2019 Taiwan Industrial Outlook

Applied Biotechnology Industry

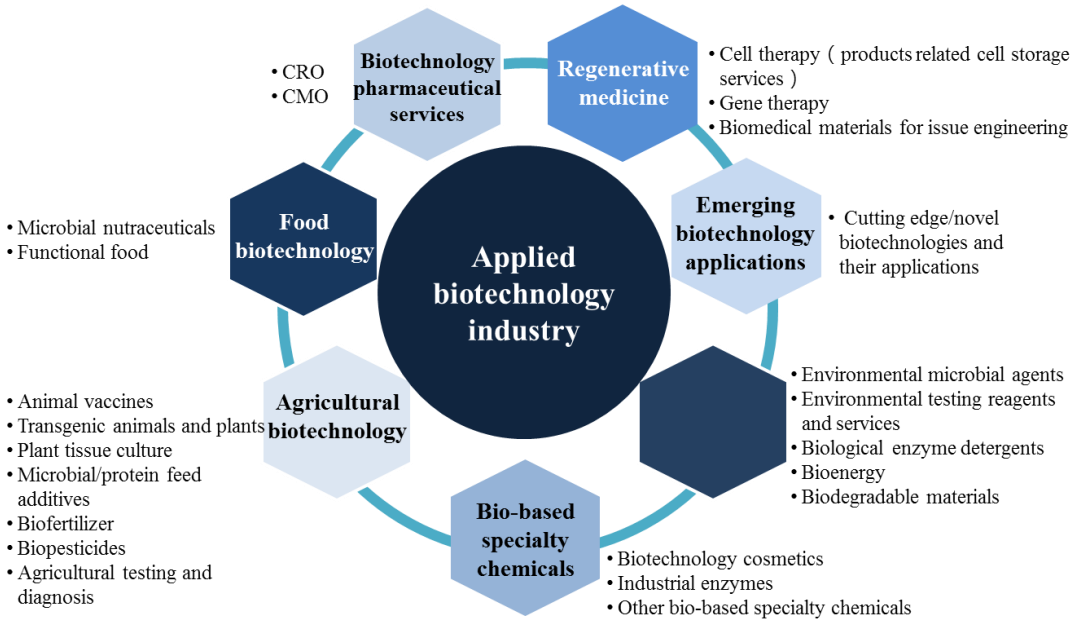
Development Center for Biotechnology(DCB)

ITIS Research Team

1. Industry Scope

There is a wide range of applications for biotechnology. A country's definition and usage of biotechnology differs depending on its stage of development, competitive advantages, its desire to push for biotechnology as well as the country's resources and needs. However, the majority of countries will combine the advantages they already possess to develop assets that will be competitive globally. Taiwan defines the applied biotechnology industry based on its usage (e.g. genomics, proteomics, gene reconstruction, cell reconstruction, cell culture, fermentation engineering, enzyme conversion). The objective of conducting research, manufacturing products and raising product quality is to improve the quality of people's lives.

Beyond areas directly related to the pharmaceutical field, applied biotechnology in the form of products and services is also closely tied to people's everyday lives. These include seven areas, namely, regenerative medicine, medicinal biotechnology production services, food biotechnology, agricultural biotechnology, Bio-based specialty chemicals, environmental biotechnology, and emerging applied biotechnology.



Data source: DCB ITIS Research Team (2019.07)

Figure 1 Diagram showing Taiwan's applied biotechnology industries and their products/services

2.2018 Applied Biotechnology Industry Overview

(1) Status of the Global Applied Biotechnology Industry

Based on a report from Global Market Insights,the global biotechnology market scale was estimated to be US$ 399.4 billion in 2017. The report projected the Compound Annual Growth Rate (CAGR) to be 9.9% in 2018-2024. The value of the global biotechnology market will thus exceed US$ 775 billion. Besides consumer demand driving growth in the biotechnology industry, innovations within the field in terms of new industries and products in the future are expected to produce market growth. With innovative technology and government policy incentives, the U.S. maintains a leading role in the biotechnology industry, giving it a high CAGR of 11.1%.

