)

A permitted manufacturer intending to notify the abolition of a business under paragraph (1) of Article 20 of the Act shall submit a written notification in Form 8 to the Minister of Economy, Trade and Industry through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business pertaining to said abolition.

Article 9 (Report)

A permitted manufacturer shall submit a report, within three months after the end of each business year, which contains the monthly quantity of manufacture, the monthly quantity of stock and the monthly quantity of sales for each customer during said business year of the Class I Specified Chemical Substance pertaining to the permission under paragraph (1) of Article 6 of the Act, to the Minister of Economy, Trade and Industry through the Director of a Regional Bureau of Economy, Trade and Industry who exercises jurisdiction over the location of the place of business.

Article 9-2 (Procedures Using Flexible Disks)

(1) Submission of the documents listed in the left-hand column of the following table may be made by submitting flexible disks which contain the matters to be recorded in said documents in the forms listed in the right-hand column of said table, together with a flexible disk submission sheet in Form 8-2.

A written application under Article 2 and documents to be attached which are listed in items (ii) through (ix) (excluding item (vi)) of said Article	Form 8-3
A written application under Article 3 and a description of the changes to be attached	Form 8-4
A written notification under Article 4	Form 8-5
A written application under Article 5 and documents to be attached which are listed in items (i), (ii), and (iv) of said Article	Form 8-6
A written notification under Article 6	Form 8-7
A written notification under Article 8	Form 8-8

(2) Submission of a report under Article 9 may be made by submitting flexible disks which contain the matters to be recorded in said report, together with a flexible disk submission sheet in Form 8-2.

Article 9-3 (Structure of Flexible Disks)

The flexible disks set forth in the preceding Article shall fall under any of the following items:

(i) A 90-millimeter flexible disk cartridge that complies with the Japanese Industrial Standards (hereinafter referred to as "JIS") X6221 based on the Industrial Standardization Act (Act No. 185 of 1949)

(ii) A 90-millimeter flexible disk cartridge that complies with JIS X6223

Article 9-4 (Recording Method of Flexible Disks)

(1) The recording onto a flexible disk under Article 9-2 shall be in accordance with the methods listed below:

(i) The track format shall use a method prescribed in JIS X6222 where the recording is made onto a flexible disk set forth in item (i) of the preceding Article, and a method prescribed in JIS X6225 where the recording is made onto a flexible disk set forth in item (ii) of said Article

(ii) The volume and file structure shall use a method prescribed in JIS X0605

(iii) Character encoding shall use a method prescribed in Annex 1 of JIS X0208

(2) The recording onto a flexible disk under Article 9-2 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 9-5 (Documents to be Attached to Flexible Disks)

The documents listed below shall be attached to a flexible disk set forth in Article 9-2 in the labeling area prescribed in JIS X6221 or X6223:

(i) The name of the submitter

(ii) The date of submission

Article 10 (Notification of the Quantity of Manufacture, etc. of Monitoring Chemical Substances)

(1) The matters specified by an Ordinance of the Ministry of Economy, Trade and Industry under paragraph (1) of Article 5-3, paragraph (1) of Article 23, and paragraph (1) of Article 25-2 of the Act shall be as follows:

(i) The name of the monitoring chemical substance

(ii) The quantity of the monitoring chemical substance shipped during the preceding fiscal year

(iii) In the case where a person has manufactured a monitoring chemical substance, the name and address of the place of business where the said monitoring chemical substance was manufactured; and in the case where a person has imported a monitoring chemical substance, the name of the country or region where the said monitoring chemical substance was manufactured

(2) The notification set forth in paragraph (1) of Article 5-3, paragraph (1) of Article

23, and paragraph (1) of Article 25-2 of the Act shall be made by submitting a written notification in Form 9 by June 30 each fiscal year to the Minister of Economy, Trade and Industry.

Article 11 (Exceptions to the Publication of Quantity of Manufacture, etc.)

