

# **Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Article 4 of the Supplementary Provisions unenforced, etc.)**

(Act No. 117 of October 16, 1973)

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## **Chapter I General Provisions**

(Purpose)

Article 1 The purpose of this Act is to establish a system for evaluating the properties of new chemical substances before their manufacture or import and for implementing 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 by chemical substances that poses a risk of impairing human health or of interfering with the population and/or growth of flora and fauna.

(Definitions, etc.)

Article 2 (1) The term "chemical substance" as used in this Act means a chemical compound created by causing chemical reactions to occur to elements or compounds (excluding radioactive substances and the following substances):

- (i) Any poison specified under 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 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 population and/or growth of higher trophic level predator animals (which means animals that fall under the category of flora and fauna in the human living environment (flora and fauna for which interference with their population and/or growth would pose a risk of interfering with the preservation of the human living environment; the same shall apply hereinafter) in 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 such chemical transformation 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 specified by Cabinet Order which falls under either of the following items and which is thought to pose a risk of damaging human health or the population and/or growth of flora and fauna in the human living environment due to a considerable amount of the chemical substance remaining in the environment over a substantially extensive area or because it is reasonably likely that such a situation will arise in the near future in view of its properties and manufacture, import, use, etc.:

- (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 likely to pose 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) (limited to such a naturally generated chemical substance that is not likely to undergo a chemical transformation through natural processes itself).
- (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 likely to pose a risk of interfering with the population and/or growth of flora and fauna in the human living environment if the flora and fauna ingest or are exposed to said chemical substance 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) (limited to a naturally generated chemical substance that is not likely to undergo a chemical transformation through natural processes itself).
- (4) The term "Chemical Substance Subject to Type I Monitoring" as used in this Act means a chemical substance (excluding a new chemical substance) designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment that falls under either of the following items:
  - (i) A chemical substance that falls under paragraph (2), item (i)(a) and where it is unclear whether or not (b) of said item applies
  - (ii) A chemical substance that is likely to undergo a chemical transformation through natural processes which, when so transformed, falls under the preceding item.
- (5) The term "Chemical Substances subject to Type II Monitoring" as used in this Act means a chemical substance suspected of falling under paragraph (3), item (i) (including a chemical substance that falls under said item but which has not been designated as a Class II Specified Chemical Substance) which 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 "Chemical Substance subject to Type III Monitoring" as used in this Act means a chemical substance that falls under either of the following items and which has been designated by the Minister of Economy, Trade and Industry and the Minister of the Environment:

- (i) A chemical substance that is likely to pose a risk of interfering with the population and/or growth of flora and fauna (excluding one that falls under paragraph (2), item (i) and one that falls under paragraph (3), item (ii)(a) which has been designated a Class II Specified Chemical Substance)
  - (ii) A chemical substance that is likely to undergo a chemical transformation through natural processes for which the chemical substance (including an element) generated by such chemical transformation falls under the preceding item (limited to a chemical substance that is not likely to undergo a chemical transformation through natural processes).
- (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 cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2 by replacing the terms, and where 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 Chemical Substance subject to Type II Monitoring (including one for which such designation has been rescinded pursuant to the provisions of Article 25, item (ii))
  - (v) A Chemical Substance subject to Type III Monitoring
  - (vi) A chemical substance (excluding any of those set forth in the preceding items) listed among the existing chemical substances prescribed in Article 2, paragraph (1) of the Supplementary Provisions of this Act that has been publicly announced 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 Article 4, paragraph (7) (including 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 Chemical Substance subject to Type I Monitoring or Chemical Substance subject to Type II Monitoring 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 Chemical Substance subject to Type III Monitoring pursuant to the provisions of paragraph (6),

he/she shall give public notice of its name without delay.

## **Chapter II Evaluation and Regulations Concerning New Chemical Substances**

(Notification of Manufacture, etc.)

Article 3 (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 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 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 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 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 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 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 population 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
- (vi) Where the new chemical substance is a polymer and where a person has received 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 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 new chemical substance does not pose a risk of causing damage to human health or damage to the population and/or growth of flora and fauna in the human living environment by causing environmental pollution; and said new chemical substance will be manufactured or imported
- (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 new chemical substance exceeds the quantity specified by 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 cases listed in the following items, 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) receives 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 cases listed in the following items, 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) receives said confirmation by wrongful means
  - (ii) Where the person who has received the confirmation under item (v) of paragraph (1) 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 item (v) of paragraph (1) pertains poses a risk of causing damage to human health or damage to the population and/or growth of flora and fauna in the human living environment by causing environmental pollution
- (5) In any of the cases listed in the following items, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall rescind confirmation under item (vi) of paragraph (1):
- (i) Where the person who has received confirmation under item (vi) of paragraph (1) receives said confirmation by wrongful means
  - (ii) Where it is found that the new chemical substance pertaining to the confirmation set forth in item (vi) of paragraph (1) poses a risk of causing damage to human health or damage to the population and/or growth of flora and fauna in the human living environment by causing environmental pollution

(Evaluation)

Article 4 (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

determine 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 already 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 chemical substance that falls under any of the items of paragraph (2) of Article 2

(ii) A chemical substance that falls under (a) and does not fall under (b):

(a) A chemical substance that falls under any of the following:

1. A chemical substance that is suspected to fall under Article 2, paragraph (3), item (i)(a) (including one falling under (a) of said item and limited to a chemical substance that is not likely to undergo a chemical transformation through natural processes)

2. A chemical substance that is likely to undergo a chemical transformation through natural processes for which the chemical substance (including an element) generated by such chemical transformation falls under (1)

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

1. A chemical substance that falls under Article 2, paragraph (6), item (i) (limited to a chemical substance that is not likely to undergo a chemical transformation through natural processes).

