

TRANSBOUNDARY MOVEMENT, ETC. OF LIVING MODIFIED ORGANISMS ACT

Act No. 6448, Mar. 28, 2001
Amended by Act No. 8356, Apr. 11, 2007
Act No. 8762, Dec. 21, 2007
Act No. 8852, Feb. 29, 2008
Act No. 9241, Dec. 26, 2008
Act No. 9428, Feb. 6, 2009
Act No. 9882, Dec. 30, 2009
Act No. 9932, Jan. 18, 2010
Act No. 11536, Dec. 11, 2012
Act No. 11690, Mar. 23, 2013
Act No. 12844, Nov. 19, 2014
Act No. 14839, Jul. 26, 2017
Act No. 15181, Dec. 12, 2017

Article 1 (Purpose)

The purpose of this Act is to prevent risks posed by living modified organisms to the public health and the conservation and sustainable use of biological diversity, to improve the living conditions of people and to promote international cooperation by prescribing the matters necessary for the implementation of the Cartagena Protocol on Biosafety and the matter necessary to ensure safety on the development, production, import, export, distribution, etc. of living modified organisms.

Article 2 (Definitions)

The definitions of the terms used in this Act shall be as follows: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. The term "living organism" means any biological entity capable of transferring or replicating genetic material (including sterile organisms, viruses, and viroids);
2. The term "living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of each of the following modern biotechnology:
 - (a) Techniques that artificially recombine genes or directly inject nucleic acids comprising a gene into cells or organelles;
 - (b) Techniques that are the fusion of cells beyond the taxonomic family;

3. The term “stacked event” means a living modified plant obtained by breeding between living modified plants subjected to risk review pursuant to Article 7-2;
4. The term “release into the environment” means the intentional exposure of living modified organisms to the natural environment without contained measures taken within a facility, installation, or physical structure;
5. The term “relevant central administrative agency” means any central administrative agency having jurisdiction over any of the following affairs as prescribed by Presidential Decree:
 - (a) Affairs related to the development, production, import (including cases of import by means of hand baggage or postal parcels), export, sale, transportation, storage, use, etc. (hereinafter referred to as “export, import, etc.”) of living modified organisms;
 - (b) Biosafety-based affairs of research and development of living modified organisms and the promotion of related industries.

Article 3 (Scope of Application)

This Act shall not apply to living modified organisms used as pharmaceuticals for humans.

Article 4 (Relationship with Other Acts)

Unless specially prescribed by other Acts, this Act shall apply to the handling and safety management of living modified organisms when they are exported, imported, etc.

Article 5 (Duties and Responsibilities of the State, etc.)

(1) The State and a local government shall implement policies necessary to prevent risks to public health and to the conservation and sustainable use of biological diversity, that may be posed by living modified organisms.

(2) The persons engaging in the business of the export, import, etc. of living modified organisms shall manage them safely preventing risk to the public health and environment. <Newly Inserted by Act No. 11536, Dec. 11, 2012>

Article 6 (Competent National Authority, etc.)

(1) The national focal point under Article 19 of the Cartagena Protocol on Biosafety (hereinafter referred to as the "Protocol") shall be the Ministry of Foreign Affairs, and the competent national authority shall be the Ministry of Trade, Industry and Energy. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690. Mar.23, 2013>

(2) The head of the competent national authority under paragraph (1) (hereinafter referred to as the “competent national authority”) shall perform the administrative functions necessary for implementing the Protocol in its capacity as competent national authority, as prescribed by Presidential Decree. <Amended by Act No. 11536, Dec. 11, 2012>

Article 7 (Establishment and Implementation of Plans for Safety Management of Living Modified Organisms)

(1) The head of the relevant central administrative agency shall establish and implement a plan for the safety management of living modified organisms (hereinafter referred to as "plan for safety management")

on the basis of the affairs under its respective jurisdiction. <Amended by Act No. 11536, Dec. 11, 2012>

(2) The plan for safety management shall include the following:

1. Matters concerning the basic policy on safety management following the export, import, etc. of living modified organisms;
2. Matters concerning the safety of facilities and workers handling living modified organisms;
3. Matters concerning the technical development of living modified organisms and assistance thereto;
4. Other important matters concerning the safety management of living modified organisms.

(3) When the head of the relevant central administrative agency intends to formulate and implement the plan for safety management, he/she shall refer it to the Biosafety Committee for deliberation under Article 31 in advance. <Amended by Act No. 11536, Dec. 11, 2012>

(4) The head of the relevant central administrative agency shall formulate and implement a detailed implementation plan for the implementation of the plan for safety management; and if necessary, he/she may determine and publicly announce guidelines on safety management. <Amended by Act No. 11536, Dec. 11, 2012>

Article 7-2 (Risk Review of New Living Modified Organisms)

(1) Any of the following persons shall, prior to obtaining approval under Articles 8, 12, and 22-4, respectively, undergo a risk review conducted by the relevant central administrative agency, as prescribed by Presidential Decree, by submitting documents necessary for the risk review as prescribed by Presidential Decree: Provided That, this shall not apply where any person falling under subparagraph 2 or 3 produces or uses any living modified organism which has been subjected to the risk review as at the time of its import under subparagraph 1:

1. Persons who intend to import a new living modified organism pursuant to Article 8;
2. Persons who intend to produce a new living modified organism pursuant to Article 12;
3. Persons who intend to use a new living modified organism pursuant to Article 22-4.

(2) Persons who have developed a new living modified organism may, prior to the risk review under paragraph (1), undergo a risk review conducted by the head of the relevant central administrative agency. In such case, the head of the said relevant central administrative agency may conduct in a simplified manner or exempt the risk review, as prescribed by Presidential Decree, which a person intending to import, produce, or use a new living modified organism is to undergo pursuant to paragraph (1).

