

# **Bio-Strategy 2020**

(basic measures)

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26 June 2020

**Decision of the Council for Integrated Innovation Strategy**

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## 1 Overview

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- Bio-Strategy 2019 was formulated in June 2019 as a comprehensive policy package aimed at “achieving the world’s state-of-the-art bioeconomy<sup>1</sup> society by 2030”. Presented were basic policies such as market area setting, backcasting, continuous commitment, integration of bio- and digital technologies, establishment of an international hub, regional networking, and investment promotion, etc., as well as four social visions and nine market areas. It was decided that this grand design for bio-strategy should be updated every year for the time being.
- Since the formulation of the strategy, a market area roadmap, etc. have been discussed with the participation of many industry organisations and companies. With an investment of about 6.2 billion yen in the government’s fiscal 2019 budget, technological development, etc. have been promoted for the demonstration and study of data linkages and for the substantiation of bio-production. The promotion of bioeconomy is steadily progressing in countries around the world.
- On the other hand, the global pandemic of the novel coronavirus<sup>2</sup> has had a significant impact on economic and social activities, including a rapid economic downturn and supply constraints stemming from disruptions in supply chains. We should accelerate the development of therapeutic drugs and vaccines, and achieve a prompt economic recovery. It is also necessary to transform the country into a robust economic structure through innovation, and to recognise anew the importance of data strategies.
- The social issues pointed out in Bio-Strategy 2019, such as the growing concern over environmental problems, difficulty in securing food supply, increases in lifestyle-related diseases, and rising demand for pharmaceuticals, remain unchanged. Moreover, the utilisation of biotechnology<sup>3</sup> in the development of vaccines, therapeutic drugs, etc. for infectious diseases, as well as the utilisation of renewable biological resources (biomass), which are necessary for self-sustainability and decentralisation of energy and resources, has become increasingly important.
- The promotion of bioeconomy has become more and more important in light of both measures for pandemic containment and future economic recovery. It is necessary to promote the bio-strategy without delay while flexibly responding to changes in circumstances by carrying out the basic measures in line with Bio-Strategy 2019 and developing measures for changes in circumstance in a parallel way, with a view to the rapid economic recovery after containment of the pandemic.
- Therefore, Bio-Strategy 2020 (basic measures) formulated herein summarises immediate measures for research and development, etc. in order to contain the current pandemic, as well as fundamental measures that should be taken without delay in accordance with Bio-Strategy 2019 with a view to ensuring quick economic recovery after containment of the pandemic.
- Based on these changes in circumstances, a market area roadmap and the Bio-Strategy 2020 (with a finalised market area policy) will be worked out and implemented by this winter.
- The main points of Bio-Strategy 2020 (basic measures) are as follows:
  - (1) Promotion of research and development, etc. pertaining to countermeasures against COVID-19
    - Promotion of research and development, including the development of diagnostic and therapeutic methods, vaccines, devices, and systems
    - Development of an environment for research and development, etc. international cooperation, etc.

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<sup>1</sup> Concept of utilising biotechnology, renewable biological resources, etc. in order to expand a sustainable, renewable, and recycling-oriented economic society

<sup>2</sup> COVID-19

<sup>3</sup> “Biotechnology” in the bio-strategy refers to technology for adapting the results from fundamental bio-science research to industrial or commercial purposes.

- Development of a system for the early commercialisation of vaccines
- (2) Promotion of data linkage to achieve market acquisition
  - Formulation of the Guidelines for Linkage and Utilisation of Bio-Data (provisional title)
- (3) Formation of global bio-communities and local bio-communities
  - Designation of global bio-communities and local bio-communities, promotion of partnerships, promotion of market areas, and dissemination of information at home and abroad
  - Substantiation of bio-production and development of human resource development functions in the global bio-community
- (4) Promotion of basic measures for market areas that warrant actions without delay in line with Bio-Strategy 2019
  - Development of a data infrastructure, formation of bio-communities, establishment of systems, etc. pertaining to market areas that warrant actions without delay in accordance with Bio-Strategy 2019
- (5) Enhancement of the command function to promote the bio-strategy
  - Set KPIs for evaluation of the overall objectives, and perform evaluation at an advisory council from quantitative and qualitative perspectives
  - Promote the strategy on the basis of the formulation of a market area roadmap, designation of bio-communities, and the formulation of guidelines, and link measures of each ministry.

