

**Law Concerning the Evaluation of Chemical Substances and  
Regulation of Their Manufacture, etc.**

**Law No. 117, October 16, 1973  
as last amended by  
Law No.49 May 28, 2003  
(PROVISIONAL TRANSLATION)**

Table of Contents

Chapter 1. General Rules (articles 1 and 2)

Chapter 2. Evaluation and Regulation Concerning New Chemical Substances (articles 3 through 5-2)

Chapter 3. Regulations Concerning Class I Specified Chemical Substances, etc.

Section 1. Measures Concerning Type I Monitoring Chemical Substances (articles 5-3 through 5-5)

Section 2. Regulations Concerning Class I Specified Chemical Substances (articles 6 through 22)

Chapter 4. Regulations Concerning Class II Specified Chemical Substances, etc.

Section 1. Measures Concerning Type II Monitoring Chemical Substances (articles 23 through 25)

Section 2. Measures Concerning Type III Monitoring Chemical Substance (articles 25-2 through 25-4)

Section 3. Regulations Concerning Class II Specified Chemical Substances (articles 26 through 28)

Chapter 5. Miscellaneous (articles 29 through 41)

Chapter 6. Penalties (articles 42 through 48)

Supplementary Provisions

## **Chapter 1. General Rules**

### **Purposes**

**Article 1** The purposes of this Law are to establish a system to evaluate the properties of new chemical substances and determine before their manufacture or import whether or not they are persistent, etc., and to implement the necessary regulations with respect to the manufacture, import, and use, etc., of chemical substances, with due consideration of their properties, etc., in order to prevent environmental pollution caused by chemical substances that are persistent and have the potential to be hazardous to human health or impair the life and/or growth of flora and fauna.

### **Definitions, etc.**

**Article 2** In this Law, the term “chemical substance” means any chemical compound obtained by causing chemical reactions to elements or compounds, and excludes any radioactive substance and the following substances:

- (1) any specified poison prescribed in paragraph 3, article 2 of the Poisonous and

Deleterious Substances Control Law (Law No. 303, 1950),

- (2) any stimulant prescribed in paragraph 1, article 2 of the Stimulant Drug Control Law (Law No. 252, 1951); and any raw material for stimulants prescribed in paragraph 5 of the same article, and
  - (3) any narcotic, as defined in clause 1, article 2 of the Narcotics and Psychotropics Control Law (Law No. 14, 1953).
2. In this Law, a “Class I Specified Chemical Substance” means any chemical substance that falls under clause (1) or clause (2) below and is specified by cabinet order as a “Class I Specified Chemical Substance”:
- (1) a chemical substance that is
    - (a) unlikely to undergo a chemical transformation through natural processes and is likely to accumulate in living organisms , and
    - (b) that either
      - (i) has the potential to be hazardous to human health if taken in continuously, or
      - (ii) has the potential to impair the life and/or growth of animals at the top of the food chain (animals that are associated with flora and fauna in the human living environment [flora and fauna, of which harmful effect on the life and growth results in the harmful effect on the human living environment; the same definition applies hereinafter] for which chemical substances in subclause (a) above are most likely to bioaccumulate through the food chain; the same definition applies hereinafter) if taken in continuously.
  - (2) a chemical substance where it is likely to undergo a chemical transformation through natural processes, that generates any chemical substance (including an element), falling under subclauses (a) and (b) above, by chemical transformation through natural processes.
3. In this Law, a “Class II Specified Chemical Substance” means any chemical substance that falls under clause (1) or clause (2) below, is thought to have the potential to cause damage to human health or to the life and/or growth of flora and fauna in the human living environment because a considerable amount of the chemical substance persists in the environment over an extensive area or it is reasonably likely that such a situation will arise in the near future in view of the conditions under which it is manufactured, imported, used, etc., and is specified by cabinet order as a “Class II Specified Chemical Substance”.
- (1) Any chemical substance that falls under subclause (a) or subclause (b) below:
    - (a) a chemical substance (excluding any that falls under clause (1) of the preceding paragraph) that is unlikely to undergo a chemical transformation through natural processes, and has the potential to be hazardous to human health if taken in continuously; or
    - (b) a chemical substance, where it is likely to undergo a chemical transformation through natural processes, generates any chemical substances (including an element), falling under

- subclause (a) of this paragraph, by the chemical transformation through natural processes.
- (2) Any chemical substance that falls under subclause (a) or subclause (b) below:
    - (a) a chemical substance (excluding any that falls under clause (1) of the preceding paragraph) that is unlikely to undergo a chemical transformation through natural processes, and that has the potential to impair the life and/or growth of flora and fauna in the human living environment if the flora and fauna continuously take in or are exposed to the said chemical substance; or
    - (b) a chemical substance where it is likely to undergo a chemical transformation through natural processes that generates any chemical substance (including an element), falling under subclause (a) of this paragraph, by the chemical transformation through natural processes.
  4. In this Law, a “Type I Monitoring Chemical Substance” means any chemical substance (excluding any new chemical substance) that falls under one of the clauses below and has been so designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment (hereinafter referred to collectively as “the Ministers”):
    - (1) a chemical substance that falls under subclause (a) of clause (1) of paragraph 2, and for which it is not known whether or not subclause (b) of the same clause applies; or
    - (2) a chemical substance, where it is likely to undergo a chemical transformation through natural processes, that generates any chemical substance (including an element), generated by the chemical transformation through natural processes, that falls under the preceding clause.
  5. In this Law, a “Type II Monitoring Chemical Substance” means any chemical substance suspected of falling under clause (1) of paragraph 3 (including any chemical substance that falls under the said clause but has not been designated as a Class II Specified Chemical Substance) and has been so designated by the Ministers.
  6. In this Law, a “Type III Monitoring Chemical Substance” means any chemical substance that falls under one of the clauses below and has been so designated by the Minister of Economy, Trade and Industry and the Minister of the Environment:
    - (1) any chemical substance that is unlikely to undergo a chemical transformation through natural processes, and has the potential to impair the life and/or growth of flora and fauna (excluding any chemical substance that falls under clause (1) of paragraph 2 and subclause (a) of clause (2) of paragraph 3 and has been designated as a Class II Specified Chemical Substance); or
    - (2) a chemical substance, where it is likely to undergo a chemical transformation through natural processes, any chemical substances (including an element), falling under the preceding clause by the chemical transformation through natural processes.
  7. In this Law, a “new chemical substance” is any chemical substance that does not fall under any of the following clauses:
    - (1) any chemical substance for which the Ministers have made a public announcement under the provisions of paragraph 4 of article 4 (including cases in which it is applied *mutatis mutandis* in paragraph 9 of article 4-2, and cases in which it is applied *mutatis mutandis* in paragraph 2

- of article 5-2);
- (2) any Class I Specified Chemical Substance;
  - (3) any Class II Specified Chemical Substance;
  - (4) any Type II Monitoring Chemical Substance (including any chemical substance for which designation has been cancelled under the provisions of clause (2) of article 25);
  - (5) any Type III Monitoring Chemical Substance; or
  - (6) any chemical substance (excluding one under preceding clauses) for which the Minister of International Trade and Industry has made a public announcement under the provisions of paragraph 4 of the article 2 of the Supplementary Provisions of this Law and that has been listed in the List of Existing Chemical Substances prescribed in paragraph 1 of the said article.
8. The Ministers shall make the designation in paragraph 5 based on the results of the tests prescribed in paragraph 7 of article 4 (including cases in which it is applied *mutatis mutandis* in paragraph 9 of article 4-2).
  9. When the Ministers designate any chemical substance as a Type I Monitoring Chemical Substance or Type II Monitoring Chemical Substance under the provisions of paragraph 4 or 5, they shall make a public announcement of its name without delay.
  10. When the Minister of Economy, Trade and Industry and the Minister of the Environment designate any chemical substance as a Type III Monitoring Chemical Substance under the provisions of paragraph 6, they shall make a public announcement of its name without delay.