(3) Where the head of the relevant central administrative agency intends to conduct the risk review under paragraphs (1) and (2), he/she shall consult with the Minister of Health and Welfare on the effects of any living modified organism on humans, and shall consult with the head of the agencies as specified according to the following divisions, on living modified organisms which are released or are likely to be released into the environment: <Amended by Act No. 11690, Mar. 23, 2013>

1. Effects on crop cultivation environment: Ministry of Agriculture, Food and Rural Affairs;
2. Effects on natural ecosystem: Ministry of Environment;

3. Effects on fisheries environment and marine ecosystem: Ministry of Oceans and Fisheries.

(4) Standards and methods for the risk review of living modified organisms, and other necessary matters shall be determined and publicly announced by the head of the relevant central administrative agency, in consideration of the possibility of the release of living modified organisms into the environment; the objective of using living modified organisms; whether they are stacked events; and other similar matters.

(5) The head of the relevant central administrative agency may require an entity designated as prescribed by Presidential Decree (hereinafter referred to as the “risk review agency”) to conduct the affairs concerning risk review of living modified organisms on his/her behalf.

(6) Notwithstanding paragraph (5), the Minister of Oceans and Fisheries may delegate or entrust the affairs concerning the risk review of the effects on the fisheries environment and the marine ecosystem under paragraph (3) 3, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

(7) When the head of the relevant central administrative agency or the entity delegated or entrusted pursuant to paragraph (6) conducts a risk review of living modified organisms, he/she shall inform the public of the information regarding those living modified organisms as prescribed by Presidential Decree.

Article 8 (Approval, etc. for Import)

(1) A person intending to import any living modified organism shall obtain approval from the head of the relevant central administrative agency, as prescribed by Presidential Decree.

(2) Notwithstanding paragraph (1), a person intending to import any living modified organism used for release into the environment shall file an application for approval for import with the head of the relevant central administrative agency via the head of the competent national authority. In this case, the head of the competent national authority and the head of the relevant central administrative agency shall comply with the procedures necessary for transboundary movements of living modified organisms under Articles 8 through 10 of the Protocol, as prescribed by Presidential Decree.

(3) If a person who has obtained approval pursuant to paragraph (1) intends to modify any approved matter, he/she shall obtain approval for modification thereof: Provided, That in the case of intending to modify any of the minor matters prescribed by Presidential Decree, he/she shall file a report for modification thereof.

(4) Where determining whether to grant approval for any import, the head of the relevant central administrative agency shall take into consideration the socioeconomic effects that the relevant living modified organism would have on the value of the domestic biological diversity.

(5) The head of the relevant central administrative agency shall notify the head of the competent national authority of the information of such approval and the content of such report under paragraphs (1) and (3).

(6) Necessary matters concerning methods and procedures for approval obtained and reports filed under paragraphs (1) and (3) shall be prescribed by Presidential Decree.

Article 9 (Import of Living Modified Organisms for Research and Development, etc.)

(1) Notwithstanding Article 8 (1), a person intending to import any living modified organism for research and development, or an arrangement of an exposition or exhibition shall file a report thereon to the head of

the relevant central administrative agency: Provided, That where the living modified organism falls under any of the following, he/she shall obtain approval by the head of the relevant central administrative agency: <Amended by Act No. 11536, Dec. 11, 2012>

1. A living modified organism obtained using any microorganism, the taxa species name of which is not specified and the human pathogenicity of which is not proved;
 2. A living modified organism capable of producing any such protein toxins to vertebrates as publicly announced by the Minister of Health and Welfare;
 3. A living modified organism to which a drug resistance gene is deliberately transferred: Provided, That this shall not apply to living modified organisms which have any such drug-resistance gene as publicly announced by the Minister of Health and Welfare;
 4. A living modified organism obtained using any pathogenic microorganism the national management of which the Minister of Health and Welfare has publicly announced is necessary for public health.
- (2) If a person who has filed a report under paragraph (1) intends to modify any reported matter, he/she file a report for modification thereof. <Newly Inserted by Act No. 11536, Dec. 11, 2012>
- (3) Article 8 (3) and (5) shall apply mutatis mutandis to approval for import obtained and reports filed under paragraphs (1) and (2). <Amended by Act No. 11536, Dec. 11, 2012>
- (4) Necessary matters concerning methods and procedures for approval and report under paragraphs (1) through (3) shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 11536, Dec. 11, 2012>

Article 10 (Import Inspection)

- (1) Before the completion of customs clearance procedures, the head of the relevant central administrative agency may inspect imported living modified organisms imported (excluding living modified organisms the reports on which have been filed pursuant to the main sentence of Article 9 (1)) to confirm whether they are consistent with the information of such approval or the content of such report under Article 8 or 9. <Newly Inserted by Act No. 11536, Dec. 11, 2012>
- (2) Notwithstanding paragraph (1), if any living modified organism, for which approval under Article 8 or 9 has not been obtained or on which report under Article 8 or 9 has not been filed, is enclosed or is suspected to be enclosed in any international mail, the head of a custom house shall notify the head of the relevant central administrative agency of such fact without delay. <Amended by Act No. 11536, Dec. 11, 2012>
- (3) Upon receipt of notification made by the head of the customs house pursuant to paragraph (2), the head of the relevant central administrative agency shall inspect the relevant international mail and take proper measures, including destruction or return thereof. <Amended by Act No. 11536, Dec. 11, 2012>
- (4) Where a person who has received any international mail enclosing a living modified organism becomes aware that approval for or a report on such living modified organism under Article 8 or 9 has not been granted or filed, he/she shall file a report thereon with the head of the relevant central administrative agency without delay and handle such organism as ordered by the head of the relevant central administrative agency.

(5) Necessary matters concerning the scope of, and methods for, inspection under paragraphs (1) through (4) shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 11536, Dec. 11, 2012>

Article 11 (Designation of Ports of Import, etc.)

(1) Where the head of competent national authority acknowledges it necessary for the safety management of living modified organisms, he/she may designate ports, airports, etc. through which living modified organisms are imported after consultation with the head of the relevant central administrative agency.

