

Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms

(Act No. 97 of June 18, 2003)

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Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to preserve biological diversity through international cooperation, by ensuring the smooth and proper implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as "the Protocol") and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (hereinafter referred to as "the Supplementary Protocol"), thereby contributing to the welfare of people around the world and helping to assure healthy, cultured lives in both the present and the future, by devising measures to regulate the use of living modified organisms..

(Definitions)

Article 2 (1) In this Act, "organism" means a single cell (excluding a single cell forming a cell colony) or a cell colony which is stipulated by Order 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" means an organism that contains nucleic acid, or a replicated product thereof, obtained through use of the any of

the following technologies:

- (i) technologies stipulated by Order of the competent ministries, for the processing of nucleic acid extracellularly;
 - (ii) technologies, as stipulated by Order of the competent ministries, for fusing the cells of organisms belonging to different taxonomical families.
- (3) In this Act, "use" means using, cultivating and growing, processing, storing, transporting and disposing of living modified organisms, and other related actions, to provide food, animal feed, or for other related purposes.
- (4) In this Act, "biological diversity" means biological diversity as stipulated in Article 2 of the Convention on Biological Diversity.
- (5) In this Act, "type-1 use of living modified organisms" means the use of living modified organisms not subject to the measures stipulated in the following paragraph.
- (6) In this Act, "type-2 use of living modified organisms" means use of living modified organisms with the aim 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, or other measures stipulated by Order of the competent ministries.
- (7) In this Act, "containment measures" means measures taken, when using facilities or through other means in handling living modified organisms, to prevent the dispersal of those living modified organisms into the air, water or soil outside those facilities.

(Publication of Basic Particulars)

Article 3 The competent ministers is to stipulate and publicly announce the particulars set forth below (hereinafter referred to as "basic particulars") to ensure the smooth and proper implementation of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol. The same applies whenever those particulars are changed:

- (i) basic particulars concerning the implementation of measures designed to prevent adverse effects caused by the use of living modified organisms that pose an unacceptable risk that impairs biological diversity (hereinafter referred to as an "adverse effect on biological diversity");
- (ii) basic particulars that have to be taken into account by a person who makes use of living modified organisms in order to do so in an appropriate manner;
- (iii) beyond what is listed in the preceding two items, important particulars designed to ensure that the use of living modified organisms is undertaken in an appropriate manner;
- (iv) basic particulars concerning the implementation of measures in order to restore damage caused to biological diversity brought about by using living

modified organisms (limited to species and regions specified by Order of the Ministry of the Environment as especially important for biological diversity) when damage, or a high chance of damage to biological diversity exists.

Chapter II Measures to Regulate the Use of Living Modified Organisms in Japan

Section 1 Type-1 Use of Living Modified Organisms

(Approval of Regulations on 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 each type of living modified organism (hereinafter referred to as "regulations on type-1 use"), and must obtain the approval of the competent ministers, provided, however, that this does 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 ministers as organisms that clearly cause no adverse effect on biological diversity through type-1 use (hereinafter referred to as "specified living modified organisms"), or when wishing to make type-1 use as stipulated in regulations on type-1 use for which the approval of the competent ministers has been obtained under the provisions of this paragraph or Article 9, paragraph (1) (or, in the case of regulations on type-1 use that have been altered by the competent ministers under the provisions of Article 7, paragraph (1) (including cases where it is applied *mutatis mutandis* pursuant to Article 9, paragraph (4)), those regulations on type-1 use after alteration), or in other cases stipulated by Order of the competent ministries.
- (2) A person who wishes to obtain the approval stipulated in the preceding paragraph must assess the adverse effect on biological diversity caused by type-1 use of each type of living modified organism as stipulated by the competent ministers, and must submit to the competent ministers an application form detailing the following particulars, together with a document detailing the results of this assessment (hereinafter referred to as a "biological diversity risk assessment report") and other documents stipulated by Order 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 applies in Article 13, paragraph (2), item (i) and Article 18, paragraph (4), item (ii));
 - (ii) regulations on type-1 use of living modified organisms.
- (3) Regulations on type-1 use of living modified organisms are to stipulate the following particulars, as stipulated by Order of the competent ministries:
- (i) names of types of living modified organisms;

