

# **Regulations related to the Enforcement of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms**

## **(Tentative Translation)**

### (Definition of Living Organisms)

Article 1: Single cell (excluding single cells that form cell colonies) or cell colonies (hereinafter “the cell”) stipulated in the ordinance of the competent ministries under Article 2 paragraph 1 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (hereinafter “the Law”) shall be single cell or cell colonies other than those shown in the following.

1. Human cells
2. Single cell or cell colonies (excluding individuals and gametes) which are capable of differentiating or have differentiated and which do not grow to individuals in natural conditions.

### (Technology used in order to obtain living modified organism)

Article 2: Technologies stipulated in the ordinance of the competent ministries under Article 2 paragraph 2 subparagraph 1 of the Law shall be the technology for processing nucleic acid extracellularly for the purpose of introducing the nucleic acid into cells, viruses or viroids to transfer or replicate the nucleic acid, while excluding those mentioned in the following.

- (i) Technology for processing by using, as nucleic acid to be introduced into cells, only the nucleic acid shown in the following
  - A. The nucleic acid of living organism belonging to the same species as that of the living organism which the cells originate from.
  - B. The nucleic acid of living organism belonging to the species that exchanges nucleic acid with the species of the living organism which the cells originate from in natural conditions
- (ii) Technology for processing by using, as nucleic acid to be introduced into viruses or viroids, only the nucleic acid of viruses or viroids that exchanges nucleic acid with the viruses or viroids in natural conditions

Article 3: Technology stipulated in the ordinance of the competent ministries under Article 2 paragraph 2 subparagraph 2 of the Law shall exclude technology that has been used traditionally, such as hybridization among technologies for fusing cells of living organisms belonging to different taxonomic families.

### (Measures Specifying Type 2 Use)

Article 4: Measures stipulated in the ordinance of the competent ministries under Article 2 paragraph 6 of the Law shall be as stipulated in the following subparagraphs for the cases

mentioned respectively in these subparagraphs.

(i) When the Use of living modified organisms (excluding transportation), facilities that fall under any of those mentioned in the following shall be used.

A. Laboratories (including animal breeding rooms and plant growing rooms involved in research and development) which have the function of preventing the living modified organisms from dispersing into the air, water or soil outside the facilities (hereinafter “the containment function” in this paragraph).

B. Installations which have the containment function and are used for culture or fermentation, and installations for incidental use thereto which have the containment function

C. Besides those mentioned in A and B, facilities having the containment function and having signs, which state that the Use is made with the intention to prevent living modified organisms from dispersing into the air, water or soil outside the facilities, posted in easily visible places

(ii) When living modified organisms are transported, capped or sealed test tubes and other facilities with the containment function, for use to transport living modified organisms for the Use in the facilities mentioned in the preceding subparagraph shall be used.

2. Even though the measures mentioned in the preceding subparagraphs are taken, when the Use of living modified organism falls under the case stipulated under the proviso to Article 4 paragraph 1 of the Law, irrespective of the provisions of the preceding paragraph, the measures shall not be considered as measures under Article 2 paragraph 6 of the Law.

(Exemption from Approval of Competent Minister)

Article 5: Cases stipulated in the ordinance of the competent ministers in the proviso to Article 4 paragraph 1 of the Law shall be as follows.

(i) Cases separately stipulated by the competent minister as those which urgently require Type 1 Use of living modified organisms as measures for the protection of human life or body or temporary measures against disaster

(ii) Cases where the minimum necessary Type 1 Use is made to perform testing on the basis of Article 17, Article 31 or Article 32 of the Law, or prepare for the testing

(iii) Cases where a living modified organism is mixed in imported living organisms (limited to cases where the Type 1 Use of the living modified organism not conforming to the Type 1 Use Regulations approved by the competent minister under the provisions of Article 4 paragraph 1 or Article 9 paragraph 1 of the Law [for Type 1 Use regulations changed by the competent minister under the provisions of Article 7 paragraph 1 of the Law (including the those applied mutatis mutandis in Article 9 paragraph 4 of the Law), those after change.

Hereinafter “approved Type 1 Use regulations”], or not having obtained approval of Type 1 Use Regulations is inevitable in the use of the imported living organisms, and is separately stipulated by the competent minister)

- (iv) Cases where one has a living modified organism in his or her body and makes Type 1 Use of the living modified organism in his or her daily life
- (v) Cases where one makes Type 1 Use of a living modified organism transferred or supplied or is entrusted to make Type 1 Use of a living modified organism without knowing that the Type 1 Use is not conforming with approved Type 1 Use Regulations or the same has not obtained approval of Type 1 Use Regulations
- (vi) Cases where the minimum necessary Type 1 Use is made to prevent adverse effect on biological diversity caused by living modified organisms used not conforming with Type 1 Use Regulations or not having obtained approval of Type 1 Use Regulations.

(Documents Attached to Application)

Article 6: Documents to be stipulated in the ordinance of the competent ministries under Article 4 paragraph 2 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law; the same applies to the following Article and Article 41) shall be those showing the content of measures, which are useful for efficient prevention of adverse effects on biological diversity, taken by a person who wishes to obtain approval provided in Article 4 paragraph 1 or Article 9 paragraph 1 (only when the competent minister recognizes the necessity).