<Amended by Act No. 11536, Dec. 11, 2012>

(2) Where the head of the competent national authority designates ports, airports, etc. as prescribed in paragraph (1), he/she shall publicly announce them without delay.

Article 12 (Approval, etc. for Production)

(1) A person intending to produce any living modified organism shall obtain approval by the relevant central administrative agency as prescribed by Presidential Decree.

(2) Where a person who has obtained approval pursuant to paragraph (1) intends to modify any approved matter, he/she shall obtain approval for modification thereof: Provided, That where it is intended to modify any of the minor matters prescribed by Presidential Decree, he/she shall file a report for modification thereof.

(3) Article 8 (4) and (5) shall apply mutatis mutandis to approval for production obtained and reports filed under paragraphs (1) and (2). In such cases, "import" shall be construed as "production."

(4) Necessary matters concerning methods and procedures for approval obtained and reports filed under paragraphs (1) and (2) shall be prescribed by Presidential Decree.

Article 13 Deleted. <by Act No. 11536, Dec. 11, 2012>

Article 14 (Prohibition, etc. of Import or Production)

(1) The head of the relevant central administrative agency may prohibit or restrict the import or production of any of the following living organisms: <Amended by Act No. 11536, Dec. 11, 2012>

1. A living modified organism acknowledged to pose, or acknowledged that it is likely to pose, a risk to public health and to the conservation and sustainable use of biological diversity;
2. A living organism obtained by breeding with a living modified organism falling under subparagraph 1;
3. A living modified organism acknowledged to have, or acknowledged that it is likely to have, socio-economically negative effects on the value of the domestic biological diversity.

(2) Where the head of the relevant central administrative agency prohibits or restricts the import or production of living modified organisms as prescribed in paragraph (1), he/she shall notify it to the head of the competent national authority. <Amended by Act No. 11536, Dec. 11, 2012>

(3) The head of the competent national authority shall publicly announce matters necessary for the items, etc. of organisms, the import or production of which is prohibited or restricted as prescribed in the subparagraphs of paragraph (1).

Article 15 Deleted. <by Act No. 11536, Dec. 11, 2012>

Article 16 (Legal Fiction, etc. as Approval for Import under the Foreign Trade Act)

(1) A living modified organism for the import of which the head of the relevant central administrative agency has granted approval under Article 8 or 9 or on the import of which he/she has accepted a report under the same Article, shall be deemed a living modified organism the import of which the Minister of Knowledge Economy has granted approval under Article 11 (2) of the Foreign Trade Act. <Amended by Act No. 8852, Feb. 29, 2008; Act No. No. 11536, Dec. 11, 2012; Act No. 11690, Mar. 23, 2013 >

(2) A living modified organism in respect of which a person intending to export has provided notification of the detailed export to the head of the relevant central administrative agency pursuant to Article 20 shall be deemed a living modified organism the export of which the Minister of Trade, Industry and Energy has granted approval under Article 11 (2) of the Foreign Trade Act. <Amended by Act No. 8852, Feb. 29, 2008; Act No. No. 11536, Dec. 11, 2012; Act No. 11690, Mar. 23, 2013>

Article 17 (Revocation of Approval)

(1) In any of the following cases, the head of the relevant central administrative agency may revoke approval for import or production of a living modified organism under Article 8, 9, or 12: Provided, That in cases falling under subparagraph 1 or 2, he/she shall revoke approval for import or production: <Amended by Act No. 11536, Dec. 11, 2012>

1. Where it has been discovered that the living modified organism for which approval for import or production has been obtained poses or is likely to pose a risk to public health and to the conservation and sustainable use of biological diversity;
2. Where approval for import or production has been obtained by deceit or fraudulent methods;
3. Where the living modified organism for which approval for import or production has been obtained is used for any other purpose than the approved purpose;
4. Where the living modified organism has been imported or produced without obtaining approval for modification or filing a report for modification, in violation of Article 8 (3), 9 (3) or 12 (2);
5. Where the type of the living modified organism have not been identified, in violation of Article 24 (1) or (2), or have been identified fraudulently, or the identification has been modified or deleted arbitrarily;
6. Where the standards for handling and management have not been complied with, in violation of Article 25 (1);
7. Where the records of export, import, etc. of the living modified organism have not been prepared and kept, in violation of Article 26;
8. Where a person knew the adverse effect of the living modified organism and fails to notify the head of the relevant central administrative agency or the head of the competent national authority of the details, in violation of Article 27 (2);
9. Where a person has refused to submit report, data, or samples, or has refused, obstructed, or evaded access and inspection, under Article 36 (1), without a justifiable reason;

10. Others cases falling under the reasons prescribed by Presidential Decree.

(2) Where the head of the relevant central administrative agency has revoked approval for import or production under paragraph (1), he/she shall notify the head of the competent national authority thereof.

<Amended by Act No. 11536, Dec. 11, 2012>

Article 18 (Re-Examination)

(1) A person who is dissatisfied with a disposition under Articles 8, 12, and 17 (1) may request re-examination by the head of the relevant central administrative agency, as prescribed by Presidential Decree. *<Amended by Act No. 11536, Dec. 11, 2012>*

(2) Where the head of the relevant central administrative agency is requested for re-examination under paragraph (1), he/she shall determine the re-examination after deliberation thereon by the Biosafety Committee under Article 31. *<Amended by Act No. 11536, Dec. 11, 2012>*

Article 19 *[Moved to Article 23-2]*

Article 20 (Notification of Export)

A person who intends to export living modified organisms shall notify in advance the head of the relevant central administrative agency of such matters prescribed by Presidential Decree as items, quantity, and importing country. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11536, Dec. 11, 2012>*

Article 21 (Filing Report of Transit)

A person who intends to export living modified organisms to another country after loading and unloading them at a domestic harbor, airport, or any other place prescribed by Presidential Decree shall file a report of such matters prescribed by Presidential Decree as items, quantity, exporting country, and importing country to the head of the relevant central administrative agency. *<Amended by Act No. 11536, Dec. 11, 2012>*

Article 22 (Establishment and Operation of Research Facilities)

(1) A person who intends to establish and operate facilities in which any living modified organism is developed or any experiment is conducted using such living modified organism (hereinafter referred to as the "research facilities") shall obtain permission by the head of the relevant central administrative agency, or file a report with the head of the relevant central administrative agency, for each biosafety level of research facilities.

