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Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, 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 obtained by causing chemical reactions to elements or compounds (excluding a radioactive substance and the following substances):

- (i) Any specified poison prescribed in paragraph (3) of Article 2 of the Poisonous and Deleterious Substances Control Act (Act No. 303 of 1950)
- (ii) Any stimulant prescribed in paragraph (1) of Article 2 of the Stimulant Drug Control Act (Act No. 252 of 1951) and any raw material for stimulants prescribed in paragraph (5) of said Article
- (iii) Any narcotic prescribed in item (i) of Article 2 of the Narcotics and Psychotropics Control Act (Act No. 14 of 1953)

(2) The term "class I specified chemical substance" as used in this Act means a chemical substance that falls under either of the following items and is specified by Cabinet Order:

- (i) A chemical substance that falls under (a) and (b):
 - (a) A chemical substance that is not likely to undergo a chemical transformation through natural processes and is bioaccumulative
 - (b) A chemical substance that falls under either of the following:
 - 1. A chemical substance that poses a risk of impairing human health if ingested continuously

2. A chemical substance that, if ingested continuously, poses a risk of interfering with the inhabitation and/or growth of predator animals at higher trophic level (which mean animals that fall under the category of flora and fauna in the human living environment [which means flora and fauna for which interference with their inhabitation and/or growth would pose a risk of interfering with the preservation of the human living environment; the same shall apply hereinafter] for which chemical substances falling under (a) are most likely to bioaccumulate through the food chain; the same shall apply hereinafter)
- (ii) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by chemical transformation through natural processes falls under (a) and (b) of the preceding item
- (3) The term "class II specified chemical substance" as used in this Act means a chemical substance that is specified by Cabinet Order and falls under either of the following items and is thought to pose a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment 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 a chemical substance that is not likely to undergo a chemical transformation through natural processes).
- (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 inhabitation

- and/or growth of flora and fauna in the human living environment if the flora and fauna continuously ingest or are exposed to said chemical substance
- (b) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under (a) (limited to a chemical substance that is likely to undergo a chemical transformation through natural processes).
- (4) The term "monitoring chemical substance" as used in this Act means a chemical substance (excluding a new chemical substance) that falls under either of the following items and has been designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment:
- (i) A chemical substance that falls under (a) of item (i) of paragraph (2), and where it is unclear whether or not (b) of said item applies
- (ii) In the case of a chemical substance that is likely to undergo a chemical transformation through natural processes, one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under the preceding item
- (5) The term "chemical substances requiring prior assessment" as used in this Act means chemical substances for which it is not clear whether they fall under either of the items of paragraph (3) from the perspective of currently available knowledge on the chemical substances, which are found to remain in the environment in considerable amounts or are expected to remain in such a situation in view of the knowledge and the state of manufacture, import, etc., and which are found to be likely to damage human health or to damage the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution by the chemical substance; they are therefore designated by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment as chemical substances that are found to require priority assessment of the likelihood of the chemical substances having the above risks through the collection of information on their properties and through the clarification of the status of their use, etc.
- (6) The term "new chemical substance" as used in this Act means a chemical

substance other than the chemical substances listed in the following items:

- (i) A chemical substance for which public notice has been given by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment pursuant to the provisions of paragraph (4) of Article 4 (including the cases where it is applied *mutatis mutandis* pursuant to paragraph (9) of Article 5 by replacing the terms, and the cases in which it is applied *mutatis mutandis* pursuant to paragraph (2) of Article 7)
 - (ii) A class I specified chemical substance
 - (iii) A class II specified chemical substance
 - (iv) A chemical substance requiring priority assessment (including one for which the designation has been rescinded pursuant to the provisions of Article 11 [limited to the part pertaining to (d) of item (ii)])
 - (v) A chemical substance (excluding any of those set forth in the preceding items) listed in the list of existing chemical substances prescribed in paragraph (1) of Article 2 of the Supplementary Provisions of this Act that has been publicly notified by the Minister of International Trade and Industry pursuant to the provisions of paragraph (4) of said Article
 - (vi) A chemical substance (excluding any of those set forth in the preceding items) listed in the list prescribed in Article 4 of the Supplementary Provisions of this Act that is publicized by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment
- (7) The term "general chemical substance" as used in this Act means a chemical substance listed in the following (excluding chemical substances requiring priority assessment, monitoring chemical substances, class I specified chemical substances, and class II specified chemical substances):
- (i) A chemical substance listed in items (i), (v) or (vi) of the preceding paragraph
 - (ii) A chemical substance for which designation as a chemical substance requiring priority assessment is rescinded pursuant to the provisions of Article 11 (limited to the part pertaining to (d) of item (ii))
- (8) 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 monitoring chemical substance or chemical substance requiring priority assessment pursuant to the provisions of paragraph (4) or (5), he/she shall

give public notice of its name without delay.

