

This English translation of the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms has been prepared (up to the revisions of Act No. 8 of 2007 (Effective April 1, 2007)) in compliance with the Standard Bilingual Dictionary (March 2007 edition).

This is an unofficial translation. Only the original Japanese texts of laws and regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations.

The Government of Japan shall not be responsible for the accuracy, reliability or currency of the legislative material provided in this Web site, or for any consequence resulting from use of the information in this Web site. For all purposes of interpreting and applying law to any legal issue or dispute, users should consult the original Japanese texts published in the Official Gazette.

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

### **CONTENTS**

Chapter 1 General Provisions (Article 1-Article 3)

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 (Article 4-Article 11)

Section 2 Type 2 Use of Living Modified Organisms (Article 12-Article 15)

Section 3 Testing of Organisms (Article 16-Article 24)

Section 4 Provision of Information (Article 25 and Article 26)

Chapter 3 Measures Concerning Export (Article 27-Article 29)

Chapter 4 Miscellaneous Provisions (Article 30-Article 37)

Chapter 5 Penal Provisions (Article 38-Article 48)

Supplementary Provisions

### **Chapter I General Provisions**

#### Article 1 (Purpose)

This Act shall have the purpose of ensuring the precise and smooth implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as "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.

#### Article 2 (Definitions)

(1) In this Act, "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 Act, “living modified organism” shall mean an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of the any of the following technologies.
- (i) Those technologies as stipulated in the ordinance of the competent ministries, for the processing of nucleic acid extracellularly
  - (ii) Those technologies, as stipulated in the ordinance of the competent ministries, for fusing of the cells of organisms belonging to different taxonomical families
- (3) In this Act, “use” shall mean use for provision as food, animal feed or other purposes, cultivation and other growing, processing, storage, transportation and disposal, and other acts attendant with these.
- (4) In this Act, “biological diversity” shall mean biological diversity as provided for in Article 2 of the Convention on Biological Diversity.
- (5) In this Act, “Type 1 Use” shall mean use not subject to taking the measures provided for in the following paragraph.
- (6) In this Act, “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 referred to as “Facilities”) in accordance with measures specifying this fact or other measures stipulated in the ordinance of the competent ministries.
- (7) In this Act, “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.

### Article 3 (Announcement of Basic Matters)

The competent minister shall stipulate and publicly announce the matters set forth below (hereinafter referred to as “Basic Matters”) to ensure the precise and smooth implementation of the Protocol. The same shall apply whenever such matters 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 posing unacceptable risks that impair biological diversity (hereinafter referred to as “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 properly
- (iii) In addition to what is listed in the preceding two items, important matters designed to ensure that the use of living modified organisms is undertaken properly

## Chapter II 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

#### Article 4 (Approval of Type 1 Use Regulations Concerning Type 1 Use of Living Modified Organisms)

- (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 referred to as "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 referred to as "Specified 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 where it is applied mutatis mutandis pursuant to 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 referred to as "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 item 1 and Article 18 paragraph 4 item 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 referred to as "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 of impairment to the preservation of species or populations of wild fauna or flora or any 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.

#### Article 5 (Amendment of Type 1 Use Regulations)

- (1) When the competent minister recognizes 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 the Type 1 Use of living modified organisms pertaining to said Type 1 Use Regulations is acknowledged as 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.

#### Article 6 (Obligations of Approval Recipient)

- (1) A person who has obtained the approval in Article 4 paragraph 1 (referred to as "Approval Recipient" in the following paragraph) must, when a change has occurred in the matters listed in paragraph 2 item 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 Approval Recipient pertaining to said Type 1 Use Regulations.

#### Article 7 (Changes to Approved Type 1 Use Regulations)

- (1) The competent minister must, when it has come to be recognized that, due to environmental changes that could not have been foreseen at the time of the approval in Article 4 paragraph 1 or the progress of scientific knowledge after the date of said approval, there exists a risk that an Adverse Effect on Biological Diversity could arise even when Type 1 Use of living modified organisms is made in accordance with the Type 1 Use Regulations for which the approval has been obtained, change or abolish said Type 1 Use Regulations to the extent necessary to prevent such 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.

