

## **Revision of Biotechnology Support Act for Accelerating the Bioeconomy**

**Hyeon-su Kim<sup>\*</sup>, Seong-hee Yoo<sup>\*\*</sup>, Min Seol<sup>\*\*\*</sup>, Seong-hoon  
Moon<sup>\*\*\*\*</sup>, Heung-yeol Kim<sup>\*\*\*\*\*</sup>**

**Abstract** The Biotechnology Support Act has provided a legal basis for promoting the biotechnology field as the highest legal authority in the biosciences since its enactment in 1983, and has contributed to enhancing Korea's biotechnology research and development (R&D) capabilities and to revitalizing bioscience ecosystems by establishing policies for supporting biotechnology, expanding the government research and development, and promoting industrial applications.

The revised bill of the Biotechnology Support Act is the law that reflects changes in the technological and social environment and that provides a legal basis for practical support of government policies such as total periodic research support, commercialization empowerment, and creation of an innovative research environment, and it will come into effect in November, 2020 after a six-month grace period.

The main contents of the revised bill are 1) increasing status as a general norm in the biotechnology field, 2) establishing data evidence-based policies, 3) inducing biotechnology innovation, and 4) promoting regulatory science, especially research and development.

This revision has been reorganized in a timely manner in accordance with the current technological advancements, changes in society and environment, and both quantitative and qualitative growth of the domestic bioscience ecosystems and its competitiveness are expected by systematic supports and promotions of the government during the whole period in terms of research and development (R&D) as well as business and industrialization.

---

Submitted, December 11, 2020; 1st Revised, December 25, 2020; Accepted, December 28, 2020

\* Researcher, Biotech Policy Research Center, Korea Research Institute of Bioscience & Biotechnology, Daejeon, Korea; lawghost@kribb.re.kr

\*\* Researcher, Biotech Policy Research Center, Korea Research Institute of Bioscience & Biotechnology, Daejeon, Korea; ysh3513@kribb.re.kr

\*\*\* Researcher, Biotech Policy Research Center, Korea Research Institute of Bioscience & Biotechnology, Daejeon, Korea; rosebud@kribb.re.kr

\*\*\*\* Principal, Biotech Policy Research Center, Korea Research Institute of Bioscience & Biotechnology, Daejeon, Korea; shnb8@kribb.re.kr

\*\*\*\*\* Corresponding, Director, Biotech Policy Research Center, Korea Research Institute of Bioscience & Biotechnology, Daejeon, Korea; yeolhee@kribb.re.kr



This work is licensed under a Creative Commons  
Attribution-NonCommercial 4.0 International License.

**Keywords** Biotechnology Support Act, Bio-economy, K-Bio, Regulatory Science, South Korea

## **I. Introduction**

The Biotechnology Support Act was first enacted as the ‘Gene Engineering Support Act’ in 1983 and has provided a legal basis for promoting the biotechnology field. Since the enactment of the Act, it has contributed to enhancing Korea’s biotechnology research and development capabilities and to vitalizing the biosciences ecosystem by establishing biotechnology support policies, expanding the government research and development, and promoting industrial applications.

Based on the accumulated R&D capabilities by this time, the domestic biosciences ecosystem is growing rapidly with the investment for domestic ventures in the biosciences exceeding KRW 1 trillion, which surpasses the investment made on information and communication technology (ICT).<sup>1</sup> Since 2005, in addition, 67 out of 87 listed corporations with technology exemptions (companies with technological prowess and growth potential listed by technology evaluation of specialized evaluation agencies or by recommendation of the listing agent even if the current operating performance is insignificant) are bio-related companies (77%), and all of five companies with high market capitalization among them are drug discovery companies, which demonstrates the technological prowess of domestic corporations with successive technology exemption listing.<sup>2</sup>

※ HELIXMITH (KRW 1.82 trillion), GENEXINE (KRW 1.37 trillion), SILLAJEN (KRW 0.99 trillion), ABL BIO (KRW 0.98 trillion), ALTEOGEN (KRW 0.85 trillion)

In particular, Korean diagnostic kits (technology) were welcome all over the world and exported to 106 countries in the unprecedented COVID-19 pandemic crisis, confirming the growth potential and possibilities of ‘K-Bio.’<sup>3</sup>

---

<sup>1</sup> ETNews(2019), Technology exports exceeded KRW 8 trillion -Bio companies shone. Retrieved from <https://www.etnews.com/20191230000311>

<sup>2</sup> Korea Exchange(2020), Performance and evaluation after the introduction of the KOSDAQ listing with technology exception (2005), January 20.