Chapter II Evaluation and Regulation 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 7 and has received notice to the effect that the new chemical substance to which said notification pertains falls under any of items (ii) through (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 7, 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 5) 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 inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution, and that person shall manufacture or import said new chemical substance in a quantity of no more than that to which said confirmation pertains during the relevant fiscal year

(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 inhabitation 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 5 pertains) relating to a single 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) had received 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 inhabitation 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 inhabitation 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 make a determination as to which of the following items the new chemical substance falls under, within three months from the date of receipt of the notification, based on the available knowledge on the composition, properties, etc., of the new chemical substance to which said notification pertains, and shall notify the result thereof to the person who has given the notification:

(i) A 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 (a) of item (i) of paragraph (3) of Article 2 (including those that fall under (a) of said item and limited to chemical substances that are not likely to undergo a chemical transformation through natural processes)

2. 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 1

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

1. A chemical substance that is likely to pose a risk of interfering with the inhabitation and/or growth of flora and fauna (limited to chemical substances that are not likely to undergo a chemical transformation through natural processes and excluding those that fall under item (i) of paragraph (2) of Article 2)
2. 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 1
 - (iii) A chemical substance that does not fall under (a) of the preceding item and that falls under (b) in said 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 (a) or (b) of item (ii)
 - (vi) A substance where it is unclear as to whether or not it falls under items (i) to (iv)
- (2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have determined that a new chemical substance to which a notification under paragraph (1) of the preceding Article pertains falls under item (vi) of the preceding paragraph, they shall promptly make a determination as to which one of items (i) through (v) of said paragraph the new chemical substance falls under, based on the results of tests conducted on the new chemical substance, and shall notify the result thereof to the person who has given the notification.
- (3) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find it necessary in order to make a determination under the preceding paragraph, they may request the person who has given the notification under paragraph (1) of the preceding Article to submit materials stating the results of tests prescribed in paragraph (5) 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 any of items (ii) through (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; provided, however, that this shall not apply to a new chemical substance that has been designated pursuant to the provisions of paragraph (5) of Article 2.

(5) 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.

(6) 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 5 (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 make a determination as to whether or not said new chemical substance falls under either of the following items in the case where it falls under

item (vi) of paragraph (1) of the preceding Article:

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

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

(b) A chemical substance where it is unclear as to whether or not it falls under items (ii) through (iv) of paragraph (1) of the preceding Article

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

(2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a request under the preceding paragraph, if they find that the new chemical substance to which said request pertains falls under item (vi) of said paragraph at the time of making a determination under item (i) of the preceding Article, they shall, notwithstanding the provisions of said paragraph, make a determination as to which of the following items said new chemical substance falls under, in lieu of a determination to the effect that it falls under item (vi) of paragraph (1) of the preceding Article, based on already available knowledge on the composition, properties, etc., of the new chemical substance to which said request pertains, within three months from the date of receipt of a notification under item (i) of Article 3, and shall notify the result thereof to the person who has made the request under the preceding paragraph; in this case, the provisions of paragraph (2) of said Article shall not apply:

(i) A substance that falls under any of the items of the preceding paragraph

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

(iii) A chemical substance where it is unclear as to whether or not it falls under any of the items of the preceding paragraph

(3) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have determined that the new chemical substance to which a request under paragraph (1) pertains falls under item (iii) of the preceding paragraph, they shall promptly make a determination as to which one of items (i) or (ii) of said paragraph said new

chemical substance falls under, based on the results of tests conducted on said new chemical substance, and shall notify the result thereof to the person who has made the request.

(4) A person who has received notice to the effect that the new chemical substance to which a request made under the provisions of paragraph (2) or the preceding paragraph pertains falls under item (i) of paragraph (2) may make a request in advance, each fiscal year, to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment and receive a confirmation to the effect that the manufacture or import of the new chemical substance to which said notice pertains falls under the following items, pursuant to the provisions of Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment:

(i) The planned quantity of manufacture or planned quantity of import of said new chemical substance during the fiscal year to which the request pertains is not more than the quantity specified by Cabinet Order.

(ii) Determined by already available knowledge, etc., the new chemical substance is not one that poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution.

(5) In cases where the sum of the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of the preceding paragraph pertains (including the planned quantity of manufacture and planned quantity of import to which the confirmation under the provisions of item (v) of paragraph (1) of Article 3 pertains) relating to a single new chemical substance exceeds the quantity specified by Cabinet Order set forth in item (i) of the preceding paragraph, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall not issue the confirmation under said item.

(6) In any of the 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 person who has received the confirmation under paragraph (4) has

received said confirmation by wrongful means

(ii) Where the person who has received the confirmation under paragraph (4) is found to be manufacturing or importing the new chemical substance to which said confirmation pertains in excess of the quantity to which said confirmation pertains

(iii) In addition to the cases set forth in the preceding items, where it is found that the new chemical substance to which the confirmation under paragraph (4) pertains poses a risk of causing damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution

(7) A person who has received notice to the effect that the new chemical substance to which his/her request pertains falls under item (i) of paragraph (2), pursuant to the provisions of paragraph (2) or paragraph (3) may, when he/she finds it necessary, make a request to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment to make a determination under the following paragraph with regard to the new chemical substance to which said notice pertains, pursuant to the provisions of Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.

