

# BIOTECHNOLOGY SUPPORT ACT

Act No. 4938, Jan. 5, 1995

Amended by Act No. 4980, Dec. 6, 1995

Act No. 5400, Aug. 28, 1997

Act No. 6400, Jan. 29, 2001

Act No. 7014, Dec. 30, 2003

Act No. 7284, Dec. 31, 2004

Act No. 8852, Feb. 29, 2008

Act No. 9932, Jan. 18, 2010

Act No. 10872, Jul. 21, 2011

Act No. 11683, Mar. 23, 2013

## Article 1 (Purpose)

The purpose of this Act is to develop and support biotechnology more efficiently by laying the foundation of biotechnology research and to contribute to the sound progress of the national economy by facilitating the industrialization of the technology.

## Article 2 (Definitions)

The term "biotechnology" in this Act means the science and technology falling under each of the following subparagraphs:

1. The science and technology that are aimed at researching and exploiting the biotechnological system, biomass, dielectrics or other materials derived therefrom in order to manufacture industrially useful products and to improve the production process; and
2. The science, including physiology, pathology and pharmacology (hereinafter referred to as the "basic medical science"), which is aimed at providing the basic knowledge of biotechnology by researching the origin of vital phenomenon, the cause of diseases and the process of the outbreak of illness.

## Article 3 (Scope of Application)

Except as otherwise prescribed by other Acts, matters concerning biotechnology shall be governed by this Act. *<Amended by Act No. 4938, Jan. 5, 1995; Amended by Act No. 11683, Mar. 23, 2013>*

## Article 4 (Establishment of Basic Plan for Biotechnology Support)

(1) The heads of the ministries and agencies concerned, pursuant to Article 13, shall submit plans related to biotechnology support to the Minister of Science, ICT and Future Planning by the jurisdiction of each

ministry and agency. <Amended by Act No. 4938, Jan. 5, 1995; Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>

(2) The Minister of Science, ICT and Future Planning shall formulate the basic plan for biotechnology support (hereinafter referred to as "basic plan") by integrating and coordinating the plans on biotechnology support relating to matters within the jurisdiction of such ministries and agencies which are submitted by the heads of the ministries and agencies concerned pursuant to paragraph (1). <Amended by Act No. 4938, Jan. 5, 1995; Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>

(3) The basic plan under paragraph (2) shall include the followings: <Amended by Act No. 4938, Jan. 5, 1995; Act No. 5400, Aug. 28, 1997; Act No. 11638, Mar. 23, 2013>

1. Comprehensive plans and guidelines on fundamental studies of biotechnology and the promotion of studies for industrial application thereof;
2. Guidelines related to a comprehensive development plan and an efficient utilization of human resources necessary for the research in biotechnology; and
3. Plans and guidelines related to research in biotechnology and the international exchange of industrial and technology manpower and the utilization of overseas scientists who engage in bio-technological research.

(4) If the Minister of Science, ICT and Future Planning intends to formulate the basic plan, he shall undergo the deliberation by the Council for Comprehensive Biotechnology Policy as referred to in Article 6. <Amended by Act No. 4938, Jan. 5, 1995; Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>

#### **Article 5 (Establishment, etc. of Annual Implementation Plan for Biotechnology Support)**

(1) The heads of the ministries and agencies concerned shall establish the annual implementation plan for biotechnology support (hereinafter referred to as "implementation plan") in accordance with the basic plan and implement it. <Amended by Act No. 4938, Jan. 5, 1995; Act No. 11638, Mar. 23, 2013>

(2) If the heads of the ministries and agencies concerned intend to establish their implementation plans, they shall consult with the Minister of Science, ICT and Future Planning in advance. <Amended by Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>

(3) The Minister of Science, ICT and Future Planning, if deemed necessary, may establish the basic guidelines necessary for establishing an implementation plan and inform the heads of the ministries and agencies concerned thereof. <Amended by Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>

(4) Necessary matters for the establishment and implementation of the such plan shall be prescribed by Presidential Decree. <Amended by Act No. 11638, Mar. 23, 2013>