<sup>3</sup> KITA(2020), Korea’s Covid-19 diagnostic kit exports surge-106 countries, 139t. Retrieved from [https://www.kita.net/cmmrcInfo/cmmrcNews/cmmrcNews/cmmrcNewsDetail.do?pageIndex=1&ndex=57698&sSiteid=1&searchReqType=detail&searchCondition=TITLE&searchStartDate=&searchEndDate=&categorySearch=1&searchKeyword&logGb=A9400\\_01](https://www.kita.net/cmmrcInfo/cmmrcNews/cmmrcNews/cmmrcNewsDetail.do?pageIndex=1&ndex=57698&sSiteid=1&searchReqType=detail&searchCondition=TITLE&searchStartDate=&searchEndDate=&categorySearch=1&searchKeyword&logGb=A9400_01)

At this point, the Biotechnology Support Act was revised on May 19, 2020 to reflect changes in the technological and social environment and to provide a legal basis for practical support for government policies such as total periodic research support, enhancement of commercialization capabilities, and creation of an innovative research environment, and it is scheduled to come into effect on November 20 after a six-month grace period.

## **1. Research Methodology**

The purpose of this study is to introduce the case of the Republic of Korea in which various policies have been established and implemented based on the enactment of the Biotechnology Support Act, a framework law for the promotion of biotechnology, which is rare in other countries. Therefore, this study analyzes the problems of the previous Biotechnology Support Act and examines in which direction the Act was revised. For the study, various reports, research papers, and press releases were reviewed.

## **2. Review of Preceding Studies**

There are not many studies on the Biotechnology Support Act in Korea. This may be because the impact or expectations of biotechnology on the industrial ecosystem so far have not been very high. In a recent study by Chongmin Yoon (2018)<sup>4</sup>, nevertheless, biotechnology is an emerging field with an important means to solve human issues such as diseases, the environment, food and energy, and it is predicted that biotechnology will lead to bio-based economic growth with the collaboration of other fields such as chemistry and physics, not only with ICT. In the process, it analyzes the operating system and the main contents of the previous Biotechnology Support Act and proposes revised measures. In the preceding studies, however, the analysis of opinions of universities, research institutes and industry collaboration experts was omitted on the necessity of a revision, and it was not reviewed how the actual legislations were revised and how the government policies were operated and implemented based on it. Therefore, this study also analyzes and describes these issues.

---

<sup>4</sup> Yoon, Chongmin. (2018), A Study on the Improvement of Legislation on Biotechnology Support Act in the Age of Bio-Economy, *Law Research* 29(1), pp. 373-405.

## **II. The Necessity of a Revision**

### **1. Foreign Policies for Promoting the Biotechnology Field**

The importance of biotechnology is being emphasized as an optimal alternative that can solve human issues such as aging, infectious diseases, food security, and climate change. In addition, it is a representative and promising field in the era of the fourth industrial revolution that can create new added value such as new technologies and new industries through convergence with other scientific technologies including ICT and nanotechnology (NT). Particularly, it is receiving attention as a representative field of innovative growth that can create economic effects such as technology start-ups and technology transfer throughout the entire R&D process, not only by the sale of products and services as the final results, and that can secure technology-based high-quality jobs.

Accordingly, major countries are preparing a national level bio-economic blueprint and are actively participating in global competition due to the preoccupation of the biotechnology market-leading, and therefore, review legislations for promoting and supporting biotechnology, focusing on the United States and Japan.

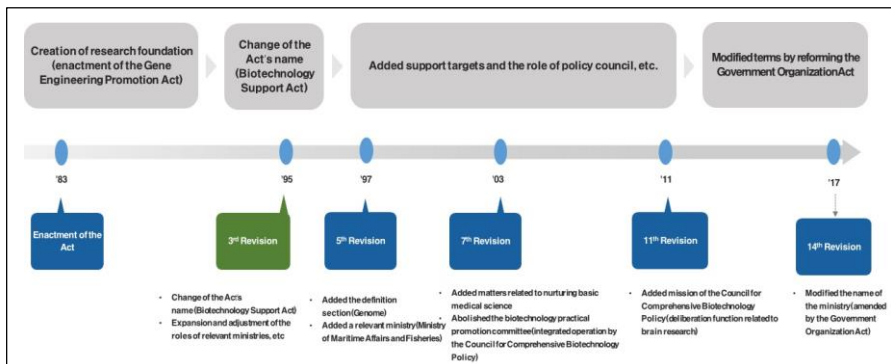
Unlike in Korea, first of all, any legislations that act as framework laws do not exist outside of the biotechnology field in foreign countries, and the biotechnology field is being promoted and supported according to individual laws that apply to national policies and certain issues. The United States enacted the National Institutes of Health (NIH) Reform Act of 2006. As biomedicine and public health research became more important, the Act was enacted to enhance its functions through reorganization of the National Institutes of Health, and it was the basis for the program adjustment and planning in NIH, the establishment of a strategic initiative department, a common fund-raising, and operational management of the Scientific Management Review Board. It induced technological innovation and vitalization of the industrial ecosystem by accelerating collaboration among NIH research institutes and by promoting pilot projects (human microbiome project, etc.). In addition, the 21st Century Cures Act was enacted in December 2016. The Act is aimed at accelerating medical product development and bringing new innovations and advances to patients more quickly and efficiently. Specially, it provides the basis for supporting cancer, stem cell and brain research, and presents the rationalization direction of unnecessary regulations for innovation.