2. A chemical substance that is likely to undergo a chemical transformation through natural processes for which the chemical substance (including an element) generated by such chemical transformation falls under (1)

(iii) A chemical substance that falls under (b) but not under (a) of the preceding item

(iv) A chemical substance that falls under both (a) and (b) of item (ii)

(v) A chemical substance that does not fall under item (i) or item (ii)(a) or (b)

(vi) A chemical substance for which the application of items (i) to (iv) is uncertain

(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 determine 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 determine 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 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 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 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 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 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 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.

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

Article 4-2 (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 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 determine whether 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 whether 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 paragraph (1) of the preceding Article, they shall, notwithstanding the provisions of said paragraph, determine 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 paragraph (1) 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 chemical substance that falls under any of the items of the preceding paragraph

(ii) A chemical substance that does not fall under any of the items of the preceding paragraph

(iii) A chemical substance where it is unclear whether 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 determine 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) Where a person receives notice effect that a new chemical substance, which is subject to a request under the provisions of paragraph (2) or the preceding paragraph, falls under paragraph (2), item (i), the person may make a request in advance to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment each fiscal year and receive confirmation 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 the Ordinances of the Ministry of Health, Labour and Welfare, the Ordinances of the Ministry of Economy, Trade and Industry, and the Ordinances of the Ministry of the Environment:
- (i) The planned quantity of the manufacture or import of said new chemical substance during the fiscal year to which the request pertains does not exceed that specified by Cabinet Order.
  - (ii) According to already available knowledge, etc., the new chemical substance does not pose a risk of causing damage to human health or to the population 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 import of a new chemical substance 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 Article 3, paragraph (1), item (v) pertains) exceeds the quantity specified by 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 confirmation under said item.
- (6) In any of the cases listed in the following items, 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 recipient of the confirmation under paragraph (4) obtained it by wrongful means
  - (ii) Where the recipient of 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 specified quantity

- (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 population 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 determine under the following paragraph with regard to the new chemical substance to which said notice pertains, pursuant to the provisions of 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 determine 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 (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 (6) of said Article shall be deemed to be replaced with "paragraph (8) of Article 4-2."

(Restrictions on Manufacture, etc.)

Article 5 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 paragraph (4) to (6) of Article 4 (including the cases where it is applied mutatis mutandis pursuant to paragraph (9) of the preceding Article by replacing the terms) 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) In the case where, the person has received 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 (excluding cases where confirmation is rescinded pursuant to the provisions of paragraph (6) of said Article), where the quantity of manufacture or import of said new chemical substance shall be not more than the quantity to which said confirmation pertains

(Evaluation, etc., of a New Chemical Substance Pertaining to a Manufacturer, etc., in a Foreign State)

Article 5-2 (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 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 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 III Regulations, etc. Concerning Class I Specified Chemical Substance**

#### **Section 1 Measures Concerning Chemical Substances subject to Type I Monitoring**

(Notification of the Quantity, etc. of Manufacture, etc.)

Article 5-3 (1) A person who has manufactured or imported any Chemical Substance subject to Type I Monitoring 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 Ordinance of the Ministry of Economy, Trade and Industry for each Chemical Substance subject to Type I Monitoring, pursuant to the provisions of 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 Chemical Substance subject to Type I Monitoring 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 Chemical Substance subject to Type I Monitoring; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Chemical Substance subject to Type I Monitoring is less than the quantity specified by Ordinance of the Ministry of Economy, Trade and Industry.

(Study of Hazardous Properties of Chemical Substances subject to Type I Monitoring)

Article 5-4 (1) If a Chemical Substance subject to Type I Monitoring poses a risk of causing environmental pollution if it falls under any of the items under Article 2, paragraph (2) in view of the state of its manufacture, import, use, etc., 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 the Chemical Substance subject to Type I Monitoring falls under any of the items under said paragraph, they may find it necessary to determine whether in fact the Chemical Substance subject to Type I Monitoring falls under any of the items under said paragraph. In such a case, pursuant to the provisions of 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, they may instruct a person operating the business of manufacturing or importing of said Chemical Substance subject to Type I Monitoring (including a person who has been operating such business and who is specified by Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by 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 higher trophic level predator animals if ingested continuously; the same shall apply in paragraph (3)) and to report the results thereof.

- (2) When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment receive a report under the preceding paragraph, they shall determine whether the Chemical Substance subject to Type I Monitoring to which said report pertains falls under any of the items under Article 2, paragraph (2) and notify the reporting person of the result.
- (3) When the Minister of Economy, Trade and Industry finds it particularly necessary to ensure 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, he/she may establish standards concerning the method and proportions of the sharing of the expenses required for said study of the hazardous properties.

(Rescission of Designation as Chemical Substance subject to Type I Monitoring)

Article 5-5 When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find that a Chemical Substance subject to Type I Monitoring falls under either of the following items, they shall rescind the designation and publicize to that effect without delay:

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

(Provision of Information)

Article 5-6 Where a person who operating the business of manufacturing a Chemical Substance subject to Type I Monitoring, a person using a Chemical Substance subject to Type I Monitoring as his/her business and any other person handling a Chemical Substance subject to Type I Monitoring as his/her business (hereinafter collectively referred to as a "business operator handling a Chemical Substance subject to Type I Monitoring") transfers or provides a Chemical Substance subject to Type I Monitoring to another business operator, he/she shall endeavor to provide information to the other party to whom he/she makes the transfer or provision to the effect that the name of said Chemical Substance subject to Type I Monitoring and the substance to be transferred or provided is a Chemical Substance subject to Type I Monitoring.

