

Bioeconomy Strategy

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Integrated Innovation Strategy

Promotion Council Decision

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1. Introduction

In 2019, the Japanese government established the strategy which laid out a goal of “realizing the world’s most advanced bioeconomy¹ society by 2030.” Under this strategy, Japan has promoted efforts to expand bio-related markets in the health and medical fields, such as biomanufacturing and primary production, toward continuous economic growth and solving climate changes and social challenges.

In addition to the global climate changes and global population increase, the recent COVID-19 pandemic and the international situations such as those in Ukraine and in Israel and Palestine, among other things, have formed the background for major challenges that are common worldwide -- achieving carbon neutrality, achieving a circular economy, securing food and energy, and dealing with health and medical issues. Under these circumstances, countries have established their national strategy on bioeconomy and have enhanced and accelerated their efforts, such as investments and rulemaking, in order to solve various challenges and sustainably grow their economy by using biotechnology and biomass. In addition to this, the introduction of the planetary boundaries concept—which asserts that exceeding the boundaries within which humans can safely engage in their activities will cause irreparable changes to the natural resources on which humans rely—has increased the momentum for efforts that integrate health, medicine, food, etc. from the viewpoint of planetary health (i.e., a concept that aims to achieve total health of humans, society, and natural ecosystems on a global scale).

In September 2022, the U.S. president signed the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, whose purposes include promoting return of biotechnology-related industries to the U.S. and enhancing domestic supply chains. The U.S. government analyzed that biomanufacturing would replace one-third of the world’s manufacturing industry in 10 years’ time, with a potential market scale of up to \$30 trillion (approx. 4,000 trillion yen).² The government announced a policy of making intensive investments toward expanding biomanufacturing, among other things. European countries have actively developed regulatory strategies, including the amendment of the Renewable Energy Directive in December 2023 (RED III), with the particular aim of building a circular bioeconomy as an integration of the concepts of bioeconomy and circular economy.

In Japan, the Grand Design and Action Plan for a New Form of Capitalism sets a goal of

¹ A concept that expands a sustainable and renewable circular economy by using biotechnology, renewable biological resources, etc.

² Calculated at the rate of 140 yen/USD.

solving social challenges and achieving economic growth at the same time by converting social challenges into driving force for growth, through investments in science, technology, and innovations, including those in the field of biotechnology. With its decreasing population and aging society, as well as its heavy reliance on importation of food, resources, energy, pharmaceuticals, etc., Japan is facing particularly serious challenges including securing a stable supply of these essentials. The country has seen a rapid development of discussions on Green Transformation (GX), circular economy, economic security, food security, and enhancement of drug discovery capabilities, among others.

In these circumstances, expectations have risen for bioeconomy based on the development of biotechnology, such as synthetic biology and big data-related technologies. In fiscal 2022, full-scale national projects were started by allocating a huge budget³ in the order of 1 trillion yen in total to biomanufacturing and other fields of biotechnology. We must strongly push forward efforts to expand bioeconomy markets to solve social challenges, such as environmental, food, and health issues, and to achieve a circular economy and sustainable economic growth.

Bioeconomy will contribute mainly to:

- (1) departing from fossil fuels and achieving a resource-autonomous economy, through biomanufacturing which produces various materials from modified microorganisms or plant or animal cells, etc.;
- (2) a stable supply of food by increasing productivity while reducing the environmental burden, such as chemical fertilizers, through developing new varieties by taking advantage of genome information;
- (3) a healthy life through biopharmaceuticals that have larger molecules and more complex structures than existing low-molecule pharmaceuticals; and
- (4) promoting entry of new players into the healthcare area from other areas and creating new markets, through digitalization and data linkage of healthcare information etc., among other means.

Japan's unique climate, natural features, and culture have produced a number of strengths that will provide a foundation for bioeconomy, such as abundant biological resources (biomass resources) and genetic resources, culture and fermentation technologies, capabilities to develop high-quality crop varieties, and drug discovery capabilities. In order to expand bioeconomy markets by taking advantage of these strengths, the private and public sectors must work together

³ Major projects include: the Green Innovation Fund Project; the Biomanufacturing Revolution Promotion Project; the Green Technologies of Excellence (GteX) Program; the Project of Developing Biopharmaceutical Manufacturing Sites to Strengthen Vaccine Production; and the Strengthening Program for Pharmaceutical Startup Ecosystem.

to accelerate technology development and to improve the market and business environments in the target markets on a market-by-market basis, while dealing with challenges such as the constraints on biomass raw materials, the decreasing number and aging of farmers, hollowing of the drug discovery industry, decrease in the research capabilities in basic life sciences, and innovation ecosystems that need to be enhanced. Efforts must also be made to enhance the research capabilities in basic life sciences and to develop human resources who will support this task.

Toward expansion of bioeconomy markets, this strategy has been revised from the strategy established in 2019 , to the “Bioeconomy Strategy.” This strategy provides a summary of the directions of the efforts to be made under the science, technology and innovation policy toward the year 2030.

2. Review of Progress and Major Challenges

Since the establishment of the "Bioeconomy Strategy 2019", efforts have been promoted to expand bioeconomy markets, while updating and following up the strategy. These efforts include forming biocommunities to invite human resources and investments from within and outside Japan and to supply products and services to the markets, and linking and utilizing data necessary for R&D and commercialization.

Regarding the emergence of new players toward creating markets, the biomanufacturing industry has seen: more active investments in start-ups with advanced biotechnologies, such as microorganism/cell design platform technology; more active movements for conversion into bioprocesses in large businesses; and the beginning of movements for collaboration between start-ups and large businesses, such as joint promotion of biofoundry businesses.

In addition, eight biocommunities have been certified since 2021 under an open application program. Efforts that have been made through these communities include: promoting communication between parties participating in the biocommunities; enhancing cooperation with relevant government agencies, etc.; forming nationwide networks; and visualizing events and investment status to invite investments from overseas.

Furthermore, the scope of markets is expected to expand further from the existing fields such as materials and plastics, as seen in the rising global interest in new bioeconomy markets against a backdrop of social challenges, such as FoodTech and sustainable aviation fuel (SAF). In R&D activities in the field of biotechnology, digital transformation (DX) is underway, which is centered around the acquisition and analysis of big data.

These developments toward expansion of new bioeconomy markets have come with the following challenges to be dealt with, which makes it necessary to enhance our efforts.

Creating new bioeconomy markets requires inviting human resources and investments from within and outside the country, by increasing the predictability of the markets through showing strategic efforts to convert from existing technologies and products, based on analysis of challenges in cost competitiveness and other issues in each industry toward expanding demand for new products and services, such as bio-derived products.

Japan has lagged behind in the globally undergoing transition from low-molecule pharmaceuticals to biopharmaceuticals and other new modalities. We need to accelerate

supporting ventures that put academia-derived seeds into practical use, and developing ecosystems, such as fostering CDMOs⁴.

With the expansion of investments in the biotechnology fields, it is necessary: to develop and secure future human resources that will be needed for new industries and research studies; to enhance research capabilities; and to foster surrounding industries corresponding to new supply chains. We must promote the creation of new business models through improving the environment to promote data linkage and utilization across the existing markets, as well as fulfilling the functions of innovation ecosystems, such as biocommunities.

⁴ Contract Development and Manufacturing Organizations.

3. Basic Idea

In order to contribute to balancing between sustainable economic growth and solution of various environmental, food, health, and other issues, we aim to achieve the following through expanding bioeconomy markets: a “circular society where all industries are linked with each other”; a “society where sustainable primary production that meets diversifying needs takes place”; a “society where materials are produced by bioprocess using sustainable manufacturing methods”; and a “society where medical services and healthcare services are coordinated with each other and which allows long-standing social participation.”⁵

Toward achieving these societies, the following five markets⁶ are set as bioeconomy markets whose expansion is sought by this strategy, by taking into account Japan’s characteristics and strengths, the world’s trends, and the growth potential of markets, among other things. Through stimulating private investments, efforts will be promoted with the aim of creating markets in the order of 100 trillion yen in Japan and abroad by 2030. For each market, goals for the year 2030 are set. To achieve the goals by backcasting, we will present the directions of our policy, such as accelerating technology development and improving the market and business environments, strengthen the path from basic research to practical use and dissemination, and promote efforts in which industry, government, academia, and finance collaborate with each other.

In doing so, care should be taken to ensure that bioeconomy will contribute to solving social challenges more closely to the expectations, by appropriately assessing, based on scientific knowledge, the possibility that bioeconomy will contribute to solving social challenges, such as environmental, food, and health issues, as expected. Furthermore, the bioeconomy markets are similar in that biotechnology and biomass are developed and utilized, which allows the development of a wide variety of products and services. Many of these markets also have similarities to or closely related with each other in such aspects as: formation of rules and regulations; technologies utilized; circulatory use of resources; and data linkage and utilization. Therefore, efforts to expand the bioeconomy markets will be promoted by giving attention to producing the synergy between the markets and to opening up new markets in areas that span across existing markets.

Five markets:

- ① Biomanufacturing and bio-derived products: Biochemicals (high-functional biomaterials,

⁵ The images of society presented in the Bioeconomy Strategy 2019.

⁶ The nine markets listed in the existing Bioeconomy Strategy 2019 were changed into these five markets by integrating and expanding the biomanufacturing and bio-derived product market.

bioplastics, etc.), textiles, fragrances and cosmetics, biofuels, agricultural chemicals and fertilizers, food (cell-based food, etc.), novel enzymes, biofoundries, organic waste and wastewater treatment, measuring and analytical instruments, etc.

- ② Sustainable primary production systems: Agricultural machines, etc. utilizing smart agriculture technology, new cultivars, etc. developed by utilizing genome information, etc.
- ③ Large-scale buildings utilizing wood and smart forestry: Mid-rise wooden buildings, timber for building use, etc.
- ④ Industries related to biopharmaceuticals, regenerative medicine, and cell and gene therapies: Vaccines, antibody drugs (monoclonal antibodies), nucleic acid therapeutics, iPS cells, CAR-T cell therapeutics, gene therapy products, etc.
- ⑤ Lifestyle improvement healthcare and digital health: Health promotion services, apps, wearable devices, fitness, livelihood support services, robot nursing care devices

In accelerating technology development, the situation of each industry should be analyzed to focus on the creation of innovative technologies and innovations that will give us advantages in the future by international standards. In addition, efforts to strategically utilize intellectual property will be promoted under an open-close strategy, to support new commercialization starting from the stage of technology development.

Toward improvement of the market environment, efforts will be promoted such as: increasing the economic value of products, appropriate evaluation and labeling, regulations and programs, public procurement and other efforts to create and expand markets, and forming public acceptance.

Toward improvement of the business environment and related ends, efforts will be promoted such as: developing and securing human resources; developing large-scale demonstration centers, CDMOs, and other manufacturing sites; improving the environment where start-ups are created and grow; cultivating surrounding industries; promoting utilization and protection of intellectual property; and collaboration, international standardization, and rulemaking toward international development.

In addition, the following fundamental and/or cross-sectional efforts should be promoted in coordination with related measures: developing human resources supporting life science research, which will be a source for expanding bioeconomy; promoting basic life sciences, such as studies focusing on the life course⁷; strengthening databases, bioresources, biobanks, and other research infrastructures; promoting efforts to fulfill the functions of biocommunities; and data linkage and

⁷The series of processes spanning from the birth and regeneration of life to aging.

utilization toward integration of biotechnology and digital technology.

4. Measures to Expand Bioeconomy Markets

For each of the five bioeconomy markets covered by this strategy, a target market scale for the year 2030 will be set, toward which efforts such as acceleration of technology development and improvement of the market and business environments will be promoted across all governmental agencies.

(1) Biomanufacturing/bio-derived products

1) Trends in the overall market area

Global-scale social challenges have emerged, such as worsening climate change issues, resource constraints, deterioration of natural capital,⁸ loss of biodiversity, food crisis, ocean pollution, and supply chain risks. To deal with these social challenges, discussions are developing in Japan as well as the rest of the world, such as those on GX, circular economy, economic security, and FoodTech. Expectations are rising that conversion of materials and processes and promotion of biomanufacturing and use of bio-derived products⁹ may contribute to solving these social challenges as well as achieving economic growth.

In particular, recent years have seen global attention to biomanufacturing, which produces target materials by utilizing genetic technology that uses microorganisms, animal or plant cells, etc. Technology development has been rapidly underway toward the social implementation of biomanufacturing. It is a technology that is utilized in various industrial fields, such as chemicals and materials, fuels, pharmaceuticals, animal textiles, and food. More specifically, biomanufacturing is a technology that produces useful materials through the metabolic functions of microorganisms, animals, plants or other organisms, or that creates foundations for producing useful materials using animal cells or the like, by increasing these cells or growing them to high density. In doing so, it is possible to produce valuable target materials or to increase productivity by modifying the genes or editing the genomes of the cells, etc.

Biomanufacturing is expected to contribute to solving or mitigating not only climate changes but also various other social challenges (Table 1). On a global level, not only the U.S. and China but also Europe, Singapore, Korea, and other countries have been involved in growing competition in industrial policy to invite investments into their countries, in anticipation of considerable expansion of the biomanufacturing and bio-derived product

⁸Forests, soil, water, air, biological resources, and other types of capital (or stock) created by nature.

⁹Products produced by using biomass as materials or by utilizing biotechnology.

market in the future. For instance, in September 2022 U.S. president Biden signed the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy and announced the National Biotechnology and Biomanufacturing Initiative. The U.S. has also published a fact sheet which contains an analysis that predicts that biomanufacturing will replace one-third of the global production of the manufacturing industry, which is equivalent to approximately USD30 trillion (approximately 4,000 trillion yen) in terms of money, within a 10 years' time. In March 2023, the U.S. published the Bold Goals for U.S. Biotechnology and Biomanufacturing which presents more specific directions to go.

The Japanese industrial world, too, has seen rising interest in biomanufacturing, as indicated in, among others, the “Biotransformation (BX) Strategy: BX for Sustainable Future” published by the Japan Business Federation in March 2023, which showed the directions in which bioeconomy should be promoted in the industrial world.

Table 1: Expectations for Biomanufacturing

Social challenges	Expectations for solving social challenges
Climate changes	<ul style="list-style-type: none"> • Reducing greenhouse gas (GHG) emissions through process conversion. • Decarbonization by converting raw materials from fossil resources to biomass resources. • Increasing CO₂ absorption by utilizing microorganisms, etc. that use chemosynthesis using CO₂ as a material.
Resource constraints	<ul style="list-style-type: none"> • Stable supply of new energy sources that utilize biomass materials. • Achieving a resource-autonomous economy that utilizes biotechnology, such as by utilizing and recycling unused resources in the country.
Deterioration of natural capital and loss of biodiversity	<ul style="list-style-type: none"> • Reducing the burden on natural capital by conversion from fossil fuel-derived materials to sustainable materials utilizing biotechnology. • Conserving biological and genetic resources that form a foundation for biomanufacturing.
Food crisis	<ul style="list-style-type: none"> • Increasing domestic production. • Reducing environmental burden by replacing existing products.

Ocean pollution	<ul style="list-style-type: none"> • Reducing ocean pollution by expanding the use of biodegradable products.
Economic security	<ul style="list-style-type: none"> • Securing important technologies and securing supply networks by overcoming the geographical constraints of Japan. • Stabilizing domestic supply chains by increasing domestic production, and stabilizing global supply chains through international cooperation with like-minded countries.
Other (labor issues, safety and security, improving QOL, etc.)	<ul style="list-style-type: none"> • Solving various challenges, such as solving labor issues by converting raw materials and improving safety. • Avoiding reduction in product quality by balancing between dealing with social challenges and replacing general-purpose goods; and improving QOL by high value-added goods.