- (ii) content and means of type-1 use of living modified organisms.
- (4) The competent ministers must, on receiving an application for the approval stipulated in paragraph (1), consult persons with specialized knowledge and experience concerning adverse effects on biological diversity (hereinafter referred to as "experts") with regard to regulations on type-1 use of living modified organisms in relation to that application, as stipulated by Order of the competent ministries.
- (5) The competent ministers 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 through type-1 use of living modified organisms in accordance with the regulations on type-1 use of living modified organisms in relation to an application for approval as in paragraph (1), give approval for that regulations on type-1 use of living modified organisms, taking account of the content of consultation with experts under the provisions of the preceding paragraph and the relevant basic particulars.
- (6) Experts who have been consulted under the provisions of paragraph (4) must not divulge or appropriate secrets obtained concerning regulations on type-1 use of living modified organisms with respect to an application for approval in paragraph (1) or the biological diversity risk assessment report thereof.
- (7) Beyond what is specified in the preceding paragraphs, essential particulars concerning the approval in paragraph (1) are stipulated by Order of the competent ministries.

(Amendment of Regulations on Type-1 Use of Living Modified Organisms)

- Article 5 (1) If the competent ministers recognizes that an adverse effect on biological diversity could arise from type-1 use of living modified organisms made in accordance with the regulations on type-1 use of living modified organisms with respect to an application for approval in paragraph (1) of the preceding Article, the competent ministers must instruct the applicant, as stipulated by Order of the competent ministries, to amend that regulations on type-1 use of living modified organisms, provided, however, that this does not apply when the type-1 use of living modified organisms made in accordance with regulations on type-1 use of living modified organisms is acknowledged as being inappropriate.
- (2) If a person who has received instructions under the provisions of the preceding paragraph does not amended regulations on type-1 use of living modified organisms based on those instructions within the time limit stipulated by the competent ministers, the competent ministers is to reject that person's application for approval.
- (3) In the case provided for in the proviso to paragraph (1), the competent

ministers must refuse that approval.

(Obligations of Recipients of Approval)

Article 6 (1) A person who has obtained the approval in Article 4, paragraph (1) (referred to as "recipient of approval" in the following paragraph) must, when a change has occurred in the particulars listed in paragraph 2, item (1) of the same Article, notify the competent ministers to that effect and of reason therefor, as stipulated by Order of the competent ministries.

(2) The competent ministers may, when wishing to study changes to or the repeal of regulations on type-1 use of living modified organisms under the provisions of paragraph (1) of the following Article, or when otherwise necessary to gather information concerning those regulations on type-1 use, seek the provision of essential information from the recipient of approval regarding those regulations on type-1 use of living modified organisms.

(Changes to Approved Regulations on Type-1 Use of Living Modified Organisms)

Article 7 (1) The competent ministers 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 progression of scientific knowledge after the date of that 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 regulations on type-1 use of living modified organisms for which the approval has been obtained, change or repeal the regulations on type-1 use of living modified organisms to the extent necessary to prevent an adverse effect on biological diversity.

(2) The competent ministers is to consult experts in advance, as stipulated by Order of the competent ministries, concerning changes or repeals under the provisions of the preceding paragraph.

(3) Experts who have been consulted under the provisions of the preceding paragraph must not divulge or appropriate secrets obtained concerning changes or repeals on regulations on type-1 use of living modified organisms under the provisions of paragraph (1) or the biological diversity risk assessment report thereof.

(4) Beyond what is provided for in the preceding three paragraphs, essential information concerning changes or repeals under the provisions of paragraph (1) is stipulated by Order of the competent ministries.

(Announcement of Approved Regulations on Type-1 Use of Living Modified Organisms)

Article 8 (1) The competent ministers must make the particulars stipulated in

each of the following items public without delay, in accordance with the categories listed in those items, as stipulated by Order of the competent ministries:

- (i) when giving the approval in Article 4, paragraph (1): an announcement to that effect and the approved regulations on type-1 use;
 - (ii) when changing regulations on type-1 use under the provisions of paragraph (1) of the preceding Article: an announcement to that effect and the regulations on type-1 use after that change;
 - (iii) when repealing regulations on type-1 use under the provisions of paragraph (1) of the preceding Article: an announcement to that effect.
- (2) Announcements under the provisions of the preceding paragraph are to be made by public notice.

