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## **Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.**

**(Act No. 117 of October 16, 1973)**

### **Chapter 1 General Provisions**

#### **Article 1 (Purpose)**

The purpose of this Act is to establish a system to evaluate, before manufacture or import, whether or not new chemical substances have properties such as persistence, and to implement necessary regulations with respect to the manufacture, import, use, etc. of chemical substances, with due consideration to their properties, etc., in order to prevent environmental pollution caused by chemical substances that are persistent and pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna.

#### **Article 2 (Definitions, etc.)**

- (1) The term “chemical substance” as used in this Act means a chemical compound obtained by causing chemical reactions to elements or compounds (excluding a radioactive substance and the following substances):
- (i) Any specified poison prescribed in paragraph (3) of Article 2 of the Poisonous and Deleterious Substances Control Act (Act No. 303 of 1950)
  - (ii) Any stimulant prescribed in paragraph (1) of Article 2 of the Stimulant Drug Control Act (Act No. 252 of 1951) and any raw material for stimulants prescribed in

paragraph (5) of said Article

(iii) Any narcotic prescribed in item (i) of Article 2 of the Narcotics and Psychotropics Control Act (Act No. 14 of 1953)

(2) The term “Class I Specified Chemical Substance” as used in this Act means a chemical substance that falls under either of the following items and is specified by a Cabinet Order:

(i) A chemical substance that falls under (a) and (b):

(a) A chemical substance that is not likely to undergo a chemical transformation through natural processes and is bioaccumulative

(b) A chemical substance that falls under either of the following:

1. A chemical substance that poses a risk of impairing human health if ingested continuously

2. A chemical substance that, if ingested continuously, poses a risk of interfering with the inhabitation and/or growth of animals at the top of the food chain (which mean animals that fall under the category of flora and fauna in the human living environment [which mean flora and fauna for which interference with their inhabitation and/or growth would pose a risk of interfering with the preservation of the human living environment; the same shall apply hereinafter] for which chemical substances falling under (a) are most likely to bioaccumulate through the food chain; the same shall apply hereinafter)

(ii) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by chemical transformation through natural processes falls under (a) and (b) of the preceding item

(3) The term “Class II Specified Chemical Substance” as used in this Act means a chemical substance that falls under either of the following items and is thought to pose a risk of causing damage pertaining to human health or damage pertaining to the inhabitation and/or growth of flora and fauna in the human living environment because a considerable amount of the chemical substance remains in the environment over a substantially extensive area or it is reasonably likely that such a situation will arise in the near future in view of the state of its manufacture, import, use, etc., and is specified by a Cabinet Order:

(i) A chemical substance that falls under either (a) or (b):

(a) A chemical substance (excluding one that falls under item (i) of the preceding paragraph) that is not likely to undergo a chemical transformation through natural processes, and poses a risk of impairing human health if ingested continuously

(b) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural

- processes falls under (a)
- (ii) Any chemical substance that falls under either (a) or (b):
    - (a) A chemical substance (excluding one that falls under item (i) of the preceding paragraph) that is not likely to undergo a chemical transformation through natural processes, and that poses a risk of interfering with the inhabitation and/or growth of flora and fauna in the human living environment if the flora and fauna continuously ingest or are exposed to said chemical substance
    - (b) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under (a)
- (4) The term “Type I Monitoring Chemical Substance” as used in this Act means a chemical substance (excluding a new chemical substance) that falls under either of the following items and has been designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment:
- (i) A chemical substance that falls under (a) of item (i) of paragraph (2), and where it is unclear whether or not (b) of said item applies
  - (ii) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under the preceding item
- (5) The term “Type II Monitoring Chemical Substance” as used in this Act means a chemical substance suspected of falling under item (i) of paragraph (3) (including a chemical substance that falls under said item but has not been designated as a Class II Specified Chemical Substance) and has been designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment.
- (6) The term “Type III Monitoring Chemical Substance” as used in this Act means a chemical substance that falls under either of the following items and has been designated by the Minister of Economy, Trade and Industry and the Minister of the Environment:
- (i) A chemical substance that is not likely to undergo a chemical transformation through natural processes, and poses a risk of interfering with the inhabitation and/or growth of flora and fauna (excluding one that falls under item (i) of paragraph (2) and one that falls under (a) of item (ii) of paragraph (3) which has been designated as a Class II Specified Chemical Substance)
  - (ii) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural

- processes falls under the preceding item
- (7) The term “new chemical substance” as used in this Act means a chemical substance other than the chemical substances listed in the following items:
- (i) A chemical substance for which public notice has been given by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment pursuant to the provisions of paragraph (4) of Article 4 (including the cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2 by replacing the terms, and the cases in which it is applied mutatis mutandis pursuant to paragraph (2) of Article 5-2)
  - (ii) A Class I Specified Chemical Substance
  - (iii) A Class II Specified Chemical Substance
  - (iv) A Type II Monitoring Chemical Substance (including one for which designation has been rescinded pursuant to the provisions of item (ii) of Article 25)
  - (v) A Type III Monitoring Chemical Substance
  - (vi) A chemical substance (excluding any of those set forth in the preceding items) listed in the List of Existing Chemical Substances prescribed in paragraph (1) of Article 2 of the Supplementary Provisions of this Act that has been publicly notified by the Minister of International Trade and Industry pursuant to the provisions of paragraph (4) of said Article
- (8) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall make the designation set forth in paragraph (5) based on the results of the tests prescribed in paragraph (7) of Article 4 (including the cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2).
- (9) When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, or the Minister of the Environment has designated a chemical substance as a Type I Monitoring Chemical Substance or Type II Monitoring Chemical Substance pursuant to the provisions of paragraph (4) or (5), he/she shall give public notice of its name without delay.
- (10) When the Minister of Economy, Trade and Industry or the Minister of the Environment has designated a chemical substance as a Type III Monitoring Chemical Substance pursuant to the provisions of paragraph (6), he/she shall give public notice of its name without delay.

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

### **Article 3 (Notification of Manufacture, etc.)**

- (1) A person who intends to manufacture or import a new chemical substance shall notify the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, in advance, of the name of said new

chemical substance and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment; provided, however, that this shall not apply to a case that falls under any of the following items:

- (i) Where a person intends to import, from a person who has submitted a notification under paragraph (1) of Article 5-2 and has received notice to the effect that the new chemical substance to which said notification pertains falls under item (v) of paragraph (1) of the following Article in accordance with the provisions of paragraph (1) or (2) of said Article as applied mutatis mutandis pursuant to paragraph (2) of Article 5-2, the new chemical substance to which said notification pertains
- (ii) Where a person intends to manufacture or import a new substance for testing and research purposes
- (iii) Where a person intends to manufacture or import a new chemical substance as a reagent (which means a chemical substance used for the detection or quantification of a substance by a chemical process, or for the experimental synthesis of a substance, or for the measurement of the physical characteristics of a substance; the same shall apply hereinafter)
- (iv) Where a person has received a confirmation from the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, to the effect that the manufacture or import falls under a case specified by a Cabinet Order as one where the new chemical substance does not pose a risk of causing environmental pollution in consideration of the intended method of handling said new chemical substance and other matters, and said new chemical substance will be manufactured or imported in accordance with the particulars for which said confirmation has been received
- (v) Where the planned quantity of manufacture or planned quantity of import (in the case of a person who intends to manufacture and import said new chemical substance, the sum of these quantities; the same shall apply in paragraph (1) and item (i) of paragraph (4) of Article 4-2) of said new chemical substance in one fiscal year is not more than the quantity specified by a Cabinet Order, and where a person has received a confirmation from the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, in accordance with an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, to the effect that, as determined by already available

knowledge, etc., said new chemical substance is not one that poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution, and that person shall manufacture or import said new chemical substance in a quantity of no more than that to which said confirmation pertains during the relevant fiscal year