Japan is considered to have the following advantages in promoting bio-derived products by biomanufacturing, etc.:

(i) Japan has abundant biological and genetic resources.

Japan has a wide variety of climate conditions and a geographical environment with mountains, oceans, etc. The country also has an easy access to international cooperation with Southeast Asia, in which many businesses are based. For these reasons, Japan is in an environment that provides it with an easy access to biomass resources and biologically diverse genetic resources.

(ii) Japan has well-developed fermentation techniques.

Japan has a long tradition of manufacturing fermented foods, such as soybean paste (*miso*), sake, and soy sauce, which has resulted in an accumulation of techniques for manufacturing methods using fermentation, including the handling of microorganisms.

(iii) Japan has advanced manufacturing technologies.

Materials produced using microorganisms are made into finished products through separation, purification, and processing. Japan has the manufacturing industry whose long-standing strengths are these processes. Japan has seeds for competitiveness in biomanufacturing and other production processes for bio-derived products.

In addition to these strengths, it is of particular note that Japan has potential for microorganisms that may give it advantages in industries as compared to overseas. For instance, hydrogen-oxidizing bacteria, which are a type of chemoautotrophic bacteria, fix

CO₂ using the high chemical energy of hydrogen, which makes it possible to culture the bacteria at high rate to high density and gives the bacteria a high potential for commercialization. The possibility has been suggested that biomanufacturing using hydrogen-oxidizing bacteria will emit considerably less CO₂ than does matter production using fossil-derived resources, due to its double effects by not only reducing CO₂ emissions but also absorbing CO₂ in the production process. Still other types of those microorganisms include *Corynebacterium glutamicum*, which can produce aromatic compounds that normally exhibit biological toxicity; *Halomonas elongata*, a halophilic and alkalophilic bacterium that allows matter production by avoiding contamination by other microorganisms; and *koji* mold, which has been studied for a long time in food manufacturing processes and has high matter production potentials.

While it is difficult to accurately predict the growth potential of the biomanufacturing and bio-derived product market, the market is expected to grow rapidly on a global level. However, conversion of production processes from the existing chemical processes to bioprocesses requires advanced technology development and new capital investment on a short-term basis. Therefore, in the areas of general-purpose products, such as minimally processed basic chemicals that are mass-produced at low price, producing these products through bioprocesses will not produce sufficient return on investment for the time being, due to their low unit prices. On the other hand, there are growing needs for bio-derived products in the areas of high value-added products, such as products with innovative functions that can be more easily achieved through bioprocesses or products with lower environmental burden.

As for sustainable aviation fuel (SAF), demand for it is expected to increase due to, among other things, the targets for reduction in CO₂ emissions in the field of international air transportation set by the International Civil Aviation Organization (ICAO), which is an international organization in the aviation industry. An increasing number of businesses have started the production of SAF by utilizing biotechnology. This is an example where a new market is created as a result of regulations triggered by a social challenge and where this leads to utilization of biomanufacturing. Based on the circumstances described above, it is important to take a phased strategy where the first target markets should be focused on high value-added areas, followed by discussions on technology development for cost reduction, mass production, and horizontal development and on regulatory and market approaches necessary to solve social challenges, before targeting general-purpose product market areas on a medium- to long-term basis.

2) Individual industry areas

Based on the current technological trends, biomass and biotechnology are expected to be utilized in a wide range of industrial areas, such as the chemical and material, textile, pulp and paper, cosmetic and fragrance, food, and fuel areas. Although biomanufacturing is expected to contribute to solving global social challenges, different industrial areas have different social challenges to be dealt with and different ways in which biotechnology should appropriately be used. The following are trends in each of these industrial areas and prospects for utilization of biotechnology and for bioconversion in it.

(Chemical and material areas)

The chemical industry accounts for approximately 20% of the CO₂ emissions from all industries. Achieving carbon neutrality is a major challenge in that industry. To achieve carbon neutrality, it is important to concurrently advance: “fuel conversion,” i.e., conversion of fuels such as the heat source for naphtha cracking furnaces, or coal or firepower, into ammonia or other decarbonized fuels; and “raw material conversion,” i.e., conversion of petroleum-derived raw materials for naphtha into biomass-derived raw materials (e.g., production of chemicals from bioethanol, etc.). “Raw material conversion” has a particularly high potential, since existing facilities can be utilized for polymerization processes, etc. Some /businesses have emerged that work on the production of basic chemicals, high-functional monomers, etc. using microorganisms. At present, chemical processes have the advantage of being low-cost and highly efficient in many matter production processes. However, bioprocesses have an advantage in the production of complicated substances with multiple carbons because it is generally not necessary for a bioprocess to involve multiple steps of reactions.

As for plastics, global challenges that have emerged are: reducing the usage of fossil resources and other exhaustible resources; controlling GHG emissions; and dealing with environmental pollution caused by plastic waste in oceans, etc. Bioplastics are expected to reduce the usage of fossil resources and GHG emissions. Marine biodegradable plastics, which have the property of being biodegraded to CO₂ and water in oceans, are expected to have the effect of preventing ocean pollution. Japan has a wealth of know-how in the appropriate treatment and “3Rs” of plastics. In addition, the country’s abundant biomass and genetic resources and competitive information on the physical properties of materials constitute promising resources for the development of bioplastics. It is important to continue developing bioplastics and supporting capital investments, spread and expand the use of bioplastics, and develop global markets, all pursuant to the Roadmap for Bioplastics Introduction. As for marine biodegradable plastics among bioplastics, an increase in its

introduction should be promoted pursuant to the Roadmap for Popularizing Development and Introduction of Marine Biodegradable Plastics Formulated.

In April 2022, the Act on Promotion of Resource Circulation for Plastics came into effect. To coincide with this, the Guidelines for Designing Plastic Products were established, covering, among other things, the use of bioplastics to promote efforts under the “3R + Renewable” policy in the stage of designing plastic products. This is intended to lead to further acceleration of plastic resource circulation. In addition, development of technologies is underway for producing novel plastics by biomanufacturing using CO₂ as a raw material.

Furthermore, technologies have been developed for producing materials such as cellulose nanofibers (CNFs), which have various characteristics such as light and highly strong, and glycol lignin, which is highly workable and heat resistant. These could be high-functional materials that take advantage of the properties of their original polymeric molecules.

(Textile industry [apparel])

The textile industry has been considered to be environmentally unfriendly due to its high energy usage for manufacturing and to its short lifecycle. Reducing its burden on the environment is an imminent challenge. Aside from chemical textiles, even natural textiles (such as cotton), which may be generally considered environmentally friendly, use a lot of water and agricultural chemicals when their raw materials are cultivated. It is expected that the textile industry will be required to convert from environment-unfriendly material production, (i) based on the concept of Nature Positive, which was indicated in the Kunming-Montreal Global Biodiversity Framework adopted in December 2022 and containing new global targets, and (ii) through the Taskforce on Nature-related Financial Disclosure (TNFD). In particular, efforts have been underway mainly in Europe toward transition to a circular economy, such as reuse and repair of clothes and other recycling and long use of products, and effective use of used textiles. In addition, global brands and the like in Europe have growing demand particularly for environmentally friendly textiles.

Currently, while development of material/chemical recycling technologies is underway, Japan’s Textile Industry’s Vision states that bio-textiles should also be utilized. Specifically, it is expected that biomass material-derived textiles will be developed and that high-functional, sustainable bio-textiles will be utilized, such as “structural protein textiles” that are made by the action of microorganisms. On the other hand, up to what price range of textiles will be converted to bio-derived materials in the future depends on technologies, profitability, etc.

(Pulp and paper)

The pulp and paper industry is facing reduction in production due to a decline in demand for paper caused by the progress of digitalization and due to rising raw material and fuel prices, among other causes. In this industry, carbon neutrality has been pursued through active efforts to utilize waste liquid (black liquor), which is generated in the pulp purification process and contains high levels of lignin, etc., as a non-fossil heat source. However, the decline in demand for paper resulted in reduced pulp production on which paper production is based, which, in turn, has resulted in a reduced amount of black liquor as a byproduct from pulp production, which may affect achievement of carbon neutrality in the entire pulp and paper industry. Pulp and paper companies have originally established their raw material supply chain for woody biomass. This gives them a structure that makes it easy for them to transition to production of various bio-derived compounds and sugars that serve as raw materials for these compounds, or production of bioethanol for SAF or other purposes, among other things, by diverting or converting excess pulp and/or production facilities arising from reduced paper production. In fact, an increasing number of companies have accelerated bioconversion. Additional efforts have been underway to utilize black liquor as biofuel or chemical products, instead of a heat source.

(Cosmetics and fragrances)

Together with the U.S., China and others, Japan is one of the largest cosmetics manufacturers. Amid the rising sustainability trend and environmental awareness, it is expected that bioconversion will tend to take place for cosmetic products with high unit prices. On a global level, some manufacturers have set the goal of switching many of the raw materials to natural or bio-derived ingredients obtained from circular processes. Similarly, domestic manufacturers have been increasingly active in converting base materials and containers for cosmetic products to bio-derived products.

Fragrance materials are basically natural products or their derivatives or analogs. In many cases, materials to be extracted are contained in small amounts in natural products and have complicated molecular structures. For this reason, fragrance materials are extremely difficult to be chemically synthesized, while it is easier for biomanufacturing, which utilizes synthetic biology, to enter this industrial area. Although Europe and the U.S. are ahead of Japan in efforts in this area, we can increase the competitiveness of our fragrances as high value-added products by developing technologies for replacing major ingredients of fragrances, such as monoterpene and phenylpropanoid, with products from biomanufacturing.

(Food)

To deal with social challenges, such as food security and environmental protection in the context of the global population increase, efforts are underway including development of technologies for utilizing various protein sources and highly productive cultivars, such as: plant-based foods; foods made from insects; agricultural, forestry and fishery products obtained by genome-editing technology; cell-based foods; foods made from microorganisms; precision fermentation technology; and use of algae as resources. Up-front investments in FoodTech ventures are already underway in the U.S., Singapore, Korea, etc. In some countries, rules have been established and the manufacture and sale of such food products have been started. It is expected that technologies for highly efficient mass production will be necessary in the future.

As for cell-based foods, scientific knowledge on their safety is being collected in Japan at present. Another issue to be discussed on cell-based foods is appropriate labeling that provides consumers with appropriate opportunities to make choices. To discuss this issue, the safety of cell-based foods must be verified in the very first place. This issue must be dealt with through cooperation between relevant governmental agencies. Similarly, as for precision fermentation technology, relevant issues must be dealt with to utilize technologies and to create and expand markets, through cooperation between relevant governmental agencies.

(Energy [SAF])

The world's supply of SAF as of 2022 is estimated to be approximately 300 thousand KL, which correspond to about 0.1% of the world's supply of jet fuel. On the other hand, the International Air Transport Association (IATA), which is an industry association consisting of airline companies worldwide, has announced the goal of reducing the total CO₂ emissions in the air transportation field for the year 2050 to net zero. The amount of SAF required to achieve this goal is estimated to be 449 billion liters (approximately 450 million KL). It will be necessary to build a system which, in anticipation of future increase in demand for SAF, allows (i) securing of a manufacturing capacity and a raw material supply chain (including any development-and-import scheme) for producing necessary and sufficient SAF in Japan, and (ii) a stable supply of SAF at internationally competitive price.

(Other)

Depending on future technology development and business trends, biomanufacturing and bio-derived products may expand into new areas other than those described above.

For instance, needs for them have arisen in the semiconductor member/material area, such as: for conversion from fossil raw materials of semiconductor raw materials to biomass raw materials, toward achievement of carbon neutrality; or for utilization of biotechnology that efficiently breaks down resin used in semiconductors. It is necessary to appropriately keep track of these latest business trends, etc. and to flexibly reflect them in measures to be taken.

3) Past efforts

Since the establishment of the Bioeconomy Strategy 2019, the Ministry of Economy, Trade and Industry, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of the Environment, and the Ministry of Agriculture, Forestry and Fisheries have implemented the following respective budgeted projects related to biomanufacturing and/or bio-derived products.

(Ministry of Economy, Trade and Industry)

- The “Development of Production Technology for Bio-based Products to Accelerate the Realization of Carbon Recycling” has been implemented since fiscal 2023, in order to spread and expand the use of bio-derived products by increasing the efficiency and reducing the cost of bioproduction.
- The project for the “Promotion of Carbon Recycling Using CO₂ from Biomanufacturing Technology as a Direct Raw Material” was set up under the Green Innovation Fund Project created under the third supplementary budget for fiscal 2020, with the aim of changing the industrial structure through social implementation of novel bio-manufactured products made by using CO₂ as a raw material and through the use of CO₂ as a resource. This project was started from fiscal 2023.
- The “Biomanufacturing Revolution Promotion Project” was set up under the supplementary budget for fiscal 2022 and was started from fiscal 2023, in order: (i) to collect unused resources to be used in biomanufacturing and to engage in the development, demonstration, etc. of technologies for using these resources as raw materials; and (ii) to support (a) the development of microorganism/cell design platform businesses, which hold sources of the added value of biomanufacturing, (b) the development of technologies for improving microorganisms, etc., and (c) the development, demonstration, etc. of manufacturing technologies for mass production.

(Ministry of Education, Culture, Sports, Science and Technology)

- The “Green Technologies of Excellence (GteX)” Program was set up under the supplementary budget for fiscal 2022 and was started from fiscal 2023, in order to accelerate fundamental research and human resource development aimed at creating innovative technologies that will bring about disruptive innovations toward achievement of carbon neutrality. Biomanufacturing has been set as an area where Japan’s academia is particularly expected to make future contributions.
- The “Advanced Technologies for Carbon Neutral (ALCA-Next)” Program was launched from fiscal 2023 in order to create game-changing technology seeds toward achievement of carbon neutrality. Green biotechnology and resource circulation have been set as key technology areas, and basic research is being promoted at universities and other institutions.

(Ministry of the Environment)

- Since fiscal 2019, the Ministry has implemented a demonstration project toward conversion from fossil-derived resource plastics to bioplastics, etc. and toward social implementation of this conversion, as well as a project for supporting the introduction of facilities, etc. for manufacturing renewable resource-derived materials.
- Under the “Technology Development and Demonstration Project for Regional Symbiosis and Cross-Sectoral Carbon Neutrality,” the Ministry has supported, since fiscal 2022, the development and demonstration of technologies which are highly effective on the reduction of CO₂ emissions and whose development and demonstration do not proceed sufficiently solely by voluntary efforts in the private sector due to such issues as development risk. The project includes support to the expansion of the use of biomass.
- Under the “Demonstration Project of Innovative Catalyst Technology for Decarbonization through Regional Resource Recycling,” the Ministry has supported, since fiscal 2022, the technology development and demonstration of innovative catalyst technologies utilizing quantum technology or AI or other digital technologies.
- Under the “Project for Acceleration of Social Implementation and Dissemination of Components (GaN) and Materials (CNF) for Realizing Innovative CO₂ Emission Reduction,” the Ministry has supported, since fiscal 2020, innovations toward prompt commercialization of products utilizing CNFs.

- Under the “Project for Promoting Development of Carbon-Circulating Society Models That Recycle CO₂ as a Resource (technology development and demonstration for the manufacture of chemicals by utilizing CO₂ from waste treatment facilities),” the Ministry demonstrated the manufacture of ethanol from CO₂ contained in exhaust gas from a waste incineration plant by utilizing microorganisms as a catalyst.
- Under the “Project for Development and Demonstration of Models for Reducing the Cost of Hydrogen Supply by Utilizing Existing Infrastructure (project for development and demonstration of hydrogen supply chains using methanation by utilizing renewable energy-derived hydrogen and food waste-derived biogas in urban areas),” the Ministry has supported, since fiscal 2022, the demonstration of methane production from renewable energy-derived hydrogen and food waste-derived biogas.

