ENFORCEMENT DECREE OF THE TRANSBOUNDARY MOVEMENT, ETC. OF LIVING MODIFIED ORGANISMS ACT

Presidential Decree No. 19062, Sep. 30, 2005
Amended by Presidential Decree No. 20678, Feb. 29, 2008
Presidential Decree No. 21214, Dec. 31, 2008
Presidential Decree No. 22075, Mar. 15, 2010
Presidential Decree No. 22467, Nov. 2, 2010
Presidential Decree No. 22857, Apr. 5, 2011
Presidential Decree No. 23931, Jul. 4, 2012
Presidential Decree No. 24442, Mar. 23, 2013
Presidential Decree No. 24993, Dec. 11, 2013
Presidential Decree No. 25050, Dec. 30, 2013
Presidential Decree No. 26703, Dec. 10, 2015
Presidential Decree No. 27046, Mar. 22, 2016
Presidential Decree No. 28212, Jul. 26, 2017
Presidential Decree No. 29279, Nov. 6, 2018

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters delegated by the Transboundary Movement, etc. of Living Modified Organisms Act and matters necessary for enforcing the same.

Article 2 (Affairs of Relevant Central Administrative Agencies)

(1) "Central administrative agency prescribed by Presidential Decree" in subparagraph 5 of Article 2 of the Transboundary Movement, etc. of Living Modified Organisms Act (hereinafter referred to as the "Act") means a central administrative agency in charge of affairs classified as follows: <*Amended by Presidential Decree No. 23931, Jul. 4, 2012; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 28212, Jul. 26, 2017*>

1. Any of the following living modified organisms used for testing or research: The Ministry of Science and ICT:

(a) A living modified organism used at research facilities;

(b) A living modified organism imported or exported to undertake tests, research, or development;

(c) A living modified organism used for experiments related to environmental release, such as field tests, to undertake tests, research, or development;

(d) Any other living modified organisms used for the purpose of conducting tests or research;

2. Any of the following living modified organisms used for agriculture, forestry, livestock industry, or for drugs for animals (referring to drugs for animals under the jurisdiction of the Minister of Agriculture, Food and Rural Affairs provided for in Article 85 (1) of the Pharmaceutical Affairs Act; hereinafter the same shall apply in this subparagraph): The Ministry of Agriculture, Food and Rural Affairs:

(a) A living modified organism which is a seed (including trophosomes and fertilized eggs) used for the purpose of being released into the environment;

(b) A living modified organism imported in the original form to be used as or processed into feed;

(c) A living modified organism imported in the original form for the purpose of being used for processing in agriculture;

(d) A living modified organism used as a drug for animals;

(e) Deleted; *<by Presidential Decree No. 24442, Mar. 23, 2013>*

(f) Any other living modified organisms used for agriculture, forestry, or livestock industry;

3. Living modified organisms used in such industrial sectors as textiles, machinery, chemistry, electronics, energy, and resources (excluding any living modified organism specified in subparagraph 1 or 2, or subparagraphs 4 through 7): The Ministry of Trade, Industry and Energy;

4. Any of the following living modified organisms which requires national management for public health: The Ministry of Health and Welfare:

(a) A living modified organism used to undertake tests, research, or development at research facilities;

(b) A living modified organism imported or exported to undertake tests, research, or development;

(c) Any other living modified organisms used in the health and medical services sector;

5. Living modified organisms used to reduce or remove environmental pollutants or to restore the environment: The Ministry of Environment;

6. Living modified organisms used for the marine industry, fisheries, or for drugs for animals (referring to drugs for animals under the jurisdiction of the Minister of Oceans and Fisheries provided for in Article 85 (1) of the Pharmaceutical Affairs Act; hereinafter the same shall apply in this subparagraph): The Ministry of Oceans and Fisheries;

7. Living modified organisms used in the food or medical device sector: The Ministry of Food and Drug Safety.

(2) Where it is deemed necessary to adjust competent central administrative agencies because the classification thereof according to the criteria specified in each subparagraph of paragraph (1) is unclear, the heads of relevant central administrative agencies shall consult and coordinate with each other. In such cases, the heads of relevant central administrative agencies may hear opinions of the Biosafety Committee

established pursuant to Article 31 of the Act (hereinafter referred to as the "Biosafety Committee"). *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

Article 3 (Duties of Competent National Authority)

The head of the competent national authority provided for in Article 6 (1) of the Act (hereinafter referred to as the "competent national authority") shall perform the following duties pursuant to Article 6 (2) of the Act: *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

1. Giving prior import consent for living modified organisms used for the purpose of being released into the environment pursuant to Article 9;
2. Deleted; *<by Presidential Decree No. 24993, Dec. 11, 2013>*
3. Exchanging information with the Biosafety Clearing House provided for in Article 30;
4. Making an integrated public announcement on public notices or public announcements given or made under the Act or this Decree;
5. Managing information submitted by the heads of relevant central administrative agencies prescribed in the Act or this Decree;
6. Any other matters necessary for implementing the Cartagena Protocol on Biosafety (hereinafter referred to as the "Protocol") as a Party to the Protocol.

Article 4 (Formulation, etc. of Plans for Safety Management of Living Modified Organisms and Detailed Implementation Plans)

The head of a relevant central administrative agency shall formulate a plan for the safety management of living modified organisms by jurisdiction every five years pursuant to Article 7 (1) and (4) of the Act; and formulate and implement a detailed implementation plan for executing the plan for the safety management of living modified organisms each year. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

Article 4-2 (Materials and Procedures Necessary for Risk Review)

(1) "Materials prescribed by Presidential Decree, which are necessary for a risk review" in the main sentence of Article 7-2 (1) of the Act means the materials determined and publicly notified by the head of a relevant central administrative agency in connection with the name and use of any living modified organism subject to import, production or use, genetic modification technology used, its impacts on human health and the environment, etc.

(2) A person who intends to undergo a risk review pursuant to paragraph (1) and the former part of paragraph (2) of Article 7-2 of the Act (hereinafter referred to as "risk review") shall submit an application for risk review to the head of the relevant central administrative agency, including the materials necessary for the risk review provided for in paragraph (1), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

(3) Upon receipt of an application for risk review prescribed in paragraph (2), the head of the relevant central administrative agency shall complete the review within 270 days after receipt of the application; and notify the applicant of the results of the review, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(4) Where necessary to conduct a risk review prescribed in paragraph (3), the head of the relevant central administrative agency may require the applicant to submit necessary materials within a specified period.

(5) The head of the relevant central administrative agency shall publicly announce the following information on its website for at least 30 days pursuant to Article 7-2 (7) of the Act:

1. The applicant for the risk review;
2. The purpose and end use of the risk review;
3. Results of the risk review conducted under paragraph (3);
4. The developer of the relevant living modified organism;
5. The name and characteristics of the relevant living modified organism.

Article 4-3 (Exemption from Risk Review)

The head of a relevant central administrative agency may exempt a risk review conducted under the latter part of Article 7-2 (2) of the Act if the person who intends to import, manufacture, or use a new living modified organism meets all of the following requirements: *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

1. A person who has developed a new living modified organism must have undergone a risk review before he/she imports, produces, or uses the living modified organism;
2. The purpose of importing, producing or using the relevant living modified organism must be the same as the purpose of using the risk review specified in subparagraph 1.