(2) Where a person who has obtained permission pursuant to paragraph (1) intends to modify any permitted matter, he/she shall obtain permission for modification thereof: Provided, That it is intended to modify any of the minor matters prescribed by Presidential Decree, he/she shall file a report for modification of the minor matter.

(3) Where a person who has filed a report pursuant to paragraph (1) intends to modify any reported matter, he/she shall file a report for modification of the reported matter.

(4) Where a person who has obtained permission or has filed a report pursuant to paragraph (1) intends to close any of the research facilities, he/she shall file a report on the details of such closure with the head of the relevant central administrative agency.

(5) The head of the relevant central administrative agency shall notify the head of the competent national authority of the information on the permission for the establishment and operation of such research facilities and of the content of such reports under paragraphs (1) through (3) and the details of closure of such research facilities under paragraph (4).

(6) Each person who has obtained permission for or has filed a report on the establishment and operation of research facilities pursuant to paragraphs (1) through (3) shall comply with such matters to be observed at each biosafety level of research facilities, as prescribed by Presidential Decree.

(7) Necessary matters concerning the scope of research facilities under paragraphs (1) through (4); each biosafety level thereof; standards and procedures for permission for, and reporting of, the establishment and operation thereof; and standards and procedures for the closure thereof shall be prescribed by Presidential Decree.

Article 22-2 (Research on and Development of Living Modified Organisms)

(1) Where a person who has obtained permission to establish and operate research facilities or has filed a report thereon pursuant to Article 22 intends to research and develop any living modified organism which is highly likely to cause any risk prescribed by Presidential Decree, he/she shall obtain approval therefor from the head of the relevant central administrative agency.

(2) Where the person who has obtained approval pursuant to paragraph (1) intends to modify any approved matter, he/she shall obtain approval to modify such: Provided, That when intending to modify any of the minor matters prescribed by Presidential Decree, he/she shall file a report for modification thereof.

(3) The head of the relevant central administrative agency shall notify the head of the competent national authority of the information on the approval for the research on and development of such living modified organism and the content of such report pursuant to paragraphs (1) and (2).

Article 22-3 (Establishment and Operation of Production Facilities Using Living Modified Organisms)

(1) A person who intends to establish and operate a facility in which any living modified organism is used in the production process (hereinafter referred to as “production facility using a living modified organism”) shall, according to biosafety level, obtain permission from the head of the relevant central administrative agency or file a report to the head of the relevant central administrative agency. *<Amended by Act No. 15181, Dec. 12, 2017>*

(2) Where a person who has obtained permission pursuant to paragraph (1) intends to modify any permitted matter, he/she shall obtain permission to modify such matters: Provided, That when intending to modify minor matters prescribed by Presidential Decree, he/she file a report for modification thereof.

(3) Where a person who has filed a report pursuant to paragraph (1) intends to modify any reported matter, he/she shall file a report for modification thereof.

(4) Where a person who has obtained permission or has filed a report pursuant to paragraph (1) intends to close the production facility, he/she shall file a report on the details of the closure with the head of the

relevant central administrative agency.

(5) The head of the relevant central administrative agency shall notify the head of the competent national authority of the information on the permission for the establishment and operation of such production facilities and the content of such reports under paragraphs (1) through (3) and the details of the closure of such production facilities using living modified organisms under paragraph (4).

(6) Necessary matters concerning the scope of production facilities using living modified organisms under paragraphs (1) through (4); each biosafety level thereof; standards and procedures for granting permission for, and reporting of, the establishment and operation thereof; and standards and procedures for the closure thereof shall be prescribed by Presidential Decree.

Article 22-4 (Use of Living Modified Organisms)

(1) If a person who has obtained permission for a production facility using a living modified organism or has filed a report thereon under Article 22-3 intends to use the living modified organism at such production facility, he/she shall obtain approval therefor by the head of the relevant central administrative agency as prescribed by Presidential Decree. *<Amended by Act No. 15181, Dec. 12, 2017>*

(2) If the person who has obtained approval pursuant to paragraph (1) intends to modify any approved matter, he/she shall obtain approval for modification thereof: Provided, That where it is intended to modify minor matters prescribed by Presidential Decree, he/she shall file a report for modification thereof.

(3) Article 8 (4) and (5) and Article 18 shall apply mutatis mutandis to approval for use under paragraph (1). In such cases, "import" shall be construed as "use."

(4) Necessary matters concerning standards, procedures, and methods for granting approval and reporting under paragraphs (1) and (2) shall be prescribed by Presidential Decree.

Article 23 (Revocation, etc. of Permission)

(1) Where a person who has been permitted to establish and operate a research facility or has filed a report thereon pursuant to Article 22 (1) falls under any of the following, the head of the relevant central administrative agency may revoke the permission, issue an order to close the relevant research facility, or issue an order to suspend operation of the facility specifying a period not exceeding one year: Provided, That in cases falling under subparagraph 1, he/she shall revoke the permission or issue an order to close such research facility: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. Where obtaining permission or filing a report by deception or in other unjust means;
2. Where modifying any content of such permission or report without obtaining permission for modification or filing a report for modification pursuant Article 22 (2) or (3);
3. Where failing to comply with such matters to be observed under Article 22 (6);
4. Where failing to meet the standard for granting permission or reporting under Article 22 (7);
5. Where conducting research on and development of any living modifying organism without approval under Article 22-2 (1);
6. Where modifying details of such permission or report without obtaining approval for modification or filing a report for modification, pursuant Article 22-2 (2).