(Approval of Regulations on Type-1 Use of Living Modified Organisms by Exporters to Japan)

- Article 9 (1) A person who wishes to have other persons make type-1 use of living modified organisms, such as through exporting living modified organisms to Japan and have other persons make type-1 use thereof may, as stipulated by Order of the competent ministries, determine regulations on type-1 use for each type of living modified organism and obtain the approval of the competent ministers thereto.
- (2) A person who does not have an address in Japan (or, in the case of a corporation, its main office; hereinafter the same applies in this paragraph and in paragraph (4)) and wishes to obtain the approval in the preceding paragraph must, when applying for that approval, appoint, from among persons who have an address in Japan or other persons stipulated by Order of the competent ministries, a person to whom necessary measures are to be entrusted to ensure the proper use of living modified organisms in Japan.
- (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 that paragraph (hereinafter referred to as a "Japan-based administrator"), notify the competent ministers to that effect and of reason therefor.
- (4) The provisions of Article 4, paragraph (2) through paragraph (7); Article 5 and the preceding Article apply mutatis mutandis to the approval in paragraph (1), the provisions of Article 6 to a person who has obtained the approval in that paragraph (or, when that person does not have an address in Japan, the Japan-based administrator for that person), and the provisions of Article 7 to regulations on type-1 use approved under the provisions of that paragraph. In these cases, the term "name and address" in Article 4, paragraph (2) item (i) is 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) is deemed to be replaced with "Article 9, paragraph (1)".

(Orders for Measures Concerning Type-1 Use of Living Modified Organisms)

Article 10 (1) The competent ministers may order a person who is making or has made 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 effects on biological diversity.

(2) The competent ministers may, when recognizing urgency to be necessary in order to prevent adverse effects 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 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 had another person make type-1 use of living modified organisms (and, in cases recognized as requiring particular urgency, including the Japan-based administrator) to suspend that type-1 use of living modified organisms or take other necessary measures, within the limits necessary to prevent an adverse effect on biological diversity.

(3) The Minister of the Environment may, when type-1 use of living modified organisms is or has been made by a person in violation of Article 4, paragraph (1), and the effects of this use damage or are highly likely to damage biological diversity, order that person to take necessary measures to restore damage they have caused through type-1 use of living modified organisms, or prevent future damage to biological diversity (limited to species and regions specified by Order of the Ministry of the Environment as especially important for preserving biological diversity. The same applies hereinafter in this item).

(Measures in the Event of Accidents Concerning Type-1 Use of Living Modified Organisms)

Article 11 (1) A person who is making type-1 use of living modified organisms must, when they are no longer able to comply with the approved regulations on type-1 use of 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 effects on biological diversity, as well as promptly notifying the competent ministers of the accident and the outline of the measures taken.

(2) The competent ministers may, when recognizing that the person specified in

the preceding paragraph has not taken the emergency measures listed in that paragraph, order that person to take emergency measures specified in that paragraph.

Section 2 Type-2 Use of Living Modified Organisms

(Implementation of Containment Measures Stipulated by Order of the Competent Ministry)

Article 12 A person who makes type-2 use of living modified organisms must, when containment measures to be taken in connection with that type-2 use are stipulated by Order of the competent ministry, take those containment measures during the period of that 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 that type-2 use of living modified organisms are not stipulated by Order of the competent ministries in the preceding Article (except when making type-2 use of specified living modified organisms or when otherwise stipulated by Order of the competent ministries), take containment measures confirmed in advance by the competent ministers during the period of that use.

(2) Application for the confirmation in the preceding paragraph must be made by submitting an application form detailing the following particulars:

- (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) beyond what is listed in the preceding three items, particulars stipulated by Order of the competent ministries.

(3) Beyond what is provided for in the preceding two paragraphs, necessary particulars concerning the confirmation in paragraph (1) are stipulated by Order of the competent ministries.

(Orders for Measures Concerning Type-2 Use)

Article 14 (1) The competent ministers may order a person who is making or has made 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 by Order of the competent ministries in Article 12, or to take other necessary measures.

