

# Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

(Tentative Translation)

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## Chapter 1 General Provisions

(Purpose)

### Article 1

This Law shall have the purpose of ensuring the precise and smooth implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter “the Protocol”), thereby contributing to the welfare of humankind and helping to assure healthy cultural lives for the people now and in the future, by devising measures to regulate the use of living modified organisms in order for the conservation and the sustainable use of biological diversity through international cooperation.

(Definitions)

### Article 2

1. In this Law, “organism” shall mean a single cell (excluding a single cell forming a cell colony) or a cell colony which is stipulated in the ordinance of the competent ministries as having the capacity to transfer or replicate nucleic acid, and viruses and viroids.
2. In this Law, “living modified organism” shall mean an organism that possesses nucleic acid, or a replicated product thereof, obtained using the technologies set forth in the following.
  - (i) Technology for processing nucleic acid extracellularly which is stipulated in the ordinance of the competent ministries
  - (ii) Technology for fusing cells of organisms belonging to different taxonomical families, which is stipulated in the ordinance of the competent ministries
3. In this Law, “use” shall mean use for provision as food, animal feed or other purposes, cultivation and other growth, processing, storage, transportation and disposal, and other acts subsidiary to these.
4. In this Law, “biological diversity” shall mean biological diversity as provided for in Article 2 of the Convention on Biological Diversity.
5. In this Law, “Type 1 Use” shall mean use not subject to taking the measures provided for in the following paragraph.
6. In this Law, “Type 2 Use” shall mean use undertaken with the intention of preventing the dispersal of living modified organisms into the air, water or soil outside facilities, equipment or other structures (hereinafter “Facilities”) in accordance with measures specifying this fact or other measures stipulated in the ordinance of the competent ministries.

7. In this Law, “containment measures” shall mean measures taken to prevent the dispersal of living modified organisms into the air, water or soil outside Facilities when using living modified organisms by making use of Facilities or by another necessary method.

(Announcement of Basic Matters)

#### Article 3

The competent minister shall stipulate and publicly announce the matters defined in the following (hereinafter “Basic Matters”) to ensure the precise and smooth implementation of the Protocol. The same shall apply whenever these are changed.

- (i) Basic matters concerning the implementation of measures designed to prevent adverse effects that are caused by the use of living modified organisms and pose unacceptable risks that impair biological diversity (hereinafter “Adverse Effect on Biological Diversity”)
- (ii) Basic matters that have to be taken into account by a person who makes use of living modified organisms in order to undertake such acts correctly
- (iii) Besides those stipulated in the preceding two subparagraphs, important matters designed to ensure that the use of living modified organisms is undertaken correctly

### Chapter 2 Measures to Prevent Adverse Effects on Biological Diversity Caused by the Use of Living Modified Organisms in Japan

#### Section 1 Type 1 Use of Living Modified Organisms

(Approval of Type 1 Use Regulations Concerning Type 1 Use of Living Modified Organisms)

#### Article 4

1. A person who wishes to create or import and make Type 1 Use of living modified organisms or other persons who wish to make Type 1 Use of living modified organisms must stipulate regulations for said Type 1 Use for each type of living modified organism (hereinafter “Type 1 Use Regulations”), and must obtain the approval of the competent minister for the same, provided, however, that this shall not apply when wishing to make Type 1 Use of living modified organisms which, by virtue of their properties or other features, are designated by the competent minister as organisms that clearly cause no Adverse Effect on Biological Diversity due to Type 1 Use (hereinafter “Specific

Living Modified Organisms”), or when wishing to make Type 1 Use as stipulated in Type 1 Use Regulations for which the approval of the competent minister has been obtained under the provisions of this paragraph or Article 9 paragraph 1 (or, in the case of Type 1 Use Regulations that have been altered by the competent minister under the provisions of Article 7 paragraph 1 (including cases applied mutatis mutandis in Article 9 paragraph 4), said Type 1 Use Regulations after alteration), or in other cases stipulated in the ordinance of the competent ministries.

2. A person who wishes to obtain the approval in the preceding paragraph must assess the Adverse Effect on Biological Diversity caused by the Type 1 Use of each type of living modified organism as stipulated by the competent minister, and must submit to the competent minister an application form detailing the following matters., together with a document detailing the results of this assessment (hereinafter “Biological Diversity Risk Assessment Report”) and other documents stipulated in the ordinance of the competent ministries

(i) Name and address (or, in the case of a corporation, its name, the name of its representative and the address of its main office; the same shall also apply in Article 13 paragraph 2 subparagraph 1 and Article 18 paragraph 4 subparagraph 2)

(ii) The Type 1 Use Regulations

3. Type 1 Use Regulations shall stipulate the following matters, as stipulated in the ordinance of the competent ministries.

(i) Names of types of living modified organisms

(ii) Content and method of Type 1 Use of living modified organisms

4. The competent minister must, on receiving an application for approval in paragraph 1, consult persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity (hereinafter “Experts”) with regard to the Type 1 Use Regulations pertaining to the said application, as stipulated in the ordinance of the competent ministries.

5. The competent minister must, when recognizing that no adverse effect that could pose an unacceptable risk that impairs the preservation of species or populations of wild fauna or flora or no other Adverse Effect on Biological Diversity could arise when making Type 1 Use in accordance with the Type 1 Use Regulations pertaining to an application for approval in paragraph 1, give approval for said Type 1 Use Regulations, taking account of the content of consultation with Experts under the provisions of the preceding paragraph and the Basic Matters.

6. Experts who have been consulted under the provisions of paragraph 4 may not divulge or appropriate secrets gleaned concerning Type 1 Use Regulations pertaining to

an application for approval in paragraph 1 or the Biological Diversity Risk Assessment Report thereof.

7. Besides those provided for in the preceding paragraphs, necessary matters concerning the approval in paragraph 1 shall be stipulated in the ordinance of the competent ministries.