(8) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have given notice to the effect that the new chemical substance to which a request under paragraph (1) pertains falls under item (ii) of paragraph (2), pursuant to the provisions of paragraph (2) or paragraph (3), where they have not issued a confirmation to the effect that the manufacture or import of the new chemical substance to which a request under paragraph (4) pertains falls under the items of said paragraph, where they have rescinded the confirmation under said paragraph, or where they have received a request under the preceding paragraph, they shall promptly make a determination as to which one of items (i) through (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 (5) and paragraph (6) of the preceding Article shall

apply mutatis mutandis to a determination under paragraph (2), the provisions of paragraph (3), paragraph (5) and paragraph (6) of said Article shall apply mutatis mutandis to a determination under paragraph (3), and the provisions of paragraphs (3) through (6) 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 paragraph (4) of said Article shall be deemed to be replaced with "paragraph (8) of Article 5."

(Restrictions on Manufacture, etc.)

Article 6 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) 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 7 (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 Notification for General Chemical Substances

(Notification of Quantity, etc. of Manufacture)

Article 8 A person who manufactures or imports general chemical substances shall in every fiscal year, pursuant to Ordinance of the Ministry of Economy, Trade and Industry, notify the Minister of Economy, Trade and Industry of the quantity of manufacture, quantity of import or other matters specified by Ordinance of the Ministry of Economy, Trade and Industry for each general chemical substance in the preceding fiscal year; provided, however, that this shall not apply if the person falls under any of the following items:

(i) Where a person manufactures or imports a general chemical substance for testing and research purposes

(ii) With regard to a general chemical substance, where the quantity of manufacture or quantity of import of the general chemical substance by the person (in the case of a person who manufactures and imports said general chemical substance, the sum of these quantities) is less than the quantity specified by Cabinet Order

(iii) Where a person manufactures or imports a chemical substance that is found not to fall under any of the items of paragraph (2) or the items of paragraph (3) of Article 2 and other chemical substances that are specified by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment as chemical substances for which it is not found necessary to conduct an assessment as prescribed in paragraph (5) of said Article

(2) The provisions of the preceding paragraph (excluding item (iii)) shall apply

mutatis mutandis to a person who manufactures or imports a new chemical substance pertaining to the notice prescribed in paragraph (4) of Article 4 (including cases where it is applied mutatis mutandis pursuant to paragraph (9) of Article 5 by replacing the terms) (this person shall be limited to a person who has received said notification) and to a person who imports a new chemical substance pertaining to notification as prescribed in paragraph (4) of Article 4 as applied mutatis mutandis pursuant to paragraph (2) of the preceding Article from a person who has received said notification.

Chapter IV Measures for Chemical Substances Requiring Priority Assessment

(Notification of Quantity, etc. of Manufacture)

Article 9 (1) A person who manufactures or imports a chemical substance requiring priority assessment (excluding one that is designated as a class II specified chemical substance by falling under any of the items of paragraph (3) of Article 2; the same shall apply hereinafter in this Article, and in Articles 12 and 41) shall in every fiscal year, pursuant to Ordinance of the Ministry of Economy, Trade and Industry, notify the Minister of Economy, Trade and Industry of the quantity of manufacture, quantity of import or other matters specified by Ordinance of the Ministry of Economy, Trade and Industry for each general chemical substance in the preceding fiscal year; provided, however, that this shall not apply if the person falls under any of the following items:

- (i) Where a person manufactures or imports a chemical substance requiring priority assessment for testing and research purposes
- (ii) With regard to a chemical substance requiring priority assessment, where the quantity of manufacture or quantity of import of the chemical substance requiring priority assessment pertaining to the person (in the case of a person who manufactures and imports said chemical substance requiring priority assessment, the sum of these quantities) is less than the quantity specified by Cabinet Order

(2) The Minister of Economy, Trade and Industry shall, in every fiscal year, publicize the sum of the quantity of manufacture and quantity of import in the preceding paragraph pertaining to the notification set forth in the preceding paragraph; provided, however, that this shall not apply when the sum of the quantity of

manufacture and quantity of import of a chemical substance requiring priority assessment is less than the quantity specified by Ordinance of the Ministry of Economy, Trade and Industry.

(Study of Hazardous Properties of Chemical Substances Requiring Priority Assessment)

Article 10 (1) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find it necessary to conduct the assessment prescribed in paragraph (5) of Article 2 for a chemical substance requiring priority assessment, they may request that a person who engages in the business of manufacturing or importing said chemical substance requiring priority assessment (including a person who used to engage in these businesses and is specified by Ordinance of the Economy, Trade and Industry; the same shall apply in the following paragraph) submit materials in which the results of the tests that are prescribed in paragraph (5) of Article 4 on the properties of said chemical substance requiring priority assessment and that are 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.

(2) With regard to a chemical substance requiring priority assessment, where it is found that there are reasons to suspect that it falls under any of the items of paragraph (3) of Article 2 from the perspective of the results of tests set forth in the preceding paragraph and other already available knowledge on said chemical substance requiring priority assessment and if said chemical substance requiring priority assessment falls under any of the items of said paragraph based on its properties and the status of its manufacture, import, use, etc., it is expected that said chemical substance requiring priority assessment is likely to cause damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution; so that when the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find it necessary to judge whether or not said chemical substance requiring priority assessment falls under any of the items of said paragraph, they may instruct a person who engages in the

manufacture or import of said chemical substance requiring priority assessment to conduct a study of hazardous properties 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 study means a study of the effects of said chemical substance on human health and its effects on the inhabitation and/or growth of flora and fauna in the human living environment if ingested continuously; the same shall apply in paragraph (4)) and report the results.