## Section 2 Regulations Concerning Class I Specified Chemical Substance

### (Permission to Manufacture)

- Article 6 (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.

### (Disqualification Clause)

- Article 8 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

### (Standards for Permission)

Article 9 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 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.

(Permission for Changes, etc.)

Article 10 (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 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 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).

(Permission to Import)

Article 11 (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 person's name and domicile, and the name of the representative person

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

(Standards for Permission, etc.)

Article 12 (1) Where the Minister of Economy, Trade and Industry receives 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 to meet the demand for said Class I Specified Chemical Substance.

- (2) The provisions of Article 8 shall apply mutatis mutandis to permission under paragraph (1) of the preceding Article.

(Restrictions on Import of Products)

Article 13 (1) No person shall import any product that is specified by 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 after consideration of such matters as the circumstances of the use of said Class I Specified Chemical Substance overseas.

(Restrictions on Use)

Article 14 No person shall use a Class I Specified Chemical Substance for any usages other than those specified by 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) It shall not be likely to pose a risk of causing damage to human health or damage to the population and/or growth of flora and fauna in the human living environment by causing environmental pollution attributable to said Class I Specified Chemical Substance that is used for said usage.

(Notification of Use)

Article 15 (1) A person who intends to use a Class I Specified Chemical Substance as his/her business 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 as his/her business 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.

(Succession)

- Article 16 (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."

(Obligation of Conformity to Standards)

- Article 17 (1) A permitted manufacturer shall maintain its manufacturing equipment in such a manner as to conform to the technical standards specified by 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 permitted manufacturer, a person using a Class I Specified Chemical Substance or any product that is specified by Cabinet Order and in which a Class I Specified Chemical Substance is used (hereinafter collectively referred to as a "Class I Specified Chemical Substance, etc.") as his/her business or any other person handling a Class I Specified Chemical Substance, etc. as his/her business (hereinafter referred to as a "business operator handling a Class I Specified Chemical Substance, etc.") handles a Class I Specified Chemical Substance, etc., he/she shall follow the technical standards specified by ordinance of the competent ministry.

(Labeling, etc.)

Article 17-2 (1) For each Class I 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 the environmental pollution attributable to said Class I Specified Chemical Substances, to be indicated on containers, packaging, or invoices for the Class I Specified Chemical Substance, etc.

- (2) Where a business operator handling a Class I Chemical Substance, etc. transfers or provides a Class I Specified Chemical Substance, etc., he/she shall implement labeling, pursuant to the provisions of 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, in accordance with the public notice given pursuant to the provisions of the preceding paragraph.

(Order for Improvement)

Article 18 (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 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 business operator handling a Class I Specified Chemical Substance, etc. fails to use a Class I Specified Chemical Substance, etc. in accordance with the technical standards specified by ordinance of the competent ministry under paragraph (2) of Article 17, he/she may order said business operator handling the Class I Specified Chemical

Substance, etc. to take the necessary measures for improving the method of handling the Class I Specified Chemical Substance, etc.

- (3) Where any business operator handling a Class I Specified Chemical Substance, etc. violates the provisions of paragraph (2) of the preceding Article, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may order said business operator handling the Class I Specified Chemical Substance, etc. to implement labeling in accordance with the public notice given pursuant to the provisions of paragraph (1) of said Article.

(Books)

Article 19 (1) A permitted manufacturer shall keep books and enter therein the items specified by 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 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 "Ordinance of the Ministry of Economy, Trade and Industry" in these provisions shall be deemed to be replaced with "ordinance of the competent ministry."

(Notification of Abolition)

Article 20 (1) A permitted manufacturer shall notify the Minister of Economy, Trade and Industry, and a notifying user shall notify the competent minister, of the termination of his/her business without delay,.

- (2) Where a permitted manufacturer has terminated 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."

(Rescission of Permission, etc.)

Article 21 (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 the manufacturer's 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 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).

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

- Article 22 (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 IV Regulations, etc. Concerning Class II Specified Chemical Substance**

##### **Section 1 Measures Concerning Chemical Substances subject to Type II Monitoring**

(Notification of the Quantity of Manufacture, etc.)

- Article 23 (1) A person who has manufactured or imported any Chemical Substance subject to Type II Monitoring 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 Ordinance of the Ministry of Economy, Trade and Industry for each Chemical Substance subject to Type II Monitoring, pursuant to the provisions of 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 Chemical Substance subject to Type II Monitoring 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 Chemical Substance subject to Type II Monitoring; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Chemical Substance subject to Type II Monitoring is less than the quantity specified by Ordinance of the

Ministry of Economy, Trade and Industry.

(Study of Hazardous Properties of Chemical Substances subject to Type II Monitoring)

Article 24 (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 Chemical Substance subject to Type II Monitoring, found it necessary to determine whether said Chemical Substance subject to Type II Monitoring falls under item (i) of paragraph (3) of Article 2 since said Chemical Substance subject to Type II Monitoring poses a risk of causing damage to human health through environmental pollution if said Chemical Substance subject to Type II Monitoring falls under said item, in view of the results of the tests under paragraph (8) of Article 2 and other available knowledge concerning said Chemical Substance subject to Type II Monitoring as well as the state of its manufacture, import, use, etc., they may, pursuant to the provisions of 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 Chemical Substance subject to Type II Monitoring (including a person who has operated such business formerly and who is specified by Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by 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 receive a report under the preceding paragraph, they shall determine whether the Chemical Substance subject to Type II Monitoring to which said report pertains falls under Article 2, paragraph (3), item (i) and notify the reporting person of the result thereof.