The definition of the biotechnology industry internationally is largely created from the technology used to manufacture products. Biotechnology is a fundamental tool that applies different technology to organisms and utilizes them to provide a better living environment. This includes enhancing flora and fauna, developing micro-organisms for specific uses and developing medicine. A number of industries can make use of biotechnology. A such, there is no uniform definition for the scope of the biotechnology industry across all governments. A country's definition will instead focuses on its advantages and industrial support. Taiwan identifies biotechnology as the "applied biotechnology industry". This definition refers to corporations using biotechnology in its production or improving of products. The industry has a broad scope. Based on the products utilizing biotechnology, there are six major industries: regenerative medicine, biotechnology pharmaceutical services, food biotechnology, agriculture biotechnology, biotechnology cosmetics (biocosmetics) and, environmental biotechnology. The effect of the overall environment on each industry's development varies depending on the features of that particular field.

According to research report from MarketsandMarkets, the global regenerative medicine market includes cell therapy, immunotherapy, gene therapy and tissue engineering products. In 2018, the market was valued at US$ 10.5 billion and is expected to nearly double, reaching US$ 25.3 billion by 2022. The regenerative medicine market has a CAGR of 24.6% in 2018-2022. Examining the regenerative medicine market based on region, one will note that North America, the EU, and the Asia-Pacific region are key areas for developing regenerative medicine. Because of simplifing the process for regenerative medicine product review via The U.S. FDA , the demand for cell therapy and gene therapy continues to increase in North America, an increased awareness of personalized medicine and the storage capacity of organizations were the major drivers for this growth. In North America, the U.S. in general show rapid growth in the regenerative medicine industry. The Asia-Pacific region has seen development in the regenerative medicine industry as governments gradually place more value in it. Japan is a leading country in this area due to its government policies as well as its excellent research and application of induced Pluripotent Stem Cells (iPS). However, Taiwan, South Korea, and China trail closely behind Japan.

Biotechnology pharmaceutical services can be divided into two sub-categories: Contract Research Organization (CRO) and Contract Manufacturing Organization (CMO). Based on estimates by BCC Research, the global CRO market was valued at US$ 50.1 billion in 2018 and is expected to increase to US$ 72.3 billion by 2022 (see figure 1-2-1). The CRO market's CAGR is 9.6% between 2018 and 2022. Examining the market by region shows that the North American region (including the U.S. and Canada) has the largest CRO market in the world at 43.3%. Following that is the EU and countries with emerging markets, 32.0% and 24.7% respectively. The number of clinical trials conducted in the U.S. has dropped In recent years, while clinical trials in emerging markets, particularly those in Asia, has increased steadily. Clinical trials globally are gradually shifting to emerging countries for development. In 2018 the global CMO market was valued at approximately US$ 40.5 billion. It is estimated to reach US$ 49.5 billion by 2022 with a CAGR of 5.1 between 2018 and 2022. At a regional level, North America has the largest CMO market at an estimated 54.7%. This is followed by the EU and emerging countries, which is at 23.4% and 21.8% respectively. When comparing the CAGR of these regional markets between 2018-2022, EU has the highest growth with a CAGR of around 6.2%. North America shows signs of slower growth with a CAGR at 4.4%.

Nutritional health care products increasingly have become a key target for consumers as lifespans have extended and the rate of diseases stemming from one's lifestyle has increased. Besides these factors, the increased medical expenses in developed countries have prompted consumers to use health products to maintain their health and reduce the chances of needing medical care. According to data from Euromonitor, in 2018 the global nutritional supplement market is valued at US$ 106.3 billion with a CAGR of 3.6% between 2014-2018. It is expected that chronic disease prevention and demand for nutritional supplements from consumers in emerging markets will be drivers of growth in the future, giving the market a CAGR of 5.3% between 2018-2022. In 2022, the market for nutritional supplement products may reach as high as US$ 130.8 billion. Increases in income in the Asia-Pacific region, particularly in emerging markets such as China and India have allowed for consumers to focus more on their appearances and health. As a country with the longest lifespans in the

world, Japan actively faces its increasingly severe health issues related to aging. Japanese consumers' uses of nutritional products to maintain body function and slow the affects of aging has driven demand in this area. As such, the Asia-Pacific region represents 47.4% of the global nutritional products market. They are followed by North America at 30% and Western Europe which is 10%.

Agriculture biotechnology broadly refers to the application of molecular biology and genetic engineering in agricultural products or the manufacturing process. The term also encompasses the genetic modification of animal and plant products, the enhancement of economic profit from crops and livestock, raising agricultural production, increasing disease prevention and ecosystem protections. The market is divided into two subcategories based on the types of products produces: crops and animal products. The secondary industry related to crops includes genetically modified organisms (GMO), biopesticides, and biofertilizers. For the secondary industry surround animals products, there are animal vaccinations, detection for diseases, and additives to animal feed.