(3) Where the report set forth in the preceding paragraph is made, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall judge whether or not the chemical substance requiring priority assessment pertaining to said report falls under any of the items of paragraph (3) of Article 2 and notify the person who made the report of the results.

(4) Where the Minister of Economy, Trade and Industry finds it particularly necessary to ensure that the expenses required for the tests pertaining to the request pursuant to the provisions of paragraph (1) or the study of hazardous properties pertaining to the instruction pursuant to the provisions of paragraph (2) are divided fairly among the business operators concerned, he/she may establish standards concerning the method and proportion for sharing the expenses required for said tests or said study of hazardous properties.

(Rescission of Designation as a Chemical Substance Requiring Priority Assessment

Article 11 Where a chemical substance requiring priority assessment falls under any of 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 designation and publicize the rescission without delay:

(i) Where the chemical substance requiring priority assessment is designated as a class I specified chemical substance, a class II specified chemical substance (limited to cases where it falls under all of the items of paragraph (3) of Article 2) or a monitoring chemical substance

(ii) Where the chemical substance requiring priority assessment falls under any of the following (a) through (d) based on the submission of materials set forth in

paragraph (1) of the preceding Article, the report set forth in paragraph (2) of said Article or on knowledge that has been otherwise obtained and the status of its manufacture, import, use, etc.:

- (a) Where said chemical substance requiring priority assessment is designated as a class II specified chemical substance falling under item (i) of paragraph (3) of Article 2, when it is found that said chemical substance requiring priority assessment is not likely to cause damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution
- (b) Where said chemical substance requiring priority assessment is designated as a class II specified chemical substance falling under item (ii) of paragraph (3) of Article 2, when it is found that said chemical substance requiring priority assessment is not likely to cause damage to human health by causing environmental pollution
- (c) Where said chemical substance requiring priority assessment is designated as a class II specified chemical substance falling under any of the items of paragraph (3) of Article 2, when it is found that said chemical substance requiring priority assessment falls under an item other than said item
- (d) Where it is found that said chemical substance requiring priority assessment is not likely to cause either damage to human health or damage to the inhabitation and/or growth of flora and fauna in the human living environment by causing environmental pollution

(Provision of Information)

Article 12 Where a person who engages in the business of manufacturing a chemical substance requiring priority assessment, a person who uses a chemical substance requiring priority assessment as his/her business and any other person who handles a chemical substance requiring priority assessment as his/her business (hereinafter collectively referred to as a "business operator handling a chemical substance requiring priority assessment") transfers or provides a chemical substance requiring priority assessment 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

requiring priority assessment and the substance to be transferred or provided is a chemical substance requiring priority assessment.

Chapter V Regulations, etc. Concerning Class I Specified Chemical Substances
Section 1 Measures Concerning Monitoring Chemical Substances

(Notification of the Quantity of Manufacture, etc.)

Article 13 (1) A person who has manufactured or imported any monitoring chemical substance shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or the quantity of import in the preceding fiscal year and other matters specified by Ordinance of the Ministry of Economy, Trade and Industry for each monitoring chemical substance, 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 monitoring chemical substance for testing and research purposes.

(2) The Minister of Economy, Trade and Industry shall publicize, each fiscal year, the sum of the quantity of manufacture and quantity of import in the preceding fiscal year to which the notification under the preceding paragraph pertains for each monitoring chemical substance; provided, however, that this shall not apply to the case where the sum of the quantity of manufacture and quantity of import for one monitoring chemical substance is less than the quantity specified by Ordinance of the Ministry of Economy, Trade and Industry.

(Study of Hazardous Properties of Monitoring Chemical Substances)

Article 14 (1) In the case where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find sufficient reason to suspect that any single monitoring chemical substance falls under any of the items of paragraph (2) of Article 2, if they have found it necessary to make a determination as to whether or not said monitoring chemical substance falls under any of the items of said paragraph since said monitoring chemical substance is expected to poses a risk of causing environmental pollution if said monitoring chemical substance falls under any of the items of said paragraph, in view of the state of its manufacture, import, use, etc., they may instruct 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 a person engages in the business of manufacturing or importing of said monitoring chemical substance (including a person who engaged in 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 predator animals at higher trophic level if ingested continuously; the same shall apply in paragraph (3)) and to report the results thereof.

(2) Where the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment have received a report under the preceding paragraph, they shall make a determination as to whether or not the monitoring chemical substance to which said report pertains falls under any one of the items of paragraph (2) of Article 2 and notify the result thereof to the person who has made the report.

(3) When the Minister of Economy, Trade and Industry finds it particularly necessary for ensuring that the expenses for the study of the hazardous properties to which the instruction under the provisions of paragraph (1) pertains are shared out fairly among the business operators concerned, 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 Monitoring Chemical Substance)

Article 15 When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment find that a monitoring chemical substance falls under either of the following items, they shall rescind the designation and publicize to that effect without delay:

(i) Where said chemical substance 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 16 Where a person who engages in the business of manufacturing a monitoring chemical substance, a person who uses a monitoring chemical substance as his/her business and any other person who handles a monitoring chemical substance as his/her business (hereinafter collectively referred to as a "business operator handling a monitoring chemical substance") transfers or provides a monitoring chemical substance 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 monitoring chemical substance and the substance to be transferred or provided is a monitoring chemical substance.