Article 4-4 (Consultations on Risk Review)

Upon receipt of a request for consultation on a risk review, the Minister of Agriculture, Food and Rural Affairs, the Minister of Health and Welfare, the Minister of Environment, or the Minister of Oceans and Fisheries shall review matters under his/her jurisdiction specified in Article 7-2 (3) of the Act; and notify the head of the central administrative agency who has made the request for consultations of the results thereof. In such cases, the head of the central administrative agency who has made the request for consultations shall incorporate the details notified into the risk review, except in extenuating circumstances.

Article 4-5 (Designation, etc. of Risk Review Agencies)

(1) The head of a relevant central administrative agency shall designate a risk review agency provided for in Article 7-2 (5) of the Act (hereinafter referred to as "risk review agency") after deliberation by the Biosafety Committee upon receipt of an application by a person who intends to be designated as a risk review agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) Upon designating a risk review agency pursuant to paragraph (1), the head of a relevant central administrative agency shall publicly announce the following matters on its website:

1. Name and address of the risk review agency as well as the name of its representative;
2. Locations of its offices (referring to all of its offices, such as the main office, local offices, and overseas offices);

3. The scope of risk review conducted on behalf of the relevant central administrative agency;

4. The date of designation of the risk review agency.

Article 5 (Approval, etc. for Import of Living Modified Organisms)

(1) A person who intends to obtain approval for import of any living modified organism pursuant to Article 8 (1) of the Act shall submit to the head of the relevant central administrative agency an application for import approval, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

1. through 3. Deleted; *<by Presidential Decree No. 24993, Dec. 11, 2013>*

4. An import contract (including an import agency contract if the person vicariously imports the living modified organism; hereinafter the same shall apply) or an order sheet;

5. A transportation contract stating the transportation routes, means of transportation and carrier, or a self-transportation plan;

6. Materials on safety management measures concerning handling and storage as well as on the status of professional human resources and facilities necessary for safety management.

(2) Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) The head of a relevant central administrative agency shall determine whether to grant approval for import within 10 days after receipt of an application for import approval prescribed in paragraph (1); and notify the applicant of his/her determination on the application, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(4) Where necessary for determining whether to grant approval for import, etc. prescribed in paragraph (3), the head of a relevant central administrative agency may require the applicant to submit necessary materials within a specified period. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

(5) The head of a relevant central administrative agency shall determine and publicly notify the standards for, and other specific details of, living modified organisms that are imported unintentionally by being mixed in with other imported organisms. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 6 (Approval for Modification of Matters Approved for Import)

(1) A person who intends to obtain approval for modification prescribed in the main sentence of Article 8 (3) of the Act shall submit to the head of the relevant central administrative agency an application for modification of approved matters, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013>*

1. A written import approval;

2. A document verifying the details of modification.

(2) The head of the relevant central administrative agency shall determine whether to grant approval for modification within ten days after receipt of the application for modification of approved matters

prescribed in paragraph (1); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

(3) Except as otherwise expressly provided for in paragraphs (1) and (2), Article 5 (4) shall apply mutatis mutandis to approval for modification of matters approved for import. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 7 Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 8 (Approval, etc. for Import of Living Modified Organisms Used for Release into Environment)

(1) A person who intends to import any living modified organism used for the purpose of being released into the environment prescribed in the former part of Article 8 (2) of the Act shall submit to the head of the relevant central administrative agency an application for import approval prescribed by Ordinance of the Ministry of Trade, Industry and Energy, including the following documents: *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

1. The documents specified in each subparagraph of Article 5 (1);
2. A written prior import consent specified in Article 9 (3).

(2) Article 5 (3) and (4) shall apply mutatis mutandis to approval for import of living modified organisms used for the purpose of being released into the environment. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 9 (Prior Import Consent, etc. to Living Modified Organisms Used for the Purpose of Being Released into Environment)

(1) An exporting country or person (hereinafter referred to as "exporting country, etc.") who intends to export for the first time any living modified organism used for the purpose of being released into the environment prescribed in the latter part of Article 8 (2) of the Act shall submit to the head of the competent national authority an application for prior import consent, including the relevant import contract or order sheet, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(2) The head of the competent national authority shall take the following measures within ten days after receipt of the application for prior import consent prescribed in paragraph (1): *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. He/she shall notify the head of the relevant central administrative agency of the details of the application received;
2. He/she shall notify the exporting country, etc. of the receipt of the application in writing, expressly specifying the following matters:

(a) The receipt date of the application for prior import consent;

(b) Whether the documents specified in paragraph (1) have been received;

(c) Procedures for handling prior import consent.

(3) The head of the relevant central administrative agency shall verify the completion of a risk review of the relevant living modified organism within ten days after receipt of the notice prescribed in paragraph (2) 1; and notify the head of the competent national authority of his/her determination by classifying it into prior import consent granted; conditional prior import consent granted; and prior import consent not granted. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(4) Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

(5) The head of the competent national authority shall notify the relevant exporting country, etc. of whether to grant prior import consent within ten days after receipt of the notice prescribed in paragraph (3), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy; and also notify the International Biosafety Clearing House established pursuant to Article 21 of the Protocol (hereinafter referred to as the "International Biosafety Clearing House") of such fact via the Biosafety Clearing House designated pursuant to Article 32 of the Act (hereinafter referred to as the "Biosafety Clearing House"). *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

(6) The head of the relevant central administrative agency may re-examine and alter his/her determination on the living modified organism used for the purpose of being released into the environment, for which he/she has decided to grant prior import consent or conditional import consent pursuant to paragraph (3), based on new scientific information. In such cases, the head of the relevant central administrative agency shall notify the head of the competent national authority of the details and grounds of the alteration within 15 days from the date he/she decides to alter his/her decision, while the head of the competent national authority shall notify the person who has received import consent or conditional import consent pursuant to paragraph (3) of such alteration within 15 days after receipt of the notice; and also notify the International Biosafety Clearing House of the alteration via the Biosafety Clearing House. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

Article 10 (Reporting on Modification of Matters Approved for Import)

(1) "Minor matters prescribed by Presidential Decree" in the proviso to Article 8 (3) of the Act means any of the following matters:

1. Modification of the quantity within the limit not exceeding 1/100 of the imported quantity (referring to the volume or mass if it is impracticable to calculate the quantity; hereinafter the same shall apply) of any living modified organism other than microorganisms;
2. Modification of the trade name, address, or contact information of an importer.

(2) A person who intends to file a report on modification of any matters specified in any subparagraph of paragraph (1) under the proviso to Article 8 (3) of the Act shall submit to the head of the relevant central administrative agency a report on modification of approved matters, including a document on the matters specified in any subparagraph of paragraph (1), as prescribed by Ordinance of the Ministry of Trade,

Industry and Energy.

(3) If requested by a person who has filed a report on modification under the proviso to Article 8 (3) of the Act, the head of the relevant central administrative agency shall issue a verification of receipt of the report on modification to the reporter, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 11 (Procedures for Importing Living Modified Organisms for Testing, Research, etc.)

(1) A person who intends to report the import of any living modified organism prescribed in the main sentence of Article 9 (1) of the Act shall submit to the head of the relevant central administrative agency an import declaration, including documents on the following matters, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy:

1. The documents specified in each subparagraph of Article 5 (1);
2. The name, characteristics and intended use of the relevant living modified organism;
3. A plan to use the relevant living modified organism for testing or research; or a plan to exhibit the relevant living modified organism for any exposition or exhibition.

