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BIOTECHNOLOGY R&D POLICY: REPUBLIC OF KOREA

by Kyung-Soo Hahm, Korea Research Institute of Bioscience and Biotechnology

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NOTE BY THE SECRETARIAT

1. The attached report was prepared by Dr. Kyung-Soo Hahm, Korea Research Institute of Bioscience and Biotechnology, under a contract from the OECD, as an element of the activity relating to new Member countries.

Action required

2. For information on the present state of Korean R&D policy on biotechnology.

BIOTECHNOLOGY R&D POLICY: REPUBLIC OF KOREA

by

Kyung-Soo Hahm

Korea Research Institute of Bioscience and Biotechnology

Introduction

Korea has a traditionally sound basis for biotechnological research and related industrial capabilities including a substantial food industry with a long tradition in fermentation as illustrated in such products as soy sauce and a fermented vegetables (*Kimchi*) which have been used for thousands of years in Korean society. Industrial production of alcoholic beverages, amino acids and antibiotics by fermentation already possesses strong competitiveness in the world market. However, it was not until the 1980s that a systematic effort for developing biotechnology was launched at a national level.

In the beginning of the 1980s when the Korean economy was trying to make the transition from traditional manufacturing sectors into high technologies, and the world's genetic engineering and new biotechnology was booming, an urgent need to set the development of biotechnology as a national priority was recognised by the government and industry leaders. The first successful result was the establishment in March 1982 of the Korea Genetic Engineering Research Association (now changed to the "Korea Biotechnology Research Association"), a consortium of 13 companies with active interests in biotechnology. In the same year, the Ministry of Science and Technology included biotechnology as one of the strategic areas of national technology development.

An important milestone in government policy for biotechnology was the enactment of the "Genetic Engineering Promotion Law" (now changed to the "Biotechnology Promotion Law") in 1983, and it has greatly contributed to the establishment of a solid foundation for biological science and technology in Korea. Article I of the law declares government's responsibility for the development and commercialisation of genetic engineering and also stipulates the establishment of a national centre for genetic engineering research. The law also prescribes the responsibilities of various other governmental agencies and ministries for the promotion of biotechnology.

With the help of the law, the Genetic Engineering Centre (now changed to the Korea Research Institute of Bioscience and Biotechnology) was established in 1985. Many universities also opened new departments related to genetic engineering and biotechnology, and started to establish genetic engineering research centres within the universities. Also industry, realising the growing world-wide biotechnology market and the need to cultivate the domestic bioindustrial environment and to restructure the industrial sector, established the Bioindustry Association of Korea in 1991.

Since then the scientific environment in Korea has been improving spectacularly and funding for biotechnology research has been increasing rapidly along with the booming Korean economy. The

national R&D expenditure in biotechnology increased to about US\$ 158 million in 1994, which is nearly a 20-fold increase from only US\$ 8 million in 1983. The support for basic research is also greatly expanding and the Korean government plans to allocate up to 4 per cent of GNP to the development of science and technology by 1998, which registers an even higher proportion than what the United States, Japan or Germany spends on their science programs. Industries have also raised their R&D spending; it now accounts for 80 per cent of total research dollars in Korea compared with 28 per cent in 1971. Many research institutes and supporting systems have been established during the last decade and the national pool of trained scientists and technological experts have increased enormously over the past two decades.

The Korean government now recognises that biotechnology is the key discipline in Korea that will allow the nation to become one of the top developed countries in the world in the 21st century. Such a view strongly encourages the nation's policy makers to support life science and biotechnology as the highest priority in R&D investment in order to enhance the nation's industrial competitiveness. However, basic and fundamental research in science and biotechnology of Korea is evaluated to be yet at an immature stage. In order to enhance the nation's international competitiveness in biotechnology, a national strategic plan is necessary, based on close co-operation between industry and government, to come up with a harmonized as well as a consistent plan to foster biotechnology.

Therefore, at the end of 1993 it was considered most appropriate to implement the national strategic plan for the promotion of biotechnology in a well balanced and effective manner, "Biotech 2000 Program", a Korean initiative for biotechnology development. This 14 year program aims to bring Korean scientific and biotechnological capabilities to a competitive level with the world's leading countries, and also to accelerate the technological transfer of biotechnology research to commercial applications. Due to the broad applicability of the missions imposed on these ministries it was proposed in the program that biotechnological research is to be supported by seven different ministries. Therefore, the biotechnology R&D budget for the participating ministries was significantly increased from 2.7 per cent in 1992 to 5 per cent in 1997. With the expected volume of US\$ 1.3 billion matching funds from industry during the 14 year period, the total sum of investment for the program is expected to be US\$ 20 billion.

In summary, there exists a great expectation that by the early 21st century Korea will become one of the top developed countries in biotechnology once a successful follow-up of national biotechnology developments are made. In this report the present status and prospects of biotechnology in Korea are reviewed followed by an over-view of national R&D policy on biotechnology being carried out by individual ministries or at the inter-ministerial level.

Present status of biotechnology in Korea

Present level and prospects of biotechnology

The present level of Korean biotechnology is mainly at the stage of improving technology imported from the advanced countries and in part concentrating efforts in order to develop innovative products. From 1986 to 1995, Korean industry imported 3 039 technologies among which only 43 are biotechnology related technologies and exported only 11 biotechnology related technologies during the same period. Technologies were imported mainly from the developed countries including the United States, Japan, Germany and Italy, whereas exports were made mostly to developing countries including India, China and Indonesia. No new biotechnology related technology has been exported so far, indicating the level of biotechnology in Korean industry.

Table 1 indicates that the level of basic technology in biotechnology is now getting close to the developed countries according to the report by the Korea Academy of Industrial Technology in 1994. Among production technologies, fermentation technology is at the level of advanced countries as indicated by the fact that almost 20 per cent of the world market for amino acid is shared by Korean companies such as the Miwon Company, and the Cheiljedang Corporation. In addition, fermentation technology for antibiotics and production of diagnostics and vaccines for Hepatitis B viral infection is also at the internationally competitive level.

However, other production technologies including separation technology and development technologies for new biomaterials are still at an early stage of development requiring more concentrated efforts including manpower reinforcement. The report also indicated that more concentrated investigation on infrastructure development including screening and safety evaluation is needed in order to be able to develop any innovative biotechnological products in the near future.

Table 1. **Present level of technology**

Classification	Technology	Relative index of technology level*
Basic technology	Recombinant DNA technology	75
	Hybridoma technology	70
	Protein engineering	65
Production technology	Fermentation technology	90
	Cell culture technology	60
	Bioprocess technology	60
	Bioengineering technology	30
Development technology for new materials	Screening technology	20
	Safety evaluation technology	20
Overall		50

Note: * The value was estimated by comparing from 100 for the most advanced country for each technology.

Source: Korea Academy of Industrial Technology, December 1994.

When the technology level of various bioindustries is compared with the developed countries, the levels of industries for biochemicals and the bioenergy industry are about 50-70 per cent of the developed countries, and the levels of industries for biopharmaceuticals, agriculture and environment are around 40-60 per cent of the most advanced country. However, the level of the biofood industry is the lowest, only about 30-50 per cent of the level of the developed countries. In addition, product development using biotechnology is either at the introduction phase or growth phase with the exception of recombinant proteins and amino acids which are at an early stage of the mature phase. This indicates that bioindustry in Korea, in general, is at its early stage of commercialisation.

Table 2 shows the prediction of future technology development. The list was evaluated and selected by scientists from the 92 items included in the report "Future Technology of Korea, 1994". The table indicates that the level of technology of Korea is around 40 per cent of the most advanced country and the difference in years for the achievement between Korea and the most advanced country is about 5-6 years. Although the prediction shows a less encouraging prospect of Korean biotechnology, it is also possible to

predict a better result in specific areas by proper and concentrated investigation in the technology since the technology itself is in its growth stage world-wide.

Table 2. **Prediction of technology development (year of achievement)**

Technology	World	Korea
Mass purification technology for recombinant medical proteins	1998	2001
Screening and separation technology for new biological activity modifiers	1999	2002
Cancer diagnosis and treatment using monoclonal antibodies	2000	2005
Biodegradable polymers from biomass	2000	2005
Toxicity and safety assessment systems	2000	2005
Insertion of foreign genes into specific positions of animal genome	2001	2005
Bioremediation technology	2000	2005
Establishment of vector-host system for useful proteins and RNA	2000	2005
Production of useful materials by plant cell culture	2000	2005
Development of genetically engineered micro-organisms for degradation of nondegradable materials	2000	2005
Microbial products for protection from diseases and parasites, and storage for agroproducts	2000	2005
Biosensors	2002	2005
Commercialisation of bone marrow cell culture	2002	2005
Early diagnosis of cancer using simple, highly sensitive and efficient methods	2002	2005
Utilisation of micro-organisms for pollutants	2001	2005
Development of insect-resistant and disease-resistant plants	2001	2005
Non-polluting and low-toxic insecticides from natural and microbial products	2000	2005
Technology for restricting the expression of harmful genes or propagation of viruses	2002	2007
Production of disease model animals	2001	2007
Technology for designing protein structures having specific functions	2003	2009
Disease-treatment by gene-transfer	2005	2010
Elucidation of immune cell functions	2005	2010
Resolution of signal transduction in carcinogenesis	2005	2010
Commercialisation of semi-permanent culture and storage of organs	2005	2010
Commercialisation of methods for prevention of cancer metastasis	2004	2010
Commercialisation of gene therapy	2005	2010
Utilisation as food for genetically engineered plants	2005	2010
Increase in food production using improved photosynthetic function	2005	2010
Technology for complete screening of genes for specific disease and metabolic processes	2006	2013
Commercialisation of solar energy transformation into biological energy	2005	2013
Clinical application of organ transplantation using propagation and regeneration of recipient cells	2006	2013
Resolution of molecular mechanisms for organ regeneration	2010	2014
Commercialisation of artificial organs containing human cells and tissues	2010	2014
Completion of whole protein data library of humans	2010	
Molecular level resolution of brain development	2010	
Resolution of carcinogenesis by oncogenes for all cancers	2010	
Completion of DNA sequences of whole human genome	2010	

Source: Author.

Present status and prospects of the biotechnology market

According to A.D. Little (United States), the world market for biotechnology was US\$ 10 billion in 1992, and is expected to reach US\$ 100 billion in 2000 and US\$ 305 billion in 2005 (Table 3). At present the US market is the largest (about 50 per cent) and the United States, Japan, and Europe will share an equal

portion of the market in 2000. It is expected that biopharmaceuticals will lead the market but markets for biofoods, agricultural and environmental products will increase steadily.

Biotechnology in Korea has been steadily developed since the early 1980s, when new biotechnology was introduced there, as a result of effort by the government, industry and academia. Along with the expansion of capabilities for adopting new biotechnology products, the improvement of the economy and an increase in interest in health care, welfare, and the environment helped the market to rapidly grow in the 1990s. Table 4 shows the Korean market for biotechnology products developed and imported and Table 5 shows the Korean market for individual biotechnology products.

Table 3. **World market for biotechnology products**

Area	1992	2000	2005
Biopharmaceuticals	60	500	1 200
Agricultural bioproducts	8	100	305
Biofoods	9	127	578
Environmental	10	150	408
Biochemicals	8	70	244
Bioenergy	2	30	214
Others	3	20	91
Total	100	1 000	3 050

Note: Unit: US\$ 100 million.

Source: Korea Academy of Industrial Technology, December 1994.

Table 4. **Korean market for biotechnology products developed and imported**

	1991	1992	1993	1994	1995
Developed domestically	44	74	119	152	215
Imported	21	49	91	94	112
Total market	65	121	210	246	327

Note: Unit: US\$ million.

Source: Survey study by the Bioindustry Association of Korea, 1996.