## **Chapter 2. Evaluation and Regulation Concerning New Chemical Substances**

### **Notification of Manufacture, etc.**

**Article 3** A person who intends to manufacture or import a new chemical substance shall notify the Ministers, in advance, of particulars such as the name of the chemical substance and other matters specified by a ministerial ordinance issued jointly by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment (hereinafter referred to collectively as “joint ministerial ordinance”) in accordance with a joint ministerial ordinance. However, this provision shall not apply to cases where any of the following conditions apply:

- (1) where a person intends to import a new chemical substance from a person who has submitted a notification under paragraph 1 of article 5-2 and has received notice that the said new chemical substance falls under clause (5) of paragraph 1 of the following article under the provisions of paragraph 1 or 2 of the said article that is applied *mutatis mutandis* in paragraph 2 of article 5-2;
- (2) where the new substance is to be manufactured or imported for testing and research purposes;
- (3) where the new chemical substance is to be manufactured or imported as a reagent (defined specifically as any chemical substance used for the detection or quantification of a substance by a chemical process, or for experimental synthesis of a substance, or for measurements of

- the physical characteristics of a substance; this definition applies hereinafter);
- (4) where a confirmation of the Ministers has been received in accordance with a joint ministerial ordinance, indicating that in consideration of the intended method of handling the said new chemical substance, the said substance does not have the potential to cause environmental pollution, and the said substance will be manufactured or imported in accordance with the confirmation that has been received; or
  - (5) where the planned quantity of manufacture or planned quantity of import (for any person who intends to manufacture and import the said new chemical substance, the sum of the two; the same applies in paragraph 1 and clause (1) of paragraph 4 of article 4-2) in any one fiscal year<sup>#</sup> of the said new chemical substance is not more than the quantity specified by cabinet order; and where a confirmation of the Ministers has been issued in accordance with a joint ministerial ordinance, indicating that based on available information the said new chemical substance is not one that has the potential to cause environmental pollution and cause damage to human health or to the life and/or growth of flora and fauna in the human living environment; and where the quantity of the said new chemical substance that will be manufactured or imported during the relevant fiscal year is not more than the quantity relating to the confirmation.
2. In cases where the national sum of the planned quantity of manufacture and planned quantity of import relating to the confirmation under clause (5) of the preceding paragraph (including the planned quantity of manufacture and planned quantity of import relating to confirmation under the provisions of paragraph 4 of article 4-2) relating to any new chemical substance exceeds the quantity specified by the cabinet order of the said clause, the Ministers shall not issue the confirmation under the said clause.
  3. Where any of the following clauses applies, the Ministers shall cancel the confirmation issued under clause (4) of paragraph 1:
    - (1) where the person who received the confirmation under clause (4) of paragraph 1 did so through fraudulent means;
    - (2) where the person who received the confirmation under clause (4) of paragraph 1 is deemed not to be manufacturing or importing the new chemical substance in accordance with the conditions under which the said confirmation was issued; or
    - (3) in addition to cases under the clauses above, where it is deemed that the new chemical substance relating to the confirmation under clause (4) of paragraph 1 has the potential to cause environmental pollution.
  4. Where any of the following clauses applies, the Ministers shall cancel the confirmation issued under clause (5) of paragraph 1:
    - (1) where the person who received the confirmation under clause (5) of paragraph 1 did so through fraudulent means;

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<sup>#</sup> : Fiscal year in this law is the period from 1 April of one year until 31 March of the following year.

- (2) where the person who received the confirmation under clause (4) of paragraph 1 is deemed to be manufacturing or importing the new chemical substance relating to the confirmation in an amount that is more than the quantity relating to the confirmation; or
- (3) in addition to cases under the clauses above, where it is deemed that the new chemical substance relating to the confirmation under clause (5) of paragraph 1 has the potential to cause environmental pollution and cause damage to human health or to the life and/or growth of flora and fauna in the human living environment.

## **Evaluation**

**Article 4** Where the Ministers receive a notification under paragraph 1 of the preceding article, they shall make a judgement as to which of the following clauses the new chemical substance falls under:

- (1) a substance that falls under one of the clauses of paragraph 2 of article 2;
- (2) a substance is suspected to fall under clause (1) of paragraph 3 of article 2 (including a substance that does fall under the said clause; this also applies to clause (4)) and does not fall under either of the clauses of paragraph 6 of the said article;
- (3) a substance that is not suspected to fall under clause (1), paragraph 3 of article 2 and does fall under either of the clauses of paragraph 6 of the said article;
- (4) a substance that is suspected to fall under clause (1), paragraph 3 of article 2, and does fall under either of the clauses of paragraph 6 of the said article;
- (5) a substance that does not fall under either of the clauses of paragraph 2 of article 2 or either of the clauses of paragraph 6 of the said article, and is not suspected to fall under clause (1) of paragraph 3 of the said article; or
- (6) a substance for which it is unclear whether or not it falls under clauses (1) to (4) above.

The Ministers shall make this judgement within three months from the date of receipt of the notification, based on the available information on the composition, properties, etc., of the new chemical substance, and shall provide notice of the result thereof to the person who submitted the notification.

2. Where the Ministers make a judgement that the new chemical substance relating to the notification under paragraph 1 of the preceding article falls under clause (6) of the preceding paragraph, they shall promptly judge, based on the results of tests conducted on the new chemical substance, which one of clauses (1) through (5) of the said paragraph applies to the said substance, and shall provide notice of the result thereof to the person who submitted the notification.
3. Where the Ministers deem it necessary in order to make the judgement in the preceding paragraph, they may order the person who submitted the notification under paragraph 1 of the preceding article to submit documentation including the results of tests specified in paragraph 7 on the properties of the new chemical substance relating to the said notification, and other documentation that is specified by a joint ministerial ordinance.
4. Where the Ministers provide notice under the provisions of clause (5) of paragraph 1 that the said

new chemical substance for which the notification of paragraph 1 of the preceding article was given under the provisions of paragraph 1 or 2 of this article, they shall make a public announcement of the name of the said new chemical substance, in accordance with a joint ministerial ordinance.

5. Where the Ministers provide notice under the provisions of paragraph 1 or 2 that the new chemical substance relating to paragraph 1 of the preceding article, for which notification has been given, falls under clause (2) or clause (4) of paragraph 1, they shall make a designation of the said chemical substance without delay, under the provisions of paragraph 5 of article 2.
6. Where the Minister of Economy, Trade and Industry and the Minister of the Environment provide notice under the provisions of paragraph 1 or 2 that the new chemical substance relating to paragraph 1 of the preceding article, for which notification has been given, falls under clause (3) or (4) of paragraph 1, they shall make a designation of the said chemical substance without delay, under the provisions of paragraph 6 of article 2.
7. Items to be tested and other technical matters required for the judgement under paragraphs 1 and 2 of this article shall be specified by joint ministerial ordinance.
8. In laying down the joint ministerial ordinance under the preceding paragraph, efforts shall be made to fully consider international trends in the establishment of items to be tested relating to evaluation of the safety of chemical substances, as well as other trends in technical standards relating to the safety evaluation of chemical substances.

### **Special Cases, etc., When Planned Quantity of Manufacture etc., Is Not More Than a Certain Defined Quantity**

Article 4-2 A person who intends to provide a notification under paragraph 1 of article 3 and for whom the planned quantity of manufacture or planned quantity of import of the new chemical substance relating to the notification during any one fiscal year will be not more than the quantity specified by the cabinet order under clause (1) of paragraph 4, when making the notification may make a request to the Ministers in accordance with a joint ministerial ordinance, in cases where the said new chemical substance falls under clause (6) of paragraph 1 of the preceding article, that they make a judgement as to whether or not the said new chemical substance falls under any of the following clauses.

- (1) Any chemical substance that falls under subclauses (a) and (b) below:
    - (a) a new chemical substance that is unlikely to undergo a chemical transformation through natural processes and is not likely to accumulate in living organisms; and
    - (b) a chemical substance for which it is unclear whether or not it falls under clauses (2) to (4) of paragraph 1 of the preceding article.
  - (2) a new chemical substance, where it is likely to undergo a chemical transformation through natural processes, that generates any chemical substance (including an element) falling under the preceding clause, by the chemical transformation through natural processes.
2. Where the Ministers receive a request under the preceding paragraph, in cases where they deem

that the said new chemical substance falls under clause (6) of the said paragraph at the time of making the judgement under clause (1) of the preceding article, notwithstanding the provisions of the said clause, the Ministers shall make a judgement as to which of the following clauses the said new chemical substance falls under, instead of making the judgement of matters that fall under clause (6) of paragraph 1 of the preceding article:

- (1) a substance that falls under one of the clauses of the preceding paragraph;
- (2) a substance that does not fall under one of the clauses of the preceding paragraph; or
- (3) a substance for which it is unclear whether or not it falls under one of the clauses of the preceding paragraph.

The Ministers shall make this judgement within three months from the date of receipt of the notification under clause (1) of article 3, based on the available information on the composition and properties, etc., of the new chemical substance in the said request, and shall provide notice of the result thereof to the person who submitted the notification. In such a case, the provisions under paragraph 2 of the said article do not apply.

3. Where the Ministers make a judgement that the new chemical substance for which the request has been made relating to paragraph 1 falls under clause (3) of the preceding paragraph, they shall promptly judge, based on the results of tests conducted on the said new chemical substance, which one of clauses (1) or (2) of the said paragraph the said substance falls under, and shall provide notice of the result thereof to the person who submitted the notification.
4. A person who has received notice that the new chemical substance relating to the request made under the provisions of paragraph 2 or the preceding paragraph falls under clause (1) of paragraph 2, may in advance of each fiscal year make a request to the Ministers in accordance with a joint ministerial ordinance that they issue a confirmation that the manufacture or import relating to the said notice falls under the following clauses:
  - (1) the planned quantity of manufacture or planned quantity of import of the said new chemical substance during the fiscal year relating to the request is not more than the quantity specified by cabinet order; or
  - (2) based on available information, the said new chemical substance is not one that has the potential to cause environmental pollution and cause damage to human health or to the life and/or growth of flora and fauna in the human living environment.
5. In cases where the national sum under the preceding paragraph of the planned quantity of manufacture and planned quantity of import (including the planned quantity of manufacture and planned quantity of import relating to the confirmation under the provisions of clause (5), paragraph 1 of article 3 for a new chemical substance relating to the confirmation exceeds the quantity specified by the cabinet order of clause (1) of the preceding paragraph, the Ministers shall not give the confirmation under that clause.
6. Where any of the following clauses applies, the Ministers shall cancel the confirmation issued under paragraph 4:
  - (1) where the person who received the confirmation under paragraph 4 did so through fraudulent



means;