(2) Upon receipt of an import declaration prescribed in paragraph (1), the head of the relevant central administrative agency shall issue a verification of import declaration within 30 days after receipt thereof, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(3) A person who intends to obtain import approval prescribed in the proviso to Article 9 (1) of the Act shall submit to the Minister of Health and Welfare an application for import approval, including the documents specified in each subparagraph of paragraph (1), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(4) The Minister of Health and Welfare shall determine whether to grant import approval within 60 days after receipt of the application for import approval prescribed in paragraph (3); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

(5) A person who intends to modify any reported matter pursuant to Article 9 (2) of the Act shall submit to the head of the relevant central administrative agency a report on modification of the reported matter, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy:

1. A verification of import declaration of the relevant living modified organism for testing or research, or for any exposition or exhibition;
2. A document verifying the details of modification.

(6) If requested by a person who has submitted a report on modification of reported matters pursuant to paragraph (5), the head of the relevant central administrative agency shall issue a verification of modification of import declaration to such person within ten days, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(7) Where a person who has obtained import approval pursuant to paragraph (4) intends to modify any approved matter, he/she shall submit an application for modification of approved matters to the Minister

of Health and Welfare, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy, including the following documents:

1. A written import approval for the relevant living modified organism for testing or research, or for an exposition or exhibition;
2. A document verifying the details of modification.

(8) The Minister of Health and Welfare shall determine whether to grant approval for modification within 60 days after receipt of the application for modification of approved matters prescribed in paragraph (7); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(9) Where necessary to determine whether to grant import approval prescribed in paragraph (3) or approval for modification prescribed in paragraph (8), the Minister of Health and Welfare may require the relevant applicant to submit necessary materials within a specified period.

Article 12 (Procedures for Conducting Import Inspection)

(1) The head of a relevant central administrative agency may conduct an import inspection (hereinafter referred to as "import inspection") for any imported living modified organism pursuant to Article 10 (1) of the Act by sampling or any other method.

(2) Where the head of a relevant central administrative agency discovers any living modified organism, which has failed to obtain import approval or which has not been reported, through import inspection, he/she may issue an order for destruction, return, etc. of the living modified organism to the person who intends to import it.

(3) The head of a relevant central administrative agency shall determine and publicly notify the following matters necessary for import inspection:

1. Items subject to import inspection;
2. Procedures for filing an application for import inspection;
3. Procedures for conducting import inspection at national boundaries;
4. Procedures for notifying the results of import inspection;
5. Follow-up measures for import inspection, such as destruction or return;
6. Any other matters the Minister of Trade, Industry and Energy deems necessary for import inspection.

Article 13 (Approval, etc. for Production)

(1) A person who intends to obtain approval for production of any living modified organism pursuant to Article 12 (1) of the Act shall submit to the head of the relevant central administrative agency an application for approval for production, including a document stating safety management measures concerning handling, storage, etc. thereof as well as the status of professional human resources, facilities and equipment necessary for safety management, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

1. and 2. Deleted; *<by Presidential Decree No. 24993, Dec. 11, 2013>*

3. Deleted; *<by Presidential Decree No. 27046, Mar. 22, 2016>*

4. Deleted. *<by Presidential Decree No. 22467, Nov. 2, 2010>*

(2) Upon receipt of an application filed under paragraph (1), the head of the relevant central administrative agency shall verify the applicant's certificate of matters filed in the register of the relevant corporation (limited to corporations) by sharing administrative information prescribed in Article 36 (1) of the Electronic Government Act. *<Newly Inserted by Presidential Decree No. 22467, Nov. 2, 2010>*

(3) Article 5 (3) and (4) shall apply mutatis mutandis to approval for production of living modified organisms prescribed in Article 12 (1) of the Act. In such cases, "approval for import" provided for in Article 5 (4) shall be construed as "approval for production". *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 14 (Approval for Modification of Matters Approved for Production)

(1) A person who intends to modify any approved matter prescribed in the main sentence of Article 12 (2) of the Act shall submit to the head of the relevant central administrative agency an application for modification of approved matters, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

1. A written approval for production;

2. A document verifying the details of modification.

(2) The head of the relevant central administrative agency shall determine whether to grant approval for modification within ten days after receipt of the application for modification of approved matters prescribed in paragraph (1); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) Article 5 (4) shall apply mutatis mutandis to approval for modification of matters approved for production of living modified organisms. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 15 (Reporting, etc. on Modification of Matters Approved for Production)

(1) "Minor matters prescribed by Presidential Decree" in the proviso to Article 12 (2) of the Act means any of the following matters: Provided, That no living modified microorganism shall constitute the minor matters prescribed in the proviso to Article 12 (2) of the Act even if it falls under subparagraph 1: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. Modification of the quantity of production within the limit not exceeding 1/100;

2. Modification of the trade name, address, or contact information of a producer.

(2) A person who intends to file a report on modification under the proviso to Article 12 (2) of the Act shall submit to the head of the relevant central administrative agency a report on modification of reported matters, including a document on the matters specified in any subparagraph of paragraph (1), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 24993,*

Dec. 11, 2013>

(3) Upon receipt of a report on modification of approved matters prescribed in paragraph (2), the head of the relevant central administrative agency shall issue a verification of receipt of the report on modification if requested by the reporting person. *<Newly Inserted by Presidential Decree No. 24993, Dec. 11, 2013>*

Articles 16 and 17 Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 18 (Other Grounds, etc. for Revocation of Approval)

(1) "Case constituting the grounds prescribed by Presidential Decree" in Article 17 (1) 10 of the Act means any of the following cases: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. Where the status of professional human resources, facilities, etc. necessary for safety management is considerably inferior to that at the time of approval;
2. Where a document verifying approval for import or production of the relevant living modified organism is transferred or lent to a third party.

(2) Upon receipt of a notice on the revocation of approval for import of any living modified organism pursuant to Article 17 (2) of the Act, the head of the competent national authority shall notify the head of the International Biosafety Clearing House thereof via the Biosafety Clearing House. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

Article 19 (Requests, etc. for Reexamination)

(1) A person who intends to request reexamination pursuant to Article 18 (1) of the Act shall submit to the head of the relevant central administrative agency a request for reexamination prescribed by Ordinance of the Ministry of Trade, Industry and Energy, including a document verifying the grounds for requesting reexamination, within 30 days from the date a disposition is taken under Article 8, 12, or 17 (1) 1 of the Act. *<Amended by Presidential Decree No. 20678, Feb. 29, 2008; Presidential Decree No. 24442, Mar. 23, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

(2) The head of the relevant central administrative agency shall notify the person who has requested reexamination of the results of reexamination within 90 days after receipt of such request made under paragraph (1). *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

Article 20 Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 21 (Matters Subject to Prior Notification of Export)

(1) "Matters prescribed by Presidential Decree" in Article 20 of the Act means items, quantities, the importing country, and the information on Appendix II (referring to Appendix I of the Protocol if any living modified organism used for release into the environment is exported) of the Protocol. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

(2) A person who intends to give notification of export prescribed in Article 20 of the Act shall submit to the head of the relevant central administrative agency an export notification, including materials to verify the information specified in paragraph (1), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Newly Inserted by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) Upon receipt of notification of export prescribed in Article 20 of the Act, the head of the relevant central administrative agency shall notify the head of the competent national authority thereof. *<Newly Inserted by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 22 (Filing Reports on Transit)

(1) A person who intends to file a report on transit pursuant to Article 21 of the Act shall submit a report on transit to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(2) Upon receipt of a report filed under Article 21 of the Act, the head of a relevant central administrative agency shall notify the head of the competent national authority thereof. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 23 (Permission for and Reporting on Establishment and Operation of Research Facilities)

(1) The classification of biosafety levels of research facilities provided for in Article 22 (1) of the Act (hereinafter referred to as "research facilities") and research facilities subject to permission or reporting shall be as specified in attached Table 1. In such cases, a research facility means any of the following facilities:

1. A general research facility;
2. A research facility for mass culture;
3. A research facility using animals;
4. A research facility using plants;
5. An isolated packaging facility.