(Form of Application)

Article 7: The form of an application stipulated in Article 4 paragraph 2 of the Law shall be Form No. 1.

(Matters mentioned in Type 1 Use Regulations)

Article 8: Type 1 Use Regulations shall be set forth on the matters mentioned in the respective subparagraphs of Article 4 paragraph 3 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law) as stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

- (i) The name of the type of a living modified organism: Such a name shall enable the living organism to be clearly distinguished from other living modified organisms and shall include the name of species of the recipient organism (a living organism in which nucleic acid, or a replicated product thereof, obtained by using the technology provided in Article 2 paragraph 2 subparagraph 1 of the Law is transferred. Hereinafter the same applies.) of the living modified organism or the parental organisms (a living organism from which nucleic acid, or a replicated product thereof, obtained by using the technology provided in Article 2 paragraph 2 subparagraph 2 of the Law , originates. Hereinafter the same applies.) and the characteristics of the living modified organism.
- (ii) The content of Type 1 Use of the living modified organism: A series of the Use to be made for the living modified organism shall be laid down.
- (iii) The method of Type 1 Use of the living modified organism: Measures to be taken for the

prevention of adverse effect on biological diversity in making the Type 1 Use shall be laid down (only when required for the prevention of adverse effect on biological diversity).

(Consultation with Experts)

Article 9: In consulting experts under the provisions of Article 4 paragraph 4 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law); the competent minister shall consult persons listed in the register of names of experts in the following Article.

(Register of Names of Experts)

Article 10: The competent minister shall select persons with special knowledge and experience concerning adverse effect on biological diversity, and shall prepare and announce the register of names of the experts.

(Instructions concerning Amendment of Type 1 Use Regulations)

Article 11: Instructions under the provisions of Article 5 paragraph 1 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law) shall be issued in writing and with an indication of a reason or reasons thereof, and the time limit under Article 5 paragraph 2 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law).

(Notification of Change)

Article 12: The notification under the provisions of Article 6 paragraph 1 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law) shall be made by the submission of a written notice in Form No. 2 within two weeks from the date on which any of the matters cited in Article 4 paragraph 2 subparagraph 1 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law) is changed.

(Consultation with Experts on Change in Type 1 Use Regulations)

Article 13: The provisions of Article 9 shall be applied mutatis mutandis when experts are consulted under the provisions of Article 7 paragraph 2 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law). In this case, "next Article" shall be read as "Article 10."

(Method of Announcement of Type 1 Use Regulations)

Article 14: The announcement under the provisions of Article 8 paragraph 1 of the Law (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law) shall be published in the official gazette.

(Person to Order Measures for Correct Use)

Article 15: A person stipulated in the ordinance of the competent ministries under Article 9

paragraph 2 of the Law shall be the office representative of a foreign corporation having an office in Japan.

(Exemption from Requiring Confirmation of Competent Minister)

Article 16: The cases stipulated in the ordinance of the competent ministries under Article 13 paragraph 1 of the Law shall be as follows.

- (i). Cases separately stipulated by the competent minister as those which urgently require Type 2 Use of living modified organisms as measures for the protection of human life or body or temporary measures against disaster
- (ii). Cases where the minimum necessary Type 2 Use is made to perform testing on the basis of Article 17, Article 31 or 32 of the Law, or prepare for the testing.
- (iii) Cases where the Type 2 Use is made without knowing the necessity of obtaining the confirmation of containment measures because of false information received.
- (iv) Cases where the minimum necessary Type 2 Use is made to prevent dispersal of living modified organisms used in violation of the Law

(Notice of Import)

Article 17: Notification under the provisions of Article 16 of the Law shall be made through the submission of a written notice in Form No. 3 no later than the date designated separately by the competent minister.

(Order for Testing of Organisms)

Article 18: An order under the provisions of Article 17 paragraph 1 of the Law shall be issued in writing, indicating the conditions stipulated in paragraph 3 of the same Article therein.

(Request for Testing by Person Receiving Order for Testing of Living Organism)

Article 19: The request for testing of a living organism shall be made through the submission of an application in Form No. 4.

- 2. The written request provided in the preceding paragraph shall be accompanied by a copy of the document stipulated in the preceding Article.

(Application for Registration of Registered Testing Body)

Article 20: To apply for registration under the provisions of Article 18 paragraph 1 of the Law, an application using Form No. 5 shall be submitted.

- 2. The following documents must be attached to the application stipulated in the preceding paragraph.
  - (i) Certified copies of the articles of association and register, or documents corresponding to them
  - (ii) A balance sheet and income statement as of the business year preceding a business year in

which the date of the application falls, or documents corresponding to them (in the case of a corporation established in the business year in which the date of the application falls, inventory of its estate as of its establishment)

- (iii) A document verifying that the applicant meets the requirements provided in Article 18 paragraph 3 subparagraphs 1 to 3 of the Law
- (iv) A document describing an outline of the business that the applicant is currently performing
- (v) Besides those mentioned in the preceding subparagraphs, documents describing matters for reference

(The Matter to Be Described in Ledger of Registered Testing Body)

Article 21: The matter stipulated in the ordinance of the competent ministries under Article 18 paragraph 4 subparagraph 3 shall be the names of types of living organisms subject to testing.