(2) The competent ministers 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 Order of the competent ministry in Article 12 or

the confirmation in paragraph (1) of the preceding Article, urgency is necessary in order to prevent the dispersal of living modified organisms outside facilities, order a person who is making or has made type-2 use of living modified organisms with containment measures stipulated by Order 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 those containment measures or to take other necessary measures.

- (3) The Minister of the Environment may, when type-2 use of living organisms is or has been made by a person in violation of Article 12, or the previous Article, paragraph (1), and the effects of that use damage or are highly likely to damage biological diversity, order that person to take necessary measures to restore damage they have caused through type-2 use of living modified organisms, or prevent future damage to biological diversity (limited to species and regions specified by Order of the Ministry of the Environment as especially important for preserving biological diversity. The same applies hereinafter in this item).

(Measures in the Event of Accidents through Type-2 Use of Living Modified Organisms)

Article 15 (1) A person who is making type-2 use of living modified organisms must, when a breakage or other accident has occurred in facilities which utilize containment measures, and when no longer able to take containment measures stipulated by Order of the competent ministries in Article 12, or the containment measures subject to confirmation as in Article 13, paragraph (1) for those living modified organisms, immediately take emergency measures against that accident, as well as promptly notify the competent ministers of the circumstances regarding the accident and an outline of measures taken.

- (2) The competent ministers may, when recognizing that the person stipulated in the preceding paragraph has not taken the emergency measures listed in that paragraph, order that person to take emergency measures provided for in that paragraph.

Section 3 Testing of Organisms

(Notification of Imports)

Article 16 When there is a high likelihood that living modified organisms that could potentially give rise to adverse effects on biological diversity are imported without knowledge of that fact, and in view of the circumstances of the producing area or other circumstances, or when corresponding to other similar cases that have been designated by the competent ministers, a person who wishes to make imports in relation to the designation must notify the

competent ministers to that effect on each occasion, as stipulated by Order of the competent ministries.

(Order to Test Organisms)

Article 17 (1) The competent ministers may order a person who has made a notification under the provisions of the preceding Article to undergo testing of organisms which that person imports (referred to in paragraph (3) and paragraph (5) as "organisms subject to testing"), by the competent ministers or a person registered by the competent ministers (hereinafter referred to as a "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 "organism testing"), as stipulated by Order of the competent ministries.

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

(3) Until undergoing organism testing 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 ministers including the use of facilities, and must not transfer or supply organisms subject to testing.

(4) When the notification in the preceding paragraph is made by a registered inspection body, it is to be made via the competent ministers.

(5) The competent ministers may, when recognizing that a person as stipulated in paragraph (3) has violated the provisions of that paragraph, order that person to use organisms subject to testing based on the conditions in that paragraph or take other necessary measures.

(Registered Inspection Body)

Article 18 (1) The registration in paragraph (1) of the preceding Article (hereinafter in this Section referred to as "registration") is carried out following an application by a person who wishes to undertake the testing of organisms.

(2) A person who falls under any of the following items must not receive registration:

(i) a person who has committed an offense and received a sentence 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 falls under any of the preceding two items.

(3) The competent ministers must grant registration when the person who has applied for that registration (hereinafter in this paragraph referred to as an "applicant") satisfies all of the following. In these cases, the procedures needed for registration are stipulated by Order 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 places of business undertaking the 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 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 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 a "business that uses living modified organisms"):

(a) when the applicant is a stock company, that a business that uses living modified organisms 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 membership company (referring to a membership company under Article 575, paragraph (1) of the Company Act), managing member) are officers or employees of a business that uses living modified organisms (including persons who were officers or employees of that business that uses living modified organisms within the last two years).

- (c) that the applicant (or, in the case of a corporation, an officer with the right to represent) is an officer or employee of a business that uses living modified organisms (including persons who were officers or employees of that business that uses living modified organisms within the last two years).
- (4) Registration is to be implemented by detailing the particulars 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) beyond what is listed in the preceding two items, particulars stipulated by Order of the competent ministries.