- (2) In cases where the sum of the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of item (v) of the preceding paragraph pertains (including the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of paragraph (4) of Article 4-2 pertains) relating to a single new chemical substance exceeds the quantity specified by a Cabinet Order set forth in said item, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall not issue the confirmation under said item.
- (3) In any of the following cases, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall rescind the confirmation set forth in item (iv) of paragraph (1):
  - (i) Where the person who has received the confirmation under item (iv) of paragraph (1) had received said confirmation by wrongful means
  - (ii) Where the person who has received the confirmation under item (iv) of paragraph (1) is found not to be manufacturing or importing the new chemical substance to which said confirmation pertains in accordance with the particulars for which said confirmation has been received
  - (iii) In addition to the cases set forth in the preceding items, where it is found that the new chemical substance to which the confirmation under item (iv) of paragraph (1) pertains poses a risk of causing environmental pollution
- (4) In any of the following cases, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall rescind the confirmation under item (v) of paragraph (1):
  - (i) Where the person who has received the confirmation under item (v) of paragraph (1) had received said confirmation by wrongful means
  - (ii) Where the person who has received the confirmation under item (v) of paragraph (1) is found not to be manufacturing or importing the new chemical substance to which said confirmation pertains in excess of the quantity to which said confirmation pertains
  - (iii) In addition to the cases set forth in the preceding items, where it is found that the new chemical substance to which the confirmation under item (v) of paragraph (1) pertains poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution

#### **Article 4 (Evaluation)**

- (1) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a notification under paragraph (1) of the preceding Article, they shall make a determination as to which of the following items the new chemical substance falls under, within three months from the date of receipt of the notification, based on the available knowledge on the composition, properties, etc., of the new chemical substance to which said notification pertains, and shall notify the result thereof to the person who has given the notification:
  - (i) A substance that falls under any of the items of paragraph (2) of Article 2
  - (ii) A substance that is suspected of falling under item (i) of paragraph (3) of Article 2 (including a substance that falls under said item; the same shall apply in item (iv)) and that falls under neither of the items of paragraph (6) of said Article
  - (iii) A substance that is not suspected of falling under item (i), paragraph (3) of Article 2 and that falls under either of the items of paragraph (6) of said Article
  - (iv) A substance that is suspected of falling under item (i), paragraph (3) of Article 2 and that falls under either of the items of paragraph (6) of said Article
  - (v) A substance that falls under neither of the items of paragraph (2) of Article 2 and neither of the items of paragraph (6) of said Article and that is not suspected of falling under item (i) of paragraph (3) of said Article
  - (vi) A substance where it is unclear as to whether or not it falls under items (i) to (iv)
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have determined that a new chemical substance to which a notification under paragraph (1) of the preceding Article pertains falls under item (vi) of the preceding paragraph, they shall promptly make a determination as to which one of items (i) to (v) of said paragraph the new chemical substance falls under, based on the results of tests conducted on the new chemical substance, and shall notify the result thereof to the person who has given the notification.
- (3) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find it necessary in order to make a determination under the preceding paragraph, they may request the person who has given the notification under paragraph (1) of the preceding Article to submit materials stating the results of tests prescribed in paragraph (7) relating to the properties of the new chemical substance to which said notification pertains and any other documents specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.
- (4) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have given notice to the effect that

the new chemical substance to which a notification under paragraph (1) of the preceding Article pertains falls under item (v) of paragraph (1), pursuant to the provisions of paragraph (1) or (2), they shall give public notice of the name of said new chemical substance, in accordance with an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.

- (5) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have given notice to the effect that the new chemical substance to which a notification under paragraph (1) of the preceding Article pertains falls under item (ii) or item (iv) of paragraph (1), pursuant to the provisions of paragraph (1) or (2), they shall make a designation under the provisions of paragraph (5) of Article 2 with regard to said chemical substance without delay.
- (6) Where the Minister of Economy, Trade and Industry and the Minister of the Environment have given notice to the effect that the new chemical substance to which a notification under paragraph (1) of the preceding Article pertains falls under item (iii) or item (iv) of paragraph (1), pursuant to the provisions of paragraph (1) or (2), they shall make a designation under the provisions of paragraph (6) of Article 2 with regard to said chemical substance without delay.
- (7) The items to be tested and any other technical matters necessary for making a determination under paragraphs (1) and (2) of this Article shall be specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.
- (8) In determining the order under the preceding paragraph, efforts shall be made to consider fully the international trends regarding the establishment of items to be tested relating to the evaluation of the safety of chemical substances, and other trends regarding the technical standards relating to the evaluation of the safety of chemical substances.

**Article 4-2 (Exception to Evaluation in the Case Where the Planned Quantity of Manufacture etc., is Not More Than a Certain Quantity, etc.)**

- (1) A person who intends to give 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 to which the notification pertains during one fiscal year will be not more than the quantity specified by the Cabinet Order set forth in item (i) of paragraph (4) may, when giving the notification, make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, to make a

determination as to whether or not said new chemical substance falls under either of the following items in the case where it falls under item (vi) of paragraph (1) of the preceding Article:

- (i) A chemical substance that falls under (a) and (b):
    - (a) A chemical substance that is not likely to undergo a chemical transformation through natural processes and is not bioaccumulative
    - (b) A chemical substance where it is unclear as to whether or not it falls under items (ii) to (iv) of paragraph (1) of the preceding Article
  - (ii) In the case of a new chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under the preceding item
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a request under the preceding paragraph, if they find that the new chemical substance to which said request pertains falls under item (vi) of said paragraph at the time of making a determination under item (i) of the preceding Article, they shall, notwithstanding the provisions of said paragraph, make a determination as to which of the following items said new chemical substance falls under, in lieu of a determination to the effect that it falls under item (vi) of paragraph (1) of the preceding Article, based on already available knowledge on the composition, properties, etc., of the new chemical substance to which said request pertains, within three months from the date of receipt of a notification under item (i) of Article 3, and shall notify the result thereof to the person who has made the request under the preceding paragraph; in this case, the provisions of paragraph (2) of said Article shall not apply:
- (i) A substance that falls under any of the items of the preceding paragraph
  - (ii) A substance that does not fall under any of the items of the preceding paragraph
  - (iii) A chemical substance where it is unclear as to whether or not it falls under any of the items of the preceding paragraph
- (3) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have determined that the new chemical substance to which a request under paragraph (1) pertains falls under item (iii) of the preceding paragraph, they shall promptly make a determination as to which one of items (i) or (ii) of said paragraph said new chemical substance falls under, based on the results of tests conducted on said new chemical substance, and shall notify the result thereof to the person who has made the request.
- (4) A person who has received notice to the effect that the new chemical substance to which a request made under the provisions of paragraph (2) or the preceding paragraph pertains falls under item (i) of paragraph (2) may make a request in advance, each fiscal year, to the Minister of Health, Labour and Welfare, the Minister

of Economy, Trade and Industry, and the Minister of the Environment and receive a confirmation to the effect that the manufacture or import of the new chemical substance to which said notice pertains falls under the following items, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment:

- (i) The planned quantity of manufacture or planned quantity of import of said new chemical substance during the fiscal year to which the request pertains is not more than the quantity specified by a Cabinet Order.
  - (ii) Determined by already available knowledge, etc., the new chemical substance is not one that poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution.
- (5) In cases where the sum of the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of the preceding paragraph pertains (including the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of item (v) of paragraph (1) of Article 3 pertains) relating to a single new chemical substance exceeds the quantity specified by a Cabinet Order set forth in item (i) of the preceding paragraph, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall not issue the confirmation under said item.
- (6) In any of the following cases, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall rescind the confirmation set forth in paragraph (4):
- (i) Where the person who has received the confirmation under paragraph (4) has received said confirmation by wrongful means
  - (ii) Where the person who has received the confirmation under paragraph (4) is found to be manufacturing or importing the new chemical substance to which said confirmation pertains in excess of the quantity to which said confirmation pertains
  - (iii) In addition to the cases set forth in the preceding items, where it is found that the new chemical substance to which the confirmation under paragraph (4) pertains poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution
- (7) A person who has received notice to the effect that the new chemical substance to which his/her request pertains falls under item (i) of paragraph (2), pursuant to the provisions of paragraph (2) or paragraph (3) may, when he/she finds it necessary, make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment to make a determination under the following paragraph with regard to the new chemical substance to which

said notice pertains, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.

- (8) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have given notice to the effect that the new chemical substance to which a request under paragraph (1) pertains falls under item (ii) of paragraph (2), pursuant to the provisions of paragraph (2) or paragraph (3), where they have not issued a confirmation to the effect that the manufacture or import of the new chemical substance to which a request under paragraph (4) pertains falls under the items of said paragraph, where they have rescinded the confirmation under said paragraph, or where they have received a request under the preceding paragraph, they shall promptly make a determination as to which one of items (i) to (v) of paragraph (1) of Article 4 said new chemical substance falls under, based on the results of tests conducted on said new chemical substance, and shall notify the result thereof to the person who has made the request under paragraph (1) with regard to the new chemical substance.
- (9) The provisions of paragraph (7) and paragraph (8) of the preceding Article shall apply mutatis mutandis to a determination under paragraph (2), the provisions of paragraph (3), paragraph (7) and paragraph (8) of said Article shall apply mutatis mutandis to a determination under paragraph (3), and the provisions of paragraph (3) to paragraph (8) of said Article shall apply mutatis mutandis to a determination under the preceding paragraph. In these cases, the phrase “paragraph (1) or paragraph (2)” in the provisions of paragraph (4) to paragraph (6) of said Article shall be deemed to be replaced with “paragraph (8) of Article 4-2.”