(2) The Minister of Science and ICT and the Minister of Health and Welfare shall determine and publicly notify standards for the following matters in relation to permission for and reporting on the establishment and operation of research facilities prescribed in Article 22 (1) of the Act: *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

1. Facilities, technical capabilities and personnel necessary for conducting research and development of living modified organisms as well as safety management regulations;
2. Facilities, technical capabilities and personnel to prevent living modified organisms from causing any risk to human health and the environment as well as safety management regulations;
3. Safety management standards for operating research facilities.

(3) A person who intends to establish and operate a research facility subject to permission according to attached Table 1 shall submit an application for permission to the Minister of Science and ICT if it is a research facility relating to any risk to the environment, and to the Minister of Health and Welfare if it is a research facility relating to any risk to human health, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

1. A design document for the relevant research facility or a copy thereof;

2. A document verifying the scope of the relevant research facility as well as the ownership of or rights to use the facility;

3. A basic design document for the relevant risk prevention facility or a copy thereof;

4. A document verifying that the standards for permission provided for in paragraph (2) are satisfied.

(4) The Minister of Science and ICT or the Minister of Health and Welfare shall notify the applicant of the results of examination by classifying it into permission and non-permission within 60 days after receipt of the application for permission prescribed in paragraph (3). In such cases, the Minister shall issue a permit for establishment and operation of the relevant research facility if he/she grants permission therefor. *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

(5) A person who intends to establish and operate a research facility subject to reporting according to attached Table 1 shall submit a report to the Minister of Science and ICT, including the documents specified in paragraph (3) 1 through 3, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: Provided, That where a national or public research institute intends to establish and operate a research facility, it shall submit a report to the head of the relevant central administrative agency having jurisdiction over research affairs of the research institute. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016; Presidential Decree No. 28212, Jul. 26, 2017>*

(6) Upon receipt of a report filed under paragraph (5), the head of the relevant central administrative agency shall issue a verification of receipt of the report to the reporting person within 60 days after the receipt thereof, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-2 (Modification, etc. of Matters Permitted to Establish and Operate Research Facilities)

(1) A person who intends to obtain permission for modification prescribed in the main sentence of Article 22 (2) of the Act shall submit to the Minister of Science and ICT or to the Minister of Health and Welfare an application for modification of permitted matters, including a document verifying the grounds for and details of modification of matters permitted to establish and operate the relevant research facility, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

(2) The Minister of Science and ICT or the Minister of Health and Welfare shall notify the applicant of the results of examination within 60 days after receipt of an application for modification of permitted matters prescribed in paragraph (1). *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

(3) Where it is deemed necessary to supplement documents in connection with permission to modify a research facility prescribed in paragraph (2), the Minister of Science and ICT or the Minister of Health and Welfare may require the submission of necessary materials within a specified period not exceeding 30 days. *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

(4) "Minor matters prescribed by Presidential Decree" in the proviso to Article 22 (2) of the Act means any of the following matters: *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

1. Address or contact information of a person who establishes and operates a research facility (limited to natural persons);

2. Name, address, and contact information of a person who establishes and operates a research facility (limited to corporations) as well as the name, address, and contact information of its representative;

3. Name, address, and contact information of a person in charge of research and a person in charge of biosafety management.

(5) A person who intends to file a report on modification under the proviso to Article 22 (2) of the Act shall submit a report on modification of permitted matters to the Minister of Science and ICT or the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016; Presidential Decree No. 28212, Jul. 26, 2017>*

(6) Upon receipt of a report on modification of permitted matters prescribed in paragraph (5), the Minister of Science and ICT or the Minister of Health and Welfare shall issue a verification of receipt of the report on modification if requested by the reporting person. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016; Presidential Decree No. 28212, Jul. 26, 2017>*

Article 23-3 (Reporting on Modification of Matters Reported to Establish and Operate Research Facilities)

(1) A person who intends to file a report on modification pursuant to Article 22 (3) of the Act shall submit a report on modification of reported matters to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) Upon receipt of a report on modification of reported matters prescribed in paragraph (1), the head of the relevant central administrative agency shall reissue a verification of receipt of the report, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-4 (Reporting, etc. on Closure of Research Facilities)

(1) A person who intends to file a report on closure of any research facility pursuant to Article 22 (4) of the Act shall submit to the head of the relevant central administrative agency a report on closure, including a document verifying that the research facility has been closed, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) Upon receipt of a report on closure prescribed in paragraph (1), the head of the relevant central administrative agency shall issue a verification of receipt of the report on closure of the relevant research facility if requested by the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(3) Where any research facility (limited to permitted research facilities; hereinafter in this paragraph, the same shall apply) is closed pursuant to Article 22 (4) of the Act, the methods, procedures, etc. for closing the research facility, such as disinfecting the facility and inactivating living modified organisms, shall be determined and publicly notified by the Minister of Science and ICT or the Minister of Health and Welfare. *<Amended by Presidential Decree No. 28212, Jul. 26, 2017>*

Article 23-5 (Matters to Be Observed When Research Facilities Are Established and Operated)

"Matters to be observed, which are prescribed by Presidential Decree" in Article 22 (6) of the Act means the matters determined and publicly notified jointly by the Minister of Science and ICT and the Minister

of Health and Welfare through mutual consultations in relation to experimental zones, air ventilation, securing biosafety, laboratory equipment, waste disposal, etc. <*Amended by Presidential Decree No. 28212, Jul. 26, 2017*>

Article 23-6 (Research and Development of Living Modified Organisms)

(1) "Where research and development is conducted for any living modified organism which is highly likely to cause any risk prescribed by Presidential Decree" in Article 22-2 (1) of the Act means any of the following cases:

1. Where research and development is conducted using any microorganism whose species name is not specified and whose risk to human health is unknown;
2. Where research and development is conducted using a gene coding for proteins toxic for vertebrates with its toxicity at or above the level publicly notified by the Minister of Health and Welfare;
3. Where research and development is conducted involving intentional transfer of any drug resistance gene to any organism in a manner that does not occur naturally: Provided, That this shall not apply to cases recognized and publicly notified by the Minister of Health and Welfare as safe;
4. Where research and development is conducted using any pathogenic microbe publicly notified by the Minister of Health and Welfare as requiring national management for public health;
5. Where research relating to release into the environment, such as field trials, is conducted;
6. Any other cases where research and development is conducted for any living modified organism recognized and publicly notified by the head of the competent national authority as highly likely to cause any risk, after deliberation by the Biosafety Committee.