#### **Article 6 (Council for Comprehensive Biotechnology Policy)**

(1) The Council for Comprehensive Biotechnology Policy (hereinafter referred to as the "Council") shall be formed under the authority of the Minister of Science, ICT and Future Planning for the management of affairs relating to establishment of the basic plan and execution and coordination thereof. <Amended by Act

*No. 4938, Jan. 5, 1995; Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>*

(2) The Council shall deliberate and make decisions regarding the following matters: *<Amended by Act No. 4938, Jan. 5, 1995; Act No. 5400, Aug. 28, 1997; Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 10872, Jul. 21, 2011; Act No. 11638, Mar. 23, 2013>*

1. Formation of plans on fundamental studies of biotechnology and the promotion of studies for industrial application thereof, and the coordination of application of such plans;
2. The establishment of the basic plan for research and technology development in biotechnology and establishment of major policy pursuant to the basic plan and coordination of its implementation;
3. Comprehensive planning for the development and utilization of human resources in the field of biotechnology and establishment of major policy and guidelines for the utilization of human resources, and coordination of its implementation;
4. Establishment of the basic plan for the development and exchange of biotechnology research and its industrial and technology manpower as well as establishment of a plan for the utilization of overseas scientists and engineers and the coordination of its implementation;
5. Establishment of research and development planning for utilization and preservation of genetic resources and coordination of its implementation;
6. Establishment and modification of a basic plan for brain research promotion under Article 5 (2) of the Brain Research Promotion Act, followed by establishment of major policies and adjustment to the implementation of such policies;
7. Matters related to expanding budget for brain research, including the plan for expansion of investments in brain research under Article 9 of the Brain Research Promotion Act;
8. Establishment of a comprehensive plan for the development and exchange of human resources in the brain research field, followed by establishment of major policies and guidelines for human resource management, and adjustment to the implementation thereof;
9. Establishment of a plan for utilization and preservation of the outcomes of brain research, and adjustment to the implementation thereof;
10. Other matters that the Minister of Science, ICT and Future Planning deems necessary for the support for biotechnology and promotion of brain research.

(3) The Council shall consist of not more than 17 members, including one chairman. *<Newly Inserted by Act No. 7014, Dec. 30, 2003>*

(4) The Minister of Science, ICT and Future Planning shall be the chairman of the Council and persons falling under each of the following subparagraphs shall be the members of the Council: *<Newly Inserted by Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 11638, Mar. 23, 2013>*

1. Vice-Ministerial level public officials of central administrative agencies concerned who are prescribed by Presidential Decree;
2. Persons specializing in biotechnology in academia, research institutes and the industrial sector, and experts on life ethics.

(5) Necessary matters concerning the organization and operation, etc. of the Council, with the exception of the matters prescribed by this Act, shall be prescribed by Presidential Decree. <Newly Inserted by Act No. 7014, Dec. 30, 2003>

**Article 7 Deleted.** <by Act No. 7014, Dec. 30, 2003>

**Article 8 Deleted.** <by Act No. 7014, Dec. 30, 2003>

**Article 9 (Research and Technological Cooperation)**

The Minister of Science, ICT and Future Planning shall make efforts to promote international cooperation in bio-technological research and technological development and establish efficient policies for inducing advanced technologies.

**Article 10 (Promotion of Cooperative Research)**

The Government shall promote cooperative activities among academia, research institutes and industry for efficient research and technological development in biotechnology.

**Article 11 (Assistance in Facilitating Industrial Application of Biotechnology)**

The Government may take policy steps to provide assistance in the matters falling under each of the following subparagraphs in order to vitalize the research and development of biotechnology and to facilitate the industrial application of the results thereof:

1. Matters concerning assistance in the production of goods using new biotechnology-related technology;
2. Matters concerning research and development aimed at facilitating the industrial application of the results of biotechnology research and the building of regional research and development bases; and
3. Matters concerning assistance in the start-up of small and medium venture enterprises involved in biotechnology.