Next, Japan enacted the Act to Promote Healthcare and Medical Strategy in 2016. The Act was enacted in order to comprehensively and systematically promote research and development for providing world-class standards of medical services with the aim of contributing to the formation of a society of

health and longevity. Moreover, this Act became the basis of the necessity of promoting consistent policies from basic research to practical use in the health and medical field and for the establishment of the Japan Agency for Medical Research and Development (AMED). In addition, the Next Generation Medical Infrastructure Act (2018) was enacted in order to ease regulations on the prior consent of personal medical information, and improve research and development and digitization in the medical field. The Act was published as a national policy in order to utilize medical data and provides the basis for processing personal information anonymously. This made the identification of a specific individual impossible.

## 2. Progress on the Revision of the Domestic System (Biotechnology Support Act)

The beginning of the Biotechnology Support Act dates back to December 31, 1983. The Biotechnology Support Act, enacted first under the name of the Gene Engineering Support Act, has been revised 15 times: 10 times have been due to the revision of other laws and 5 times have been substantial revisions.



**Figure 1 Progress on the Revision of the Biotechnology Support Act<sup>5</sup>**

The year 1983 was a time when expectations for the life sciences were ripening by technological development such as genetic reassembly, cell fusion, and cell nuclear transfer. These circumstances were reflected in the name of the Gene Engineering Support Act. However, the field of genetic engineering simply could not cover all biotechnology areas since genetic engineering technology has developed rapidly and both protein engineering and bioprocessing

<sup>5</sup> Yoon, Chongmin. (2018), A Study on the Improvement of Legislation on Biotechnology Support Act in the Age of Bio-Economy, Law Research 29(1), pp. 373-405.

technology have become important. In order to overcome these limitations, the name of the Act changed to the Biotechnology Support Act in 1995, and it has redefined the biotechnology field.

In 1997, the genome, the basis of biotechnology, was readjusted to be included in the scope of the biotechnology field and the Ministry of Maritime Affairs and Fisheries was added as the relevant ministry. This was a measure that reflected the development of life science at the time. In 2003, in addition, basic medical science was included in the policy target for efficient support of biotechnology and a bill was prepared to designate and promote the organization of basic medical science in order to achieve this goal. In the revision of 2011, matters related to the 'Basic Plan for Brain Research Promotion' were added to the deliberations of the Council for Comprehensive Biotechnology Policy which is a policy conciliation institution. The last major revision was in 2003 and inter-ministerial works related to biotechnology promotion were readjusted in accordance with the reorganization of the Government Organization Act that unifies the Ministry of Science and Technology and the Ministry of Information and Communication.

### **3. Limitations of the Biotechnology Support Act**

Although the existing Biotechnology Support Act had legislative purposes established to create the foundation for the biotechnology research, to support and develop biotechnology more efficiently, and to promote the industrialization of the development technologies, the regulations were insufficient for commercialization, industrialization, and infrastructure development. In particular, the definitions of the terminologies regarding biotechnology did not reflect the stream of times and there was no provision to support research and development directly, and the applicable provisions were insufficient for promoting industrialization and commercialization. The definition of biotechnology had not been changed since the revision in 2003 so that there was a limit in generating new value and establishing business by convergence with IT and NT. Although research and development should be activated in order to revitalize the biotechnology field, there was no provision to support it systematically so that the system was insufficient in tasks such as citing other laws including the Framework Act on Science and Technology. Even though there were provisions for promotion of commercialization and industrialization in the existing legislations, the contents were general and abstract, including support for producing new technology products related to biotechnology, matters for establishing regional bases, and support for small and medium-sized enterprises (SMEs) and start-ups.

According to the study results by Chongmin Yoon, etc. (2017)<sup>6</sup>, in particular, the governmental support factors required in the field were identified for total periodic support from R&D to industrialization regarding biotechnology, creation of the research environment, and enhancement of the private ecosystem capability, and the main results are as follows. First, the biotech workers had a high degree of the overall understanding of the Biotechnology Support Act, and the response rate was very high that the current Biotechnology Support Act needs to be revised to fit the stream of times due to insufficient matters on the technological innovation and the industrialization promotion (91.2%).