#### **Article 5 (Restrictions on Manufacture, etc.)**

A person who has given a notification under paragraph (1) of Article 3 shall not manufacture or import the new chemical substance to which the notification pertains pursuant to the provisions of paragraph (1) or (2) of Article 4 or paragraph (8) of the preceding Article until after the receipt of notice prescribed in the provisions of paragraphs (4) to (6) of Article 4 (including the cases where it is applied mutatis mutandis pursuant to paragraph (9) of the preceding Article) relating to said new chemical substance; provided, however, that this shall not apply to either of the following cases:

- (i) Where the manufacture or import of the new chemical substance to which said notification pertains falls under any of the items of paragraph (1) of Article 3
- (ii) Where, in the case that the person has received a confirmation under the provisions of paragraph (4) of the preceding Article regarding the manufacture or import of the new chemical substance to which said notification pertains, the quantity of manufacture or import of said new chemical substance shall be not more than the

quantity to which said confirmation pertains

**Article 5-2 (Evaluation, etc., of a New Chemical Substance Pertaining to a Manufacturer, etc., in a Foreign State)**

- (1) A person who intends to manufacture in a foreign state a new chemical substance to be exported to Japan or a person who intends to export a new chemical substance to Japan may, in advance, notify the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment of the name of said new chemical substance and any other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.
- (2) The provisions of Article 4 shall apply mutatis mutandis to the notification under the preceding paragraph. In this case, the term “within three months” in paragraph (1) of said Article shall be deemed to be replaced with “within four months.”

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

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

**Article 5-3 (Notification of the Quantity of Manufacture, etc.)**

- (1) A person who has manufactured or imported any Type I Monitoring Chemical Substance shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or the quantity of import in the preceding fiscal year and other matters specified by an Ordinance of the Ministry of Economy, Trade and Industry for each Type I Monitoring Chemical Substance, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry; provided, however, that this shall not apply to the case where the person has manufactured or imported a Type I Monitoring Chemical Substance for testing and research purposes.
- (2) The Minister of Economy, Trade and Industry shall publicize, each fiscal year, the sum of the quantity of manufacture and quantity of import in the preceding fiscal year to which the notification under the preceding paragraph pertains for each Type I Monitoring Chemical Substance; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Type I Monitoring Chemical Substance is less than the quantity specified by an Ordinance of the Ministry of Economy, Trade and Industry.

**Article 5-4 (Study of Hazardous Properties of Type I Monitoring Chemical Substances)**

- (1) In the case where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find sufficient reason to suspect that any single Type I Monitoring Chemical Substance falls under any of the items of paragraph (2) of Article 2, if they have found it necessary to make a determination as to whether or not said Type I Monitoring Chemical Substance falls under any of the items of said paragraph since said Type I Monitoring Chemical Substance poses a risk of causing environmental pollution if said Type I Monitoring Chemical Substance falls under any of the items of said paragraph, in view of the state of its manufacture, import, use, etc., they may, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, instruct a person operating the business of manufacturing or importing of said Type I Monitoring Chemical Substance (including a person who has been operating such business formerly and who is specified by an Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment (which means a study on the effects of said chemical substance on human health or on the life and/or growth of animals at the top of the food chain if ingested continuously; the same shall apply in paragraph (3)) and to report the results thereof.
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a report under the preceding paragraph, they shall make a determination as to whether or not the Type I Monitoring Chemical Substance to which said report pertains falls under any one of the items of paragraph (2) of Article 2 and notify the result thereof to the person who has made the report.
- (3) The Minister of Economy, Trade and Industry may, when he/she finds it particularly necessary for ensuring that the expenses for the study of the hazardous properties to which the instruction under the provisions of paragraph (1) pertains are shared out fairly among the business operators concerned, establish standards concerning the method and proportions of the sharing of the expenses required for said study of the hazardous properties.

#### **Article 5-5 (Rescission of Designation as Type I Monitoring Chemical Substance)**

When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find that a Type I Monitoring Chemical Substance falls under either of the following items, they shall rescind the designation and publicize to that effect without delay:

- (i) Where said chemical substance has been designated as a Class I Specified Chemical Substance

- (ii) Where said chemical substance has been found not to fall under any of the items of paragraph (2) of Article 2, based on a report under paragraph (1) of the preceding Article or on knowledge that has been otherwise obtained

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

### **Article 6 (Permission to Manufacture)**

- (1) A person who intends to operate a business of manufacturing a Class I Specified Chemical Substance shall obtain permission from the Minister of Economy, Trade and Industry for each Class I Specified Chemical Substance and for each place of business.
- (2) A person who intends to obtain permission under the preceding paragraph shall submit a written application stating the following matters to the Minister of Economy, Trade and Industry:
  - (i) The name and domicile, and in the case of a juridical person the name of the representative person
  - (ii) The location of the place of business
  - (iii) The name of the Class I Specified Chemical Substance
  - (iv) The structure and capacity of the manufacturing equipment
- (3) Where the Minister of Economy, Trade and Industry has granted permission under paragraph (1), he/she shall notify the Minister of the Environment to that effect without delay.

### **Article 7**

No person other than one who has obtained permission under paragraph (1) of the preceding Article shall manufacture a Class I Specified Chemical Substance; provided, however, that this shall not apply to the case where a person manufactures a Class I Specified Chemical Substance for testing and research purposes.

### **Article 8 (Disqualification Clause)**

Permission under paragraph (1) of Article 6 shall not be granted to a person who falls under any of the following items:

- (i) A person who has been sentenced to a fine or severer punishment for violation of this Act or any order based on this Act where two years have yet to elapse since the day on which execution of the sentence has been completed or the sentence has become no longer applicable
- (ii) A person whose permission has been rescinded pursuant to the provisions of Article 21 and for whom two years have yet to elapse since the date of the rescission
- (iii) An adult ward
- (iv) A juridical person where the officers who carry out its operations include a person(s) who falls under any of the preceding three items

#### **Article 9 (Standards for Permission)**

The Minister of Economy, Trade and Industry shall not grant permission under paragraph (1) of Article 6, unless he/she finds that the application for permission under said paragraph conforms to the following items:

- (i) The permission, if granted, shall not result in the capacity to manufacture said Class I Specified Chemical Substance excessively in light of the demand for said Class I Specified Chemical Substance.
- (ii) The manufacturing equipment shall conform to the technical standards specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.
- (iii) The applicant shall have a sufficient fiscal basis and technical capacity to implement the business appropriately.

#### **Article 10 (Permission for Changes, etc.)**

- (1) A person who has obtained permission under paragraph (1) of Article 6 (hereinafter referred to as a “permitted manufacturer”) shall receive the permission of the Ministry of Economy, Trade and Industry if he/she intends to make changes to the matters set forth in item (iv) of paragraph (2) of said Article; provided, however, that this shall not apply to the case where a person intends to make minor changes specified by an Ordinance of the Ministry of Economy, Trade and Industry.
- (2) Where a permitted manufacturer has made changes to the matters set forth in item (i) or (ii) of paragraph (2) of Article 6 or has made minor changes specified by an Ordinance of the Ministry of Economy, Trade and Industry as set forth in the proviso to the preceding paragraph, he/she shall notify the Minister of Economy, Trade and Industry to that effect without delay.
- (3) The provisions of the preceding Article shall apply mutatis mutandis to the permission under paragraph (1).
- (4) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the permission under paragraph (1) and the notification under paragraph (2).

#### **Article 11 (Permission to Import)**

- (1) A person who intends to import a Class I Specified Chemical Substance shall obtain permission from the Minister of Economy, Trade and Industry; provided, however, that this shall not apply to the case where a person intends to import a Class I Specified Chemical Substance for testing and research purposes.
- (2) A person who intends to obtain permission under the preceding paragraph shall submit a written application stating the following matters to the Minister of Economy, Trade and Industry:

- (i) The name and domicile, and in the case of a juridical person the name of the representative person
  - (ii) The name of the Class I Specified Chemical Substance
  - (iii) The import quantity
- (3) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the permission under paragraph (1).