(Method of Implementing Testing of Living Organisms)

Article 22: A method stipulated by the competent ministries under Article 19 paragraph 2 of the Law shall be separately stipulated by the competent minister in consideration of matters such as the types of living organisms subject to testing.

(Notification of Change)

Article 23: A notification of Change under the provisions of Article 19 paragraph 3 of the Law shall be made through the submission of a written notice in Form No. 6.

(Items to Be Mentioned in Regulations concerning Implementation of the Work of Testing of Living Organisms)

Article 24: The regulations concerning the implementation of the work of Testing of Living Organisms in Article 19 paragraph 4 of the Law shall stipulate the following matters.

- (i) Matters concerning hours in which Testing of Living Organisms is implemented and holidays
- (ii) Matters concerning the office in which Testing of Living Organisms is implemented
- (iii) Matters concerning the implementation system of Testing of Living Organisms
- (iv) Matters concerning the receipt of fees
- (v) Matters concerning the preservation of confidentiality pertaining to Testing of Living Organisms
- (vi) Matters concerning the control of ledgers and documents related to Testing of Living Organisms
- (vii) Besides those mentioned in the preceding subparagraphs, necessary matters concerning the implementation of Testing of Living Organisms

(Application for Approval of Regulations concerning Implementation of the Work of Testing of Living Organisms)

Article 25: When a Registered Testing Body wishes to obtain the approval stipulated in the first part of paragraph 4 of Article 19 of the Law, an application in Form No. 7 shall be submitted, along with Regulations concerning the implementation of the Work of Testing of Living Organisms, to the competent minister.

2. When a Registered Testing Body wishes to obtain the approval stipulated in the latter part of paragraph 4 of Article 19 of the Law, an application using Form 8 shall be submitted to the competent minister.

(Electromagnetic Method)

Article 26: The method stipulated in the ordinance of the competent ministries under Article 19 paragraph 6 subparagraph 3 of the Law shall be the one showing matters recorded in electromagnetic records on paper or on the image screen of an output device.

2. The electromagnetic method stipulated in the ordinance of the competent ministries in Article 19 paragraph 6 subparagraph 4 of the Law shall be as follows.

(i) Of the method of using an electronic information processing system in which a computer used by a transmitter is connected with a computer used by a recipient through an electric communication circuit, those of transmitting information through the electronic communication circuit and recording information in a file in the computer used by the recipient.

(ii) The method of delivering information recorded in a file on a magnetic disc or some means corresponding to it which is capable of recording certain information without fail.

3. The methods mentioned in the subparagraphs of the preceding paragraph should be capable of preparing a document when the recipient outputs the record in the file.

(Ledgers)

Article 27: The matters stipulated in the ordinance of the competent ministries in Article 19 paragraph 7 of the Law shall be as follows.

(i) The name and address of a person who requests Testing of Living Organisms (if it is a corporation, its name, the name of its representative and the address of its main office)

(ii) The date on which a request for Testing of Living Organisms is received

(iii) The name of the type of living organisms subject to testing

(iv) The result of Testing of Living Organisms

(v) The date on which the result of Testing of Living Organisms is notified

(Application for Approval of Suspension or Discontinuation of Work of Testing of Living Organisms)

Article 28: A registered testing body that wishes to apply for approval under the provisions in

Article 19 paragraph 8 of the Law must submit an application in Form No. 9 to the competent minister.

(Form of Certificate in Article 22 paragraph 2 of the Law)

Article 29: The means of identification in Article 22 paragraph 2 of the Law shall be an identification card using Form No. 10.

(Payment of Fees for Testing of Living Organisms)

Article 30: The fee stipulated in Article 24 of the Law shall be paid; when paid to the government, by means of attaching a revenue stamp equivalent to the amount of the fee to the written request stipulated in Article 19 paragraph 1, or when paid to a registered testing body, as stipulated in regulations concerning the implementation of work of testing of living organisms under Article 19 paragraph 4 of the Law.

2. Fees paid under the provisions of the preceding paragraph shall not be returned.

(Announcement of Information on Correct Use)

Article 31: The announcement under the provisions of Article 25 paragraph 2 of the Law shall be published in the official gazette, indicating the name of the type of the living modified organism.

(Provision of Information)

Article 32: The provision of information under the provisions of Article 26 paragraph 1 of the Law shall be made for each transfer, provision or entrustment (hereinafter "Transfer") of a living modified organism except in cases laid down in the following subparagraphs.

(i) In cases where a living modified organism on which Type 1 Use Regulations are stipulated is transferred or supplied or the Use thereof is entrusted, when Information on Correct Use is not stipulated

(ii) When a living modified organism is intended to be transported on consignment

(iii) When the Use of a living modified organism by a person who wishes to transfer or supply, or entrust the Use of the living modified organism (hereinafter "Assigner") falls under Article 5 subparagraphs 3 to 5 or Article 16 subparagraph 3

(iv) When Type 2 Use of living modified organism by Assigner is made without taking containment measures to be taken in Type 2 Use because of false information received

(v) When a person makes Transfer of a Specific Living Modified Organisms

2. Despite the provisions of the preceding paragraph, when Transfer is made more than twice to a person who receives a living modified organism transferred or supplied or is entrusted of the Use thereof (hereinafter "Transferee"), the provision of information to the Transferee shall be made only in the initial Transfer with the agreement of the Transferee of the living modified organism.