The Korean biotechnology market was US\$ 327 million in 1995 which is a five-fold increase from 1991 (US\$ 65 million), indicating the potential for growth in biotechnology. On the other hand the production structure of bioindustry in Korea is relatively weak showing the high level of dependency on imports which were 32 per cent in 1991, 43 per cent in 1993, 38 per cent in 1994, and 52.3 per cent in 1995. The pharmaceutical industry showed the highest dependency on import (55 per cent in 1992, 52 per cent in 1993, 42 per cent in 1994, and 53.4 per cent in 1995). In 1995, the cost of biopharmaceutical imports was 74 per cent of total import of biotechnology products (Table 5).

Table 6 shows the domestic market size and the prospect of biotechnology products according to various industries. The biopharmaceutical industry leads the market followed by the environmental and biofood industry. The market for agricultural products and biochemicals is very small and the market for bioenergy industry has not really been established. The current market size of biotechnology products in

Korea is estimated to be US\$ 1.5 billion (excluding alcoholic beverages). In 1993, sales of new biotechnology products in Korea reached US\$ 125 million, and are expected to increase up to US\$ 5 billion in the next 10 years. Box 1 shows examples of Korean biotechnology products with international competitiveness.

According to the report by the Korea Academy of Industrial Technology, the market for domestic biotechnology products will reach US\$ 3.6 billion in 2000 and more than US\$ 15 billion in 2005 including increases in every sector of bioindustry (Table 6). It is noteworthy to see the rapid growth expected in the bioenergy market which is not yet established. This prediction is a relatively optimistic but possible one in view of the prediction of the Japanese market being about US\$ 28 billion (about eight times that of the Korean market) in 2000.

Table 5. Korean market for biotechnology products developed and imported

Product	1993		1994		1995		
	Dev.*	Imp.	Dev.	Imp.	Dev.	Imp.	
Pharmaceuticals	Antibiotics	46.2	35.3	52.7	1.2	58.2	4.5
	Vaccines	4.8	17.7	4.0	21.0	29.1	13.9
	Interferons	5.5	2.6	9.9	3.9	19.8	4.1
	Insulin	–	5.7	–	4.0	6.1	5.0
	Anti-inflammatory	4.3	–	4.2	–	4.4	–
	Anaemia	–	4.7	–	0.8	–	8.2
	Growth-hormone	7.4	4.8	14.7	4.9	19.7	4.1
	Anticoagulant	–	0.1	2.7	0.4	2.8	0.8
	Others	4.3	–	2.6	3.0	3.6	0.7
	Diagnostics	6.8	14.0	10.4	34.9	15.4	43.7
(sub total)	(79.3)	(84.9)	(101.2)	(74.1)	(159.1)	(85.0)	
Food	Phenyl-alanine	6.9	–	–	–	–	–
	Sweeteners	14.0	–	9.7	–	13.4	–
	Functional food	–	–	0.6	–	0.7	–
	(sub total)	(20.9)	(–)	(10.3)	(–)	(14.1)	(–)
Environment	Microbial products	3.7	–	11.8	1.2	9.0	0.7
	Waste water treatment	10.0	–	7.2	–	8.2	–
	(sub total)	(13.7)	(–)	(19.0)	(1.2)	(17.2)	(0.7)
Chemicals	Cosmetics	1.3	–	1.2	–	0.9	–
	Enzymes	0.3	1.6	1.5	2.0	2.3	3.9
	Biopolymers	0.6	–	1.4	–	1.5	–
	(sub total)	(2.2)	(1.6)	(4.1)	(2.0)	(4.7)	(3.9)
Agriculture	Animal diagnostics	0.1	–	0.5	0.4	8.3	1.4
	Feed additives	0.5	–	2.2	3.2	1.0	1.0
	(sub total)	(0.6)	(–)	(2.7)	(3.6)	(9.3)	(2.4)
	Bioreactor	2.5	5.8	8.0	12.9	10.3	20.1
(sub total)	(2.5)	(5.8)	(8.0)	(12.9)	(10.3)	(20.1)	
Total	119.2	92.3	145.3	93.8	214.7	112.1	
	356.8		239.1		326.8		

Note: Unit: US\$ million. * Dev.: Developed; Imp.: Imported.

Source: Survey study by the Bioindustry Association of Korea, 1996.

Table 6. **The domestic market of biotechnology products**

Area	1992	1994	2000	2005
Biopharmaceuticals	83	175	1 636	5 133
Agricultural products	3	6	285	1 556
Biofoods	17	17	533	2 800
Environment	14	20	356	1 711
Biochemicals	6	6	356	1 711
Bioenergy	–	–	249	1 867
Bioprocess	–	21	142	778
Total	123	245	3 557	15 556

Notes: Unit: US\$ million.

Source: Korea Academy of Industrial Technology, 1994.
Bioindustry Association of Korea, 1996.

Box 1. Examples of Korean biotechnology products with international competitiveness	
– Amino acids:	World market share of 20 per cent (US\$ 75 million). (Miwon Co. and Cheiljedang Corp.)
– Rifamycin:	World market share of 10 per cent (US\$ 7.5 million). The technology was transferred to India. (Yuhan Corp. and Chong Kun Dang Corp.)
– Hepatitis B vaccine:	Developed in 1987 by Korea Green Cross Corp. Rapid increase in world market share is expected (40 per cent in 1998).
– Bioinsecticide (BT):	Developed in 1990 by KRIBB. Patent filed in 27 countries.
– Recombinant human growth hormone:	Developed by LG Chemical Ltd. (90) and its domestic sales reached to US\$ 40 million in 1993.

Source: Author.

Present status and prospects of the major industrial areas

Biopharmaceuticals

At present biopharmaceuticals account for more than 60 per cent of the total biotechnology market of more than US\$ 10 billion; the major portion of the biopharmaceuticals is diagnostics. Many developed countries including the United States and Japan have already had some success in technology development and commercialisation through strong investment by the government and major participation by industry. On the other hand, only a few big companies have any capabilities for developing technologies, and the dependency on foreign technology is close to 80 per cent in Korea. However, the majority of domestic scientists predict that the biopharmaceutical industry is the most promising industry

in Korea among the various bioindustries, in spite of the country's relatively weak technical capabilities and limited R&D funding.

According to the report published by PhRMA (Pharmaceutical Research and Manufacturers of America) in 1996, there are 284 biopharmaceuticals being developed in the United States which is about a 21 per cent increase from the previous year's total of 234. Approximately 40 per cent of all the biopharmaceuticals being developed are for cancers including brain tumours, renal cancer and lung cancer. The most rapidly developing area in biopharmaceuticals is human gene therapy of which 28 were being developed in 1996 from 17 in 1995. The number of vaccine products using biotechnology was 62 in 1996 which is about a 44 per cent increase from the previous year.

Although the total R&D investment in biotechnology, especially in the field of biopharmaceuticals, has increased a great deal due to the government's policy to promote bioindustry as a strategic industry in the 21st century and to satisfy the public need for increasing welfare, the present level of the technology is at the level of importing, imitating, and improving the technology already developed by developed countries.

However, the development and commercialisation of vaccines are being pursued very actively. For example, the number of patents filed domestically between 1980 and March 1995 on the Hepatitis B virus vaccine was 29, with 21 of them (78 per cent) involving biotechnology. The Korea Green Cross Corporation was designated as the official institute for vaccine development for rota virus by the Federal Trade Commission of the United States in October 1996.

Agricultural products

It is apparent that biotechnology will play a very important role in solving food problems in the world by improving the quality and productivity of crops and by developing crops which are resistant to viruses, parasites, high temperatures, droughts or floods. In addition, the technology could be useful in solving the disease problems of livestock and improving the productivity of livestock by strain development.

The production of seeds by tissue culture technology in Korea is considered world-class and there have been some successes in production of biomaterials and new species by recombinant DNA technology and cell culture technology, indicating a bright future in the plant biotechnology related industry. Hundreds of species of horticultural plants including orchids and carnations are being produced annually. Mass-production technology of disease-free seed potatoes, developed at KRIBB, is expected to hold a large share of the international market. Recently, mass production technology of disease free seed garlic has been successful and it is in the commercialisation stage. In addition, commercialisation of virus-free tobacco, green peppers and petunias, developed by recombinant DNA technology, is being pursued.

On the other hand, the research on animal biotechnology is still at the early stage and research including embryo transfer technology and animal feed additives are being initiated by several related companies. Although some large companies including DooSan Corporation are actively participating in the development of animal biotechnology, the present level of the technology is still too immature for its commercialisation. In view of the present environment, including the UR Treaty or pressure for open trade, more concerted investment in this field is required.

Environmental area

Biotechnology could be used for environmental protection and restoration by using microbial products and processing technology. It is predicted that environmental technology will progress rapidly with the involvement of new biotechnology. The environment has become one of the biggest issues around the world and many nations are now trying to transform their industries into environmentally protective ones.

In Korea, the environmental industry has become a specialty industry since the 1980s when the nation experienced rapid industrial development. There are now around 9 000 companies involved in the development of environmental technology and their annual sales amount to over US\$ 1 billion. However, environmental products using biotechnology are at present minimal and limited to microbial products or bio-polymers for waste-water treatment.

The government established a 10 year plan for the development of environmental science from 1992 to 2001 and plans to promote environmental industry as one of Korea's export industries.

Biochemicals

Most of the chemical processes for the production of chemicals require large amounts of energy under high pressure and temperature, and cause serious environmental pollution because of their nondegradable toxic wastes. In contrast, biotechnological processes do not generally cause any environmental problems because of their characteristics and can be called a green technology.

Development of high-value-added chemicals by biotechnology utilising biological organisms or catalysts has been pursued competitively by many developed countries. The progress of this field will be accelerated by the advancement of recombinant DNA technology, research on metabolism and biological reactors.

Although the rate for commercialisation for chemicals by biotechnology is relatively slow compared to other industries such as biopharmaceuticals or agriculture, the ratio of chemicals out of the total bioindustry is predicted to be 5-7 per cent in 2000, according to SRI International (1992). The market for ethanol which holds the largest production volume in the world is being lead by the United States and Brazil, but a pilot experiment for its production as fuel is progressing in Korea. The market for insecticides and herbicides using microbial organisms among biological agricultural chemicals is growing rapidly and is expected to reach around US\$ 400-500 million in 2000, indicating an annual growth of 20 per cent.

History of Korean biotechnology development and distribution of R&D resources*History of Korean biotechnology*

In order to fully understand the technology innovation system and characteristics of its components in Korea, it is necessary to look at the history of biotechnology development, especially in the development of the capability for technology innovation (Table 7). It is useful to divide the history into three periods: birth (up to 1979), technology importation and propagation (1980-1991), and early growth (after 1991). The birth period is the period when life science became an independent science centring on traditional biology and the very basic foundation for research was established. The period of technology import and propagation is the period when research on biotechnology began after the introduction of recombinant

technology into Korea and diffusion of biotechnology to universities and industry. The period of early growth is the period during which more active biotechnology R&D was carried out by research institutes, academia and industries with strong support from the government and when the results of the commercialisation efforts of biotechnology began appearing.

Birth period (up to 1979)

In a general economic view, this period comprises the revitalisation from the ruins of the Korean War up to the establishment of the minimal basis for industrialisation. In respect to biotechnological development during this time, life science centred on classical biology was first introduced to Korea and was developed into an independent science. In the 1950s, since any bench work was almost impossible, labour-intensive research such as systematics, population genetics, and marine biology, etc., were the core of all research. Furthermore, due to the weak scientific base, no biotechnological industry was developed, except those using traditional biotechnology.

In the 1960s, lab-work became possible, and international exchange programs opened the way for introducing physiology, cell biology, and developmental biology as new fields in national scientific research. Also biochemistry and microbiology had their beginnings at this time. In 1966, there were 15 universities with a biology department, and in 1969 the Korea Institute of Science and Technology (KIST) was established by the government. The development of food and fermentation techniques originated from the Food Engineering Research Group of this institution. Furthermore, with the foundation of the National Institute of Health, medical care related research began, which involved disease control and approval of pharmaceuticals. In agriculture, several governmental institutions under the auspices of the Office of Rural Development (ORD) began research on crop improvement, including rice. In reference to industry, this period is marked by governmental encouragement in investment in light industry, which pushed the development of pharmaceutical and food industries.