**Article 12 (Standards for Permission, etc.)**

- (1) Where the Minister of Economy, Trade and Industry has received an application for permission under paragraph (1) of the preceding Article, he/she shall not grant permission under said paragraph unless he/she finds that the import of the Class I Specified Chemical Substance to which said application pertains is necessary for meeting the demand for said Class I Specified Chemical Substance.
- (2) The provisions of Article 8 shall apply mutatis mutandis to the permission under paragraph (1) of the preceding Article.

**Article 13 (Restrictions on Import of Products)**

- (1) No person shall import any product that is specified by a Cabinet Order and in which a Class I Specified Chemical Substance is used (hereinafter referred to as a “product using a Class I Specified Chemical Substance”).
- (2) The Cabinet Order under the preceding paragraph shall be established for each Class I Specified Chemical Substance by giving consideration to such matters as the circumstances of the use of said Class I Specified Chemical Substance overseas.

**Article 14 (Restrictions on Use)**

No person shall use a Class I Specified Chemical Substance for any usages other than those specified by a Cabinet Order for each Class I Specified Chemical Substance as being compliant with the following requirements; provided, however, that this shall not apply to the case where a person uses a Class I Specified Chemical Substance for testing and research purposes:

- (i) It shall be difficult to substitute said chemical substance with any other substance with regard to said usage.
- (ii) Said usage shall not be related to the manufacture or processing of products provided mainly for use in the daily lives of general consumers, and the use of said Class I Specified Chemical Substance for said usage shall not pose a risk of causing environmental pollution attributable to said Class I Specified Chemical Substance.

**Article 15 (Notification of Use)**

- (1) A person who intends to use a Class I Specified Chemical Substance on a regular basis shall notify the competent minister of the following matters, in advance, for each

place of business; provided, however, that this shall not apply to the case where a person intends to use a Class I Specified Chemical Substance on a regular basis for testing and research purposes:

- (i) The name and domicile, and in the case of a juridical person the name of the representative person
  - (ii) The location of the place of business
  - (iii) The name of the Class I Specified Chemical Substance and the usage
- (2) Where a person who has given a notification under the preceding paragraph (hereinafter referred to as a “notifying user”) has made any changes to the matters under the items of the preceding paragraph, he/she shall notify the competent minister to that effect without delay.
- (3) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the notification under the preceding two paragraphs.

#### **Article 16 (Succession)**

- (1) Where a permitted manufacturer, a person who has obtained permission under paragraph (1) of Article 11 (hereinafter referred to as a “permitted importer”), or a notifying user has become subject to inheritance or a merger, the heir (where there are two or more heirs and an heir who should succeed to the business has been selected by their unanimous consent, such person who has been selected) or the juridical person surviving the merger or the juridical person incorporated by the merger shall succeed to the status of the permitted manufacturer, the permitted importer, or the notifying user.
- (2) A person who has succeeded to the status of permitted manufacturer, permitted importer, or notifying user pursuant to the provisions of the preceding paragraph shall notify the Minister of Economy, Trade and Industry, in the case of a person who has succeeded to the status of permitted manufacturer or a permitted importer, and notify the competent minister, in the case of a person who has succeeded to the status of notifying user, to that effect without delay together with a document proving such fact.
- (3) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the notification under the preceding paragraph. In this case, the term “Minister of Economy, Trade and Industry” in paragraph (3) of said Article shall be deemed to be replaced with “Minister of Economy, Trade and Industry or the competent minister.”

#### **Article 17 (Obligation of Conformity to Standards)**

- (1) A permitted manufacturer shall maintain its manufacturing equipment in such a manner as to conform to the technical standards specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment under item (ii) of Article 9.

- (2) Where a notifying user uses a Class I Specified Chemical Substance, he/she shall follow the technical standards specified by an ordinance of the competent ministry.

#### **Article 18 (Order for Improvement)**

- (1) Where the Minister of Economy, Trade and Industry finds that the manufacturing equipment of a permitted manufacturer does not conform to the technical standards specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment under item (ii) of Article 9, he/she may order said permitted manufacturer to repair or remodel the manufacturing equipment or to take any other necessary measures.
- (2) Where the competent minister finds that a notifying user fails to use a Class I Specified Chemical Substance in accordance with the technical standards specified by an ordinance of the competent ministry under paragraph (2) of the preceding Article, he/she may order said notifying user to take the necessary measures for improving the method of use of the Class I Specified Chemical Substance.

#### **Article 19 (Books)**

- (1) A permitted manufacturer shall keep books and enter therein the items specified by an Ordinance of the Ministry of Economy, Trade and Industry with respect to the manufacture of the Class I Specified Chemical Substance.
- (2) The books under the preceding paragraph shall be preserved in accordance with the provisions of an Ordinance of the Ministry of Economy, Trade and Industry.
- (3) The provisions of the preceding two paragraphs shall apply mutatis mutandis to a notifying user. In this case, the term “an Ordinance of the Ministry of Economy, Trade and Industry” in these provisions shall be deemed to be replaced with “ministerial ordinance of the competent ministry.”

#### **Article 20 (Notification of Abolition)**

- (1) Where a permitted manufacturer or a notifying user has abolished his/her business, he/she shall notify the Minister of Economy, Trade and Industry, in the case of a permitted manufacturer, and notify the competent minister, in the case of a notifying user, to that effect without delay.
- (2) Where a permitted manufacturer has discontinued his/her business, the relevant permission shall lose its effect.
- (3) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the notification under paragraph (1). In this case, the term “Minister of Economy, Trade and Industry” in paragraph (3) of said Article shall be deemed to be replaced with “Minister of Economy, Trade and Industry or the competent minister.”

**Article 21 (Rescission of Permission, etc.)**

- (1) Where a permitted manufacturer falls under any of the following items, the Minister of Economy, Trade and Industry may rescind the relevant permission or order the suspension of business for a specified period:
  - (i) Where the permitted manufacturer has fallen under item (i), (iii) or (iv) of Article 8
  - (ii) Where the permitted manufacturer has made any changes to matters for which permission must be obtained pursuant to the provisions of paragraph (1) of Article 10 without obtaining such permission
  - (iii) Where the permitted manufacturer has violated an order under the provisions of paragraph (1) of Article 18
  - (iv) Where the permitted manufacturer has violated the conditions under paragraph (1) of Article 31
- (2) Where a permitted importer has fallen under item (i), (iii) or (iv) of Article 8 as applied mutatis mutandis pursuant to paragraph (2) of Article 12, the Minister of Economy, Trade and Industry may rescind the relevant permission, but only prior to the import of the Class I Specified Chemical Substance to which the permission pertains.
- (3) The provisions of paragraph (3) of Article 6 shall apply mutatis mutandis to the rescission of permission under the preceding two paragraphs or an order to suspend business under paragraph (1).

**Article 22 (Order to Take Measures in Connection with Designation, etc. of Class I Specified Chemical Substances)**

- (1) Where any chemical substance has been designated as a Class I Specified Chemical Substance, if the competent ministers find it particularly necessary for preventing the spread of environmental pollution attributable to said chemical substance, they may, to the extent necessary, order persons who were operating the business of manufacturing or importing said chemical substance or a product in which said chemical substance is used at the time of said designation to make efforts to recall said chemical substance or said product and to take any other measures necessary for preventing the spread of environmental pollution attributable to said chemical substance.
- (2) Where any product has been designated as a product using a Class I Specified Chemical Substance, if the competent ministers find it particularly necessary for preventing the spread of environmental pollution attributable to the Class I Specified Chemical Substance being used in said product, they may, to the extent necessary, order persons who were operating the business of importing said product at the time of said designation to make efforts to recall said product which they imported and to take any other measures necessary for preventing the spread of environmental pollution attributable to the Class I Specified Chemical Substance being used in said product.
- (3) In any of the cases listed in the following items, if the competent ministers find it

particularly necessary for preventing the spread of environmental pollution attributable to the Class I Specified Chemical Substance, they may, to the extent necessary, order the persons respectively specified in those items to make efforts to recall the Class I Specified Chemical Substance which they manufactured, imported or used or the product using a Class I Specified Chemical Substance which they imported and to take any other measures necessary for preventing the spread of environmental pollution attributable to said Class I Specified Chemical Substance:

- (i) Where a Class I Specified Chemical Substance has been manufactured in violation of the provisions of Article 7-the person who has manufactured said Class I Specified Chemical Substance
- (ii) Where a Class I Specified Chemical Substance has been imported in violation of the provisions of paragraph (1) of Article 11-the person who has imported said Class I Specified Chemical Substance
- (iii) 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 has imported said product using a Class I Specified Chemical Substance
- (iv) Where a Class I Specified Chemical Substance has been used in violation of the provisions of Article 14-the person who has used 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**

###### **Article 23 (Notification of the Quantity of Manufacture, etc.)**

- (1) A person who has manufactured or imported any Type II Monitoring Chemical Substance shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or quantity of import in the preceding fiscal year and other matters specified by an Ordinance of the Ministry of Economy, Trade and Industry for each Type II Monitoring Chemical Substance, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry; provided, however, that this shall not apply to the case where the person has manufactured or imported a Type II Monitoring Chemical Substance for testing and research purposes.
- (2) The Minister of Economy, Trade and Industry shall publicize, each fiscal year, the sum of the quantity of manufacture and quantity of import in the preceding fiscal year to which the notification under the preceding paragraph pertains for each Type II Monitoring Chemical Substance; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Type II Monitoring Chemical Substance is less than the quantity specified by an Ordinance of the Ministry of Economy, Trade and Industry.