- (2) where the person who received the confirmation under paragraph 4 is deemed to be manufacturing or importing more than the quantity of the new chemical substance relating to the confirmation; or
  - (3) in addition to cases under the clauses above, where it is deemed that the new chemical substance relating to the confirmation under paragraph 4 has the potential to cause environmental pollution and cause damage to human health or to the life and/or growth of flora and fauna in the human living environment.
7. A person who has received notice that the new chemical substance referred to in the request made under the provisions of paragraph 2 or paragraph 3 falls under clause (1) of paragraph 2, may when that person deems it necessary make a request to the Ministers as specified by a joint ministerial ordinance that the judgement in the following paragraph be made relating to the new chemical substance relating to the said notice.
  8. Where the Ministers have provided notice under paragraph 2 or paragraph 3 that the new chemical substance relating to the request under paragraph 1 falls under clause (2) of paragraph 2, where they have not confirmed that the manufacture or import of the new chemical substance relating to the request under paragraph 4 falls under the clauses of the said paragraph, where they have cancelled the confirmation under the said paragraph, or where the request in the preceding paragraph has been made, the Ministers shall promptly make a judgement, based on the results of tests conducted on the new chemical substance, which one of clauses (1) to (5) of paragraph 1 of article 4 the said new chemical substance falls under, and shall provide notice of the result thereof to the person who made the request under paragraph 1 relating to the new chemical substance.
  9. The provisions under paragraph 7 and paragraph 8 of the preceding article shall apply *mutatis mutandis* to the judgement under paragraph 2; the provisions under paragraph 3, paragraph 7 and paragraph 8 of the same article shall apply *mutatis mutandis* to the judgement in paragraph 3; and the provisions under paragraph 3 to paragraph 8 of the same article shall apply *mutatis mutandis* to the judgement under the preceding paragraph. In these cases, the phrase “paragraph 1 or paragraph 2” in the provisions under paragraph 4 to paragraph 6 of the same article shall read “paragraph 8 of article 4-2.”

### **Restrictions on Manufacture, etc.**

**Article 5** A person who has submitted a notification under paragraph 1 of article 3 shall not manufacture or import the new chemical substance relating to the notification under the provisions of paragraph 1 or 2 of article 4 or paragraph 8 of the preceding article, prior to receipt of the notice prescribed in the provisions of paragraphs 4 through 6 of article 4 (including cases in which paragraph 9 of the preceding article is applied *mutatis mutandis*) relating to the said new chemical substance. However, this provision shall not apply to cases in which any of the following conditions apply:

- (1) where the manufacture or import of the new chemical substance relating to the said

- notification falls under one of the clauses of paragraph 1 of article 3; or
- (2) in cases where confirmation has been received under the provisions of paragraph 4 of the preceding article regarding the manufacture or import of the new chemical substance relating to the said notification(excluding the case where the conformation has been cancelled under the provisions of paragraph 6 of the said article) , where the quantity of manufacture or import of the said new chemical substance will be not more than the quantity relating to the said confirmation.

### **Evaluation, etc., of a New Chemical Substance Associated with a Manufacturer, etc., in a Foreign Country**

**Article 5-2** A person who intends to manufacture in a foreign country a new chemical substance to be exported to Japan or who intends to export a new chemical substance to Japan may, in advance, in accordance with a joint ministerial ordinance, notify the Ministers of particulars such as the name of the said substance and other matters specified by joint ministerial ordinance.

2. The provisions of article 4 shall apply *mutatis mutandis* to the notification prescribed in the preceding paragraph. In this case, “within three months” in paragraph 1 of the same article shall read “within four months.”

## **Chapter 3. Regulations Concerning Class I Specified Chemical Substances, etc.**

### **Section 1. Measures Concerning Type I Monitoring Chemical Substance**

#### **Reports on Quantity of Manufacture**

**Article 5-3** A person who has manufactured or imported any Type I Monitoring Chemical Substance shall each fiscal year in accordance with a ministerial ordinance issued by the Ministry of Economy, Trade and Industry, hereinafter referred to as “METI ordinance”, notify the Minister of Economy, Trade and Industry of the quantity of each Type I Monitoring Chemical Substance manufactured or imported in the previous fiscal year, as well as other matters specified by a METI ordinance. However, this provision shall not apply to the manufacture or import of a Type I Monitoring Chemical Substance intended for testing and research purposes.

2. The Minister of Economy, Trade and Industry shall publish each fiscal year the national sum of the quantities of each Type I Monitoring Chemical Substance manufactured and imported during the previous fiscal year, relating to the notification in the preceding paragraph. However, this provision shall not apply where the national sum of the quantities of any one Type I Monitoring Chemical Substance is less than the quantity specified by a METI ordinance.

#### **Study of Hazardous Properties of Type I Monitoring Chemical Substances**

**Article 5-4** Where it is deemed necessary to make a judgement as to whether or not a Type I Monitoring Chemical Substance falls under any of the clauses of paragraph 2 of article 2 if

sufficient reason exists to suspect that the said Type I Monitoring Chemical Substance falls under one of the said clauses, because the said Type I Monitoring Chemical Substance has the potential to cause environmental pollution in cases where the said Type I Monitoring Chemical Substance falls under one of the said clauses, and in view of the conditions under which it is manufactured, imported, or used, the Ministers may, in accordance with a joint ministerial ordinance, instruct persons engaged in the manufacture or import of the said chemical substance (including persons who were previously engaged in the said manufacture or import and specified by a METI ordinance) to conduct a study of the hazardous properties specified by joint ministerial ordinance (i.e., here and in paragraph 3 below, a study of the effects of the said chemical substance on human health or on the life and/or growth of animals at the top of the food chain if taken in continuously) and may instruct them to submit a report concerning the results thereof.

2. Upon receipt of the report under the preceding paragraph, the Ministers shall make a judgement as to whether or not the said Type I Monitoring Chemical Substance falls under any one of the clauses of paragraph 2 of article 2 and provide notice concerning the result thereof to the person who submitted the report.
3. The Minister of Economy, Trade and Industry may establish standards in terms of methods and proportions for the sharing of expenses required for the said study of the hazardous properties relating to the instruction under the provisions of paragraph 1, where the minister deems it especially necessary to do so in order to ensure that the expenses for the said study are shared fairly by the persons involved.

### **Cancellation of Designation as a Type I Monitoring Chemical Substance**

**Article 5-5** Where a Type I Monitoring Chemical Substance falls under either of the following clauses, the Ministers shall cancel its designation, and shall publish a notice of the cancellation of the designation without delay:

- (1) where the said substance has been designated as a Class I Specified Chemical Substance; or
- (2) where the said substance has been deemed not to fall under any of the clauses of paragraph 2 of article 2, based on knowledge obtained from the reports under paragraph 1 of the preceding article and other available knowledge.

## **Section 2. Regulations Concerning Class I Specified Chemical Substances**

### **Authorization to Manufacture**

**Article 6** A person who intends to engage in the manufacture of a Class I Specified Chemical Substance must obtain the authorization of the Minister of Economy, Trade and Industry for each Class I Specified Chemical Substance and for each manufacturing premise.

2. A person seeking the authorization described in the preceding paragraph must submit an application to the Minister of Economy, Trade and Industry, providing
  - (1) name and address, and in the case of a corporation the name of the head of the

- corporation,
  - (2) location of the manufacturing premise,
  - (3) name of the Class I Specified Chemical Substance, and
  - (4) structure and production capacity of the manufacturing equipment.
3. Where the Minister of Economy, Trade and Industry has granted the authorization prescribed in paragraph 1, he shall provide notice to that effect without delay to the Minister of the Environment.

**Article 7** Class I Specified Chemical Substances shall not be manufactured by any person other than those who have obtained authorization under paragraph 1 of the preceding article. However, this provision shall not apply to cases in which Class I Specified Chemical Substances are to be manufactured for testing and research purposes.

#### **Disqualification Clause**

**Article 8** The following persons shall not be given the authorization described in paragraph 1, article 6:

- (1) a person who has violated this Law or any orders issued under this Law and who has been subject to a fine or more serious punishment and for whom a period of at least two years has not yet elapsed after the date on which the execution of the punishment was completed or suspended,
- (2) a person whose authorization has been canceled under the provisions of article 21 and for whom a period of at least two years has not yet elapsed after the date of this cancellation, or
- (3) a person who is an adult ward of the court, or
- (4) a corporation having a director or directors to whom any of the preceding three clauses apply.

#### **Standards for Authorization**

**Article 9** The Minister of Economy, Trade and Industry shall not grant authorization under paragraph 1, article 6, unless he deems the application involved to have satisfied each of the following conditions:

- (1) authorization, if granted, would not result in excessive capacity to manufacture the said Class I Specified Chemical Substance, as compared to the demand for the said Class I Specified Chemical Substance;
- (2) the manufacturing equipment shall conform to the technical standards specified by a joint ministerial ordinance; and
- (3) the applicant shall have an adequate fiscal basis and technical capacity to ensure proper business operations.