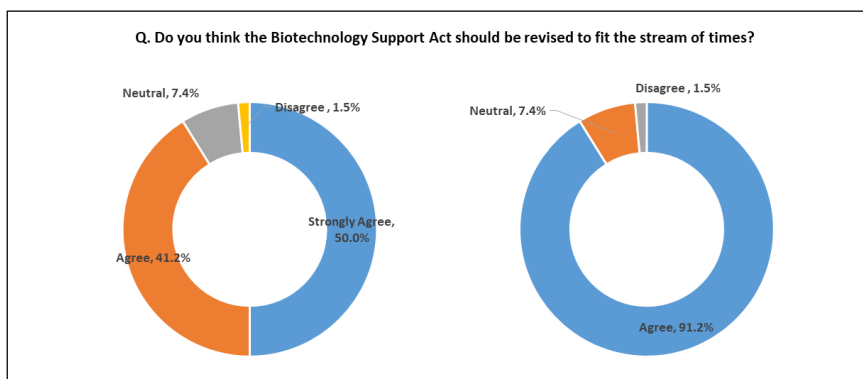
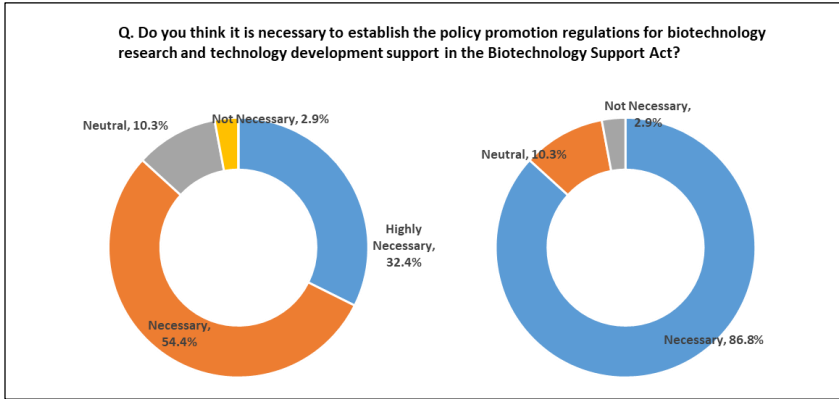


Figure 2 Survey results on the revision of the Biotechnology Support Act

Next, although the Act is a general norm in the biotechnology field, it was mentioned that the policy promotion regulations are insufficient for biotechnology research and technology development support.

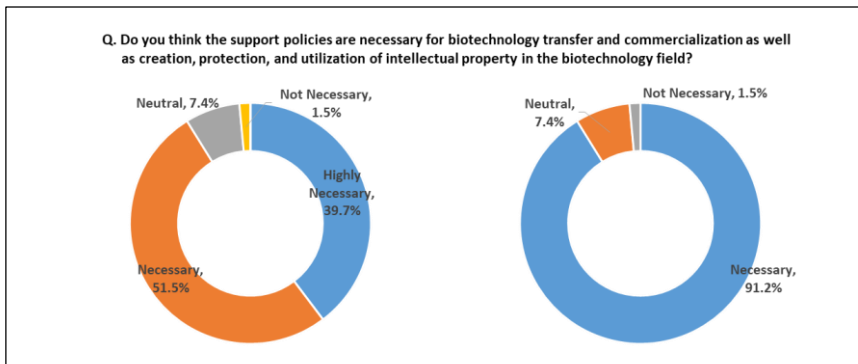
---

<sup>6</sup> Yoon, Chongmin. et al(2017), A Study on the Improvement Method of Legal Systems for Innovation of Biotechnology and Industrialization Promotion, National Research Foundation of Korea.



**Figure 3 Survey Results on the necessity of preparing the policy promotion regulations in the Biotechnology Support Act**

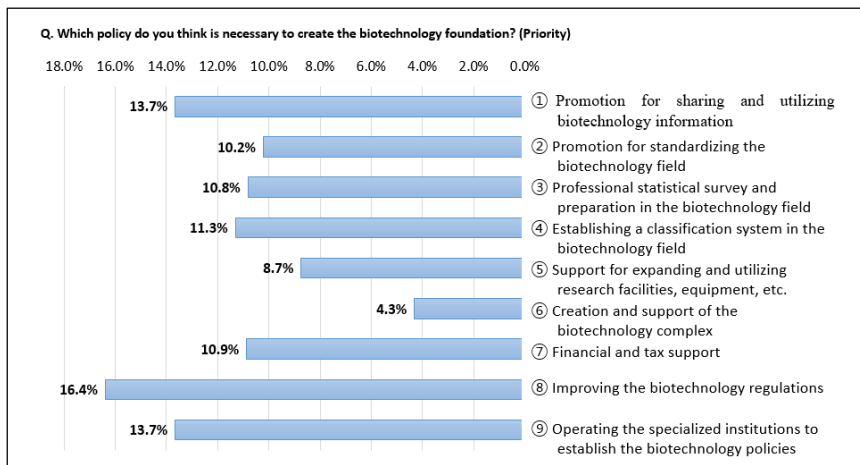
In particular, there were many opinions that the support policies are necessary for the transfer and commercialization of biotechnology and for creation, protection, and utilization of intellectual property in biotechnology.