(Contents of Information)

Article 33: Matters stipulated in the ordinance of the competent ministries under Article 26 paragraph 1 of the Law shall be as stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

- (i) When a living modified organism in Type 1 Use is intended to be transferred or supplied or the Use thereof is entrusted: The matters mentioned in the following A to D
  - A. The name of the type of the living modified organisms (If it has no name or its name is unknown, such fact shall be mentioned.)
  - B. That Type 1 Use Regulations for the Type 1 Use of the living modified organism have been approved by the competent minister or that the Use is made on the basis of Article 5 subparagraph 1, 2 or 6
  - C. Information on Correct Use (only if it is stipulated)
  - D. The name and address of the Assigner (in the case of a corporation, the name of the corporation, and the name and contact details of the responsible person)
- (ii) When a living modified organism in Type 2 Use is intended to be transferred or supplied or the Use thereof is entrusted: The matters mentioned in the following A to D
  - A. That Type 2 Use of a living modified organism is being made
  - B. The name of the recipient organism or the parental organism of the living modified organism and the name of nucleic acid, or a replicated product thereof, obtained using the technologies set forth in Article 2 paragraph 2 subparagraph 1 of the Law. (If it has no name or its name is unknown, such fact shall be mentioned.)
  - C. When the Assigner is making Use under Article 16 subparagraph 1, 2 or 4, that said Use is being made
  - D. The name and address of the Assigner (in the case of a corporation, the name of the corporation, and the name and contact details of a responsible person)

(Method of Provision of Information)

Article 34: Methods stipulated in the ordinance of the competent ministries under Article 26 paragraph 1 of the Law shall be any of the following.

- (i) Issuance of a document
- (ii) Indication on a living modified organism or the package or container thereof
- (iii) Transmission using a facsimile machine
- (iv) Of a transmission using an electronic information processing system which connects a computer used by the Assigner with a computer used by the Transferee through an electric communication circuit, those of transmitting matters stipulated in the subparagraphs of the preceding Article through the electronic communication circuit, and recording the matters in a file in the computer used by the Transferee

(Method of Notifying Export)

Article 35: The notification of export under the provisions of Article 27 of the Law shall be made, in Form No. 11, to the competent national authority of the Party of import in Article 8-1 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter “the Protocol” in the following Article).

(Exemption from Notification of Export)

Article 36: Cases stipulated in the ordinance of the competent ministries under the proviso to Article 27 of the Law shall be as follows.

- (i) Exporting a living modified organism to a country other than the Parties to the Protocol
- (ii) Exporting a living modified organism in anticipation of being used in an importing country with containment measures in conformity with the standards provided by the importing country
- (iii) Exporting a living modified organism for use as food, feed or for processing in an importing country
- (iv) Exporting a living modified organism falling under the category of import which the importing country notifies as falling under Article 13-1-(b) of the Protocol to the Biosafety Clearing-House stipulated in Article 20 of the Protocol
- (v) Exporting a living modified organism not corresponding to the initial import of a living modified organism in the importing country

(Content and Method of Documentation for Export)

Article 37: Documentation for the export in Article 28 of the Law shall be made in forms stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

- (i) Exports as living modified organisms for use in importing countries with containment measures in conformity with standards stipulated by the respective importing countries:  
Form No. 12
- (ii) Exports as living modified organisms for use as food or feed, or for processing in importing countries (excluding those mentioned in the preceding subparagraph): Form No. 13
- (iii) Living modified organisms not falling under either of the preceding two subparagraphs:  
Form No. 14

(Exemption from Documentation for Export)

Article 38: Cases stipulated in the ordinance of competent ministries in the proviso to Article 27 of the Law applied mutatis mutandis in Article 28 of the Law shall be those mentioned in Article 36 subparagraph 1.

(Form of Certificate in Article 31 paragraph 2 of the Law)

Article 39: The form of certificate stipulated in Article 31 paragraph 2 of the Law shall be Form No. 15.

(Competent Ministers)

Article 40: The competent ministers in Chapter 2 Section 1 (excluding Articles 10 and 11), Article 25 and Chapter 3 (excluding Article 29) of the Law shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

- (i) Matters concerning living modified organisms in the phase of research and development (excluding the phase of use toward commercialization or practical use of living modified organisms preferred to be examined in accordance with the ideas shown in the recommendation, dated July 16, 1986, of the Council of the Organization for Economic Cooperation and Development concerning Considerations on the Safety in Using Recombinants in Industry, Agriculture and Environment (“the Recommendation of the Council” in paragraph 3), and the phase of use for clinical study such as gene therapy clinical study; the same applies to the rest of this Article and next Article): the Minister of Education, Science and Technology, and the Minister of the Environment
- (ii) Matters other than those mentioned in the preceding subparagraph: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the production or circulation of the living modified organisms, and the Minister of the Environment