In the 1970s, basic life science including cell biology using cell culture techniques and enzyme purification as well as research on biochemical phenomena was established. With this basis, fermentation and enzyme research on enzyme immobilisation and applied microbiology began, and in 1973 the Bioengineering Department at KIST opened which began supplying the human resources needed in industry and research institutes.

Period of technology importation and propagation (1980-1991)

This period is the beginning of biotechnology research by the introduction of genetic engineering technology and increased support for biotechnology not only by MOST (Ministry of Science and Technology), but also by the ministries like MOTIE (Ministry of Trade, Industry and Energy), MOHW (Ministry of Health and Welfare), and MOAFF (Ministry of Agriculture, Forestry and Fishery). In particular, industry saw the possibility for success in this new field, and began participating in technical development and was successful in the commercialisation of some items which lead to further investment.

In 1982 MOST included biotechnology in government funded projects and the industry established the Korean Biotechnology Research Association (KBRA). Furthermore, the government enacted the Biotechnology Promotion Law and established KRIBB as an affiliated institute of KIST in 1985. Since then KRIBB has been playing a central role in national biotechnology development by introducing and mastering genetic engineering techniques from advanced countries.

With the boom in genetic engineering of the early 80s, MOAFF also pushed the development of agricultural biotechnology mainly through the Office of Rural Development (ORD). In 1991, ORD established the Agricultural Genetic Engineering Research Institute, and encouraged the introduction of the latest genetic engineering techniques into traditional breeding technology in other pre-existing institutes under the auspices of ORD. In 1989, MOTIE also established a strategy for the development of bio-industries, and included bioindustry in the development funding for industry. Furthermore, MOHW reorganised and enlarged the structure of the NIH and established the National Institute of Safety Research as an independent institution, thereby assuring a sound basis for evaluating the safety and efficacy of new drugs as well as developing and securing essential genetic engineering techniques for disease research and new drug development.

Period of early growth (after 1991)

In this period, based on established research results, the government as well as industry began to vigorously promote biotechnology R&D and commercialisation. In 1992, MOST started the Highly Advanced National (HAN) Project which included two biotechnology related programs; i.e. development of new functional biomaterials and development of new pharmaceuticals and agro-chemicals. Furthermore, in 1993, after the civil government took power, the most ambitious national plan for the development of biotechnology, the “Biotech 2000 Program”, involving several ministries, was established. Also, in 1992 MOTIE started additional support for bioindustry by integrating the technology in the Fundamental Industrial Techniques Development Program, and in 1994, established a bioindustry development plan up to 2005. MOHW has also been supporting a new drug development program in the HAN project and its own drug development project which includes the use of new biotechnology.

With the intention to promote bioindustry as a strategic industry in the 21st century, industry is also accelerating support on biotechnology by establishing research institutes and beginning to realise results for commercialisation. Also, the universities, which had been the weakest part in research activities, have begun to obtain results and reinforce research functions from the research centres (science research centres (SRC), engineering research centres (ERC), and Genetic Engineering Research Institutes) which had been established from 1989 on. Until recently, improvement of processing procedures developed in advanced countries was the core of the bioindustry. However, as the basic research in universities is reinforced and the government as well as industry is continuing their support for biotechnology R&D, it will not be long before some new biotechnology products with world-wide impact are developed by the nation’s own research capabilities.

Mobilisation and distribution of R&D resources

R&D investment

Total investment for biotechnology R&D in 1996 in Korea was US\$ 311 million which represents an increase of US\$ 40 million from 1995 (Table 8). However, the ratio of biotechnology R&D investment in total R&D investment has been less than 2 per cent since 1991, with the exception of 1995, indicating that R&D investment by government and industry has not yet reflected the importance of the rapidly growing bioindustry. In addition, R&D investment by industry is relatively small as compared with total R&D investment. In 1991, the ratio between R&D investment in biotechnology by government and industry was 28:72 and the ratio was changed to 50:50 in 1996, indicating a remarkable increase in government investment in biotechnology.

Table 7. History of government policy on biotechnology R&D

Year	Remarks
1966	Establishment of biology department in 15 major universities
1969	Establishment of KIST which includes the "Division of Food Engineering"
1973	Set-up of the "Department of Biological Engineering" in KAIST which was established in 1971
1979	KIST reorganised and set up the "Division of Bioengineering"
1980	Introduction of recombinant DNA technology
1982	Inclusion of biotechnology in national R&D program by MOST Establishment of the Korean Genetic Engineering Research Association and Scientific Committee for Genetic Engineering
1983	Enactment of the Biotechnology Promotion Law
1985	KRIBB was established as an affiliated institute of KIST MOE began supporting university affiliated Genetic Engineering Research Institutes
1987	MOTIE began supporting the Industrial Basic Technology Development Program
1988	MOTIE started funding the project for alternative energy
1990	Biotechnology was included in support program of the industry development fund by MOTIE
1991	Establishment of the Bioindustry Association of Korea Agricultural Genetic Research Institute was established by MOAFF MOAFF began supporting the biological diversity program and environmental protection program
1992	Inclusion of bioindustry in the basic industry technology development program by the MOTIE Establishment of the HAN Project including development of new functional materials and new pharmaceuticals and agricultural products in the biotechnology area
1993	Established a committee for the evaluation of policy on biotechnology and a steering committee Establishment of a national basic plan for the promotion of biotechnology (Biotech 2000 Program)
1994	Proclamation of the Year of Biotechnology MOST began funding the Biotech 2000 Program Establishment of a vision for the development of bioindustry by MOTIE MOAFF started supporting the agricultural biotechnology development program including marine resources
1995	MOHW began funding biomedical technology development research MOHW began funding the new drug development program and medical bioengineering research Medical engineering technology is included in HAN Project
1996	Establishment of the Implementation Action Plan '96 for the promotion of biotechnology (MOST, MOE, MOAFF, MOTIE, MOEN, MOHW)

Source: Author.

The government's funding in biotechnology R&D was 50 per cent of total investment in 1996, which is relatively high from about 20 per cent of total investment in all industries in Korea. This figure is better than that of Japan where the government shares 20 per cent of total biotechnology R&D investment, but is lower than in the United States where government investment shows 60 per cent of total funding. The ratio of biotechnology R&D investment in total government R&D investment was 4.8 per cent in 1995, which is relatively low compared to the United States (5.6 per cent in 1993) and Japan (5.0 per cent in 1992).

Table 9 shows the R&D investment in biotechnology by individual government ministries which indicates that 51 per cent of all investment was from the Ministry of Science and Technology in 1996, reflecting the

role of MOST in S&T development. Even though total government investment is not yet sufficient, the R&D investment on biotechnology has been increasing greatly every year, indicating the government's policy promoting biotechnology.

Table 8. **Investment for biotechnology research and development**

	1991	1992	1993	1994	1995	1996
A. Overall investment	5 365	6 276	7 691	9 816	12 260	NA
- Government	(1 046)	(1 109)	(1 299)	(1 553)	(2 312)	
- Private	(4 319)	(5 167)	(6 392)	(8 263)	(9 948)	
B. Biotech investment	93	99	153	168	271	311
- Government	(26)	(32)	(59)	(68)	(113)	(154)
- Private	(67)	(67)	(94)	(100)	(138)	(157)
B/A (per cent)	1.7	1.6	2.0	1.7	2.4	NA

Note: Unit: US\$ million.

Source: Survey report on science and technology R&D, MOST, 1991-1995. Biotech 2000 Action Plan '96, MOST, 1996.

Manpower

The manpower for biotechnology stood at 3 382 in 1994 and the annual growth rate has been about 16 per cent which is slightly higher than the 15 per cent of total R&D manpower in Korea (Table 10). Manpower in industry increases most rapidly (annual growth rate of 27.7 per cent) indicating the efforts in biotechnology R&D by industry. The total manpower in the industry exceeded the total in academia from 1993 and this trend is expected to continue. Despite the rapid growth of manpower in the industry, the growth rate of R&D investment by industry does not match the growth rate of manpower, indicating that industry is still trying to establish a research basis by spending a large portion of investment securing manpower.

On the other hand, the annual growth rate (16 per cent) of total biotechnology R&D manpower is lower than the growth rate of R&D investment (23 per cent) which indicates the possibility of future manpower shortages and the need to strengthen investment in order to secure manpower trained in domestic and foreign universities.

In industry, manpower for production is also increasing rapidly (Table 11). Manpower almost doubled between 1992 and 1994 and this trend is expected to continue. However, there are almost no programs at present for training manpower for production of biotechnology products and there is therefore an urgent need to establish new or additional programs for training manpower for production lines by establishing special engineering schools or departments in the universities.

Governmental policy on biotechnology R&D

Although the application of biotechnology has great potential for solving problems in public health, food, and the environment, the technology is still in its early stage, requiring long term investment and having high risk. In addition, projects like human genome research often need huge investment. Therefore, government support for biotechnology innovation is vital.

Table 9. **Biotechnology R&D investment by government ministries**

	1993	1994	1995	1996	Annual growth rate (per cent)
MOST	41	45	55	70	19.5
MOE	2	3	5	6	43.2
MOAFF	12	13	27	32	38.4
MOTIE	2	3	3	10	78.7
MOEN	1	1	1	2	32.6
MOHW	1	4	6	15	169.9
Total	59	69	97	135	31.9

Note: Unit: US\$ million.

MOST: Ministry of Science and Technology

MOE: Ministry of Education

MOAFF: Ministry of Agriculture, Forestry and Fishery

MOTIE: Ministry of Trade, Industry and Energy

MOEN: Ministry of Environment

MOHW: Ministry of Health and Welfare.

Source: Biotech 2000 Action Plan '96, MOST, 1996.

Table 10. **Manpower related to biotechnology**

	1991	1992	1993	1994	Annual growth rate (per cent)
Industry	652	921	1 290	1 357	27.7
Academia	1 034	1 145	1 184	1 224	5.8
GSRI	483	625	707	801	18.4
Total	2 169	2 091	3 181	3 382	16.0

Source: "Survey on bioindustry", Bioindustry Association of Korea, 1995.

"Trends in Biotechnology", KRIBB 1995. 3.

Table 11. **Manpower engaged in production by bioindustry**

Year	Ph. D.	MSc	BSc	Others	Total
1992	6	31	114	531	682
1994	4	51	137	979	1 171
1996	10	82	234	1 054	1 380

Source: "Survey on Bioindustry", Bioindustry Association of Korea, 1997.

The Korean government played a central role promoting biotechnology even before its first introduction in the early 1980s. In the early period of introduction of biotechnology, the government approved establishing government supported research institutes and national or public research institutes. In addition, the government started to fund basic research on food, fermentation, plant breeding, demographic studies and drug evaluation. This kind of governmental support for traditional biotechnology and basic research contributed to establishing a basis for active research in new biotechnology when it was introduced and acknowledged as a field of discipline.

The government started to support biotechnology more aggressively as the recombinant DNA technology was introduced and public interest in genetic engineering was rising in the early 1980s. Starting from 1982, the Ministry of Science and Technology (MOST) of Korea began funding genetic engineering research. In addition, the government enacted a law called the “Genetic Engineering Promotion Law” (the name was changed to the “Biotechnology Promotion Law” in 1995) in 1985 and established a genetic engineering centre (now called the “Korea Research Institute of Bioscience and Biotechnology”, KRIBB) affiliated with the Korea Institute of Science and Technology (KIST), as a national centre for conducting biotechnology research. Around the same time, the Ministry of Agriculture, Forestry and Fishery (MOAFF) also started to support the Office of Rural Development (ORD) to do research on agricultural application of biotechnology, and the National Institute of Health (NIH), under the Ministry of Health and Welfare (MOHW) started research on basic technology of research on diseases and drug development, including safety evaluation.