(2) A person who intends to obtain approval for research and development pursuant to Article 22-2 (1) of the Act shall submit an application for approval to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(3) The head of the relevant central administrative agency shall notify the applicant of the results of examination within 60 days after receipt of the application for approval prescribed in paragraph (2).

Article 23-7 (Modification of Approval for Research and Development of Living Modified Organisms)

(1) A person who intends to obtain approval for modification pursuant to Article 22-2 (2) of the Act shall submit an application for modification of approved matters to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) The head of the relevant central administrative agency shall notify the applicant of the results of examination within 60 days after receipt of the application for modification of approved matters prescribed in paragraph (1).

(3) A person who intends to file a report on modification under the proviso to Article 22-2 (2) of the Act shall submit a report on modification of approved matters to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(4) Upon receipt of a report on modification of approved matters prescribed in paragraph (3), the head of the relevant central administrative agency shall issue a verification of receipt of the report on modification

if requested by the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(5) "Minor matters prescribed by Presidential Decree" in the proviso to Article 22-2 (2) of the Act means any of the following:

1. Address and contact information of the business place of the applicant;
2. Name, address, and contact information of a person in charge of research;
3. Name, address, and contact information of a person in charge of biosafety management.

Article 23-8 (Permission for and Reporting on Establishment and Operation of Production Facilities Using Living Modified Organisms)

(1) The classification of biosafety levels of production facilities using living modified organisms provided for in Article 22-3 (1) of the Act and such production facilities subject to permission or reporting shall be as specified in attached Table 2.

(2) A person who intends to establish and operate a production facility using a living modified organism subject to permission according to the classification of biosafety levels of production facilities using living modified organisms provided for in paragraph (1) shall submit to the head of the relevant central administrative agency an application for permission, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy:

1. A design document for the relevant production facility using a living modified organism, or a copy thereof;
2. A document verifying the scope of the relevant production facility using a living modified organism as well as the ownership of or rights to use the facility;
3. A basic design document for the relevant risk prevention facility or a copy thereof;
4. A document verifying that the standards for permission provided for in Article 23-12 are satisfied.

(3) The head of the relevant central administrative agency shall notify the applicant of the results of examination within 60 days after receipt of an application for permission prescribed in paragraph (2).

(4) A person who intends to establish and operate a production facility using a living modified organism subject to reporting according to the classification of biosafety levels of production facilities using living modified organisms provided for in paragraph (1) shall submit to the head of the relevant central administrative agency a report, including the documents specified in paragraph (2) 1 through 3, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(5) Upon receipt of a report filed under paragraph (4), the head of the relevant central administrative agency shall issue a verification of receipt of the report to the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-9 (Modification of Matters Permitted to Establish and Operate Production Facilities Using Living Modified Organisms)

(1) A person who intends to obtain approval for modification under the main sentence of Article 22-3 (2) of the Act shall submit an application for modification of permitted matters to the head of the relevant

central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) The head of the relevant central administrative agency shall notify the applicant of the results of examination within 60 days after receipt of the application for modification of permitted matters prescribed in paragraph (1).

(3) "Minor matters prescribed by Presidential Decree" in the proviso to Article 22-3 (2) of the Act means any of the following matters:

1. Name and address of the relevant production facility using a living modified organism;
2. Names, addresses, and contact information of the representative and operator of the relevant production facility using a living modified organism;
3. Name and address of a person in charge of biosafety management.

(4) A person who intends to file a report on modification prescribed in the proviso to Article 22-3 (2) of the Act shall submit a report on modification of permitted matters to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(5) Upon receipt of a report on modification of permitted matters prescribed in paragraph (3), the head of the central administrative agency shall issue a verification of receipt of the report on modification if requested by the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-10 (Reporting on Modification of Matters Reported to Establish and Operate Production Facilities Using Living Modified Organisms)

(1) A person who intends to file a report on modification pursuant to Article 22-3 (3) of the Act shall submit a report on modification of reported matters to the head of the relevant central administrative agency, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) Upon receipt of a report on modification of reported matters prescribed in paragraph (1), the head of the relevant central administrative agency shall reissue a verification of receipt of the report, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-11 (Reporting on Closure of Production Facilities Using Living Modified Organisms)

(1) A person who intends to file a report on closure of any production facility using a living modified organism pursuant to Article 22-3 (4) of the Act shall submit to the head of the relevant central administrative agency a report on closure, including a document verifying that such facility has been closed, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(2) Upon receipt of a report on closure prescribed in paragraph (1), the head of the relevant central administrative agency shall issue a verification of receipt of the report on closure if requested by the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-12 (Permission, etc. to Establish and Operate Production Facilities Using Living Modified Organisms)

The head of a relevant central administrative agency shall determine and publicly notify the standards for granting permission for and reporting on the establishment and operation of production facilities using

living modified organisms in relation to the following matters pursuant to Article 22-3 (6) of the Act:

1. Facilities, technical capabilities and personnel necessary for using living modified organisms as well as safety management regulations;

2. Facilities, technical capabilities and personnel to prevent living modified organisms from causing any risk to human health and the environment as well as safety management regulations;

3. Safety management standards for operating production facilities using living modified organisms.

Article 23-13 (Approval for Use of Living Modified Organisms)

(1) A person who intends to obtain approval for use of any living modified organism pursuant to Article 22-4 (1) of the Act shall submit to the head of the relevant central administrative agency an application for approval for use, including documents on the following matters, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

1. Safety management measures concerning handling, storage, etc. of the living modified organism;

2. The status of professional human resources and facilities necessary for safety management.

(2) Upon receipt of an application filed under paragraph (1), the head of the relevant central administrative agency shall verify the applicant's certificate of matters filed in the register of the relevant corporation (limited to corporations) by sharing administrative information prescribed in Article 36 (1) of the Electronic Government Act.

(3) The head of the relevant central administrative agency shall determine whether to grant approval for use within ten days after receipt of the application for approval for use under paragraph (1); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(4) Where necessary for determining whether to grant approval for use prescribed in paragraph (3), the head of the relevant central administrative agency may require the applicant to submit necessary materials within a specified period.

Article 23-14 (Modification of Matters Approved for Use)

(1) A person who intends to obtain approval for modification under the main sentence of Article 22-4 (2) of the Act shall submit to the head of the relevant central administrative agency an application for modification of approved matters, including the following documents, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy: *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

1. A written approval for use;

2. A document on modification of the use of living modified organisms.

(2) The head of the relevant central administrative agency shall determine whether to grant approval for modification within ten days after receipt of the application for modification of approved matters prescribed in paragraph (1); and notify the applicant of his/her determination, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(3) Where necessary for determining whether to grant approval for modification prescribed in paragraph (2), the head of the relevant central administrative agency may require the applicant to submit necessary

materials within a specified period.

(4) "Minor matters prescribed by Presidential Decree" in the proviso to Article 22-4 (2) of the Act means the name of a person who uses any living modified organism (referring to the name of the relevant corporation if the person is a corporation), his/her address, or contact information. *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

(5) A person who intends to file a report on modification prescribed in the proviso to Article 22-4 (2) of the Act shall submit to the head of the relevant central administrative agency a report on modification of approved matters, including the documents specified in each subparagraph of paragraph (1), as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

(6) Upon receipt of a report on modification of approved matters prescribed in paragraph (5), the head of the relevant central administrative agency shall issue a verification of receipt of the report on modification if requested by the reporting person, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy.