#### Article 8 (Announcement of Approved Type 1 Use Regulations)

- (1) The competent minister must make public announcement of the matters stipulated in each of the following items in accordance with the categories listed in said items, 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 public notice.

#### Article 9 (Approval of Type 1 Use Regulations Pertaining to Exporters to Japan)

- (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; hereinafter the same shall apply 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 proper 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 referred to as "Domestic Administrator"), 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 Administrator 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, the term "Name and address" in Article 4 paragraph 2 item 1 shall be deemed to be replaced with "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 the term "Article 4 paragraph 1" in Article 7 paragraph 1 shall be deemed to be replaced with "Article 9 paragraph 1".

#### Article 10 (Orders for Measures Concerning Type 1 Use)

- (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 the cases where it is applied mutatis mutandis pursuant to 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 Administrator) to suspend said Type 1 Use or take other necessary measures, within the limits necessary to prevent Adverse Effect on Biological Diversity.

Article 11 (Measures in the Event of Accidents Concerning Type 1 Use)

- (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 listed 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**

Article 12 (Implementation of Containment Measures Stipulated in Ordinance of the Competent Ministries)

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.

Article 13 (Implementation of Confirmed Containment Measures)

- (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 Specified 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) In addition to what is listed in the preceding three items, 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.

#### Article 14 (Orders for Measures Concerning Type 2 Use)

- (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 progress 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.

#### Article 15 (Measures in the Event of Accidents Concerning Type 2 Use)

- (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 listed in the said paragraph, order said person to take emergency measures as provided for in the said paragraph.

### **Section 3 Testing of Organisms**

#### Article 16 (Notification of Import)

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.

#### Article 17 (Order for Testing of Organisms)

- (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 referred to as "Registered Inspection Body"), to identify whether they are the living modified organisms that were subject to the designation in the same Article (hereinafter referred to as "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 Inspection 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.

#### Article 18 (Registered Inspection Body)

- (1) The registration in paragraph 1 of the preceding Article (hereinafter in this Section referred to as "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 items may not receive Registration.
  - (i) A person who has committed an offense and received a sentence for punishment as provided for in this Act, 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 items.

- (3) The competent minister must grant Registration when the person who has applied for said Registration (hereinafter in this paragraph referred to as "Applicant") satisfies all of the following items. In such cases, the procedures needed for Registration shall be stipulated in the ordinance of the competent ministries.
- (i) That the 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 place of business undertaking Testing of Organisms.
    - (a) Persons who have graduated from a university (excluding junior colleges) based on the School Education Act (Act 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 Act 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 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 item referred to as "Living Modified Organism Using Business").
    - (a) When the Applicant is a business corporation, that a Living Modified Organism Using Business is its parent company [referring to parent companies under Article 879 paragraph 1 of the Company Act (Act No. 86 of 2005)].
    - (b) That more than half of the officers of the Applicant [or, in the case of a partnership or joint stock limited partnership (referring to a partnership or joint stock limited partnership under Article 575 paragraph 1 of the Company Act), managing member] 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 Applicant (or, in the case of a corporation, an officer with representation power) 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 Registry of Registered Inspection Bodies.
  - (i) Date and number of Registration
  - (ii) Name and address of the person who received Registration
  - (iii) In addition to what is listed in the preceding two items, matters stipulated in the ordinance of the competent ministries

Article 19 (Observance, etc.)

- (1) A Registered Inspection 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 Inspection Body must implement Testing of Organisms fairly, and using a method stipulated in the ordinance of the competent ministries.
- (3) A Registered Inspection Body must, when wishing to change the address of the place of business implementing Testing of Organisms, notify the competent minister no less than 2 weeks before the scheduled date of the change.
- (4) A Registered Inspection 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 Inspection Body must, no more than 3 months after the end of each business year, prepare an inventory of property, 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; hereinafter the same shall apply in this paragraph and the following paragraph); hereinafter referred to as "Financial Statements"], which must be filed for 5 years at the place of business.
- (6) A person who wishes to undergo Testing of Organisms or other interested persons may request the matters listed in the following, at any time within the working hours of the Registered Inspection Body, provided, however, that when requesting the matters in item 2 or item 4, a fee determined by the Registered Inspection Body must be paid.
  - (i) When Financial Statements have been prepared in the form of documents, a request for inspection or copies of said documents
  - (ii) A request for transcripts of or extracts from the documents in the preceding item
  - (iii) When Financial Statements have been prepared in the form of electromagnetic