(Rules to be Observed)

- Article 19 (1) A registered inspection body must, when requested to implement the testing of organisms, do so without delay, except when there are justifiable reasons for not doing so.
- (2) A registered inspection body must implement the testing of organisms fairly, and through means stipulated by Order of the competent ministries.
- (3) A registered inspection body must, when wishing to change the address of the place of business implementing the testing of organisms, notify the competent ministers no less than 2 weeks before the scheduled date of the change.
- (4) A registered inspection body must, before starting the testing of organisms, determine regulations concerning the implementation of the testing of organisms, as stipulated by Order of the competent ministries, and obtain the approval of the competent ministers thereto. The same applies when wishing to change those regulations.
- (5) A registered inspection body must, no more than 3 months after the end of each business year, prepare an inventory of property, a 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 electronic or magnetic records when these are prepared in place of the above (referring to records that are prepared by electronic or magnetic, or other means that cannot be recognized by human perception alone, and which are provided for computer data processing; hereinafter the same applies 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 particulars listed in the following, at any time within the working hours of the registered inspection body, provided, however, that when requesting the particulars in item (ii) or item (iv), 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 those 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 electronic or magnetic records, a request for an inspection or a copy of the particulars recorded in those electronic or magnetic records displayed by means stipulated by Order of the competent ministries;
 - (iv) A request for provision of the particulars recorded in the electronic or magnetic records in the preceding item using electronic or magnetic means stipulated by Order of the competent ministries, or a request for the issue of a document detailing those particulars.
- (7) A registered inspection body must, as stipulated by Order of the competent ministry, prepare books and file particulars stipulated by Order of the competent ministries in connection with the testing of organisms.
- (8) A registered inspection body must not, without permission from the competent ministers, suspend or discontinue all or part of its work on the testing of organisms.

(Obligation to Maintain Confidentiality)

- Article 20 (1) The present or former officers or employees of a registered inspection body must not divulge secrets obtained concerning the testing of organisms.
- (2) The officers or employees of a registered inspection body engaged in the testing of organisms are regarded as employees engaged in public service pursuant to laws and regulations, with respect to the application of the Penal Code (Code No. 45 of 1907) or other penal provisions.

(Order to Comply)

- Article 21 (1) The competent ministers may, when recognizing that a registered inspection body is no longer in compliance with any of the items of Article 18, paragraph (3), order that registered inspection body to take necessary measures to comply with the provisions thereof.
- (2) The competent ministers 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 that registered inspection body to implement the testing of organisms or take necessary measures to improve the means of testing organisms or means of conducting other affairs.
- (3) The competent ministers 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 ministers must cancel registration when a registered inspection body has come to fall under Article 18, paragraph (2) item (i) or item (iii).
- (5) The competent ministers 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 testing of organisms to be suspended in whole or in part:
- (i) when it has violated the provisions of Article 19, paragraph (3) through 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) through paragraph (3);
 - (v) when it has received registration through wrongful means.

(Collecting Reports and On-Site Inspections)

Article 22 (1) The competent ministers may, within the limits necessary to enforce the provisions of this Section, request a registered inspection body to submit reports on its testing of organisms, or may have the concerned personnel enter the office of a registered inspection body, inspect the books, documents or other necessary articles of the registered inspection body, or question relevant persons.

- (2) The relevant personnel conducting on-site inspections under the provisions of the preceding paragraph must carry a certificate of their identification and present it to the relevant persons.
- (3) The authority to conduct on-site inspections under the provisions of paragraph (1) must not be construed as being permitted for the purpose of criminal investigation.

(Public Notice)

Article 23 The competent ministers must, in any of the cases listed below, make a 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 testing of organisms to be

suspended in whole or in part under the provisions of that paragraph.

(Fees)

- Article 24 (1) A person who wishes to undertake the testing of organisms must pay a fee to the government (or, when a registered inspection body undertakes the testing of organisms, the registered inspection body) of an amount stipulated by Cabinet Order, of an amount that reflects actual costs incurred.
- (2) Fees paid to a registered inspection body under the provision of the preceding paragraph are to be included in the revenue of the registered body.

Section 4 Providing Information

(Information on Proper Use)

- Article 25 (1) The competent ministers is to, whenever necessary to ensure that type-1 use of living modified organisms subject to regulations on type-1 use of living modified organisms that have been approved as 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 type-1 use of living modified organisms to another person (hereinafter referred to as "information on proper use"), or change this information.
- (2) The competent ministers must, when stipulating information on proper use under the provisions of the preceding paragraph, or changing this information, make an announcement of the content thereof without delay, as stipulated by Order of the competent ministries.
- (3) Announcements under the provisions of the preceding paragraph are to be made by public notice.