## 2 Background

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### 2.1 Economic and social trends

- In the past six months, approximately 9.07 million people were infected with COVID-19 and 470,000 deaths have been reported in more than 200 countries and regions worldwide. The scale and impact of this novel coronavirus is much greater than recent global epidemics such as severe acute respiratory syndrome (SARS) and H1N1 influenza<sup>4,56</sup>
- The flow of goods, capital, and human resources at home and abroad has sharply slowed down owing to measures such as city-wide lockdowns and restrictions on outings in countries, a significant drop in demand, supply constraints due to disruptions of supply chains, and restricted investment by foreign corporations<sup>7</sup>, and a negative growth to a degree far exceeding the economic downturn precipitated by the Lehman Brothers bankruptcy in 2008 is projected.<sup>8</sup>
- Given that people will have to live with this infectious disease for the time being and that similar pandemics may occur in the future, Japan should take this opportunity to prop up measures against future public health crises. From the perspective of economy, the country should also understand and review global supply chains and data collection and distribution, and transform itself into an economic structure with more resilience and sustainability through innovation.
- It should not be forgotten that, while the centre of economic power is shifting from developed countries to Asia and Africa, social problems such as the growing concern over environmental problems, difficulty in securing food supply, increase in lifestyle-related diseases, and rise in demand for medicinal products remain the same. Following the adoption of the Paris Agreement and the SDGs, the promotion of bioeconomy that contributes to the simultaneous pursuit of sustainable economic growth and social problem solving has been positioned as a national strategy in major countries, with ESG investment<sup>9</sup> by institutional investors being expanded, as shown in Section 2.4.
- Due to the impact of this novel coronavirus infection, the global flow of goods, capital, and human resources is expected to slow down in the short term, and over-centralisation in the urban area is expected to be re-examined to prevent overcrowding in the medium to long term. In the post-COVID-19 era, it is necessary to shift from searching for the cheapest suppliers from around the world and building an efficient supply chain, to building a strategic supply chain that combines globalisation and self-sustainability, as well as centralisation and decentralisation.  
Apart from the concept of emphasising economic efficiency, the understanding of consumers and taxpayers is also essential in order to determine how to reasonably bear the costs of maintaining such an economic and social system.
- The recent global outbreak of COVID-19 has made us realise once again that human beings are also a part of nature and we must survive by adapting to changes in the natural environment. In this regard, the importance of sustainability,

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<sup>4</sup> Pandemic (H1N1) 2009: Infections were confirmed in 214 countries and regions around the world and resulted in 18,449 deaths (WHO statistics, 1 August 2010).

<sup>5</sup> WHO statistics, 24 June 2020

<sup>6</sup> Infections caused by the SARS coronavirus that resulted in 8,422 confirmed infections and 916 confirmed deaths worldwide from November 2002 to August 2003

<sup>7</sup> Following the spread of COVID-19 infections, this was done to prevent foreign investors from acquiring domestic health and medical companies, or companies with high technological strength, when such acquisitions are not in the interest of the people of the country. Stronger restrictions were enacted by the European Union (EU), Australia, Canada, and other countries. In Japan as well, public comment procedures were started in May of this year aimed at adding the pharmaceutical and specially controlled medical device industries to the industries where advance notification is required for investment by foreign companies under the Foreign Exchange and Foreign Trade Act.

<sup>8</sup> International Monetary Fund (IMF), *World Economic Outlook, April 2020* (released on 14 April 2020)

<sup>9</sup> Investment which incorporates consideration for non-financial information including Environment, Social and Governance matters.

society with an environmentally sound material cycle, and health (wellness<sup>10</sup>), which are keywords for overcoming social problems as pointed out in Bio-Strategy 2019, has become more obvious than before.

In addition to the utilisation of biotechnology in the development of vaccines, therapeutic drugs, etc. for infectious diseases, the utilisation of renewable biological resources (biomass), etc. that can contribute to self-sustainability and decentralisation of energy and resources is indispensable for the establishment of a strategic supply chain.

- The promotion of bioeconomy aiming to utilise biotechnology, renewable biological resources, etc. in order to expand a sustainable, renewable, and recycling-oriented economic society is becoming increasingly important for both containing the pandemic and future economic recovery.