(Amendment of Type 1 Use Regulations)

Article 5

1. When recognizing that Adverse Effect on Biological Diversity could arise from Type 1 Use made in accordance with the Type 1 Use Regulations pertaining to an application for approval in paragraph 1 of the preceding Article, the competent minister must instruct the applicant, as stipulated in the ordinance of the competent ministries, to amend said Type 1 Use Regulations, provided, however, that this shall not apply when Type 1 Use of living modified organisms pertaining to said Type 1 Use Regulations is recognized inappropriate.

2. If a person who has received instructions under the provisions of the preceding paragraph does not amend Type 1 Use Regulations based on said instructions within the time limit stipulated by the competent minister, the competent minister shall reject that person's application for approval.

3. In the case provided for in the proviso to paragraph 1, the competent minister must refuse said approval.

(Obligations of Persons Obtaining Approval)

Article 6

1. A person who has obtained the approval in Article 4 paragraph 1 (referred to as "Person Obtaining Approval" in the following paragraph) must, when a change has occurred in the matters set forth in paragraph 2 subparagraph 1 of the same Article, notify the competent minister to that effect with the reason in writing, as stipulated in the ordinance of the competent ministries.

2. The competent minister may, when wishing to study changes to or the abolition of Type 1 Use Regulations under the provisions of paragraph 1 of the following Article or when otherwise necessary to gather information concerning said Type 1 Use Regulations, seek the provision of necessary information from the Person Obtaining Approval pertaining to said Type 1 Use Regulations.

(Changes to Approved Type 1 Use Regulations)

## Article 7

1. The competent minister must, when it has come to be recognized that, due to environmental changes that could not be foreseen at the time of the approval in Article 4 paragraph 1 or the amplification of scientific knowledge after the date of said approval, Adverse Effect on Biological Diversity could arise even when Type 1 Use of living modified organisms is made in accordance with Type 1 Use Regulations for which the approval has been obtained, change or abolish said Type 1 Use Regulations within the limits necessary to prevent Adverse Effect on Biological Diversity.
2. The competent minister shall consult Experts in advance, as stipulated in the ordinance of the competent ministries, concerning changes or abolition under the provisions of the preceding paragraph.
3. Experts who have been consulted under the provisions of the preceding paragraph may not divulge or appropriate secrets gleaned concerning Type 1 Use Regulations pertaining to changes or abolition under the provisions of paragraph 1 or the Biological Diversity Risk Assessment Report thereof.
4. Besides those provided for in the preceding three paragraphs, necessary matters concerning changes or abolition under the provisions of paragraph 1 shall be stipulated in the ordinance of the competent ministries.

(Announcement of Approved Type 1 Use Regulations)

## Article 8

1. The competent minister must make public announcement of the matters stipulated in each of the following subparagraphs in accordance with the categories set forth in said subparagraphs, as stipulated in the ordinance of the competent ministries, without delay.
  - (i) When giving the approval in Article 4 paragraph 1: Announcement to that effect and the approved Type 1 Use Regulations
  - (ii) When changing Type 1 Use Regulations under the provisions of paragraph 1 of the preceding Article: Announcement to that effect and the Type 1 Use Regulations after the change
  - (iii) When abolishing Type 1 Use Regulations under the provisions of paragraph 1 of the preceding Article: Announcement to that effect
2. Announcement under the provisions of the preceding paragraph shall be made by official notification.

(Approval of Type 1 Use Regulations Pertaining to Exporters to Japan)

## Article 9

1. A person who wishes to export living modified organisms to Japan and cause other persons to make Type 1 Use thereof, or other persons who wish to cause other persons to make Type 1 Use of living modified organisms may, as stipulated in the ordinance of the competent ministries, determine Type 1 Use Regulations for each type of living modified organism and obtain the approval of the competent minister thereto.
2. A person who wishes to obtain the approval in the preceding paragraph must, when that person does not have an address (or, in the case of a corporation, its main office; the same shall also apply henceforth in this paragraph and in paragraph 4) in Japan, appoint, from among persons who have an address in Japan or other persons stipulated in the ordinance of the competent ministries, a person to whom necessary measures shall be entrusted to ensure the correct use of living modified organisms in Japan, when applying for said approval.
3. A person who has made an appointment under the provisions of the preceding paragraph must, when changing the person appointed under the provisions of the said paragraph (hereinafter “Domestic Manager”), notify the competent minister to that effect with the reason .
4. The provisions of Article 4 paragraph 2 to paragraph 7, Article 5 and the preceding Article shall apply mutatis mutandis to the approval in paragraph 1, the provisions of Article 6 to a person who has obtained the approval in paragraph 1 (or, when that person does not have an address in Japan, the Domestic Manager pertaining to that person), and the provisions of Article 7 to Type 1 Use Regulations approved under the provisions of paragraph 1. In these cases, “Name and address” in Article 4 paragraph 2 subparagraph 1 shall be read as “Name and address of the person who wishes to obtain the approval in Article 9 paragraph 1 and, when that person does not have an address (or, in the case of a corporation, its main office) in Japan, of a person appointed under the provisions of paragraph 2 of the same Article”, and “Article 4 paragraph 1” in Article 7 paragraph 1 shall be read as “Article 9 paragraph 1”.

(Orders for Measures Concerning Type 1 Use)

## Article 10

1. The competent minister may order a person who has made or is making Type 1 Use of living modified organisms in violation of the provisions of Article 4 paragraph 1 to take steps to recall living modified organisms or to take other necessary measures, within the limits necessary to prevent Adverse Effect on Biological Diversity.
2. The competent minister may, when recognizing urgency to be necessary in order to

prevent Adverse Effect on Biological Diversity (except as provided for in paragraph 1 of the following Article) in the cases provided for in Article 7 paragraph 1 (including cases applied mutatis mutandis in paragraph 4 of the preceding Article) or when other exceptional circumstances have arisen, order a person who is making, has made, or has caused another person to make Type 1 Use of living modified organisms (and, in cases recognized to require particular urgency, including the Domestic Manager) to suspend said Type 1 Use or take other necessary measures, within the limits necessary to prevent Adverse Effect on Biological Diversity.