(3) The Minister of Economy, Trade and Industry may, when he/she finds it particularly necessary to ensure that the expenses for the study of the hazardous properties to which the instruction under the provisions of paragraph (1) pertains are fairly shared among the business operators concerned, he/she may establish standards concerning the method of determining and apportionment of said expenses.

(Rescission of Designation as a Chemical Substance subject to Type II



Monitoring)

Article 25 When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find that a Chemical Substance subject to Type II Monitoring falls under either of the following items, they shall rescind the designation and publicize such rescission without delay:

- (i) Where a chemical substance has been designated as a Class II Specified Chemical Substance as a result of its falling under Article 2, paragraph (3), item (i) (including a case where a Chemical Substance subject to Type II Monitoring has been so designated as a result of its falling under item (ii) of said paragraph and said Chemical Substance subject to Type II Monitoring has subsequently been found 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 Chemical Substance subject to Type III Monitoring**

(Notification of the Quantity of Manufacture, etc.)

Article 25-2 (1) A person who has manufactured or imported any Chemical Substance subject to Type III Monitoring (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 Ordinance of the Ministry of Economy, Trade and Industry for each Chemical Substance subject to Type III Monitoring, pursuant to the provisions of 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 Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one Chemical Substance subject to Type III Monitoring is less than the quantity specified by Ordinance of the Ministry of Economy, Trade and Industry.

(Study of Hazardous Properties of Chemical Substance subject to Type III Monitoring)

- Article 25-3 (1) In the case that the Minister of Economy, Trade and Industry and the Minister of the Environment have, with regard to any single Chemical Substance subject to Type III Monitoring, found it necessary to determine whether said Chemical Substance subject to Type III Monitoring falls under item (ii) of paragraph (3) of Article 2 since said Chemical Substance subject to Type III Monitoring poses a risk of causing damage to the population and/or growth of flora and fauna in the human living environment through environmental pollution if said Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring as well as the state of its manufacture, import, use, etc., they may, pursuant to the provisions of 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 Chemical Substance subject to Type III Monitoring (including a person who has operated such business formerly and who is specified by Ordinance of the Ministry of Economy, Trade and Industry) to conduct a study of the hazardous properties specified by 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 population 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; 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 determine whether the Chemical Substance subject to Type III Monitoring 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.

(Rescission of Designation as a Chemical Substance subject to Type III Monitoring)

Article 25-4 (1) Where a Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring has been designated as a Class II Specified Chemical Substance as a result of falling under item (i) of said paragraph and said Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring 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 Chemical Substance subject to Type III Monitoring without delay.

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

(Notification of the Planned Quantity of Manufacture, etc.)

Article 26 (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 Ordinance of the Ministry of Economy, Trade and Industry, pursuant to the provisions of 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 provided notification under the provisions of paragraph (1) shall not manufacture or import in excess of the planned quantity to which said notification pertains (where a notification of change under the provisions of the preceding paragraph has been provided, the quantity after the change).
- (4) Where, in light of the state of the manufacture, import, use, etc. of a Class II Specified Chemical Substance or product using a Class II Specified Chemical Substance as well as the effect of the implementation of measures under the provisions of the following Article and Article 28 in relation to said Class II Specified Chemical Substance, 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 population and/or growth of flora and fauna in the human living environment due to environmental pollution attributable to said Class II 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 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 notification under the provisions of paragraph (1) to change the planned quantity to be manufactured or imported to which said notification pertains (where notification of a 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 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 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).

(Publication of Technical Guidelines, etc.)

Article 27 (1) For each Class II Specified Chemical Substance, the competent ministers shall publish technical guidelines on the measures to be taken by persons who operating the business of manufacturing said Class II Specified Chemical Substance, persons using said Class II Specified Chemical Substance

or products that are specified by Cabinet Order in which said Class II Specified Chemical Substance is used (hereinafter collectively referred to as a "Class II Specified Chemical Substance, etc.") as their business, and any other persons handling said Class II Specified Chemical Substance, etc. as their business (hereinafter referred to as a "business operator handling a Class II Specified Chemical Substance, etc.") in order to prevent environmental pollution attributable to the Class II Specified Chemical Substance they handle.

- (2) Where the competent ministers have published technical guidelines pursuant to the provisions of the preceding paragraph, if they find it necessary, they may make a necessary recommendation to business operator handling a Class II Specified Chemical Substance, etc. pertaining to 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.

(Labeling, etc.)

Article 28 (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, etc.

- (2) Where a business operator handling a Class II Specified Chemical Substance, etc. transfers or provides a Class II Specified Chemical Substance, etc. he/she shall, pursuant to the provisions of 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 the preceding paragraph.

- (3) In the case where any business operator handling a Class II Specified Chemical Substance, etc. 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 business operator handling a Class II Specified Chemical Substance, etc. to implement labeling in accordance with the public notice given pursuant to the provisions of paragraph (1).

## **Chapter V Miscellaneous Provisions**

(Recommendations)

Article 29 (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 as his/her business.

(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 as his/her business.

(Guidance and Advice)

Article 30 Where the competent ministers find it particularly necessary for preventing environmental pollution attributable to a Chemical Substance subject to Type I Monitoring, a Chemical Substance subject to Type II Monitoring or a Chemical Substance subject to Type III Monitoring (hereinafter collectively referred to as a "chemical substance subject to monitoring" in Article 31-2) or a Class II Specified Chemical Substance, they may provide a business operator handling a Chemical Substance subject to Type I Monitoring pertaining to said Chemical Substance subject to Type I Monitoring, a person operating the business of manufacturing said Chemical Substance subject to Type II Monitoring or Chemical Substance subject to Type III Monitoring, or a person using said Chemical Substance subject to Type II Monitoring or Chemical Substance subject to Type III Monitoring as his/her business, or any other person handling said Chemical Substance subject to Type II Monitoring or Chemical Substance subject to Type III Monitoring as his/her business, or a business operator handling a Class II Specified Chemical Substance, etc. pertaining to said Class II Specified Chemical Substance with the necessary guidance and advice concerning the method of handling the chemical substance.