Based on statistics from Mordor Intelligence, the usage of biological pesticides and biofertilizers increased in tandem with the expansion of organic farming. The global biological pesticide market scale was US$ 3.15 billion in 2018, making up 5.0% of the total global pesticide market. It is predicted that the global biological pesticide market scope will increase to US$ 6.93 billion by 2024. The CAGR is 14.0% in 2018-2024. North America is the largest market, and making up 41.6% of the global market for biological pesticides, by its heavy investment in research and implementation of Integrated Pest Management (IPM) systems. In the U.S. the process for registering biopesticides has been simplified in an effort to promote its usage, making the U.S. the largest market for biopesticides. Biofertilizers are environmental microbial agents that work well with the environment, which works through the fertility of the soil to produce more and better crops. According to data from Mordor Intelligence, the global market scope of biofertilizers was US$ 1.43 billion and is expected to reach a scope of US$ 2.53 billion in 2024. It has a CAGR of 10.1% for 2018-2024. North America is the largest regional market for biofertilizers as of 2018 with a market share of 27.7%. The EU is second, then followed by the Asia-

Pacific region; however, the Asia-Pacific region is experiencing the fastest growth.

Gene editing technology, which is widely applied to plant species, had a global market scope of US$ 7.57 billion in 2018, according to Marketsandmarkets. It is expected that the global market will increase to US$ 14.6 billion in 2023 with a CAGR of 14.0% in 2018-2023. The U.S. market is presently the largest. Animal vaccine development, improving animal feed and swift detection of animal diseases are key areas for maintaining the growth and quality of livestock. According to data from Mordor Intelligence, the global market scale of animal vaccines was US$ 7.2 billion in 2018. The global market scope is estimated to increase to US$ 10.1 billion in 2024 due to heightened awareness regarding animal health, new vaccine technology, and support via government policies as well as trends in animal feeds. The market's CAGR is estimated to be 5.8% in 2018-2024 with North America as the largest regional market.

The global animal feed additive market scale was US$ 31.7 billion in 2018 based on data from Mordor Intelligence. It is estimated that the global market scope will reach US$ 41.6 billion by 2024 with a CAGR of 4.6% in 2018-2024. The Asia-Pacific region is the largest as well as fastest growing region. Animal diagnostic reagents, used to quickly diagnose an animal disease, have seen fast growth in market scale over the past few years. Mordor Intelligence data shows that the global market scale of animal diagnostic reagents was US$ 2.6 billion. It is estimated to grow to US$ 4.0 billion by 2023 with a CAGR of 8.8% in 2018-2023. North America is the largest market with 73.0%, followed by the EU and the Asia-Pacific region, which is seeing the fastest growth.

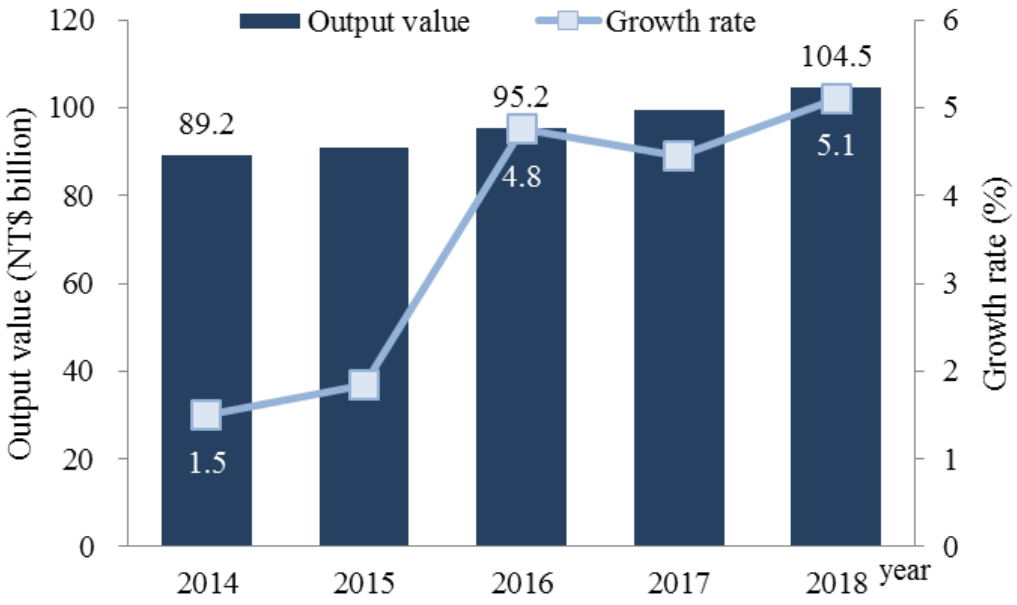
The bio-based specialty chemicals including biocosmetics, industrial enzymes and other bio-based specialty chemical products, such as amino acid and collagen. Among these products, industrial enzymes and biocosmetics are presently the two major areas for the application of bio-based specialty chemicals. Based on 2018 estimates from the top industrial enzymes company,