records, a request for inspection or copy 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 item 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 Inspection Body must, as stipulated in the ordinance of the competent ministries, prepare books and filing matters stipulated in the ordinance of the competent ministries in connection with Testing of Organisms.
- (8) A Registered Inspection Body may not, without permission from the competent minister, suspend or discontinue all or part of its work of Testing of Organisms.

#### Article 20 (Obligation to Maintain Confidentiality)

- (1) The present or former officers or staff of a Registered Inspection Body shall not divulge secrets gleaned concerning the Testing of Organisms.
- (2) The officers or staff of a Registered Inspection Body engaged in Testing of Organisms shall be regarded as staff engaged in public service by act, with respect to the application of the Penal Code (Code No. 45 of 1907) or other penal provisions.

#### Article 21 (Orders for Compliance)

- (1) The competent minister may, when recognizing that a Registered Inspection Body is no longer in compliance with any of the items of Article 18 paragraph 3, order said Registered Inspection Body to take necessary measures to comply with the provisions thereof.
- (2) The competent minister may, when recognizing that a Registered Inspection 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 Inspection Body are not appropriate, order said Registered Inspection 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 Inspection Body falls under Article 18 paragraph 2 item 1 or item 3.
- (5) The competent minister may, when a Registered Inspection Body falls under any of the following items, 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 justifiable reason, refused a request under the provisions of the items 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 wrongful means.

#### Article 22 (Report Collection and On-Site Inspections)

- (1) The competent minister may, within the limits necessary to enforce the provisions of this Section, require a Registered Inspection Body to submit reports on its work for Testing of Organisms, or may authorize staff members to enter the office of a Registered Inspection Body, inspect the books, documents or other necessary properties of the Registered Inspection Body, or question relevant persons.
- (2) Staff members conducting on-site inspections under the provisions of the preceding paragraph must carry means of certificate 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.

#### Article 23 (Public Notice)

The competent minister must, in any of the cases listed below, make public notice 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.

#### Article 24 (Fees)

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

### **Section 4 Provision of Information**

#### Article 25 (Information on Proper Use)

- (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 properly in accordance with this Act, 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 referred to as "Information on Proper Use"), or shall change the same.
- (2) The competent minister shall, when stipulating Information on Proper Use under the provisions of the preceding paragraph, or changing the same, make 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 public notice.

#### Article 26 (Provision of Information)

- (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 Proper 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 III Measures Concerning Export**

#### Article 27 (Notification of Export)

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 Act (Act No. 145 of 1960); hereinafter the same shall apply 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.

#### Article 28 (Indication for Export)

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 indicated 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.

#### Article 29 (Orders Concerning Export)

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 IV Miscellaneous Provisions**

#### Article 30 (Collection of Reports)

The competent minister may, within the limits necessary to enforce this Act, require a person who is using or has used living modified organisms (including organisms suspected of being living modified organisms; hereinafter the same shall apply 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 Administrator, 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.

#### Article 31 (On-Site Inspections)

- (1) The competent minister may, within the limits necessary to enforce this Act, 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 Administrator, 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 removing under the provisions of the preceding paragraph (hereinafter referred to as "On-Site Inspections") carry a certificate for identification and produce it to the people

concerned.

- (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.