(2) Where a person who has obtained permission to establish and operate a production facility using a living modified organism or has filed a report thereon pursuant to Article 22-3 falls under any of the following, the head of the relevant central administrative agency may revoke the permission, order the closure of the production facility using a living modified organism, or order the person to suspend operation of the facility specifying a period not exceeding one year: Provided, That in cases falling under subparagraph 1 or 2, he/she shall revoke the permission or order the closure of the production facility using a living modified organism: <Newly Inserted by Act No. 11536, Dec. 11, 2012; Act No. 15181, Dec. 12, 2017>

1. Where obtaining permission or filing a report in a false or other unjustifiable manner;
 2. Where modifying any content of the permission or content of the report without obtaining permission for modification or filing a report for modification pursuant Article 22-3 (2) or (3);
 3. Where failing to comply with the standard for granting permission or reporting under Article 22-3 (6);
 4. Where using any living modified organism without obtaining approval under Article 22-4 (1);
 5. Where modifying the details of approval without obtaining approval for modification or filing a report for modification pursuant Article 22-4 (2);
 6. Where failing to meet the standard for granting approval or reporting under Article 22-4 (4).
- (3) Where it has been discovered that the research on and development of, or the use of, any living modified organism that has been approved under the proviso to Articles 22-2 (1) and 22-4 (1) poses or is likely to pose risks to public health and to the conservation and sustainable use of biological diversity, the head of the relevant central administrative agency may revoke such approval. <Amended by Act No. 11536, Dec. 11, 2012>

Article 23-2 (Order for Destruction, Return, etc.)

(1) The head of the relevant central administrative agency may order the owner of any of the following living modified organisms to destroy or return the living modified organism, specifying a period, as prescribed by Presidential Decree: <Amended by Act No. 11536, Dec. 11, 2012>

1. A living modified organism, for which approval or approval for modification from the head of the relevant central administrative agency under Article 8, 9, 12, 22-2, or 22-4 has not been obtained, or on which the report to the head of the relevant central administrative agency under Article 8, 9, 12, 22-2, or 22-4 has not been filed;
- 1-2. A living modified organism with respect to which approval or approval for modification from the head of the relevant central administrative agency under Article 8, 9, 12, 22-2, or 22-4 has been obtained by deception or in other unjust means;
2. A living modified organism, the import or production of which has been prohibited or restricted under Article 14;
3. A living modified organism, with respect to which approval for import, approval for production, approval for research and development, or approval for use under Article 17 or 23 (3) has been revoked.

(2) Where the owner of any living modified organism fails to comply with an order for destruction or return under paragraph (1), the head of the relevant central administrative agency may have a public official under his/her control directly destruct or return the living modified organism at the owner's expense as prescribed by Presidential Decree. <Amended by Act No. 11536, Dec. 11, 2012>

(3) With regard to any imported living modified organism, when the head of the relevant central administrative agency has issued an order for destruction or return pursuant to paragraph (1), he/she shall notify the Commissioner of the Korea Customs Service thereof. <Amended by Act No. 11536, Dec. 11, 2012>

Article 24 (Identification)

(1) A person who develops, produces, or imports living modified organisms shall identify the matters prescribed by Presidential Decree, such as the types of living modified organisms, on the living modified organisms or on the receptacles, packages, or import invoice thereof. <Amended by Act No. 11536, Dec. 11, 2012>

(2) No person shall apply any false mark under paragraph (1), or modify or delete such mark arbitrarily.

(3) The head of the relevant central administrative agency shall determine and publicly announce the method of identification under paragraph (1) and other necessary matters. <Amended by Act No. 11536, Dec. 11, 2012>

Article 25 (Handling and Management)

(1) When exporters, importers, etc. of living modified organisms handle or manage living modified organisms, they shall comply with the standards for handling and management prescribed by Presidential Decree, such as contained transportation.

(2) The methods for handling and management under paragraph (1) and other necessary matters shall be determined and publicly announced by the head of the relevant central administrative agency. <Amended by Act No. 11536, Dec. 11, 2012>

Article 26 (Preservation of Records of Management and Operation)

Exporters, importers, etc. of living modified organisms and persons who establish and operate research facilities shall prepare and keep the records of export, import, etc. of living modified organisms and the records of management and operation of research facilities, as prescribed by Ordinance of the Ministry of Knowledge Economy. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 11690, Mar. 23, 2013.>

Article 26-2 (Investigations into Environmental Impact, etc. Caused by Living Modified Organisms)

(1) In order to ascertain the impacts living modified organisms domestically distributed have on the public health and environment, if deemed necessary, the head of the relevant central administrative agency may investigate research facilities, production facilities using living modified organisms, places of business, storage places, and neighboring areas of the above-mentioned facilities and places.

(2) When necessary for investigations under paragraph (1), the head of the relevant central administrative agency may request the heads of other relevant central administrative agencies for assistance. In such cases, the head of a relevant central administrative agency, in receipt of such request, shall comply with such request unless there exist a special reason not to do so.

(3) The head of the relevant central administrative agency shall disclose the results of investigations under paragraph (1) to the public in accordance with the procedures and methods prescribed by Presidential Decree.

(4) Necessary matters concerning the methods and procedures for investigations under paragraph (1) shall be prescribed by Presidential Decree.

Article 27 (Measures for Risk Prevention)

(1) Where it is acknowledged that living modified organisms are inflicting or are likely to inflict adverse effects on public health, and on the conservation and sustainable use of biological diversity, the head of the relevant central administrative agency shall take necessary measures without delay as prescribed by Presidential Decree. *<Amended by Act No. 11536, Dec. 11, 2012>*

(2) Where exporters, importers, etc. of living modified organisms have become aware of the adverse effects of living modified organisms, they shall notify the head of the relevant central administrative agency or the head of the competent national authority of the details thereof without delay. *<Amended by Act No. 11536, Dec. 11, 2012>*

Article 28 (Protection of Information)

The heads of the relevant central administrative agency, of the competent national authority, of any of the risk assessment institutes that the head of the relevant central administrative agency designates for risk review under Article 7-2 (1) as prescribed by Presidential Decree (hereinafter referred to as the "risk assessment institutes"), of the risk review agency, and of the Biosafety Clearing House under Article 32, which are handling information on living modified organisms (hereinafter referred to as the "information handling organizations"), shall take measures necessary for the protection of the information on living modified organisms so that such information may not be stolen, divulged, or corrupted. *<Amended by Act No. 11536, Dec. 11, 2012>*

Article 29 (Restriction on Use and Supply of Information)

(1) No head of an information handling organization shall use information on living modified organisms for any commercial purpose or supply it to another person except for the cases prescribed by Presidential Decree.