(Ministry of Agriculture, Forestry and Fisheries)

- Under the “Project for Development and Demonstration of Technologies for Achieving the MIDORI Strategy,” the Ministry has worked on the development of high value-added, high-functional plastics, etc. containing glycol lignin since fiscal 2020 and on the development of ethical plastics, etc. containing softwood bark since fiscal 2022.
- Under the “Strategic Technology Development and Demonstration Project,” the Ministry has supported, since fiscal 2021, the development and demonstration of CNF and other wood-derived novel materials that will contribute to making high-functional and/or high value-added products or substitutes for fossil resource-derived plastics by utilizing wood- or forest-derived ingredients.

4) Goals for the year 2030

(i) Target market size

53.3 trillion yen

(Related indices)

- Increasing government and private investments in biomanufacturing to 3 trillion yen per year by 2030.
- Introducing approximately 2 million tons of bioplastics by 2030.

(ii) Specific aims

Bioeconomy is expected to expand substantially in the international community on a medium- to long-term basis. Japan aims to maintain its international competitiveness in the process. To this end, our aim for the year 2030 is that conversion to biomanufacturing has

progressed in each relevant industry, and that, as an initial stage of expanding biomanufacturing, markets are actively being captured particularly in high value-added product areas. We also aim that the utilization of unused resources in Japan has progressed, and that the strength of domestic supply chains has increased.

Through these aims, we seek to advance our efforts to deal with social challenges through biomanufacturing, such as efforts to increase Japanese businesses' international competitiveness and to achieve decarbonization and a circular economy.

As an index for continuous expansion of biomanufacturing, we aim to increase the total government and private investments to the order of 3 trillion yen per year by 2030. As for bioplastics, we aim to introduce a maximum amount of bioplastics (approximately 2 million tons) by 2030 based on the Roadmap for Bioplastics Introduction.⁶

5) Directions of future efforts

(i) Overall

While the biomanufacturing area has seen intensifying international competitions, such as large-scale investments already made in the U.S. and China ahead of Japan, it is still a new area with immature markets without dominant players. Based on this understanding, Japan intends to focus on areas that are likely to give it advantages in light of domestic players' technologies and the characteristics of the domestic industrial structure, while seeking to solve structural issues facing Japan, such as its reliance on overseas suppliers for raw materials. We also intend to promote the utilization of biomass, pursuant to the Basic Plan for Promoting Biomass Utilization (Cabinet Decision of September 6, 2022).

While keeping in mind early market creation and expansion, we specifically focus on hosts that are likely to give us advantages, such as hydrogen-oxidizing bacteria, in helping the development of microorganism/cell design platforms that will be a source of the added value of biomanufacturing. We also intend to make focused efforts on culture, fermentation, and other production processes that have long been worked on in Japan. On top of these efforts, we intend to concurrently seek to resolve constraints on raw materials by utilizing unused resources, among other means.

In terms of the market environment, the greatest challenge in creating and expanding markets of bio-derived products is cost competitiveness. When a more cost-competitive, fossil resource-derived product produced by chemical process is substituted by a bio-derived product, the process cost is expected to increase due to reduced productivity or other causes,

in addition to having to make a new capital investment. In this situation where the added values of bio-derived products have not sufficiently appealed to demanders, we cannot forecast demand for bio-derived products if the market is left solely up to market principles. In order to eliminate this uncertainty of demand and to increase market predictability from the viewpoint of businesses, we intend to advance the improvement of the market environment, with an eye to the global market.

At the same time, we will improve the business environment by, among others, developing human resources who, and supporting start-ups which, will work on biomanufacturing as a new area. We will also support suppliers and other related industries.

As for bioplastics, whose social implementation has already been underway, we intend to implement measures such as promoting their use, spreading their use among consumers, increasing consumers' awareness of bioplastics, and improving production systems, pursuant to the Roadmap for Bioplastics Introduction.

(ii) Acceleration of technology development

Microorganism/cell design platform technology is a source of the added value of biomanufacturing. In order to increase Japan's international competitiveness, it is important to foster microorganism/cell design platform businesses with advanced technologies. Currently, however, Japan's microorganism/cell design platform businesses lag behind their counterparts in the U.S. and China. In order to foster these businesses, it is necessary to increase the number of microorganism species that give Japan characteristics, while focusing on hosts that are likely to give Japan its own advantages, such as hydrogen-oxidizing bacteria. We will also promote support to the development of technologies that will form a foundation for accelerating the DBTL¹⁰ cycle, such as bioinformatics and robotics utilizing AI, in addition to DNA and RNA synthesis, genome editing, and genome sequencing that will provide a foundation for microorganism/cell design platform technology. Specifically, in the "Biomanufacturing Area" under the Green Technologies of Excellence (GteX) Program of the Ministry of Education, Culture, Sports, Science and Technology, technology development will be promoted, such as development of novel metabolic pathways that will allow the production of various chemicals, and development of innovative DBTL technologies that will enable rapid and flexible modification of microorganisms. Under the Advanced Technologies for Carbon Neutral (ALCA-Next) Program, R&D of technologies

¹⁰ Design-Build-Test-Learn, which consists of four steps: design, where cells are designed; Build, where the host is developed; Test, where the productivity is evaluated; and Learn, where the results are learned. Using the DBTL cycle is considered to help efficiently create biological cell materials with capability to produce high-functional materials.

will be promoted, such as next-generation breeding technologies for plants to realize high-yield, environment-friendly biomass production, and new synthesis technologies to produce high-performance, high-functional materials from biomass with low environmental impact and high efficiency.

Since biological genetic resources provide a foundation for microorganism/cell design platform technology, we will continue to develop the infrastructure for biological genetic resource/data platforms to collect biological genetic resources and related information, such as characteristic and omics information on organisms. By not only newly collecting microorganisms and related data that will contribute to biofoundries but by also bringing together, promoting the use of, and linking data from, information on biological genetic resources in the possession of businesses, public institutions, universities, etc., we will advance the development of environments where biotechnology and digital technology are fused together. This will accelerate the social implementation of biomanufacturing.

On the other hand, when we turn our eyes toward technologies for production phase, we find that the “scale-up problem” has been a major challenge. It is a problem where, even if certain microorganisms are successfully developed or modified on a laboratory scale, the project fails in the mass production phase due to the microorganisms’ failure to sufficiently multiply or to produce the target substance. Mass production requires advanced fermentation technologies and large, expensive culture equipment. Not only small venture companies but also large companies sometimes give up development due to inability to make sufficient capital investment because of the high risk. For this reason, under the Development of Production Technology for Bio-based Products to Accelerate the Realization of Carbon Recycling that has been implemented by the Ministry of Economy, Trade and Industry since fiscal 2020 (until fiscal 2026), the development is underway of a bioproduction system in which bacterial strains, culture conditions, omics information, etc. are accumulated. We intend to develop infrastructures for biofoundries that will make active use of the results of this project, will expand and improve bioresources such as enzymes and hosts designed to serve as a source of matter production, and will effectively build a bridge to practical production.

Furthermore, efforts toward social implementation will be concurrently advanced in the course of technology development in an integrated manner. Specifically, under the Green Innovation Fund Project and the Biomanufacturing Revolution Promotion Project, both controlled by the Ministry of Economy, Trade and Industry, strategic efforts to capture markets will be promoted by such means as: setting up subjects that provide an overview of

a supply chain; promoting inter-business alignment in cooperative areas between subjects (life cycle assessment: LCA), international standardization, branding methods, data, etc.; and advancing rulemaking focusing on highly motivated players. As for the Technology Development and Demonstration Project for Regional Symbiosis and Cross-Sectoral Carbon Neutrality and the Demonstration Project of Innovative Catalyst Technology for Decarbonization through Regional Resource Recycling, both controlled by the Ministry of the Environment, these projects will be steadily advanced to promote the development and demonstration of biotechnologies that are highly effective in reducing CO₂ emissions.

In the aspect of raw materials, non-edible biomass, for which Japan relies on overseas suppliers, has particularly faced challenges, including stable procurement, GHG emissions during transit, and cost increase caused by fuel cost, tariffs, etc. Domestic procurement of raw materials has faced challenges including difficulty in efficiently collecting non-edible biomass in geographical areas producing woody biomass, etc. and difficulty in developing pretreatment technologies and reducing costs. Based on this background, we intend to promote the efforts required under the Basic Plan for Promoting Biomass Utilization, in order to effectively and comprehensively utilize biomass existing in Japan. We will also pursue biomanufacturing that directly utilizes non-edible biomass or CO₂, which are not subject to the constraints imposed by food security, or that uses waste materials or the like as raw materials. This is also a key to achieve solution of the social challenges such as climate changes and resource constraints.

(iii) Efforts to improve the market environment

In terms of the market environment, the greatest challenge in creating and expanding markets of bio-derived products is cost competitiveness. The challenge is that these markets offer no predictability for businesses if the markets are left solely up to market principles. When a more cost-competitive, fossil resource-derived product produced by chemical process is substituted by a bio-derived product, the process cost is expected to increase due to reduced productivity or other causes, in addition to having to make a new capital investment. On the demanders' side, major challenges include whether or not they accept genome editing, genetic modification, etc. and whether or not the added value arising from being bio-derived appeals to them. It is also uncertain how well the cost of bio-derived products will be accepted by demanders, based on the status of the challenges described above. Another challenge is that some bio-derived products often have appearance or ingredients that are similar to those of some existing fossil resource-derived products, making it difficult for consumers to make choices in their consumption activities.

In light of these challenges, we will, concurrently with cost reduction through technology development, promote efforts to increase the economic value of bio-derived products and to create markets of these products.

In areas where mass production and mass consumption of fuels, basic chemicals, etc. take place, cost is given particularly high priority. Therefore, economic rationality makes it difficult to achieve conversion to bioprocesses in these fields for the time being. On the other hand, needs for bio-derived products have emerged in high value-added areas, such as products with innovative functions or performance or products that are expected to provide added values, such as being environment-friendly. There are also cases where, as seen in the requirement for conversion from aviation fuel to SAF toward decarbonization, a new market is created as a result of regulations triggered by a social challenge and leads to the utilization of biomanufacturing.

In light of these trends, a practical policy for capturing markets through biomanufacturing is to first focus on high value-added areas, followed by discussions on technology development for cost reduction, mass production, and horizontal development and on regulatory and market approaches necessary to solve social challenges, before targeting general-purpose product market areas, where mass production and mass consumption take place, on a medium- to long-term basis.

Efforts have already been underway by the national government to solve social challenges and achieve economic growth at the same time in areas such as: achievement of a decarbonized society or a circular economy; FoodTech, and economic security. Biomanufacturing is expected to contribute to solving various social challenges. The intended measures will be utilized in light of these purposes of the policy.

Particularly in terms of decarbonization, the following measures will be taken based on the “Pro-Growth Carbon Pricing Concept” under the Strategy for Promoting Structural Transition based on Decarbonization (GX Promotion Strategy): providing bold support to up-front investments utilizing the “GX Economy Transition Bond,” etc. (e.g., a regulation-and-support integrated investment promotion policy); providing incentives for GX up-front investments by introducing carbon pricing (an emissions trading system, surcharge on fossil fuel supply, etc.); and using new financing methods. In the emissions trading system (ETS), reductions in emissions by businesses will be traded in the form of environmental values. In order to use these measures to promote biomanufacturing that will contribute to decarbonization, we intend to determine how specifically these measures should be utilized,

while further considering challenges specific to biomanufacturing, such as means to quantify environmental values.

To create and expand markets, it is important to appropriately assess and calculate, and visualize, added values such as the effect of reducing environmental burden in terms of raw materials, manufacturing processes, and life cycle. In order to support businesses working on bioconversion of raw materials or processes, we will also promote discussions on how the following should be set up and work: systems for quantitatively assess environmental values by utilizing biomass technology or biotechnology, such as utilizing carbon footprints (CFPs) or establishing a life cycle assessment (LCA) method for bio-derived product; certification and credit systems; and methods of labeling of bio-derived products that will reduce environmental burden. Furthermore, we will promote discussions on methods for assessing and utilizing values other than environmental values of bio-derived products. To promote these efforts, we will strategically promote international standardization and international rulemaking for LCA, product labeling, etc., with an eye to the global market from an early stage.

Efforts to create markets include promoting discussions on measures to generate demand based on, among other things, the Act on Promoting Green Purchasing, in order to promptly create and expand markets of bio-derived products.

Efforts toward demanders, i.e., B-to-C businesses and consumers, include advancing efforts to make the value of bio-derived products appeal to these demanders, such as disseminating information to the public on cases of biomanufacturing or on bio-derived products, or making risk communications about them. We will also promote discussions on labeling and other systems that would allow consumers to choose and make appropriate judgment on bio-derived products.

To achieve the 2050 carbon neutrality target and the 2030 reduction target, we will achieve our people's "new rich life" and the creation of high demand for products, services, etc. in accordance with the "10-Year Roadmap for Our Life," which was established in fiscal 2023 to explain challenges and bottlenecks and to show our road to measures and efforts to structurally solve them from the viewpoint of citizens, in all fields of their life including clothing, food and housing, work, transportation, shopping, etc., regarding "DEKO KATSU," which is a new national movement to strongly support changes in public and consumer behavior and lifestyle toward decarbonization.

We will continuously and strongly promote changes in public behavior and lifestyle by, in particular, advancing cooperative social implementation projects to provide the public with mechanisms for solving challenges and bottlenecks. This will be done through public and private cooperation using a matching fund method.

(iv) Establishing domestic industrial infrastructures by improving the business environment

In terms of the business environment, biomanufacturing is specifically a new business area where the business environment and supply chains have not been fully established. Taking a glance of the industrial structure in Japan, it is not uncommon that a company with fair competitiveness mainly in manufacturing does not have sufficient accumulation of or experience in biotechnology. For this reason, in order to convert fossil resource-based manufacturing processes into biotechnology-based processes, it is important that cooperation be formed between companies with equipment and capability to produce final products and companies with expert techniques and knowledge, such as microorganism/cell design platform businesses. It is also important that microorganism/cell design platform businesses proceed with cooperation with downstream production businesses and with the internal development of their products from early on, in order to ensure that they will be able to handle social implementation of their products in a wide range of areas.

We will promote increase in business efficiency and cooperation between players by cooperating with overseas players and promoting standardization and commonization of data handling, workflows, etc., while paying attention to what to open (such as standards) and what to keep closed (intellectual property, patents, etc.). Specifically, toward expansion of markets of bio-derived products such as structural protein fibers, we will strategically promote the establishment of international standards for bio-derived products by such means as actively participating in investigations related to international standardization or in international standardization activities themselves, and supporting domestic players working in that area.

Challenges that have been pointed out to be facing our efforts to promote biomanufacturing and other forms of manufacturing bio-derived products include: a shortage of demonstration centers for businesses to conduct large-scale production demonstration, such as culture or fermentation; and a shortage of human resources for biomanufacturing.

As for the first challenge, we will continue to develop biofoundry centers in accordance with the “Development of Production Technology for Bio-based Products to Accelerate the

Realization of Carbon Recycling” project that has been implemented since fiscal 2020, and will consider developing more demonstration facilities.

As for the second challenge, we will advance our efforts to develop and secure human resources required in the industrial world, after identifying the different needs for knowledge and human resources required by different value chains in the biomanufacturing area, in light of the fact that biomanufacturing now requires a wide variety of knowledge, such as that on AI and other digital fields, engineering, and business management to lead businesses to success, in addition to expert knowledge about synthetic biology or fermentation production. We will also advance the development of human resources who are capable of building a bridge between advanced research and the industrial world, by continuing the human resources development program for biomanufacturing that has been implemented by utilizing biofoundry centers, through making active use of, among others, the “Development of Production Technology for Bio-based Products to Accelerate the Realization of Carbon Recycling” project that has been implemented since fiscal 2020. In implementing the Green Technologies of Excellence (GteX) Program, we will encourage the appointment of young researchers to key positions and their participation in forums and other opportunities for discussing the directions of R&D, as well as the participation of doctoral students from a wide range of fields, and will provide the industrial sector with highly-qualified human resources, including holders of doctoral degrees.