2. The competent ministers in Articles 10, 11 and 29 of the Law shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

- (i) Matters concerning living modified organisms in the phase of research and development: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the undertakings performed by persons to whom orders are given under the provisions of Article 10 paragraph 1 or 2, Article 11 paragraph 2 or Article 29 of the Law, or persons who notify under the provisions of Article 11 paragraph 1, the Minister of Education, Science and Technology, or the Minister of the Environment.
- (ii) Matters other than those mentioned in the preceding paragraph: Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the undertakings performed by persons to whom orders are given under the provisions of Article 10 paragraph 1 or 2, Article 11 paragraph 2 or Article 29, or persons who notify under the provisions of Article 11 paragraph 1, or among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry or Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the production or circulation of the living modified organisms, or the Minister of the Environment

3. The competent ministers in Chapter 2 Section 2 of the Law (excluding Article 13 paragraph 1,

Article 14 and Article 15) shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

(i) Matters concerning Type 2 Use of living modified organisms involved in research and development (excluding use toward commercialization or practical use of living modified organisms preferred to be examined in accordance with the Recommendation of the Council; the same applies to the rest of this Article: The Minister of Education, Science and Technology and the Minister of the Environment

(ii) Matters other than those mentioned in the preceding subparagraph: Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the undertakings performed by persons who make the Type 2 Use of the living modified organisms, and the Minister of the Environment

4. The competent ministers in Article 13 paragraph 1 of the Law shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

(i) Matters concerning Type 2 Use of living modified organisms involved in research and development: The Minister of Education, Science and Technology

(ii) Matters other than those mentioned in the preceding subparagraph: Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; the Minister of Economy, Trade and Industry; and the Minister of the Environment, the Minister who has jurisdiction over the undertakings performed by persons who perform the Type 2 Use of the living modified organisms (if the Type 2 Use of living modified organisms is not made as undertakings, the Minister of the Environment)

5. The competent ministers in Articles 14 and 15 of the Law shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

(i) Matters concerning Type 2 Use of living modified organisms involved in research and development: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over undertakings performed by persons to whom an order is given under the provisions of Article 14 paragraph 1 or 2 or Article 15 paragraph 2, or persons who notify under the provisions of paragraph 1 of the same Article, the Minister of Education, Science and Technology or the Minister of the Environment

(ii) Matters other than those mentioned in the preceding subparagraph: Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the undertakings performed by persons to whom an order is given under the provisions of Article 14 paragraph 1 or 2 or Article 15 paragraph 2, or persons who notify under the provisions of

- paragraph 1 of the same Article, or the Minister of the Environment
6. The competent minister in Chapter 2 Section 3 of the Law shall be, among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; the Minister of Economy, Trade and Industry; and the Minister of the Environment, the Minister who has jurisdiction over the production or circulation of living organisms subject to testing.
7. The competent ministers in Article 26 paragraph 1 shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.
- (i) Matters concerning Type 1 Use of living modified organisms: Ministers stipulated in the following for categories respectively mentioned therein.
- A. Matters concerning living modified organisms in the phase of research and development: The Minister of Education, Science and Technology and the Minister of the Environment
- B. Matters other than those mentioned in A: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the production or circulation of living modified organizations, and the Minister of the Environment
- (ii) Matters concerning Type 2 Use of living modified organisms: Ministers stipulated in the following for categories respectively mentioned therein.
- A. Matters concerning Type 2 Use of living modified organisms in the phase of research and development: The Minister of Education, Science and Technology and the Minister of the Environment
- B. Matters other than those mentioned in (A): Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over undertakings performed by persons who make the Type 2 Use of the living modified organisms, and the Minister of the Environment
8. The competent ministers in Article 26 paragraph 2, Article 30 and Article 31 of the Law shall be ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.
- (i) Matters concerning Type 1 Use of living modified organisms: Ministers stipulated in the following for the matters mentioned respectively therein.
- A. Matters concerning living modified organisms in the phase of research and development: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the undertakings performed by persons subject to orders under the provisions of Article 26 paragraph 2 of the Law, the submission of reports under the provisions of Article 30 of the Law, or On-Site Inspection under the provisions of

Article 31 paragraph 1 of the Law, the Minister of Education, Science and Technology or the Minister of the Environment

B. Matters other than those mentioned in (A): Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over undertakings performed by persons subject to orders under the provisions of Article 26 paragraph 2 of the Law, the submission of reports under the provisions of Article 30 of the Law, or On-Site Inspection under the provisions of Article 31 paragraph 1 of the Law, or, among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over the production or circulation of living modified organisms, or the Minister of the Environment

(ii) Matters concerning Type 2 Use of living modified organisms: Ministers stipulated in the following for the matters mentioned respectively therein.

A. Matters concerning Type 2 Use of living modified organisms involved in research and development: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; or the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over undertakings performed by persons subject to orders under the provisions of Article 26 paragraph 2 of the Law, the submission of reports under the provisions of Article 30 of the Law, or On-Site Inspection under the provisions of Article 31 paragraph 1 of the Law, the Minister of Education, Science and Technology or the Minister of the Environment

B. Matters other than those mentioned in A: Among the Minister of Finance; the Minister of Education, Science and Technology; the Minister of Health, Labour and Welfare; the Minister of Agriculture, Forestry and Fisheries; and the Minister of Economy, Trade and Industry, the Minister who has jurisdiction over undertakings performed by persons subject to orders under the provisions of Article 26 paragraph 2 of the Law, the submission of reports under the provisions of Article 30 of the Law, or On-Site Inspection under the provisions of Article 31 paragraph 1 of the Law, or the Minister of the Environment

(Submission of Application)

Article 41: When an application and other documents (hereinafter in this Article, “the Application”) is submitted to one of the competent ministers on the basis of the provisions of Article 4 paragraph 2 of the Law, the submission shall be made to the competent ministers stipulated in the following subparagraphs for the cases mentioned respectively in these subparagraphs.