## 2.2 Industry trends

### 2.2.1 Overseas trends

- With the recent development of synthetic biology, genome editing technology, etc., biotechnology is giving rise to a revolution in health, medical care, nursing care<sup>11</sup>, agriculture, forestry, and fisheries<sup>12</sup>, as well as industry.
- Progress has also been made in the utilisation of renewable biological resources. Industries have grown that convert waste and wastewater into products such as feed, compost, nutrients, and cosmetics through processing of waste and wastewater by algae and microorganisms. In the construction industry, attempts have been made to switch from steel and concrete to wood<sup>13</sup>, and some wooden high-rise buildings<sup>14</sup> have been completed, with the utilisation of biotechnology advancing in all industrial sectors.
- While the United States, Europe, and China are focusing on the production of microorganisms, etc. that produce the desired substances through biotechnology and competition is intensifying, development in the field of efficient and stable cultivation of microorganisms, etc. for industrialisation has made little progress in any corner of the world. Our success in the biotechnology market depends upon whether we can succeed in this field.

### 2.2.2 Domestic trends

- We must admit that Japan's presence in the global bio-based industry is obscure. Although bioventures have been supported, many start-ups have disappeared due in part to the economic downturn precipitated by the Lehman Brothers bankruptcy in 2008. Without scientific and international perspectives in commercialisation, commercialisation and start-up ecosystems are not functioning adequately.<sup>15</sup>
- Given Japan's diminishing international competitiveness, it is necessary for the country to focus on the downstream side of the market and, even if foreign companies acquire the technology ahead of us, we should consider a strategy that

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<sup>10</sup> This is a concept that addresses health in a broad sense that includes more than just the physical body. It is said that the original definition was promoted by U.S. physicians as a "dynamic, almost shining, state of health".

<sup>11</sup> This refers to the construction of international cooperative relationships in order to standardise programs for digital health. With improvements in technologies that can acquire a wide range of biological data, we are now progressing from the Big Data collection and analysis stage to the stage of adding value to and monetising the data. The shift towards utilising AI for evidence-based individualised and stratified medical care, remote diagnosis and nursing care is accelerating.

<sup>12</sup> Rapid digitalisation and mechanisation is taking place in the United States and Europe primarily for the purposes of achieving sustainable agriculture and improving productivity. Sensors, drones, and other devices are extensively used to collect data, which is then used to improve production technologies. In breeding as well, major seed and seedling companies are working to collaborate with or acquire IT companies and accelerate the digitalisation process.

<sup>13</sup> The European bio-economy strategy that was revised in 2018 indicates that replacing 1t of concrete with 1t of wood achieves a 2t reduction in greenhouse gas emissions.

<sup>14</sup> According to *CTBUH Journal* 2017 Issue II, a total of 17 ten-storey or taller high-rise timber buildings will be completed by the end of 2020 (including those already completed). At present, the tallest such building is Mjøstårnet in Norway (85.4 m, 18 storeys).

<sup>15</sup> According to *Ito Report 2.0, a report of the study group for encouraging dialogue between biotech venture businesses and investors, biomedical edition* (Ministry of Economy, Trade and Industry, April 2018), market capitalisation of venture companies in the biotech sector (as of January 2018) was 59 trillion yen in the U.S., 8.3 trillion yen in Europe, 8.9 trillion yen in China, 10.5 trillion yen in Korea and 1.6 trillion yen in Japan.

is so ambitious that we can add value through the development of improved and peripheral technologies to turn the tide.

- Meanwhile, the amount of investment in the biotechnology field is on the increase<sup>16</sup>, and the following efforts are expected of Japanese companies.
  - Further offering of biodegradable plastics developed and produced by Japanese companies in the domestic and international markets<sup>17</sup>
  - Undertaking the world's first clinical trial of a new drug candidate discovered through the use of AI in joint development with a foreign company<sup>18</sup>
  - Undertaking the world's first clinical trial of a bioprinted-cell-based vascular graft<sup>19,20</sup>
  - Undertaking construction of high-rise wooden buildings<sup>21</sup> in Japan

## 2.3 Research trends

### 2.3.1 Overseas trends

- In addition to the hypothesis-testing approach, the data-driven approach of discovering laws from a vast amount of biological information has made progress in understanding biological phenomena, thanks to a substantial reduction in the cost and time required for genome sequencing, improvements in the performance of computing machinery, and creation of vast amounts of data. Against a backdrop of these developments, synthetic biology, which accumulates data by repeating the cycle of designing, building, testing, and learning (DBTL<sup>22</sup> cycle) and thereby understands biological functions, has developed rapidly.
- It is self-evident that research will flourish to understand the integrated view of individual elements and the correlation and spatiotemporal behaviour of genes and proteins in vivo.
- Due to the fact that handling such a large amount of data has become mainstream, there has been a rapid shift in the field of biotechnology from a decentralised research style based on individual laboratories to big science (high-throughput-oriented<sup>23</sup> and higher cost), open science, centralisation, and networking. Developed Western countries have responded to this trend by assembling teams from different disciplines, sharing advanced research equipment and research support specialists, and establishing under-one-roof laboratories<sup>24</sup> with data management functions, etc.