### **Authorization for Changes, etc.**

**Article 10** A person who has obtained authorization under paragraph 1, article 6 (hereinafter referred to as an “authorized manufacturer”) shall obtain authorization from the Ministry of Economy, Trade and Industry if the person intends to make changes in the matters specified in clause (4), paragraph 2 of the same article. However, this provision shall not apply to minor changes specified by a METI ordinance.

2. Where an authorized manufacturer has made changes in the matters described in clause (1) or (2), paragraph 2, article 6, or minor changes specified by the METI ordinance referred to in the preceding paragraph, the authorized manufacturer shall submit a notification without delay stating the changes to the Minister of Economy, Trade and Industry.

3. The provisions of the preceding article shall apply *mutatis mutandis* to the authorization under paragraph 1.

4. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to authorization under paragraph 1 and notification under paragraph 2.

### **Authorization to Import**

**Article 11** A person who intends to import a Class I Specified Chemical Substance shall obtain the authorization of the Minister of Economy, Trade and Industry. However, this provision shall not apply to cases in which Class I Specified Chemical Substances are to be imported for testing and research purposes.

2. A person seeking authorization as described in the preceding paragraph shall submit an application to the Minister of Economy, Trade and Industry, providing

(1) name and address, and in the case of a corporation the name of the head of the corporation,

(2) name of the Class I Specified Chemical Substance, and

(3) quantity to be imported.

3. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to the authorization under paragraph 1.

### **Standards for Authorization, etc.**

**Article 12** Where the Minister of Economy, Trade and Industry receives an application for the authorization under paragraph 1 of the preceding article, the minister shall not grant authorization unless the minister deems that the import of the Class I Specified Chemical Substances is necessary to meet the demand for the Class I Specified Chemical Substance.

2. The provisions of article 8 shall apply *mutatis mutandis* to authorization prescribed in paragraph 1 of the preceding article.

### **Restrictions on the Import of Products**

**Article 13** No person shall be allowed to import any product that is specified by cabinet order and in

which a Class I Specified Chemical Substance is used (hereinafter a “product using a Class I Specified Chemical Substance”).

2. The cabinet order under the preceding paragraph shall be established with consideration of matters relating to the conditions of use, etc., of the said Class I Specified Chemical Substance in foreign countries, for each Class I Specified Chemical substance.

### **Restrictions on Use**

**Article 14** No person shall be allowed to use a Class I Specified Chemical Substance for any uses other than those that meet the following conditions and are specified by cabinet order, for each Class I Specified Chemical Substance:

- (1) substitution by any other substance for the said use is difficult, and
- (2) the said use is not related to the manufacture or processing of products intended mainly for daily use by general consumers, and even if the specific Class I Specified Chemical Substance were to be applied to the said use, environmental pollution is not likely to occur by the said Class I Specified Chemical Substance.

However, this provision shall not apply to cases in which a Class I Specified Chemical Substance is to be used for testing and research purposes.

### **Notice of Use**

**Article 15** A person who intends to use a Class I Specified Chemical Substance commercially shall provide notice to the competent minister of such intention, in advance, providing for each business premise

- (1) name and address, and in the case of a corporation the name of the head of the corporation,
- (2) address of the business premise, and
- (3) name and use of the Class I Specified Chemical Substance.

However, this provision shall not apply to cases in which a Class I Specified Chemical Substance is to be used for testing and research purposes.

2. Where a person who has submitted a notice under the preceding paragraph (hereinafter referred to as a “user who has provided notice”) subsequently makes any changes in any of the clauses in the preceding paragraph, the person shall notify the competent minister of such changes without delay.

3. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to the notice under the preceding two paragraphs.

### **Succession**

**Article 16** Where an authorized manufacturer, a person who has obtained authorization under paragraph 1, article 11 (hereinafter referred to as an “authorized importer”), or a user who has

provided notice, has become subject to a succession or merger of business, the successor (where there are two or more successors, the successor who has been selected by unanimous agreement as the successor to continue the business), the corporation remaining in existence after the merger, or the corporation established by the merger shall succeed to the status of the authorized manufacturer, the authorized importer, or the user who has provided notice.

2. A person who has succeeded to the status of authorized manufacturer, authorized importer, or user who has provided notice under the provisions of the preceding paragraph shall provide notification of this fact without delay, together with documents attesting to this fact. A person who has succeeded to the status of authorized manufacturer or authorized importer shall provide the said notification to the Minister of Economy, Trade and Industry. A person who has succeeded to the status of a user who has provided notice shall provide the notification of succession to the competent minister.

3. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to the notification under the preceding paragraph. In this case, “the Minister of Economy, Trade and Industry” described in paragraph 3 of the same article shall read “the Minister of Economy, Trade and Industry, or the competent minister.”

### **Obligation of Conforming to Standards**

**Article 17** An authorized manufacturer shall maintain its manufacturing equipment in such a manner as to conform to the technical standards specified by the Joint ministerial ordinance under clause (2), article 9.

2. Where a user who has provided notice uses Class I Specified Chemical Substances, he shall follow the technical standards specified by a ministerial ordinance of the competent ministry.

### **Orders to Improve**

**Article 18** Where the Minister of Economy, Trade and Industry deems that the manufacturing equipment of an authorized manufacturer does not conform to the technical standards specified by the Joint ministerial ordinance under clause (2), article 9, the minister may order the said authorized manufacturer to repair or remodel the manufacturing equipment, or to take other necessary measures.

2. Where the competent minister deems that a user who has provided notice does not use a Class I Specified Chemical Substance in accordance with the technical standards specified by the ministerial ordinance of the competent ministry under paragraph 2 of the preceding article, the minister may order the said user who has provided notice to take measures necessary to improve the manner of using the Class I Specified Chemical Substance.

### **Records**

**Article 19** An authorized manufacturer shall keep records and enter in them the items specified by a METI ordinance with respect to the manufacture of the Class I Specified Chemical Substance.

2. The records specified in the preceding paragraph shall be maintained in accordance with a METI ordinance.

3. The provisions of the preceding two paragraphs shall apply *mutatis mutandis* to a user who has provided notice. In this case, the term “a METI ordinance” shall read “a ministerial ordinance of the competent ministry.”

### **Notification of Discontinuance**

**Article 20** Where an authorized manufacturer or a user who has provided notice has discontinued business operations, that person shall provide notification of this fact without delay to the Minister of Economy, Trade and Industry in the case of an authorized manufacturer, and to the competent minister in the case of a user who has provided notice.

2. Where an authorized manufacturer has discontinued his business, the authorization to manufacture shall become invalid.

3. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to the notification under paragraph 1. In this case, “the Minister of Economy, Trade and Industry” as described in paragraph 3 of the same article shall read “the Minister of Economy, Trade and Industry or the competent minister.”

### **Cancellation of Authorization, etc.**

**Article 21** The Minister of Economy, Trade and Industry may cancel the authorization or order the suspension of the authorized business operations for a specified period of time where an authorized manufacturer

- (1) is in a condition to which clause (1), (3) or (4) of article 8 applies,
- (2) has made any change in matters for which an authorization is required under the provisions of paragraph 1, article 10 without such an authorization,
- (3) has violated the order under the provisions of paragraph 1, article 18, or
- (4) has violated the conditions under paragraph 1, article 31.

2. Where an authorized importer falls under clause (1), (3) or (4) of article 8 which applies *mutatis mutandis* in paragraph 2, article 12, the Minister of Economy, Trade and Industry may cancel the authorization, but only before the Class I Specified Chemical Substance involved is imported.

3. The provisions of paragraph 3, article 6 shall apply *mutatis mutandis* to cancellation of authorization under the preceding two paragraphs or the order to suspend business under paragraph 1.

### **Orders Requiring Measures to be Taken in Connection with the Designation of Class I Specified Chemical Substances**

**Article 22** Where any chemical substance has been designated as a Class I Specified Chemical Substance and a competent minister deems that measures are particularly necessary in order to



prevent the spread of environmental pollution by the said chemical substance, the said minister may, to the extent necessary, order persons who at the time the said designation was made were engaged in the manufacture or import of the said chemical substance, or of a product in which the said chemical substance is used, to make efforts to recover the said chemical substance or the said product, and to take other measures necessary to prevent the spread of environmental pollution by the said chemical substance.

2. Where a product has been designated as a product using a Class I Specified Chemical Substance and a competent minister deems that measures are particularly necessary in order to prevent the spread of environmental pollution by the said substance being used in the said product, the said minister may, to the extent necessary, order persons who at the time the said designation was made were engaged in the import of the said product to make efforts to recover the said product involved in the said import, and to take other measures necessary to prevent the spread of environmental pollution by the Class I Specified Chemical Substance being used in the said product.
3. Where a competent minister, for each case listed in the clauses below, deems that measures are particularly necessary in order to prevent the spread of environmental pollution by the Class I Specified Chemical Substance, the said minister may, to the extent necessary, order the persons specified by the clauses below to make efforts to recover the Class I Specified Chemical Substance involved in the said manufacture, or import or use, or the product using a Class I Specified Chemical Substance involved in the said import, and to take other measures necessary to prevent the spread of environmental pollution by the Class I Specified Chemical Substance:
  - (1) where a Class I Specified Chemical Substance has been manufactured in violation of the provisions of article 7 — the person who manufactured the said Class I Specified Chemical Substance;
  - (2) where a Class I Specified Chemical Substance has been imported in violation of the provisions of paragraph 1 of article 11 — the person who imported the said Class I Specified Chemical Substance;
  - (3) where a product using a Class I Specified Chemical Substance has been imported in violation of the provisions of paragraph 1 of article 13 — the person who imported the said product using a Class I Specified Chemical Substance; and
  - (4) where a Class I Specified Chemical Substance has been used in violation of the provisions of article 14 — the person who used the said Class I Specified Chemical Substance.