Novozymes, the global market scale for industrial enzymes was US$ 3.1 billion in 2018, showing growth of 1.9% since 2017. The global industrial enzyme market scale is expected to continue its growth and is estimated to reach US$ 3.4 billion in 2022 with a CAGR of 2.3% in 2018-2022. According to BCC Research's surveys, the three key market regions for industrial enzyme demand are North America, Asia-Pacific, and the EU. The global cosmetics market, as seen in Euromonitor's data, was US$ 503.3 billion in 2018. This is 5.6% higher than 2017. The market has a CAGR of 4.7% The market scale is estimated to grow to US$ 635.3 billion in 2022 with a CAGR of 6.0% in 2018-2022. This growth is due to increasing demand from emerging markets and the expansion of consumer groups. In 2018 Asia-Pacific, Western Europe, and North America represent the three largest markets for cosmetics with a cumulative market share of over 70%.

The environmental biotechnology industry includes bioenergy, biodegradable materials, environmental microbial agents, environmental microbial test reagents and services as well as biological enzyme detergents. Among these, bioenergy and biodegradable materials are seeing a more complete form of development and hold a higher market share. They are both industries that have significant impact on the value of the environmental biotechnology industry. Based on data from ResearchStore.biz, the global market scale of bioenergy was US$ 165.8 billion in 2018. It is expected to grow to US$ 233.6 billion by 2025 with a CAGR of 5.0% in 2018-2025. In terms of market regions, North America is the largest regional at 39.8% with Asia being the second largest. The biodegradable materials market makes up 1% of the total plastics market and had a global market scale of US$ 3.0 billion according to MarketsandMarkets. This market scale is expected to reach US$ 6.1billion in 2023 with a CAGR of 15.1%. The EU is the largest market region in this category, making up 55%. North America is the second, with Asia-Pacific will be the fastest growth region.

(2) Status of Taiwan's Applied Biotechnology Industry

The applied biotechnology industry in Taiwan has shown steady growth in its output value over recent years. This increase stems from companies continuing to manufacture new products, expand sales channels, development of sales strategies, integrate the sales resources, and concentrate of product lines. In addition, companies have maintained their status within international markets. These factors drove output value growth in the applied biotechnology industry to NT$ 104.5 billion, a 5.1% increase over 2017.