As the technology basis was somewhat established by the government’s strong support and more companies were becoming involved in various projects, the Ministry of Trade, Industry, and Energy (MOTIE) classified biotechnology as a separate technology and started to support research and development by industry in 1992. In 1993, a very ambitious national program, the basic plan for the promotion of biotechnology (Biotech 2000), involving various ministries, was established by the government. The first stage of the program will be finished by the end of 1997 and a detailed implementation plan for the second stage is being drafted by specialists from academia, research institutes, industry, and government.

In conclusion, the government played a major role in establishing the scientific and technological basis of biotechnology by research institutes and industry. The government’s support also prompted the industry to engage in research on biotechnology by establishing their own research institutes. However, since the overall industrial basis of biotechnology is still considered to be weak, a more aggressive government role is expected in order to support research and establish the infrastructure of the technology.

Organisational framework

Generally speaking, ministries maintain autonomous S&T policies and conduct separate R&D programmes under an umbrella co-ordinating mechanism. In principle, MOST has the authority and responsibility to formulate national S&T policies and basic plans as part of the five-year economic and social development plan. However, a number of S&T related ministries also carry out various research programs and/or take supportive measures, depending on their needs. The overall co-ordination of national S&T policy is assured through two major channels, program co-ordination and budgetary control.

MOST is entitled to play a decisive role for S&T program co-ordination, at least in principle. In formulating national plans, MOST uses two mechanisms to co-ordinate, rather indirectly, the S&T plans and activities of other ministries. One is the Presidential Council on Science and Technology which provides the President with relevant advice and information. The 11-member council, which was established as a permanent organisation in 1991, consisting of distinguished experts from universities, government research institutes, and private industry meets every other week and its chairman reports to the President on a monthly basis. The other is the National Science and Technology Council (NSTC), which co-ordinates and integrates inter-ministerial agendas under the chairmanship of the Prime Minister and meets once a year. The NSTC, which was established in 1973, currently consists of 18 members including 12 S&T-related government officials from relevant ministries and four distinguished experts from industry, academia, and government supported research institutes.

With respect to budgetary control, the Ministry of Finance and Economy (MOFE) exercises substantial influence. At the start of the fiscal year, MOFE allocates an S&T budget to ministries on either a lump-sum or a project basis. Each ministry then decides the detailed distribution of the budget package on the basis of its program. Since ministries compete for funds, the budgetary control function of MOFE requires both co-ordination and authority.

As for the biotechnology R&D policies, MOST operates two committees, one being the Policy Council of Biotechnology (PCB) and the other the Biotechnology Research Planning Group (BRPG). The PCB is chaired by the minister of MOST and the members include vice-ministers of relevant ministries. The BRPG is chaired by the director of the R&D Policy and Co-ordination Office. In addition, the Science and Technology Policy Institute (STEPI) under MOST is responsible for managing national projects including inter-ministerial projects and has a direct reporting channel to MOST.

R&D policy by ministries

Ministry of Science and Technology (MOST)

The ministry which plays the central and major role in the research and development of biotechnology is the Ministry of Science and Technology (MOST). MOST was established as an independent ministry in 1967 and its main functions are:

- to provide technology forecasting and to set basic policy for S&T development and promotion;
- to develop core technology, future compound technology, big science and technology, and nuclear technology;
- to support basic and applied R&D conducted by the government supported research institutes, university R&D centres, and the private sector;
- to make policy for R&D investment, human resources, information, and international S&T co-operation;
- to promote public understanding of S&T.

MOST began supporting research on biotechnology as one of the key strategic technologies in 1982 and established the Korea Biotechnology Research Association (KBRA) in the same year with 13 member companies in order to strengthen the R&D basis in the industrial sector. The member companies include nine pharmaceutical companies, five chemical, three food, one textile, and one brewery. The association now has 19 members and has been fulfilling its role in encouraging private companies to expand their R&D activities in biotechnology. Created as a collaborative effort between MOST and industry, MOST initially provided up to 70 per cent of the association's research funds which are now made up mostly by contributions from the member companies. The total budget for R&D of KBRA in 1996 was US\$ 14 million; including US\$ 7 million from MOST and US\$ 7 million from industry .

The basis for supporting biotechnology research was considerably strengthened when the government enacted the "Biotechnology Promotion Law" in 1983. According to the law, the Korea Research Institute of Bioscience and Biotechnology (KRIBB) was then established as an affiliated institute of KIST in 1985.

The Ministry began supporting centres of excellence (Table 12) in universities in 1989 in order to promote the research functions of the university in addition to the support through national research projects. The centres of excellence are being supported by the Korea Science and Engineering Foundation (KOSEF)

under the Ministry. There are Science Research Centres (SRC) which perform core research on basic science and Engineering Research Centres (ERC) which perform research on high technology having a high industrial demand. In addition, MOST provides research funds to the Regional Research Centres (RRC) in universities in order to support balanced research and encourage regional characteristic research. There are now 17 SRCs (6 in 1990, 8 in 1991, 3 in 1995), 21 ERCs (7 in 1990, 9 in 1991, 5 in 1994) and 13 RRCs (3 in 1995, 10 in 1996). There are at least eight biotechnology related SRCs including the Molecular Microbiology Research Centre (Seoul National University), the Plant Molecular Biology Research Centre (Gyung-sang University), the Cell Differentiation Research Centre (Seoul National University), the Cancer Research Centre (Seoul National University), the Agricultural New Biomaterials Research Centre (Seoul National University), and the Hormone Research Centre (Chunnam National University). There are also at least four biotechnology related ERCs including the Bioprocess Research Centre (KAIST), the Animal Resources Research Centre (Kunkuk University), and the Bioindustrial Materials Research Centre (Yonsei University). Through 1995, KOSEF funded US\$ 128.1 million to 38 centres of excellence for 5 877 research projects resulting in 15 624 research papers (including 6 608 international papers) and 887 patents (including 177 international patents). MOST plans to increase the total number of centres of excellence to 50 by 1998. For RRC, KOSEF funded US\$ 7 million for 13 RRCs in 1996.

The HAN (Highly Advanced National) Project launched in 1992 is a national R&D program initiated by MOST. The purpose of the project is to increase the competitiveness of domestic industries by increasing indigenous S&T capabilities and to share 2 per cent of the global biotechnology market by 2001. The program was formulated with a “top-down” approach, marking a significant turn-around from the past “bottom-up” approach by the committee organised by MOST, including scientists and technologists from government, national research institutes, firms, and universities. As shown in Table 13, the committee selected 11 technologies; five product-oriented technologies and six fundamental technologies. Among the technologies selected, those including new medicine and agricultural chemicals and new functional biomaterials are the major biotechnology related technologies. According to the plan, the government will spend US\$ 688 million (US\$ 374 million by government and US\$ 314 million by industries) for these two technologies by 2001 (Table 14).

In the first phase of the project (1992-1994), more than twenty medium-size projects were carried out in the major biotechnology HAN Project which is the “new functional biomaterials” program. The projects were categorised as screening technology (including cell growth regulators, biologically active peptides, DNA materials for gene therapy, and recombinant microbial organisms), improvement technology (including new functional proteins and enzymes, transgenic plants and animals, and traditional foods), production technology (including biodegradable polymers and cell culture/bioreactor), and basic supporting technology including the rice genome. In addition, some international projects with countries like the United States, Japan, France, and Russia were also carried out. The result of the first phase of the program can be illustrated by the number of scientific papers published (498 in total, including 177 in international journals) and patents filed (138 in total, including 16 foreign patents).

In 1996, a total of 70 organisations including university (40), government supported research institutes (4), public research institutes (6), and industry affiliated research institutes (11) participated in the program (new functional biomaterials program) with partial financial support made by 75 companies. The total manpower engaged in the program in 1996 was 2 289 including 955 doctorate and 947 masters degree holders. The manpower can be divided into academia (876), research institutes (806), and industry (607).

Table 12. **Centres of excellence**

Year	Number of centres	Research funds provided by KOSEF (Unit: US\$ million)	Number of projects	Total manpower	Number of research papers published	Number of Ph.D.s produced	Number of patents filed
1990	13	3.4	224	494	702	46	11
1991	30	16.0	878	1 168	2 134	143	55
1992	30	22.1	940	1 229	2 694	237	135
1993	30	22.8	1 121	1 228	2 985	299	166
1994	35	28.3	1 313	1 506	3 815	331	281
1995	38	35.5	1 401	1 625	3 294	350	239
Total	38	128.1	5 877		15 624	1 406	887

Source: Author.

Table 13. **Key technologies of the HAN project**

Product-oriented technologies	Fundamental technologies
1. Highly integrated semiconductors	1. New materials in information service, electronics, and energy
2. Integrated services and data network	2. Next-generation transportation systems including machines and parts
3. High-definition television	3. New functional biomaterials
4. New medicine and agricultural chemicals	4. Environmental engineering technology
5. Advanced production system	5. New energy resources
	6. New atomic reactor and verification

Source: Author.

Table 14. **R&D investment for biotechnology within the HAN project**

Year	New functional biomaterials		New medicine and agricultural chemicals	
	Government	Private	Government	Private
1992-1994	3.0	1.5	45.6	18.4
1995	18.6	9.1	23.1	13.0
1996	19.3	9.6	29.3	14.4
1997	22.5	11.5	30.9	17.2
Total	63.4	31.7	128.9	63.0

Note: Unit: US\$ million.

Source: Author.

Furthermore, the Ministry of Science and Technology established an ambitious national biotechnology development program called "Biotech 2000" in December 1993 and declared 1994 as the Year of Biotechnology. The Biotech 2000 program is a 14 year program (1994-2007) involving various government ministries with an aim to improve the scientific and technological basis of biotechnology in

Korea and the total sum of the investment for the planned 14 year period is US\$ 20 billion. In the program, the following ten implementation strategies were identified:

- promote inter-ministerial co-operation to establish the interdisciplinary R&D basis of biotechnology;
- provide concentrated support for major R&D projects identified;
- accelerate the development of medium-technology and transfer to commercial applications;
- increase and continue support for on-going biotechnology projects in HAN projects;
- promote basic and fundamental research in life science;
- expand education and training programs to ensure the necessary human resources for the development of biotechnology;
- establish a nation-wide bio-techno belt for the promotion of a regional R&D basis for biotechnology research;
- strengthen the infrastructure and supporting functions for biotechnology R&D;
- promote international co-operation for biotechnology development;
- improve the institutional and legislative systems to promote biotechnology R&D and marketing.

Seven different government ministries (MOST, MOFE, MOTIE, MOHW, MOAFF, MOEN, and MOE) are involved in the program and each ministry is required to prepare an implementation action plan according to the program.

The Korea Research Institute of Bioscience and Biotechnology (KRIBB), the Korea Research Institute of Chemical Technology (KRICT), the Korea Atomic Energy Research Institute (KAERI), and KAIST are the research institutes involved in some degree of biotechnology R&D among government supported research institutes under MOST. Among them KRIBB is the major biotechnology research institute whose main function is biotechnology R&D but other institutes contain some degree of biotechnology R&D in their functions. For example, KAERI is involved in biotechnology in remedying the environmental problems caused by atomic energy and KAIST is involved in biomedical research through its biomedical centre and the department of biotechnology.

KRIBB, established in 1985 with only about 30 scientists as the Genetic Engineering Centre affiliated to KIST, now boasts a manpower of more than 500 (509 as of July 1997), including more than 200 doctorate and 150 master degree holders with a total budget of US\$ 36 million in 1997. KRIBB plays an important role in building up the national R&D infrastructure and leading the progress in the field of biotechnology, and functions as a centre of excellence to promote strong co-operation among industry, universities, and national research institutes. The research areas covered by KRIBB are in almost every area of biotechnology including biopharmaceutical, agricultural, food, and environmental areas in six research divisions including molecular and cell biology, protein engineering, plant and animal cell technology, biomolecular, applied microbiology, and bioprocess technology. In addition, KRIBB houses the genetic resources centre which includes bioinformatics, the biopilot plant, laboratory animals, and the gene bank, all playing an important role in establishing the infrastructure for biotechnology R&D across the nation. Since its establishment, KRIBB has been productive in publishing research results (535 in international journals including 139 in 1996) and in obtaining intellectual property rights (331 patents filed including 30 international patents). KRIBB also made 27 contracts for technology transfer leading to royalties of US\$ 0.85 million until 1995 (Table 15).