Article 23-15 (Orders for Destruction or Return)

(1) The head of a relevant central administrative agency may issue an order to destroy or return any living modified organism within a specified period not exceeding 30 days pursuant to Article 23-2 (1) of the Act.

(2) Where the head of a relevant central administrative agency issues an order for destruction pursuant to Article 23-2 (1) of the Act, he/she may designate a place for destruction.

(3) Where the head of a relevant central administrative agency issues an order for destruction or return pursuant to Article 23-2 (1) of the Act, he/she shall notify the head of the competent national authority of the details thereof; and verify whether such order has been complied with.

(4) A a public official affiliated with a relevant central administrative agency, who destroys or returns any living modified organism pursuant to Article 23-2 (2) of the Act, shall present an identification certificate indicating his/her authority to relevant persons. *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

(5) Where a public official affiliated with a relevant central administrative agency directly destructs or returns any living modified organism under Article 23-2 (2) of the Act, the head of the said agency shall determine the amount and due date of payment and notify the owner of the living modified organism. *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

Article 24 (Matters to Be Indicated)

Matters to be indicated in the receptacle, package, or import invoice of a living modified organism pursuant to Article 24 (1) of the Act shall be as follows: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

1. Name, type, use, and characteristics of the living modified organism;
2. Precautions for safe handling of the living modified organism;
3. Name, address (in detail), and phone number of the developer, producer, exporter, or importer of the living modified organism;

4. The fact that the relevant organism is a living modified organism;

5. Whether the relevant organism is a living modified organism used for the purpose of being released into the environment.

Article 25 (Standards for Handling and Management)

(1) "Standards for handling and management prescribed by Presidential Decree" in Article 25 (1) of the Act means the following matters:

1. When moved, any living modified organism as determined by the head of a relevant central administrative agency, such as living modified organisms for testing or research, must be transported in a sealed container;

2. A person exclusively in charge of or person responsible for handling and management of living modified organisms must be designated;

3. Facilities for handling and management of living modified organisms must be properly maintained and managed to ensure that they can perform their original functions;

4. Relevant persons must be aware of precautions for handling of living modified organisms as well as the method of taking emergency measures to prevent risk.

(2) Details about the matters specified in each subparagraph of paragraph (1) shall be determined and publicly notified by the head of a relevant central administrative agency.

Article 25-2 (Methods and Procedures for Investigating Environmental Impacts, etc.)

(1) Where the head of a relevant central administrative agency discovers any living modified organism through an investigation conducted under Article 26-2 (1) of the Act, he/she shall notify both the head of the relevant competent central administrative agency and the head of the competent national authority of such fact. In such cases, if it is unclear who is the head of the relevant competent central administrative agency having jurisdiction over the discovered living modified organism, the head of the relevant central administrative agency who has discovered it shall handle it through consultation with the head of the competent national authority.

(2) Upon receipt of a notice prescribed in paragraph (1), the relevant competent central administrative agency shall collect and remove the living modified organism discovered: Provided, That if the scale of the living modified organism discovered is small, the head of the relevant central administrative agency who has discovered it may collect and remove it.

(3) Where the head of the relevant competent central administrative agency in receipt of a notice prescribed in paragraph (1) deems that the living modified organism discovered in the course of conducting an investigation has an adverse impact on public health as well as on the conservation and sustainable use of biodiversity, he/she may investigate the impact of such living modified organism.

(4) Where the head of the relevant central administrative agency makes public the results of an investigation or the action conducted or taken under paragraphs (1) through (3), pursuant to Article 26-2 (3) of the Act, he/she shall consult with the head of the competent national authority prior to making the results public.

(5) The head of a relevant central administrative agency shall publicly notify the details about investigations into the environmental impact caused by any living modified organism conducted pursuant to Article 26-2 of the Act and about handling thereof through consultation.

Article 26 (Measures for Risk Prevention)

(1) The head of a relevant central administrative agency shall take risk prevention measures as follows pursuant to Article 27 (1) of the Act:

1. He/she must secure and appoint a person in charge of safety management;
2. He/she must eliminate the cause of any risk and take measures to prevent damage;
3. He/she must take safety measures, such as safety education for persons, etc. handling any living modified organism;
4. He/she must promptly provide information on risk prevention measures to the head of the competent national authority.

(2) The head of the competent national authority shall notify the International Biosafety Clearing House of the information on risk prevention measures provided pursuant to paragraph (1) 4.

Article 26-2 (Designation, etc. of Risk Assessment Institutes)

(1) The head of a relevant central administrative agency may designate a risk assessment institute to verify materials necessary for conducting a risk review pursuant to Article 28 of the Act.

(2) A person that intends to be designated as a risk assessment institute pursuant to paragraph (1) shall submit to the head of the relevant central administrative agency an application, including documents relating to the following information, as prescribed by Ordinance of the Ministry of Trade, Industry and Energy:

1. Information on the reasonableness of the scope of and procedures for conducting risk assessment;
2. Information on the appropriateness of a plan to operate a risk assessment institute;
3. Information on the scale and level of an organization exclusively in charge of risk assessment, professional human resources, and technical capabilities;
4. Information on the appropriateness of research facilities and equipment relating to risk assessment;
5. Information on financial stability.

(3) Upon receipt of an application filed under paragraph (2), the head of the relevant central administrative agency shall determine whether to designate the relevant person as a risk assessment institute; and notify the applicant of his/her determination within 90 days after receipt of the application.

(4) Article 4-2 (3) shall apply mutatis mutandis to risk assessment institutes. In such cases, "risk review agency" shall be construed as "risk assessment institute" and "risk review vicariously conducted" as "risk assessment".

Article 27 (Exceptions to Restrictions on Use and Supply of Information)

"Case prescribed by Presidential Decree" in Article 29 (1) of the Act means any of the following cases: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. Where an exporting country, etc. gives a written consent;

2. Where the relevant information is necessary for compiling statistics or for conducting academic research or market surveys; and a particular living modified organism and any organisms relevant thereto are supplied by processing them into an unrecognized form;

3. Where any of the following information is provided:

(a) Name and location of an exporting country, etc.;

(b) General technology on living modified organisms;

(c) An abstract of risk assessment;

(d) A method and plan for taking risk prevention measures prescribed in Article 26.