(Conditions for Permission)

Article 31 (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.

(Reporting, etc., of Hazardous Properties)

- Article 31-2 (1) A person engaged in the business of manufacturing or importing any chemical substance subject to monitoring, any Class II Specified Chemical Substance, any chemical substance of which the public has been notified pursuant to the provisions of Article 4, paragraph (4) (including where it is applied mutatis mutandis pursuant to Article 4-2, paragraph (9) and pursuant to Article 5-2, paragraph (2)), or any chemical substance in the list of existing chemical substances prescribed in Article 2, paragraph (1) of the Supplementary Provisions of which the public has been 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 report to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment when he/she has conducted tests with regard to the substance subject to reporting under the items prescribed in Article 4, paragraph (7) or studies of hazardous properties prescribed in Article 5-4, paragraph (1), Article 24, paragraph (1) or Article 25-3, paragraph (1) (including cases in which information equivalent to that which would be obtained from said tests (limited to information that is not publicly known) has been obtained). When, as a result of said tests, the person obtains information specified by 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 indicating that the substance subject to reporting possesses the following properties, he/she shall report to that effect and give the details of such information, pursuant to the provisions of Ordinance of the Ministry of Health, Labour and Welfare, and Ordinance of the Ministry of Economy; provided, however that this shall not apply where said person has obtained said information as a result of a study of hazardous properties to which an instruction under the provisions of Article 5-4, paragraph (1), Article 24, paragraph (1) or Article 25-3, paragraph (1) pertains, and where said person is reporting the details of said information pursuant to these provisions:
- (i) The chemical substance subject to reporting is not likely to undergo a chemical transformation through natural processes.
  - (ii) The chemical substance subject to reporting is bioaccumulative.
  - (iii) The chemical substance subject to reporting poses a risk of impairing

- human health if ingested continuously.
- (iv) The chemical substance subject to reporting poses a risk of interfering with the population 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) The provisions of the main clause of the preceding paragraph shall apply mutatis mutandis to a person who engages in the business of manufacturing or importing a new chemical substance pertaining to the confirmation set forth in items (v) or (vi) of paragraph (1) of Article 3 or paragraph (4) of Article 4-2 (limited to a person who obtains said confirmation), a person who engages in the business of manufacturing or importing a new chemical substance pertaining to the notification prescribed in paragraph (4) of Article 4 (including cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 4-2 by replacing the terms) (limited to a person who obtains said confirmation) and a person who imports a new chemical substance pertaining to the notification prescribed in paragraph (4) of Article 4 as applied mutatis mutandis pursuant to paragraph (2) of Article 5-2 from another person who obtains said notification.
- (3) Where a person who engages in the business of manufacturing or importing a chemical substance subject to monitoring or a class II specified chemical substance has knowledge of the composition, properties, etc. of the chemical substance subject to monitoring or the class II specified chemical substance that he/she has manufactured or imported as specified by 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 (the knowledge is limited to that which is not publicly known, and excluding that which is to be reported pursuant to the provisions of paragraph (1) of Article 5-4, paragraph (1) of Article 24, paragraph (1) of Article 25-3 or paragraph (1) of this Article), he/she shall endeavor to report to that effect and the details of said knowledge 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 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 found, based on a report under paragraph (1) (including in cases as applied mutatis mutandis pursuant to paragraph (2)) or the preceding paragraph or knowledge that has



been otherwise obtained, that any substance subject to reporting or any new chemical substance pertaining to the report set forth in paragraph (1) as applied mutatis mutandis pursuant to paragraph (2) 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.

(Reporting on the Status of Handling)

Article 31-3 The competent ministers may request that a business operator handling a Chemical Substance subject to Type I Monitoring or a business operator handling a Class II Specified Chemical Substance, etc. report the status of their handling of a Chemical Substance subject to Type I Monitoring or a Class II Specified Chemical Substance, etc.

(Collection of Reports)

- Article 32 (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) to (vi) 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 business operator handling Class I Specified Chemical Substance, etc, 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.

(On-Site Inspections, etc.)

Article 33 (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) to (vi) 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, a permitted importer, a business operator handling Class I Specified Chemical Substance, etc. or a 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), it shall report the results thereof to the Minister of Economy, Trade and Industry in accordance with the instructions under the preceding paragraph.
- (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 to include the authority to conduct criminal investigations.

(Orders to NITE)

Article 33-2 Where the Minister of Economy, Trade and Industry finds it necessary in order to secure 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 orders concerning said

operations to NITE.

(Request for Examination Regarding the Taking of Samples by NITE)

Article 33-3 Any person who objects to 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.

(Notification)

Article 34 Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, or the Minister of the Environment obtains knowledge, etc. of the properties, etc. of a chemical substance based on this Act, in order to contribute to measures based on another Act concerning said chemical substance, he/she shall notify the Ministers governing the offices responsible for the enforcement of said other Act of the details of said knowledge, etc where needed.

(Requests)

Article 34-2 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

(Fees)

Article 35 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 Cabinet Order in consideration of the actual expenses.

(Special Provisions on Hearings)

Article 36 (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 of 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.

(Hearing of Opinion in Procedures for Objection)

- Article 37 (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.