**Figure 4 Survey Results on the necessity of the support policies in the biotechnology field**

Lastly, the foundation and the environment such as the establishment of related ecosystems should be properly equipped in order to facilitate technology development and industrialization in the biotechnology field, and ‘improving the biotechnology regulations’ was considered as the most necessary policy for creating the biotechnology foundation, followed by ‘operating the specialized institutions to establish the biotechnology policies’ and ‘promotion for sharing and utilizing biotechnology information.’





**Figure 5 Survey Results on Necessary Policies for Creating the Foundation in the Biotechnology Field**

The survey results confirmed that a consensus was formed for revising the existing Biotechnology Support Act, which is a framework law and a general norm in the biotechnology field, in order to properly respond to current and future issues such as technology convergence, industrialization, and governance, according to the changes of times and the environment.

In other words, a revision should contain various policy tools to promote the technology and industry, and should have a legislative structure governing the purpose, target, requirements, and procedures of promotion and support.

### **III. Main Contents of the Revision**

The revised bill is intended to reorganize a basis for reflecting technology development and changes in the society and the environment, enhancing total periodic capabilities from R&D to industrialization, and systematically creating and promoting practical results of biotechnology, a new growth engine of the future, in order to establish an innovative research environment.

Especially, in order to systematic support of bio-industry as a new growth engine in the future, the revision was promoted in four aspects to establish a legal basis for overseeing technological innovation and industrialization promotion. Specifically, it regulates that the government may establish and promote comprehensive policies on biotechnology development and industrialization promotion by removing partitions among ministries and

agencies and that universities, research institutes and industry collaborations may actively carry out technology development and make efforts to be utilized industrially. Furthermore, a legal basis was provided to improve unnecessary regulations that disrupt biotechnology innovation and the creation of new industries.

## **1. Securing Status as a General Norm for Biotechnology**

The principles of biotechnology promotion and industrial development were clarified in order to promote systematic development and utilization of new technologies in the biotechnology field, and the policy promotion system was supplemented to establish more substantial policies. Specifically, the responsibilities (Article 3<sup>7</sup>) were regulated in such a way so that the government, enterprises, universities, and research institutes as principals of biotechnology promotion and industrial development may perform technology development actively and its achievements should be utilized industrially.

Since the articles on the responsibilities explicitly assign the obligation to establish and enforce the policies that the legislations intend to achieve by placing those in the framework laws<sup>8</sup>, it is significant that the Biotechnology Support Act is expressly stipulated to act as a framework law on the biotechnology promotion and development. In particular, the basic plan for biotechnology support (Article 5<sup>9</sup>) newly included mid to long-term policy goals

---

### **7 Article 3 (Responsibilities of the Government, etc.)**

- ① The government shall establish and promote comprehensive policies for the biotechnology development and the industrialization promotion in order to achieve the purpose of this Act.
- ② Local governments shall establish and proceed the promotion policies for the biotechnology development and the industrialization promotion, reflecting national policies and regional characteristics.
- ③ Companies, universities, research institutes, and biotechnology-related institutions and organizations shall actively carry out the biotechnology development and endeavor to utilize the results thereof.

<sup>8</sup> Korea Ministry of Government Legislation(2019), Legislative Manuals and Aids. Retrieved from <https://www.moleg.go.kr/menu.es?mid=a10105030000>

### **9 Article 5 (Establishment of the Basic Plan for Biotechnology Support)**

- ③ The basic plan shall include the followings.
  1. Matters concerning the mid and long-term policy goals and directions for the biotechnology development and the industrialization promotion
  2. Matters concerning the biotechnology research and development, such as both basic and resource research of biotechnology, industrial application research, convergence research, etc.
  3. Matters concerning the protection and the utilization of intellectual property rights of the biotechnology achievements, technology transfer, and commercialization promotion
  4. Matters concerning promotion and support of the biotechnology-related industries and promotion of startups

such as protection of intellectual property rights, promotion of technology transfer and commercialization, and policies for developing infrastructures such as human resources, information, and statistics. The basis for the establishment of a working committee (Article 7<sup>10</sup>) was provided to pre-review deliberation matters in order to promote the operations of the Council for Comprehensive Biotechnology Policy. The working committee, the highest decision-making body in the biotechnology field, provides a ground for revitalizing in-depth discussions on policies in the biotechnology field.

## **2. Establishment of Policies based on Data Evidence**

The Act redefined the different classification system depending on the purpose and technical scope of ministries and agencies (Article 20<sup>11</sup>) and provided the grounds for promoting statistical survey (Article 21<sup>12</sup>) which is a research and

---

5. Matters concerning the creation and the support of the biotechnology foundation, such as biotechnology-related human resources, information, statistics, facilities, etc.