(2) When the head of an information handling organization supplies information on living modified organisms to another person, he/she may put restrictions on the purpose of use, method of use, etc., or request the person to take measures necessary for the protection of information.

Article 30 (Obligation of Executive Officers and Employees of Information Handling Organization)

An executive officer or employee of an information handling organization or a former executive officer or employee of the information handling organization shall not use the information that he/she learned in the course of performing his/her duties for unjust purposes, including leaking the information, and supplying the information for others to use it.

Article 31 (Biosafety Committee)

(1) In order to deliberate the following matters concerning the export, import, etc. of living modified organisms, the Biosafety Committee shall be established under the jurisdiction of the Minister of Trade, Industry and Energy: *<Amended by Act No. 11536, Dec. 11, 2012; Act No. 11690, Mar. 23, 2013>*

1. Matters concerning the implementation of the Protocol;
2. Establishment and implementation of a plan for safety management;
3. Deleted; *<by Act No. 11536, Dec. 11, 2012>*
4. Re-examination under Articles 18 and 22-4 (3);
5. Matters concerning statutes, public announcement, etc. relating to the export, import, etc. of living modified organisms and to the safety management thereof;
6. Matters concerning the prevention of, and countermeasures against, risks from living modified organisms;
7. Other matters referred by the chairperson of the Committee or the head of the competent national authority to the Committees for deliberation.

(2) The Biosafety Committee shall be comprised of 15 to 20 members, including one chairperson. *<Amended by Act No. 11536, Dec. 11, 2012>*

(3) The Minister of Trade, Industry and Energy shall become the chairperson of the Biosafety Committee, and the following persons shall become members: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11536, Dec. 11, 2012; Act No. 11690, Mar. 23, 2013; Act No. 12844, Nov. 19, 2014; Act No. 15181, Dec. 12, 2017>*

1. The Vice-minister of Strategy and Finance, the Vice-minister of Education, the Vice-minister of Science and ICT, the Vice-minister of Foreign Affairs, the Vice-minister of Agriculture, Food and Rural Affairs, the Vice-minister of Health and Welfare, the Vice-minister of Environment and the Vice-minister of Oceans and Fisheries;
2. Persons commissioned by the chairperson from among those prescribed by Presidential Decree.

(4) When the chairperson of the Biosafety Committee intends to commission the members thereof pursuant to paragraph (3) 2, he/she shall consult with the head of the relevant central administrative agency in advance. *<Amended by Act No. 11536, Dec. 11, 2012>*

(5) The Biosafety Committee may have subcommittees and working committees. *<Amended by Act No. 11536, Dec. 11, 2012>*

(6) The Biosafety Committee may have an executive secretary, who shall be designated by the chairperson from among public officials belonging to the Minister of Trade, Industry and Energy. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 11536, Dec. 11, 2012; Act No. 11690, Mar. 23, 2013>*

(7) Matters concerning the composition, function, operation, etc. of the Biosafety Committee, subcommittees, and working committees thereof shall be prescribed by Presidential Decree. *<Amended by Act No. 11536, Dec. 11, 2012>*

Article 32 (Biosafety Clearing House)

(1) The head of the competent national authority may designate the Biosafety Clearing House which is specialized in the management and exchange of information on living modified organisms (hereinafter referred to as the "Biosafety Clearing House").

(2) The Biosafety Clearing House shall conduct the following affairs: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. Disclosure of information on the safety of living modified organisms;
2. The collection, management, provision, publicity, and exchange of information on living modified organisms and related industries;
3. Other affairs prescribed by Presidential Decree.

(3) The head of the competent national authority may contribute expenses incurred in the establishment and operation of the Biosafety Clearing House, within budgetary limits. *<Newly Inserted by Act No. 9882, Dec. 30, 2009>*

Article 33 (Subsidization of Funds, etc.)

(1) In order to promote the public's understanding of, and to raise consumer awareness on living modified organisms or to secure the research and development of living modified organisms based on biosafety and the sound development of related industries, the Government may conduct the following projects:

1. Education and projects on the safety of research facilities and production facilities using living modified organisms;
2. Development of technology regarding living modified organisms and techniques for risk assessment;
3. Support for the detection and monitoring of living modified organisms;
4. Education and public relations regarding living modified organisms and risk review thereof.

(2) The Government may contribute or subsidize necessary funds, etc. to the institutions and organizations which conduct affairs related to the subparagraph of paragraph (1).

Article 34 (Securing Funds, etc.)

The head of the competent national authority shall prepare a plan for securing funds to ensure stability in preparation for the cases of damage to public health and to the conservation and sustainable use of biological diversity with regard to the export, import, etc. of living modified organisms.

Article 35 (Service Charges)

(1) A person who falls under any of the following shall pay service charges: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. A person who intends to undergo the risk review pursuant to Article 7-2;
2. A person who intends to obtain approval for import pursuant to Article 8 (1) and (2);
3. A person who intends to obtain approval for import pursuant to the proviso to Article 9 (1);
4. A person who intends to obtain approval for production pursuant to Article 12 (1);
5. A person who intends to obtain permission for the establishment and operation of research facilities pursuant to Article 22 (1);

6. A person who intends to obtain permission to establish and operate a production facility using a living modified organism under Article 22-3 (1);
 7. A person who intends to obtain permission for use pursuant to Article 22-4 (1).
- (2) Matters concerning the amount of service charges applicable under paragraph (1), methods of payment, period for payment, etc. shall be prescribed by Presidential Decree.