(1) The quantity specified by an Ordinance of the Ministry of Economy, Trade and Industry under the proviso of paragraph (2) of Article 5-3 of the Act shall be 1 ton.

(2) The quantity specified by an Ordinance of the Ministry of Economy, Trade and Industry under the proviso of paragraph (2) of Article 23 and the proviso of paragraph (2) of Article 25 of the Act shall be 100 tons.

Article 12 (Persons Subject to Instructions to Conduct a Study of Hazardous Properties)

The persons specified by an Ordinance of the Ministry of Economy, Trade and Industry under paragraph (1) of Article 5-4, paragraph (1) of Article 24, and paragraph (1) of Article 25-3 of the Act shall be persons who have operated the business of manufacturing or importing the monitoring chemical substance pertaining to said study within three years prior to the day on which the instruction to conduct a study of hazardous properties is issued.

Article 13 (Notification of Planned Quantity of Manufacture, etc. of Class II Specified Chemical Substances)

(1) The matters specified by an Ordinance of the Ministry of Economy, Trade and Industry under paragraph (1) of Article 26 of the Act shall be as follows:

(i) The name of the Class II Specified Chemical Substance or the product using the Class II Specified Chemical Substance

(ii) The planned quantity of shipments of the Class II Specified Chemical Substance or the product using the Class II Specified Chemical Substance

(iii) In the case where a person intends to manufacture a Class II Specified Chemical Substance, the name and address of the place of business where said Class II Specified Chemical Substance is to be manufactured; and in the case where a person intends to import a Class II Specified Chemical Substance or a product using a Class II Specified Chemical Substance, the name of the country or region where said Class II Specified Chemical Substance or said product using the Class II Specified Chemical Substance is manufactured.

(2) The notification set forth in paragraph (1) of Article 26 of the Act shall be made by one month prior to the date of the manufacture or import of said Class II Specified Chemical Substance or the import of said product using the Class II Specified Chemical Substance (hereinafter referred to as the “manufacture, etc. of a Class II Specified Chemical Substance”) for said fiscal year by submitting a written notification in Form 10 to the Minister of Economy, Trade and Industry.

(3) With regard to the application of the provisions of the preceding paragraph regarding the notification set forth in paragraph (1) of Article 26 of the Act pertaining to the manufacture, etc. of a Class II Specified Chemical Substance for the fiscal year including the date of the designation of said Class II Specified Chemical Substance or said product using the Class II Specified Chemical Substance (hereinafter referred to as the "fiscal year of designation"), and the next fiscal year of the fiscal year of designation (limited to years when the date of designation is included in the last two months of said fiscal year of designation), the term "one month prior to the date of the manufacture or import of said Class II Specified Chemical Substance or the import of said product using the Class II Specified Chemical Substance (hereinafter referred to as the "manufacture, etc. of a Class II Specified Chemical Substance") for said fiscal year" shall be deemed to be replaced with "the date one month prior to the date of the manufacture or import of said Class II Specified Chemical Substance or the import of said product using the Class II Specified Chemical Substance (hereinafter referred to as the "manufacture, etc. of a Class II Specified Chemical Substance") for said fiscal year or the date one month after the date of the designation of said Class II Specified Chemical Substance or said product using the Class II Specified Chemical Substance, whichever comes later."

Article 14 (Notification of Changes to Planned Quantity of Manufacture, etc. of Class II Specified Chemical Substances)

A person intending to submit a notification of the changes set forth in paragraph (2) of Article 26 of the Act shall submit a written notification in Form 10 to the Minister of Economy, Trade and Industry.