Article 28 (Organization, etc. of Biosafety Committee)

(1) "Persons prescribed by Presidential Decree" in Article 31 (3) 2 of the Act means persons with abundant knowledge about and experience in biosafety. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(2) The term of office of a member commissioned under paragraph (1) shall be two years, but it may be renewed: Provided, That the term of office of a member commissioned for filling a vacancy shall be the remaining term of his/her predecessor. *<Amended by Presidential Decree No. 27046, Mar. 22, 2016>*

Article 29 (Operation, etc. of Biosafety Committee, Subcommittees, and Working Committees)

(1) Where the Chairperson of the Biosafety Committee intends to convene a meeting of the Committee pursuant to Article 31 (7) of the Act, he/she shall notify each member of the Committee of the timing, place, and agenda items of the meeting in writing seven days before the meeting is held: Provided, That this shall not apply where the meeting is urgent or where extenuating circumstances exist. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013; Presidential Decree No. 27046, Mar. 22, 2016>*

(2) Meetings of the Biosafety Committee shall commence with the attendance of a majority of all incumbent members, and resolutions shall be adopted with a consent of a majority of the members present. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) The Biosafety Committee may have a subcommittee and working committee for each field of expertise. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(4) Each subcommittee shall be comprised of not more than ten members, including one chairperson; the chairperson of each subcommittee shall be appointed by the Chairperson of the Biosafety Committee from among the members specified in Article 31 (3) 1 of the Act; members of each subcommittee shall be elected by the Biosafety Committee from among its members; and any member of the Biosafety Committee may serve as a member of at least two subcommittees. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(5) Each working committee shall be comprised of not more than ten members, including one chairperson; the chairperson of each working committee shall be appointed by the Chairperson of the Biosafety Committee from among public officials in general service who belong to the competent national authority; and members of a working committee shall be commissioned by the chairperson of the working committee

from among persons with abundant knowledge about and experience in the relevant field. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(6) Subcommittees shall deliberate on matters delegated by the Biosafety Committee among matters subject to deliberation by the Biosafety Committee; and working committees shall conduct prior reviews, surveys, or research on agenda items referred to the Biosafety Committee for deliberation and shall perform affairs instructed by the Biosafety Committee. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(7) Where deemed necessary for performing affairs, such as deliberation on agenda items, the Biosafety Committee, a subcommittee, or a working committee may require any interested person or relevant expert to state his/her opinion at its meeting or to submit necessary materials. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(8) Allowances may be provided and travel expenses reimbursed within budgetary limits to members, interested persons, and experts who attend a meeting of the Biosafety Committee, a subcommittee, or a working committee: Provided, That this shall not apply where a member who is a public official attends such meeting in direct relation to his/her duties. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(9) Except as otherwise expressly provided for in this Decree, details necessary for operating the Biosafety Committee, subcommittees, and working committees shall be determined by the Chairperson of the Biosafety Committee following a resolution of the Biosafety Committee. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 29-2 (Disqualification of, Challenge to, and Refrainment by Members)

(1) A member of the Biosafety Committee shall be excluded from deliberations and decisions of the Committee in any of the following cases: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. Where the member or his/her spouse or former spouse is a party to the relevant agenda item or is a joint rights holder or obligor with a party to the agenda item;
2. Where the member is or was a relative of a party to the relevant agenda item;
3. Where the member has testified, made a statement, provided advice or services, or conducted research or an appraisal in relation to the relevant agenda item;
4. Where the member or a corporation to which the member belongs is or was an agent of a party to the relevant agenda item.

(2) Where it is impracticable to expect fair deliberations and decisions of a member, a party to the relevant agenda item may file a request for a challenge to the member with the Biosafety Committee; and the Committee shall make a determination on such request by resolution. In such cases, the challenged member shall abstain from such resolution. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) Where a member of the Biosafety Committee constitutes the grounds for exclusion specified in any subparagraph of paragraph (1), he/she shall personally refrain from all deliberations and determinations on the relevant agenda item.

Article 29-3 (Dismissal of Members)

(1) The Chairperson of the Biosafety Committee may dismiss any member specified in Article 31 (3) 2 of the Act if:

1. The member becomes unable to perform his/her duties due to any mental or physical disorder on his/her part;
2. The member has engaged in any misconduct in relation to his/her duties;
3. The member is deemed unfit as a member due to neglecting his/her duties, losing dignity, or other grounds;
4. The member fails to personally refrain although he/she falls under any subparagraph of Article 29-2 (1);
5. The member voluntarily indicates that it is impracticable to perform his/her duties.

(2) The chairperson of a working committee may dismiss any member of the committee specified in Article 29 (5) if the member falls under any subparagraph of paragraph (1) 1 through 3 or 5.

Article 30 (Biosafety Clearing House)

(1) The information on living modified organisms and related industries provided for in Article 32 (2) 2 of the Act means the following information: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. Information on export, import, etc. of living modified organisms;
2. Information on risk assessment or risk reviews of living modified organisms;
3. Information on statutes, systems, statistics, trends, and patents relating to living modified organisms (including related industries);
4. Information on prevention of and response to any risk posed by living modified organisms as well as on relevant measures;
5. General information on research, development, and production of living modified organisms;
6. Information on unintentional or illegal transboundary movement of living modified organisms;
7. Any other information on safety management of living modified organisms as well as on related industries.

(2) "Affairs prescribed by Presidential Decree" in Article 32 (2) 3 of the Act means providing information to the International Biosafety Clearing House under Article 20 of the Protocol. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(3) Where necessary for performing the affairs provided for in paragraph (2), the President of the Biosafety Clearing House may request the head of the competent national authority or the head of a relevant central administrative agency to provide information specified in paragraph (1): Provided, That where the President of the Biosafety Clearing House makes such request to the head of a central administrative agency, he/she shall go through the head of the competent national authority. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

(4) Deleted. *<by Presidential Decree No. 24993, Dec. 11, 2013>*

Article 31 (Service Charges)

(1) Service charges provided for in Article 35 (2) of the Act shall be as specified in attached Table 3: Provided, That any of the following persons may be exempt from service charges: *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

1. A university, college, industrial college, junior college, or technical college prescribed in the Higher Education Act;
2. A Government-funded research institute established under the Act on the Establishment, Operation and Fostering of Government-Funded Science and Technology Research Institutes, Etc.;
3. A national or public research institute;
4. A Government-funded research institute established under the Act on the Establishment, Operation and Fostering of Government-Funded Research Institutes, Etc.;
5. A specific research institute prescribed in the Specific Research Institutes Support Act;
6. The Korea Health Industry Development Institute established under the Korea Health Industry Development Institute Act.

(2) Service charges provided for in paragraph (1) may be paid by a revenue stamp, electronic money or electronic payment using an information and communications network, or by any other method. *<Amended by Presidential Decree No. 22857, Apr. 5, 2011>*

Article 32 (Procedures for Making Reports and Conducting Inspections)

The head of a relevant central administrative agency shall determine and publicly notify details necessary for making a report, submitting materials or samples, or for conducting an inspection pursuant to Article 36 of the Act.