#### **Article 24 (Study of Hazardous Properties of Type II Monitoring Chemical Substances)**

- (1) In the case where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have, with regard to any single Type II Monitoring Chemical Substance, found it necessary to make a determination as to whether or not said Type II Monitoring Chemical Substance falls under item (i) of paragraph (3) of Article 2 since said Type II Monitoring Chemical Substance poses a risk of causing damage to human health through environmental pollution if said Type II Monitoring Chemical Substance falls under said item, in view of the results of the tests under paragraph (8) of Article 2 and other available knowledge concerning said Type II Monitoring Chemical Substance as well as the state of its manufacture, import, use, etc., they may, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, instruct a person operating the business of manufacturing or importing said Type II Monitoring Chemical Substance (including a person who has operated such business formerly and who is specified by an Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment (which means a study on the effects of said chemical substance on human health if ingested continuously; the same shall apply in paragraph (3)) and to report the results thereof.
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a report under the preceding paragraph, they shall make a determination as to whether or not the Type II Monitoring Chemical Substance to which said report pertains falls under item (i) of paragraph (3) of Article 2 and notify the result thereof to the person who has made the report.
- (3) The Minister of Economy, Trade and Industry may, when he/she finds it particularly necessary for ensuring that the expenses for the study of the hazardous properties to which the instruction under the provisions of paragraph (1) pertains are shared out fairly among the business operators concerned, establish standards concerning the method and proportions of the sharing of expenses required for said study of hazardous properties.

#### **Article 25 (Rescission of Designation as a Type II Monitoring Chemical Substance)**

When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find that a Type II Monitoring Chemical Substance falls under either of the following items, they shall rescind the designation and publicize to that effect without delay:

- (i) Where said chemical substance has been designated as a Class II Specified Chemical Substance as a result of falling under item (i) of paragraph (3) of Article 2 (including the case where a Type II Monitoring Chemical Substance has been designated as a Class II Specified Chemical Substance as a result of falling under item (ii) of said paragraph and said Type II Monitoring Chemical Substance has been found subsequently to fall under item (i) of said paragraph)
- (ii) Where said chemical substance has been found not to fall under item (i) of paragraph (3) of Article 2, based on a report under paragraph (1) of the preceding Article or on knowledge that has been otherwise obtained.

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

### **Article 25-2 (Notification of the Quantity of Manufacture, etc.)**

- (1) A person who has manufactured or imported any Type III Monitoring Chemical Substance (excluding one that has been publicly notified by the Minister of Economy, Trade and Industry and the Minister of the Environment pursuant to the provisions of paragraph (2) of Article 25-4; hereinafter the same shall apply in this Article and the following Article) shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or quantity of import in the preceding fiscal year and any other matters specified by an Ordinance of the Ministry of Economy, Trade and Industry for each Type III Monitoring Chemical Substance, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry; provided, however, that this shall not apply to the case where the person has manufactured or imported a Type III Monitoring Chemical Substance for testing and research purposes.
- (2) The Minister of Economy, Trade and Industry shall publicize, each fiscal year, the sum of the quantity of manufacture and quantity of import in the preceding fiscal year to which the notification under the preceding paragraph pertains for each Type III Monitoring Chemical Substance; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Type III Monitoring Chemical Substance is less than the quantity specified by an Ordinance of the Ministry of Economy, Trade and Industry.

### **Article 25-3 (Study of Hazardous Properties of Type III Monitoring Chemical Substances)**

- (1) In the case that the Minister of Economy, Trade and Industry and the Minister of the Environment have, with regard to any single Type III Monitoring Chemical Substance, found it necessary to make a determination as to whether or not said Type III Monitoring Chemical Substance falls under item (ii) of paragraph (3) of Article 2 since said Type III Monitoring Chemical Substance poses a risk of causing damage to the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution if said Type III Monitoring Chemical Substance falls

- under said item, in view of the results of the tests prescribed in paragraph (7) of Article 4 (including the cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2) and any other available knowledge concerning said Type III Monitoring Chemical Substance as well as the state of its manufacture, import, use, etc., they may, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry and Ordinance of the Ministry of the Environment, instruct a person operating the business of manufacturing or importing said Type III Monitoring Chemical Substance (including a person who operated such business formerly and who is specified by an Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by an Ordinance of the Ministry of Economy, Trade and Industry and Ordinance of the Ministry of the Environment (which means a study on the effects of said chemical substance on the inhabitation and/or growth of flora and fauna in the human living environment if ingested continuously; the same shall apply in paragraph (3)) and to report the results thereof.
- (2) Where the Minister of Economy, Trade and Industry and the Minister of the Environment have received a report under the preceding paragraph, they shall make a determination as to whether or not the Type III Monitoring Chemical Substance to which said report pertains falls under item (ii) of paragraph (3) of Article 2 and notify the result thereof to the person who has made the report.
- (3) The Minister of Economy, Trade and Industry may, when he/she finds it particularly necessary for ensuring that the expenses for the study of hazardous properties to which the instruction under the provisions of paragraph (1) pertains are shared out fairly among the business operators concerned, he/she may establish standards concerning the method and proportions of the sharing of expenses required for said study of hazardous properties.

**Article 25-4 (Rescission of Designation as a Type III Monitoring Chemical Substance)**

- (1) Where a Type III Monitoring Chemical Substance has been designated as a Class II Specified Chemical Substance as a result of falling under item (ii) of paragraph (3) of Article 2 (including the case where a Type III Monitoring Chemical Substance has been designated as a Class II Specified Chemical Substance as a result of falling under item (i) of said paragraph and said Type III Monitoring Chemical Substance has been found subsequently to fall under item (ii) of said paragraph), the Minister of Economy, Trade and Industry and the Minister of the Environment shall rescind the designation as a Type III Monitoring Chemical Substance and publicize to that effect without delay.
- (2) Where the Minister of Economy, Trade and Industry and the Minister of the Environment have found that a Type III Monitoring Chemical Substance does not fall under item (ii) of paragraph (3) of Article 2, based on a report under paragraph (1) of the preceding Article or on knowledge that has been otherwise obtained, they shall give public notice of the name of said Type III Monitoring Chemical Substance without

delay.

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

#### **Article 26 (Notification of the Planned Quantity of Manufacture, etc.)**

- (1) 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, notify the Minister of Economy, Trade and Industry, each fiscal year, of the planned quantity of manufacture or planned quantity of import of said Class II Specified Chemical Substance or the planned quantity of import of said product using a Class II Specified Chemical Substance, and other matters specified by an Ordinance of the Ministry of Economy, Trade and Industry, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry; provided, however, that this shall not apply to the case where a person manufactures or imports a Class II Specified Chemical Substance or imports a product using a Class II Specified Chemical Substance for testing and research purposes.
- (2) Where a person who has given a notification under the provisions of the preceding paragraph has made changes to the matters to which the notification under said paragraph pertains, he/she shall notify the Minister of Economy, Trade and Industry to that effect without delay.
- (3) A person who has given 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 to which said notification pertains (where a notification of change under the provisions of the preceding paragraph has been given, such quantity after the change).
- (4) In the case of the occurrence of a situation where it is necessary to restrict the manufacture or import of a Class II Specified Chemical Substance or the import of a product using a Class II Specified Chemical Substance in order to prevent damage to human health or to the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution attributable to said Class II Chemical Substance, in light of the state of the manufacture, import, use, etc. of said Class II Specified Chemical Substance or product using a Class II Specified Chemical Substance as well as the effects of the implementation of measures under the provisions of the following Article and Article 28 taken in relation to said Class II Specified Chemical Substance, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall make an acknowledgement to that effect, pursuant to the provisions of an Ordinance of

the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.

