

# ENFORCEMENT DECREE OF THE BIOTECHNOLOGY SUPPORT ACT

Presidential Decree No. 14731, Jul. 13, 1995  
Amended by Presidential Decree No. 16326, May 24, 1999  
Presidential Decree No. 17048, Dec. 29, 2000  
Presidential Decree No. 17115, Jan. 29, 2001  
Presidential Decree No. 18452, Jun. 29, 2004  
Presidential Decree No. 20740, Feb. 29, 2008  
Presidential Decree No. 22075, Mar. 15, 2010  
Presidential Decree No. 24423, Mar. 23, 2013

## **Article 1 (Purpose)**

The purpose of this Decree is to prescribe matters delegated by the Biotechnology Support Act (hereinafter referred to as the "Act") and matters necessary for the enforcement of the Act. <Amended by Presidential Decree No. 14731, Jul. 13, 1995>

## **Article 2 (Basic Plan for Biotechnology Support)**

The Minister of Science, ICT and Future Planning shall devise a basic plan for biotechnology support under Article 4 (2) of the Act every five years, and notify the heads of the ministries and agencies concerned thereof as referred to in Article 13 (1) 2 through 7 of the Act. <Amended by Presidential Decree No. 14731, Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>

## **Article 3 (Establishment of Annual Implementation Plan for Biotechnology Support and Notification of Its Modification)**

Where the heads of the ministries and agencies concerned as referred to in Article 13 (1) 2 through 7 of the Act has established the annual implementation plan for the biotechnology support (hereinafter referred to as "implementation plan") or modified it, he shall notify the Minister of Science, ICT and Future Planning thereof under Article 5 (1) of the Act. <Amended by Presidential Decree No. 14731, Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>

## **Article 4 (Formulation of Basic Guidelines for Implementation Plan)**

The Minister of Science, ICT and Future Planning shall undergo the deliberation of the Council for Comprehensive Biotechnology Policy (hereinafter referred to as the "Council") provided for in Article 6

(1) when the basic guidelines necessary for the establishment of the implementation plan are formulated under Article 5 (3) of the Act. <Amended by Presidential Decree No. 14731, Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>

#### **Article 5 (Composition of Council)**

(1) Deleted. <by Presidential Decree No. 18452, Jun. 29, 2004>

(2) The term "central administrative agencies concerned that are pre- scribed by Presidential Decree" in Article 6 (4) 1 of the Act means the agencies falling under each of the following subparagraphs: <Amended by Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24423, Mar. 23, 2013>

1. The Ministry of Strategy and Finance;
2. The Ministry of Science, ICT and Future Planning;
3. The Ministry of Education;
4. The Ministry of Agriculture, Food and Rural Affairs;
5. The Ministry of Trade, Industry and Energy;
6. The Ministry of Health and Welfare;
7. The Ministry of Environment;
8. The Ministry of Oceans and Fisheries.

(3) The members provided for in Article 6 (4) 2 of the Act shall be commissioned by the Minister of Science, ICT and Future Planning and the terms of office for the commissioned members shall be two years. <Amended by Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>

#### **Article 6 (Duties of Chairman of Council)**

(1) The chairman of the Council shall exercise overall control and supervision of Council affairs and convene and preside over meetings.

(2) If the chairman is prevented from performing his duties, a councilmember designated by the chairman of the Council shall act for the chairman.

#### **Article 7 (Meeting)**

(1) The meetings of the Council shall be divided into regular and special meetings.

(2) Regular meetings shall be convened once a year on a date designated by the Council, and special meetings shall be convened by the chairman as the occasion arises.

(3) The meetings shall come to order with a majority of all the registered members attending and resolutions shall be adopted by an affirmative vote of a majority of members present.

#### **Article 8 (Secretary)**

(1) One secretary shall be appointed to the Council to handle general affairs of the Council.