6. Matters concerning investment expansion and financing plans for the biotechnology development and the industrialization promotion

7. Matters concerning cooperation among biotechnology-related companies, universities, research institutions, and medical institutions

8. Matters concerning promotion of biotechnology-related international cooperation and support for overseas expansion

9. Matters concerning establishment and maintenance of systems for the biotechnology development and the industrialization promotion

10. Other important matters concerning the biotechnology development and the industrialization promotion

### **<sup>10</sup> Article 7 (Working Committee for Comprehensive Biotechnology Policy)**

⑤ A working committee may be established at the council in order to review the deliberation matters under paragraph (2) in advance and to process works, etc. delegated by the council.

### **<sup>11</sup> Article 20 (Establishment of Classification System)**

① The heads of the central administrative agencies concerned shall establish the biotechnology classification system and continuously improve and develop it for efficient management of information, human resources, technology, products and services in the biotechnology field.

② Necessary matters concerning the establishment of the classification system under paragraph (1) shall be prescribed by Presidential Decree.

### **<sup>12</sup> Article 21 (Biotechnology Statistical Survey and Analysis)**

① The heads of the central administrative agencies concerned shall research, analyze, and maintain relevant statistics in order to efficiently establish policies for the biotechnology development and the industrialization.

② The heads of the central administrative agencies concerned, if deemed necessary for statistical survey under paragraph (1), may request the related materials to the heads of the other central administrative agencies concerned, the heads of local governments, the heads of

analysis of quantified information that can observe the trend by managing continuously and systematically, research on the actual condition (Article 9<sup>13</sup>) for securing specific quantitative and qualitative information for policy establishment, and information research analysis (Article 19<sup>14</sup>) for the collection, management, and utilization of biotechnology information generated by innovation principals such as universities, research institutes, industries and medical institutions.

---

corporations, universities, research institutions, medical institutions, or other public institutions and organizations.

③ Any person in receipt of a request to furnish the materials under paragraph (2) shall comply with the request unless there are extraordinary circumstances, such as any sensitive information prescribed by Article 23 of the Personal Information Protection Act, etc.

④ Necessary matters concerning the subjects and methods of statistical survey and analysis under paragraph (1) and (2) shall be prescribed by Presidential Decree.

<sup>13</sup> **Article 9 (Research on the Actual Condition)**

① The heads of the central administrative agencies concerned may conduct research on the actual condition of the biotechnology development and the industrialization in order to secure the basic materials necessary for the biotechnology development and the industrialization promotion.

② The heads of the central administrative agencies concerned, if deemed necessary for the research on the actual condition under paragraph (1), may request to furnish the necessary materials to the heads of the other central administrative agencies concerned, the Special Metropolitan City Mayor, Metropolitan City Mayors, Special Self-Governing Province Mayor, Do Governors, Special Self-Governing Province Governors, the heads of corporations, universities, research institutions, medical institutions, or other public institutions and organizations.

③ Any person in receipt of a request to furnish the materials under paragraph (2) shall comply with the request unless there are extraordinary circumstances, such as any sensitive information prescribed by Article 23 of the Personal Information Protection Act, etc.

④ Necessary matters concerning procedures and methods of the research on the actual condition under paragraph (2) shall be prescribed by Presidential Decree.

<sup>14</sup> **Article 19 (Collection, Management, and Utilization of Biotechnology Information)**

① The government shall prepare a plan for systematically and comprehensively collecting, managing, and utilizing biotechnology-related information in order to revitalize the biotechnology research and development and promote the industrialization.

② The Minister of Science and ICT shall periodically investigate the information in order to collect, manage, and utilize biotechnology-related information, and if deemed necessary, may request the biotechnology information and the related materials to the central administrative agencies concerned and both national and public research institutions.

③ Necessary details concerning the scope of the biotechnology information, the investigation time, target institutions, etc. under paragraph (2) shall be prescribed by Presidential Decree.

### **3. Innovation Inducement of Biotechnology**

First of all, a directly applicable provision (Article 11<sup>15</sup>) was newly established to promote the government's research and development on biotechnology. Joint and convergence research (Article 12<sup>16</sup>) was enhanced in order to revitalize the researcher-led joint and convergence research ecosystems through openness and cooperation. In addition, it improved the support for promising general-purpose technologies, which have national importance and the promotion of technology transfer and commercialization (Article 15<sup>17</sup>).