On the other hand, the Korea Marine Research Institute (now under the Ministry of Marine Affairs) is involved in some biotechnology R&D, including development of new breeds of fish and marine environment, and the Korea Ginseng and Tobacco Research Institute (now under the Ministry of Finance and Economy), involved in some biotechnology R&D related to ginseng and tobacco.

Table 15. **Statistics of productivities in KRIBB**

Year	Publications		Patents filed		Technology transfer contracts
	International	Domestic	International	Domestic	
85	3	15	–	2	–
86	11	38	–	4	–
87	16	24	–	18	1
88	15	52	2	8	2
89	19	51	–	14	1
90	19	55	1	11	1
91	33	102	2	9	3
92	38	124	1	15	1
93	47	118	–	25	5
94	68	137	5	43	2
95	127	165	8	88	8
96	139	166	11	64	3
Total	535	1 047	30	301	27

Source: Author.

Ministry of Agriculture, Forestry and Fishery (MOAFF)

Even before the introduction of recombinant DNA technology to Korea, MOAFF was involved in technology development for crop improvement for the purpose of increasing crop production at research institutes under the Office of Rural Development (ORD). In the early 1980s, when recombinant DNA technology was introduced and interest in genetic engineering was rising, MOAFF established a genetic engineering research institute (expanded to the Agricultural Science Institute in 1994) under ORD in 1986 in order to establish the basis for agricultural biotechnology R&D. In addition, other research institutes under ORD started to introduce new biotechnology into traditional plant and animal breeding.

Beginning in 1994, MOAFF supported various R&D programs carried out in research institutes under ORD, the Office of Forestry, and the Office of Marine Products, and the Korea Food Research Institute in order to develop agricultural and food biotechnology. Included in these programs are the development of new agricultural technology, the development of agricultural biotechnology, the development of technology for improvement, the application of animal and plant resources, the development of food biotechnology, and biological diversity and environmental protection technology. For biotechnology related areas in the above programs, MOAFF plans to invest US\$ 107 million by 1997 and US\$ 375 million by 2004.

Ministry of Health and Welfare (MOHW)

The Ministry of Health and Welfare (MOHW) established the National Institute of Health (NIH) in order to do health care research, including a prevalence study of diseases and drug safety testing. MOHW later expanded the function of NIH and established the National Health Safety Research Institute as an independent institute in order to establish infrastructure for safety and efficacy testing of the drugs being developed. In addition, the ministry has been providing grants for basic research on diseases in the universities.

Furthermore the ministry began supporting a drug development program in 1991 from its own budget and the ministry spent US\$ 2 million in 1992, US\$ 2.4 million in 1993, US\$ 3.6 million in 1994, US\$ 6.5 million in 1995, US\$ 9 million in 1996, and US\$ 10 million in 1997 (it will be increased to more than US\$ 11 million in 1998). According to the ministry's program for promotion of the biopharmaceutical industry as a strategic export industry in the 21st century, MOHW will spend US\$ 1.2 billion for R&D between 1995 and 2010, including US\$ 53 million (including US\$ 13 million from private investment) for drug development using biotechnology from 1995 to 1997. The investment for biotechnology will be US\$ 150 million from 1997 to 2005 for development of basic technology for biopharmaceutical development, development of safety and efficacy testing technology and establishment of safety regulation of biotechnology. In addition MOHW is now developing guidelines for gene therapy through the NIH.

Ministry of Trade, Industry and Energy (MOTIE)

The ministry had not been directly involved in R&D policy since MOST assumed administrative control of the research institutes, but it began to take a very active posture toward R&D policy in 1989 when it was successful in establishing the Korea Academy of Industrial Technology and began supporting commercialisation of the biotechnology by including bioindustry in the five year plan for the promotion of new industries.

In addition, realising that bioindustry contributes most significantly to the economic development of the country by the commercialisation of biotechnology based products, the ministry established the Bioindustry Association of Korea (BAK) in November 1991. The main purpose of BAK is to become the core of R&D and industrialisation for the development of biotechnology by enforcing a systematic co-operative relationship among government, laboratories, academies and industrial firms, and contributing to the cultivation of a domestic bioindustrial environment and transformation of the industrial structure. The general membership of BAK consists of 52 companies including 18 pharmaceutical and 12 chemical companies. Special members of BAK include eight organisations including KRIBB and 140 individuals.

In 1994 the ministry established a development plan for bioindustry until 2005 and is now actively involved in the promotion of bioindustry. Support for biotechnology by MOTIE is mainly through programs such as development of energy substitutes and development of basic technology for industry. The ministry invested in bioenergy development a total sum of US\$ 22 million from 1988 to 1996, and plans to invest more than US\$ 4 million annually from 1997.

Since 1990 the ministry has included bioindustry in the Industry Development Fund which is a loan program for the promotion of new industries. In addition, the ministry started funding biotechnology projects included in the program for the development of basic technology for industry in 1992 and increased support by classifying biotechnology as a separate technology from 1995. According to the

ministry's plan, it will increase support for safety testing technology essential for the infrastructure of biotechnology and strengthen the co-operation system between industry, research institutes, and academia by establishing a centre for commercialisation of technology in the Korea Academy of Industrial Technology by 2000.

However, the actual funding by the ministry for biotechnology so far has been minimal, amounting to US\$ 3.2 million in 1995, but it is expected that investment will greatly increase in the future.

Ministry of Environment (MOEN)

MOEN began showing interest in biotechnology when the need for clean technology and alternative technology arose because of the international movement for environmental regulation as well as increasing domestic concern for the environment. The importance of biotechnology was recognised because of biotechnology's potential as an environmentally sound and sustainable technology (ESST).

The ministry is supposed to be responsible for the development of environmental technology for waste treatment and pollution prevention in addition to the preservation and application of biological diversity according to the Biotechnology Promotion Law. Accordingly, MOEN invested US\$ 7 million for environmental technology development from 1994 to 1997 and plans to invest US\$ 88 million for the biodiversity program from 1994 to 2004. The research is being conducted by research institutes of universities and industry including the National Institute of Environmental Research which plays the central role and is under MOEN.

Ministry of Education (MOE)

MOE played an important role for manpower education in biotechnology by establishing related departments such as departments of genetic engineering and departments of molecular biology in universities in addition to providing research funds for basic research starting from 1982 (US\$ 1.25 million). In May 1994, the ministry established a ten year comprehensive plan for the promotion of basic research which includes the investment of a basic research grant of 15 per cent of total national R&D investment by 2000, from 7.6 per cent in 1992.

The ministry also initiated the establishment of the International Vaccine Institute, a United Nations institute, as the first international organisation in Korea and the first international research institute specialising in vaccine research. The institute was established in October 1997 at the campus of Seoul National University and will begin vaccine research in 2000 with 200 researchers and supporting staff following its construction.

Evaluation of governmental policy

There is no doubt that the Korean government played a very important role for S&T development including biotechnology and the build-up of technology capabilities in government supported research institutes and industry since biotechnology was recognised as an independent discipline. In the beginning of the 1980s, the government started supporting biotechnology R&D and established research institutes. The government also helped to promote biotechnology by enacting the "Biotechnology Promotion Law" which became the legal basis of the government's role in developing biotechnology. In addition, the increased and continued financial support for biotechnology in industry and universities was initiated by

various ministries in recent years. Along with the government's effort to promote biotechnology, industry also started to promote biotechnology by establishing independent research institutes resulting in the establishment of significant R&D capabilities. Until recently, direct support by the government was possible, but the government's policy is being changed from direct support because of, in part, the increased capabilities of private industry to pursue R&D by themselves, and the UR Treaty.

However, researchers and investors, including industry, point out that the government should play a more aggressive role in establishing infrastructure. For example, governmental support and efforts should be made in areas such as establishment of a drug safety evaluation system, information service of property rights and technology trends, efficient regulations for commercialisation of biotechnology products, and promotion of public understanding of biotechnology products and venture business. In addition, it has also been emphasized that the government's support should be made with a long-term R&D plan rather than expecting a short term return in addition to strengthening research capabilities in universities.

Some problems related to the government supported R&D programs have been identified. For example, there have been inconsistencies with the governmental policies and difficulties for small and medium industries in participating in national projects. In addition, there have been complaints about planning ability, fairness of evaluation, and difficulties with industries participating in the planning stages of programs.

Biotechnology R&D is now supported by various ministries. Some researchers argue that it is almost impossible to set a national goal, hard to differentiate the characteristics of different ministries' programs, and difficult to establish close co-operation between academia, government supported research institutes, and industry. However, some feel that the present system has an advantage for promoting diversity and creativity through individual ministries according to their function. It is however recommended that there should be a mechanism for information sharing between ministries.

The government supported research institutes have contributed a great deal to the introduction and dissemination of biotechnology and as think-tanks for government policy making. However, the role of the government supported research institutes should be more clearly defined, in terms of securing national leadership in the field, in managing the national goal, bridging between research in academia and industry, and in performing research including international projects which can not be carried out by industry.

The "Biotech 2000" program is considered to be successful so far since it has contributed helping the policy makers in various governmental ministries to understand the importance and impact of biotechnology leading to the increased biotechnology R&D investment by the government. However, more close co-operation between ministries and public support for biotechnology are needed for continued success of the program.

Conclusions

Korea is one of the most rapidly growing countries in the world and the potential of the Korean economy can be appreciated at a higher level when we understand the progress in science and technology. The Korean government's strong commitment to science and technology ensures promising future roles for Korea in the Asia-Pacific region and in the world.

Recognising that the coming 21st century will be an era of information and biotechnology, the Korean government has been taking the initiative for the promotion of biotechnology by establishing an ambitious

strategic plan for national R&D in biotechnology – the “Biotech 2000” program through which Korea wants to become a leading economic sector in the world in the 21st century.

At present the basis for R&D and the environment for commercialisation has been somewhat established in Korea since the government started supporting biotechnology in the early 1980s. However, there are still insufficient capabilities for the basic research required for technology innovation, R&D investment by industries, and technology infrastructure needed for technology development and commercialisation. Even though industry has had some success in commercialisation of biotechnology products by importing or imitating technology from advanced countries, the growth is limited since the market is restricted in the country. In addition, the industry is in need of developing research capabilities and securing manpower in order to develop innovative technologies and products. Furthermore, the ever increasing competition between industries domestically and internationally due to the increasing pressure on intellectual properties rights and rapid globalization requires a restructuring of the national overall technology innovation system and policy in order to promote bioindustry as a key industry in the 21st century.

The basic goal of long term Korean biotechnology development is the establishment of a biotechnology basis for the realisation of an advanced welfare society and of bioindustry as a strategic export industry. In order to achieve the basic goal, the government will set up detailed strategic goals including establishment of innovative basic technology in order to attain international competitiveness and achieve higher technological capabilities.

In addition, the Korean government has recently taken several important measures in order to facilitate the globalization of the scientific and technological activities of Korea. Realising that the success of globalization depends critically upon scientific and technological capabilities, the government is now readjusting the focus of S&T policy from facilitating “learning” to fostering “innovation”. To this end, the government enacted in April 1997 the “Special Law for Scientific and Technological Innovation”, which provides the legal basis for the government’s reinforced efforts for innovation.

In general, Korea is attempting to change its historical role as a latecomer in S&T and to take up the role of a catalyst for international co-operation in which biotechnology will be one of the most important components.

ANNEX 1
NATIONAL BIOTECHNOLOGY DEVELOPMENT PROGRAM – “BIOTECH 2000”
A KOREAN INITIATIVE FOR BIOTECHNOLOGY DEVELOPMENT
(1994 – 2007)

Aims and strategic objectives

The basic promotional strategies for biotechnology for the “Biotech 2000” program were identified as:

- to strengthen basic and fundamental research in biological science and technology, and subsequent development of indigenous applied technology, which will eventually lead to competitive levels of biotechnology R&D capabilities for Korea;
- to establish full cycle R&D systems and the supporting infrastructure;
- to promote international marketing by enhancing competitiveness of Korean bioindustries and their products.