Furthermore, it is important to accelerate investments in start-ups, such as microorganism/cell design platform businesses or businesses with fundamental technologies, such as DNA/RNA synthesis, genome editing, or microorganism hunting, and to establish domestic industrial infrastructures, due to such reasons as Japan’s reliance on overseas suppliers for some peripheral equipment and materials supporting biomanufacturing, such as experimental devices, measuring instruments, sensors, and reagents. Regarding improvement of the environment where start-ups are created and grow, we will promote support to start-ups based on the industrial structure of the domestic biomanufacturing area and its players’ needs and challenges facing them, in coordination with the start-up supporting measures taken across the government, in order to provide environments that support the creation and growth of start-ups. We will also support start-ups and the like engaging in R&D that will contribute to environment preservation in the “Environmental Start-up-Specific Research and Development Support” project and the Technology Development and Demonstration Project for Regional Symbiosis and Cross-Sectoral Carbon Neutrality.

As for the establishment of domestic industrial infrastructures, including those for surrounding industries, we will promote discussions on supporting measures to increase the competitiveness of domestic players involved in experimental devices, measuring instruments, sensors, reagents, members and materials, consumable supplies, etc., demand for which is expected to rise with expansion of the biomanufacturing area. The global market of measuring and analytical instruments is expanding and is expected to be led by the life science field as before. However, the domestic market of these devices has been stagnant, with its players facing competition with overseas manufacturers. We intend to promote the activation of domestic markets of experimental devices and measuring and analytical instruments, by working on measures that would allow manufacturers to identify users' needs, such as by promoting cooperation with users through providing forums or creating systems for collaboration in domestic basic research fields, or by promoting shared use of analytical devices at shared laboratories or at shared facilities of academia, or at demonstration facilities for industrial technologies. Japan has promising element technologies, such as optical mass spectrometry, mechatronics, and robotics. In order to accelerate their practical application and to increase their international competitiveness in the future, we will promote the systemization of bio-related analytical, measuring, and experimental processes and the international standardization of measuring methods.

Furthermore, since biotechnology is a cross-sectional field, it is important, in terms of improving the business environment, to coordinate rules and regulations through cooperation between government agencies. In particular, we must appropriately take necessary national action with respect to international discussions on, and movements toward making rules related to, climate changes, circular economy, economic security, natural capital, biodiversity preservation, and other topics that are directly connected to the social significance of promoting biomanufacturing. Furthermore, it is necessary to flexibly revise definitions, programs, etc. in accordance with social implementation, since there will be those that no longer fit cutting-edge biotechnologies or products.

(v) Data utilization and linkage

Ample biological genetic resources are one of the sources of the competitiveness of microorganism/cell design platform businesses. We will advance the development of infrastructures for cross-sectional platforms toward the integration of biotechnology and digital technology, as well as further aggregating, upgrading, and expanding biological resource data and promoting the utilization of this data. We will also promote discussions on how data should be utilized and linked to increase the competitiveness of domestic players involved in biomanufacturing.

(2) Sustainable primary production systems

1) Trends in the overall market area

Food, agriculture, and agricultural communities in Japan are faced with challenges and significant changes in the situation related to food security. While the global population has increased rapidly mainly in developing countries and demand for food has also increased, the global food production and supply have become more unstable due to the frequent occurrence of abnormal weather caused by climate changes and due to an increase in geopolitical risk, among other causes. The development of global warming has resulted in the frequent occurrence of abnormal weather, such as heat, drought, and large-scale flood. Since the year 2000, regional poor harvests have occurred almost every year in different parts of the world. The 2022 Russian invasion of Ukraine has led to restrictions on the international trade of both countries, which are major producers of wheat and other products, giving a significant impact on global food security.

Due to the combination of these and other factors, crop prices have repeated steep rises and sharp falls every few years. A country relying on imported wheat, soybeans, feed crops, etc., Japan has evidently been affected, such as facing increasing difficulty in procuring these products stably on a long-term basis. In addition, while Japan's economic growth has slowed down due to the long deflationary economy, the economies of China, India, and other emerging countries have grown rapidly. This has resulted in a slip in Japan's economic position with respect to the rest of the world, making it no longer easy for Japan to import food or production materials it needs.

When we turn our eyes toward domestic agriculture, we find the decreasing and aging agricultural population and a concern over the potential decline of agricultural communities. Amid this situation, the total population turned to a declining trend in 2009, making the shrinking domestic market an inevitable challenge facing the country. Japan's population decline occurred in agricultural communities ahead of others, resulting in the marked decrease and aging of the agricultural population. The number of core persons mainly engaged in farming decreased by half, from 2.4 million in 2000 to 12.3 million in 2022, with the largest age group being 70 years and older. The current age group of below 60 years, which is expected to be the central component of the core persons mainly engaged in farming in 20 years, consists only of approximately 250 thousand persons, representing only about 20% of the total.

In addition, efforts toward and public awareness of the Sustainable Development Goals (SDGs) have spread and permeated worldwide. This has led to the social expectation that the

agriculture and food industry, which is based on natural capital and the environment, should give consideration to and take action toward the environment, biodiversity, etc. Sustainability is now understood as the most important topic in terms of the development and new growth of agriculture and food production. For these reasons, the Ministry of Agriculture, Forestry and Fisheries formulated the MIDORI Strategy in May 2021, toward the development of a sustainable food system. Under the strategy, the Ministry has promoted the development and social implementation of innovative technologies and production systems throughout the supply chain from procurement, production, processing, and distribution to consumption.

Due to Japan's declining and aging population, its domestic food market is expected to see a decline in both demand per capita and aggregate demand, which will inevitably lead to a rapid shrinkage of the market. With the growing global population, on the other hand, the international food market is on a growing trend. The food and drink market size in major countries is expected to increase by 50% during the period from 2015 until 2030. In particular, the Asian region is the center of global economic development and has seen an increase in the number of high-income earners, which has led to the acceptance of Japanese food. This has caused a growing demand for Japanese agricultural products and processed foods. In 2021, Japan's export of agricultural, forestry, and fishery products and foods exceeded 1 trillion yen for the first time. It is expected that there will be room for further increase. In addition, FoodTech markets are emerging worldwide as a new business that may lead to the solution of social challenges, such as food supply to cover the growing population, or environmental protection.

2) Goals for the year 2030

(i) Target market size

Up to 14.9 trillion yen (up to domestic: 1.7 trillion yen, overseas: 13.2 trillion yen)

(Related indices)

- Proportion at which smart agriculture technology is used¹¹
- KPIs for the MIDORI Strategy (environment preservation)¹²

(ii) Specific aims

To achieve increased productivity through smart agriculture technology and through developing and introducing new varieties, among other means, and to thereby establish a highly productive food supply system that is able to maintain the same level of production

¹¹Specific indices are to be discussed.

¹²The target is to reduce the chemical pesticides usage (as converted to risk value) by 10% and 50% by 2030 and 2050, respectively. The target is to reduce the chemical fertilizer usage by 20% and 30% by 2030 and 2050, respectively. As for organic agriculture, the target is to increase the area on which organic agriculture is performed to 63,000 ha by 2030 and to 1 million ha (by 25%) by 2050.

even with the declining population. To increase the sustainability of food supply by establishing a food system that is harmonized with the environment by promoting, among other things, efforts to reduce environmental burden based on the MIDORI Strategy. To secure a stable food supply by maintaining the domestic production infrastructures despite the shrinking domestic market due to the declining population, by promoting export in response to the increasing demand from overseas and promoting the utilization, etc. of new technologies.

3) Directions of future efforts

(i) Overall

It is obvious that the combination of the existing measures will not be able to eliminate the gap between the situation described under the heading “Trends in the overall market area” and the goals for the year 2030. We must enhance agricultural and food innovations. Under the MIDORI Strategy, we aim to boost the productivity potential and sustainability in the agriculture, forestry, fisheries and food industries with innovation. At the same time, we will promote efforts to drastically enhance our food security in accordance with the “New Direction in the Development of Food, Agriculture, and Rural Area Policies.”

With the forecast that the agricultural population will considerably decrease in the future, it will be necessary to provide domestic food supply by a considerably smaller number of agricultural operations than today. We must enhance the infrastructures for agricultural operations in addition to increasing the agricultural area and consolidating farmlands. To establish a highly productive food supply system that is able to maintain the same level of production even with the declining agricultural population, it will also be essential to accelerate the practical introduction of smart agriculture technologies that will contribute to increasing the efficiency of agricultural tasks, among others. It is therefore necessary to foster agricultural operations that focus on productivity by introducing new varieties and new technologies, such as robot, AI, IoT and other advanced technologies or smart agriculture that utilizes data.

While concerns have arisen as to the securing of agricultural income, due to such factors as the shrinking domestic market and the rising prices of production materials, the functionality and environmental friendliness and other sustainability of foods and other products that contribute to the maintenance and promotion of health have been recognized as new values. This diversification of values is expected to continue into the future. In addition, in light of the existing development of biotechnologies, digital technologies, etc. that will contribute to a sustainable food supply, it is necessary to create new demands by

promoting the fostering of start-ups or new business models that aim to utilize and commercialize these new technologies. As for the FoodTech market that is attracting global attention as a new business, we must help the creation of businesses that utilize FoodTech in Japan and abroad, by promoting, among other things, the introduction of new technologies by food businesses, etc., while paying full attention to securing risk communications when new technologies are introduced.

From the viewpoint of sustainable growth and risk diversification of the agriculture and food industry and the viewpoint of maintenance of the infrastructures for agricultural production, we must ensure that the industry will look not only at the domestic market but also at the overseas market that is on an expanding trend with the growing global population. In the course of aiming the conversion to an agriculture that looks also at the overseas market, it is an extremely important challenge to appropriately protect and utilize intellectual property that serves as a source of the advantages of Japan's agriculture, in order not only to maintain and enhance the competitiveness of Japan's agriculture but also to continue research and development through obtaining appropriate consideration.

(ii) Acceleration of technology development

First, as for smart agriculture, certain focused development goals, whose details up to implementation will be planned at the initiative of the national government, will be specified in accordance with the “Details of the Specific Measures Based on the New Direction of Development of Food, Agriculture, and Rural Area Policies,” in order to accelerate the practical application of smart agriculture in the situation where a rapid decline of the agricultural population is expected due to the declining population. R&D and other activities will then be promoted by strengthening industry-academia-government collaboration through such means as making facilities of the National Agriculture and Food Research Organization (NARO) available to start-ups and other businesses working on R&D and other activities in line with those goals. At the same time, we will promote the conversion of production methods, such as by revising cultivation systems to fit smart agriculture technology, while cooperating with services providers and others supporting the utilization of smart agriculture technology. Furthermore, in order to provide more integrated support to these activities through taxation systems, financing, etc., the Bill of Act on Promotion of the Utilization of Smart Agricultural Technology to increase Agricultural Productivity was submitted to the 213rd ordinary session of the Diet.

On-site guidance and other services will be provided by smart support teams, whose aim is developing smart agriculture technologies with an eye on the declining population,

developing fundamental new cultivars whose growth and cultivation characteristics are improved for smart technology, promoting open APIs (application programming interfaces) for agriculture ICT (information and communication technology) services, fostering and growing agriculture support service providers to allow everyone to utilize smart agriculture at low cost, developing capabilities to handle technologies, and developing human resources.

In addition, generative AI that supports farmers, including new ones, in cultivation, management, sales, and various other respects will be developed and be provided to farmers through a private company's application. Furthermore, in order to further develop generative AI in the field of agriculture, we will improve and strengthen agricultural data collaboration platforms, such as WAGRI, and other infrastructures such as NARO's supercomputer Shiho.

Toward the realization of the MIDORI Strategy in order to increase the sustainability of the agriculture, forestry, fishery, and food industries, the following will be promoted at the initiative of the national government: acceleration of the development of cultivars; changes in people's behavior toward solving climate changes and other new challenges; creation of innovations by utilizing biotechnology; and R&D activities to meet practical needs that are participated in by parties ranging from upstream to downstream.

As for breeding, we will promote the development of new cultivars that will contribute to labor saving and other aspects, such as cultivars that are fit for machine harvesting or other methods used in conjunction with smart agriculture technology. In addition, we will, based on the Green Cultivar Development Policy which was established to realize the MIDORI Strategy, promote the improvement and strengthening of the infrastructures for smart breeding system, which allows, by utilizing genome information, etc., the prompt development of new cultivars with epoch-making characteristics intended to balance between sustainability and increased productivity, such as high yield, high quality, disease and pest resistance, and heat resistance to deal with climate changes.

We will promote, among other things, the development of biological nitrification inhibition (BNI)-enabled crops or varieties whose yield or quality is less likely to be affected by smaller amount of fertilizer.

The Ministry of Agriculture, Forestry and Fisheries and the Ministry of Land, Infrastructure, Transport and Tourism will play a central role in promoting the R&D and demonstration of technologies that will contribute to reducing the chemical fertilizer usage and to breaking the excessive reliance on import, such as technologies that efficiently recover

raw materials for fertilizer from sewage sludge resources, etc. or that make effective use of sewage sludge resources, etc. and use them as fertilizer.

In the field of livestock industry, we will promote, among other things, the development of non-contact individual biological monitoring devices, and smart livestock barn systems that can precisely control the environment in the barn in response to temperature and humidity.

In the field of fishery industry, we will promote the development of technologies for promoting quantity management in fixed-net fishing, etc. by utilizing ICT, etc. We will also foster and support partners who lead efforts to introduce and spread smart technologies in local areas, and we will strive to spread smart fisheries with support from those partners. On top of these efforts, we will promote, among others, the development of fishmeal replacements, such as insects. In promoting the enhancement of blue carbon ecosystems, which is expected to serve as an effective CO₂ absorption, we will develop seaweed supply systems (seaweed banks) by utilizing fishing ports and reinforcement technologies related to the efficient creation and expansion of new seaweed (macroalga) beds, in order to achieve the efficient and broad development and restoration of seaweed beds.

In order to supply food in response to the growing population, we will promote, among other things, R&D of foods utilizing microorganisms, such as protein sources generated by utilizing hydrogen-oxidizing bacteria or *koji* mold.

In addition, we will support bioeconomy activities, whose aims include creating start-ups and new businesses and cooperating with overseas parties by combining human resources, funds, technologies, equipment and devices, and various other resources in the “Field for Knowledge Integration and Innovation,” which is a system for promoting the creation of innovative technologies, products, and services through open innovations by introducing ideas, technologies, etc. from various fields to the fields of agriculture, forestry, fisheries, and food. In relation to the above, we will promote technology development in the following additional projects:

- In the “Building a Resilient and Nourishing Food Chain for a Sustainable Future” project, which is Phase 3 of the Strategic Innovation Promotion Program (SIP), we work on the construction of a food chain that balances between increased productivity and reduced environmental burden, while securing nutritiousness throughout the stages from procurement, production, processing, distribution, to consumption of food. Specifically,

we will continue to work on the following five sub-themes: development of infrastructures for smart breeding of soybeans (plant proteins) and establishment of cultivation techniques for them; development of a domestic recycling system for fertilizer; development of next-generation cultivation systems for animal proteins (fishery products); development of nutritious food design systems utilizing domestic soybeans, etc.; and R&D toward realization of high-quality dietary lifestyle using behavior science-based approaches.