#### **Chapter 4. Regulations Concerning Class II Specified Chemical Substances, etc.**

##### **Section 1. Measures Concerning Type II Monitoring Chemical Substances**

###### **Reports on Quantity of Manufacture**

**Article 23** A person who has manufactured or imported a Type II Monitoring Chemical Substance shall each fiscal year, in accordance with a METI ordinance, notify the Minister of Economy,

Trade and Industry of the quantity of each Type II Monitoring Chemical Substance manufactured or imported in the previous fiscal year, as well as other matters specified by a METI ordinance. However, this provision shall not apply to the manufacture or import of a Type II Monitoring Chemical Substance intended for testing and research purposes.

2. The Minister of Economy, Trade and Industry shall publish each fiscal year the national sum of the quantities of each Type II Monitoring Chemical Substance manufactured and imported during the previous fiscal year, relating to the notification in the preceding paragraph. However, this provision shall not apply where the national sum of the quantities of any one Type II Monitoring Chemical Substance is less than the quantity specified by a METI ordinance.

### **Study of Hazardous Properties of Type II Monitoring Chemical Substances**

**Article 24** Where it is deemed necessary to make a judgement as to whether or not a Type II Monitoring Chemical Substance falls under clause (1) of paragraph 3 of article 2, because the said Type II Monitoring Chemical Substance has the potential to cause environmental pollution and cause damage to human health in cases where the said Type II Monitoring Chemical Substance falls under the said clause, in view of the test results under paragraph 8 of the said article or knowledge already available with respect to the said Type II Monitoring Chemical Substance and the conditions under which it is manufactured, imported, or used, the Ministers may, in accordance with a joint ministerial ordinance, instruct persons engaged in the manufacture or import of the said chemical substance (including persons who were previously engaged in the said manufacture or import and specified by a METI ordinance) to conduct a study of the hazardous properties specified by joint ministerial ordinance (i.e., here and in paragraph 3 below, a study of the effects of the said chemical substance on human health if taken in continuously) and may instruct them to submit a report concerning the results thereof.

2. Upon receipt of the report under the preceding paragraph, the Ministers shall make a judgement as to whether or not the said Type II Monitoring Chemical Substance falls under clause (1) of paragraph 3 of article 2 and provide notice concerning the result thereof to the person who submitted the report.
3. The Minister of Economy, Trade and Industry may establish standards in terms of methods and proportions for the sharing of expenses required for the said study of the hazardous properties relating to the instruction under paragraph 1, where the minister deems it especially necessary to do so in order to ensure that the expenses for the said study are shared fairly by the persons involved.

### **Cancellation of Designation as a Type II Monitoring Chemical Substance**

**Article 25** Where a Type II Monitoring Chemical Substance falls under either of the following clauses, the Ministers shall cancel its designation as and shall publish a notice of the cancellation of the designation without delay:

- (1) where the said substance has been designated as a Class II Specified Chemical Substance because it falls under clause (1) of paragraph 3 of article 2 (including where the said Type II

- Monitoring Chemical Substance is deemed to fall under clause (1) of the said paragraph, in cases where the said Type II Monitoring Chemical Substance is designated as a Class II Specified Chemical Substance because it falls under clause (2) of the said paragraph); or
- (2) where the said substance has been deemed not to fall under clause (1) of paragraph 3 of article 2, based on knowledge obtained from the reports under paragraph 1 of the preceding article and other available knowledge.

## **Section 2      Measures Concerning Type III Monitoring Chemical Substances**

### **Reports on Quantity of Manufacture, etc.**

**Article 25-2**      A person who has manufactured or imported a Type III Monitoring Chemical Substance (excluding a substance for which the Minister of Economy, Trade and Industry and the Minister of the Environment have made a public announcement under the provisions of paragraph 2 of article 25-4; the same applies hereinafter in this and the following article) shall each fiscal year in accordance with a METI ordinance, notify the Minister of Economy, Trade and Industry of the quantity of each Type III Monitoring Chemical Substance manufactured or imported in the previous fiscal year, as well as other matters specified by a METI ordinance. However, this provision shall not apply to the manufacture or import of Type III Monitoring Chemical Substance intended for testing and research purposes.

2. The Minister of Economy, Trade and Industry shall publish each fiscal year the national sum of the quantities of each Type III Monitoring Chemical Substance manufactured and imported during the previous fiscal year, relating to the notification in the preceding paragraph. However, this provision shall not apply where the national sum of the quantities of any one Type III Monitoring Chemical Substance is less than the quantity specified by a METI ordinance.

### **Study of Hazardous Properties of Type III Monitoring Chemical Substances**

**Article 25-3**      Where it is deemed necessary to make a judgement as to whether a Type III Monitoring Chemical Substance falls under clause (2) of paragraph 3 of article 2, because the said Type III Monitoring Chemical Substance has the potential to cause environmental pollution and cause damage to the life and/or growth of flora and fauna in the human living environment in cases where the said Type III Monitoring Chemical Substance falls under the said clause, in view of the test results under paragraph 7 of article 4 (including cases in which the said clause applies *mutatis mutandis* to paragraph 9 of article 4-2) or knowledge already available with respect to the said Type III Monitoring Chemical Substance and the conditions under which it is manufactured, imported, or used, the Minister of Economy, Trade and Industry and Minister of the Environment may, in accordance with a joint ordinance of the Ministry of Economy, Trade and Industry and Ministry of the Environment, instruct persons engaged in the manufacture or import of the said Type III Monitoring Chemical Substance (including persons who were previously engaged in the said manufacture or import and specified by a METI ordinance) to conduct a study of the

hazardous properties specified by joint ministerial ordinance (i.e., here and in paragraph 3 below, a study of the effects of the said chemical substance on the life and/or growth of flora and fauna in the human living environment if they continuously take it in or are exposed to it) and may instruct them to submit a report concerning the results thereof.

2. Upon receipt of the report under the preceding paragraph, the Minister of Economy, Trade and Industry and Minister of the Environment shall make a judgement as to whether or not the said Type III Monitoring Chemical Substance falls under clause (2) of paragraph 3 of article 2 and provide notice concerning the result thereof to the person who submitted the report.
3. The Minister of Economy, Trade and Industry may establish standards in terms of methods and proportions for the sharing of expenses required for the said study of the hazardous properties relating to the instruction under paragraph 1, where the minister deems it especially necessary to do so in order to ensure that the expenses for the said study are shared fairly by the persons involved.

### **Cancellation of Designation as a Type III Monitoring Chemical Substance**

**Article 25-4** Where the Minister of Economy, Trade and Industry and the Minister of the Environment have designated a Type III Monitoring Chemical Substance as a Class II Specified Chemical Substance because it falls under clause (2) of paragraph 3 of article 2 (including where the said Type III Monitoring Chemical Substance is deemed to fall under clause (2) of the said paragraph, in cases where the said Type III Monitoring Chemical Substance is designated as a Class II Specified Chemical Substance because it falls under clause (1) of the said paragraph), they shall cancel its designation as a Type III Monitoring Chemical Substance and shall publish a notice of the cancellation of the designation without delay.

2. Where the Minister of Economy, Trade and Industry and the Minister of the Environment have deemed that the said Type III Monitoring Chemical Substance does not fall under clause (2) of paragraph 3 of article 2, based on knowledge obtained from the reports under paragraph 1 of the preceding article and other available knowledge, they shall make a public announcement of the name of the said Type III Monitoring Chemical Substance without delay.

### **Section 3. Regulations Concerning Class II Specified Chemical Substances**

#### **Notification of Planned Quantity of Manufacture, etc.**

**Article 26** A person who manufactures or imports a Class II Specified Chemical Substance, or a person who imports a product that is specified by cabinet order and in which a Class II Specified Chemical Substance is used (hereinafter referred to as a “product using a Class II Specified Chemical Substance”) shall, for each Class II Specified Chemical Substance or each product using a Class II Specified Chemical Substance, in accordance with a METI ordinance, notify the Minister of Economy, Trade and Industry, each fiscal year, of the planned quantity of manufacture or planned quantity of import of the said Class II Specified Chemical Substance, the planned quantity of import of the said product using any Class II Specified Chemical Substance, and other

matters specified by a METI ordinance. However, this provision shall not apply to cases in which a Class II Specified Chemical Substance is to be manufactured or imported for testing and research purposes, or in which a product using Class II Specified Chemical Substance is to be imported for testing and research purposes.