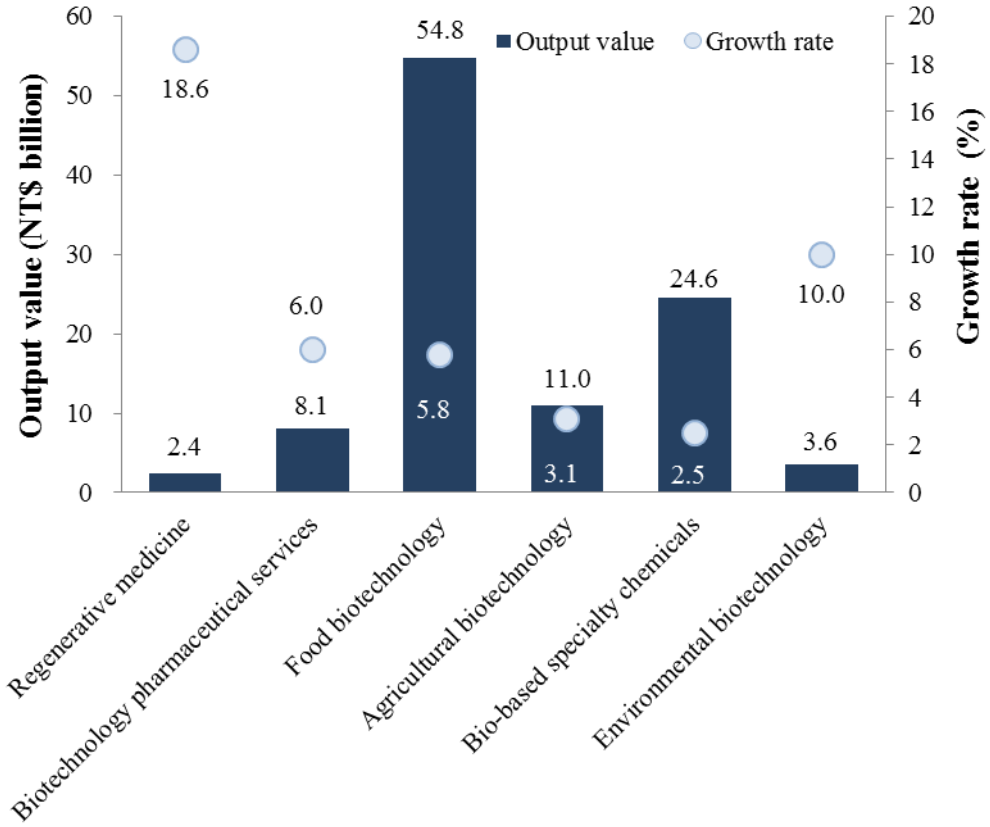


Data source: "Questionnaire Survey of Biotechnology Manufacturers in Taiwan" (2018); Financial statements/annual reports of public companies. Estimation by DCB ITIS Research Team (2019.07)

Figure 2 Changes in the output value of the applied biotechnology industry in 2014 and 2018

In 2018, the output value of the food biotechnology industry was the highest among secondary industries within Taiwan's applied biotechnology industry. It grew to NT$ 54.8 billion and represented 52.4% of the entire applied biotechnology output value. The next highest output value was the bio-based

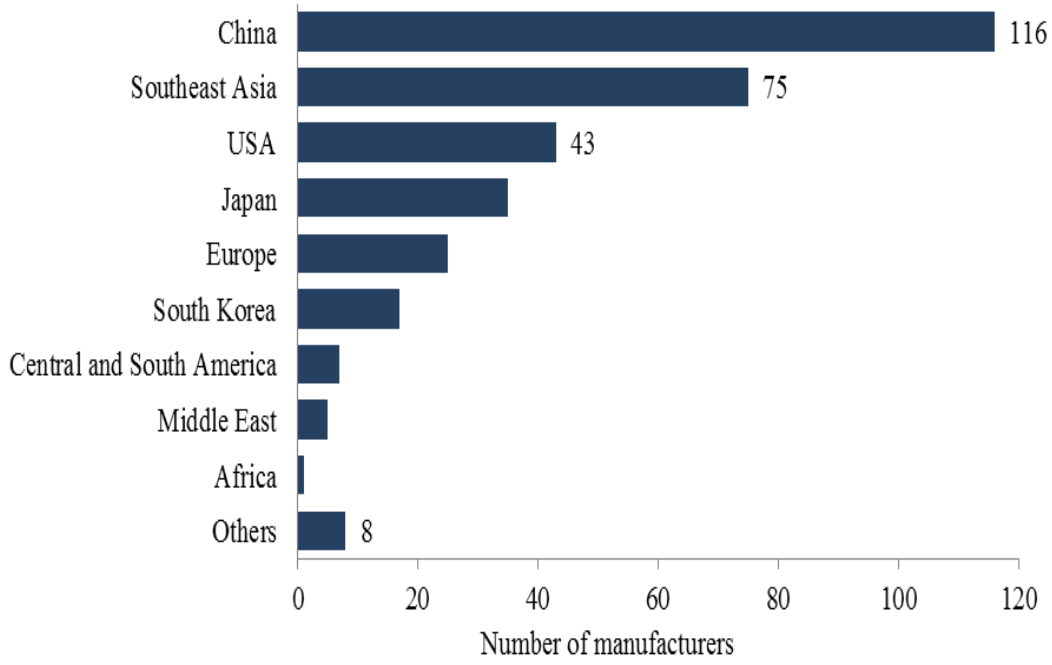
specialty chemicals industry at NT$ 24.6 billion and making up over 20% of the overall market. Regenerative medicine showed the highest growth among industries in 2018. This was primarily caused by an increase in cell banking revenue, development of new products for tissue engineering products, and increases in market demand, resulting in output value growth of 18.6% for the regenerative medicine market. Environmental biotechnology was second in terms of its growth rate. Output value is expected to continue growing because of biodiesel companies' successful developments in foreign markets. The market demand for biodegradable materials has risen as a result of calls for reducing the usage of coal and an increase in environmental awareness globally. The environmental biotechnology market maintained a growth in output value of 10.0% in 2018.