- (5) Where the acknowledgment under the preceding paragraph has been made, the Minister of Economy, Trade and Industry may order the person who has given a notification under the provisions of paragraph (1) to change the planned quantity of manufacture or the planned quantity of import to which said notification pertains (where a notification of change under the provisions of paragraph (2) has been given, the quantity after the change). In this case, the provisions of paragraph (3) shall apply *mutatis mutandis*.
- (6) A person who has given a notification under the provisions of paragraph (1) shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or the quantity of import in the preceding fiscal year and other matters specified by an Ordinance of the Ministry of Economy, Trade and Industry, for each Class II Specified Chemical Substance or each product using a Class II Specified Chemical Substance, pursuant to the provisions of an Ordinance of the Ministry of Economy, Trade and Industry.
- (7) The provisions of paragraph (2) of Article 13 shall apply *mutatis mutandis* to the Cabinet Order set forth in paragraph (1).

#### **Article 27 (Publication of Technical Guidelines, etc.)**

- (1) For each Class II Specified Chemical Substance, the competent ministers shall publicize technical guidelines on measures to be taken by persons who operate the business of manufacturing said Class II Specified Chemical Substance, persons who use said Class II Specified Chemical Substance on a regular basis, and any other persons who handle said Class II Specified Chemical Substance on a regular basis (hereinafter referred to as a “handler” in this section) in order to prevent environmental pollution attributable to the Class II Specified Chemical Substance they handle.
- (2) Where the competent ministers have publicized technical guidelines pursuant to the provisions of the preceding paragraph, if they find it necessary, they may make a necessary recommendation to a handler of said Class II Specified Chemical Substance with regard to the measures that should be taken for preventing environmental pollution attributable to said Class II Specified Chemical Substance, by taking said technical guidelines into consideration.

#### **Article 28 (Labeling, etc.)**

- (1) For each Class II Specified Chemical Substance, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall determine and publicize the labeling information with respect to measures, etc., for preventing environmental pollution attributable to said Class II

Specified Chemical Substances, to be indicated on containers, packaging, or invoices for the Class II Specified Chemical Substance or products that are specified by a Cabinet Order and in which the Class II Specified Chemical Substance is used.

- (2) Where a handler transfers or provides a Class II Specified Chemical Substance or a product that is specified by a Cabinet Order and in which a Class II Specified Chemical Substance is used as set forth in the preceding paragraph, he/she shall, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment, implement labeling in accordance with the public notice given pursuant to the provisions of said paragraph.
- (3) In the case where any handler has violated the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may recommend said handler to implement labeling in accordance with the public notice given pursuant to the provisions of paragraph (1).

## **Chapter 5 Miscellaneous Provisions**

### **Article 29 (Recommendations)**

- (1) Where the competent ministers find a sufficient reason to suspect that a chemical substance other than a Class I Specified Chemical Substance falls under any of the items of paragraph (2) of Article 2, they may, to the extent necessary for preventing the spread of environmental pollution attributable to said chemical substance, make any necessary recommendation concerning a restriction on the manufacture, import, use, etc. of said chemical substance to a person operating the business of manufacturing or importing said chemical substance or to a person using said chemical substance on a regular basis.
- (2) Where the competent ministers find a sufficient reason to suspect that a chemical substance other than a Class II Specified Chemical Substance falls under the requirements set forth in paragraph (3) of Article 2, they may, to the extent necessary for preventing the spread of environmental pollution attributable to said chemical substance, make any necessary recommendation concerning a restriction on the manufacture or import of said chemical substance or an improvement in the method of use of said chemical substance to a person operating the business of manufacturing or importing said chemical substance or to a person using said chemical substance on a regular basis.

### **Article 30 (Guidance and Advice)**

Where the competent ministers find it particularly necessary for preventing environmental pollution attributable to a Type I Monitoring Chemical Substance, a Type

II Monitoring Chemical Substance or a Type III Monitoring Chemical Substance (hereinafter collectively referred to as a “monitoring chemical substance”) or a Class II Specified Chemical Substance, they may provide a person operating the business of manufacturing said monitoring chemical substance or Class II Specified Chemical Substance, or a person using said monitoring chemical substance or Class II Specified Chemical Substance on a regular basis, or any other person handling said monitoring chemical substance or Class II Specified Chemical Substance on a regular basis with the necessary guidance and advice concerning the method of handling the chemical substance.

**Article 31 (Conditions for Permission)**

- (1) Conditions may be attached to any permission, and the conditions attached may be changed.
- (2) The conditions under the preceding paragraph shall be limited to the minimum required for ensuring the secure implementation of the matters to which the permission pertains, and shall not impose undue obligations on the person who obtains the permission.

**Article 31-2 (Reporting, etc., of Hazardous Properties)**

- (1) A person operating the business of manufacturing or importing any monitoring chemical substance, any Class II Specified Chemical Substance, any chemical substance that has been publicly notified pursuant to the provisions of paragraph (4) of Article 4 (including the cases in which it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2 and the cases in which it is applied mutatis mutandis pursuant to paragraph (2) of Article 5-2), any new chemical substance to which the confirmation under item (v) of paragraph (1) of Article 3 or paragraph (4) of Article 4-2 pertains, or any chemical substance listed in the List of Existing Chemical Substances prescribed in paragraph (1) of Article 2 of the Supplementary Provisions that has been publicly notified by the Minister of International Trade and Industry pursuant to the provisions of paragraph (4) of said Article (hereinafter referred to as a “substance subject to reporting”) shall, when he/she has conducted tests pertaining to the items to be tested prescribed in paragraph (7) of Article 4 or pertaining to the studies of hazardous properties prescribed in paragraph (1) of Article 5-4, paragraph (1) of Article 24, or paragraph (1) of Article 25-3 (including the cases in which knowledge equivalent to that which would be obtained from said tests [limited to knowledge that is not publicly known] has been obtained) with regard to the substance subject to reporting he/she has manufactured or imported and if he/she has obtained, as a result thereof, knowledge specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment as one indicating that the substance subject to reporting

possesses the following properties, report to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment to that effect and the details of said knowledge, pursuant to the provisions of an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment; provided, however, that this shall not apply to the case where said person has obtained said knowledge as a result of a study of hazardous properties to which an instruction under the provisions of paragraph (1) of Article 5-4, paragraph (1) of Article 24, or paragraph (1) of Article 25-3 pertains and is reporting the details of said knowledge pursuant to these provisions:

- (i) The substance subject to reporting is not likely to undergo a chemical transformation through natural processes.
  - (ii) The substance subject to reporting is bioaccumulative.
  - (iii) The substance subject to reporting poses a risk of impairing human health if ingested continuously.
  - (iv) The substance subject to reporting poses a risk of interfering with the inhabitation and/or growth of flora and fauna.
  - (v) In the case that the substance subject to reporting is likely to undergo a chemical transformation through natural processes, it is one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under any of the preceding items.
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have found, based on a report under the preceding paragraph or knowledge that has been otherwise obtained, that any substance subject to reporting falls under any of the items of paragraph (2), any of the items of paragraph (3), any of the items of paragraph (4), or any of the items of paragraph (6) of Article 2, or is suspected of falling under item (i) of paragraph (3) of said Article, they shall make a designation as a Class I Specified Chemical Substance and take any other necessary measures without delay.

### **Article 32 (Collection of Reports)**

- (1) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may, to the extent necessary for enforcing this Act, have a person who has received a confirmation under item (iv) or item (v) of paragraph (1) of Article 3 or under paragraph (4) of Article 4-2 make a report concerning his/her operations.
- (2) The Minister of Economy, Trade and Industry or the competent minister may, to the extent necessary for enforcing this Act, have, respectively, a permitted manufacturer, a permitted importer, a notifying user, or a person who has given a notification under the provisions of paragraph (1) of Article 26 make a report concerning his/her

operations.

- (3) The competent ministers may, to the extent necessary for enforcing this Act, have a person prescribed in Article 22 or Article 29 make a report concerning his/her operations.