2. Where any changes have been made in the matters notified under the provisions of the preceding paragraph, the person who submitted the notification under the provisions of that paragraph shall notify the Minister of Economy, Trade and Industry of such changes, without delay.
3. A person who has submitted a notification under the provisions of paragraph 1 shall not manufacture or import in excess of the planned quantity of manufacture or the planned quantity of import stated in the notification (where a notification of change has been submitted under the provisions of the preceding paragraph, the quantities after the change).
4. Where it is necessary to restrict manufacture or import of a Class II Specified Chemical Substance or import of a product using a Class II Specified Chemical Substance to prevent damage to human health or to the life and/or growth of flora and fauna in the human living environment arising from environmental pollution by the said Class II Chemical Substance, in light of the actual conditions under which the said substance and product is manufactured, imported, or used and in light of the effects of the implementation of measures taken in relation to the said Class II Specified Chemical Substance under the provisions of the following article and article 28, the Ministers shall make a determination that it is necessary to do so, in accordance with a joint ministerial ordinance.
5. Where the determination under the preceding paragraph is made, the Minister of Economy, Trade and Industry may order the person who has submitted a notification under the provisions of paragraph 1 to change the planned quantity of manufacture or the planned quantity of import (where a notification of change has been submitted under the provisions of the paragraph 2, the quantities after the change). In this case, the provisions of paragraph 3 shall apply *mutatis mutandis*.
6. A person who has submitted a notification under the provisions of paragraph 1 shall each fiscal year notify the Minister of Economy, Trade and Industry of the quantities manufactured or imported during the preceding fiscal year and other matters specified by a METI ordinance, for each Class II Specified Chemical Substance, or each product using a Class II Specified Chemical Substance, in accordance with a METI ordinance.
7. The provisions of paragraph 2 of article 13 shall apply *mutatis mutandis* to the cabinet order specified in paragraph 1.

#### **Publication of Technical Guidelines, etc.**

**Article 27** For each Class II Specified Chemical Substance, the competent minister shall publish technical guidelines of measures to be taken by a person engaged in the manufacture of the said Class II Specified Chemical Substance, a person using the said Class II Specified Chemical Substance in the course of business, or a person handling the said Class II Specified Chemical Substance in the course of business (referred to in this section as “handler”) in order to prevent

environmental pollution by the said Class II Specified Chemical Substance.

2. Where the competent minister has published the technical guidelines under the provisions of the preceding paragraph, the competent minister may issue necessary cautionary notices, when deemed necessary, to the handler of the said Class II Specified Chemical Substance with respect to the measures to be taken to prevent environmental pollution by the said substance, taking into account the technical guidelines.

### **Labeling, etc.**

**Article 28** For each Class II Specified Chemical Substance, the Ministers shall determine the labeling information, with respect to measures, etc., for the prevention of environmental pollution by Class II Specified Chemical Substances, to be provided on containers, packages, or invoices for a Class II Specified Chemical Substance or a product that is specified by cabinet order and in which a Class II Specified Chemical Substances is used, and shall publish a notice concerning such labeling information.

2. Where a handler transfers or supplies a Class II Specified Chemical Substance or a product that is specified by the cabinet order in the preceding paragraph and in which a Class II Specified Chemical Substance is used, the handler shall provide labeling information in accordance with the notice published under the provisions of the same paragraph, in accordance with a Joint ministerial ordinance.

3. In the case of a violation, by a handler, of the provisions of the preceding paragraph, the Ministers may issue cautionary notices the said handler to provide labeling information in accordance with the notice published under the provisions of paragraph 1.

## **Chapter 5. Miscellaneous**

### **Cautionary Notices**

**Article 29** Where the competent minister deems that sufficient reason exists to suspect that a chemical substance other than Class I Specified Chemical Substances may fall under any of the clauses in paragraph 2, article 2, the minister may issue cautionary notices as necessary regarding restrictions on the manufacture, import, or use of the said substance to persons engaged in the manufacture or import of the said substance, or to persons using the said substance in the course of business, to the extent necessary to prevent the spread of environmental pollution by the said chemical substance.

2. Where the competent minister deems that sufficient reason exists to suspect that a chemical substance other than Class II Specified Chemical Substance may be subject to the requirements of paragraph 3, article 2, the minister may issue cautionary notices as necessary regarding restrictions on the manufacture or import of the said substance or improvements in the way of using the said substance to persons engaged in the manufacture or import of the said substance, or to persons using the said substance in the course of business, to the extent necessary to prevent the spread of environmental pollution by the said substance.

## **Guidance and Advice**

**Article 30** Where the competent minister deems it especially necessary in order to prevent environmental pollution by a Type I Monitoring Chemical Substance, a Type II Monitoring Chemical Substance, or a Type III Monitoring Chemical Substance (hereinafter a “monitoring chemical substance”) or a Class II Specified Chemical Substance, the minister may provide persons engaged in the manufacture of the said monitoring chemical substance or Class II Specified Chemical Substance, or persons engaged in the use or handling, in the course of business, of the said monitoring chemical substance or Class II Specified Chemical Substance, with the necessary guidance and advice concerning the way to handle the chemical substance.

## **Conditions for Authorization**

**Article 31** Conditions may be attached to any authorization, and the conditions attached may be changed.

2. The conditions under the preceding paragraph shall be limited to the minimum required to ensure the implementation of the items referred to in the authorization, and shall not impose undue obligations upon persons who receive the authorization.

**Reporting of Hazardous Properties, etc.****Article 31-2** Persons engaged in the manufacture or import of any monitoring substance, any Class II Specified Chemical Substance, any chemical substance relating to a public announcement under the provisions of paragraph 4 of article 4 (including cases in which they apply *mutatis mutandis* to paragraph 9 of article 4-2, or cases in which they apply *mutatis mutandis* to paragraph 2 of article 5-2 ), any new chemical substance relating to the confirmation under clause (5) of paragraph 1 of article 3 or paragraph 4 of article 4-2, or any chemical substance for which the Minister of International Trade and Industry has made a public announcement under the provisions of paragraph 4 of article 2 of the Supplementary Provisions and that have been listed in the List of Existing Chemical Substances prescribed in paragraph 1 of the said article (hereinafter a “substance subject to reporting”) shall report to the Ministers the findings and the details of the information obtained, in accordance with a joint ministerial ordinance, relating to the said substance subject to reporting that have been manufactured or imported, when testing has been conducted relating to items to be tested as prescribed under paragraph 7 of article 4 or studies of hazardous properties under the provisions of paragraph 1 of article 5-4, paragraph 1 of article 24, or paragraph 1 of article 25-3 (including cases in which information is obtained that is equivalent to what would be obtained from the said tests [limited to information not generally known]) in cases where information specified by a joint ministerial ordinance has been obtained that indicates that the substance subject to reporting possesses the properties listed below:

- (1) it is unlikely to undergo a chemical transformation through natural processes;
- (2) it is likely to accumulate in living organisms;

- (3) it may be hazardous to human health if taken in continuously;
- (4) it has the potential to impair the life and/or growth of flora and fauna; or
- (5) where the substance subject to reporting is likely to undergo a chemical transformation through natural processes, any chemical substance (including an element) generated by the chemical transformation through natural processes falls under one of the preceding clauses.

However, this provision shall not apply in cases where the said findings have been obtained from a study of hazardous properties relating to the instructions under the provisions of paragraph 1 of article 5-4, paragraph 1 of article 24, or paragraph 1 of article 25-3, and their details are reported under these provisions.

2. Where the Ministers have deemed, based on knowledge obtained from the reports under the preceding paragraph and other available knowledge, that any substance subject to reporting falls under one of the clauses of paragraph 2 of article 2, one of the clauses of paragraph 3, one of the clauses of paragraph 4, or one of the clauses of paragraph 6, or is suspected of falling under one of the clauses of paragraph 6, they shall without delay make a designation as a Class I Specified Chemical Substance or take other measures that may be necessary.

### **Collection of Reports**

**Article 32** The Ministers may, to the extent necessary to enforce this Law, order persons who have received a confirmation under the provisions of clause (4) or clause (5) of paragraph 1 of article 3, or under the provisions of paragraph 4 of article 4-2, to submit reports related to their business operations.

2. The Minister of Economy, Trade and Industry or the competent minister may, to the extent necessary to enforce this Law, order authorized manufacturers, authorized importers, users who have provided notice, or persons who have submitted notifications under the provisions of paragraph 1 of article 26, to submit reports related to their business operations.
3. The competent minister may, to the extent necessary to enforce this Law, order persons specified in article 22 or article 29 to submit reports on their business operations.

### **On-Site Inspections, etc.**

**Article 33** The Ministers may, to the extent necessary to enforce this Law, order ministry personnel to enter the offices or other business premises of persons who have received a confirmation under clause (4) or (5) of paragraph 1 of article 3 or paragraph 4 of article 4-2, and to inspect records, documents, and other items, to make inquiries to the relevant persons, and to sample the smallest quantity of chemical substances necessary for testing.

2. The Minister of Economy, Trade and Industry or the competent minister may, to the extent necessary to enforce this Law, order ministry personnel to enter the offices or other business premises of authorized manufacturers, authorized importers, users who have provided notice or persons who have submitted notifications under paragraph 1 of article 26, and to inspect records, documents, and other items, to make inquiries to the relevant persons, or to sample the smallest



quantity of chemical substances necessary for testing.