- In the “programs for Bridging the gap between R&D and the IDEal society (society 5.0) and Generating Economic and society value (BRIDGE),” we will promote R&D that will contribute to, among other things: securing a stable food supply; balancing between increased productivity and sustainability in food, agriculture, forestry, and fishery industries; production of useful substances by utilizing agricultural, forestry and fishery products, etc.; and conversion to an agriculture that looks also at the overseas market.
- Regarding the goal related to agriculture under the Moonshot R&D Program (Goal 5: Creation of the industry that enables sustainable global food supply by exploiting unused biological resources by 2050), R&D activities have been underway toward creating a sustainable food supply industry, such as resource circulation-type cell culture techniques utilizing algae and a technology that balances between improved productivity and reduction of methane gas generated from cattle. We will continue these efforts, as well as accelerating efforts toward social implementation of excellent research results.
- We will continue to work on, among other things: development of breeding technologies that allow the creation of agricultural, forestry and fishery products with increased productivity and/or functionality by utilizing genome editing technologies developed in Japan, that do not infringe basic patents held by U.S. or European universities; creation of high-performance biomaterials, such as pharmaceutical raw materials, utilizing the functions of organisms including plants, silkworms, etc., and establishment of their supply chains; and development of innovative animal vaccines, such as African swine fever vaccine utilizing genome editing technology and a new porcine cell line. We will also work on the development of: novel foods that are excellent in nutrition, functionality and/or palatability by utilizing fermentation microorganisms; and technologies for making effective use of food by-products, etc.

(iii) Efforts to improve the market environment

Regarding improvement of the market environment, the Bill of Act on Promotion of the

Utilization of Smart Agricultural Technology to Increase Agricultural Productivity was submitted to the 213rd ordinary session of the Diet. Toward realizing the MIDORI Strategy, we aim to develop sustainable food systems by promoting efforts to reduce environmental burden in each of the procurement, production, processing, distribution, and consumption stages through such means as providing for exceptions to taxation and financing under Act on the Promotion of Smart Agricultural Technology Utilization to Improve Agricultural Productivity” (Act No. 37 of 2022).

Toward expanding efforts on carbon credits derived from the agriculture, forestry, and fisheries sectors, the formation of projects and the development of new methodologies under the J-Credit Scheme which aim to reduce GHG emissions from crop and/or livestock will be promoted. We will also promote the visualization of environmental burden reduction efforts, using a system in which farmers’ efforts to reduce environmental burden are evaluated and communicated to consumers in an easy-to-understand manner in the form of number of stars indicated on the label. As for agricultural products, we will strive to spread efforts on visualization in accordance with the applicable guidelines. As for livestock products, we will proceed with the creation of a simplified GHG calculation tool for visualization.

In combination with promoting R&D, such as the creation of innovations utilizing biotechnology, we will promote the understanding of advanced technologies and acceptance by consumers, etc. by actively disseminating information mainly to young generations.

By making maximum use of support by Official Development Assistance (ODA) and by demonstration projects sponsored by fund distribution agencies, we will promote the expansion of Japan’s advanced technologies into overseas markets, as well as standardization necessary to capture overseas markets.

(iv) Establishing domestic industrial infrastructures by improving the business environment

As for improvement of the business environment, we will develop environments that will allow effective R&D and spread of its results by such means as: promoting the utilization of agricultural data not only in production settings but also in midstream and downstream settings by promoting the utilization of data collaboration platforms, such as the agricultural data collaboration platform WAGRI and the smart food chain platform “ukabis” that allows mutual utilization of data from production, processing, distribution, marketing to consumption; and securing human resources, including those from different fields, by developing industry-academia-government collaboration centers and strengthening support

to start-ups and cooperation between start-ups and other businesses. In addition, NARO will develop facilities that will serve as research infrastructures necessary to promote the development of smart agricultural technology and varieties through industry-academia-government collaboration, and will also strive to improve and strengthen infrastructures such as: the Genebank, which is a storage facility of genetic resources; agricultural data collaboration platforms such as WAGRI; and NARO's supercomputer Shiho.

In order to increase the level of education provided at agricultural colleges, agricultural high schools, etc., we will support their introduction of agricultural machinery and equipment, enhancement of curriculums on such topics as smart agriculture, and provision of field training programs and outreach programs, among other things.

In order to protect and utilize intellectual property, we will promote efforts of breeders' rights management organizations which effectively deal with infringements by registering varieties and granting licenses overseas on behalf of breeders' right holders. As part of these efforts, we will promote efforts to realize a cycle through which royalty proceeds from overseas are invested in the development of new varieties in accordance with the Overseas License Guidelines.

As for livestock genetic resources, we will promote the distribution management of these resources and the protection of their value as intellectual property, by implementing various measures to ensure the appropriate distribution of these resources and the prevention of unfair competition under the Act on Improvement and Increased Production of Livestock and the Act on Prevention of Unfair Competition on Genetic Resources of Livestock.

We will help develop start-ups in the fields of agriculture, forestry, fisheries, and food by steadily promoting, among other things: stage-specific partnering support to start-ups aiming to develop or commercialize new technologies; and large-scale technology demonstration projects (Phase 3) conducted by utilizing the Small and Medium Enterprise Innovation Creation Promotion Fund.

As for FoodTech, we will promote efforts being made under the FoodTech Promotion Vision and the Roadmap for FoodTech Promotion (both established in February 2023) formulated by The Food-Tech Public-Private Council, as well as government-private collaborative efforts to promote the resolution of challenges in cooperative areas or to support the development of new markets. We will also promote the creation of new demands by such means as utilizing new technologies, through such efforts as supporting the

demonstration of business models utilizing FoodTech, or supporting FoodTech businesses aiming to expand their business overseas. In addition, the Ministry of Agriculture, Forestry and Fisheries will, in collaboration with the Ministry of Economy, Trade and Industry, promote the prompt social implementation of new technologies by such means as supporting technology development and demonstration worked on jointly by businesses and others.

Based on the “ASEAN-Japan MIDORI Cooperation Plan” adopted at the ASEAN-Japan Ministers of Agriculture and Forestry Meeting in October 2023, we will promote cooperation projects with the ASEAN countries through utilizing Japan’s technologies to enhance both productivity and sustainability in the ASEAN region, and ultimately, to contribute to its food security. In the course of these efforts, we will strive to spread and expand our environment-friendly agricultural technologies, through measures such as utilizing the Joint Crediting Mechanism for reduction of methane emissions from rice fields in collaboration with the Asian Development Bank. In addition, we will participate in international rulemaking efforts by continuing to present, at international conferences and other venues, the MIDORI Strategy as a model effort on sustainable food systems in the Asia-Monsoon region.

Furthermore, we will participate in international initiatives for promoting agricultural innovations, such as AIM for Climate led by the U.S. and other countries.

In order to promote the deployment of the technologies that contribute to climate change mitigation and sustainable agriculture in Asia-Monsoon region, we will conduct collection, analysis and dissemination of the information of technologies scalable in the Asia-Monsoon region under the advice of the International Science Advisory Board for the MIDORI Strategy. Also, we will conduct the joint research to facilitate the application of these technologies in various regions. As a project with CGIAR, we will promote the development of the agricultural cultivation technologies that contribute to developing sustainable food systems.

(v) Data utilization and linkage

As for data utilization and linkage, we will develop environments that will allow effective R&D and spread of its results by such means as: promoting the utilization of agricultural data not only in production settings but also in midstream and downstream settings by promoting the utilization of data collaboration platforms, such as the agricultural data collaboration platform WAGRI and the smart food chain platform “ukabis” that allows mutual utilization of data from production, processing, distribution, marketing to consumption; and securing human resources, including those from different fields, by developing industry-academia-government cooperation centers and strengthening support to

start-ups and cooperation between start-ups and other businesses (reiteration from above). NARO will develop facilities that will serve as research infrastructures necessary to promote the development of smart agricultural technology and cultivars through industry-academia-government cooperation, and will also strive to improve and strengthen infrastructures such as: the Genebank, which is a storage facility of genetic resources; agricultural data collaboration platforms such as WAGRI; and NARO's supercomputer Shiho.

(3) Large-scale buildings utilizing wood and smart forestry

1) Trends in the overall market area

Wood is a renewable resource produced from forests. It contains carbon which derives from CO₂ in the atmosphere, which is absorbed by forests in the process of their growth. Utilizing wood, particularly in buildings, while ensuring the circulation of forest resources, allows wood to contain larger amount of carbon for longer period of time, which will strengthen removals by forest carbon sinks. Wood is also a material which contributes to reducing CO₂ emissions from construction, since the energy consumption during the manufacturing and processing of timber is relatively small as compared to that of other construction materials such as iron and concrete.

For these reasons, recent years have seen a growing global interest in the utilization of wood in buildings as one of the important efforts to deal with climate change and contribute to the transition to a circular economy. This movement has led to the spread of mid- to high-rise wooden buildings around the world, mainly noticeable in Europe and the U.S.

In Japan, about 70% of its land is covered by forests. The country has a long history of making effective use of wood as a resource. Now that the forests planted post-war are entering their period of use, it is essential in Japan to sustainably utilize wood produced from those forests, especially in buildings, to achieve a bioeconomy and to contribute to achieving the 2050 carbon neutrality target.

While low-rise housing has long been the main source of demand for wood in Japan, it is now important for building sector to develop new markets in light of the anticipated decrease in the number of housing construction projects, along with the declining population in Japan. For this reason, and partly in response to global trends, attention has been drawn to the utilization of wood in large-scale buildings (excluding low-rise housing; the same applies hereinafter), in which wood has not been utilized very much so far. There are also expectations that overseas markets will be captured by exporting high value-added wood products for use in wooden buildings, etc. overseas.

On the other hand, increasing the utilization of wood in large-scale buildings, etc. inevitably requires that parties involved in the supply chain of wood, from upstream to downstream, share the understanding of the significance of increasing mutual profit as well as their own profit, while developing a system that allows increased profitability of forestry as well as sustainable, stable supply of wood. This makes it necessary in forestry operations to improve its productivity and safety, while giving consideration to the conservation of

forest lands. This is predicated on defining forest boundaries and on consolidating forest lands to allow for integrated operations. While working on these tasks, we must promote smart forestry that utilizes AI, ICT, and other digital technologies.

As countermeasures against hay fever, which has become a social issue in Japan, it is also important to promote the felling, replacing, etc. of cedar plantations that are pollen sources and to increase the utilization of cedar in the building sector.

Thus, in this market area we must increase the profitability of forestry by increasing the utilization of wood and increasing the productivity of forestry, which in turn will promote a circular use of forest resources where wood is harvested, utilized, planted, and grown, which, together with the promotion of countermeasures against hay fever, will contribute to realizing a bioeconomy society.

When we look back on the recent market trends based on the above understanding, we find that after the year 2020, the environment surrounding Japan's construction market has been significantly affected by: the stagnant economy and the disrupted supply chain caused by the spread of the COVID-19 pandemic; the shortage and price rise of imported timber that occurred in 2021 (the so-called "wood shock"); the Russian invasion of Ukraine in 2022; and the price rise of materials and energies caused by a weak yen and other factors. Under these circumstances, the market of large-scale buildings, particularly large-scale buildings utilizing wood, is currently facing a stagnant growth in size.

On the other hand, amid the high expectations for action in the building sector toward achieving the 2050 carbon neutrality, and partly from the viewpoint of ESG investing, the utilization of wood continues to attract high interest from real estate and construction businesses handling large-scale buildings, resulting in the emergence of the growing number of wooden buildings, particularly med-rise and higher ones. In terms of wood supply, the proportion of domestic timber has almost doubled to around 50% in the past two decades.

In October 2021, the Act for Promotion of the Use of Wood in Buildings to Contribute to the Realization of a Decarbonized Society (commonly known as the Urban Timber Construction Promotion Act) came into effect, which has led to ongoing, concerted efforts across the government to promote the use of wood not only in public buildings but also private ones.

In 2023, the documents such as "Overall Picture of Hay Fever Countermeasures", was

formulated by the Council of Ministers on Hay Fever toward solving hay fever as a social issue. These documents set targets such as: accelerating the felling, replacing, etc. of cedar plantations as countermeasures against pollen sources, to achieve in 10 years an approximately 20% reduction in pollen-emitting cedar plantations and to increase the proportion of low-pollen cedar seedlings in the total production of cedar seedlings to at least 90%; and increasing the demand for cedar timber to 17.1 million m³ (by 4.7 million m³) in 10 years.

While there is a growing momentum and necessity for the use of wood as described above, we are still in the process of: developing and spreading wood products necessary to economically build large-scale buildings utilizing wood, as well as reasonable design and construction technologies for that purpose; developing human resources who engage in construction projects of large-scale buildings utilizing wood; developing environments that promote the sustainable use of wood; and extending these environments to include demanders and consumers. As for the export of wood products, it is necessary to ensure conformity to regulations and standards in importing countries.

Toward a sustainable, stable supply of domestic wood, the forestry industry has seen an increase in harvest productivity from 1.6 m³/person-day in 1990 to 7.3 m³/person-day in 2021 due to the introduction of high-performance forestry machines among others, as well as a long-term decreasing trend in the number of casualties at forestry work. Nonetheless, it is necessary to further promote smart forestry to further increase productivity and safety. In addition, as for the acceleration of the felling, replacing, etc. of cedar plantations, these efforts should be promoted and, by utilizing biotechnology, be combined with the promotion of increased production of low-pollen seedlings, such as those derived from “elite trees,” which are characterized by low pollen and excellent growth rate and are even expected to increase CO₂ absorption.

In order to produce raw wood to meet demand, it is also important to keep track of information on forestry resources and to work on collaboration and other efforts by utilizing digital technologies between raw wood suppliers (such as forestry businesses), raw wood demanders (such as timber mills and plywood factories), and other parties involved. The infrastructures for utilizing digital technologies have been steadily developed, as seen in the fact that 56% of the privately-owned forests across the country were covered by the forestry resources information system using airborne laser altimetry as of the end of fiscal 2022. However, digital technologies in forestry are utilized only by some people or in a segmented manner. There are expectations for full use of digital technologies in the whole geographical

areas.

2) Goals for the year 2030

(i) Target market size

Large-scale buildings utilizing wood: 1.0 trillion yen (domestic)

(Related indices)

- Using the new construction floor area of large-scale buildings utilizing wood (in Japan) as the benchmark, the target is to exceed about double the level of 2018 in 2030.

(ii) Specific aims

- To contribute to CO₂ emission reduction and have fewer countermeasures by spreading large-scale buildings utilizing wood.
- To capture overseas markets of high value-added wood products for use in wooden buildings, etc.
- To establish forestry as a sustainable, growing industry and to achieve the appropriate development and circular use of forests, through utilization of domestic wood and dramatic increase in the profitability of forestry.

3) Directions of future efforts

(i) Overall

To further promote: developing and spreading wood products necessary to economically build large-scale buildings utilizing wood, as well as reasonable design and construction technologies for that purpose; developing human resources who engage construction projects of large-scale buildings utilizing wood; developing environments that promote the sustainable use of wood; raising the awareness of the utilization of wood in demanders and consumers. In addition, toward exportation of wood products, we will work to ensure conformity to regulations and standards in importing countries.

In addition, we will further promote smart forestry to further increase the productivity and safety of forestry and to produce raw wood to meet demand, by such means as keeping track of information on forestry resources and promoting full use in forestry of digital technologies in the whole geographical regions through collaboration and other efforts between raw wood suppliers, raw wood demanders, and other parties involved. Furthermore, we will promote increased production of seedlings that utilizes biotechnology.