According to the basic strategies suggested, the aims and strategic objectives of the “Biotech 2000” program are outlined in Box 1.

Box 1. The aim and strategic objectives of the “Biotech 2000” program	
Aim:	<ul style="list-style-type: none"> – place the Korean scientific and technological capabilities of biotechnology at competitive levels to those of the world’s leading countries; – accelerate technological transfer of biotechnological research to commercial applications.
Strategic objectives:	<ul style="list-style-type: none"> – first stage (1994 – 1997): Develop bioprocessing/manufacturing technology and improve industrial biotechnology R&D capabilities; – second stage (1998 – 2002): Extend scientific and technical foundations for development of new bio-technology; – third stage (2003 – 2007): Extend world market basis of biotechnological products of Korea.

Source: Author.

In order to fulfil the goals and strategic objectives, ten implementation strategies were proposed accordingly, as shown in Box 2.

Implementation strategies

Implementation action plan (1): Promotion of inter-ministerial co-operation to establish interdisciplinary R&D basis of biotechnology.

Considering the diversified applicability of biotechnology, e.g. for production of biopharmaceuticals, environmental protection, crop improvement, etc., concerted endeavour for increased investment from the governmental ministries is emphasized. This should be supported by the national consensus to promote biotechnology.

Figure 2. Ten major implementation strategies for the “Biotech 2000” program

Implementation strategies:

- promote inter-ministerial co-operation to establish the interdisciplinary R&D basis of biotechnology;
- provide concentrated support for major strategic R&D projects identified;
- accelerate the development of medium-technology and transfer to commercial applications;
- provide an increased and continued support for on-going biotechnology projects in HAN projects;
- promote basic and fundamental research in life science;
- expand education and training programs to ensure the human resources needed for the development of biotechnology;
- establish a Bio-Technobelt for the promotion of a regional R&D basis of biotechnology;
- strengthen the infrastructure and supporting functions for biotechnology R&D;
- promote international co-operation for biotechnology development;
- improve the institutional and legislative systems to foster the development of biotechnology.

Source: Author.

Therefore, in order to demonstrate the national commitment and to diffuse the public consensus for the promotion of biotechnology, the year 1994 was declared the “Year of Biotechnology” by the government. This governmental action was then to be followed by the successive preparation of the action plans of the participating ministries: MOST, MOFE, MOTIE, MOHW, MOAFF, MOEN, and MOE. The ministries were assigned the tasks to prepare the action plans for participating in the “Biotech 2000” program, as described in Table 1.

The criteria for selecting the strategic R&D projects were as follows:

- needs identified for enhancing international competitiveness of technological basis already established in Korea;
- on-going R&D projects supported as national R&D programs should have higher priorities;
- emerging technologies for the advancement of high-tech industries, which should also contribute to the long-term establishment of biotechnology R&D basis;

- basic technologies for the development of indigenous products or those appropriate for domestic demands.

Table 1. **Major areas of biotechnology for inter-ministerial co-operation**

Ministry	Major task areas	Approaches
MOST	Biomaterials related to technology Target-oriented fundamental research	Interministerial co-operation Interdisciplinary R&D basis
MOHW	Health care products related to biotechnology	
MOTIE	Bioenergy technology Industrial application of biotechnology	
MOAFF	Agricultural biotechnology Food biotechnology	
MOEN	Environment, safety management and utilisation of bioresources	
MOE	Basic research in biological science and technology	

Source: Author.

Implementation action plan (2): Concentrated support for major strategic R&D projects.

Ten strategic research projects were identified in six categories as shown in Table 2.

Table 2. **Ten strategic R&D projects in the “Biotech 2000” program**

I.	Biomaterials
	1. Development of new functional biomaterials
	2. Industrial application of biological functions
II.	Health care
	3. Molecular biological study of human functions (Human biotechnology)
	4. Biomedical engineering
	5. Genome analysis
III.	Agriculture and Foods
	6. Molecular breeding of biological resources and cell culture technology
	7. Food biotechnology
IV.	Environment, Bio-safety, and Biodiversity
	8. Environmental biotechnology and biodiversity
	9. Assessment study of environment and bio-safety
V.	Alternative Energy
	10. Technology for bio-energy production
VI.	Basic Life Sciences

Source: Author.

These projects were supported with the funds from the government and private sectors which total US\$ 1.9 billion during the period of 1994-1997. The government will invest one-third of this fund

(approximately US\$ 625 million) and, in this way, the proportion of biotechnology in the total governmental R&D investment is scheduled to increase to 5 per cent in 1997 from 2.7 per cent in 1993.

Implementation action plan (3): Accelerate the development of medium technology and transfer to commercial applications.

Industry is just beginning to apply biotechnology to a wide spectrum of manufacturing processes to produce a variety of biotechnological products. In order to strengthen the international competitiveness of biotechnological products, it is considered to be of immediate importance to support and foster the bioengineering/manufacturing technologies. Policy is therefore directed to the improvement of the process technologies currently being used, diversification of product development and creation of new high-tech venture capital by fusing new and traditional biotechnology. Efforts for developing more economic and environmentally sound bioprocesses should be encouraged through the research projects to develop advanced bioprocess technology.

Member companies of the Bioindustry Association of Korea (BAK) and the Korea Biotechnology Research Association (KBRA) are strongly encouraged to expand their research activities and to participate in the strategic research projects identified. In line with developing the medium technology related to bioprocessing/manufacturing technologies, six biotechnological research projects were proposed by the member companies of KBRA and started in 1994 with the fund of US\$ 136 000, half of which was matched by the participating companies and the rest from the Ministry of Science and Technology.

Implementation action plan (4): Provide an increased and continued support for on-going HAN projects.

High advanced national (HAN) projects were started in 1992 with an aim to improve technological levels of Korean industry through tight co-operation between academia, government-supported research institutes, and private industries. The program "Development of New Functional Biomaterials" is the project related to biotechnology which was planned as a ten-year program for the period of 1992-2001. During this period, it has been projected to invest the total sum of US\$ 500 million for the program. Actually the government invested US\$ 6 million in 1993 and this increased to US\$ 17 million in 1994. The matching investment by the bioindustries was US\$ 4 million and US\$ 7.5 million in 1993 and 1994, respectively. These figures of investment are larger than those originally planned (Table 3), and they are expected to grow rapidly with the progress of the program. This biotechnology program in HAN projects was included in the "Biotech 2000" program and its continued support is strongly recommended.

Table 3. Investment plan for the biotechnology HAN project ("Development of New Functional Biomaterials") in 1992-2001

Year	Phase I			Phase II			Phase III			Total	
	1992	1993	1994	1995	1996	1997	1998	1999	2000		2001
Government	9	11	18	21	27	29	30	31	32	32	240
Private	3.9	4	5	5.6	7.5	11	25	45	69	84	260
Total	12.9	15	23	26.5	34.5	40	55	76	91	116	500

Note: Unit: US\$ million.

Source: Author.

Implementation action plan (5): Promotion of basic and fundamental research in life science.

New biotechnology has had its great impact in the area of human health care through the development of new diagnostics, pharmaceuticals, and other biomedical products. Technological advances will ensure its continued contribution to human health, and a constant flow of fundamental biological knowledge and creative approaches to its practical application are a requirement for the progress of biotechnology. Biotechnology has grown out of an attempt to understand the molecular basis of life phenomena. Therefore, biotechnological research provides powerful tools for understanding the molecular basis of disease which represents the ultimate answer to the fundamental question of what causes diseases, and by implication, the specific targets for early diagnosis and effective intervention.

Promotion of basic and fundamental research in life science is thus considered essential in pursuing the success of the “Biotech 2000” program. Therefore, a strategic approach to challenge the frontier research in life science is recommended, e.g. biomedical research including drug design, protein engineering, glycobiology, gene therapy, brain research, and so on. Increased support for the fundamental life science research will be made through the Korea Science and Engineering Foundation (KOSEF) which already invested US\$ 11 million in 1993 and US\$ 54 million in 1997 including funding for Science Research Centres (SRC) and Engineering Research Centres (ERC). Expansion of the support for basic research in life science is also expected to be made by the Ministry of Education which runs a promotional program for academic research.

Implementation action plan (6): Expansion of training programs to ensure human resources for the development of biotechnology.

Human resource is recognised as the key element for the successful implementation of the “Biotech 2000” program. It is forecasted that 4 800 research and development personnel will be required in Korea by 1997, of which 1 700 with doctoral degrees and 3 100 with master’s degrees.

In order to supply the manpower, expansion of graduate training programs at universities is strongly recommended along with the activation of the scientists exchange program. The supporting systems funded by KOSEF including the post-doctoral training grants and the “Brain Pool” system for experienced scientists trained in foreign countries are being expanded. Training is critically needed in the fields of protein engineering, glycobiology, carbohydrate chemistry, structural biology, neurobiology, gene therapy, etc. In addition to strong discipline-based training in the fundamental research critical to biotechnology, there is an increasing need for training at the interfaces of biotechnology-related disciplines. Training programs are needed to enhance the expertise at the interfaces between engineering and cellular and molecular biology; between mathematics, biology, and computer science; and between biology, chemistry, and physics. Clinical researchers have a significant need for translating biotechnology discovery from the laboratory bench to the production line.

In this context, it was also proposed in the program that the Biotechnology Training Centre be established at the Korea Research Institute of Bioscience and Biotechnology (KRIBB) which is the only government-supported biotechnology research institute in Korea.

Implementation action plan (7): Establishment of a “Bio Techno-belt” for the promotion of regional R&D basis of technology.

The “Biotech 2000” program also identifies the need for establishing the nation-wide foundation for biotechnological development. The establishment of a “Bio Techno-Belt” through identifying five different regional sectors in Korea with specialised R&D fields was thus suggested. The activation of a

sectorial co-operative system by formation of an R&D consortium among universities and industries was also strongly recommended. Among these, the “Daeduck Science Town” is to play the central role in the “Bio Techno-Belt”, due to its central location in Korea and to the relatively abundant biotechnology-related manpower. The Korea Research Institute of Bioscience and Biotechnology (KRIBB) is to play a major leading role in organising the R&D activities of the “Belt”, and KRIBB is supposed to become the “Centre of Excellence” in biotechnology research in Korea with international recognition.

Implementation action plan (8): Strengthen the infrastructure and supportive functions for biotechnological research and development.

Expansion of supportive functions and necessary R&D infrastructure was strongly recommended to promote biotechnology R&D, such as:

- a gene bank program;
- conservation of useful bioresources;
- bioinformatics;
- a bio-pilot plant;
- evaluation for biosafety and biodiversity;
- preclinical and clinical studies.

These programs are directly supported by the Ministry of Finance and Economy with co-operation from the relevant ministries.

Implementation action plan (9): Promotion of international co-operation for biotechnological development.

Internationalisation or globalization is the main theme of the current Korean government in every field of governmental administrative activities. International co-operation is also considered to be the most efficient measure for absorbing advanced technology and for up-grading the scientific basis. International co-operative effort by Korea has been made by most of all R&D sectors for biotechnology in universities, research institutes and industries with appropriate counterparts around the world. The United States, Japan and European countries have been the major collaborative counterparts. Recently, developing countries including China, Malaysia, Thailand, Brazil and eastern European countries have joined the list of countries for international co-operation in biotechnology.

As a practical measure, the Ministry of Science and Technology recommends that 10 per cent of the total research budget of the “Biotech 2000” program should be used for carrying out international co-operation.

It is particularly emphasized in the “Biotech 2000” program that Korea will enhance its effort to participate in global biotechnological projects initiated by advanced countries. Examples of such global projects are the Human Frontier Science Program and the Human Genome Project.

It is further suggested that new global projects be formulated by Korean initiative in the long term.

Implementation action plan (10): Improvement of institutional and legislative systems for fostering biotechnological development.