(Measures in the Event of Accidents Concerning Type 1 Use)

#### Article 11

1. A person who is making Type 1 Use of living modified organisms must, when no longer able to comply with the approved Type 1 Use Regulations concerning said living modified organisms due to the occurrence of an accident, and when an Adverse Effect on Biological Diversity could arise, immediately take emergency measures to prevent Adverse Effect on Biological Diversity, as well as promptly notifying the competent minister of the situation of said accident and the outline of the measures taken.
2. The competent minister may, when recognizing that the person provided for in the preceding paragraph has not taken the emergency measures set forth in the said paragraph, order said person to take emergency measures as provided for in the said paragraph.

#### Section 2 Type 2 Use of Living Modified Organisms

(Implementation of Containment Measures Stipulated in Ordinance of the competent ministries)

#### Article 12

A person who makes Type 2 Use of living modified organisms must, when containment measures to be taken in connection with said Type 2 Use are stipulated in the ordinance of the competent ministries, take said containment measures during the period of said use.

(Implementation of Confirmed Containment Measures)

#### Article 13

1. A person who makes Type 2 Use of living modified organisms must, when containment measures to be taken in connection with said Type 2 Use are not stipulated



in the ordinance of the competent ministries in the preceding Article (except when making Type 2 Use of Specific Living Modified Organisms or when otherwise stipulated in the ordinance of the competent ministries), take containment measures confirmed in advance by the competent minister during the period of said use.

2. Application for the confirmation in the preceding paragraph must be made by submitting an application form detailing the following matters.

- (i) Name and address
- (ii) Properties of living modified organisms to be subject to Type 2 Use
- (iii) Containment measures to be taken in Type 2 Use
- (iv) Besides those stipulated in the preceding three subparagraphs, matters stipulated in the ordinance of the competent ministries

3. Besides those provided for in the preceding two paragraphs, necessary matters concerning the confirmation in paragraph 1 shall be stipulated in the ordinance of the competent ministries.

(Orders for Measures Concerning Type 2 Use)

Article 14

1. The competent minister may order a person who has made or is making Type 2 Use of living modified organisms in violation of the provisions of Article 12 or paragraph 1 of the preceding Article to take containment measures stipulated in the ordinance of the competent ministries in Article 12, or to take other necessary measures.

2. The competent minister may, when it has come to be recognized that, due to the amplification of scientific knowledge concerning living modified organisms after the date of establishment of the ordinance of the competent ministries in Article 12 or the confirmation in paragraph 1 of the preceding Article, urgency is necessary in order to prevent dispersal of living modified organisms outside Facilities, order a person who is making or has made Type 2 Use with containment measures stipulated in the ordinance of the competent ministries in Article 12, or a person who has received the confirmation in paragraph 1 of the preceding Article, to take measures to improve said containment measures or to take other necessary measures.

(Measures in the Event of Accidents Concerning Type 2 Use)

Article 15

1. A person who is making Type 2 Use of living modified organisms must, when breakage or other accident has occurred in Facilities pertaining to containment measures, and when no longer able to take containment measures stipulated in the ordinance of the

competent ministries in Article 12 or the containment measures subject to the confirmation in Article 13 paragraph 1 with respect to said living modified organisms, immediately take emergency measures against said accident, as well as promptly notifying the competent minister of the situation of said accident and the outline of the measures taken.

2. The competent minister may, when recognizing that the person provided for in the preceding paragraph has not taken the emergency measures set forth in the said paragraph, order said person to take emergency measures as provided for in the said paragraph.

### Section 3 Testing of Organisms

(Notification of Import)

#### Article 16

When there is a high likelihood that living modified organisms that could not be considered not to give rise to Adverse Effect on Biological Diversity are imported without knowledge of that fact, in view of the situation of the producing area or other circumstances, or when corresponding to other similar cases, that have been designated by the competent minister, a person who wishes to make imports pertaining to the designation must notify the competent minister to that effect on each occasion, as stipulated in the ordinance of the competent ministries.

(Order for Testing of Organisms)

#### Article 17

1. The competent minister may order a person who has made notification under the provisions of the preceding Article to undergo testing of organisms pertaining to import by that person (referred to in paragraph 3 and paragraph 5 as “Organisms Subject to Testing”), by the competent minister or a person registered by the competent minister (hereinafter “Registered Testing Body”), to identify whether they are the living modified organisms that were subject to the designation in the same Article (hereinafter “Testing of Organisms”), as stipulated in the ordinance of the competent ministries.

2. When the competent minister issues an order under the provisions of the preceding paragraph, the minister must do so immediately after receiving notification under the provisions of the preceding Article.

3. Until undergoing Testing of Organisms and receiving notification of the results thereof, a person who has received an order under the provisions of paragraph 1 must

use the Organisms Subject to Testing based on the conditions designated by the competent minister including the use of Facilities , and shall not transfer or supply Organisms Subject to Testing.

4. When the notification in the preceding paragraph is made by a Registered Testing Body, it shall be made via the competent minister.

5. The competent minister may, when recognizing that a person as provided for in paragraph 3 has violated the provisions of the said paragraph, order that person to use Organisms Subject to Testing based on the conditions in the said paragraph or take other necessary measures.

(Registered Testing Body)

#### Article 18

1. The registration in paragraph 1 of the preceding Article (hereinafter in this Section “Registration”) shall be carried out following an application from a person who wishes to undertake Testing of Organisms.

2. A person who falls under any of the following subparagraphs may not receive Registration.

(i) A person who has committed an offense and received a sentence for punishment as provided for in this Law, when less than 2 years have passed since the date of completion or rescission of that sentence.

(ii) A person whose Registration has been cancelled under the provisions of Article 21 paragraph 4 or paragraph 5, when less than 2 years have passed since the date of that cancellation.

(iii) A corporation whose officers engaged in the business thereof fall under any of the preceding two subparagraphs.

3. The competent minister must grant Registration when the person who has applied for said Registration (hereinafter in this paragraph “Registration Applicant”) satisfies all of the following subparagraphs. In such cases, the procedures needed for Registration shall be stipulated in the ordinance of the competent ministries.

(i) That the Registration Applicant possesses a freeze-drying device, pulverizer, weighing scales, centrifugal separation device, spectrophotometer, nucleic acid amplifier and electrophoretic apparatus.