(ii) Acceleration of technology development

In large-scale building utilizing wood, highly strong, highly fire-resistant wooden structural member is required under building standards. For this reason, we will further promote, among other things: developing technologies involved in timber sawing, cross laminated timber (CLT), fire-resistant wooden members, etc.; and demonstrating advanced construction projects build with building materials such as CLT. In order to spread large-scale buildings utilizing wood at an accelerated rate, we will promote the development of technologies toward standardization of members and will also create and spread standard models for wooden buildings that will allow architects with no experience of engaging in large-scale wooden construction projects. In doing so, a particular focus will be placed on med-rise wooden buildings, which will constitute the largest group in large-scale buildings. In addition, we will spread design and construction technologies that will lead to efficient use of wood, such as mixed structure buildings consisting of wooden and other structures. Furthermore, in order to contribute to hay fever countermeasures through increasing the use of cedar, we will work on the development of technologies for cedar products that could be used in large-scale buildings utilizing wood.

In forestry operations supplying wood, technology development and demonstration will be promoted toward automation, remote control, etc. of forestry machines by utilizing AI and other technologies, in accordance with the Forestry Innovation Field Implementation Promotion Program in order to increase productivity and safety.

Toward increased production of low-pollen seedlings, we will promote, among other things, developing pollen-free cedar by utilizing genome editing technology based on “elite trees” and others, and developing technologies for mass producing seedlings by utilizing cell proliferation technology.

(iii) Efforts to improve the market environment

Toward expansion of the market of large-scale buildings utilizing wood, we will foster momentum in society at large by spreading knowledge about, and raising awareness of, the significance and effects of using wood in buildings, not only among real estate and construction businesses engaging in construction but also among building owners, investors, and financial institutions investing in construction as well as among general consumers who use buildings. In particular, in order to ensure that large-scale buildings utilizing wood will be evaluated appropriately in ESG investing, etc., we will, based on international standards and others, promote: (i) spreading methods, etc. for evaluating, among other things, (a) the contribution of the use of wood in buildings to carbon neutrality or (b) sustainable use of wood; and (ii) developing methods for estimating emissions throughout the life cycle of

buildings (i.e., life cycle carbon). In addition, we will promote the development of environments where cedar and other domestic wood products are actively chosen, through visualization of environmental values, among other means. Furthermore, by utilizing the Wood Change Council, which is a public-private council participated in by a wide range of parties from downstream to upstream, as well as utilizing various granting awards of recognition, we will promote discussions on challenges and solutions toward spreading the use of wood in private buildings among others, as well as dissemination of information on progressive approaches among others.

(iv) Establishing domestic industrial infrastructures by improving the business environment

Toward developing and securing architects and building contractors for large-scale buildings utilizing wood, we will promote, among other things, the creation of manuals for structural designing, etc., the provision of seminars for architects and building contractors, and the aggregation and publication of technical information. In addition, in light of the movement toward increasing the use of BIM¹³ across the construction field, we will promote, among other things: discussions on standard processes for designing and material procurement utilizing BIM in the projects of large-scale building utilizing wood as well as in other projects; the development of standard BIM objects for wooden members; and the development of an information database for production plants, etc. of JAS structural materials. Toward exportation of wood products, we will collect information on laws and regulations, standards, etc. in importing countries.

In terms of wood supply, we will promote the development of a supply system for JAS structural materials, whose quality and performance are assured, and the organization of a supply chain. In addition, in order to promote smart forestry and other approaches that help increase the productivity, safety, and profitability of forestry, forestry businesses are matched with businesses and other entities from other fields at the Forestry Innovation Hub Center to help the introduction and establishment of new technologies in forestry operations.

(v) Data utilization and linkage

We will continue to develop and provide public access to the high-precision forestry resources information system using airborne laser altimetry, etc. At the same time, we will promote the creation of “strategic digital forestry centers,” which consist mainly of regional consortiums comprising a large number of parties including prefectural and municipal

¹³Building Information Model: a system that allows the development, on computer, of 3D construction models with various attribute information such as specifications for members.

governments, forestry businesses, timber mills, plywood factories, and human resources and institutions from other fields, and which make full use of digital technologies in forestry activities ranging from forest surveys to the production and distribution of raw wood, in the whole geographical areas.

(4) Industries related to biopharmaceuticals, regenerative medicine, and cell and gene therapies

1) Trends in the overall market area

Progress of R&D of biopharmaceuticals, regenerative medicine, etc., and bio-digital convergence, raise expectations for the full-scale commercialization and the creation of new huge markets in these industries. Japan traditionally has a solid foundation of basic research. Japan's traditional fermentation industries have developed microbial and cell culture techniques. These assets are promising resources. Our approach in manufacturing process such as “*Kaizen* (improvement)” and quality control is another strength. We intend to capture the large markets once regenerative medicine, etc. is fully commercialized by: introducing digital, AI, and automation technologies in cell culture, transportation, contract manufacture, etc. that are important on the downstream side; developing a seamless system from the supply of cells and other raw materials to manufacturing; and seizing markets of related industries common to the field of drug discovery.

The main trends in drug discovery have shifted from low-molecule compounds to biopharmaceuticals, and the market size is growing rapidly. In the pharmaceutical market, new modalities such as nucleic acid therapeutics, regenerative medicine, and cell and gene therapy are rapidly growing elements. However, some study predicts that Japan's biopharmaceutical market will grow less than in other countries, indicating that Japan is falling behind the rest of the world. Japan's pharmaceutical import surpasses its export by 2 to 3 trillion yen per year, with the excess amount of import being on an increasing trend. Although Japan has a world-class track record of drug discovery, its sales of pharmaceuticals are on a declining trend. The reasons for this include: chemically synthesized pharmaceuticals account for more than biopharmaceuticals in Japan's drug discovery while a low-molecule pharmaceutical market is stagnant; the number of antibody drugs sold in Japan is on an increasing trend, but approximately 90% of them are manufactured overseas, suggesting a heavy reliance on overseas production sites; the number of registered multi-national clinical trials is not large. These circumstances have caused Japan's sales of pharmaceuticals to fall behind the rest of the world.

Therefore, it is important to enhance Japan's capability of biopharmaceutical discovery and development. In particular, it is desired to improve the capability of drug discovery and development in areas of high global needs such as highly functional biopharmaceuticals, medium-molecule medicines that can act effectively on the causes of diseases at low cost and be taken orally, by departing from a traditional industry focusing on the development of low-molecule pharmaceuticals. According to the Council for the Development of Regenerative Medicine and Cell and Gene Therapy, “regenerative medicine and cell therapy”

includes treatment using tissue stem cells, ES cells and iPS cells, whereas “gene therapy” *ex vivo* and *in vivo* gene therapies. These technologies are considered to be at an emerging or introductory stage.

In other countries, R&D in regenerative medicine and cell and gene therapy are actively conducted in recent years, and the number of relevant products approved in Japan is growing year by year. Cell transplantation and gene therapy have been a strong driving force of the market expansion. There are estimates that by around 2040 the market size will be about 20 times larger than in 2020.

Governments of many countries have developed supportive actions. In the UK, the Cell Therapy Catapult was established in 2012, followed by the start of the Regenerative Medicine Platform in 2013. In 2018, the government’s support was extended to the field of gene therapy. In the US, the NIH’s investment in iPS cells has continuously increased, with more than 70% of the invested research projects in this field being in *ex vivo* gene therapy. In Japan, seamless support is provided from basic research to practical application, mainly by the programs under the Japan Agency for Medical Research and Development (AMED). The world’s first clinical research projects in this field have been conducted. By FY2023, 20 regenerative medical products have received regulatory approval (for practical application). While regenerative medicine and cell and gene therapy have potential for achieving therapies for diseases that has no cure or treatment available today, it is not rare that the products in R&D phases in this field have failed to show clear efficacy in clinical phases, indicating that unmet medical needs have not been sufficiently met yet.

In research in regenerative medicine and particularly in the field of iPS cells, Japan has boasted the second largest number of publications and patents, both after the US, which demonstrates the significant role Japan has played. However, medical research in Japan has not integrated with other academic disciplines as much as in other countries. In addition, a gap still exists between academia and businesses, leaving some barriers to overcome to transform basic research into practical applications. Furthermore, there are not so many multi-national clinical trials that Japan participates in, which has led to drug lags and drug losses. Moreover, while startups have now been the main developers of new drugs globally, commercialization of new drugs developed by startups is scarce in Japan, for it is more difficult in Japan than in Europe, the U.S. and other countries for such startups to smoothly raise funds necessary for their development activities.

In light of these background, the government has promoted the following six integrated

projects centering on new modalities (i.e., techniques and methods), in accordance with the 2nd Medical Research and Development Implementation Plan: pharmaceuticals; medical devices and healthcare; regenerative medicine and cell and gene therapy; genome data infrastructures; basic disease research; and seeds development and research infrastructures. In addition, based on the Strategy for Strengthening the Vaccine Development and Production System decided by the Cabinet in June 2021, the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) was established under AMED in March 2022 as a leading body of R&D activities in normal times in order to promptly conduct vaccine development in case of emergency involving infectious disease. Under the leadership of personnel well versed in various specialist disciplines, such as immunology and medicine, or in R&D, practical application and management of biopharmaceuticals, SCARDA has developed a system that extensively collects and analyzes information on infectious diseases and vaccines in Japan and abroad, and has advanced R&D support while overviewing the overall situation of vaccine development and practical application. Under this structure, we will work on programs such as: intensive support to industry-academia-government research projects for practical application using new drug discovery methods; creation of world-leading R&D centers; and fostering of drug discovery and development startups. Efforts additional to those by AMED include initiatives that are necessary to develop a system that enables prompt development and supply of vaccines, such as developing sites for dual-use vaccine production.

In addition, based on the Action Plan for Whole Genome Analysis 2022 published in September 2022, whole genome analysis is underway for cancer and intractable diseases, and a system is being developed so the industry, academia and government can extensively utilize the results of the whole genome analysis. This includes promoting the development of transgenic technologies, gene expression control technologies, high-functional biopharmaceuticals, drug delivery systems, and imaging, as well as forming technical foundations by combining those element technologies together. In addition, the Ministry of Education, Culture, Sports, Science and Technology is further strengthening the genome data infrastructures, such as: developing and sophisticating large-scale biobanks that will serve as an infrastructure for genome research; developing a biobank cross-search system by putting major domestic biobanks into a network; and conducting advanced genome R&D projects based on global trends. Furthermore, efforts are underway to promote and otherwise support healthcare industries that are not covered by public insurance, such as by promoting: health-oriented business administration; community-based and occupation-based cooperations; and efforts to individuals' health.

In the fields related to regenerative medicine and cell and gene therapy, efforts have been underway on, among other things: the development of innovative therapies through convergence research projects and multi-disciplinary cooperation; research on common foundational technologies such as genome editing; pathogenesis and drug discovery research using disease-specific iPS cells or patient-derived organoids; and the strengthening of strategic partnering support, the development of manufacturing infrastructures, etc. for R&D targeting commercialization. In addition, the development of hubs that enables reverse translational research (rTR) by seamless data acquisition from manufacturing to treatment has been started, and discussions have been undergoing on appropriate data accumulation and data systems through utilizing regenerative medicine data registration systems. Furthermore, in the Foundational Technology Development Project for Commercialization of Regenerative Medicine and Gene Therapy, the development of fundamental manufacturing technologies for gene therapy has been underway, including the development of manufacturing technologies for domestically produced virus vector producing cells or for vectors using these cells. Other developments under the project include, among others: the establishment of technological infrastructures that allow the efficient, stable production of human cell-processed products; and the development of MPS (microphysiological system) devices that use various organ cells differentiated from iPS cells. Efforts such as R&D and the strengthening of manufacturing infrastructures are underway toward promoting clinical research and clinical trials of, and commercializing, new medical technologies in this area. Innovative R&D is underway on topics such as: the application of genome editing technology in gene therapy to regenerative and cell therapies; and organoids (i.e., miniaturized versions of organs artificially made in test tubes) on which the efficacy and other aspects of drugs can be tested to personalize treatment.

Currently, several issues have been pointed out.

① Promotion of R&D

It is necessary to effectively roll out new medical technologies and techniques to various diseases by conducting R&D on a modality (technique, method or the like)-by-modality basis without limiting target diseases. It is also necessary to further promote convergence research, instead of splitting between regenerative medicine and cell and gene therapy. We should also focus on the bridging basic and clinical research, as well as on rTR and industry-academia collaboration. It is also essential to strengthen basic research to create innovative seeds that will lead to next-generation medical technologies or drug discoveries. Also important is the bridging between large companies and academia through venture companies. In taking these actions, we must

further promote the collaboration with AI and data science, such as by utilizing them in searching for drug discovery targets or in verifying their validity.

② Development of biocommunities

In order to accelerate and enhance actions toward various diseases, such as emerging infectious diseases, it is necessary to strengthen disease biology research, such as supporting R&D of infectious disease. From the viewpoint of drug discovery, businesses are expected to make efforts toward developing infrastructures for drug discovery environments for biopharmaceuticals including antibody-drug conjugates (ADCs), as well as toward establishing drug discovery ecosystems. In addition, in order to develop a system that allows prompt supply of safe pharmaceuticals, including vaccines and therapeutics, it is essential to improve CDMOs and other manufacturing sites and to secure human resources for on-site manufacturing operations in preparation for pandemics and other emergencies for safety assurance purposes.

③ Strengthening of manufacturing systems

For some pharmaceuticals or their drug substances or raw materials, such as those for which Japan relies heavily on overseas suppliers, actions should be taken from the viewpoint of economic security as well as from other viewpoints in order to ensure the public's health and safety, and it is important to proceed with those actions in a strategic manner.

④ Development of human resources

It is effective to provide hands-on support through human resources who are capable of providing advice toward practical application of technologies. Advice from academic personnel with commercialization experiences also works. It is also necessary to enhance human resources, such as those for clinical study design consulting services, for the development of culture or purification processes or for manufacturing.

⑤ Biopharmaceuticals, regenerative medicine, and cell and gene therapy

It is important to keep overseas regulations and standards in mind from an early stage in R&D. It is necessary to develop cell supply systems with an eye to commercial use and to develop manufacturing sites such as CDMOs that are capable of commercial production. Establishing efficacy requires not only accumulation of clinical data but also rTR after combining manufacturing data. It will be necessary to develop

connected data systems. Since human resources are scarce in the field of gene therapy, it is necessary to strengthen basic research and to provide research centers for developing young researchers. As license fees for vector or genome-editing technologies increase, support should be provided to medium- to long-term basic research projects on these technologies with an eye to conversion of Japan's unique technologies into intellectual property. It is necessary to develop stable supply systems for domestically produced virus vector producing cells. It is also necessary to establish domestic manufacturing capacity for transgenic cells.

⑥ Regulation of research

It has been pointed out that when conducting R&D of vaccines or the like urgently in case of a pandemic, prompt conduct of research may be prevented by the requirement for the competent minister's confirmation in R&D stage imposed under the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms. It has also been pointed out that, in light of the current scientific knowledge, the requirement for the minister's confirmation makes the relevant formalities too complicated. It is necessary to revise the formalities to ensure that they are commensurate with the risk involved.

2) Goals for the year 2030

(i) Target market size

Up to 58.6 trillion yen (up to domestic: 3.3 trillion yen, overseas: 55.3 trillion yen)

(Related indices)

- Number of regenerative medical products approved/ launched: 2 or more (as of the end of fiscal 2024)
- Targets for fiscal 2025 onward will be considered during discussions on the 3rd Health and Medicine Strategy.

(ii) Specific aims

Japan-originated antibody drugs, nucleic acid/medium molecule drugs, and regenerative medicine and cell and gene therapy products are globally rolled out, and full-scale commercialization and the creation of new huge markets are underway in these areas. As Japan-originated products contribute to the provision of individually optimized, high-quality medical care, Japan leads the world standards in these fields and Japan's attractiveness to and presence in the international community increases.