#### Article 32 (On-Site Inspections by Centers)

- (1) The Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare may, when recognizing it necessary in cases listed in paragraph 1 of the preceding Article, Food and Agricultural Materials Inspection Center (Incorporated Administrative Agency), the National Center for Seeds and Seedlings (Incorporated Administrative Agency), the National Livestock Breeding Center (Incorporated Administrative Agency), the Fisheries Research Agency (Incorporated Administrative Agency), the National Institute of Technology and Evaluation (Incorporated Administrative Agency) or the Pharmaceuticals and Medical Device Agency (Incorporated Administrative Agency) (hereinafter referred to as "Centers"), in accordance with the categories of Centers listed 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 Administrator, 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 remove living modified organisms, at no cost, limited to the minimum amount necessary for inspection.
  - (i) Food and Agricultural Materials Inspection Center, National Center for Seeds and Seedlings, National Livestock Breeding Center, and Fisheries Research Agency: Minister of Agriculture, Forestry and Fisheries
  - (ii) National Institute of Technology and Evaluation: Minister of Economy, Trade and Industry
  - (iii) Pharmaceuticals and Medical Device Agency: Minister of Health, Labour and Welfare
- (2) The Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare shall, when authorizing Centers to conduct On-Site Inspections under the provisions of the preceding paragraph, in accordance with the categories of Centers listed in the items 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 item of the said paragraph, in accordance with the categories of Centers listed in the items 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, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare, in accordance with the categories of Centers listed in the items of the said paragraph, as stipulated in the ordinance of the Ministry of Agriculture, Forestry and Fisheries, the ordinance of the Ministry of Economy, Trade and Industry or the Minister of Health, Labour and Welfare.
- (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.

#### Article 33 (Orders to Centers)

The Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry or the Minister of Health, Labour and Welfare may, when recognizing it necessary in order to ensure the proper 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 listed in the items of the said paragraph.

#### Article 34 (Measures for Progress of Scientific Knowledge)

The government must endeavor to collect, arrange 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.

#### Article 35 (Public Consultation)

The government shall publicly announce information pertaining to the assessment of Adverse Effect on Biological Diversity, information that has been collected, arranged 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 Act and encourage mutual exchanges of information and opinions between the parties concerned.

#### Article 36 (Competent Minister)

- (1) The competent minister in this Act, 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 Act shall be orders issued by the competent minister.

#### Article 36-2 (Delegation)

The authority of the competent minister provided for in this Act may, as stipulated in the ordinance of the competent ministries delegate to a head of a local branch or department.

#### Article 37 (transitional measure)

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

### **Chapter V 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 with work 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 items shall be punished by imprisonment with work 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 or other wrongful means

#### Article 40

A person who falls under any of the following items shall be punished by imprisonment with work 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 pursuant to 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 Inspection 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 with work 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 items 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 wrongful 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 indication under the provisions of Article 28, or making false indication for exports

#### Article 43

A person who falls under any of the following items 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 removal 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 Inspection Body who fall under any of the violations in the following items 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 books.
- (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 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 with regard to the business of said juridical person or individual, not only the offender shall be punished but also said juridical person or individual shall be punished by the fine prescribed in the Articles.

#### Article 46

A person who fails to make notification under the provisions of Article 6 paragraph 1 (including the cases where it is applied mutatis mutandis pursuant to 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 Inspection Body who fall under any of the violations in the following items 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 justifiable reason, they refuse a request under the provisions of the items 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**

#### Article 1 (Effective Date)

This Act shall come into force as from the date on which the Protocol takes effect in Japan, provided, however, that the provisions listed in the following items shall come into force as from the date stipulated in the respective item.

- (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 item): 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 Act on Pharmaceuticals and Medical Device Agency (Act No. 192 of 2002)]: The effective date of this Act (hereinafter referred to as "Effective Date") or the effective date of the Act on Pharmaceutical and Medical Device Agency, whichever is later

#### Article 2 (Transitional Measures)

- (1) A person who wishes to obtain the approval in Article 4 paragraph 1 or Article 9 paragraph 1 may, even before the Effective Date, 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 Effective Date. 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 Effective Date 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 Act 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 Effective Date, 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 Effective Date, 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 Effective Date, 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 Effective Date 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 Act and who has not taken containment measures for which the confirmation in the said paragraph has been received, shall, for 6 months from the Effective Date, 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 Effective Date.
- (2) The competent minister may, when an application has been made under the provisions of the preceding paragraph, make such Registration even before the Effective Date, 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 Effective Date 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 Effective Date.
- (2) The competent minister may, when an application has been made under the provisions of the preceding paragraph, grant approval even before the Effective Date, 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 Effective Date under the provisions of the said paragraph.

#### Article 6 (Delegation to Cabinet Order)

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

#### Article 7 (Review)

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