New institutional and legislative systems may be necessary in order to facilitate biotechnological research and its commercial application. In this context, the “Genetic Engineering Promotion Law”, which was enacted in 1983, has been amended to the “Biotechnology Promotion Law”, reflecting national recognition of the importance of the technology for the Korean economy.

The Korean government is taking measures to remove any institutional and legislative barriers to the promotion of biotechnological research and its commercial application. Tax benefits for research investment is one of the examples for the promotion of bioindustries. Since mid- and small-size industries are also considered especially important in biotechnology development, measures should be taken to help and promote their creation and growth including new venture capital.

The “Committee for Reformation of Institutional Systems” for the promotion of biotechnology was formed in 1994 with specialists from universities, research institutes, and government. The suggestions made by the committee will be reviewed by the “Advisory Council for Biotechnology Policy”. If approved by the governmental body, the “National Policy Council for Biotechnology Policy”, the reform shall be reflected in the amendment and/or new legislation of corresponding legal systems.

Research programs

Bio-materials

Research strategy

Stage	Objectives	Research tasks
1st stage (1994-1997)	Establish the basic and applied technologies for the industrial use of novel biomaterials	Development of biodegradable polymers Identification and development of novel biomaterials for industrialisation
2nd stage (1998-2002)	Application of biological functions for production of biomaterials Large-scale production and practical use of biomaterials	Application of novel biomaterials(bioactive compound) Application of biopolymers Production of bioactive compounds in animal and plant cell cultures Development of environmentally sound and sustainable technologies
3rd stage (2003-2007)	Establish the economically competitive production technologies for biomaterials and industrial uses of biological processes	Design of high level bioreactors and processes Market development for biopharmaceuticals Development of biosensor/ biochips

Source: Author.

Development of new functional biomaterials (HAN Project)

New functional biomaterials include novel biopharmaceuticals and other materials of biological origin. The program in Highly Advanced National (HAN) Projects, “Development of New Functional Biomaterials”, is the one to promote the development of useful materials by applying biotechnology; screening, isolation and identification of novel biomaterials, and their improvement and large-scale production technologies are the main subjects of the program. The program has been actively carried out since 1992 and will be continued until the year 2001. Active participation by bioindustries and

co-operative endeavour from academia and public research institutes were considered to be essential for the success of the program. Therefore, it was required to form a research team involving manpower from these three sectors prior to submitting a research proposal including matching funds of the research budget from the participating industry. However, for more productive and creative development of biomaterials, selected basic research in biological phenomena was also considered necessary, in which case industrial participation was waived and the project supported by government funding only. Projects for the establishment of microbial screening systems, bioinformatics, and structural analysis of biological substances are examples of government support in the program without matching funds from industry, and these projects are supported by the Ministry of Science and Technology (MOST).

Industrial Application of Biological Functions

In addition, the program entitled “Industrial Application of Biological Functions” is identified in order to further promote industrial participation in biotechnological development. This program is initiated by the Ministry of Trade, Industry and Energy (MOTIE).

Health Care

Research strategy

Stage	Objectives	Research tasks
1st stage (1994–1997)	Establish R&D basis for biopharmaceuticals Fundamental research on biomedical engineering	Development of diagnostics and vaccines Development of biomedical instruments Human genome research
2nd stage (1998–2002)	Development of high value added biopharmaceuticals Establishment of basic technology for biomedicine development	Application of genome research Development of methods to detect and treat genetically inherited diseases Studies on factors of the brain and neural systems Advancement of biomedical instruments
3rd stage (2003–2007)	Establishment of commercial application basis of biopharmaceutical research	Application of neuro–regulatory factors as novel biomedicines Studies on factors in ageing Application of genome data basis

Source: Author.

Biomedical engineering technology, molecular biological study of human functions (Human Biotechnology), and genome analysis

Biotechnology provides powerful tools with which to develop new approaches to the prevention, diagnosis, and treatment of various human diseases. An understanding of the molecular basis of diseases can provide us with novel diagnostics and therapeutic measures which can produce a significant market. Therefore, there have been great efforts in the molecular biological study of human functions, which can be called “Human Biotechnology”, but current knowledge is too limited to be able to solve problems including cancer, AIDS and many other infectious diseases. In order to maintain the current support for health-related biotechnological research and to capitalise on the potential applications for human health, continued and even further enhanced support is strongly recommended.

The signal transduction mechanism is one of the examples suggested in the program, which may provide us with the powerful means to diagnose and treat various cancers. Studies on brain function could also provide information on neuro-regulatory factors which can then be converted into potential biopharmaceuticals. Genome analysis is also regarded as a powerful tool which will provide the necessary information about human functions at the genetic level, which can contribute to the expansion of current knowledge on human functions and lead to the development of many targeted biopharmaceuticals.

The health-care related biotechnological research is proposed to be mainly supported by the Ministry of Health and Welfare (MOHW) with co-operation from the Ministry of Science and Technology (MOST).

Agriculture and foods

Research strategy

Stage	Objectives	Research tasks
1st stage (1994–1997)	Establishment of key technologies of agriculture and foods	<ul style="list-style-type: none"> Application of cloning techniques of useful genes in plants and animals Establish basic technology for transgenic plants and animals Molecular breeding technology for staple and horticultural crops, live-stock and fish Development of biopesticide Development of food biotechnology
2nd stage (1998–2002)	Development of utilisation technology in agriculture and foods	<ul style="list-style-type: none"> Application technology of useful genes in agriculture Development of indigenous food materials with new functions Productivity enhancement technology for transgenic animals and plants Improvement and application technology for marine resources Productivity enhancement technology for forest resources Plant genome analysis and data base establishment
3rd stage (2003–2007)	Development and transfer of a highly productive materials in agriculture and foods	<ul style="list-style-type: none"> Development of utilisation technology for new forms of crops and live stock with high productivity Utilisation technology of high value added marine resources Strain maintenance of laboratory animals and development of disease model animals Commercial production of food material with new functions

Source: Author.

Molecular breeding of biological resources and cell culture technology

One of the greatest impacts of biotechnology is expected in the field of agriculture and foods. Agricultural biotechnological research is applicable to food, feed and even to forestry production. Traditional biotechnology techniques have been practised in agriculture since the beginning of human civilisation through animal and plant breeding. Currently, the knowledge basis for the application of modern biotechnology to plants, animals and microbes of agricultural significance is relatively smaller than that for human health. However, there are now opportunities to obtain essential information for the application of new biotechnological techniques for agriculture. Techniques are now available for producing higher quality food, crops and animals with greater tolerance to various types of stress.

Food biotechnology

It is also very timely to develop new agricultural biotechnology in Korea, since there exists an urgent demand to improve competitiveness of domestic agricultural products. High quality is believed to be the only merit for securing the competitiveness of domestic agricultural products against imported as, since the UR treaty, the opening of the market for agricultural products is inevitable. Therefore it is necessary to establish highly efficient agricultural production systems by applying biotechnology. This program is supported and initiated by the Ministry of Agriculture, Forestry and Fisheries with co-operation from the Ministry of Science and Technology.

*Environment, biosafety and biodiversity***Research strategy**

Stage	Objectives	Research tasks
1st stage (1994-1997)	Establishment of technologies for biological treatment of pollutants Technological assessment of environmental pollutants Conservation technology for bioresources	Technology development for treatment of environmental pollutants Biological treatment technology of pollutants Waste recycling technology <i>In situ</i> or <i>ex situ</i> preservation of bioresources
2nd stage (1998-2002)	Application of biological treatment technologies Assessment of environmental impacts of developed technologies	Pollution-reducing technology Bioremediation technology Monitoring marine pollution and restoration
3rd stage (2003-2007)	Practical application of biological waste treatment technologies	Highly efficient biological treatment technologies for pollutants Conservation and utilisation of bioresources

Source: Author.

Environmental biotechnology and preservation of biodiversity; assessment study of environment and bio-safety

The environmental effects of modern industrial society require a significant measure for environmental restoration and protection. Biotechnology is considered to be the most efficient measure for this purpose. Examples of recent developments include the engineering of micro-organisms that degrade specific toxic chemicals like benzene, toluene and xylene. The waste treatment process by using biotechnology also

shows great promise. In relation to the world's movement towards environmental preservation, there exists great concern in the preservation of biodiversity, and also in the development of environmentally sound and sustainable technology.

Korea has had similar environmental problems due to rapid industrialisation in the past 30 years. Water and air pollution by industrial and municipal waste/pollutants have become serious problems, and in addition, soil contamination has become a serious hazard in certain areas near mining businesses. Bioremediation technology is therefore a high priority in the "Biotech 2000" program. This program is supported mainly by the Ministry of Environment with co-operation from the Ministry of Science and Technology.

Alternative energy

Research strategy

Stage	Objectives	Research Tasks
1st stage (1994–1997)	Development of alternative energy resources and their basic technologies	Technology development for alternative energy production using biomass Development of bioresources for production of alternative energy Basic technology development of photosynthetic bioresources
2nd stage (1998–2002)	System construction for utilisation and management of alternative energy resources	Mass production technology development of alternative energy (economical point) Utilisation technologies for photo-synthetic bioresources Development of bioprocess technology
3rd stage (2003–2007)	Utilisation of alternative energy technology	Utilisation of biological alternative energy Practical application of energy saving bioprocess technology

Source: Author.

Development of technologies for bioenergy production

Korea does not possess any petroleum resources and has been totally dependent on imported oil. This situation, coupled with increasing energy consumption, requires the development of alternative energy. A rational long-term energy plan includes the increased use of biological systems to maximise the efficient and economic use of both renewable and fossil fuels while also decreasing the environmental impacts of energy production and use. Biological production of hydrogen and ethanol can be useful measures although their large-scale production are not yet economical. This program has been supported by the Ministry of Trade, Industry and Energy for the past ten years, and will be significantly increased as its potential is recognised.

Basic life science

- structural analysis of biological materials;
- regulation of gene expression in eukaryotic cells;
- signal transduction;
- mechanism of differentiation in immune system;
- proliferation and propagation of viruses;
- biochemical and biophysical characterisation of enzymes;
- molecular biology of brain.

Research strategy

Stage	Objectives	Research tasks
1st stage (1994–1997)	Structural biology and gene expression mechanism	Structural analysis of biological materials Mechanisms of gene expression regulation Signal transduction Molecular biology of viruses
2nd stage (1998–2002)	Basic approaches in therapy for genetic diseases and ageing	Molecular analysis of ageing Analysis of gene information system
3rd stage (2003–2007)	Fundamental basic research in neurobiology	Basic researches in brain and neural functions Analysis of the ageing process

Source: Author.

Research in basic life science can provide biotechnologists with innovative ideas which lead to practical applications. Many novel biopharmaceuticals have been found through basic and fundamental research in life science. They are also needed to support the development of indigenous technology and bioproducts.

Supportive functions and infrastructure***Supportive functions***

Biotechnological research involves many problems at the interface of various academic disciplines and often requires collaborative research between scientists and engineers with diverse skills and expertise. It also requires vast investment to set up supportive functions to facilitate biotechnological research. For more efficient investment, centralised systems for the gene bank, the bio-pilot plant, experimental animals, safety and efficacy evaluation, and preclinical study programs, are suggested to cover the entire biotechnological research activities of universities, public research institutes, and industries in Korea. The investment for these supportive functions are heavily dependent on governmental funding because of their rather public nature.

Gene Bank Program

This program contributes to the enhancement of the national capacity of acquiring, maintaining, preserving and distributing collections of micro-organisms, genetic resources and data bases containing scientific data on DNA sequence, microscopic image and systematic profiles, etc. It also supports the establishment of several small size repositories of specialised genetic resources. The Korea Research Institute of Bioscience and Biotechnology (KRIBB) should support the federation of those culture collections.

Biological Resources Program

This program contributes to the enhancement of strain maintenance of internationally registered laboratory animals and insects. It also provides functions of monitoring and technological development for conservation of domestic animal resources, and utilisation and distribution of laboratory animals and insects.