These achievements are brought to by the ecosystem in Japan where people, materials,

funds, technology, and information circulate under regulations and systems that Japan takes the lead in proposing and that are harmonized with international counterparts. These achievements also encourage players to gather in this area from various other fields in Japan and abroad, such as new players working with the supply chain, spanning from cell supply, culture, transportation, contract manufacture, commercialization, commercial production to market supply in addition to existing ones such as pharmaceutical companies.

The ecosystem is supported by a strong supply chain having development and manufacturing demonstration platforms (biofoundries) at its core and by platforms consisting of genome data infrastructures. Innovations are created through co-creative interactions between the platforms mentioned above, disease biology research based on cutting-edge science, and modality R&D. To this end, seamless R&D is being promoted through industry-academia-government collaboration, from upstream basic research and applied R&D to downstream commercialization and further to surrounding related fields.

3) Directions of future efforts

(i) Overall

In light of the status of discussions on this area at the relevant government agencies, they should provide integrated support to push the technologies forward to the next stage to take shape as next-generation medical care. To this end, the following efforts should be made:

- ① To promote collaboration and cooperation between research projects, in order to promote “practical application” based on the results of basic research.
- ② To create new values through “convergence” research spanning across regenerative medicine and cell and gene therapy.
- ③ To promote “innovative R&D,” such as next generation iPS cells, organoids, exosomes, and new gene therapies using genome editing.

In addition, in order to steadily advance practical application and commercialization, it is important to further enhance each of the following efforts: support in the aspects of regulations, ethics, and intellectual property; collaboration between the relevant government agencies; collaboration between academia and industry; and collaboration between basic researchers and clinical researchers.

(ii) Acceleration of technology development

In order to accelerate technology development, we will promote R&D projects for: antibody drugs; nucleic acid/medium molecule drugs; microbiome-related pharmaceuticals;

vaccines; cell medicine; gene therapy; basic and applied research; infectious disease research; cancer research; and support to bridging and practical application. In addition, for the sake of innovative R&D, we will promote the Moonshot R&D Program in the fields of health and medicine. Since it is also important to gain public understanding while promoting practical application, we will promote R&D by giving consideration to patients' and public participation in research, while also promoting ELSI¹⁴ research.

In order to promote the development of biocommunities that conduct seamless R&D, with development and manufacturing demonstration facilities at their core and containing hospitals, biobanks, and supply chain-related industries, collaboration should be undertaken between industry, academia, and government. In order to establish international development and manufacturing demonstration platforms where relevant industries that support the supply chain of development and manufacturing such as CROs¹⁵ and CDMOs accumulates within and outside Japan as well as to accommodate R&D, efforts will be considered and undertaken that are necessary to, among other things: develop infrastructures for utilizing data; ensure the smooth utilization of human-derived samples and other research resources; and develop facilities that allow for nonclinical studies. As for biobanks, we will strategically advance their development, including making decisions as to their composition and the types of samples and specimens to be stored by them. Through industry-academia-government collaboration, a system will be considered and developed that allows biobanks to be utilized by relevant parties as a research infrastructure intended for clinical and/or social implementation purposes, including utilization by private entities in the future.

In order to prepare for the next infectious disease crisis and to strengthen the domestic vaccine development and production system, we will steadily promote the Strategy for Strengthening the Vaccine Development and Production System (Cabinet Decision of June 1, 2021).¹⁶ At the same time, we will promote R&D for securing means of prevention, diagnosis, and treatment of priority infectious diseases, including antimicrobial-resistant (AMR) diseases, with an eye to global-scale efforts across the boundaries between humans, animals, etc. (the One Health approach).

We will discuss and take necessary measures to ensure that the requirement for the minister's confirmation of "Type 2 Use," etc. in R&D stage, imposed under the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use

¹⁴Ethical, Legal and Social Issues.

¹⁵Contract Research Organizations.

¹⁶As policy measures necessary to develop a system that allows for the prompt development and supply of vaccines, the policy lists, among others: developing world-class R&D centers; developing vaccine manufacturing sites; and fostering drug discovery ventures.

of Living Modified Organisms, will be amended to a more appropriate requirement, on the precondition that appropriate risk control will be carried out.

(iii) Efforts to improve the market environment

We will make revisions, improvements, etc. to regulations and programs in order to promote commercialization. Specific actions will include, for instance: considering the appropriate evaluation of innovations in the drug pricing system, etc. in order to promote the development of innovative pharmaceuticals, medical devices, etc. and; considering support to the development of CDMOs and other manufacturing sites that are capable of commercial production of cells, vectors, etc. in the fields of regenerative medicine and cell and gene therapy, which will see particular increase in demand in the future. Regarding consumer-targeted gene testing businesses, guidance and/or other documents will be developed that provide an overview of compliance rules for businesses targeting consumers.

(iv) Establishing domestic industrial infrastructures by improving the business environment

In order to develop human resources, we will promote the development and securing of human resources for bioinformatics, those for cybersecurity for data linking tasks, and those for the manufacturing of biopharmaceuticals, etc. We will also strengthen our international collaboration activities by participating in the activities of IHCC¹⁷ and G2MC,¹⁸ which have their sights set on taking international collaboration to the implementation stage of genome medicine.

Through the Strengthening Program for Pharmaceutical Startup Ecosystem, we will continue to provide support to resolve the short supply of development funds, by targeting nonclinical studies and phase 1 and 2 clinical studies for which drug discovery ventures face difficulty in financing. We will also strengthen the connection between the ecosystem in Japan and those in foreign countries, to enhance the creation of Pharmaceutical Startup. In addition, in order to strengthen the support to start-ups during seed stage, which is as yet insufficient, through the Program for supporting academia-launched medical startups, we will, through Centers for Advancing Translational Research with know-how and a track record in practical application of medical technologies, provide expert partnering support for launching university medical startups, provide financial support necessary for nonclinical research, and recruit and develop young entrepreneurs who aim to start up their own businesses by finding medical needs.

¹⁷ IHCC: International Health & Care Collaboration.

¹⁸ G2MC: Global Genomic Medicine Collaborative.

As for the support to startups, we will promote specific discussions in light of the uniqueness of the healthcare industry market, which includes the fact that there are expectations for advanced healthcare needs and accumulation of high-quality data on healthcare and nursing care through medical DX in Japan that is entering to ultra-aging society, and that rulemaking on regulations is critical.

(v) Data utilization and linkage

In order to promote the linkage of public, industrial, and research data which serves as an infrastructure for R&D and services (i.e., the development of a traceable and secure genome data infrastructure intended for international cooperation), we will promote efforts to develop large-scale integrated cohort studies¹⁹ and biobanks²⁰

In order to utilize data obtained from AMED-supported R&D projects in industry, academia and government R&D projects, we will, by linking multiple databases, etc. provide a wide range of parties with platforms that have a cross-sectional search function across metadata extracted from genome information, etc. and that allow for the handling of data in R&D projects including those in the industry (i.e., environments available for access on a visiting basis with a security level that allows for data import and handling). On the AMED's data utilization platform, we will sequentially start linking a wide range of R&D data other than genome data.

We aim to develop a large-scale healthy volunteer cohort biobank in a stepwise manner, while exploring, through collaboration between the administrators of healthy volunteer cohorts, etc., its size and other aspects so that it will serve as a sufficient infrastructure to support Japan's international competitiveness. As for disease cohorts, while we will consider utilizing control groups, we will accelerate efforts on those cohorts by introducing whole genome analyses and will promote comparative analyses with healthy volunteer cohorts.

As for healthy volunteer cohort biobanks, we will integrate and analyze genome information, as well as biochemical data including intestinal flora or metabolites, with medical history or environmental/lifestyle information. Through these efforts, we will develop environments that allow for the provision of services backed by scientific evidence in a wide variety of fields, such as health, sports, food, etc.

¹⁹ A cohort study is a study in which a certain group of people are followed up over time for their health/disease status.

²⁰ A biobank is a system for the systematic management, storage, etc. of biological samples and related information.

As for the Japan Environment and Children's Study (JECS), which is one of the large-scale cohorts, we will steadily promote gene analyses.

We will promote efforts on a large-scale genome data infrastructure by linking and developing the results from the three major biobanks: the Tohoku Medical Megabank (TMM) Project; the BioBank Japan (BBJ); and the National Center Biobank Network (NCBN).

(5) Lifestyle improvement healthcare and digital health

1) Trends in the overall market area

It is expected that the Japanese population will further age, with the elderly population over 75 years of age being expected to increase from approximately 19 million in 2021 to approximately 24 million in 2050. Population aging will be a globally occurring phenomenon (the number of elderly people in the world is expected to increase from 0.76 billion in 2021 to 1.8 billion in 2060). This has changed the structure of diseases, with lifestyle-related diseases accounting for a growing proportion in health challenges facing the public. Amid this situation, there is a growing significance not only of treatment in medical care settings but also of prevention and health promotion through changes in everyday life behavior. With emerging social challenges such as working carers who are engaged in nursing care of their family members while working at a job, the working age population is expected to decrease from 75 million in 2020 to 52 million in 2050, indicating a possibility that Japan may no longer be able to maintain a workforce necessary for continuous economic growth. The significance of health promotion is increasing in order to increase work productivity as well as to promote workforce participation by all people.

Investments in health promotion and maintenance of home life (nursing care) depend on individual lifestyles, and there is no definite image of utilization of related services. In addition, lifestyle-related diseases are associated with few subjective symptoms or signs until reaching severe stages, which makes the relevant health challenges less visible, making it more likely that the patient makes only limited investments. As it is thus hard to promote health investments by individuals, it is necessary to call for investments from all possible sources, such as by further promoting and increasing health investments by businesses (to increase productivity and to support employees' work-life balance by promoting employees' health) as part of their human capital formation.

Health promotion relates to all aspects of our life. It not only relates to healthcare-specific industries (pharmaceuticals, medical devices, etc.) but may also relate to any of the industries where businesses related to daily life ("lifestyle-related industries") are operated. Therefore, we will not only provide support to individual areas but also promote digitalization and other developments that would bring structural changes in whole industry. In addition, based on the understanding that health promotion, medical care, and nursing care are inseparable from each other, it is necessary to develop infrastructures (such as data linkage) toward realization of a seamless life for people.

2) Goals for the year 2030

(i) Target market size

39.1 trillion yen

(Related indices)

- To increase the number of Certified KIH outstanding Organizations to 33,000 corporations by the end of fiscal 2027.
- To match at least 120 healthcare ventures with supporting organizations via Innohub by the end of fiscal 2027.
- To increase the number of businesses linked to Myna Portal API to 50 companies by the end of fiscal 2027.

(ii) Specific aims

As the country most ahead of others in facing challenges involved in its aging population, Japan will establish measures to deal with it by promoting investments through increasing new demand in the field of healthcare as a growth area, and will work on those measures with an eye to rolling them out to other countries that will follow the path to an aging society. In order to promote entry to the healthcare area from other fields (i.e., promotion of structural changes in industry), we will focus on developing data infrastructures and programs that will serve as a foundation for such entry.

With the fusion of biotechnology and digital technology, Japan will become a society where diagnosis/treatment and prevention/coexistence are linked, allowing for long-standing social participation of its people. A social system will be established where there is a seamless link between self-care/early detection in healthy/premorbidity stage, prevention of metabolic disorder, treatment of organ disorder and prevention of its progression to severe stages. This will achieve both improvement of the quality of medical care and development of industry.

3) Directions of future efforts

(i) Overall

Our healthcare policy is meant to be measures to deal with the structural challenges facing Japan that have been triggered by changes in its social environment, such as the aging, declining population, by (i) promoting people's health (i.e., extending their healthy life expectancy), which in turn will develop a foundation (such as increased working population and productivity) for (ii) economic growth (i.e., the continuous growth of businesses), and will, as such, (iii) contribute to a sustainable social security system.

The social issues caused by the aging society will enter their most serious stage only in

the future, and require proactive actions. It is important to clarify the various values of health and to promote healthcare as “investment” that makes individuals’ life and economic society richer, instead of as mere “consumption.” It is necessary to use healthcare to promote transformation that increases the added values in all fields of industry.

Health promotion relates to all aspects of our life. It is necessary to improve the market environment in cooperation not only with healthcare-specific industries (pharmaceuticals, medical devices, etc.) but also with lifestyle-related industries. We will promote not only support in individual areas but also digitalization and other developments that would bring structural changes in whole industry.

Furthermore, we will strive to create new demand by developing environments that allow people to comfortably use not only services covered by public insurance but also products and services not covered by public insurance, including those from non-healthcare fields, so that people’s daily life will serve as a basis for health promotion.

(ii) Acceleration of technology development

We will develop, build evidence of, and commercialize, app services, etc. that contribute to disease prevention and health promotion by utilizing health and medical information (i.e., non-SaMD [Software as a Medical Device]).

In areas such as dementia and mental health maintenance and promotion, we will build evidence of, among other things: interventions that utilize digital or other new technologies; and evaluation indices that can be used by non-healthcare professionals.

(iii) Efforts to improve the market environment

In order to develop environments where the quality of healthcare services is assured, we will support the establishment of voluntary standards, guidelines, etc. by industry or trade associations or organizations based on the Guidelines on Healthcare Service Guidelines.

In order to promote the social implementation of high-quality healthcare services, we will develop standards that ensure the reliability of these services are assured by industry associations or medical society. At the same time, we will consider mechanisms for promoting the development of services as per those standards.

(iv) Establishing domestic industrial infrastructures by improving the business environment

We will strengthen our support to ventures and our measures to promote new entry by disseminating information through integrated contact points, supporting consultancies, and supporting networking between new businesses and supporting organizations. We will invite

investments from within and outside Japan, through seminars, pitch events, etc. We will also promote the utilization of the Healthcare Innovation Hub to support the overseas expansion of healthcare start-ups.

(v) Data utilization and linkage

Based on the belief that all lifestyle-related industries can be providers of healthcare, we will promote entry from non-healthcare fields and will standardize data and develop information handling rules through government-private collaboration, as well as promoting the utilization of PHRs,²¹ in order to provide a foundation for creating individually optimized services tailored to individuals' health status or preferences (e.g., providing an optimal sleeping environment based on the individual's medical checkup results and/or disease and taking the person's daytime activity into account, or providing optimal recipes or products based on the individual's nutritional status).

²¹Personal Health Records.

5. Basic Measures

The following fundamental and/or cross-sectional efforts should be promoted in coordination with related measures: developing human resources supporting life science research, which will be a source for expanding bioeconomy; promoting basic life sciences, such as studies focusing on the life course; strengthening databases, bioresources, biobanks, and other research infrastructures; promoting efforts to fulfill the functions of biocommunities; and data linkage and utilization toward integration of biotechnology and digital technology.

(1) Enhancement of research capabilities in basic life sciences

The research capabilities in basic life sciences plays an important role as a foundation essential to achieve a bioeconomy. However, the research capabilities in basic life sciences in Japan is in an alarming condition. For instance, the life science fields account for high proportions of the number of papers both in Japan and worldwide, i.e., approximately 30% for basic life sciences only and approximately 50% for basic life sciences plus clinical medicine. However, the proportion of papers in basic life sciences in the total number of papers published in Japan decreased by 5.2 percentage points in 40 years from 1981 to 2021. As for Japan's share in the number of papers in basic life sciences, the share increased from the 1980's and ranked 2nd in the world from the 1990's to the mid-2000's, but has now dropped to the 4th in the world. As for Japan's share in the adjusted number of top 10% most-cited papers, the share increased and ranked 4th in the world until around 2000, but has now dropped to the 12th in the world. As seen above, the research capabilities in basic life sciences have seriously decreased. There is an urgent need to work to enhance their research capabilities and to develop human resources for supporting them, to ensure the constant provision of research results in basic life sciences.