(Transitional Measures)

Article 38 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.

(Competent Ministers, etc.)

- Article 39 (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 (excluding an order given to a permitted manufacturer), 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 pursuant to the provisions of paragraph (2) of Article 18 (limited to an order given to a permitted manufacturer), the Minister of Economy, Trade and Industry
- (iii) 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 Chemical Substance subject to Type III Monitoring) under the provisions of Article 30, the collection of reports under the provisions of Article 31-3 or paragraph (3) of Article 32, or the inspection, questioning or taking of samples under the

provisions of paragraph (3) of 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

- (iv) With regard to guidance and advice (limited to those pertaining to a Chemical Substance subject to Type III Monitoring) 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 (excluding the technical standards pertaining to permitted manufacturers), 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 business operator handling a Class I Specified Chemical Substance, etc.
  - (iii) With regard to the technical standards under Article 17, paragraph (2) (limited to the technical standards pertaining to permitted manufacturers), an order issued by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment.

(Delegation of Authority)

Article 39-2 The authority of the Minister of the Environment prescribed in this Act may be delegated to the Directors General of the Regional Environment Offices, pursuant to Ordinance of the Ministry of Environment.

(Relationship with Other Acts)

Article 40 The provisions of Article 3, Article 5-2, paragraph (1), Article 5-3, paragraph (1), Article 5-4, paragraph (1), Article 5-6, Article 6, paragraph (1), Article 7, Article 11, paragraph (1), Article 14, Article 15, paragraph (1), Article 17, paragraph (2), Article 17-2, paragraph (1), Article 22, paragraphs (1) and (3), Article 23, paragraph (1), Article 24, paragraph (1), Article 25-2, paragraph (1), Article 25-3, paragraph (1), Article 26, paragraph (1), Article 27, paragraph (1), Article 28, paragraph (1), Article 29, Article 30, Article 31-2,

paragraphs (1) (including where applied mutatis mutandis pursuant to paragraph (2) of said Article) and (3), and Article 31-3 shall not apply to the chemical substances which constitute the products listed in the following items. The provisions of Article 13, paragraph (1), Article 17, paragraph (2), Article 17-2, paragraph (1), and Article 22 shall not apply to products listed in the following items in which Class I Specified Chemical Substances are used; the provisions of Article 26, paragraph (1), Article 27, paragraph (1), Article 28, paragraph (1), Article 30 and Article 31-3 shall not apply to products listed in the following items in which Class II Specified Chemical Substances are used; and the provisions of Article 5-6, Article 14, Article 15, paragraph (1), Article 17, paragraph (2), Article 17-2, paragraph (1), Article 22, paragraph (3), Article 27, paragraph (1), Article 28, paragraph (1), Article 29, Article 30, and Article 31-3 shall not apply to the use of chemical substances as raw materials for the products 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 62 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

(Hearing of Opinion of Councils)

Article 41 (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 Cabinet Order, in advance:

- (i) When intending to plan out the establishment or revision of Cabinet Order under paragraph (2) of Article 2 (excluding the case of intending to plan out

- such establishment 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 Cabinet Order under paragraph (3) of Article 2, paragraph (1) of Article 13, Article 14, paragraph (2) of Article 17, paragraph (1) of Article 26 or paragraph (1) of Article 27
- (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 determine 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 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 determine under paragraph (2) of said Article.

## **Chapter VI 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 provide notification under the provisions of Article 5-3, paragraph (1), Article 23, paragraph (1), Article 25-2, paragraph (1) or Article 26, paragraph (6), or who has provided 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 who has refused to answer or given a false answer during questioning under these provisions

Article 46 Where the representative person of a juridical person, or an agent, employee or any other individual engaged by a juridical or natural person has committed an act in violation of any of the provisions listed in the following items with regard to the business activities of said juridical or natural person, not only shall the individual offender be punished, but said juridical person shall be punished by the fine prescribed in the relevant item and said natural person 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) Article 43, item (i), (ii) or (iv)- A fine of not more than fifty million yen
- (iii) Article 43, item (iii), 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 provide notification under the provisions of Article 10, paragraph (2), Article 15, paragraph (2), Article 16, paragraph (2), Article 20, paragraph (1) or Article 26, paragraph (2) or who has provided false notification
- (ii) A person who has failed to make a report under the provisions of paragraph (1) of Article 31-2 (including in cases where as applied mutatis mutandis pursuant to paragraph (2) of said Article) 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]**

(Effective Date)

Article 1 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.

(List of Existing Chemical Substances)

Article 2 (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 as a business 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 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.

(Transitional Measures)

Article 3 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" as used in said paragraph shall be deemed to be replaced with "within one month from the day of the enforcement of this Act."

Article 4 The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall prepare a list in which the names of Chemical Substance subject to Type II Monitorings as designated pursuant to the provisions of paragraph (5) of Article 2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. prior to their revision pursuant to the provisions of Article 2 of the Act on

the Partial Revision of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 39 of 2009; hereinafter referred to as the "revising Act" in this Article) and Chemical Substance subject to Type III Monitorings as designated pursuant to the provisions of paragraph (6) of Article 2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. prior to their revision pursuant to the provisions of Article 2 of the revising Act, and shall publish the list on the day of enforcement of the provisions listed in item (iii) of Article 1 of the Supplementary Provisions of the revising Act.

**Supplementary Provisions [Act No. 68 of July 25, 1975] [Extract]**

- (1) This Act shall come into effect as from the day specified by Cabinet Order within a period not more than one year from the day of promulgation.