Section 2 Regulations Concerning Class I Specified Chemical Substances

(Permission to Manufacture)

Article 17 (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 18 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 19 Permission under paragraph (1) of Article 17 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 33 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 20 The Minister of Economy, Trade and Industry shall not grant permission under paragraph (1) of Article 17, 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 21 (1) A person who has obtained permission under paragraph (1) of Article

17 (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 17 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 17 shall apply mutatis mutandis to the permission under paragraph (1) and the notification under paragraph (2).

(Permission to Import)

Article 22 (1) A person who intends to import a class I specified chemical substance shall obtain permission from the Minister of Economy, Trade and Industry; provided, however, that this shall not apply to the case where a person intends to import a class I specified chemical substance for testing and research purposes.

(2) A person who intends to obtain permission under the preceding paragraph shall submit a written application stating the following matters to the Minister of Economy, Trade and Industry:

(i) The name and domicile, and in the case of a juridical person the name of the representative person

(ii) The name of the class I specified chemical substance

(iii) The import quantity

(3) The provisions of paragraph (3) of Article 17 shall apply mutatis mutandis to the permission under paragraph (1).

(Standards for Permission, etc.)

Article 23 (1) Where the Minister of Economy, Trade and Industry has received an

application for permission under paragraph (1) of the preceding Article, he/she shall not grant permission under said paragraph unless he/she finds that the import of the class I specified chemical substance to which said application pertains is necessary for meeting the demand for said class I specified chemical substance.

(2) The provisions of Article 19 shall apply *mutatis mutandis* to the permission under paragraph (1) of the preceding Article.

(Restrictions on Import of Products)

Article 24 (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 by giving consideration to such matters as the circumstances of the use of said class I specified chemical substance overseas.

(Restrictions on Use)

Article 25 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 inhabitation 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 26 (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 17 shall apply mutatis mutandis to the notification under the preceding two paragraphs.

(Succession)

Article 27 (1) Where a permitted manufacturer, a person who has obtained permission under paragraph (1) of Article 22 (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 17 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 28 (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 20.

(2) Where a permitted manufacturer, a person who uses 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 who handles 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 29 (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 30 (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 20, 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 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 28, he/she may order said business operator handling the class I 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 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 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 31 (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 32 (1) Where a permitted manufacturer or a notifying user has abolished his/her business, he/she shall notify the Minister of Economy, Trade and Industry, in the case of a permitted manufacturer, and notify the competent minister, in the

case of a notifying user, to that effect without delay.

(2) Where a permitted manufacturer has discontinued his/her business, the relevant permission shall lose its effect.

(3) The provisions of paragraph (3) of Article 17 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 33 (1) Where a permitted manufacturer falls under any of the following items, the Minister of Economy, Trade and Industry may rescind the relevant permission or order the suspension of business for a specified period:

(i) Where the permitted manufacturer has fallen under item (i), (iii) or (iv) of Article 19

(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 21 without obtaining such permission

(iii) Where the permitted manufacturer has violated an order under the provisions of paragraph (1) of Article 30

(iv) Where the permitted manufacturer has violated the conditions under paragraph (1) of Article 40

(2) Where a permitted importer has fallen under item (i), (iii) or (iv) of Article 19 as applied mutatis mutandis pursuant to paragraph (2) of Article 23, 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 17 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 34 (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 18: 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 22: 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 24: 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 25: the person who has used said class I specified chemical substance

Chapter VI Regulations Concerning Class II Specified Chemical Substances
(Notification, etc. of the Planned Quantity of Manufacture)

Article 35 (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 given a notification under the provisions of paragraph (1) shall not manufacture or import in excess of the planned quantity of manufacture or the planned quantity of import to which said notification pertains (where a notification of change under the provisions of the preceding paragraph has been given, such quantity after the change).

(4) In the case of the occurrence of a situation where it is necessary to restrict the manufacture or import of a class II specified chemical substance or the import of a product using a class II specified chemical substance in order to prevent damage to

human health or to the inhabitation and/or growth of flora and fauna in the human living environment through environmental pollution attributable to said Class II Chemical Substance, in light of the state of the manufacture, import, use, etc. of said class II specified chemical substance or product using a class II specified chemical substance as well as the effects, etc. of the implementation of measures under the provisions of the following Article and Article 37 taken in relation to said class II specified chemical substance, the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment shall make an acknowledgement to that effect, pursuant to the provisions of Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment.

- (5) Where the acknowledgment under the preceding paragraph has been made, the Minister of Economy, Trade and Industry may order the person who has given a notification under the provisions of paragraph (1) to change the planned quantity of manufacture or the planned quantity of import to which said notification pertains (where a notification of change under the provisions of paragraph (2) has been given, the quantity after the change). In this case, the provisions of paragraph (3) shall apply *mutatis mutandis*.
- (6) A person who has given a notification under the provisions of paragraph (1) shall, each fiscal year, notify the Minister of Economy, Trade and Industry of the quantity of manufacture or the quantity of import in the preceding fiscal year and other matters specified by 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 24 shall apply *mutatis mutandis* to the Cabinet Order set forth in paragraph (1).