(i) Matters concerning living modified organisms in the phase of research and development: The Minister of Education, Science and Technology

(ii) Matters other than those mentioned in the preceding subparagraph: Among the Minister of Finance; the Minister of Health, Labour and Welfare; the Minister of Agriculture,

Forestry and Fisheries; the Minister of Economy, Trade and Industry; and the Minister of the Environment, the Minister who has jurisdiction over the production or circulation of living modified organisms

2. When the Application is submitted under the provisions in the preceding paragraph to one of the ministers (excluding the Minister of the Environment; the same applies to the rest of this Article) stipulated in the preceding subparagraphs, a set of copies of the Application shall be attached.
3. When the minister stipulated in each subparagraph of paragraph 1 receives the Application and copies thereof, the minister shall forward the copies to the Minister of the Environment. In this case, the Application shall be regarded as being submitted to the Minister of the Environment on the date on which the Application is received by the minister stipulated in each subparagraph of paragraph 1.

(Other Matters)

Article 42: Ordinances of the competent ministries in Article 12 and Article 13 paragraphs 2 and 3 of the Law shall be set forth separately.

(Liaison)

Article 43: On the enactment, amendment or abolition of the ministerial ordinances under the preceding Article, approvals under the provisions of Article 4 paragraph 1 or Article 9 paragraph 1 of the Law, and confirmation under Article 13 paragraph 1 of the Law, the competent minister shall arrange so that the other competent ministers concerned can obtain necessary information.

2. When issuing orders under the provisions of the Law, the competent minister shall inform the other competent ministers of said orders, or shall issue such orders jointly as occasion demands.

Supplementary Provision

This Ministerial Ordinance shall be enforced on the date of the enforcement of the Law.



international organizations when it is designated.

5.For “Content of Type 1 Use of living modified organism,” concerning the series of the Use to be made for the living modified organism, mention all intended forms of Use from “provision as food”, “provision as feed”, “provision as other purposes (describe specific use)”, “cultivation”, “other growth (describe specific use)”, “processing”, “storage”, “transportation” or “disposal”, and add the remark “acts incidental to them.”

6.For “Method of Type 1 Use of living modified organism,” if it is intended to prevent adverse effects on biological diversity from arising by limiting the method of the Use of the living modified organism, or a space and a period of time for said Use, provide a concrete description of the method of the Use, the actual name of the region or the name and address of the facility in which the method and the Use is limited, or the period of time of the Use, respectively.

7.Submit this Form together with the Biological Diversity Risk Assessment Report and other documents stipulated in Article 6 of the Regulations related to Enforcement of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.

8.Use paper of JIS A4 in size.

<p>Notice of Change of Address</p> <p style="text-align: right; margin-right: 100px;">Date:</p> <p>To the Competent Minister</p> <p style="text-align: center; margin-left: 100px;">Name</p> <p style="text-align: center; margin-left: 100px;">Notifier</p> <p style="text-align: center; margin-left: 100px;">Address</p> <p style="text-align: center; margin-left: 100px;">Signature</p> <p>Due to a change in matters mentioned in Article 4 paragraph 2 subparagraph 1 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (including those applied mutatis mutandis in Article 9 paragraph 4 of the Law), I hereby provide notification as follows under the provisions of Article 6 paragraph 1 of the Law.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 5px;">Name and address before change (in the case of a corporation, the name of its representative and the address of its main office. The same applies in the following)</td> <td style="width: 65%;"></td> </tr> <tr> <td style="padding: 5px;">Name and address after change:</td> <td></td> </tr> <tr> <td style="padding: 5px;">Reason for the change</td> <td></td> </tr> </table>		Name and address before change (in the case of a corporation, the name of its representative and the address of its main office. The same applies in the following)		Name and address after change:		Reason for the change	
Name and address before change (in the case of a corporation, the name of its representative and the address of its main office. The same applies in the following)							
Name and address after change:							
Reason for the change							

[Remarks]

1. If the notifier is a corporation, give the name of the corporation and the name of its representative for “Name of applicant” and the address of the main office for “Address of applicant.
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

Form No. 3 (Related to Article 17)