In particular, promising general-purpose technologies are making a huge change in the bio-industry ecosystem. The core of the era of the fourth industrial

---

#### <sup>15</sup> **Article 11 (Promotion of Research and Development Projects)**

- ① The government shall conduct research and development projects for the biotechnology research and the technology development in order to efficiently achieve the purpose of this Act.
- ② The heads of the central administrative agencies concerned may select research tasks, if deemed necessary, in order to promote research and development projects, and may conclude agreements with companies, universities, research institutions, medical institutions, or biotechnology-related institutions and organizations for conducting researches.
- ③ The government may support all or part of the expenses for research and development for institutions and organizations that conduct research and development projects pursuant to paragraph (2).

#### <sup>16</sup> **Article 12 (Promotion of Joint and Convergence Research)**

- ① The government shall promote joint and convergence research among academia, research institutes, medical institutions, or industries in order to efficiently promote the biotechnology research and the technology development.
- ② Necessary matters concerning joint and convergence research under paragraph (1) shall be prescribed by the Presidential Decree.

<sup>17</sup> The government shall devise the support policies for the following matters in order to revitalize the biotechnology research and development and to promote the industrial application of the results thereof.

1. Succeeding research and development for the industrial application of biotechnology
2. Convergence research of biotechnology and other fields
3. Research and service development of promising general-purpose technology in the biotechnology field (referred to the basic technology that is universally used for the production and the use of biotechnology-related products and services)
4. Biotechnology-related transfer and the commercialization promotion
5. Promotion of creation, protection and utilization of the biotechnology intellectual property
6. Establishment of regional bases for the biotechnology R&D and the industrialization promotion
7. Promotion of production and sales of new technology products related to biotechnology
8. Other matters for promoting industrial application of biotechnology

revolution is a paradigm shift that started from the process of platform competition, which emphasizes the importance of innovative technologies with generality. In other words, multidisciplinary collaboration with other fields such as physics, chemistry, biology, information or engineering is becoming more common, and new products and systems can be produced with the collaboration of other technologies due to promising general-purpose technologies, which became the base technology. Based on the related articles, the government (Ministry of Science and ICT, etc.) announced that it will simultaneously secure both the original and application technologies by proactive support for developing universal platform technologies, and that it will focus on supporting joint utilization through one-stop information supply by preparing a mid to long-term development roadmap for each technology while promoting outstanding research groups.<sup>18</sup>

#### **4. Promotion of Regulatory Science in terms of Research and Development**

Technology impact assessment (Article 10<sup>19</sup>) was established for pre-evaluating the impact of bio-innovative technologies on economic, social, and ethical and the improvement measures were devised by discovering unnecessary regulations that interfere with technological innovation and creation of new industries and by collecting opinions from the interested parties and the experts (Article 22).

---

<sup>18</sup> Ministry of Science and ICT(2020), Preparing the institutional basis for accelerating the bio-economy. Retrieved from <https://www.msit.go.kr/bbs/view.do?sCode=user&mId=113&mPid=112&pageIndex=1&bbsSeqNo=94&nntSeqNo=2874832&searchOpt=ALL&searchT xt=%EB%B0%94%EC%9D%B4%EC%98%A4+%EA%B2%BD%EC%A0%9C>

<sup>19</sup> Article 10 (Technology Impact Assessment)

- ① The Minister of Science and ICT shall evaluate the impact of new biotechnology on the economy, society, culture, ethics, and the environment in advance (hereinafter referred to as “technology impact assessment”) and may reflect the results thereof in policies.
- ② Necessary matters concerning procedures and methods of the technology impact assessment shall be prescribed by the Presidential Decree.

**Table 1 Main Contents the revised Biotechnology Support Act**

Provisions		Main Contents	
Chapter 1 General Provisions	Article 3 Responsibilities of the government, etc	newly inserted	<ul style="list-style-type: none"> <li>Regulated responsibilities of the government, local governments and companies for nurturing biotechnology</li> </ul>
Chapter 2 Planning and Promotion System for Nurturing Biotechnology	Article 5 Basic Plan	amended	<ul style="list-style-type: none"> <li>Expanded the contents including technology transfer, commercialization, and start-up support, not only existing R&amp;D and international cooperation</li> </ul>
	Article 7 Council for Comprehensive Biotechnology Policy	amended	<ul style="list-style-type: none"> <li>Established a working committee to pre-review deliberations and to handle delegated matters</li> </ul>
	Article 8 Devising of Support Policy	amended	<ul style="list-style-type: none"> <li>Sharing the roles of relevant ministries and agencies related to biotechnology by Presidential Decree</li> </ul>
	Article 9 Research on the Actual Condition	newly inserted	<ul style="list-style-type: none"> <li>Grounds for collecting basic materials for policy establishment such as basic plan</li> </ul>
	Article 10 Technology Impact Assessment	newly inserted	<ul style="list-style-type: none"> <li>Utilized as a basis for policy reflection related to new emerging technologies in biotechnology</li> </ul>
Chapter 3 Promotion of Biotechnology Research and Development	Article 11 Promotion of Research and Development Projects	newly inserted	<ul style="list-style-type: none"> <li>Provided a basis for national research and development projects on biotechnology</li> </ul>
	Article 12 Joint and Convergence Research	amended	<ul style="list-style-type: none"> <li>Modified 'joint research' to 'joint and convergence research' in order to promote biotechnology research beyond fields and technologies</li> </ul>
Chapter 4 Promotion of Biotechnology Industrialization	Article 15 Promotion of Industrial Application	amended	<ul style="list-style-type: none"> <li>Promising general-purpose technology support, technology transfer and commercialization promotion, intellectual property protection, and so on</li> </ul>
	Article 16 Promotion and Support of Innovation Principals	newly inserted	<ul style="list-style-type: none"> <li>Promotion of innovation principals such as universities, research institutes, industries and medical institutions and support of founders</li> </ul>