Data source: "Questionnaire Survey of Biotechnology Manufacturers in Taiwan" (2018); Financial statements/annual reports of public companies. Estimation by DCB ITIS Research Team (2019.07)

Figure 3 2018 Output value and annual growth rate of applied biotechnology subindustries in Taiwan

In recognizing the limited scale of the domestic market, applied biotechnology industry manufacturers have been proactively expanding overseas markets to increase revenue and recognition with selected high technology, high product quality, and competitive niche products and technology. In 2018, over 50% of companies in Taiwan operated within the international market. Among those companies, 21.0% have operated in such capacity for 3-5 years, and 12.2% have participated for 6-10 years. In analyzing the companies that found markets overseas, the majority operated in China with 116 companies moving into the Chinese market for expansion. Southeast Asia was the second area for companies to enter, particularly Malaysia, Thailand, and Vietnam.



Note: Data was obtained from 286 valid questionnaire responses with items that allowed multiple answers.

Data source: "Questionnaire Survey of Biotechnology Manufacturers in Taiwan" (2019); Investigation by DCB ITIS Research Team (2019.07)

Figure 4 Taiwanese applied biotechnology industry manufacturers in the world in 2018—categorized by the country in which they operate

3. The Opportunities and Challenges of Developing the Applied Biotechnology Industry

(1) The Status and Challenges of the Biotechnology Industry as aWhole

The demand for human medicine and changes in lifestyles has been a global issue in recent years. The pharmaceutical market is trending toward precise medicines and advanced countries are focusing on cell therapy, these trends have brought development and growth to the regenerative medicine industry and biotechnology pharmaceutical services. Under the global intelligent digital technology development, genetic editing technology development and green environmental protection appeal, governments actively develop innovative technologies and create a green and friendly environment There has been an increase in business opportunities for companies within the food biotechnology, agriculture biotechnology, bio-based specialty products and environmental biotechnology industries. Companies enter critical markets through upgrading their core technologies, modifying sales formats, and investing in or merging businesses. These methods increase a company’s competitiveness within the industry.

Due to Taiwan's small scale of the domestic market, expanding into foreign markets is the primary way to drive revenue and increase industry competitiveness. Taiwanese companies are actively striving to reach overseas markets; however due to Taiwan's inability to join certain free trade agreement organizations, it is unable to enjoy preferential tariffs , which leads to manufacturers lacking product competitive advantages under high tariffs, causing export obstacles, There is a question regarding how to assist biotechnology companies to receive preferential tariffs through dialog and coordination between governments. It is hoped that, with expect to be in line with international management trends through harmonization of regulations to increase product and technology competitive advantages and market opportunities.