3. The competent minister may, to the extent necessary to enforce this Law, order ministry personnel to enter the offices or other business premises of persons specified in article 22 and to inspect records, documents and other items, to make inquiries to the relevant persons, or to sample the smallest quantity of chemical substances necessary for testing.
4. Where the personnel enter company sites for on-site inspections under the provisions of the preceding three paragraphs, they shall carry an identification card and present it to the relevant persons.
5. Where the Minister of Economy, Trade and Industry deems it to be necessary, the said minister may order the National Institute of Technology and Evaluation (hereinafter referred to as “NITE”) to conduct the on-site inspection, make inquiries, or take samples stipulated under paragraphs 1 through 3.
6. Where the Minister of Economy, Trade and Industry orders the Institute to conduct the on-site inspection, make inquiries, or take samples under the provisions of the preceding paragraph, the minister shall provide instructions to NITE about where to conduct the on-site inspection and other matters required to implement the order.
7. Where NITE has conducted the on-site inspection, making of inquiries or taking of samples prescribed in paragraph 5, in accordance with the instructions stipulated in the preceding paragraph, it shall report the results to the Minister of Economy, Trade and Industry.
8. Where the personnel of NITE enter company sites for on-site inspections under the provisions of paragraph 5, they shall carry an identification card and present it to the relevant persons.
9. The right to conduct on-site inspections, make inquiries, and to take samples under the provisions of paragraphs 1 through 3 shall not be construed as an authorization to undertake a criminal investigation.

#### **Orders to NITE**

**Article 33-2** Where the Minister of Economy, Trade and Industry deems it necessary to ensure the proper implementation of duties relating to the on-site inspection, making of inquiries, or taking of samples under the provisions of paragraph 5 of the preceding article, the minister may issue the necessary orders to NITE relating to the said duties.

#### **Request for Examination of Sampling Activities by NITE**

**Article 33-3** Persons who have a complaint relating to the activities of NITE in taking samples may request the Minister of Economy, Trade and Industry to conduct an examination under the Administrative Appeals Law (Law No. 160, 1962).

#### **Requests**

**Article 34** Where the Minister of the Environment deems it necessary to achieve the purpose of this Law, the Minister may request the ministers referred to in either of the following clauses to take the

measures indicated in the said clause:

- (1) the Minister of Economy, Trade and Industry — the order prescribed in paragraph 1, article 18, and
- (2) the competent minister — the order prescribed in paragraph 2, article 18.

## **Fees**

**Article 35** Persons seeking authorization under the provisions of paragraph of article 6, paragraph 1 of article 10, or paragraph 1 of article 11 shall pay fees specified by cabinet order in consideration of the actual expenses.

## **Special Case for Hearings**

**Article 36** Where the Minister of Economy, Trade and Industry intends to issue an order under the provisions of paragraph 1, article 21, the Minister shall be required to hold a hearing, regardless of the category of procedure for issuing a statement of opinion under the provisions of paragraph 1, article 13 of the Administrative Procedures Law (Law No. 88, 1993).

2. Any deliberation regarding the date of a hearing concerning actions under the provisions of article 21 shall be required to be held publicly.
3. Where persons affected by the said actions have requested to participate in procedures involving the public hearing under the provisions of paragraph 1, article 17 of the Administrative Procedures Law, the organizer of the public hearing specified in the preceding paragraph shall be required to allow them to do so.

## **Hearing of Opinion in the Procedures for Notice of Objection**

**Article 37** Decisions on the notice of objection against the actions under the provisions of this law (excluding a decision to reject the objection) shall be made after giving prior notice with a sufficient period of time to the person subject to the actions and after a public hearing of opinion.

2. The date, location, and content of the issues shall be indicated in the prior notice referred to in the preceding paragraph.
3. During the hearing of opinion referred to in paragraph 1, the evidence of the issue shall be shown to the person subject to the said actions and other affected persons and they shall be given the opportunity to express their opinions.

## **Transitional Measures**

**Article 38** Where an order is issued, amended, or repealed under the provisions of this Law, transitional measures (including transitional measures concerning penalties) may be prescribed in the said order to the extent deemed necessary as a result of the issuance, amendment, or abrogation thereof.

## **Competent Ministers**

**Article 39** The competent ministers under this Law shall be as follows:

- (1) Concerning notifications under the provisions of article 15, paragraph 2 of article 16, or paragraph 1 of article 20, orders under the provisions of paragraph 2 of article 18, the collection of reports under the provisions of paragraph 2 of article 32, or inspection, making of inquiries, or taking of samples under the provisions of paragraph 2 of article 33, the competent minister shall be the minister having jurisdiction over the business activities in which persons submitting these notifications or persons subject to these orders, the collection of reports or inspection, making of inquiries, or sampling are engaged.
- (2) Concerning orders under the provisions of article 22, publication of technical guidelines under the provisions of paragraph 1 of article 27, cautionary notices under the provisions of paragraph 2 of the said article or article 29, guidance and advice (excluding those relating to Type III Monitoring Chemical Substances) under the provisions of article 30, collection of reports under the provisions of paragraph 3 of article 32, or inspection, making of inquiries or sampling under the provisions of paragraph 3 or article 33, the competent minister shall be the Ministers and the minister having jurisdiction over the business activities in which persons subject to these orders, publication of technical guidelines, cautionary notices, guidance and advice, collection of reports or inspection, making of inquiries, or sampling are engaged.
- (3) Concerning guidance and advice (limited to Type III Monitoring Chemical Substances) under the provisions of article 30, the competent ministers shall be the Minister of Economy, Trade and Industry, the Minister of the Environment, and the having jurisdiction over the business activities in which persons subject to this guidance and advice are engaged.

2. The ministerial ordinances of the competent ministry under this Law shall be as follows:

- (1) concerning the keeping, entering, and preserving of records under the provisions of paragraphs 1 and 2 of article 19 that apply *mutatis mutandis* in paragraph 3 of the same article, the ordinances shall be those issued by the minister having jurisdiction over the business in which persons using Class I Specified Chemical Substances are engaged, and
- (2) concerning the technical standards under the provisions of paragraph 2, article 17, the ordinances shall be those issued by the Ministers and the minister having jurisdiction over the business in which persons using Class I Specified Chemical Substances are engaged.

### **Relationship to Other Laws**

**Article 40** The provisions of article 3, paragraph 1 of article 5-2, paragraph 1 of article 5-3, paragraph 1 of article 5-4, paragraph 1 of article 6, article 7, paragraph 1 of article 11, article 14, paragraph 1 of article 15, paragraphs 1 and 3 of article 22, paragraph 1 of article 23, paragraph 1 of article 24, paragraph 1 of article 25-2, paragraph 1 of article 25-3, paragraph 1 of article 26, paragraph 1 of article 27, paragraph 1 of article 28, article 29, article 30 and paragraph 1 of article 31-2 shall not apply to the chemical substances listed in clauses (1) through (5) below; the provisions of

paragraph 1 or article 13 and article 22 shall not apply to the products listed below in which Class I Specified Chemical Substances are used; the provisions of paragraph 1 of article 26 and paragraph 1 of article 28 shall not apply to the products listed below in which Class II Specified Chemical Substances are used; and the provisions of article 14, paragraph 1 of article 15, paragraph 3 of article 22, paragraph 1 of article 27, paragraph 1 of article 28, article 29 and article 30 shall not apply to the use of chemical substances as raw materials for the products listed below; the laws indicated in each of the said clauses (1) through (5) shall apply *mutatis mutandis*:

- (1) foodstuffs prescribed in paragraph 1 of article 2 of the Foodstuffs Sanitation Law (Law No. 233, 1947), food additives prescribed in paragraph 2 of the said article, containers and packages prescribed in paragraph 5 of the said article; toys, prescribed in paragraph 1 of article 29 of the said Law; and detergents prescribed in paragraph 2 of the said article;
- (2) agricultural chemicals prescribed in paragraph 1 of article 1-2 of the Agricultural Chemicals Control Law (Law No. 82, 1948);
- (3) ordinary fertilizers prescribed in paragraph 2 of article 2 of the Fertilizers Control Law (Law No. 127, 1950);
- (4) animal feeds prescribed in paragraph 2 of article 2 of the Law on Security of Animal Feed Safety and Improvement of Quality (Law No. 35, 1953), and animal feed additives prescribed in paragraph 3 of the said article; and
- (5) drugs prescribed in paragraph 1 of article 2 of the Pharmaceutical Affairs Law (Law No. 145, 1960); quasi-drugs prescribed in paragraph 2 of the said article; cosmetics prescribed in paragraph 3 of the said article; and medical devices prescribed in paragraph 4 of the said article.

### **Hearings of Advisory Councils**

**Article 41** The Ministers shall seek the opinions of advisory councils, etc., specified by cabinet order (Organizations prescribed in article 8 of the National Government Organization Law (Law No. 120, 1948); the same applies in subsequent paragraphs) in advance of addressing the following cases:

- (1) when intending to submit a proposal to make or amend a cabinet order under paragraph 2 of article 2 (excluding cases when intending to submit such a proposal based on the judgement in paragraph 1 or 2 of article 4, paragraph 8 of article 4-2, or paragraph 2 of article 5-4), or when intending to submit a proposal to make or amend a cabinet order under paragraph 3 of article 2, paragraph 1 of article 13, article 14 or paragraph 1 of article 26;
- (2) when intending to make a designation under paragraphs 4 or 5 of article 2 (excluding cases when intending to make a designation based on the judgement in paragraph 1 or 2 of article 4, or paragraph 8 of article 4-2);
- (3) when intending to make a judgement under paragraph 1 or 2 of article 4, paragraph 2, 3 or 8 of article 4-2, paragraph 2 of article 5-4, or paragraph 2 of article 24;
- (4) when intending to issue an instruction under paragraph 1 of article 5-4 or paragraph 1 of

article 24; and

(5) when intending to make a determination under paragraph 4 of article 26.