**Article 12 (Collection and Distribution of Technology Information)**

The Government shall endeavor to promote research and development by gathering information for biotechnological research and distributing it to related organizations.

**Article 13 (Establishment of Policy to Support Biotechnology, etc.)**

(1) The Government shall take policy steps falling under each of the following subparagraphs with respect to the basic research in biotechnology and the research on its industrial application in order to efficiently nurture the biotechnology: Provided, That the work of facilitating the research and development of the basic medical science and nurturing the basic medical science shall be put under jurisdiction of the Minister of Science, ICT and Future Planning and the Minister of Health and Welfare: <Amended by Act No. 5400, Aug. 28, 1997; Act No. 6400, Jan. 29, 2001; Act No. 7014, Dec. 30, 2003; Act No. 7284, Dec. 31, 2004; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11638, Mar. 23, 2013>

1. The Minister of Science, ICT and Future Planning: policy measures for support and comprehensive adjustment of establishment of the basic plan under Article 4 (2) and each department's policy, support for developing basic technology related to bio-technology and cutting-edge technology, support for

studies on securing, analyzing, utilizing and preserving genes that are valuable in the field of science technology, and support for developing information and communications technology to nurture and advance bio-technology and institutions thereof;

2. The Minister of Education: policy measures that are agreed with the Minister of Science, ICT and Future Planning, which are aimed at nurturing experts to facilitate studies on bio-technology and supporting studies on basic bio-technology;

3. The Minister of Agriculture, Food and Rural Affairs: policy measures for supporting applied research on breeding and improving animals and plants as well as germs, developing new food stuff, supporting basic research on securing, analyzing, utilizing and preserving genes useful in the field of agriculture, and nurturing and advancing related research institutions;

4. The Minister of Trade, Industry and Energy: policy measures for providing assistance in enhancing the biotechnology-related industrial process, developing new and renewable energy, efficiently utilizing energy and mineral resources and developing biotechnology-related manufacturing technology, and facilitating the industrialization of such developed technology;

4-2. Deleted; <by Act No. 8852, Feb. 29, 2008>

5. The Minister of Health and Welfare: policy measures for providing assistance in facilitating the research development of technology related to biotechnology involving health, medical services and food sanitation, training the related expert workforce, nurturing projects relating to clinical tests, and supporting research;

6. The Minister of the Environment: policy measures for developing related technology and supporting basic and applied research for conservation of biodiversity, sustainable uses of its components, treatment of foul water and wastes, and prevention of environmental pollution, etc.;

7. The Minister of Oceans and Fisheries: policy measures for supporting applied research on producing useful substances using fisheries, breeding and improving species of marine creatures, and providing assistance in securing, analyzing, utilizing, and preserving useful genes in the field of oceans and fisheries, and nurturing and developing technologies for preventing marine pollution and nurture and nurturing and enhancing related research institutes.

(2) The Minister of Science, ICT and Future Planning and the Minister of Health and Welfare shall, when they intend to develop a policy step to nurture the basic medical science, consult with each other thereabout. <Newly Inserted by Act No. 7014, Dec. 30, 2003; Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No. 11683, Mar. 23, 2013>

#### **Article 14 (Safety and Clinical Tests)**

(1) The Government shall establish a system regarding safety and clinical tests for bio-technological products. <Amended by Act No. 4938, Jan. 5, 1995; Act No. 11683, Mar. 23, 2013>

(2) Necessary matters for the establishment of systems for safety and clinical tests referred to in paragraph (1) shall be prescribed by the Presidential Decree. <Amended by Act No. 11683, Mar. 23, 2013>

#### **Article 15 (Preparation and Implementation of Experimental Guidelines)**

(1) The Government shall prepare and implement experimental guidelines for promotion of biotechnological research and industrialization thereof. *<Amended by Act No. 4938, Jan. 5, 1995; Act No. 11683, Mar. 23, 2013>*