(2) Future Opportunities for the Applied Biotechnology Industry

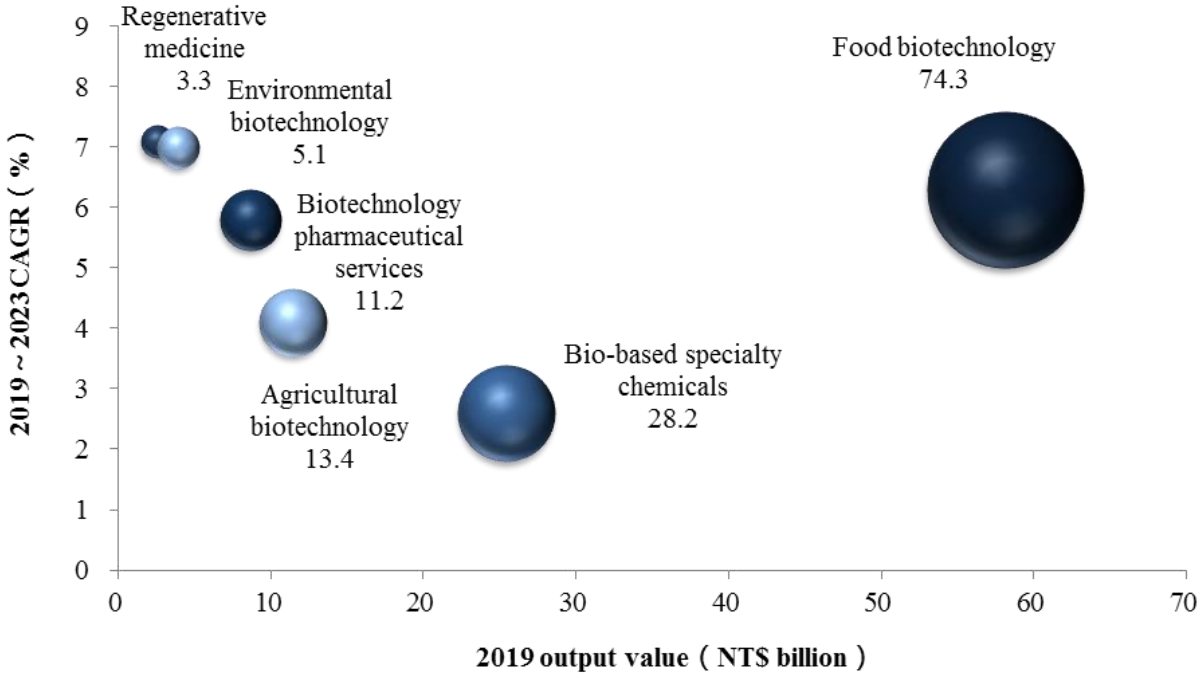
Although the global economy experienced somewhat sluggish growth in 2018, there was clear growth in emerging markets and developing economies. For example, the development of the economy within the Association of Southeast Asian Nations (ASEAN) and the heightened quality of life and buying power of consumers have meant that consumers are showing more demand for health food products and cosmetics. As such, markets within ASEAN are a key target for Taiwanese companies. In 2018, Taiwan formally became an aging society, and it is estimated that Taiwan will become a hyper-aged society by 2026. The aging population will result in an increased need for medical care to age-related chronic and cancer. Furthermore, this aged population increasingly emphasizes the importance of slowing the aging process and maintaining health lifestyles. The regenerative medicine helps consumers maintain healthy and active lifestyles through cell and tissue repair. Through food biotechnology and bio-based specialty industries, products have been developed for aged consumers to acquire healthy food products and products to slow the degradation brought about by aging and maintain a younger look. It made more business opportunities for biotechnology companies, and it's also be the competitive area for companies.

The labor force in Taiwan has been directly reduced due to the aging of society and a decreasing birth rate. Thus, industry production is moving toward smart production. With continuous innovations in smart technology and a sharp need for manpower in production, smart production will steadily enter every industry. Through the integration of cloud computing, big data analysis, automated systems and semiconductor optoelectronic technology, help to creates new products, production efficiency, and the precision of products, provides personalized services and increase product sales and their attached values. Taiwan has top-level talent and technology in the information and communications fields. With these factors, Taiwan possesses both the ability and opportunity to develop smart production and services. Once the key technologies in each subindustry of applied biotechnology industry is fully understood, the industry will be able to implent smart production and apply smart technology as

it innovates new service models and platforms. This progress will aid in the advancing of Taiwan's applied biotechnology industry and spur new industry value as well as competitiveness.

(3) Future development directions and suggested strategie for the applied biotechnology industry in Taiwan

Breakthroughs in biotechnology developments, new products and services tied to biotechnology, and companies actively creating brand along with overseas expansion will cumulatively allow for sustained growth in Taiwan's applied biotechnology industry output value. It is estimated that the applied biotechnology industry output value will reach NT$ 109.9 billion in 2019 and NT$ 135.0 billion by 2023 with a CAGR of 5.3% in 2019-2023. The expected growth of related subindustries is as follows.



Note: The size of the bubbles and figures reflect the estimated Taiwan's applied biotechnology subindustry output values in 2023. Unit: NT$ 10 billion

Data source: Estimation by DCB ITIS Research Team (2019.07)

Figure 5 Projections for the future output value growth of each applied biotechnology subindustry in Taiwan

The scope of the applied biotechnology industry in Taiwan is quite broad and can be broken down into two categories divided by the industry's attributes. One is medical and pharmaceutical industries encompassing the regenerative medicine and biotechnology pharmaceutical services subindustries. The other is related to people's daily life encompasses the subindustries of food biotechnology, agriculture biotechnology, bio-based specialized chemicals and environmental biotechnology. Because the industry characteristics, degree of maturity, and development strategies differ by subindustry, below are suggestions regarding the development directions and strategies according to the status of the applied biotechnology industry, its challenges, and future opportunities :

1. Capitalize on new technologies and Taiwan's advantages; develop niche products and services

In recent years, innovative technologies and ideas have continually broken the mold. The trends of new technologies and the industry's vigorous development can be seen via press releases and expositions. Keeping up to date on new innovative technology and inputing it to related subindustries for produce niche products as well as services will create more opportunities to cooperate internationally and technology license, heighten consumer recognition and provide further business opportunities.