Bio-Pilot Plant Program

The role of the bio-pilot plant is the provision of facilities and know-how for internal and external research groups for carrying out research on bioprocess related technology. The first model bio-pilot plant was constructed in 1995 at KRIBB and is being used by researchers from universities and industries. This program is also intended to conduct process engineering investigations on a pilot scale for the development of various biotechnological products.

Biotechnology Information Program

This program is to support the development, management, and cataloguing of databases, information resources, and electronic libraries (library information systems) relevant to biotechnology research and development through BioTech InfoNet. Examples include data bases containing literature (monographs, journals, patent dissertations, publications by public research institutions), marketing strategies, economic feasibility of new products, high quality expert resources and recent R&D activities, etc.

Assessment of Safety and Efficacy Evaluation Program

It is proposed to enhance and efficiently co-ordinate the functions related to the evaluation of safety and efficacy of bioproducts in Korea. Three relevant research organisations, the National Institute of Safety Research, the Screening and Safety Research Centre at the Korea Research Institute of Chemical Technology (KRICT), and KRIBB are to make a co-operative program to activate the pre-clinical evaluations of biotechnological products.

It is also considered necessary to promote the national capability of pre-clinical tests for new biopharmaceuticals and suggested to establish a National Preclinical Evaluation Centre (NPEC) with governmental funds.

Clinical Trial Program

This program is to enhance education and training programs of the clinical test activities in medical schools and hospitals in order to improve international credibility and to establish a national framework.

The establishment of a National Clinical Centre (NCC) is suggested in the “Biotech 2000” program under close co-operation from relevant ministries including the Ministry of Health and Welfare, the Ministry of Science and Technology, and the Ministry of Trade, Industry and Energy.

Budget planning

In order to support the successful implementation of the “Biotech 2000” program, it was suggested that the government take significant initiatives to invest in R&D efforts in biotechnology, which would in turn facilitate the increments of private investment in this field. For such a purpose, an increase in the R&D budget for the participating ministries and the use of strategic funds and subsidiary loans are also proposed in the program.

By these means the proportion of biotechnology investment in the government R&D budget is scheduled to increase up to 5 per cent in 1997 from 2.7 per cent in 1992, which corresponds to a total of US\$ 0.625 billion for the period of 1994–1997. Expected volume of matching investment from the industrial sector is US\$ 1.3 billion in the same period.

Table 10 shows the investment plan for the “Biotech 2000” program in the scheduled period until the year 2007, the sum of which totals US\$ 20 billion for the planned 14 year period. The investment plan is broken down into the respective areas and shown in Table 11.

Table 4. **Investment plan for the “Biotech 2000” program**

Source	1st stage (1994–1997)	2nd stage (1998–2002)	3rd stage (2003–2007)	Total
Government	625	1 630	4 930	7 185
Private	1 300	3 850	7 700	12 850
Total	1 925	5 480	12 630	20 035

Note: Unit: US\$ million.

Source: Author.

Table 5. Budget planning for strategic R&D areas

		1st stage			2nd stage	3rd stage
		1994	1995–1997	Total	(1998–2002)	(2003–2007)
Biomaterials	Government	16	122	138	324	973
	Industry	82	374	456	1 240	2 410
	Total	98	496	594	1 564	3 383
Health care	Government	13	88	101	250	825
	Industry	61	283	344	430	1 900
	Total	74	371	445	680	2 725
Agriculture and food	Government	9	98	107	374	825
	Industry	35	206	241	870	1 800
	Total	44	304	348	1 244	2 625
Environment, safety and conservation of bioresources	Government	7	59	66	212	687
	Industry	25	137	162	590	240
	Total	32	196	228	802	927
Alternative energy	Government	4	36	40	110	325
	Industry	17	67	84	490	650
	Total	21	103	124	600	975
Basic life science	Government	12	112	124	350	970
	Industry	–	9	9	170	400
	Total	12	121	133	520	1 370
Supportive functions and infrastructure	Government	4	45	49	110	325
	Industry	–	4	4	60	300
	Total	4	49	53	170	625
Total	Government	65	560	560	1 630	4 930
	Industry	220	1 080	1 300	3 850	7 700
	Total	285	1 640	1 925	5 480	12 630

Note: Unit: US\$ million.

Source: Author.

ANNEX 2
BIOTECHNOLOGY PROMOTION LAW

Article 1 (Purpose)

The purpose of this law is to more efficiently develop and promote biotechnology as well as to facilitate the commercialisation of the technology for the sound development of the national economy.

Article 2 (Definition)

In this law, biotechnology is defined as any scientific study and/or technology that uses living organisms (or parts of organisms) or biological systems to improve plants and animals, or to develop micro-organisms for specific uses including the manufacture of industrially useful products or the improvement of manufacturing processes.

Article 3 (The scope of application)

If there is no other special law, each issue related to biotechnology should follow this law.

Article 4 (Establishment of the National Plan for Biotechnology Promotion)

- 4-1. All incumbent ministers, listed in article 13, must submit their plans related to biotechnology promotion to the Ministry of Science and Technology (MOST).
- 4-2. The minister of MOST, following Item 1, is to formulate the National Plan for Biotechnology Promotion (NPBP) by co-ordinating the plans submitted by other ministries.
- 4-3. The NPBP should include the following:
 - 4-3-1. Guidelines related to the development and efficient utilisation of human resources in the fields of biotechnology.
 - 4-3-2. Planning and guidelines related to the international exchange of scientists and engineers as well as the utilisation of foreign scientists in the fields of biotechnology.
- 4-4. The minister of MOST should meet with the National Policy Council for Biotechnology (Article 6) as he is to formulate the NPBP.

Article 5 (Formulation of the Annual Implementation Plan for Biotechnology Promotion)

- 5-1. The related ministers should formulate and implement the Annual Implementation Plan for Biotechnology Promotion (AIPBP), following the NBPB.
- 5-2. The related ministers should take counsel with the minister of MOST as they formulate their implementation plans.
- 5-3. The minister of MOST, if necessary, may inform the relative ministers of the basic guidelines when he formulates the AIPBP.
- 5-4. Necessary issues relating to the formulation and implementation of AIPBP are to be described by the Presidential Ordinance.

Article 6 (National Policy Council for Biotechnology)

- 6-1. The National Policy Council for Biotechnology (NPCB) is formed, under the control of the minister of MOST, for the implementation and co-ordination of NBPB.
- 6-2. The NPCB will counsel and make decisions about the following items.
 - 6-2-1. Formulation of basic plans for biotechnological research and technology development as well as establishment of national policy and co-ordination of implementation.
 - 6-2-2. Comprehensive planning and co-ordination for development and utilisation of human resources in biotechnology.
 - 6-2-3. Development of biotechnological research and its industrial technology transfer as well as the planning and co-ordination of the utilisation of foreign scientists and engineers.
 - 6-2-4. R&D planning and co-ordination for the utilisation and preservation of genetic resources.
 - 6-2-5. The co-ordination of R&D plans in the process of formulating and implementing genome studies.
 - 6-2-6. Other items that the minister of MOST needs to consider for the promotion of biotechnology.

Article 7 (National Executive Committee for Biotechnology)

To prepare the agenda for the NPCB and to deal with the assignments that the NPCB has delegated, the National Executive Committee for Biotechnology (NECB) is to be created under the minister of MOST.

Article 8 (Composition of both NPCB and NECB)

- 8-1. Both NPCB and NECB consist of officials in related governmental agencies and experts from universities, research institutes and industries.

8-2. In addition to the present article, the Presidential Ordinance will make decisions and guidelines for the necessary issues related to the organization and operation of NPCB and NECB.

Article 9 (Research and technological co-operation)

The Minister of MOST should make efforts to promote international co-operation in biotechnological research and technology development including genome study with other ministries, as well as consider efficient policies for importing advanced technologies.

Article 10 (Promotion of co-operative research)

The Government should promote co-operative activities among academia, research institutes and industry for efficient biotechnology development.

Article 11 (Support for the industrial sector)

The Government may support industry in manufacturing new technology goods for efficient industrialisation of biotechnological research outcome.

Article 12 (Gathering and distribution of technology information)

The Government should make an effort to promote biotechnology R&D by gathering scientific and technological information and distributing it to the relative organisations.

Article 13 (Formulation of promoting policy for biotechnology)

The Government should set up the following policies to efficiently promote the development of biotechnology:

1. The Minister of Education should educate and nourish manpower to facilitate biotechnological research and provide support for fundamental research in biotechnology.
2. The Minister of Agriculture, Forestry and Fishery should provide support for the foundation of research institutes equipped with capacities for developing and disseminating various new species of animals, plants, marine life and new food resources, as well as R&D for exploitation and preservation of genes useful in the field of agriculture and fishery.
3. The Minister of Trade, Industry and Energy should support R&D to improve and develop the biotechnology related manufacturing process, substitute energy, efficient use of energy and mineral resources, manufacturing process technology related to biotechnology, and their technology transfer to the industrial sector.
4. The Minister of Environment should support research and technology development related to the preservation of biological diversity and its sustainable utilisation, waste and pollutant treatment by biotechnological means, and development of environmental technology for the prevention of air pollution.

5. The Minister of Health and Welfare should support biotechnological research and development related to health care, medicine, and food hygiene, support training of related specialists, and promote business related to clinical and pre-clinical tests.
6. The Minister of Science and Technology should formulate the NPBP, as described in Article 4, Item 2, and support and co-ordinate other ministerial plans for biotechnology promotion, development of fundamental and advanced biotechnology, research for utilisation and preservation of useful genetic resources, and national supporting functions of biotechnology infrastructure of public nature.

Article 14 (Safety and clinical tests)

- 14-1. The government should establish a system for safety and clinical tests for biotechnological products.
- 14-2. Any necessary matters concerning foundation and establishment of systems for safety and clinical tests in Item 1 are to be decided according to the Presidential Ordinance.

Article 15 (Preparation and implementation of experimental guidelines)

- 15-1. The government should prepare and implement experimental guidelines for the promotion of biotechnological research and industrialisation thereof.
- 15-2. The experimental guidelines should include necessary measures for preventing any biological hazards, any negative influences upon the environment and ethical problems that can arise in the course of research on biotechnology and its industrialisation.

Article 16 (Korea Research Institute for Biotechnology)

- 16-1. The Korea Research Institute for Biotechnology (hereinafter, the “Research Institute”) may be established to play essential roles for biotechnological research, utilisation and preservation of genetic resources, and to establish a mutually co-operative system among academics, research institutes and industries, and to establish a supporting infrastructure system of a public nature.
- 16-2. The Research Institute (Item 1) should be a government supported one to which the Act for Development of Government Supported Research Institutes is applied.

Article 17 (Foundation of the Biotechnology Research Fund)

- 17-1. The government may establish the Biotechnology Research Fund (hereinafter, Fund) to promote research and development in biotechnology and to facilitate the utilisation and preservation of genetic resources. It is paid for by government funds, profits from the Research Institute’s business, reserve funds and surplus funds from its closing accounts.
- 17-2. Any matters necessary for raising the Fund are decided according to the Presidential Ordinance.

Article 18 (Operation and management of the fund)

- 18-1. The Minister of Science and Technology should operate and manage the Fund.
- 18-2. Any important matters regarding operation and management of the Fund should be decided upon by the NPCB.
- 18-3. The profits from the Fund can be used to provide funds and allowances for research organisations and individuals engaged in biotechnological research, and also for related service consignments.
- 18-4. Any matter relating to the operation and management of the fund, other than the items set forth in this law, should be decided by the Presidential Ordinance.

Article 19 (Reduction of taxes, etc.)

- 19-1. In the event that it be necessary to import equipment, machinery and chemicals required for research activities in biotechnology, which are impossible to obtain from domestic sources, customs and value added taxes on the import of such items may be exempted as set forth in the Tax Reduction and Exemption Act.
- 19-2. In order to secure the safety of the imported items, which can spoil due to lengthy customs procedures, the system for approval aftermath can be a substitute for the existing process as set forth in the Presidential Ordinance.

Article 20 (The Presidential Ordinance)

Any necessary matters for implementation of this law should be decided by the Presidential Ordinance.