(ii) That Testing of Organisms is implemented by persons who fall under any of the following clauses, of whom there are 2 or more per business establishment undertaking Testing of Organisms.

(a) Persons who have graduated from a university (excluding junior colleges)

based on the School Education Law (Law No. 26 of 1947), a university based on the former Universities Edict (Edict No. 388 of 1918) or a vocational college based on the former Vocational Colleges Edict (Edict No. 61 of 1903) by completing a course in medicine, dentistry, pharmacology, veterinarian medicine, animal science, fisheries science, agricultural chemistry, applied chemistry or biology, or a course equivalent to these, and have experience of engaging in the work of molecular biological testing for one year or more.

(b) Persons who have graduated from a junior college or vocational high school based on the School Education Law by completing a course in industrial chemistry or biology, or a course equivalent to these, and have experience of engaging in the work of molecular biological testing for three years or more.

(c) Persons who have knowledge and experience equal to or greater than the persons defined in (a) and (b).

(iii) That the Registration Applicant does not fall under any of the following clauses as being controlled by a person who, as a business, makes use of living modified organisms or transfers or supplies living modified organisms (hereinafter in this subparagraph “Living Modified Organism Using Business”).

(a) When the Registration Applicant is a limited company or a public limited company, that a Living Modified Organism Using Business is its parent company (referring to parent companies under Article 211-2 paragraph 1 of the Commercial Code (Law No. 48 of 1899)).

(b) That more than half of the officers of the Registration Applicant (or, in the case of a partnership or joint stock limited partnership, employees with executive authority) are officers or staff of a Living Modified Organism Using Business (including persons who were officers or staff of that Living Modified Organism Using Business within the last two years).

(c) That the Registration Applicant (or, in the case of a corporation, an officer with representative authority) is an officer or staff member of a Living Modified Organism Using Business (including persons who were officers or staff of that Living Modified Organism Using Business within the last two years ).

4. Registration shall be implemented by detailing the matters listed below in a Register of Registered Testing Bodies.

(i) Date and number of Registration

(ii) Name and address of the person who received Registration

(iii) Besides those stipulated in the preceding two subparagraphs, matters stipulated in the ordinance of the competent ministries

(Observance, etc.)

#### Article 19

1. A Registered Testing Body must, when requested to implement Testing of Organisms, implement said Testing of Organisms without delay, except when there are justifiable reasons for not doing so.

2. A Registered Testing Body must implement Testing of Organisms fairly, and using a method stipulated in the ordinance of the competent ministries.

3. A Registered Testing Body must, when wishing to change the location of the business site implementing Testing of Organisms, notify the competent minister no less than 2 weeks before the scheduled date of the change.

4. A Registered Testing Body must, before starting the work of Testing of Organisms, determine regulations concerning the implementation of said work of Testing of Organisms, as stipulated in the ordinance of the competent ministries, and obtain the approval of the competent minister thereto. The same shall apply when wishing to change these.

5. A Registered Testing Body must, no more than 3 months after the end of each business year, prepare an inventory of assets, balance sheet, and profit and loss statement or statement of income and expenditure for the business year in question, as well as a business report (including electromagnetic records when these are prepared in place of the above (referring to records that are prepared using an electronic method, a magnetic method, or another method that cannot be recognized by human perception, and which are provided for data processing by a computer; the same shall also apply in this paragraph and the following paragraph); hereinafter "Financial Statements"), which must be filed for 5 years at the business establishment.

6. A person who wishes to undergo Testing of Organisms or other interested parties may request the matters set forth in the following, at any time within the working hours of the Registered Testing Body, provided, however, that when requesting the matters in subparagraph 2 or subparagraph 4, a fee determined by the Registered Testing Body must be paid.

(i) When Financial Statements have been prepared in the form of documents, a request for perusal or duplicates of said documents

(ii) A request for copies of or excerpts from the documents in the preceding subparagraph

(iii) When Financial Statements have been prepared in the form of electromagnetic records, a request for perusal or duplicate of the matters recorded in said

electromagnetic records displayed using a method stipulated in the ordinance of the competent ministries

(iv) A request for provision of the matters recorded in the electromagnetic records in the preceding subparagraph using a electromagnetic method that is stipulated in the ordinance of the competent ministries, or a request for the issue of a document detailing said matters

7. A Registered Testing Body must, as stipulated in the ordinance of the competent ministries, prepare ledgers for recording and filing matters stipulated in the ordinance of the competent ministries in connection with Testing of Organisms.

8. A Registered Testing Body may not, without permission from the competent minister, suspend or discontinue all or part of its work of Testing of Organisms.

(Obligation to Maintain Confidentiality)

Article 20

1. The present or former officers or staff of a Registered Testing Body may not divulge secrets gleaned concerning the Testing of Organisms.

2. The officers or staff of a Registered Testing Body engaged in Testing of Organisms shall be regarded as staff engaged in public service by law, with respect to the application of the Penal Code (Law No. 45 of 1907) or other penal provisions.

(Orders for Compliance)

Article 21

1. The competent minister may, when recognizing that a Registered Testing Body is no longer in compliance with any of the subparagraphs of Article 18 paragraph 3, order said Registered Testing Body to take necessary measures to comply with the provisions thereof.

2. The competent minister may, when recognizing that a Registered Testing Body is in violation of the provisions of Article 19 paragraph 1 or paragraph 2, or when recognizing that the details entered in the notification in Article 17 paragraph 3 made by a Registered Testing Body are not appropriate, order said Registered Testing Body to implement Testing of Organisms or take necessary measures to improve the method of Testing of Organisms or other work methods.

3. The competent minister may, when recognizing that the regulations in Article 19 paragraph 4 are no longer appropriate in terms of the fair implementation of Testing of Organisms, order those regulations to be changed.

4. The competent minister must cancel Registration when a Registered Testing Body

falls under Article 18 paragraph 2 subparagraph 1 or subparagraph 3.

5. The competent minister may, when a Registered Testing Body falls under any of the following subparagraphs, cancel its Registration, or stipulate a period of time and order the work of Testing of Organisms to be suspended in part or in whole.