### 2.3.2 Domestic trends

- Basic research capabilities, which were supposed to be Japan's strength, have declined recently. Research in our country is still undertaken by individual laboratories in a decentralised fashion, following a vertically divided structure. Awareness and mechanisms for implementing international, interdisciplinary and inter-organisational cooperation are lacking. With regard to research environments, systems to share research equipment and research-supporting personnel are insufficient, and the number of advanced research devices is not as high as in

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<sup>16</sup> According to statistics in the *Venture White Paper* published by the Venture Enterprise Center, FY 2018 investment by Japan venture capital in the biotech, medicine and health care industries was approximately 32.3 billion yen, 2.3 times the amount from FY 2015 (higher than the approximately 2.1 times increase in all fields).

<sup>17</sup> Refer to 2-1 in the materials distributed by the Bioplastics Introduction Strategic Roadmap Committee (1st meeting, 22 May 2020).

<sup>18</sup> *The Beyond Disciplines Collection: Changes in scientific technologies and innovation resulting from digital transformation* (April 2020, JST Center for Research and Development Strategy)

<sup>19</sup> Technology for printing and modelling using biological materials

<sup>20</sup> A clinical trial was started for regenerative medicine to transplant a bioprinted-cell-based vascular graft which was created with a bio 3D printer (13 November 2019 press release by Saga University and AMED).

<sup>21</sup> An 11-storey research facility and a 12-storey commercial facility

<sup>22</sup> Design, Build, Test, Learn

<sup>23</sup> Rapid advances are being made in high-speed extraction and analysis of particular compounds, genes, or other target substances from large volumes of samples.

<sup>24</sup> Broad Institute (Boston, USA), Francis Crick Institute (London, U.K.), others

other countries<sup>25</sup>. The shortage of specialists who control equipment has also been pointed out.

- In general, there is a paucity of researchers who are capable of the integration of bio- and digital technologies, which is a global trend. In particular, it is a pressing issue to secure personnel who can formulate research and development strategies based on an overview of the current state and technological development.
- Without suitably sharing and networking critical research infrastructure and data, Japan's international position will continue to decline.
- In order to improve Japan's research capability, it is urgent to abandon the sense of sectionalism, and for researchers and those allocating research funds to seriously consider how the research infrastructure and data should be and to start concrete efforts for sharing and networking. It is also necessary to examine medium- and long-term measures after analysing whether global competitiveness can be maintained with the current research style and system.
- On the other hand, our country leads the world in research on inhibitors of disease-specific protein-protein interactions related to abnormalities in protein-protein interactions that are responsible for many diseases. If we can capitalise on this and our world-class capabilities in organic synthesis and thereby promote research on the development of medium molecular compounds, continued development of new drugs is possible in Japan.<sup>26</sup>

## 2.4 Policy trends

### 2.4.1 Overseas trends

- Following the adoption of the Paris Agreement and the SDGs, there is an international demand for sustainable economic growth and solutions to social issues, and there is a global trend towards healthy longevity, stable food supply, conservation and restoration of the global environment (reduction of greenhouse gas emissions, improvement of soil and water quality, etc.), and the creation of a society with an environmentally sound material cycle. ESG investment by institutional investors is also expanding.
- In the United States, Europe, China, and other major countries, the formation of new markets through the expansion of bioeconomy is positioned as a national strategy, and there has been a major shift in thinking from the conventional seeds-oriented approach of how biotechnology should be utilised. Last year, the White House hosted a Bioeconomy Summit in the U.S., where the industry, academia, and government discussed healthcare, ICT, agriculture, industry, security, etc., and the National Biodefense Strategy was formulated. A new bioeconomy strategy was also formulated in Germany this year, indicating that policy interest in bioeconomy is increasing on a global basis.
- With regard to genome editing technologies, the following events have occurred that remind us of the need to tighten the relationship between science and society, such as ELSI and security, and that policy measures are necessary.
  - Bioethical challenges in research in the wake of the birth of twins from fertilised embryos using genome editing technology in China
  - Concerns about man-made biosecurity risks associated with the synthesis of new pathogens and genetic modifications, such as the successful artificial synthesis of a smallpox-like horse pox virus using genome editing technology

### 2.4.2 Domestic trends

- Reflecting on past bio-strategies, we formulated Bio-Strategy 2019, the first strategy for the biotechnology field in 11 years, and we shifted from the strategy of

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<sup>25</sup> For example, as of October 2018, the numbers of top class cryoelectron microscopes (Titan Krios) were 5 in Japan, 49 in the U.S., 16 in China, 23 in Germany, and 14 in the U.K. (source: Japan FEI Corporation).