**Supplementary Provisions [Act No. 57 of May 25, 1983] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day specified by Cabinet Order within a period not more than three months from the day of promulgation; provided, however, that the provisions of Article 8 shall come into effect as from the day specified by the Cabinet Order set forth in Article 1 of the Supplementary Provisions of the Act for Partial Revision of the Fertilizer Control Act (Act No. 40 of 1983).

**Supplementary Provisions [Act No. 44 of May 7, 1986]**

(Effective Date)

- (1) This Act shall come into effect as from the day specified by Cabinet Order within a period not more than one year from the day of promulgation.

(Transitional Measures)

- (2) With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain applicable.

**Supplementary Provisions [Act No. 33 of June 19, 1990] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day specified by Cabinet Order within a period not more than six months from the day of promulgation.

**Supplementary Provisions [Act No. 89 of November 12, 1993] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day of enforcement of the Administrative Procedure Act (Act No. 88 of 1993).

(Transitional Measures Concerning Adverse Dispositions Following Appeal, etc.)

Article 2 Where an appeal or other request to a council or any other panel has been filed or made prior to the enforcement of this Act under laws and regulations to require the implementation of procedures equivalent to the holding of hearings or the granting of the opportunity for explanation and other procedures allowing the airing of statements of opinion prescribed in Article 13 of the Administrative Procedure Act, with regard to the procedures concerning adverse disposition pertaining to said appeal or other request, the provisions then in force shall remain applicable notwithstanding the provisions of the relevant Acts revised by this Act.

(Transitional Measures Concerning Penal Provisions)

Article 13 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain applicable.

(Transitional Measures for the Arrangement of Provisions for Hearings)

Article 14 Procedures for hearings (excluding those concerning adverse dispositions) implemented under Acts prior to the enforcement of this Act or incidental procedures shall be deemed to have been implemented under the relevant provisions of the respective Acts revised by this Act.

(Delegation to Cabinet Orders)

Article 15 In addition to the transitional measures prescribed in Article 2 through the preceding Article of these Supplementary Provisions, the necessary transitional measures concerning the enforcement of this Act shall be specified by Cabinet Order.

**Supplementary Provisions [Act No. 151 of December 8, 1999] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as of April 1, 2000.

Article 4 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain applicable.

**Supplementary Provisions [Act No. 160 of December 22, 1999] [Extract]**

(Effective Date)

Article 1 This Act (excluding Articles 2 and 3) shall come into effect as from January 6, 2001.

**Supplementary Provisions [Act No. 96 of July 31, 2002] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day specified by Cabinet Order within a period not more than three years from the day of promulgation; provided, however, that the provisions listed in the following items shall come into effect as from the day specified in said items respectively:

(ii) The provisions of paragraph (2) of Article 2, Article 5, Article 17, Article 27, and Articles 30 through 32 of the Supplementary Provisions - the day of promulgation

(Effects of Depositions, etc.)

Article 30 Any dispositions, procedures or other acts conducted prior to the enforcement of this Act (or the respective provisions listed in the items of Article 1 of the Supplementary Provisions), pursuant to the provisions of the respective Acts prior to the revision (including orders issued under them; hereinafter the same shall apply in this Article) shall be, if the respective revised Acts contain provisions corresponding to such provisions, deemed to have been conducted under the relevant provisions of the respective revised Acts, except those otherwise provided for by the Supplementary Provisions.

(Transitional Measures Concerning Penal Provisions)

Article 31 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act (or the respective provisions listed in the items of Article 1 of the Supplementary Provisions) and acts committed after the enforcement of this Act, in cases where the provisions then in force remain applicable pursuant to the provisions of these Supplementary Provisions, the provisions then in force shall remain applicable.

(Delegation to Cabinet Orders)

Article 32 In addition to the transitional measures prescribed in these

Supplementary Provisions, the necessary transitional measures concerning the enforcement of this Act shall be specified by Cabinet Order.

**Supplementary Provisions [Act No. 49 of May 28, 2003] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day specified by Cabinet Order within a period not more than one year from the day of promulgation; provided, however, that the provisions of Article 3 of the Supplementary Provisions shall come into effect as from the day specified by Cabinet Order within the period not more than nine months from the day of promulgation.

(Transitional Measures Concerning Confirmation)

Article 2 A person who is specified by Cabinet Order among persons who actually manufacture or import a new chemical substance at the enforcement of this Act by falling under the cases specified by Cabinet Order under the proviso to Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. prior to the revision by this Act without making the notification set forth in said Article may continue to manufacture or import said new chemical substance without making the notification set forth in paragraph (1) of Article 3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. after the revision by this Act (hereinafter referred to as "new Act") for the period from the day of enforcement of this Act (hereinafter referred to as the "enforcement day") until a day when six months elapses, notwithstanding the provisions of paragraph (1) of Article 3 of the new Act.

(Preparatory Actions)

Article 3 A person who intends to manufacture or import a new chemical substance may obtain 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 the provisions of item (v) of paragraph (1) of Article 3 of the new Act even prior to the enforcement day. In this case, a person who obtains said confirmation shall be deemed to have obtained confirmation from the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment on the enforcement day, pursuant to the provisions of said item.

(Transitional Measures Concerning Application of Penal Provisions)

Article 4 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act, the provisions then in force shall remain

applicable.

(Delegation to Cabinet Orders)

Article 5 In addition to the transitional measures prescribed in these Supplementary Provisions, the necessary transitional measures concerning the enforcement of this Act shall be specified by Cabinet Order.

(Review)

Article 6 Where five years have elapsed after the enforcement of this Act, when the government finds it necessary in consideration of the state of implementation of the new Act, it shall review the provisions of the new Act and take necessary measures based on the results.