Chapter 5 Creation of Foundation for Biotechnology	Article 20 Establishment of Classification System	newly inserted	<ul style="list-style-type: none"> <li>• Reorganized and improved the classification of the biotechnology field</li> </ul>
	Article 21 Statistical Survey and Analysis	newly inserted	<ul style="list-style-type: none"> <li>• Preparation, management, and maintenance of statistics for efficient research and development in the biotechnology field</li> </ul>
	Article 22 Improvement of Regulations related to Biotechnology, etc	newly inserted	<ul style="list-style-type: none"> <li>• Promotion for resolving unnecessary regulations and improving regulations suitable for both domestic and foreign environments</li> </ul>
	Article 24 Biotechnology Policy Specialized Institution	newly inserted	<ul style="list-style-type: none"> <li>• Secured a policy establishment support system such as discovering various policy issues including technologies, industries, and systems</li> </ul>
Chapter 6 Supplementary Provisions	Article 27 Delegation and Entrustment of Authorities	newly inserted	<ul style="list-style-type: none"> <li>• Delegation of authorities for the areas which requires expertise (such as statistical survey)</li> </ul>

#### **IV. Conclusion**

The biotechnology field is a foundation of promising businesses for the next generation that influences other fields such as medicine or the food industry, as well as a technological alternative necessary to keep the country and society safe and to resolve problems facing humanity such as climate change and food security. The government is nurturing the biotechnology industry as one of the national major support industries, and our technology is now receiving the spotlight from the world due to the response to COVID-19. At this point, it is significant that systematic and balanced support for the bio-industry has become possible with two fundamental pillars: technological innovation and industrialization. The revised Biotechnology Support Act is expected to contribute to boosting the bio-economy and improving quality of life by promoting innovation in the biotechnology field. In particular, the bioscience ecosystems will be strongly established from technology, which in turn will secure the reinvestment by enhancing the total periodic support for the biotechnology field so that the bio-industry will grow into a national key industry eventually.



## References

- ETNews(2019), Technology exports exceeded KRW 8 trillion -Bio companies shone. Retrieved from <https://www.etnews.com/20191230000311>
- KITA(2020), ), Korea's Covid-19 diagnostic kit exports surge-106 countries, 139t. Retrieved from [https://www.kita.net/cmmrcInfo/cmmrcNews/cmmrcNews/cmmrcNewsDetail.do?pageIndex=1&nIndex=57698&sSiteid=1&searchReqType=detail&searchCondition=TITLE&searchStartDate=&searchEndDate=&categorySearch=1&searchKeyword&logGb=A9400\\_01](https://www.kita.net/cmmrcInfo/cmmrcNews/cmmrcNews/cmmrcNewsDetail.do?pageIndex=1&nIndex=57698&sSiteid=1&searchReqType=detail&searchCondition=TITLE&searchStartDate=&searchEndDate=&categorySearch=1&searchKeyword&logGb=A9400_01)
- Korea Exchange(2020), Performance and evaluation after the introduction of the KOSDAQ listing with technology exception (2005), January 20. (In Korean)
- Korea Ministry of Government Legislation(2019), Legislative Manuals and Aids. Retrieved from <https://www.moleg.go.kr/menu.es?mid=a10105030000>
- Ministry of Science and ICT(2020), Preparing the institutional basis for accelerating the bio-economy. Retrieved from <https://www.msit.go.kr/bbs/view.do?sCode=user&mId=113&mPid=112&pageIndex=1&bbsSeqNo=94&nttSeqNo=2874832&searchOpt=ALL&searchTxt=%EB%B0%94%EC%9D%B4%EC%98%A4+%EA%B2%BD%EC%A0%9C>
- Yoon, Chongmin. (2018), A Study on the Improvement of Legislation on Biotechnology Support Act in the Age of Bio-Economy, Law Research 29(1), pp. 373-405. (In Korean)
- Yoon, Chongmin. et al(2017), A Study on the Improvement Method of Legal Systems for Innovation of Biotechnology and Industrialization Promotion, National Research Foundation of Korea. (In Korean)