- (i) When it has violated the provisions of Article 19 paragraph 3 to paragraph 5, paragraph 7 or paragraph 8.
- (ii) When it has implemented Testing of Organisms not in accordance with the regulations in Article 19 paragraph 4.
- (iii) When it has, without just reason, refused a request under the provisions of the subparagraphs of Article 19 paragraph 6.
- (iv) When it has violated an order under the provisions of paragraph 1 to paragraph 3.
- (v) When it has received Registration through unlawful means.

(Report Collection and On-Site Inspections)

Article 22

1. The competent minister may, within the limits necessary to enforce the provisions of this Section, require a Registered Testing Body to submit reports on its work for Testing of Organisms, or may authorize staff members to enter the office of a Registered Testing Body, inspect the ledgers, documents or other necessary properties of the Registered Testing Body, or question relevant persons.

2. Staff members conducting on-site inspections under the provisions of the preceding paragraph must carry means of identification of their status and present the same to relevant persons.

3. The authority to conduct on-site inspections under the provisions of paragraph 1 shall not be construed as being permitted for the purpose of criminal investigation.

(Announcement)

Article 23

The competent minister must, in any of the cases set forth below, make public announcement to that effect in the Official Gazette.

- (i) When a Registration has been made.
- (ii) When there has been a notification under the provisions of Article 19 paragraph 3.
- (iii) When it has granted the permission in Article 19 paragraph 8.
- (iv) When it has cancelled Registration under the provisions of Article 21 paragraph 4 or paragraph 5, or ordered the work of Testing of Organisms to be suspended in part or in whole under the provisions of the said paragraph.

(Fees)

Article 24

1. A person who receives Testing of Organisms must pay a fee to the government (or, when a Registered Testing Body undertakes Testing of Organisms, the Registered Testing Body) to the amount stipulated by Cabinet Order, which takes account of the actual cost incurred.
2. Fees paid to a Registered Testing Body under the provisions of the preceding paragraph shall comprise the revenue of the Registered Testing Body.

Section 4 Provision of Information

(Information on Correct Use)

Article 25

1. The competent minister shall, whenever necessary to ensure that Type 1 Use of living modified organisms pertaining to Type 1 Use Regulations that have obtained the approval in Article 4 paragraph 1 or Article 9 paragraph 1 is made correctly in accordance with this Law, stipulate information to be provided by a person who wishes to transfer, or supply, or entrust the Type 1 Use of said living modified organisms to a person receiving said transfer or supply or receiving entrustment to make said Type 1 Use (hereinafter "Information on Correct Use"), or shall change the same.
2. The competent minister shall, when stipulating Information on Correct Use under the provisions of the preceding paragraph, or changing the same, make public announcement of the content thereof, as stipulated in the ordinance of the competent ministries, without delay.
3. Announcement under the provisions of the preceding paragraph shall be made by official notification.

(Provision of Information)

Article 26

1. A person who wishes to transfer or supply, or entrust living modified organisms shall, as stipulated in the ordinance of the competent ministries, provide Information on Correct Use and other information on matters stipulated in the ordinance of the competent ministries to a person receiving said transfer or supply, or receiving entrustment to make said Use, in the form of the issue of documents or by other methods stipulated in the ordinance of the competent ministries.



2. The competent minister may, when living modified organisms have been transferred or supplied, or entrusted for Use in violation of the provisions of the preceding paragraph, and when recognizing that Adverse Effect on Biological Diversity could arise, order the person who has transferred or supplied, or entrusted for Use of said living modified organisms to recall said living modified organisms or take other necessary measures, within the limits necessary to prevent Adverse Effect on Biological Diversity.

### Chapter 3 Measures Concerning Export

#### (Notification of Export)

##### Article 27

A person who wishes to export living modified organisms shall, as stipulated in the ordinance of the competent ministries, notify the importing country of the names of the types of living modified organisms to be exported, and other matters stipulated in the ordinance of the competent ministries, provided, however, that this shall not apply when exporting pharmaceuticals (referring to pharmaceuticals under Article 2 paragraph 1 of the Pharmaceutical Affairs Law (Law No. 145 of 1960); the same shall also apply henceforth in this Article) other than those whose purpose is solely to be used for animals, and when otherwise stipulated in the ordinance of the competent ministries.

#### (Documentation for Export)

##### Article 28

Living modified organisms shall not be exported unless the format of use of said living modified organisms and other matters stipulated in the ordinance of the competent ministries are identified on said living modified organisms or their packaging, container or consignment invoice, as stipulated in the ordinance of the competent ministries. In such cases, the provisions of the proviso to the preceding Article shall apply mutatis mutandis to export under the provisions of this Article.

#### (Orders Concerning Export)

##### Article 29

The competent minister may, when living modified organisms have been exported in violation of the provisions of the preceding two Articles, and when recognizing that Adverse Effect on Biological Diversity could arise, order the person who exported said

living modified organisms to recall said living modified organisms or take other necessary measures, within the limits necessary to prevent Adverse Effect on Biological Diversity.

#### Chapter 4 Miscellaneous Provisions

##### (Submission of Reports)

##### Article 30

The competent minister may, within the limits necessary to enforce this Law, require a person who is using or has used living modified organisms (including organisms suspected of being living modified organisms; the same shall also apply henceforth in this Article, in paragraph 1 of the following Article and in Article 32 paragraph 1), a person who has transferred or supplied living modified organisms, a Domestic Manager, a person who has exported living modified organisms, and other relevant persons to submit reports on the state of implementation of said acts and other necessary matters.

##### (On-Site Inspections)

##### Article 31

1. The competent minister may, within the limits necessary to enforce this Law, authorize staff members to enter premises where a person who has used or is using living modified organisms, a person who has transferred or supplied living modified organisms, a Domestic Manager, a person who has exported living modified organisms, and other relevant persons carry out such acts, and other places, to question relevant persons, inspect living modified organisms, Facilities, and other properties, or collect living modified organisms, at no cost, limited to the minimum amount necessary for inspection.
2. Said staff members must, when entering, questioning, inspecting or collecting under the provisions of the preceding paragraph (hereinafter “On-Site Inspections”) carry means of identification of their status and present the same to relevant persons.
3. The authority to conduct On-Site Inspections under the provisions of paragraph 1 shall not be construed as being permitted for the purpose of criminal investigation.