<p>Notice of Import</p> <p style="text-align: right;">Date:</p> <p>To the Competent Minister</p> <p style="text-align: right;">Name</p> <p style="text-align: right;">Notifier</p> <p style="text-align: right;">Address</p> <p style="text-align: right;">Signature</p> <p>I intend to engage in an act of import as designated under the provisions of Article 16 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, and hereby provide notification as follows under the provisions of the same Article.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 5px;">Name of the type of living organism to be imported</td> <td style="width: 65%;"></td> </tr> <tr> <td style="padding: 5px;">Purpose of use of living organism to be imported</td> <td></td> </tr> <tr> <td style="padding: 5px;">Exporting country or area of living organism to be imported</td> <td></td> </tr> <tr> <td style="padding: 5px;">Name of port/airport and date of arrival</td> <td></td> </tr> <tr> <td style="padding: 5px;">Quantity to be imported</td> <td></td> </tr> <tr> <td style="padding: 5px;">Name of loading ship or aircraft</td> <td></td> </tr> <tr> <td style="padding: 5px;">Form or transport</td> <td></td> </tr> <tr> <td style="padding: 5px;">Producer country of living organism to be imported</td> <td></td> </tr> <tr> <td style="padding: 5px;">Name of import agent</td> <td></td> </tr> </table>		Name of the type of living organism to be imported		Purpose of use of living organism to be imported		Exporting country or area of living organism to be imported		Name of port/airport and date of arrival		Quantity to be imported		Name of loading ship or aircraft		Form or transport		Producer country of living organism to be imported		Name of import agent	
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Quantity to be imported																			
Name of loading ship or aircraft																			
Form or transport																			
Producer country of living organism to be imported																			
Name of import agent																			

[Remarks]

1. If the notifier is a corporation, mention the name of the corporation and the name of its representative for “Name of applicant” and the address of its main office for “Address of notifier.”
2. Instead of providing a name (in the case of a corporation, the name of its representative) and

fixing a seal, the notifier him- or herself (in the case of a corporation, its representative) may sign his or her name.

3. For “Name of type of living modified organism,” mention the name of the type of the living organism as designated under the provisions of Article 16 of the Law. (If the living organism is a living modified organism, mention the name of the living modified organism and information required to specify Type 1 Use Regulations for the living modified organism.)
4. For “Purpose of use of living organism to be imported,” give information that concretely shows the intended use; for example, “for cultivation, ““for use as feed,” “for use as food (including food processing)” or “for use as industrial material.”
5. For “Form of import,” give information that clearly shows the method of transport; for example, cargo, air cargo, mail, or hand-carrying.
6. For “Name of import agent,” if there is an import agent or any person other than the notifier who is to be notified, the name of said person and contact details should be given.
7. Use paper of JIS A4 in size.

**Application for Testing Living Organism**

Date:

To the Competent Minister  
the Head of the Resistered Testing Body

Name  
**Applicant**  
Address

Signature

I hereby make this application to conduct testing of a living organism as stipulated in Article 17 paragraph 2 subparagraph 1 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.

Name of the type of living organism subject to testing	
Date of arrival at port of living organism subject to testing	
Place of storage of living organism subject to testing	
Quantity to be tested	

[Remarks]

1. If the applicant is a corporation, give the name of the corporation and the name of its representative for “Name of applicant” and the address of its main office for “Address of applicant.”
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

<b>Application for Registration of Registered Testing Body</b>	
Date:	
To the Competent Minister	
Applicant	Name
	Address
Signature	
<p>I hereby apply for registration of a Registered Testing Body as follows under the provisions of Article 18 paragraph 1 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.</p>	
Name and address of the office in which testing of living organisms is intended	
Name of the type of living organisms subject to testing	

[Remarks]

1. If the applicant is a corporation, give the name of the corporation and the name of its representative for “Name of applicant” and the address of its main office for “Address of applicant.”
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

<b>Notice of Change of Address</b>	
Date:	
To the Competent Minister	Name
Notifier	Address
Signature	
<p>Under the provisions of Article 19 paragraph 3 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, I hereby provide the following notification.</p>	
Address before change	
Address after change	
Date of intended change	

[Remarks]

1. If the notifier is a corporation, give the name of the corporation and the name of its representative for “Name of notifier” and the address of its main office for “Address of notifier.”
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

<b>Application for Approval of Regulations</b>	
Date:	
To the Competent Minister	
	Name
	Applicant
	Address
	Signature
<p>I hereby file this application for approval of the attached Regulations under the provisions in the first part of paragraph 4 of Article 19 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.</p>	

[Remarks]

1. If the applicant is a corporation, give the name of the corporation and the name of its representative for "Name of applicant" and the address of its main office for "Address of applicant."
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

<b>Application for Approval of Change in Regulations</b>	
Date:	
To the Competent Minister	
Applicant	Name
	Address
Signature	
<p>I hereby file this application for approval of the attached changed Regulations under the provisions of the latter part of paragraph 4 of Article 19 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.</p>	
Matter to be changed	
Date of intended change	
Reason for the change	

[Remarks]

1. If the applicant is a corporation, give the name of the corporation and the name of its representative for "Name of applicant" and the address of its main office for "Address of applicant."
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Use paper of JIS A4 in size.

<p>Application for Approval of Suspension (Discontinuation) of Work</p>	
<p>Date:</p>	
<p>To the Competent Minister</p>	
<p>Applicant</p>	<p>Name Address</p>
<p>Signature</p>	
<p>I hereby file this application for approval to suspend (discontinue) the work of testing of Living Organism wholly (partially) under the provisions of Article 19 paragraph 8 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.</p>	
<p>Range of the Work of Testing of Living Organisms to be suspended (discontinued)</p>	
<p>Date of intended suspension (discontinuation), and in the case of suspension, the period thereof</p>	
<p>Reason for suspension (discontinuation)</p>	

[Remarks]

1. If the applicant is a corporation, give the name of the corporation and the name of its representative for “Name of applicant” and the address of its main office for “Address of applicant.”
2. Instead of providing a name (in the case of a corporation, the name of its representative) and fixing a seal, the applicant him- or herself (in the case of a corporation, its representative) may sign his or her name.
3. Delete unnecessary letters/words.
4. Use paper of JIS A4 in size.