(Publication of Technical Guidelines, etc.)

Article 36 (1) For each class II specified chemical substance, the competent ministers shall publish technical guidelines on the measures to be taken by persons who operate the business of manufacturing said class II specified chemical substance,

persons who use said class II specified chemical substance 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 businesses, and any other persons who handle said class II specified chemical substance, etc. as their businesses (hereinafter referred to as a "business operator handling a class II specified chemical substance, etc." in this Section) in order to prevent environmental pollution attributable to the class II specified chemical substance they handle.

(2) Where the competent ministers have published technical guidelines pursuant to the provisions of the preceding paragraph, if they find it necessary, they may make a necessary recommendation to a 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 37 (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 VII Miscellaneous Provisions

(Recommendations)

Article 38 (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 39 Where the competent ministers find it particularly necessary for preventing environmental pollution attributable to a chemical substance requiring priority assessment, a monitoring chemical substance or a class II specified chemical substance, they may provide a business operator handling said chemical substance requiring priority assessment pertaining to said chemical substance requiring priority assessment, a business operator handling a monitoring chemical substance, etc. pertaining to said monitoring chemical substance or a business operator handling 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 each respective chemical substance.

(Conditions for Permission)

Article 40 (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 41 (1) A person operating the business of manufacturing or importing any chemical substance requiring priority assessment, any monitoring chemical substance, any class II specified chemical substance or any general chemical substance (hereinafter referred to as a "substance subject to reporting") shall, when he/she has conducted tests for the items to be tested prescribed in paragraph (5) of Article 4 or for the studies of hazardous properties prescribed in paragraph (2) of Article 10 or paragraph (1) of Article 14 (including those cases in which knowledge equivalent to that which would be obtained from said tests [limited to knowledge that is not publicly known] has been obtained) with regard to the substance subject to reporting that he/she has manufactured or imported and if he/she has obtained, as a result thereof, knowledge 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 that indicates that that the substance subject to reporting possesses the following properties, he/she shall report to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment to that effect and provide the details of said knowledge, 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 cases where said person has obtained said knowledge as a result of a study of hazardous properties to which an instruction under the provisions of paragraph (2) of Article 10 or paragraph (1) of Article 14 pertains and is reporting the details of said knowledge pursuant to these

provisions:

- (i) The substance subject to reporting is not likely to undergo a chemical transformation through natural processes
 - (ii) The substance subject to reporting is bioaccumulative.
 - (iii) The substance subject to reporting poses a risk of impairing human health if ingested continuously.
 - (iv) The substance subject to reporting poses a risk of interfering with the inhabitation and/or growth of flora and fauna.
 - (v) In the case that the substance subject to reporting is likely to undergo a chemical transformation through natural processes, it is one where the chemical substance (including an element) generated by the chemical transformation through natural processes falls under any of the preceding items.
- (2) 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 5 (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 5 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 7 from another person who obtains said notification.
- (3) Where a person who engages in the business of manufacturing or importing a chemical substance requiring priority assessment, a monitoring chemical substance or a class II specified chemical substance has knowledge of the composition, properties, etc. of the chemical substance requiring priority assessment, the monitoring chemical substance 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 (2) of Article 10, paragraph (1) of Article 14 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) of Article 2, 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 42 The competent ministers may request that a business operator handling a chemical substance requiring priority assessment, a business operator handling a monitoring chemical substance or a business operator handling a class II specified chemical substance, etc. report the status of their handling of a chemical substance requiring priority assessment, a monitoring chemical substance or a class II chemical substance, etc.

(Collection of Reports)

Article 43 (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 items (iv) through (vi) of paragraph (1) of Article 3 or under paragraph (4) of Article 5 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 35 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 34 or Article 38 make a report concerning his/her operations.

(On-Site Inspections, etc.)

Article 44 (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 items (iv) through (vi) of paragraph (1) of Article 3 or paragraph (4) of Article 5, 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 a class I specified chemical substance, etc. or a person who has given a notification under the provisions of paragraph (1) of Article 35, 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 34, 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) through (3).
- (6) Where the Minister of Economy, Trade and Industry has NITE conduct the on-site inspection, questioning, or taking of samples pursuant to the provisions of the preceding paragraph, he/she shall instruct NITE to conduct such on-site inspection, questioning or taking of samples by indicating the place of said on-site inspection and any other necessary matters.
- (7) Where NITE has conducted the on-site inspection, questioning, or taking of samples prescribed in paragraph (5), in accordance with the instructions under the preceding paragraph, it shall report the results thereof to the Minister of Economy, Trade and Industry.
- (8) Where an official of NITE enters a site pursuant to the provisions of paragraph (5), he/she shall carry an identification card and present it to the relevant persons.
- (9) The authority for the on-site inspection, questioning, and taking of samples under the provisions of paragraphs (1) through (3) shall not be construed as an authority granted for the purpose of criminal investigation.