##### (On-Site Inspections by Centers)

##### Article 32

1. The Minister of Agriculture, Forestry and Fisheries or the Minister of Economy,

Trade and Industry may, when recognizing it necessary in cases set forth in paragraph 1 of the preceding Article, authorize the Center for Quality Control and Consumer Service (Independent Administrative Institution), the National Center for Seeds and Seedlings (Independent Administrative Institution), the National Livestock Breeding Center (Independent Administrative Institution), the Fertilizer and Feed Inspection Station (Independent Administrative Institution), the Agricultural Chemicals Inspection Station (Independent Administrative Institution), the Fisheries Research Agency (Independent Administrative Institution) or the National Institute of Technology and Assessment (Independent Administrative Institution) (hereinafter “Centers”), in accordance with the categories of Centers set forth below, to enter premises where a person who has used or is using living modified organisms, a person who has transferred or supplied living modified organisms, a Domestic Manager, a person who has exported living modified organisms, or other relevant persons carry out such acts, or other places, and there to question relevant persons, inspect living modified organisms, Facilities, and other properties, or collect living modified organisms, at no cost, limited to the minimum amount necessary for inspection.

(i) Center for Quality Control and Consumer Service, National Center for Seeds and Seedlings, National Livestock Breeding Center, Fertilizer and Feed Inspection Station, Agricultural Chemicals Inspection Station, and Fisheries Research Agency: Minister of Agriculture, Forestry and Fisheries

(ii) National Institute of Technology and Assessment: Minister of Economy, Trade and Industry

2. The Minister of Agriculture, Forestry and Fisheries or the Minister of Economy, Trade and Industry shall, when authorizing Centers to conduct On-Site Inspections under the provisions of the preceding paragraph, in accordance with the categories of Centers set forth in the subparagraphs of the said paragraph, specify the date, place and other necessary matters for conducting On-Site Inspections and instruct Centers to conduct the same.

3. Centers must, when conducting On-Site Inspections under the provisions of paragraph 1 in accordance with instructions under the provisions of the preceding paragraph, entrust the same to staff members with knowledge and experience concerning living modified organisms, who satisfy the conditions stipulated in orders issued by the Minister stipulated in each subparagraph of the said paragraph, in accordance with the categories of Centers set forth in the subparagraphs of the said paragraph.

4. Centers must, when they have conducted On-Site Inspections under the provisions

of paragraph 1 in accordance with instructions under the provisions of paragraph 2, report the results of inspection obtained under the provisions of the said paragraph to the Minister of Agriculture, Forestry and Fisheries or the Minister of Economy, Trade and Industry, in accordance with the categories of Centers set forth in the subparagraphs of the said paragraph, as stipulated in the ordinance of the Ministry of Agriculture, Forestry and Fisheries or the ordinance of the Ministry of Economy, Trade and Industry.

5. The provisions of paragraph 2 and paragraph 3 of the preceding Article shall apply mutatis mutandis to On-Site Inspections under the provisions of paragraph 1.

(Orders to Centers)

Article 33

The Minister of Agriculture, Forestry and Fisheries or the Minister of Economy, Trade and Industry may, when recognizing it necessary in order to ensure the correct implementation of the work of On-Site Inspections under the provisions of paragraph 1 of the preceding Article, issue necessary orders to Centers concerning said work, in accordance with the categories of Centers set forth in the subparagraphs of the said paragraph.

(Measures for Amplification of Scientific Knowledge)

Article 34

The government must endeavor to gather, organize and analyze information on living modified organisms and promote research and devise other necessary measures concerning living modified organisms and the Adverse Effect on Biological Diversity arising from use thereof, in order to amplify scientific knowledge concerning the same.

(Public Consultation)

Article 35

The government shall publicly announce information pertaining to the assessment of Adverse Effect on Biological Diversity, information that has been gathered, organized and analyzed under the provisions of the preceding Article, and other information, and broadly consult the public, in order to reflect public opinion in measures based on this Law and encourage mutual exchanges of information and opinions between the parties concerned.

(Competent Minister)

Article 36

1. The competent minister in this Law, as stipulated by Cabinet Order, shall be the Minister of Finance, the Minister of Education, Culture, Sports, Science and Technology, the Minister of Health, Labour and Welfare, the Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry, or the Minister of the Environment.
2. The ordinance of the competent ministries in this Law shall be orders issued by the competent minister.

(Interim Measures)

Article 37

When orders are issued, amended or abolished under the provisions of this Law, requisite interim measures (including interim measures concerning penal provisions) may be stipulated to the degree judged reasonably necessary.

## Chapter 5 Penal Provisions

Article 38

A person who violates orders under the provisions of Article 10 paragraph 1 or paragraph 2, Article 11 paragraph 2, Article 14 paragraph 1 or paragraph 2, Article 15 paragraph 2, Article 17 paragraph 5, Article 26 paragraph 2 or Article 29 shall be punished by imprisonment of not more than 1 year or a fine of not more than one million yen, or a combination of these two.

Article 39

A person who falls under any of the following subparagraphs shall be punished by imprisonment of not more than 6 months or a fine of not more than 500,000 yen, or a combination of these two.

- (i) A person who makes Type 1 Use in violation of the provisions of Article 4 paragraph 1
- (ii) A person who obtains the approval in Article 4 paragraph 1 or Article 9 paragraph 1 through deception and other unlawful means

Article 40

A person who falls under any of the following subparagraphs shall be punished by imprisonment of not more than 6 months or a fine of not more than 500,000 yen.

- (i) A person who violates the provisions of Article 4 paragraph 6 or Article 7 paragraph 3 (including cases in which the provisions of these are applied mutatis mutandis in Article 9 paragraph 4)
- (ii) A person who violates the provisions of Article 20 paragraph 1

#### Article 41

When an officer or staff member of a Registered Testing Body violates an order to suspend the work of Testing of Organisms under the provisions of Article 21 paragraph 5, said person shall be punished by imprisonment of not more than 6 months or a fine of not more than 500,000 yen.