Form No. 10 (Related to Article 29)

(Front side)

No.	
Identification card under the provisions of Article 22 paragraph 2 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.	
Photo	Official title and name
	Issued on
	The competent minister      Seal

(Reverse Side)

<p>An excerpt from the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Submission of Report and On-Site Inspection)</p> <p>Article 22: The competent minister may, within the limits necessary to enforce the provisions of this section, require a Registered Testing Body to submit reports on its work for Testing of Organisms, or may authorize staff members to enter the office of a Registered Testing Body, inspect the ledgers, documents or other necessary properties of the Registered Testing Body or question relevant persons.</p>
<p>2. Staff members conducting on-site inspections under the provisions of the preceding paragraph must carry means of identification of their status and present the same to relevant persons.</p> <p>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.</p>
<p>Article 44: The officers or staff of a Registered Testing Body who fall under any of the following subparagraphs shall be punished by a fine of not more than 300,000 yen.</p> <p>(i) and (ii) Omitted</p> <p>(iii) When they fail to make reports as provided in Article 22 paragraph 1, or make false reports, or refuse, hinder or evade site entry or inspection under the provisions of the paragraph, or fail to answer questions, or make a false statement.</p>

Remarks: This identification card should be of JIS A6 in size.

Form No. 11 (Article 35)

Name, address and contact details of the exporter Name Address Tel, telex or fax number Contact person
Name, address and contact details of the importer Name Address Tel, telex or fax number Contact person
Name and identity of the living modified organism Name Identity
Intended date or dates of the transboundary movement, if known Date        /        /
Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety Taxonomic status Common name Point of collection or acquisition Characteristics
Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate
Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety Taxonomic status Common name Point of collection or acquisition Characteristics

Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism
Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology
Quantity or volume of the living modified organism to be transferred
A previous and existing risk assessment report consistent with Annex III to Cartagena Protocol on biosafety to the Convention on Biological Diversity
Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate
Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban
Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred
A declaration that the above-mentioned information is factually correct  I certify that the above information is factually correct.  Name                    / Signature Date :                /    /

(Notes)

1. All entries except the signature should be in English, typed, or written with pen and ink in block letters. Once entered, correction by using an eraser or applying an erasing liquid is not allowed. The signature must not be reproduced by any means.
2. Dates should be shown in a 6-digit format: For example, "01/10/03" for October 1, 2003.

Form No.12 (Related to 37 Subparagraph 1)

Living modified organisms
Requirements for the safe handling, storage, transport and use
The contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned
(1) Name, address and contact details of the exporter Name Address Tel, telex or fax number Contact person
(2) Name, address and contact details of the importer Name Address Tel, telex or fax number Contact person

(Note)

All entries except the signature should be in English, typed, or written with pen and ink in block letters. Once entered, correction by using an eraser or applying an erasing liquid is not allowed. The signature must not be reproduced by any means.

Form No. 13 (Related to Article 37 Subparagraph 2)

"may contain" living modified organisms and are not intended for intentional introduction into the environment
The contact point for further information  (1) Name, address and contact details of the exporter Name Address Tel, telex or fax number Contact person  (2) Name, address and contact details of the importer Name Address Tel, telex or fax number Contact person

(Note)

All entries except the signature should be in English, typed, or written with pen and ink in block letters. Once entered, correction by using an eraser or applying an erasing liquid is not allowed. The signature must not be reproduced by any means.



(Front side)

No.	
Identification card under Article 31 paragraph 2 of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms	
Photo	Official title and name Issued on The competent minister      Seal

(Reverse side)

<p>An excerpt from the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (On-Site Inspection)</p> <p>Article 31: The competent minister may, within the limit necessary to enforce this Law, authorize staff members to enter premises where a person who has used or is using living modified organisms, a Domestic Manager, a person who has exported living modified organisms, or other relevant persons carry out such acts, or other places, to question relevant persons, inspect living modified organisms, Facilities, or other properties, or collect living modified organisms, at no cost, limited to the minimum amount necessary for inspection.</p> <hr/> <p>2. The staff members must, when entering, questioning, inspecting or collecting under the provisions of the preceding paragraph (hereinafter "On-Site Inspection) carry means of identification of their status and present the same to the relevant persons.</p> <p>3. The authority to conduct On-Site Inspection under the provisions of paragraph 1 shall not be construed as being permitted for the purpose of criminal investigation.</p> <p>Article 43: A person who falls under any of the following subparagraphs shall be punished by a fine of not more than 300,000 yen.</p> <p>(i) Omitted</p> <p>(ii) A person who refuses, hinders or evades site entry, inspection or collection under the provisions of Article 31 paragraph 1 or Article 32 paragraph 1, or fails to answer questions, or makes false statements.</p>
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Remarks: This identification card should be of JIS A6 size.