(2) The Minister of Science, ICT and Future Planning shall appoint one secretary from among public officials under his jurisdiction. <Amended by Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree

*No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>*

**Article 9 Deleted.** *<by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 10 (Hearing of Opinions)**

The Council may, if it is deemed necessary, have related public officials or experts with professional knowledge and experience in the field of bio- technology attend meetings of the Council and state their opinions.

**Article 11 (Allowances)**

Expenses or allowances for council members, public officials and experts who attend the meetings of the Council may be paid within the limit of the budget: Provided, That this shall not apply if the public officials who are council members attend the meetings directly related with their pro- per duties. *<Amended by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 12 (Support for Joint Research)**

In order to promote joint research for the study of biotechnology, and development of technology among academic circles, research institutes and industries, the Minister of Science, ICT and Future Planning may recommend joint procurement of research equipment and instruments, reagents and joint utilization of research facilities, and may provide the necessary support for such activities. *<Amended by Presidential Decree No. 14731, Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>*

**Article 13 (Support for Manufacture of New Technology Products)**

(1) In order to support the manufacture of new technology products, and to promote the industrialization of biotechnology research results, the Minister of Science, ICT and Future Planning may request the heads of the ministries and agencies concerned to take necessary measures such as financial assistance and purchase of the products on a priority basis, etc. after undergoing the deliberation of the Council. *<Amended by Presidential Decree No. 14731, Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 24423, Mar. 23, 2013>*

(2) The heads of the ministries and agencies concerned who have received requests as referred to in paragraph (1) will take necessary measures such as financial assistance, etc. unless there exist special reasons to the contrary.

**Article 14 (Formulation of Guidelines for Clinical Test and Inspection)**

(1) In order to establish a system of clinical testing and inspection for biotechnology-related products under the provisions of Article 14 of the Act, the Minister of Agriculture, Food and Rural Affairs, the Minister of Trade, Industry and Energy, the Minister of Health and Welfare, the Minister of Environment and the Minister of Oceans and Fisheries shall formulate and implement guidelines for clinical testing and inspection after undergoing the deliberation of the Council: Provided, That this shall not apply if it is otherwise prescribed by other Acts and subordinate statutes. *<Amended by the Presidential Decree No. 13870, Mar. 6, 1993; Presidential Decree No. 14446, Dec. 23, 1994; Presidential Decree No. Jul. 13, 1995; Presidential Decree No. 18452, Jun. 29, 2004; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 22075,*

*Mar. 15, 2010; Presidential Decree No. 24423, Mar. 23, 2013>*

(2) Guidelines for clinical testing and inspection as referred to in paragraph (1) shall include the matters falling under each of the following subparagraphs: Provided, That if there are matters which cannot be covered by such guidelines due to special characteristics of biotechnology-related products, such matters may not be included in the guidelines: *<Amended by the Presidential Decree No. 14731, Jul. 13, 1995>*

1. Animal tests of commodities produced or manufactured by using genetically modified organisms;
2. Clinical tests of pharmaceuticals produced or manufactured by using genetically modified organisms;
3. Analysis of components, degree of purity and degree of activity of commodities produced or manufactured by using genetically modified organisms;
4. Other necessary matters for clinical tests and inspection of biotechnological products.

#### **Article 15 (Formulation of Guidelines for Experiments)**

(1) Under the provisions of Article 15 of the Act, the Minister of Health and Welfare shall formulate and implement guidelines for experiments to promote the research and industrialization of biotechnology after undergoing the deliberation of the Council. *<Amended by Presidential Decree No. 14446, Dec. 23, 1994; Presidential Decree No. Jul. 13, 1995; Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010>*

(2) The guidelines for experiments as referred to in paragraph (1) shall include the matters falling under each of the following subparagraphs: *<Amended by Presidential Decree No. 14731, Jul. 13, 1995>*

1. Matters necessary to prevent biological risks such as the method of inhibiting the prevention of dissemination and increase of genetically modified organisms;
2. Matters necessary to prevent the occurrence of ethical problems such as the prohibition of genetic modification of human genes, etc. which may cause effects detrimental to the dignity of human beings.