(2) The experimental guidelines as referred to in paragraph (1) shall include measures necessary to prevent biological hazards, negative influences upon the environment and any ethical problems that may arise in the course of research on biotechnology and its industrialization, and shall also include safety standards for the transfer, handling and use of genetically converted organism. *<Amended by Act No. 4938, Jan. 5, 1995; Act No. 11683, Mar. 23, 2013>*

#### **Article 16 (Korea Research Institute of Bioscience and Biotechnology)**

(1) The Korea Research Institute for Bioscience and Biotechnology (hereinafter referred to as the "Research Institute") may be established to support the biotechnological research (excluding the basic medical science; hereafter in this Article the same shall apply), the utilization and the preservation of genetic resources and to maintain and develop a mutually cooperative system among academic institutions, research institutes and industry. *<Amended by Act No. 4938, Jan. 5, 1995; Act No. 7014, Dec. 30, 2003; Act No. 11683, Mar. 23, 2013>*

(2) The Research Institute under paragraph (1) shall be a specific research institute to which the Support of Specific Research Institutions Act applies. *<Amended by Act No. 7014, Dec. 30, 2003; Act No. 11683, Mar. 23, 2013>*

(3) Deleted. *<by Act No. 4938, Dec. 6, 1995>*

#### **Article 17 (Organization in Charge of Nurturing Basic Medical Science)**

(1) The Government may designate and operate an organization in charge of nurturing the basic medical science (hereinafter referred to as the "organization in charge of nurturing the basic medical science").

(2) The Government may financially support costs necessary to operate the organization in charge of nurturing the basic medical science within limits of budget.

(3) Necessary matters concerning the designation and operation of the organization in charge of nurturing the basic medical science shall be prescribed by the Presidential Decree.

**Article 18 Deleted.** *<by Act No. 4938, Dec. 6, 1995>*

#### **Article 19 (Ex Post Facto Approval for Customs Clearance Procedures)**

(1) Deleted. *<by Act No. 7014, Dec. 30, 2003>*

(2) In order to secure the safety of items that are not domestically produced from among materials, machines or reagents necessary to carry out bio- technology research activities, which may spoil due to lengthy customs procedures, customs formalities for approval afterwards can substitute for the existing process, under the conditions as prescribed by the Presidential Decree, notwithstanding the procedures as prescribed by the Customs Act. *<Amended by Act No. 7014, Dec. 30, 2003; Act No. 11683, Mar. 23, 2013>*

**Article 20 Deleted.** *<by Act No. 7014, Dec. 30, 2003>*

## ADDENDUM

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

ADDENDA <Act No. 4268, Dec. 27, 1990>

### **Article 1 (Enforcement Date)**

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

**Articles 2 through 10 Omitted.**

ADDENDA <Act No. 4541, Mar. 6, 1993>

### **Article 1 (Enforcement Date)**

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

**Articles 2 through 5 Omitted.**

ADDENDUM <Act No. 4938, Jan. 5, 1995>

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

ADDENDA <Act No. 4980, Dec. 6, 1995>

### **Article 1 (Enforcement Date)**

This Act shall enter into force on January 1, 1996. (Proviso Omitted.)

**Article 2 Omitted.**

ADDENDUM <Act No. 5400, Aug. 28, 1997>

This Act shall enter into force three months after its promulgation.

ADDENDA <Act No. 6400, Jan. 29, 2001>

### **Article 1 (Enforcement Date)**

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

**Articles 2 through 4 Omitted.**

ADDENDUM <Act No. 7014, Dec. 30, 2003>

This Act shall enter into force six months following the date of its promulgation.

ADDENDA <Act No. 7284, Dec. 31, 2004>

### **Article 1 (Enforcement Date)**

This Act shall enter into force six months after the date of its promulgation.

**Articles 2 through 5 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.**

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

**Article 1 (Enforcement Date)**

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

**Articles 2 through 5 Omitted.**

ADDENDUM <Act No. 10872, Jul. 21, 2011>

This Act shall enter into force three months after the date of its promulgation.

ADDENDA <Act No. 11683, Mar. 23, 2013>

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