(Orders to NITE)

Article 45 Where the Minister of Economy, Trade and Industry finds it necessary for securing the proper implementation of operations relating to the on-site inspection, questioning, or taking of samples prescribed in paragraph (5) of the preceding Article, he/she may issue the necessary orders concerning said operations to NITE.

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

Article 46 Any person who is dissatisfied with the taking of samples by NITE may file a request for examination under the Administrative Appeals Act (Act No. 160 of 1962) with the Minister of Economy, Trade and Industry.

(Notification)

Article 47 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 48 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 30: the Minister of Economy, Trade and Industry
- (ii) An order prescribed in paragraph (2) of Article 30: the competent minister

(Fees)

Article 49 A person who intends to obtain permission under paragraph (1) of Article 17, paragraph (1) of Article 21, or paragraph (1) of Article 22 shall pay a fee of the amount specified by Cabinet Order in consideration of the actual expenses.

(Special Provisions on Hearings)

Article 50 (1) Where the Minister of Economy, Trade and Industry intends to issue an order under the provisions of paragraph (1) of Article 33, he/she shall hold a hearing, regardless of the category of the procedure for hearing statements of opinion under the provisions of paragraph (1) of Article 13 of the Administrative Procedure Act (Act No. 88, 1993).

(2) The proceedings on the date of a hearing to which a disposition under the provisions of Article 33 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 51 (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 52 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 53 (1) The competent ministers under this Act shall be as follows:

(i) With regard to a notification under the provisions of Article 26, paragraph (2) of Article 27, or paragraph (1) of Article 32, an order under the provisions of paragraph (2) of Article 30 (excluding an order given to a permitted manufacturer), the collection of reports under the provisions of paragraph (2) of Article 43, or the inspection, questioning, or taking of samples under the provisions of paragraph (2) of Article 44, 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 30 (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 34, the publication of technical guidelines under the provisions of paragraph (1) of Article 36, a

recommendation under the provisions of paragraph (2) of said Article or Article 38, guidance and advice under the provisions of Article 39, the collection of reports under the provisions of Article 42 or paragraph (3) of Article 43, or the inspection, questioning or taking of samples under the provisions of paragraph (3) of Article 43, 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

(2) 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 31 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 28 (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 paragraph (2) of Article 28 (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 54 The authority of the Minister of the Environment prescribed in this Act may be delegated to the Director Generals of the Regional Environment Offices, pursuant to Ordinance of the Ministry of Environment.

(Relationship with Other Acts)

Article 55 The provisions of Article 3, paragraph (1) of Article 7, paragraph (1) of

Article 8 (including in cases as applied mutatis mutandis pursuant to paragraph (2) of said Article), paragraph (1) of Article 9, paragraphs (1) and (2) of Article 10, Article 12, paragraph (1) of Article 13, paragraph (1) of Article 14, Article 16, paragraph (1) of Article 17, Article 18, paragraphs (1) of Article 22, Article 25, paragraph (1) of Article 26, paragraph (2) of Article 28, paragraph (1) of Article 29, paragraphs (1) and (3) of Article 34, paragraph (1) of Article 35, paragraph (1) of Article 36, paragraph (1) of Article 37, Article 38, Article 39, paragraphs (1) (including in cases as applied mutatis mutandis pursuant to paragraph (2) of Article 40) and (3) of Article 40 and Article 42 shall not apply to the chemical substances which constitute the articles listed in the following items; the provisions of paragraph (1) of Article 24, paragraph (2) of Article 28, paragraph (1) of Article 29 and Article 34 shall not apply to the products listed in the following items in which class I specified chemical substances are used; the provisions of paragraph (1) of Article 35, paragraph (1) of Article 36, paragraph (1) of Article 37, Article 39 and Article 42 shall not apply to the articles listed in the following items in which class II specified chemical substances are used; and the provisions of Article 12, Article 16, Article 25, paragraph (1) of Article 26, paragraph (2) of Article 28, paragraph (1) of Article 29, paragraph (3) of Article 34, paragraph (1) of Article 36, paragraph (1) of Article 37, Article 38, Article 39 and Article 42 shall not apply to the use of chemical substances as raw materials for the articles listed in the following items, but the Acts set forth in the following items shall apply to them respectively:

- (i) Food prescribed in paragraph (1) of Article 4 of the Food Sanitation Act (Act No. 233 of 1947), additives prescribed in paragraph (2) of said Article, containers and packaging prescribed in paragraph (5) of said Article, toys prescribed in paragraph (1) of Article 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 56 (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 or revision based on a determination under paragraph (1) or (2) of Article 4, paragraph (8) of Article 5, or paragraph (2) of Article 14), or when intending to plan out the establishment or revision of Cabinet Order under paragraph (3) of Article 2, paragraph (1) of Article 24, Article 25, paragraph (2) of Article 28, paragraph (1) of Article 35 or paragraph (1) of Article 36

(ii) When intending to make a designation under paragraph (4) or (5) of Article 2 (excluding the case of intending to make such designation in accordance with the procedure as prescribed in the following paragraph)

(iii) When intending to make a determination under paragraph (1) or (2) of Article 4, paragraph (2), (3) or (8) of Article 5, paragraph (3) of Article 10, or paragraph (2) of Article 14

(iv) When intending to give an instruction under paragraph (2) of Article 10 or paragraph (1) of Article 14

(v) When intending to make an acknowledgment under paragraph (4) of Article 35

(2) When the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment judge pursuant to the provisions of paragraphs (1) or (2) of Article 4 or paragraph (8) of Article 5 that a new chemical substance subject to the notification set forth in paragraph (1) of Article 3 falls under any of items (ii) through (iv) of paragraph (1) of Article 4, they

shall hear the opinions of the councils, etc., specified by the Cabinet Order set forth in the preceding paragraph without delay regarding whether or not it is necessary to provide the designation set forth in paragraph (5) of Article 2 to said chemical substance.