Article 36 (Reporting and Inspections)

(1) The head of the relevant central administrative agency or of the competent national authority may require public officials under his/her jurisdiction to enter the relevant offices, research facilities, production facilities using living modified organisms, places of business, places of storage, etc. to inspect the related documents, facilities, equipment, state of preservation, etc., of any of the following persons: Provided, That the head of the relevant central administrative agency or the head of the competent national authority may require any of the following persons under subparagraphs 1 and 3 through 7 to file reports or to submit relevant materials or samples for the safety management of living modified organisms:

<Amended by Act No. 11536, Dec. 11, 2012>

1. A person who has obtained permission or has filed a report pursuant to Article 8 (1) through (3), 9 (1) through (3), or 12 (1) and (2);
2. Deleted; *<by Act No. 11536, Dec. 11, 2012>*
3. Risk assessment institutes;
4. The risk review agency;
5. A person who has obtained permission to establish and operate research facilities or has filed a report thereon pursuant to Article 22;
6. A person who has obtained permission to establish and operate a production facility using a living modified organism or has filed a report thereon pursuant to Article 22-3;
7. A person who handles or manages living modified organisms as prescribed in Article 25;
8. A person who is suspected of engaging in the export, import, etc. of any good deemed a living modified organism for which approval has not been granted or on which no report has been filed, or a person who is suspected of operating research facilities or a production facility using a living modified organism without having obtained permission therefor or having filed a report thereon.

(2) Public officials who enter the above-mentioned premises to make inspections pursuant to paragraph (1) shall carry a certificate indicating their authority and present it to relevant parties. *<Amended by Act No. 11536, Dec. 11, 2012>*

(3) Necessary matters concerning objects to be inspected, and the standards and procedures for inspection shall be prescribed by Presidential Decree. *<Newly Inserted by Act No. 11536, Dec. 11, 2012>*

Article 37 (Hearings)

The head of the relevant central administrative agency shall hold a hearing when intending to grant any of the following dispositions: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. A disposition to revoke approval for import or production under Article 17;
2. A disposition to revoke permission for the establishment and operation of research facilities or a production facility using a living modified organism, or an order to close such facilities or to suspend the operation thereof under Article 23.

Article 37-2 (Delegation and Entrustment of Authority)

(1) Part of the authority of the head of the relevant central administrative agency as vested under this Act may be delegated or entrusted to the head of an institution under the jurisdiction of the said agency, or the head of another administrative agency, as prescribed by Presidential Decree.

(2) Some of the affairs of the head of the relevant central administrative agency may be entrusted to any relevant specialized institution or organization, as prescribed by Presidential Decree.

Article 38 (Legal Fiction as Public Officials in Application of Penalty Provisions)

A person who is not a public official from among the executive officers and employees of the following institutions and members of the Biosafety Committee shall be deemed a public official in applying the provisions of Articles 129 through 132 of the Criminal Act: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. Risk assessment institutes;
2. The risk review agency;
3. The Biosafety Clearing House;
4. The Institutions or organizations which conduct affairs entrusted by the head of the relevant central administrative agency pursuant to Article 37-2.

Article 39 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 70 million won: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. A person who imports or produces any living modified organism, the import or production of which has been prohibited or restricted due to the violation of Article 14 (including organisms under paragraph (1) 2 of the same Article);
2. A person who imports or produces any living modified organism, for which approval has been revoked pursuant to Article 17 (1) 1;
3. A person who has living modified organisms distributed in Korea in violation of an order for destruction or return under Article 23-2 (1).

Article 40 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 50 million won: *<Amended by Act No. 11536, Dec. 11, 2012>*

1. A person who imports or produces any living modified organism without approval or approval for modification under Article 8 (1) and (2), the main sentence of Article 8 (3), the proviso to Article 9 (1), Article 9 (3), Article 12 (1), or the main sentence of Article 12 (2);
2. A person who imports or produces any living modified organism for which approval is revoked pursuant to Article 17 (1) 2 through 10;

3. A person who establishes or operates research facilities without permission under Article 22 (1), or without permission for modification under the main sentence of Article 22 (2);
4. A person who conducts research and development without approval or approval for modification under Article 22-2 (1) or the main sentence of Article 22-2 (2);
5. A person who establishes or operates a production facility using a living modified organism without permission or permission for modification under Article 22-3 (1) or the main sentence of Article 22-3 (2);
6. A person who uses any living modified organism without approval or approval for modification under Article 22-4 (1) or the main sentence of Article 22-4 (2).

Article 41 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 30 million won: <Amended by Act No. 11536, Dec. 11, 2012>

1. A person who imports a living modified organism without filing a report under the main sentence of Article 9 (1);
2. A person who exports a living modified organism without making notification under Article 20;
3. A person who intends to export any living modified organism by transit through the territory of Korea without filing a report under Article 21;
4. A person who establishes and operates a research facility without filing a report under Article 22 (1);
5. A person who violates an order to close or to suspend the operation of a research facility or a production facility using a living modified organism under Article 23;
6. A person who violates an order to destruct or to return under Article 23-2 (1);
7. A person who divulges information that he/she becomes aware of in the course of performing his/her duties, or who allows another person to use such information, in violation of Article 30.

Article 42 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 20 million won:

1. A person who fails to identify the types, etc., of living modified organisms, has made a false identification, or changes or deletes the identification arbitrarily, in violation of Article 24 (1) or (2);
2. A person who fails to comply with the standards for handling and management under Article 25.

Article 43 (Joint Penalty Provisions)

Where the representative of a corporation or an agent or employee of, or any other person employed by, a corporation or an individual commits any violation referred to in Articles 39 through 42 in conducting the business affairs of the corporation or individual, the corporation or individual shall, in addition to punishing the violator accordingly, be punished by a fine prescribed in the relevant Article: Provided, That the same shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business affairs to prevent such violation.