#### Article 42

A person who falls under any of the following subparagraphs shall be punished by a fine of not more than 500,000 yen.

- (i) A person who makes Type 2 Use without receiving confirmation, in violation of the provisions of Article 13 paragraph 1
- (ii) A person who receives the confirmation in Article 13 paragraph 1 through deception or other unlawful means
- (iii) A person who undertakes import without making notification under the provisions of Article 16, or making false notification for imports
- (iv) A person who fails to provide information under the provisions of Article 26 paragraph 1, or provides false information to transfer or supply or entrust the use of living modified organisms
- (v) A person who undertakes export without making notification under the provisions of Article 27, or making false notification for exports
- (vi) A person who undertakes export without making identification under the provisions of Article 28, or making false identification for exports

#### Article 43

A person who falls under any of the following subparagraphs shall be punished by a fine of not more than 300,000 yen.

- (i) A person who fails to make reports as provided for in Article 30, or makes false reports
- (ii) A person who refuses, hinders or evades site entry, inspection or collection under the provisions of Article 31 paragraph 1 or Article 32 paragraph 1, or fails to answer questions, or makes false statements

#### Article 44

The officers or staff of a Registered Testing Body who fall under any of the violations in the following subparagraphs shall be punished by a fine of not more than 300,000 yen.

- (i) When, in violation of the provisions of Article 19 paragraph 7, they fail to record matters as provided for in the said paragraph, or record false matters, or fail to file ledgers.
- (ii) When they discontinue the work of Testing of Organisms in entirety without obtaining the permission in Article 19 paragraph 8.
- (iii) When they fail to make reports as provided for in Article 22 paragraph 1, or make false reports, or refuse, hinder or evade site entry or inspection under the provisions of the said paragraph, or fail to answer questions, or make a false statements.

#### Article 45

When the representative of a corporation, or the agent, employee and other operative of a corporation or a person, commits the violations in Article 38, Article 39, Article 42 or Article 43 in connection with the work of said corporation or person, both the person committing the act and said corporation or person shall be subject to the penalties set forth in the main text of each said Article.

#### Article 46

A person who fails to make notification under the provisions of Article 6 paragraph 1 (including those applied mutatis mutandis in Article 9 paragraph 4), or makes false notification shall be punished by a fine of not more than 200,000 yen.

#### Article 47

The officers or staff of a Registered Testing Body who fall under any of the violations in the following subparagraphs shall be punished by a fine of not more than 200,000 yen.

- (i) When they fail to prepare Financial Statements in violation of the provisions of Article 19 paragraph 5, fail to record matters that should be recorded in Financial Statements, or record false matters.
- (ii) When, without just reason, they refuse a request under the provisions of the subparagraphs of Article 19 paragraph 6.

## Article 48

When a Center violates an order under the provisions of Article 33, the officers of said Center shall be punished by a fine of not more than 200,000 yen.

## Supplementary Provisions

(Date of Enforcement)

### Article 1

This Law shall be enforced from the date on which the Protocol takes effect in Japan, provided, however, that the provisions set forth in the following subparagraphs shall be enforced from the date stipulated in the respective subparagraph.

- (i) The provisions of the following Article to Article 6 of the Supplementary Provisions and Article 15 of the Supplementary Provisions (excluding the provisions for amendment stipulated in the following subparagraph): The date of promulgation
- (ii) The provisions of Article 15 of the Supplementary Provisions (limited only to those pertaining to the provisions for amendment of Article 15 paragraph 2 of the Law Concerning the Comprehensive Organization for Medicines and Medical Equipments (Law No. 192 of 2002)): The date of enforcement of this Law (hereinafter "Date of Enforcement") or the date of enforcement of the Law Concerning the Comprehensive Organization for Medicines and Medical Equipments, whichever is later

(Interim Measures)

### Article 2

1. A person who wishes to obtain the approval in Article 4 paragraph 1 or Article 9 paragraph 1 may, even before the Date of Enforcement, apply for said approval under the example of the provisions of Article 4 or Article 9.
2. The competent minister may, when an application has been made under the provisions of the preceding paragraph, grant such approval under the example of the provisions of Article 4 or Article 9, even before the Date of Enforcement. In such cases, when approval has been obtained under the example of these provisions, the approval shall be regarded as having been obtained on the Date of Enforcement under the provisions of Article 4 paragraph 1 or Article 9 paragraph 1.
3. A person who is actually making Type 1 Use of living modified organisms upon



enforcement of this Law and who has not obtained the approval for said Type 1 Use in Article 4 paragraph 1 or Article 9 paragraph 1 shall, for 6 months from the Date of Enforcement, be regarded as having obtained approval pertaining to said Type 1 Use. If an application for approval of Type 1 Use Regulations pertaining to said Type 1 Use is made before the end of said period, the same shall apply when said period has lapsed, until the date of the approval pertaining to said application, or decision to reject the application for approval or refuse the approval.

#### Article 3

1. A person who wishes to receive the confirmation in Article 13 paragraph 1 may, even before the Date of Enforcement, apply for said confirmation under the example of the provisions of the same Article.

2. The competent minister may, when an application for confirmation has been made under the provisions of the preceding paragraph, make such confirmation even before the Date of Enforcement, under the example of the provisions of Article 13. In such cases, when confirmation has been received under the example of the provisions of the same Article, the confirmation shall be regarded as having been received on the Date of Enforcement under the provisions of paragraph 1 of the same Article.

3. A person who is actually making Type 2 Use as provided for in Article 13 paragraph 1 upon enforcement of this Law and who has not taken containment measures for which the confirmation in the said paragraph has been received, shall, for 6 months from the Date of Enforcement, be regarded as having taken containment measures for which the said confirmation has been received. If said person makes an application for confirmation before the end of said period, the same shall apply when said period has lapsed, until the date of the confirmation based on said application or decision to refuse confirmation.

#### Article 4

1. A person who wishes to receive the Registration in Article 18 paragraph 1 may apply for the same even before the Date of Enforcement.