(Providing Information)

- Article 26 (1) A person who wishes to transfer or supply, or entrust living modified organisms must, as stipulated by Order of the competent ministries, provide information on proper use and other information on particulars stipulated by Order of the competent ministries to a person receiving that transfer or supply, or receiving entrustment to make use of those living modified organisms, by issuing documents or by other means stipulated by Order of the competent ministries.
- (2) The competent ministers 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 an adverse effect on biological diversity could arise, order the person who has transferred or supplied, or entrusted for use those living modified organisms to recall them, or take other

necessary measures, to the extent necessary to prevent an adverse effect on biological diversity.

- (3) In the case prescribed in the preceding paragraph, the Minister of the Environment, when recognizing that damage, or a high chance of damage to biological diversity brought about by using living modified organisms (limited to species and regions specified by Order of the Ministry of the Environment as especially important for biological diversity. The same hereinafter in this item) exists, may order the person who has transferred or supplied, or entrusted for use those living modified organisms to take necessary measures to restore damage they have caused to biological diversity.

Chapter III Measures Concerning Exporting

(Export Notification)

Article 27 A person who wishes to export living modified organisms must, as stipulated by Order of the competent ministries, notify the importing country of the names of the types of living modified organisms to be exported, and other particulars stipulated by Order of the competent ministries, provided, however, that this does 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 applies in this Article) other than those whose purpose is solely to be used for animals, and when otherwise stipulated by Order of the competent ministries.

(Labeling for Exporting)

Article 28 Living modified organisms must not be exported unless the format use of those living modified organisms and other particulars stipulated by Order of the competent ministries are labeled on the living modified organisms or their packaging, container or consignment invoice, as stipulated by Order of the competent ministries. In these cases, the provisions of the proviso to the preceding Article apply mutatis mutandis to export under the provisions of this Article.

(Orders Concerning Exporting)

Article 29 The competent ministers may, when living modified organisms have been exported in violation of the provisions of the preceding two Articles, and when recognizing that an adverse effect on biological diversity could arise, order the person who exported those living modified organisms to recall those living modified organisms or take other necessary measures, within the limits necessary to prevent an adverse effect on biological diversity.

Chapter IV Miscellaneous Provisions

(Collecting Reports)

Article 30 The competent ministers may, to the extent necessary to enforce this Act, request a person who is using or has used living modified organisms (including organisms suspected of being living modified organisms; hereinafter the same applies 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 the acts and other necessary particulars.

(On-Site Inspections)

- Article 31 (1) The competent ministers may, to the extent necessary to enforce this Act, have personnel enter premises where a person who is using or has used 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 who carry out those acts, or other relevant premises, to question relevant persons, inspect living modified organisms, facilities, and other articles, or have them collect living modified organisms at no cost, limited to the minimum amount necessary for inspection.
- (2) The relevant personnel must, when entering, questioning, inspecting or removing under the provisions of the preceding paragraph (hereinafter referred to as "on-site inspections") carry a certificate of identification and show it to the relevant persons.
- (3) The authority to conduct on-site inspections under the provisions of paragraph (1) must not be construed as being permitted for the purpose of criminal investigation.

(On-Site Inspections by Inspection Centers)

Article 32 (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 "inspection centers"), in accordance with the categories of centers listed below, enter premises where a person who is using or has used 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 those acts, or other places, and question relevant persons, inspect living modified organisms, facilities, and other articles, or remove living modified organisms at no cost, limited to the extent necessary for inspection:

- (i) Food and Agricultural Materials Inspection Center, National Center for Seeds and Seedlings, National Livestock Breeding Center, and Fisheries Research Agency: the Minister of Agriculture, Forestry and Fisheries;
 - (ii) National Institute of Technology and Evaluation: the Minister of Economy, Trade and Industry;
 - (iii) Pharmaceuticals and Medical Device Agency: the 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 is to, when authorizing inspection centers to conduct on-site inspections under the provisions of the preceding paragraph, in accordance with the categories of inspection centers listed in the items of that paragraph, specify the date, place and other necessary particulars for conducting on-site inspections and instruct inspection centers to conduct those inspections.
- (3) Inspection 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 inspections to employees with knowledge and experience concerning living modified organisms, who satisfy the conditions stipulated in orders issued by the ministers stipulated in each item of that paragraph, in accordance with the categories of inspection centers listed in the items of that paragraph.
- (4) Inspection 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 that paragraph to the Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry or the Minister of Health, Labor and Welfare, in accordance with the categories of inspection centers listed in the items of that paragraph, as stipulated by Order of the Ministry of Agriculture, Forestry and Fisheries, the Order of the Ministry of Economy, Trade and Industry or the Order of the Minister of Health, Labour and Welfare.
- (5) The provisions of paragraph (2) and paragraph (3) of the preceding Article apply mutatis mutandis to on-site inspections under the provisions of