#### **Supplementary Provisions [Act No. 55 of May 30, 2003] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as from the day specified by Cabinet Order within a period not more than three months from the day of promulgation; provided, however, that the provisions listed in the following items shall come into effect as from the day specified in said items respectively:  
(iii) The provisions of Article 2 (excluding the provisions for revision listed in the following item), Article 6 (excluding the provisions for revision listed in the following item), Article 8 (excluding the provisions for revision listed in the following item) and Article 10 of this Act; the provisions of Articles 2 through 5, Article 8, Articles 16 through 18, Articles 21 through 26, Article 31, Article 33 and Article 35 - the day specified by Cabinet Order within a period not more than nine months from the day of promulgation

#### **Supplementary Provisions [Act No. 33 of April 27, 2005] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as of October 1, 2005.

(Transitional Measures)

Article 24 Where an order is established, revised or abolished based on the provisions of the respective Acts after their revision by this Act, the order may provide necessary transitional measures (including transitional measures concerning penal provisions) to the extent deemed reasonably necessary for their establishment, revision or abolishment.

#### **Supplementary Provisions [Act No. 39 of May 20, 2009] [Extract]**

(Effective Date)

Article 1 This Act shall come into effect as of the day specified by Cabinet Order within a period not more than three years from the day of its promulgation; provided, however, that the provisions listed in the following items shall come into effect as of the days specified in said items respectively:

- (i) The provisions of paragraph (1) of the following Article and Article 5 of the Supplementary Provisions - the day of promulgation
- (iii) The provisions of Article 2 of this Act, Article 3 (excluding paragraph (3)) and Article 7 of the Supplementary Provisions - the day specified by Cabinet Order within a period not more than two years from the day of promulgation

(Transitional Measures)

Article 2 (1) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may hear the opinions of a council, etc. as specified by Cabinet Order under paragraph (1) of Article 41 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. after the revision pursuant to the provisions of Article 1 of this Act (hereinafter referred to as the "new Act" in this Article) in order to enact or amend the Cabinet Order set forth in paragraph (2) of Article 17 or paragraph (1) of Article 27 of the new Act, even prior to the enforcement of this Act.

(2) With regard to measures pursuant to the provisions of paragraph (4) of Article 31-2 of the new Act where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have found that a substance subject to reporting (meaning a substance subject to reporting as prescribed in paragraph (1) of Article 31-2 of the new Act) falls under any of the items of paragraph (6) of Article 2 of the new Act or is suspected to fall under item (i) of paragraph (3) of said Article, they shall be taken by considering whether or not a considerable amounts of said substance subject to reporting are expected to remain in the environment.

Article 3 (1) With regard to a report which shall be made by a person who is instructed pursuant to the provisions of paragraph (1) of Article 24 or paragraph (1) of Article 25-3 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. prior to their revision pursuant to the provisions of Article 2 of this Act (hereinafter referred to as the "former Act" in this Article) and who actually engages at the time of the enforcement of the provisions listed in item (iii) of Article 1 of the Supplementary Provisions in the business of manufacturing or importing a Chemical Substance subject to Type II Monitoring as prescribed in paragraph



(5) of Article 2 of the former Act (hereinafter referred to as a "Chemical Substance subject to Type II Monitoring" in the following paragraph) or a Chemical Substance subject to Type III Monitoring as prescribed in paragraph (6) of said Article of the former Act (hereinafter referred to as a "Chemical Substance subject to Type III Monitoring"), the provisions then in force shall remain applicable.

(2) With regard to a report which shall be made by a person who actually engages at the time of the enforcement of the provisions listed in item (iii) of Article 1 of the Supplementary Provisions in the business of manufacturing or importing a Chemical Substance subject to Type II Monitoring or a Chemical Substance subject to Type III Monitoring for which the knowledge prescribed in paragraphs (1) or (3) of Article 31-2 of the former Act is obtained with respect to a Chemical Substance subject to Type II Monitoring or a Chemical Substance subject to Type III Monitoring, the provisions then in force shall remain applicable.

(3) The Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment may hear the opinions of a council, etc. as specified by Cabinet Order under paragraph (1) of Article 56 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. after their revision pursuant to the provisions of Article 2 of this Act (hereinafter referred to as the "new Act" in this Article) in order to provide a designation under paragraph (5) of Article 2 of the new Act, even prior to the day of enforcement of the provisions listed in item (iii) of Article 1 of the Supplementary Provisions.

(4) A Chemical Substance subject to Type I Monitoring that is actually designated pursuant to the provisions of Article 2, paragraph (4) of the former Act at the time of the enforcement of the provisions listed in Article 1, item (iii) of the Supplementary Provisions shall be deemed to be a chemical substance subject to monitoring as designated pursuant to the provisions of Article 2, paragraph (4) of the new Act.

#### (Transitional Measures Concerning Penal Provisions)

Article 4 With regard to the application of penal provisions to acts committed prior to the enforcement of this Act (or the provisions listed in Article 1, item (iii) of the Supplementary Provisions) and acts committed after the enforcement of this Act, in cases where the provisions then in force remain applicable pursuant to the provisions of paragraphs (1) and (2) of the preceding Article, the provisions then in force shall remain applicable.

#### (Delegation to Cabinet Orders)

Article 5 In addition to transitional measures prescribed in these

Supplementary Provisions, the necessary transitional measures concerning the enforcement of this Act (including transitional measures concerning the penal provisions) shall be specified by Cabinet Order.

(Review)

Article 6 Where five years has elapsed after the enforcement of this Act, when the government finds it necessary in consideration of the state of implementation of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. after the revision by this Act, it shall review the provisions of said Act and take necessary measures based on the results.