Chapter VIII Penal Provisions

Article 57 A person who falls under any of the following items shall be punished by imprisonment with work for not more than three years or by 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 17
- (ii) A person who has violated the provisions of Article 18, paragraph (1) of Article 24, or Article 25
- (iii) A person who has imported a class I specified chemical substance in violation of the provisions of paragraph (1) of Article 22
- (iv) A person who has violated an order to suspend business under the provisions of paragraph (1) of Article 33
- (v) A person who has violated an order under the provisions of paragraph (3) of Article 34

Article 58 A person who falls under any of the following items shall be punished by imprisonment with work for not more than one year or by 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 6
- (iii) A person who has violated an instruction under the provisions of paragraph (2) of Article 10 or paragraph (1) of Article 14
- (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 35 (including the cases where it is applied mutatis mutandis pursuant to paragraph (5) of said Article).

Article 59 A person who falls under any of the following items shall be punished by

imprisonment with work for not more than six months or by 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 21
- (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 26
- (iii) A person who has violated an order under the provisions of Article 30 or paragraph (1) or (2) of Article 34

Article 60 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 31 (including the cases where it is applied mutatis mutandis pursuant to paragraph (3) of said Article), or has failed to preserve the books in violation of the provisions of paragraph (2) of said Article (including the cases where it is applied mutatis mutandis pursuant to paragraph (3) of said Article)
- (ii) A person who has failed to give a notification under the provisions of paragraph (1) of Article 9, paragraph (1) of Article 13, paragraph (6) of Article 35 or has given a false notification
- (iii) A person who has failed to make a report under the provisions of Article 43 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) through (3) of Article 44 or has refused to answer or has given a false answer to the questioning under these provisions

Article 61 Where the representative person of a juridical person, or an agent, employee or any other worker of a juridical person or individual has committed an act in violation of any of the provisions listed in the following items with regard to the business of said juridical person or individual, not only the offender shall be punished but also said juridical person shall be punished by the fine prescribed in said relevant item or said individual shall be punished by the fine prescribed in the relevant Article:

- (i) Article 57 - A fine of not more than one hundred million yen;
- (ii) Item (i), (ii) or (iv) of Article 58 - A fine of not more than five hundred thousand yen
- (iii) Item (iii) of Article 58, Article 59, or the preceding Article - The fine prescribed in the relevant Article

Article 62 A person who falls under either of the following items shall be punished by a non-penal fine of not more than two hundred thousand yen:

- (i) A person who has failed to give notification under the provisions of paragraph (1) of Article 8 (including in cases as applied mutatis mutandis pursuant to paragraph (2) of said Article), paragraph (2) of Article 21, paragraph (2) of Article 26, paragraph (2) of Article 27, paragraph (1) of Article 32 or paragraph (2) of Article 35 or has given a false notification
- (ii) A person who has failed to make a report under the provisions of paragraph (1) of 41 (including in cases where as applied mutatis mutandis pursuant to paragraph (2) of said Article) or has submitted a false report

Article 63 In the case where an order under the provisions of Article 45 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 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 type II monitoring chemical substances 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 type III monitoring chemical substances 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 has been filed or made prior to the enforcement of this Act under the laws and regulations to a council or any other panel to require the implementation of procedures equivalent to the procedures to hold hearings or grant the opportunity for explanation and other procedures to hear statements of opinions prescribed in Article 13 of the Administrative Procedure Act, with regard to the procedures concerning adverse dispositions pertaining to said appeal or other request, the provisions then in force shall remain applicable notwithstanding the provisions for 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 of 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 that it is judged 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 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:

(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 type II monitoring chemical substance as prescribed in paragraph (5) of Article 2 of the former Act (hereinafter referred to as a "type II monitoring chemical substance" in the following paragraph) or a type III monitoring chemical substance as prescribed in paragraph (6) of said Article of the former Act (hereinafter referred to as a "type III monitoring chemical substance"), 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 type II monitoring chemical substance or a type III monitoring chemical substance for which the knowledge prescribed in paragraphs (1) or (3) of Article 31-2 of the former Act is obtained with respect to a type II monitoring chemical substance or a type III monitoring chemical substance, 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 type I monitoring chemical substance that is actually designated pursuant to the provisions of paragraph (4) of Article 2 of the former Act at the time of the enforcement of the provisions listed in item (iii) of Article 1 of the Supplementary Provisions shall be deemed to be a monitoring chemical substance as designated pursuant to the provisions of paragraph (4) of Article 2 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 respective provisions listed in the items of 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.