**Article 33 (On-Site Inspections, etc.)**

- (1) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may, to the extent necessary for enforcing this Act, have their officials enter the offices or any other places of business of a person who has received a confirmation under item (iv) or (v) of paragraph (1) of Article 3 or paragraph (4) of Article 4-2, inspect the books, documents, and any other articles, ask questions of the relevant persons, or 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 for enforcing this Act, have their officials enter the offices or any other places of business of a permitted manufacturer, permitted importer, notifying user or person who has given a notification under the provisions of paragraph (1) of Article 26, inspect the books, documents, and any other articles, ask questions of the relevant persons, or sample the smallest quantity of chemical substances necessary for testing.
- (3) The competent ministers may, to the extent necessary for enforcing this Act, have their officials enter the offices or any other places of business of a person prescribed in Article 22, inspect the books, documents and any other articles, ask questions of the relevant persons, or sample the smallest quantity of chemical substances necessary for testing.
- (4) Where an official enters a site pursuant to the provisions of the preceding three paragraphs, he/she shall carry an identification card and present it to the relevant persons.
- (5) Where the Minister of Economy, Trade and Industry finds it necessary, he/she may have the National Institute of Technology and Evaluation (hereinafter referred to as "NITE") conduct the on-site inspection, questioning, or taking of samples under the provisions of paragraphs (1) to (3).
- (6) Where the Minister of Economy, Trade and Industry has NITE conduct the on-site inspection, questioning, or taking of samples pursuant to the provisions of the preceding paragraph, he/she shall instruct NITE to conduct such on-site inspection, questioning or taking of samples by indicating the place of said on-site inspection and any other necessary matters.
- (7) Where NITE has conducted the on-site inspection, questioning, or taking of samples prescribed in paragraph (5), in accordance with the instructions under the preceding paragraph, it shall report the results thereof to the Minister of Economy, Trade and

Industry.

- (8) Where an official of NITE enters a site pursuant to the provisions of paragraph (5), he/she shall carry an identification card and present it to the relevant persons.
- (9) The authority for the on-site inspection, questioning, and taking of samples under the provisions of paragraphs (1) to (3) shall not be construed as an authority granted for the purpose of criminal investigation.

#### **Article 33-2 (Orders to NITE)**

Where the Minister of Economy, Trade and Industry finds it necessary for securing the proper implementation of operations relating to the on-site inspection, questioning, or taking of samples prescribed in paragraph (5) of the preceding Article, he/she may issue the necessary orders concerning said operations to NITE.

#### **Article 33-3 (Request for Examination Regarding the Taking of Samples by NITE )**

Any person who is dissatisfied with the taking of samples by NITE may file a request for examination under the Administrative Appeals Act (Act No. 160 of 1962) with the Minister of Economy, Trade and Industry.

#### **Article 34 (Requests)**

Where the Minister of the Environment finds it necessary to achieve the purpose of this Act, he/she may request the ministers listed in the following items to take the measures set forth respectively in those items:

- (i) An order prescribed in paragraph (1) of Article 18-the Minister of Economy, Trade and Industry
- (ii) An order prescribed in paragraph (2) of Article 18-the competent minister

#### **Article 35 (Fees)**

A person who intends to obtain permission under paragraph (1) of Article 6, paragraph (1) of Article 10, or paragraph (1) of Article 11 shall pay a fee of the amount specified by a Cabinet Order in consideration of the actual expenses.

#### **Article 36 (Special Provisions on Hearings)**

- (1) Where the Minister of Economy, Trade and Industry intends to issue an order under the provisions of paragraph (1) of Article 21, he/she shall hold a hearing, regardless of the category of the procedure for hearing statements of opinion under the provisions of paragraph (1) of Article 13 of the Administrative Procedure Act (Act No. 88, 1993).
- (2) The proceedings on the date of a hearing to which a disposition under the provisions of Article 21 pertains shall be held in public.
- (3) The presiding official of a hearing under the preceding paragraph shall, where an interested person to which said disposition pertains has requested to intervene in the

hearing process pursuant to the provisions of paragraph (1) of Article 17 of the Administrative Procedure Act, permit said person to do so.

#### **Article 37 (Hearing of Opinion in Procedures for Objection)**

- (1) A decision on an objection against any disposition under the provisions of this Act (excluding a decision to dismiss the objection) shall be made after giving an advance notice with a reasonable period of time to the person to which the disposition pertains and after a public hearing of opinions.
- (2) The date, location, and details of the case shall be indicated in a prior notice under the preceding paragraph.
- (3) At a hearing of opinions under paragraph (1), the person to which said disposition pertains and the interested person shall be given an opportunity to produce evidence and state their opinions with regard to the case.

#### **Article 38 (Transitional Measures)**

Where an order is established, revised, or abolished based on the provisions of this Act, required transitional measures (including transitional measures concerning penal provisions) may be specified by said order to the extent found reasonably necessary in line with the establishment, revision or abolition thereof.

#### **Article 39 (Competent Ministers, etc.)**

- (1) The competent ministers under this Act shall be as follows:
  - (i) With regard to a notification under the provisions of Article 15, paragraph (2) of Article 16, or paragraph (1) of Article 20, an order under the provisions of paragraph (2) of Article 18, the collection of reports under the provisions of paragraph (2) of Article 32, or the inspection, questioning, or taking of samples under the provisions of paragraph (2) of Article 33, the minister having jurisdiction over the business operated by the person giving such a notification or the person subject to such an order, the collection of reports or inspection, questioning, or taking of samples
  - (ii) With regard to an order under the provisions of Article 22, the publication of technical guidelines under the provisions of paragraph (1) of Article 27, a recommendation under the provisions of paragraph (2) of said Article or Article 29, guidance and advice (excluding those pertaining to a Type III Monitoring Chemical Substance) under the provisions of Article 30, the collection of reports under the provisions of paragraph (3) of Article 32, or the inspection, questioning or taking of samples under the provisions of paragraph (3) or Article 33, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, the Minister of the Environment and the minister having jurisdiction over the business operated by the person subject to such an order, the publication of technical guidelines, recommendation, guidance and advice, collection of reports or inspection,

questioning, or taking of samples

(iii) With regard to guidance and advice (limited to those pertaining to a Type III Monitoring Chemical Substance) under the provisions of Article 30, the Minister of Economy, Trade and Industry, the Minister of the Environment, and the minister having jurisdiction over the business operated by the person subject to such guidance and advice

(2) An ordinance of the competent ministry under this Act shall be as follows:

(i) With regard to the keeping, entering, and preservation of books under the provisions of paragraphs (1) and (2) of Article 19 as applied mutatis mutandis pursuant to paragraph (3) of said Article, an order issued by the minister having jurisdiction over the business operated by a person using a Class I Specified Chemical Substance

(ii) With regard to the technical standards under the provisions of paragraph (2) of Article 17, an order issued by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, the Minister of the Environment and the minister having jurisdiction over the business operated by a person using a Class I Specified Chemical Substance

#### **Article 39-2 (Delegation of Authority)**

The authority of the Minister of the Environment prescribed in this Act may be delegated to the Director Generals of the Regional Environment Offices.

#### **Article 40 (Relationship with Other Acts)**

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 which constitute the articles listed in the following items, the provisions of paragraph (1) or Article 13 and Article 22 shall not apply to the products listed in the following items 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 articles listed in the following items 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 articles listed in the following items, but the Acts set forth in the following items shall apply to them respectively:

(i) Food prescribed in paragraph (1) of Article 4 of the Food Sanitation Act (Act No. 233 of 1947), additives prescribed in paragraph (2) of said Article, containers and

packaging prescribed in paragraph (5) of said Article, toys prescribed in paragraph (1) of Article 29 of said Act, and detergents prescribed in paragraph (2) of said Article

- (ii) Agricultural chemicals prescribed in paragraph (1) of Article 1-2 of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948)
- (iii) Ordinary fertilizers prescribed in paragraph (2) of Article 2 of the Fertilizers Regulation Act (Act No. 127 of 1950)
- (iv) Feeds prescribed in paragraph (2) of Article 2 of the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953) and feed additives prescribed in paragraph (3) of said Article
- (v) Drugs prescribed in paragraph (1) of Article 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), quasi-drugs prescribed in paragraph (2) of said Article, cosmetics prescribed in paragraph (3) of said Article, and medical equipment prescribed in paragraph (4) of said Article