2. The Minister of Economy, Trade and Industry and the Minister of the Environment shall seek the opinions of advisory councils, etc., specified by cabinet order, in advance, when intending to make a designation under paragraph 6 of article 2 (excluding cases when intending to make a designation based on the judgement under paragraph 1 or 2 of article 4, or paragraph 8 of article 4-2), when intending to issue an instruction under paragraph 1 of article 25-3, or when intending to make a judgement under paragraph 2 of the said article.

## **Chapter 6. Penalties**

**Article 42** The following persons shall be subject to imprisonment with hard labor for not more than three years or to a fine of not more than one million yen, or both:

- (1) persons engaged in the manufacture of any Class I Specified Chemical Substance without receiving the authorization under the provisions of paragraph 1 of article 6;
- (2) persons who have violated the provisions of article 7, paragraph 1 of article 13, or article 14;
- (3) persons who have imported any Class I Specified Chemical Substance in violation of the provisions of paragraph 1 of article 11;
- (4) persons who have violated an order to suspend business under the provisions of paragraph 1 of article 21; and
- (5) persons who have violated an order under the provisions of paragraph 3 of article 22.

**Article 43** The following persons shall be subject to imprisonment with hard labor for not more than one year or to a fine of not more than five hundred thousand yen, or both:

- (1) persons who have manufactured or imported any new chemical substance in violation of the provisions of paragraph 1 of article 3;
- (2) persons who have violated the provisions of article 5;
- (3) persons who have violated an instruction under the provisions of paragraph 1 of article 5-4, paragraph 1 of article 25, or paragraph 1 of article 25-3; and
- (4) persons who have manufactured or imported any Class II Specified Chemical Substance or imported a product in which any Class II Specified Chemical Substance was used in violation of the provisions of paragraphs 1 or 3 of article 26 (including cases in which they apply *mutatis mutandis* to paragraph 5 of the said article).

**Article 44** The following persons shall be subject to imprisonment with hard labor for not more than six months or to a fine of not more than five hundred thousand yen, or both:

- (1) persons who have made changes in the structure or capacity of manufacturing equipment in violation of the provisions of paragraph 1 of article 10;
- (2) persons who have failed to submit a notification, or submitted a false notification in violation

of the provisions of paragraph 1 of article 15; and

- (3) persons who have violated an order under the provisions of article 18 or paragraphs 1 or 2 of article 22.

**Article 45** The following persons shall be subject to a fine of not more than three hundred thousand yen:

- (1) persons who have failed to keep records or make entries in them, or made false entries in them, in violation of the provisions of paragraph 1 of article 19 (including cases in which they apply *mutatis mutandis* to paragraph 3 of the said article), or failed to store records, in violation of the provisions of paragraph 2 of the said article (including cases in which they apply *mutatis mutandis* to paragraph 3 of the said article);
- (2) persons who have failed to submit a notification or submitted a false notification under the provisions of paragraph 1 of article 5-3, paragraph 1 of article 23, paragraph 1 of article 25-2, or paragraph 6 of article 26;
- (3) persons who have failed to submit a report or submitted a false report under the provisions of article 32; and
- (4) persons who have refused, obstructed, or evaded inspection or sampling under the provisions of paragraph 1 through 3 of article 33, or refused to respond to inquiries, or gave false answers under these provisions.

**Article 46** Where a head of a corporation, or an agent, a servant or any other employee of a corporation or a person has committed a violation under one of the following clauses concerning the business activities of the said corporation or the said person, the individual who committed that violation shall be punished, and furthermore the said corporation shall be subject to a fine under the relevant clause below and the said person shall be subject to a fine under each respective article:

- (1) article 42 — a fine of not more than one hundred million yen;
- (2) clauses 1, 2 or 4 of article 43 — a fine of not more than fifty million yen; and
- (3) clause 3 of article 43, article 44, or the preceding article — the fine stated in each respective article.

**Article 47** The following persons shall be subject to a fine of not more than two hundred thousand yen:

- (1) persons who have failed to submit a notification or submitted a false notification under the provisions of paragraph 2 of article 10, paragraph 2 of article 15, paragraph 2 of article 16, paragraph 1 of article 20, paragraph 2 of article 26; and
- (2) persons who have failed to submit a report or submitted a false report under the provisions of paragraph 1 of 31-2.

**Article 48** In cases where the orders under the provisions of article 33-2 have been violated, the director or directors of NITE who committed the violation shall be subject to a fine of not more

than two hundred thousand yen.

## **Supplementary Provisions (Excerpt)**

### **Date of Entry into Force**

**Article 1** This Law shall enter into force on the day six months after the day of its promulgation. However, the provisions of the following article shall be enforced on the day of the promulgation.

### **List of Existing Chemical Substances**

**Article 2** The Minister of International Trade and Industry shall compile a list (hereinafter referred to as the “List of Existing Chemical Substances”) of the names of chemical substances that are actually manufactured or imported commercially at the time of the promulgation of this Law (excluding those substances that are manufactured or imported for testing and research purposes or as reagents) and make it public within three months after the day of the promulgation of this Law.

2. Where any person deems it necessary to amend the List of Existing Chemical Substances made public under the provision of the preceding paragraph, the person may make a proposal for amendment to the Minister of International Trade and Industry, in accordance with a ministerial ordinance of the Ministry of International Trade and Industry, provided that proposal is made within one month after the day the List is made public .

3. Upon receipt of the proposal under the preceding paragraph, where the Minister of International Trade and Industry deems it reasonable, the Minister of International Trade and Industry shall add the name of the chemical substance mentioned in the proposal to or delete it from the List of Existing Chemical Substances, and shall provide notice to that effect to the person who made the proposal.

4. The Minister of International Trade and Industry shall make the List of Existing Chemical Substances public with the necessary additions or eliminations made under the preceding paragraph at least one month prior to the date of entry into force of this Law.

### **Interim Measures**

**Article 4** Among the chemical substances listed in the List of Existing Chemical Substances made public by the Minister of International Trade and Industry under the provisions of paragraph 4 of article 2 of the Supplementary Provisions (including chemical substances newly manufactured or imported after the entry into force of this Law, other than the chemical substances listed in clauses (2) through (4) of paragraph 7 of article 2 [for chemical substances listed in clause (3) of the said article, this is limited only to substances that fall under clause (1) of paragraph 3 of the said article] ), where tests under paragraph 7 of article 4 are conducted on the substances for which the Ministers deem such tests to be especially necessary (including cases in which information has been obtained that is equivalent to what would be obtained from the said tests), the test results obtained (including the said information equivalent to what would be obtained from the said tests)

concerning the application of the provisions of paragraph 8 of article 2 shall be deemed to be results obtained under paragraph 7 of article 4.

## **Supplementary Provisions (Law 49, 2003)**

### **Date of Enforcement**

**Article 1** This Law shall enter into force not more than one year after the day of its promulgation, on a date specified by cabinet order. However, the provisions of article 3 of the Supplementary Provisions shall enter into force not more than nine months after the date of its promulgation, on a date specified by cabinet order.

### **Transitional Measures relating to Confirmation**

**Article 2** When this Law enters into force, a person who is actually manufacturing or importing a new chemical substance without submitting notification under article 3 of the Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. before the amendment by this Law because the case specified by the cabinet order in the said article applies, and who is specified by the cabinet order may, without submitting notification under paragraph 1 of article 3 of the Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. that has been amended by this Law (hereinafter the “new Law”), continue to manufacture or import the said new chemical substance for the period up to the date six months after the date this Law enters into force (hereafter “date of entry into force”), notwithstanding the provisions of the said paragraph.

### **Preparatory Actions**

**Article 3** A person who intends to manufacture or import a new chemical substance may, even before the date of entry into force, receive the confirmation of the ministers under clause (5) of paragraph 1 of article 3 of the new Law. In such cases, the person who has received the said confirmation will be deemed to have received the confirmation of the ministers under the said clause on the date of entry into force.

### **Transitional Measures relating to Application of Penalties**

**Article 4** The application of penalties for actions conducted before this Law enters into force shall be based on the Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. before the amendment by this Law.

### **Delegation of Matters to Cabinet Order**

**Article 5** In addition to matters prescribed by these Supplementary Provisions, interim measures necessary for implementation of this Law shall be specified by cabinet order.



## **Review**

**Article 6** Five years after this Law has entered into force, after considering the state of enforcement of the new Law, if the government deems it necessary, a review shall be conducted on the provisions of the new Law and the necessary measures taken, based on the results of the said review.

## **Partial Amendment of the Law for the Establishment of the National Institute of Technology and Evaluation**

**Article 7** The Law for the Establishment of the National Institute of Technology and Evaluation (Law 204, 1999) shall be partially amended, as follows:

The following clause shall be added after clause (6) of paragraph 2 of article 11:

(6-2) On-site inspections, the making of inquiries, and the taking of samples as stipulated under clauses (1) through (3) of paragraph 1 of article 33 of the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 117, 1973)