2. The competent minister may, when an application has been made under the provisions of the preceding paragraph, make such Registration even before the Date of Enforcement, under the example of the provisions of Article 18. In such cases, when Registration has been received under the example of the provisions of the same Article, the Registration shall be regarded as having been received on the Date of Enforcement under the provisions of paragraph 1 of the same Article.

#### Article 5

1. A person who wishes to receive the approval of regulations in Article 19 paragraph 4 may apply for the same even before the Date of Enforcement.
2. The competent minister may, when an application has been made under the provisions of the preceding paragraph, grant approval even before the Date of Enforcement, under the example of the provisions of Article 19 paragraph 4. In such cases, when approval has been received under the example of the provisions of the said paragraph, the approval shall be regarded as having been received on the Date of Enforcement under the provisions of the said paragraph.

(Delegation to Cabinet Order)

#### Article 6

Besides those stipulated in Article 2 to the preceding Article, necessary interim measures concerning the enforcement of this Law shall be stipulated by Cabinet Order.

(Review)

#### Article 7

The government shall, after 5 years have lapsed from the enforcement of this Law, conduct a review concerning the state of enforcement of this Law and, when recognizing it necessary, shall devise requisite measures based on the results thereof.

(Partial Amendment to the Law Concerning the Center for Quality Control and Consumer Service)

#### Article 8

Part of the Law Concerning the Center for Quality Control and Consumer Service (Law No. 183 of 1999) shall be amended as follows.

Article 10 paragraph 2 shall be amended as follows.

2. Besides that set forth in the preceding paragraph, the Center shall undertake the following work.

- (i) On-site inspection under the provisions of Article 20-2 paragraph 1 of the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (Law No. 175 of 1950)
- (ii) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms

(Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the National Center for Seeds and Seedlings)

Article 9

Part of the Law Concerning the National Center for Seeds and Seedlings (Law No. 184 of 1999) shall be amended as follows.

Article 10 paragraph 2 shall be amended as follows.

2. Besides that set forth in the preceding paragraph, the Center shall undertake the following work.

(i) Collection under the provisions of Article 53-2 paragraph 1 of the Seeds and Seedlings Law (Law No. 83 of 1998)

(ii) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the National Livestock Breeding Center)

Article 10

Part of the Law Concerning the National Livestock Breeding Center (Law No. 185 of 1999) shall be amended as follows.

In Article 10 paragraph 2, subparagraph 3 shall be changed to subparagraph 4, and the following subparagraph shall be inserted after subparagraph 2.

(iii) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the Fertilizer and Feed Inspection Station)

Article 11

Part of the Law Concerning the Fertilizer and Feed Inspection Station (Law No. 186 of 1999) shall be amended as follows.

The following subparagraph shall be added to Article 10 paragraph 2.

(iv) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms

(Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the Agricultural Chemicals Inspection Station)

Article 12

Part of the Law Concerning the Agricultural Chemicals Inspection Station (Law No. 187 of 1999) shall be amended as follows.

Article 10 paragraph 2 shall be amended as follows.

2. Besides that set forth in the preceding paragraph, the Station shall undertake the following work.

(i) Collection and on-site inspection under the provisions of Article 13-2 paragraph 1 of the Agricultural Chemicals Regulation Law (Law No. 82 of 1948) and on-site inspection under the provisions of Article 15-3 paragraph 2 of said Law

(ii) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the Fisheries Research Agency)

Article 13

Part of the Law Concerning the Fisheries Research Agency (Law No. 199 of 1999) shall be amended as follows.

In Article 10 paragraph 4, “and paragraph 2” shall be amended to “, paragraph 2 and the preceding paragraph”, the said paragraph shall be changed to paragraph 5 of the same Article, and the following paragraph shall be inserted after paragraph 3 of the same Article.

4. Besides the work as provided for in paragraph 1 and paragraph 2, the Center shall undertake entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003).

In Article 12 subparagraph 1, “and paragraph 4” shall be amended to “, paragraph 4 and paragraph 5”.

(Partial Amendment to the Law Concerning the National Institute of Technology and Assessment)

#### Article 14

Part of the Law Concerning the National Institute of Technology and Assessment (Law No. 204 of 1999) shall be amended as follows.

The following subparagraph shall be added to Article 11 paragraph 2.

(10) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

(Partial Amendment to the Law Concerning the Comprehensive Organization for Medicines and Medical Equipments)

#### Article 15

The Law Concerning the Comprehensive Organization for Medicines and Medical Equipments shall be amended as follows.

Article 15 paragraph 2 shall be amended as follows.

2. Besides that set forth in the preceding paragraph, the Organization shall undertake the following work.

(i) On-site inspection, questioning and collection as stipulated by Cabinet Order under the provisions of Article 69-2 paragraph 1 or Article 80-6 paragraph 1 of the Pharmaceutical Affairs Law

(ii) Entry, questioning, inspection and collection under the provisions of Article 32 paragraph 1 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

The following Article shall be added after Article 31 of the Supplementary Provisions.

(Partial Amendment to the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms)

#### Article 31-2

The Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003) shall be amended as follows.

In Article 32 paragraph 1, “or the Minister of Economy, Trade and Industry” shall be amended to “, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare”, and “or the National Institute of Technology and Assessment (Independent Administrative Institution)” to “, the National Institute of Technology and

Assessment (Independent Administrative Institution) or the Comprehensive Organization for Medicines and Medical Equipments (Independent Administrative Institution)”, and the following subparagraph shall be added to the said paragraph.

(iii) Comprehensive Organization for Medicines and Medical Equipments: Minister of Health, Labour and Welfare

In Article 32 paragraph 2, “or the Minister of Economy, Trade and Industry” shall be amended to “, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare”, in paragraph 4 of the same Article “or the ordinance of the Ministry of Economy, Trade and Industry” to “, the ordinance of the Ministry of Economy, Trade and Industry or the ordinance of the Ministry of Health, Labour and Welfare” , and “or the Minister of Economy, Trade and Industry” to “, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare”.

In Article 33, “or the Minister of Economy, Trade and Industry” shall be amended to “, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare”.