Article 15 (Notification of the Quantity of Manufacture, etc. of Class II Specified Chemical Substances)

(1) The matters specified by an Ordinance of the Ministry of Economy, Trade and Industry under paragraph (6) of Article 26 of the Act shall be as follows:

(i) The name of the Class II Specified Chemical Substance or the product using the Class II Specified Chemical Substance

(ii) The quantity of the Class II Specified Chemical Substance or the product using the Class II Specified Chemical Substance shipped during the preceding fiscal year

(iii) In the case where a person has manufactured a Class II Specified Chemical Substance, the name and address of the place of business where said Class II Specified Chemical Substance was manufactured; and in the case where a person has imported a Class II Specified Chemical Substance or a product using a Class II Specified Chemical Substance, the name of the country or region where said Class II Specified Chemical Substance or said product using the Class II Specified Chemical Substance was manufactured.

(2) The notification set forth in paragraph (6) of Article 26 of the Act shall be made by submitting a written notification in Form 9 by June 30 each fiscal year to the Minister of Economy, Trade and Industry.

Article 15-2 (Warrant for Sampling Chemical Substances)

When an official of the Ministry of Economy, Trade and Industry samples a chemical substance pursuant to the provisions of paragraphs (1) through (3) of Article 33 of the Act, or an official of the NITE samples a chemical substance pursuant to the provisions of paragraph (5) of said Article, he/she shall deliver a warrant for sampling chemical substances in Form 11 to the person subject to the sampling.

Article 16 (Identification Card)

(1) The identification card set forth in paragraph (4) of Article 33 of the Act that the Minister of Economy, Trade and Industry has a ministry official carry shall be in accordance with Form 13.

(2) The identification card set forth in paragraph (8) of Article 33 of the Act that the NITE has its official carry shall be in accordance with Form 14.

Article 17 (Hearing of Opinions)

(1) The hearing of opinions set forth in paragraph (1) of Article 37 of the Act shall be conducted at a hearing session with a ministry official designated by the Minister of Economy, Trade and Industry presiding as chairperson.

(2) When the Minister of Economy, Trade and Industry intends to hold a hearing session, he/she shall notify the date and place of the hearing session and gist of the matter in question to the objector, and make a public announcement no later than 15 days prior to the date of said hearing session.

(3) A person intending to attend a hearing session and express his/her opinion as an interested person or the agent thereof, shall notify to that effect to the Minister of Economy, Trade and Industry no later than 10 days prior to the date of the hearing session, by submitting a document containing an outline of the opinion and a statement of fact indicating that he/she has an interest.

(4) The Minister of Economy, Trade and Industry shall designate, from among the persons who made the notification under the preceding paragraph, persons who may attend the hearing session and express opinions, and shall notify to that effect to the designated persons no later than three days prior to the date of the hearing session.

(5) When the Minister of Economy, Trade and Industry finds it necessary, he/she may request persons with relevant knowledge and experience, officials of relevant administrative organs, and other witnesses to attend the hearing session.

(6) No persons other than the objector, the persons designated under paragraph (4) or the agents thereof, and the persons requested to attend the hearing session under

the preceding paragraph, shall be allowed to express their opinions at the hearing session.

(7) At the beginning of a hearing session, the objector or the agent thereof shall be required to state the gist of and reason for the objection.

(8) When the objector or the agent thereof does not attend a hearing session, the chairperson may have the statement of objection read aloud, in lieu of the oral statement under the provisions of the preceding paragraph.

(9) When a person attending a hearing session expresses an opinion beyond the scope of the matter in question, disturbs the orderliness of the hearing session, or engages in improper conduct, the chairperson may prohibit said person from speaking or order said person to leave the room.

(10) An agent of an objector or interested person shall submit a document certifying his/her authority of representation to the chairperson.

(11) When the chairperson changes the date or place of a hearing session, he/she shall notify to that effect to persons designated under paragraph (4) and persons requested to attend the hearing session under paragraph (5).

Article 18

Deleted

Article 19

Deleted

Article 20 (Special Provisions on Procedures Using an Electronic Data Processing System)

(1) Notification under paragraph (1) of Article 5-3, paragraph (1) of Article 23, paragraph (1) of Article 25-2, or paragraph (1), paragraph (2), or paragraph (6) of Article 26 of the Act, which is to be made based on 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), shall be made by using an electronic data processing system (which means an electronic data processing system that connects a computer used by the Minister of Economy, Trade and Industry (including input-output devices; the same shall apply hereinafter) and a computer used by the notifier through an telecommunications line), which has been notified in advance to the Minister of Economy, Trade and Industry, by submitting a document in Form 17 containing the name of the notifier, the notifier confirmation code and other necessary matters.