paragraph (1).

(Orders to Inspection Centers)

Article 33 The Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry or the Minister of Health, Labor 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 inspection centers concerning the work, in accordance with the categories of inspection centers listed in the items of that paragraph.

(Measures for the Progression of Scientific Knowledge)

Article 34 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 improve scientific knowledge on those matters.

(Hearings of Public Opinions)

Article 35 The government is to publicly announce information on the assessment of adverse effects on biological diversity, information that has been collected, arranged and analyzed under the provisions of the preceding Article, and other relevant information, and broadly consult the public, in order to reflect public opinion in measures based on this Act and encourage the mutual exchange of information and opinions between the parties concerned.

(Consultation with the Competent Minister)

Article 35-2 The Minister of the Environment must, in any of the cases listed below, consult with the competent ministers:

- (i) When wishing to issue, amend or abolish an Order of the Ministry of the Environment under Article 3, paragraph (4), Article 10, paragraph (3), Article 14, paragraph (3), or Article 26, paragraph (3);
- (ii) When wishing to issue orders under the provisions of Article 10, paragraph (3), Article 14, paragraph (3) or Article 26, paragraph (3).

(Competent Ministers)

Article 36 (1) The competent ministers in this Act, as stipulated by Cabinet Order, are the Minister of Finance, the Minister of Education, Culture, Sports, Science and Technology, the Minister of Health, Labor and Welfare, the Minister of Agriculture, Forestry and Fisheries, the Minister of Economy, Trade and Industry, or the Minister of the Environment.

(2) Orders of the competent ministry in this Act are those issued by a competent minister.

(Delegation)

Article 36-2 The authority of the competent ministers provided for in this Act may, as stipulated by Order of the competent ministries, be delegated to a head of a local branch or department.

(Transitional Measures)

Article 37 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 extent considered necessary.

Chapter V Penal Provisions

Article 38 A person who violates orders under the provisions of from Article 10, paragraph (1) through paragraph (3), Article 11, paragraph (2), Article 14, paragraph (1) or paragraph (2), Article 15, paragraph (2), Article 17, paragraph (5), Article, 26 paragraph (2) or paragraph (3), or Article 29 is subject to imprisonment for not more than 1 year or a fine of not more than one million yen, or a combination of both.

Article 39 A person who falls under any of the following items is subject to imprisonment with work of not more than 6 months or a fine of not more than 500,000 yen, or a combination of both:

- (i) a person who makes type-1 use of living modified organisms 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 is subject to 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 employee of a registered inspection body violates an order to suspend the testing of organisms under the provisions of Article 21,

paragraph (5), that person is subject to imprisonment with work for 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 is subject to a fine of not more than 500,000 yen:

- (i) a person who makes type-2 use of living modified organisms without receiving confirmation, in violation of the provisions of Article 13, paragraph (1);
- (ii) a person who undertakes the confirmation in Article 13, paragraph (1) through deception or other wrongful means;
- (iii) a person who imports living modified organisms without making a notification under the provisions of Article 16, or makes a false notification of importing living modified organisms;
- (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 exports living modified organisms without making a notification under the provisions of Article 27, or makes a false notification of exporting living modified organisms;
- (vi) A person who exports living modified organisms without labeling under the provisions of Article 28, or with false labeling of exporting living modified organisms.