1) Development of human resources for supporting life science research

As with any other discipline, the life science fields face a serious shortage of environments that allow researchers to focus on research. In particular, there is a concern that the ongoing reform of physicians' work style may reduce research time allocated to clinical research. It is also necessary to invite to Japan human resources in cutting-edge life sciences and experts in the fields of mathematical science, information science, and statistics, as well as to prevent talent drain by providing support, including improved treatment, while ensuring mobility and diversity. To this end, we will develop environments that allow young researchers in life sciences to focus on research, as well as working to simplify the forms of report on research expenses to help them to secure time for research. We will also increase competitive research grants for young researchers in life sciences. In competitive research grant programs, we will accelerate the programs in which advice is provided to young researchers from advisors and

experts across the boundaries of organizations (e.g., the Sakigake/ACT-X/PRIME program). Furthermore, we will promote the international brain circulation in the life science fields, by working on the enhancement of exchanges and connections between research personnel, including young researchers, through global research. Moreover, we will promote continuous, reliable supply of research support personnel through strengthening systems for the strategic introduction, updating, and shared use of latest analytical devices in life science fields.

Amid the changes in methodologies in life sciences due to the rapid development of AI and data science, it is increasingly important to strategically secure human resources well-versed in information science. We intend to continue to work on the development of bioinformatics personnel who develop and utilize massive data. In addition, since it is important to make approaches toward elementary, junior high, and high school students in order to broaden the base supporting future life science research, we will strengthen education on exploration, STEAM,²² and entrepreneurship at elementary and secondary levels. Furthermore, we will promote the development of human resources in growth fields, including the field of biotechnology, at universities, technical colleges, etc.

2) Renaissance of basic life sciences

Due to the serious decline in the research capabilities in basic life sciences, it is important to ensure the diversity of research by promoting aggressive, exploratory, and budding basic research activities. To this end, it is necessary to increase the support to the fields of basic life sciences studying all forms of living organisms. To increase the support, it is essential to have not only a quantitative viewpoint but also the view that the following three elements should be fused together: curiosity (inquiring minds wanting to elucidate life phenomena), methodology (cutting-edge measuring and analytical techniques), and mission (response and contribution to social needs). Therefore, in addition to promoting aggressive, exploratory, and budding basic research activities, we will promote the following research activities with an eye to medium- to long-term social needs, ELSI perspectives, and research trends:

- (i) Research activities that focus on the life course (i.e., the series of processes spanning from the birth and regeneration of life to aging) through reproducing life phenomena using organoids (in promoting these activities, additional important viewpoints include focusing on early stages of the life course and supporting reproductive medicine and early childhood development and contributing to pediatric medicine through basic research).
- (ii) Research activities that, through acquiring multi-layer data including environmental

²² Science, Technology, Engineering, Arts and Mathematics.

factors and conducting integrated analysis of a wide range of massive data, focus on organ interactions, the immune system, etc. instead of on separate organs, understand a living organism as a complicated system, and turn their findings into individualized medicine and preventive/preemptive medicine.

- (iii) Research activities that, by studying the brain as a system and elucidating its mechanisms, elucidate human emotions and sociality and turn their findings into diagnosis of mental/neurological diseases, exploration of new therapies, and application to the development of AI reflecting the brain's operating principles.
- (iv) Basic research activities relating to innovative GX technologies and sustainable resource science research activities that integrate and develop plant science, chemical biology, catalytic chemistry, and biomass engineering with an eye to contributing to the use of biotechnology in solving global challenges such energy, environment/resources, agriculture, and food.

We will also promote the active use of knowledge from non-life science fields, such as AI and quantum technologies, in order to respond to changes in methodologies in life sciences resulting from, among other things, the dramatic development of measuring and analytical techniques and data science.

3) Enhancement of research infrastructures supporting life science research

(i) Databases

In order to promote data-driven research, it is important to develop data infrastructures that link existing individual databases. We have so far promoted practical operations and R&D activities relating to database integration in life science fields through the Life Science Database Integration Promotion Project, among others. We have achieved certain results, such as the construction and operation of TogoVar, a comprehensive Japanese genetic variation database, and the development of jPOST, an internationally-renowned proteome database. On the other hand, many of the internationally reputable databases rely on competitive funding, which has posed the challenge of stably maintaining and managing important databases. In addition, while we have promoted the development of integration technology to organize and integrate a wide range of related data, we still face challenges in interfaces through which intricately linked data is used. At present, it is not easy for life science researchers to make active use of those databases. Another challenge is the shortage of human resources to develop, maintain, manage, and curate databases. In light of these circumstances, while we will continue to develop life science databases through competitive funding, the Research Organization of Information and Systems will work on: the promotion of the stable maintenance and management of important databases, as well as the promotion of the

development of technologies for sophisticating databases, such as integrated search technology using AI; and the development of bioinformatics personnel necessary for the maintenance, management, and development of life science databases.

(ii) Bioresources

Bioresources are biological genetic resources consisting of, among other things, experimental animals used in research, plants, cells, genes, and microorganisms. Bioresources are precious resources that Japan is proud of, and are important also from an economic security viewpoint. The central control of bioresources at centers allows for the efficient and highly reliable maintenance and provision of bioresources. Therefore, the national government has strategically developed bioresource centers, including the RIKEN BioResource Research Center, which is a world-class bioresource center. However, we are facing the emerging challenge of sustainability of the centers, such as the aging of the facilities of the RIKEN BioResource Research Center and the securing of next-generation human resources. Under these circumstances, we will further enhance core centers that have latest facilities and equipment and are capable of stable operation, while we will also work on the fostering of next-generation young researchers who will be responsible for those centers, so as to ensure that bioresources providing a research infrastructure will be reliably collected, maintained, and provided. In addition, in light of the growing significance in recent years of promoting data-driven research through acquiring or otherwise obtaining access to genome information and other additional information, as well as providing bioresources, we will acquire and add high-precision whole genome sequence information, gene expression information, phenotype information, and other attribute information, to enhance the research infrastructures across the country. At the same time, we will promote, among other things: the active use of AI and image/video recognition technologies during the use of bioresources; and the development of new experimental methods, such as organoid and biosimulation technologies.

(iii) Biobanks

Biobanks collect, analyze, and provide human biological samples, genome information, etc. They are an important infrastructure for genome research, which is indispensable in recent life science research. It is thus necessary to develop biobanks through national government efforts. We have thus far developed the Tohoku Medical Megabank (TMM), which stores samples and health information of approximately 150,000 persons from the general population, and the BioBank Japan (BBJ), which is a disease biobank storing samples and clinical information of approximately 270,000 persons, 440,000 patients, and 51 different diseases. We will steadily develop biobanks, which will continue to serve as an infrastructure for genome research. On the other hand, promoting the utilization of biobanks has been a challenge, as seen in, among

other things, the scant number of previous studies that utilized biobanks to study diseases with high social needs, which indicates insufficient understanding of the usefulness of biobanks. Therefore, we will work on the promotion of utilization of biobanks and the production of results from them, by such means as enhancing the cooperation between the general population and disease cohort biobanks. We will also promote public access to, and sharing and depersonalization of, data held by biobanks in order to ensure broad opportunities to access cutting-edge data.

(2) Promotion of efforts to allow biocommunities to fulfill their functions

Toward expansion of the bioeconomy market, it is necessary to invite human resources and investments from within and outside Japan, to strengthen the system for supplying products and services to the market (i.e., the innovation ecosystem), and to expand into the global market. To this end, we will promote efforts on “biocommunities,” which consist of: linking regional communities together in the form of a network by using international hubs as cores; combining world-class research environments and commercialization support systems that can also make use of investments from overseas; looking upon international cooperation, fusion of different fields, and open innovation as key values; and developing systems that can invite human resources and investments from within and outside Japan.

The Cabinet Office established an open application program in which applicants meeting certain requirements (such as world-class strengths (scientific and industrial infrastructures), key entities (industry, academia, government, and/or finance), participation of key persons, the network organization’s capability to fulfill coordinating, collaborative, and other functions, and specific action plans) are certified as biocommunities. So far, two global biocommunities (the Greater Tokyo Biocommunity²³ in the Tokyo Metropolitan area and the Biocommunity Kansai [BiocK²⁴ in the Kansai region, both in April 2022) and six regional communities (Hokkaido,²⁵ Tsuruoka,²⁶ Nagaoka,²⁷ and Fukuoka²⁸ in June 2021, and Hiroshima²⁹ and Okinawa³⁰ in December 2022) have been certified.

Efforts that have been triggered by the certification of these biocommunities include: promoting communication between parties participating in the biocommunities; enhancing cooperation with relevant government agencies, etc.; forming nationwide networks; and visualizing events and investment status to invite investments from overseas.

It is expected that in the future, these certified communities will leverage their functions as biocommunities and will proceed to the stage where they: generate attractive new projects and businesses one after another from within them, by inviting human resources and investments from within and outside Japan and through flexible cooperation between R&D institutions, businesses, etc.; develop global markets while establishing links with overseas

²³ <https://gtb.jba.or.jp/>

²⁴ <https://biocok.jp/>

²⁵ <https://www.hbiocom.jp/>

²⁶ <https://tsuruoka-sp.jp/bio-community/>

²⁷ <https://nagaoka-biocommunity.jp/>

²⁸ <https://www.fbv.fukuoka.jp/>

²⁹ <https://www.biodx.org/>

³⁰ <https://okibic.jp/>

biocommunities; and have a continuous virtuous cycle in which human resources, materials, and funds from global markets lead to further human resources and investments.

What is important to achieve this state is the efforts by the network organizations which are responsible for the cooperation, coordination, etc. by their respective biocommunities. We will promote coordinated efforts to maximize the effects of the efforts by these network organizations, by making active use of the relevant agencies' and ministries' measures to expand the bioeconomy markets as well as related measures such as those for start-ups and regional revitalization. In addition, we will promote the utilization of, and efforts linked to, the functions of other innovation ecosystems, such as startup ecosystem hub cities, while keeping in mind the characteristics of business models, risks, necessary human resources and funds, etc. that are specific to the field of biotechnology.

(3) Development of data infrastructures

Value creation starting from data has attracted attention in all aspects of our economic society. This has dramatically increased the importance of digitalization and data linkage and utilization, which provide a foundation for that value creation. There is a possibility that issues such as cost or the protection of personal information may be avoided, due to the emergence of technologies that allow the amount of data to compensate for its quality, such as foundation models of generative AI (e.g., LLM and LMM), or by standardizing data format or by using secure computing technologies.

While the fields of biotechnology are based on a common scientific knowledge about life phenomena, they have exits to a wide variety of industries. In these fields, it is necessary to create, link together, and utilize high-quality digital data to create new scientific knowledge and increase the competitiveness of industries.

In doing so, it is important to make efforts, in addition to those currently expected to be made within the areas of the bioeconomy markets, to develop data infrastructures that provide environments where people are connected through information across a wide variety of areas and open up new areas.

Therefore, we will promote efforts -- which are to be made on an area-by-area basis in the bioeconomy markets -- that are made with a view to the commercialization of various services based on: microorganism/cell design platform technologies that will allow for the development of novel metabolic pathways for allowing the production of various chemicals in biomanufacturing; the integration and analysis of genome information, disease information, environmental information, lifestyle information, etc.; and the resulting scientific evidence in health, sports, food, etc.

As for efforts to be made across the areas, we will promote the utilization of the research data infrastructure system (the NII Research Data Cloud)³¹ and the efforts under the Basic Concept on Management and Utilization of Research Data with Public Funds³² In addition, toward the promotion of data linkage and utilization between different industries or between businesses and universities, we will promote: the active use of the Guidebook for Biodata Linkage and Utilization (Cabinet Office, July 2023); efforts such as disseminating and

³¹ The information infrastructure which was designated as Japan's core platform for research data management and utilization in the 6th Science, Technology, and Innovation Basic Plan (Cabinet Decision, March 2021).

³² This approach includes the following four key points: (a) the research data infrastructure system is designated as the core platform and a system should be developed that allows for metadata search in order to ensure that the system will be used broadly by industry, academia, and government; (b) R&D organizations should develop a data policy and should proceed with storing research data in their repository; (c) for all new applications for publicly offered research funds, a system should be introduced that requires the provision of metadata; and (d) researchers should define the scope of data to be managed, provide metadata, and register the metadata with the research data infrastructure system to make it available for searching.

collecting information on latest domestic and overseas trends and best practices; and leading efforts in the Phase 3 project under the SIP, the “Integrated Healthcare System.”³³

³³ Efforts are underway to develop and implement the Medical Digital Twin consisting of, among other things: infrastructures for standardizing Japan’s electronic health records (HER) and personal electronic health records (PHR) on complying HL7 and FHIR; and systems for chronologically collecting individuals’ health and medical information. The implementation of the Medical Digital Twin is expected to promote the autonomous circulation between “knowledge discovery” and “medical care provision” in the medical and healthcare fields through utilizing decentralized data linkage, and to be utilized in increasing the quality of medical care, extending healthy life expectancy, and promoting the medical industry, as well as in sustainable medical care systems.

(4) Promotion of efforts from economic security viewpoint

With the progress of biotechnology, there are growing global concerns for undesirable uses of biotechnology as well as expectations for expansion of bioeconomy. For instance, the U.S. National Biotechnology and Biomanufacturing Initiative sets as one of its goals to enhance biological risk control in biotechnology R&D, including biosafety and investment in biosecurity. It is increasingly important to secure appropriate biological risk control systems, not only to ensure the safety and security of the public from consequences of the utilization of biotechnology but also as a precondition for expanding bioeconomy through the social implementation of products and services or for building cooperative relationships with overseas parties.

In light particularly of the trends in the practical application of biotechnology, it is necessary to enhance the industrial and technological infrastructures in the field of biotechnology from economic security viewpoint. Specifically, we will work on: the exploration of cooperative areas with like-minded countries; the promotion of inter-business cooperation; and the visualization of important technologies and of players and supply chains handling these technologies.

Biotechnology-related industries have broad bases and are subject to a wide range of regulatory frameworks. Each industry is working to appropriately ensure biosecurity in the framework to which it is subject. However, with the development of biotechnology and the expansion of bioeconomy, new technologies, products, or services may emerge that cannot be adequately dealt with by the existing regulatory frameworks.³⁴ Both government and private sectors will promote necessary efforts with an eye on the development of technologies, etc.

In addition, in order to secure Japan's strong technological advantage in the international community on a medium- to long-term basis, the (Second) R&D Vision was established in August 2023 to enhance the efforts in the field of biotechnology. The vision sets forth Japan's needs in terms of economic security regarding the Key and Advanced Technology R&D through Cross Community Collaboration Program (K Program), which is designed to promote R&D that will lead not only to the private use but also to the public use of technologies, in light of the ambiguity of science and technology. We will continue to promote R&D under the R&D Vision.

³⁴ For instance, cell-based food is a novel food that is not covered by the existing food regulations. Discussions are underway as to how it should be regulated and other details.

6. Promotion System for Bioeconomy Strategy

This strategy shall be promoted in coordination with efforts in AI, quantum, and other fields under the command of the Secretariat of Science, Technology and Innovation Policy, Cabinet Office. Measures to expand the bioeconomy markets shall be organized by the following government agencies and be promoted through cooperation between relevant agencies and ministries.

Overall: Secretariat of Science, Technology and Innovation Policy, Cabinet Office

Measures to expand the bioeconomy markets:

- (1) Biomanufacturing/bio-derived products: Ministry of Economy, Trade and Industry
- (2) Sustainable primary production systems: Ministry of Agriculture, Forestry and Fisheries
- (3) Large-scale buildings utilizing wood and smart forestry: Forestry Agency
- (4) Industries related to biopharmaceuticals, regenerative medicine, and cell and gene therapy
: National Healthcare Policy Secretariat, Cabinet Office
- (5) Lifestyle improvement healthcare and digital health:
Ministry of Economy, Trade and Industry