Smart digital technology already is gradually applied in Taiwan's applied biotechnology industry. Its application allows for products and services that differ from those of the past. Under the trend of smart manufacturing, the regenerative medical industry has gradually applied smart production to cell culture such as cell screening and proliferation to avoidhuman contamination and also results in higher quality and production ability of cells as well as reduced production costs. Thus, significant increases in the production capability in Taiwan's regenerative medicine industry is possible, if Taiwanese companies can integrating Taiwan's semiconductor, optics technology, and big data into smart manufacturing through government integration or cooperation

with their respective suppliers from the communication industry. Biotechnology pharmaceutical services and agriculture biotechnology can increase the possibility of successful development, reduce costs, and accelerate production speed through the use of big data analysis and big data applied in pharmaceutical development and by upgrading the quality of agricultural production.

Industries tied to people's daily life, such as food biotechnology, bio-based specialized chemicals, and environmental biotechnology, are following the trend of personalized service as they directly interact with end consumers. These industries thus search for new materials or applications of new materials by starting with consumer preferences and needs. Companies utilize AI and big data to analyze individual consumer habits and needs, providing consumers with variety in products and services. These efforts will increase added value of products and repurchase rate and increases the product's competitiveness in the global market.

2. Integrate industry capabilities and sales resources; create new opportunities for branding

Taiwan's applied biotechnology industry has the potential to take a leading position in the international market , due to besides the need to have innovative nich products/services, high quality products and efficient production capacity, there is also a need to work with governments and associations to integrate upper, middle, and downstream product chains. Channels for the biotechnology industry to gain further exposure opportunities can be found in domestic and international expositions, media, and marketing. These avenues will increase the industry's international visibility.

Companies can increase awareness of their products through actively participate in large-scale international business expositions through the government's call to organize representative groups to join international events. The integration of marketing resources effectively provides corporate

interactions and by extension further opportunities for product exposure. Companies may also directly seek international cooperation and opportunities to gain permissions to operate in other markets. Or, they can increase product awareness through international contests and certification via governments. Increased international partners and consumer recognition and trust will provide more opportunities for oversease and Taiwan distribution and sales.

Beyond opportunities provided by the government for expansion into overseas markets, companies can also make use social networking software to combine online sales, experiences sharing ,, and conducting demonstrations. These methods allow consumers to see and learn more about products at any time, thus increasing brand visibility and product acceptance rates along with consumer trust and the company's image. Innovative sales tactics will create new business opportunities.

3. Cooperate with regulations; expand together into foreign markets

The Taiwan government utilizes a positive list regulation method for the applied biotechnology industry (e.g. health food product applications, cell therapy, and genetically modified crops). The positive list system restricts the usage of new ingredients and application for new products and technical implementation. Competent authorities can revise the positive list at any time, adding efficacy products, ingredients and cell types to the positive list. They can also produce related regulations and accompanying measures. These factors can increase a company's willingness to invest in commodifying new materials and the potential for developing new technologies.

Taiwan’s market demand for an applied biotechnology industry is low. The exploration of overseas markets is necessary to increase the market scale.. The government strives to assist companies in entering foreign markets, and with the New Southbound Policy, emerging markets with promising prospects, such as the ASEAN region, are key matket areas for Taiwan's biotechnology companies. However, Due to slight differences in national laws and regulations, and limited

by the fact that Taiwan and ASEAN countries have not signed free trade-related agreements, in the face of regulatory differences and high export tariffs, it is difficult for Taiwanese companies competing with companies from other countries in these markets. Companies can promptly respond to legal issues and allow the government to communicate with other nations through international regulatory management committees and assist with regulations harmonisation. Furthermore, signing preferential tariff agreements with key countries for sales or arranging strategic partnerships will allow for both sides to develop the local market and sales channels. If these actions are taken, it will assist Taiwan's applied biotechnology industry in expanding to overseas markets as well as faciliate industry growth.