#### **Article 41 (Hearing of Opinion of Councils)**

- (1) In the following cases, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall hear the opinions of the councils, etc., (organizations prescribed in Article 8 of the National Government Organization Act [Act No. 120 of 1948]; the same shall apply in the following paragraph) that are specified by a Cabinet Order, in advance:
  - (i) When intending to plan out the establishment or revision of a Cabinet Order under paragraph (2) of Article 2 (excluding the case of intending to plan out such establishment or revision based on a determination under paragraph (1) or (2) of Article 4, paragraph (8) of Article 4-2, or paragraph (2) of Article 5-4), or when intending to plan out the establishment or revision of a Cabinet Order under paragraph (3) of Article 2, paragraph (1) of Article 13, Article 14 or paragraph (1) of Article 26
  - (ii) When intending to make a designation under paragraph (4) or (5) of Article 2 (excluding the case of intending to make such designation based on a determination under paragraph (1) or (2) of Article 4 or paragraph (8) of Article 4-2)
  - (iii) When intending to make a determination 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
  - (iv) When intending to give an instruction under paragraph (1) of Article 5-4 or paragraph (1) of Article 24
  - (v) When intending to make an acknowledgment under paragraph (4) of Article 26
- (2) The Minister of Economy, Trade and Industry and the Minister of the Environment shall hear the opinions of councils, etc., specified by a Cabinet Order, in advance, when intending to make a designation under paragraph (6) of Article 2 (excluding the case of

intending to make such designation based on a determination under paragraph (1) or (2) of Article 4 or paragraph (8) of Article 4-2), when intending to give an instruction under paragraph (1) of Article 25-3, or when intending to make a determination under paragraph (2) of said Article.

## **Chapter 6 Penal Provisions**

### **Article 42**

A person who falls under any of the following items shall be punished by imprisonment with work for not more than three years or a fine of not more than one million yen, or both:

- (i) A person who has operated the business of manufacturing a Class I Specified Chemical Substance without obtaining permission under paragraph (1) of Article 6
- (ii) A person who has violated the provisions of Article 7, paragraph (1) of Article 13, or Article 14
- (iii) A person who has imported a Class I Specified Chemical Substance in violation of the provisions of paragraph (1) of Article 11
- (iv) A person who has violated an order to suspend business under the provisions of paragraph (1) of Article 21
- (v) A person who has violated an order under the provisions of paragraph (3) Article 22

### **Article 43**

A person who falls under any of the following items shall be punished by imprisonment with work for not more than one year or a fine of not more than five hundred thousand yen, or both:

- (i) A person who has manufactured or imported a new chemical substance in violation of the provisions of paragraph (1) of Article 3
- (ii) A person who has violated the provisions of Article 5
- (iii) A person who has violated an instruction under the provisions of paragraph (1) of Article 5-4, paragraph (1) of Article 24, or paragraph (1) of Article 25-3
- (iv) A person who has manufactured or imported a Class II Specified Chemical Substance or has imported a product using a Class II Specified Chemical Substance in violation of the provisions of paragraph (1) or (3) of Article 26 (including the cases where it is applied mutatis mutandis pursuant to paragraph (5) of said Article)

### **Article 44**

A person who falls under any of the following items shall be punished by imprisonment with work for not more than six months or a fine of not more than five hundred thousand yen, or both:

- (i) A person who has made changes in the structure or capacity of manufacturing

- equipment in violation of the provisions of paragraph (1) of Article 10
- (ii) A person who has failed to give a notification or has given a false notification in violation of the provisions of paragraph (1) of Article 15
  - (iii) A person who has violated an order under the provisions of Article 18 or paragraph (1) or (2) of Article 22

#### **Article 45**

A person who falls under any of the following items shall be punished by a fine of not more than three hundred thousand yen:

- (i) A person who has failed to keep books or make entries in them or has made false entries in them in violation of the provisions of paragraph (1) of Article 19 (including the cases where it is applied mutatis mutandis pursuant to paragraph (3) of said Article), or has failed to preserve the books in violation of the provisions of paragraph (2) of said Article (including the cases where it is applied mutatis mutandis pursuant to paragraph (3) of said Article)
- (ii) A person who has failed to give a 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 or has given a false notification
- (iii) A person who has failed to make a report under the provisions of Article 32 or has made a false report
- (iv) A person who has refused, obstructed, or evaded an inspection or the taking of samples under the provisions of paragraphs (1) to (3) of Article 33 or has refused to answer or has given a false answer to the questioning under these provisions

#### **Article 46**

Where the representative person of a juridical person, or an agent, employee or any other worker of a juridical person or individual has committed an act in violation of any of the provisions listed in the following items with regard to the business of said juridical person or individual, not only the offender shall be punished but also said juridical person shall be punished by the fine prescribed in said relevant item or said individual shall be punished by the fine prescribed in the relevant Article:

- (i) Article 42-A fine of not more than one hundred million yen
- (ii) Item (i), (ii) or (iv) of Article 43-A fine of not more than five hundred thousand yen
- (iii) Item (iii) of Article 43, Article 44, or the preceding Article-The fine prescribed in the relevant Article

#### **Article 47**

A person who falls under either of the following items shall be punished by a non-penal fine of not more than two hundred thousand yen:

- (i) A person who has failed to give a 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, or paragraph (2) of Article 26 or has given a false notification

- (ii) A person who has failed to make a report under the provisions of paragraph (1) of 31-2 or has submitted a false report

#### **Article 48**

In the case where an order under the provisions of Article 33-2 has been violated, an officer or officers of NITE who have committed said act in violation shall be punished by a non-penal fine of not more than two hundred thousand yen.

#### **Supplementary Provisions (Extract)**

##### **Article 1 (Effective Date)**

This Act shall come into effect as from the day on which six months have elapsed from the day of promulgation; provided, however, that the provisions of the following Article shall come into effect as from the day of promulgation.

##### **Article 2 (List of Existing Chemical Substances)**

- (1) The Minister of International Trade and Industry shall prepare a list (hereinafter referred to as the "List of Existing Chemical Substances") of the names of chemical substances that were manufactured or imported on a regular basis at the time of the promulgation of this Act (excluding those that were manufactured or imported for testing and research purposes and those that were manufactured or imported as reagents) and give public notice of it within three months from the day of the promulgation of this Act.
- (2) Any person may, when he/she finds it necessary to correct the List of Existing Chemical Substances of which public notice has been given pursuant to the provisions of the preceding paragraph, propose to that effect to the Minister of International Trade and Industry, pursuant to the provisions of an Ordinance of the Ministry of International Trade and Industry, only within one month from the day of the publication of the List of Existing Chemical Substances.
- (3) In the case where a proposal under the preceding paragraph has been made, if the Minister of International Trade and Industry finds grounds for said proposal, he/she shall add the name of the chemical substance to which said proposal pertains to the List of Existing Chemical Substances or delete it from the List of Existing Chemical Substances, and shall notify the person who has made the proposal to that effect.
- (4) The Minister of International Trade and Industry shall give public notice of the List of Existing Chemical Substances that has undergone any additions or deletions under the provisions of the preceding paragraph by one month prior to the date of enforcement of this Act.

### **Article 3 (Transitional Measures)**

The provisions of paragraph (1) of Article 3 shall apply to a person who was, at the time of the enforcement of this Act, operating the business of manufacturing or importing any chemical substances other than the chemical substances listed in the List of Existing Chemical Substances of which public notice has been given pursuant to the provisions of paragraph (4) of the preceding Article, by deeming said person to be a person prescribed in paragraph (1) of Article 3. In this case, the term “in advance” shall be deemed to be replaced with “within one month from the day of the enforcement of this Act.”

### **Article 4**

Where tests prescribed in paragraph (7) of Article 4 have been conducted (including the case where knowledge equivalent to that which would be obtained from said tests has been obtained) on any of the chemical substances listed in the List of Existing Chemical Substances of which public notice has been given by the Minister of International Trade and Industry pursuant to the provisions of paragraph (4) of Article 2 of the Supplementary Provisions (including chemical substances that have come to be newly manufactured or imported after the enforcement of this Act, other than the chemical substances listed in items (2) to (4) of paragraph (7) of Article 2 [for chemical substances listed in item (iii) of the same Article, they shall be limited to substances that fall under item (i) of paragraph (3) of the same Article]) for which the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment find it necessary to conduct said tests, the results of said tests (including the knowledge obtained in the case where knowledge equivalent to that which would be obtained from said tests has been obtained) shall be deemed to be the results of the tests under paragraph (7) of Article 4 with regard to the application of the provisions of paragraph (8) of Article 2.