(2) On receiving a document under the preceding paragraph, the Minister of Economy, Trade and Industry shall issue a notifier code to the person who submitted said document.

(3) For any changes to the matters notified, or for the termination of notified use of

the electronic data processing system, the person who made the notification under paragraph (1) shall notify to that effect to the Minister of Economy, Trade and Industry without delay, using Form 18 or Form 19, respectively.

Supplementary Provisions

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 87 of December 12, 1986)

This Ministerial Ordinance shall come into effect as from the date of the enforcement of the Act on the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 44 of 1986) (April 1, 1987).

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 7 of March 27, 1989)

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 17 of April 28, 1989)

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 66 of September 30, 1994)

This Ministerial Ordinance shall come into effect as from the date of the enforcement of the Administrative Procedure Act (October 1, 1994).

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 13 of March 14, 1997)

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 39 of March 27, 1997)

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 34 of March 30, 1998) (Extract)

Article 1 (Effective Date)

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

Supplementary Provisions

(Ordinance of the Ministry of International Trade and Industry No. 350 of

November 20, 2000)

This Ministerial Ordinance shall come into effect as from January 6, 2001; provided, however, that the provisions for revising Forms 1 through 8-2 (excluding the part for revising the term “Minister of International Trade and Industry” to “Minister of Economy, Trade and Industry”), the provisions for revising Forms 9 through 12 (excluding the part for revising the term “Minister of International Trade and Industry” to “Minister of Economy, Trade and Industry”), and the provisions for revising Forms 14 through 16 (excluding the part for revising the term “Minister of International Trade and Industry” to “Minister of Economy, Trade and Industry” and the part for revising the term “the Ministry of International Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” to “the Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.”) shall come into effect as from the day of promulgation.

Supplementary Provisions

(Ordinance of the Ministry of Economy, Trade and Industry No. 63 of March 29, 2002)

This Ministerial Ordinance shall come into effect as from April 1, 2002.

Supplementary Provisions

(Ordinance of the Ministry of Economy, Trade and Industry No. 43 of March 31, 2003)

This Ministerial Ordinance shall come into effect as from the day of promulgation; provided, however, that the provisions in Article 16 for revising Articles 18 and 19 of the Ministry of Economy, Trade and Industry-related Ordinance for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. and the provisions for revising Forms 14 through 19 shall come into effect as from July 31, 2003.

Supplementary Provisions

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

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

Supplementary Provisions

(Ordinance of the Ministry of Economy, Trade and Industry No. 14 of March 4, 2005)

This Ministerial Ordinance shall come into effect as from the date of the enforcement of the Real Estate Registration Act (March 7, 2005).

Form 1

Form 2

Form 3

Form 4

Form 5

Form 6

Form 7

Form 8

Form 8-2 (Related to Article 9-2)

Form 8-3 (Related to Article 9-2)

Form 8-4 (Related to Article 9-2)

Form 8-5 (Related to Article 9-2)

Form 8-6 (Related to Article 9-2)

Form 8-7 (Related to Article 9-2)

Form 8-8 (Related to Article 9-2)

Form 9 (Related to paragraph (2) of Article 10 and paragraph (2) of Article 15)

Form 10 (Related to paragraph (2) of Article 13 and Article 14)

Form 11 (Related to Article 15-2)

Form 12 Deleted

Form 13 (Related to paragraph (1) of Article 16)

Form 14 (Related to paragraph (2) of Article 16)

Form 15 Deleted

Form 16 Deleted

Form 17 (Article 21)

Form 18 (Article 20)

Form 19 (Article 20)