#### **Article 16 (Designation and Operation of Organization in Charge of Nurturing Basic Medical Science)**

(1) Any organization in charge of nurturing the basic medical science provided for in Article 17 (1) of the Act shall be designated by the Minister of Science, ICT and Future Planning and the Minister of Health and Welfare after they consult thereabout. *<Amended by Presidential Decree No. 20740, Feb. 29, 2008; Presidential Decree No. 22075, Mar. 15, 2010; Presidential Decree No. 24423, Mar. 23, 2013>*

(2) Every organization in charge of nurturing the basic medical science shall perform the work falling under each of the following subparagraphs:

1. The undertaking and management of projects for nurturing the basic medical science; and
2. Assistance in academic and research activities in the field of the basic medical science.

**Article 17 Deleted.** *<by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 18 Deleted.** *<by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 19 Deleted.** *<by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 20 Deleted.** *<by Presidential Decree No. 18452, Jun. 29, 2004>*

**Article 21 Deleted.** <by Presidential Decree No. 18452, Jun. 29, 2004>

**Article 22 Deleted.** <by Presidential Decree No. 18452, Jun. 29, 2004>

**Article 23 (Shipment Prior to Acceptance of Import Declaration)**

(1) Items that may be allowed to be shipped prior to the acceptance of an import declaration thereon under Article 19 (2) of the Act shall be the following items recognized by the Minister of Science, ICT and Future Planning:

1. Biochemical reagents;
2. Radioactive substances reagents;
3. Microbial bacteria colony and cell colony of plants and animals;
4. Genetic substances;
5. Enzyme products;
6. Biotechnology-related products corresponding to those as referred to in subparagraphs 1 through 5.

(2) A person who intends to import any item falling under each subparagraph of paragraph (1) in accordance with the procedures for the shipment prior to the acceptance of an import declaration shall submit documents containing a statement of names and volumes of the relevant items, reasons for the necessity of the shipment prior to the acceptance of an import declaration and other matters to the Minister of Science, ICT and Future Planning.

(3) Where the Minister of Science, ICT and Future Planning, upon receiving the documents under paragraph (2), deems it necessary to ship the relevant items into Korea before an import declaration is accepted after reviewing the details of the documents, he/she shall request the head of a competent customs office to approve the shipment of the relevant items prior to the acceptance of an import declaration pursuant to Article 252 of the Customs Act. In such cases, the head of the competent customs office shall approve the shipment prior to the acceptance of an import declaration unless any extenuating circumstance exists.

**ADDENDUM**

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

**ADDENDA** <Presidential Decree No. 13282, Feb. 1, 1991>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 5 Omitted.**

**ADDENDA** <Presidential Decree No. 13870, Mar. 6, 1993>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 4 Omitted.**

ADDENDA <Presidential Decree No. 14438, Dec. 23, 1994>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 5 Omitted.**

ADDENDA <Presidential Decree No. 14446, Dec. 23, 1994>

**Article 1 (Enforcement Date)**

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

**Articles 2 and 3 Omitted.**

ADDENDUM <Presidential Decree No. 14731, Jul. 13, 1995>

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

ADDENDA <Presidential Decree No. 16326, May 24, 1999>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 4 Omitted.**

ADDENDA <Presidential Decree No. 17048, Dec. 29, 2000>

**Article 1 (Enforcement Date)**

This Decree shall enter into force on January 1, 2001.

**Articles 2 through 8 Omitted.**

ADDENDA <Presidential Decree No. 17115, Jan. 29, 2001>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 5 Omitted.**

ADDENDUM <Presidential Decree No. 18452, Jun. 29, 2004>

This Decree shall enter into force on July 1, 2004.

ADDENDA <Presidential Decree No. 20740, Feb. 29, 2008>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 7 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.**

ADDENDA <Presidential Decree No. 24423, Mar. 23, 2013>

**Article 1 (Enforcement Date)**

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

**Articles 2 through 7 Omitted.**