Article 44 (Administrative Fines)

(1) Any of the following persons shall be subject to an administrative fine not exceeding ten million won:
<Amended by Act No. 11536, Dec. 11, 2012>

1. A person who fails to file a report for modification under the proviso to Article 8 (3), or Article 9 (2) and (3);
 2. A person who fails to file a report, or fails to comply with an order issued by the head of the relevant central administrative agency, under Article 10 (4);
 3. A person who imports a living modified organism through a place, including the port of import or airport not designated under Article 11 (1);
 4. A person who fails to file a report for modification under the proviso to Article 12 (2);
 5. Deleted; <by Act No. 11536, Dec. 11, 2012>
 6. A person who fails to file a report for modification under the proviso to Article 22 (2), or Article 22 (3);
 7. A person who fails to file a report under Article 22 (4);
 8. A person who fails to file a report for modification under the proviso to Article 22-2 (2);
 9. A person who fails to file a report for modification under the proviso to Article 22-3 (2), or Article 22-3 (3);
 10. A person who fails to file a report under Article 22-3 (4);
 11. A person who fails to file a report for modification under the proviso to Article 22-4 (2);
 12. A person who fails to prepare and keep records of management and operation under Article 26;
 13. A person who refuses to submit reports, materials, or samples under Article 36 (1) or (2), or refuses, obstructs, or evades access and inspection under Article 36 (1) or (2).
- (2) Administrative fines prescribed in paragraph (1) shall be imposed and collected by the head of the relevant central administrative agency or the head of the competent national authority, as prescribed by Presidential Decree. <Amended by Act No. 11536, Dec. 11, 2012>
- (3) through (5) Deleted. <by Act No. 9428, Feb. 6, 2009>

ADDENDUM

This Act shall enter into force on the date when the Protocol becomes effective in the Republic of Korea.

ADDENDA <Act No. 8356, Apr. 11, 2007>

Article 1 (Enforcement Date)

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

Articles 2 through 7 Omitted.

ADDENDA <Act No. 8762, Dec. 21, 2007>

Article 1 (Enforcement Date)

This Act shall enter into force on the date the Protocol becomes effective in the Republic of Korea.

Article 2 (Applicability to Approval for Import, etc.)

Matters concerning approval for import under the amended provisions of Article 8, and handling and management under the amended provisions of Article 25 shall apply to the living modified organisms that have been shipped in an exporting country after this Act enters into force.

Article 3 (Transitional Measures)

- (1) A person who intends to import living modified organisms may apply for a risk review under Article 8 (5) before this Act enters into force, and the head of the relevant central administrative agency may conduct the risk review under the same paragraph or under the amended provisions of Article 13 (1).
- (2) A person who intends to establish and operate a research facility may file an application therefor or a report thereon under the amended provisions of Article 22 (1), and the head of the relevant central administrative agency may grant permission therefor or accept such report under the amended provisions of the same paragraph.

Article 4 Omitted.

ADDENDA <Act No. 8852, Feb. 29, 2008>

Article 1 (Enforcement Date)

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

Articles 2 through 7 Omitted.

ADDENDUM <Act No. 9241, Dec. 26, 2008>

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

ADDENDUM <Act No. 9428, Feb. 6, 2009>

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

ADDENDUM <Act No. 9882, Dec. 30, 2009>

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

ADDENDA <Act No. 9932, Jan. 18, 2010>

Article 1 (Enforcement Date)

This Act shall enter into force two months after its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA <Act No. 11536, Dec. 11, 2012>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Article 2 (Applicability to Risk Review)

The amended provisions of Article 7-2 shall apply beginning with the living modified organism for which an application for approval is first filed after this Act enters into force.

Article 3 (Applicability to Import of Living Modified Organisms for Research and Development, etc.)

The amended provisions of Article 9 shall apply beginning with the living modified organism for research and development, etc. which is first imported after this Act enters into force.

Article 4 (Applicability to Inspection on Import)

The amended provisions of Article 10 shall apply beginning with the living modified organism which is first imported after this Act enters into force.

Article 5 (Applicability to Hearings)

The amended provisions of Article 37 shall apply beginning with the disposition which is first granted after this Act enters into force.

Article 6 (Transitional Measure concerning Approval, etc. for Production of Living Modified Organisms)

Where any approval for the production of living modified organisms has been granted pursuant to the previous provisions of Article 12 as at the time this Act enters into force, it shall be deemed as if approval or permission therefor had been granted or reporting thereon had been made, pursuant to the amended provisions of Articles 22-3 and 22-4.

Article 7 (Transitional Measure concerning Commissioned Members of the Biosafety Committee)

The members of the Biosafety Committee who were commissioned pursuant to the previous provisions as at the time this Act enters into force shall be deemed to be the members thereof who are commissioned pursuant to the amended provisions of Article 31.

Article 8 (Transitional Measure concerning Administrative Dispositions)

The administrative dispositions imposed for violations committed before this Act enters into force shall be governed by the previous provisions.

Article 9 Omitted.

ADDENDA <Act No. 11690, Mar. 23, 2013>

Article 1 (Enforcement Date)

- (1) This Act shall enter into force on the date of its promulgation.
- (2) Omitted.

Articles 2 through 7 Omitted.

ADDENDA <Act No. 12844, Nov. 19, 2014>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amendments to the Acts to be amended pursuant to Article 6 of the Addenda, which were promulgated before this Act enters into force but enforcement dates of which have yet to arrive, shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 7 Omitted.

ADDENDA <Act No. 14839, Jul. 26, 2017>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amendments to the Acts to be amended pursuant to Article 5 of the Addenda, which were promulgated before this Act enters into force but the enforcement dates of which have yet to arrive, shall enter into force on the enforcement date of the relevant Act.

Articles 2 through 6 Omitted.

ADDENDUM <Act No. 15181, Dec. 12, 2017>

This Act shall enter into force one year after the date of its promulgation.

Last updated : 2019-03-26