Article 32-2 (Delegation and Entrustment of Authority)

(1) The head of a central administrative agency may delegate any of the following authority to the head of its affiliated agency pursuant to Article 37-2 (1) of the Act: *<Amended by Presidential Decree No. 29279, Nov. 6, 2018>*

1. Conducting risk reviews, consulting on risk reviews, and designating risk review agencies pursuant to Article 7-2 of the Act;
2. Granting approval for import of living modified organisms and giving notice thereof pursuant to Article 8 of the Act;
3. Receipt of reports on import of living modified organisms for testing, research, etc.; granting approval therefor; and notifying the details thereof pursuant to Article 9 of the Act;
4. Inspecting imported living modified organisms; taking measures, such as destroying or returning them; receiving reports thereon; and issuing an order for handling pursuant to Article 10 of the Act;
5. Consulting on designation of ports, airports, etc. through which living modified organisms are imported pursuant to Article 11 of the Act;
6. Granting approval for production of living modified organisms and giving notice thereof pursuant to Article 12 of the Act;

7. Taking measures to prohibit or restrict the import or production of living modified organisms pursuant to Article 14 of the Act;

8. Revoking approval for import or production of living modified organisms; and notifying the details of such revocation pursuant to Article 17 of the Act;

9. Reexamination administered under Article 18 of the Act;

10. Receiving notification of export of living modified organisms; and notifying the details thereof pursuant to Article 20 of the Act;

11. Receipt of reports on transit of living modified organisms; and notifying the details thereof pursuant to Article 21 of the Act;

12. Granting permission for and receiving reports on the establishment and operation of research facilities for living modified organisms; receiving reports on closure of research facilities; and notifying the details of such reports pursuant to Article 22 of the Act;

13. Granting approval for research and development of living modified organisms; and notifying the details thereof pursuant to Article 22-2 of the Act;

14. Granting permission for and receiving reports on the establishment and operation of production facilities using living modified organisms; receiving reports on closure of such facilities; and notifying the details thereof pursuant to Article 22-3 of the Act;

15. Granting approval for use of living modified organisms; and notifying the details thereof pursuant to Article 22-4 of the Act;

16. Issuing an order to close research facilities for living modified organisms or production facilities using living modified organisms, which are subject to reporting, or to suspend operation of such facilities; and revoking approval for research, development, or use of living modified organisms pursuant to Article 23 of the Act;

17. Issuing an order to destroy or return any living modified organism; and notifying the details thereof pursuant to Article 23-2 of the Act;

18. Investigating environmental impacts, etc. caused by living modified organisms pursuant to Article 26-2 of the Act;

19. Taking risk prevention measures against living modified organisms pursuant to Article 27 of the Act;

20. Designating risk assessment institutes pursuant to Article 28 of the Act;

21. Requiring the submission of reports, materials, or samples; and access and inspections by public officials under his/her jurisdiction pursuant to Article 36 of the Act;

22. Holding hearings pursuant to Article 37 of the Act;

23. Imposing and collecting administrative fines pursuant to Article 44 of the Act.

(2) The head of a relevant central administrative agency may entrust any of the following duties to any relevant specialized institution or organization pursuant to Article 37-2 (2) of the Act:

1. Formulating and implementing a plan for the safety management of living modified organisms pursuant to Article 7 of the Act;

2. Receipts of applications for risk reviews or for reviews by consultation; and supporting review procedures and research pursuant to Article 7-2 of the Act;

3. Receiving various types of applications, reports, notifications, and requests in relation to living modified organisms pursuant to Articles 8, 9, 12, 18, 22-2, 22-3, 22-4, and 28 of the Act;

4. Investigating environmental impacts, etc. caused by living modified organisms pursuant to Article 26-2 of the Act;

5. Taking safety measures, such as safety education for persons, etc. handling any living modified organism pursuant to Article 27 of the Act;

6. Matters necessary for operating the Biosafety Committee, subcommittees, and working committees among the duties of the Biosafety Committee established pursuant to Article 31 of the Act.

Article 32-3 (Management of Personally Identifiable Information)

If it is inevitable in performing affairs concerning reporting, inspections, etc. prescribed in Article 36 of the Act, the head of a relevant central administrative agency (including persons delegated with authority of the head of a relevant central administrative agency pursuant to Article 32-2) or the head of the competent national authority may manage data which includes resident registration numbers provided for in subparagraph 1 of Article 19 of the Enforcement Decree of the Personal Information Protection Act.

Article 32-4 (Review of Regulation)

The Minister of Trade, Industry and Energy shall review the appropriateness of the following matters every three years (referring to the day before each third anniversary from the base date), counting from the following relevant base date; and shall take measures, such as making improvements:

1. Procedures for applying for approval for import of living modified organisms provided for in Article 5: January 1, 2014;

2. Procedures for applying for approval for production of living modified organisms provided for in Article 13: January 1, 2014;

3. Research facilities subject to permission or reporting provided for in Article 23 (1) and attached Table 1; procedures for granting permission provided for in Article 23 (3); and procedures for filing a report provided for in Article 23 (5): January 1, 2014;

4. Procedures for applying for designation of a risk assessment institute provided for in Article 26-2: January 1, 2014.

Article 33 (Criteria for Imposing Administrative Fines)

The criteria for imposing administrative fines pursuant to Article 44 (1) of the Act shall be as specified in attached Table 4. *<Amended by Presidential Decree No. 24993, Dec. 11, 2013>*

ADDENDUM

This Decree shall enter into force on the date the Protocol becomes effective for the Republic of Korea.

ADDENDA <*Presidential Decree No. 20678, Feb. 29, 2008*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

ADDENDA <*Presidential Decree No. 21214, Dec. 31, 2008*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA <*Presidential Decree No. 22075, Mar. 15, 2010*>

Article 1 (Enforcement Date)

This Decree shall enter into force on March 19, 2010. (Proviso Omitted.)

Article 2 Omitted.

ADDENDUM <*Presidential Decree No. 22467, Nov. 2, 2010*>

This Decree shall enter into force on the date of its promulgation.

ADDENDA <*Presidential Decree No. 22857, Apr. 5, 2011*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning Administrative Fines)

For the purposes of applying the criteria for imposing administrative fines to any violation committed before this Decree enters into force, the former provisions shall apply, notwithstanding the amended provisions of attached Table 3.

ADDENDUM <*Presidential Decree No. 23931, Jul. 4, 2012*>

This Decree shall enter into force on the date of its promulgation.

ADDENDA <*Presidential Decree No. 24442, Mar. 23, 2013*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 12 Omitted.

ADDENDA <*Presidential Decree No. 24993, Dec. 11, 2013*>

Article 1 (Enforcement Date)

This Decree shall enter into force on December 12, 2013.

Article 2 (Applicability to Reporting on Closure of Research Facilities)

The amended provisions of Article 23-4 shall apply, beginning with the first research facility the closure of which is reported after this Decree enters into force.

Article 3 (Applicability to Matters to Be Indicated)

The amended provisions of Article 24 shall apply, beginning with the first living modified organism shipped in an exporting country after this Decree enters into force.

Article 4 (Applicability to Service Charges)

The amended provisions of attached Table 3 shall apply, beginning with the first person who applies for a risk review; permission to establish and operate a production facility using a living modified microorganism; or approval for use of any living modified microorganism after this Decree enters into force.

ADDENDUM <*Presidential Decree No. 25050, Dec. 30, 2013*>

This Decree shall enter into force on January 1, 2014. (Proviso Omitted.)

ADDENDUM <*Presidential Decree No. 26703, Dec. 10, 2015*>

This Decree shall enter into force on the date of its promulgation.

ADDENDA <*Presidential Decree No. 27046, Mar. 22, 2016*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Article 2 (Transitional Measures concerning Notice of Determination on Approval for Import of Living Modified Organisms for Testing, Research, etc.)

Notwithstanding the amended provisions of Article 11 (4), the former provisions shall apply where an application for import approval is submitted pursuant to Article 11 (3) before this Decree enters into force.

ADDENDA <*Presidential Decree No. 28212, Jul. 26, 2017*>

Article 1 (Enforcement Date)

This Decree shall enter into force on the date of its promulgation.

Articles 2 through 4 Omitted.

ADDENDUM <*Presidential Decree No. 29279, Nov. 6, 2018*>

This Decree shall enter into force on December 13, 2018.

Last updated : 2020-04-03