Article 43 A person who falls under any of the following items is subject to a fine of not more than 300,000 yen;

- (i) a person who fails to make a report as provided for in Article 30, or makes a false report;
- (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 An officer or employee of a registered inspection body who commits any of the violations in the following items is subject to a fine of not more than 300,000 yen;

- (i) if, in violation of the provisions of Article 19, paragraph (7), they fail to record particulars as provided for in that paragraph, or records false particulars, or fails to keep books on record;
- (ii) if they discontinue the testing of organisms entirely, without obtaining the permission in Article 19, paragraph (8):
- (iii) if 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 that paragraph, or fail to answer questions, or make a false statements.

Article 45 If 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 the corporation or individual, not only is the offender subject to punishment, but the corporation or individual is also subject to the fine prescribed in those Articles.

Article 46 A person who fails to make a 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 a false notification is subject to a fine of not more than 200,000 yen.

Article 47 An officer or employee of a registered inspection body who falls under any of the violations in the following items is subject to a fine of not more than 200,000 yen:

- (i) if they fail to prepare financial statements in violation of the provisions of Article 19, paragraph (5), fail to record particulars that should be recorded in financial statements, or record false particulars;
- (ii) if, without a justifiable reason, they refuse a request under the provisions of the items of Article 19, paragraph (6).

Article 48 If an inspection center violates an order under the provisions of Article 33, the officers of that inspection center are subject to a fine of not more than 200,000 yen.

Supplementary Provisions

(Effective Date)

Article 1 This Act comes into force as of the date on which the Cartagena Protocol takes effect in Japan, provided, however, that the provisions listed in the following items come into force as of the date stipulated in each respective item:

- (i) The provisions of the following Article through 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 the "effective date") or the effective date of the Act on Pharmaceutical and Medical Device Agency, whichever is later.

(Transitional Measures)

Article 2 (1) A person who wishes to obtain the approval in Article 4, paragraph (1) or Article 9, paragraph (1) may apply for that approval under the example of the provisions of Article 4 or Article 9 even before the effective date.

(2) The competent ministers may, when an application has been made under the provisions of the preceding paragraph, grant that approval under the example of the provisions of Article 4 or Article 9 even before the effective date. In this case, when approval has been obtained under the example of these provisions, the approval is 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 approval for type-1 use of living modified organisms in accordance with Article 4, paragraph (1) or Article 9, paragraph (1) is, for 6 months from the effective date, regarded as having obtained approval for that type-1 use of living modified organisms. If an application for approval of regulations on type-1 use of living modified organisms is made before the end of that 6-month period, the same applies from when that period has lapsed, until the date of approval for the application, or until the application is dismissed or rejected.

Article 3 (1) A person who wishes to receive the confirmation in Article 13, paragraph (1) may prior to the effective date, apply for that confirmation under the example of the provisions of the same Article.

(2) The competent ministers may, when an application for confirmation has been made under the provisions of the preceding paragraph, make that confirmation prior to the effective date, under the example of the provisions of Article 13. In this case, when confirmation has been received under the example of the provisions of the same Article, that confirmation is 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 of living modified organisms 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 that paragraph has been received, is for 6 months from the effective date, regarded as having taken containment measures for which that confirmation has been received. If that person makes an application for confirmation before the end of

that 6-month period, the same applies when that 6-month period has lapsed, until the date of the confirmation or refusal of the application.

Article 4 (1) A person who wishes to receive the registration in Article 18, paragraph (1) may apply for registration prior to the effective date.

(2) The competent ministers may, if an application has been made under the provisions of the preceding paragraph, make a registration prior to the effective date, under the example of the provisions of Article 18. In this case, when registration has been made under the example of the provisions of the Article 18, the registration is regarded as having been made on the effective date under the provisions of paragraph (1) of the Article 18.

Article 5 (1) A person who wishes to receive approval of the regulations in Article 19, paragraph (4) may apply for this prior to the effective date.

(2) The competent ministers may, if an application has been made under the provisions of the preceding paragraph, grant approval prior to the effective date, under the example of the provisions of Article 19, paragraph (4). In this case, if approval has been received under the example of the provisions of that paragraph, that approval is to be regarded as having been received on the effective date under the provisions of that paragraph.

(Delegation to Cabinet Order)

Article 6 Beyond what is stipulated in Article 2 through the preceding Article, necessary transitional measures concerning the enforcement of this Act are stipulated by Cabinet Order.

(Review)

Article 7 The government is to, 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 as being necessary, devise requisite measures based on the results thereof.