<sup>26</sup> Refer to *Overview Workshop Report: Next-Generation Medical and Infrastructure Technology Trends, Prospects, and Necessary R&D Strategies* (March 2019, JST Center for Research and Development Strategy).

- utilising biotechnology to the strategy of how to realise bio-economy as an indispensable element of a new sustainable socioeconomic system.
- Since then, the following measures have been steadily promoted.
    - Drawing up market area roadmaps with the participation of many industry organisations and companies
    - Promotion of technological development, etc. for the study and substantiation of data linkages utilising the SIP and PRISM and for the substantiation of bio-production, with an investment of about 6.2 billion yen in the government's fiscal 2019 budget
    - Consideration for the formation of bio-communities
    - Implementation of the system for the handling of organisms that are not subject to the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Law)<sup>27</sup> among those obtained through the use of genome editing technology, and for the handling of food obtained through the use of such technology under the Food Sanitation Act.
  - This year, we have worked out the second stage of the health and medical care strategy, quantum technology innovation strategy, and progressive environmental innovation strategy, and have positioned them to be promoted in conjunction with the bio-strategy.
  - In addition to the above strategies, we are steadily promoting measures such as the creation of a regional recycling and symbiotic community for the realisation of a sustainable society (a civilised society compatible with the environment and life<sup>28</sup>), the selection of and support for biomass industrial cities, and drawing up a roadmap for the introduction of bioplastics based on the strategy for the recycling of plastic resources. The coordination of these strategies and measures with the bio-strategy will be beefed up.<sup>29</sup>

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<sup>27</sup> Act No. 97, 2003

<sup>28</sup> Refer to the Basic Environment Plan (adopted by cabinet resolution in April 2018).

<sup>29</sup> Concept by which steps are taken to form an autonomous and distributed society where nearby regions each complement one another's local resources

### 3 Basic concepts

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#### 3.1 Basic policy

- The following five basic policies are laid out in light of the major points of reflection of past strategies, namely overemphasis on seeds, non-identification of investment targets, lack of commitment, inadequate data management strategies, lack of international strategies, and lack of response to ELSI.

##### **(1) Market area setting, backcasting, and continuous commitment**

- After drawing up a vision of the society that we should aim for from the perspective of creating new markets and capturing overseas markets, we should present the market areas to be targeted. Shifting to the idea of transforming social issues into future value rather than viewing such issues as costs, we should formulate a roadmap through backcasting, with constant evaluation and response undertaken by the industry, academia, and government.

##### **(2) Integration of bio and digital technologies**

- The directions and sustainable measures for big data collection and the construction of a bio-data infrastructure necessary for the development of market areas and science should be put forward. Japan's strengths and craftsmanship should be reflected in AI by utilising measurement instruments and bio-data infrastructure. Research and development personnel, etc. to support these efforts should also be developed, with importance attached to quality.

##### **(3) Establishment of an international hub, regional networking, and investment promotion**

- By combining a world-class research environment and a commercialisation support system that allows foreign investment to be utilised, we should organise a social system that can attract first-class human resources and investments that are orders of magnitude higher than national investments from within and outside of the country, and create a region (international hub) that will be recognised by the world as a bio-innovation hub.
- A virtuous cycle of goods, capital, and human resources should be promoted by networking the international hub and each region.

##### **(4) Stepping up the international strategy**

- Through international harmonisation of systems and data, coordination with trade policy, and protection of intellectual property and genetic resources<sup>30</sup>, we should expand the Japanese model on a global basis and thereby increase global competitiveness.

##### **(5) Responding to ethical, legal, and social issues**

- As a basis for successfully addressing both ELSI and innovation, ELSI-related research in collaboration with the fields of humanities/social sciences and natural sciences should be promoted, as well as dialogue with the public.
- Community planning should be based on a bio-first mindset<sup>31</sup> in concerted effort among the industry, academia, and government.
- From the viewpoint of building a strategic supply chain that combines globalisation and self-sustainability, and centralisation/decentralisation, which will be of importance in the post-COVID-19 era, as described in Section 2.1, the following points are emphasised on the basis of the above five basic policies.

- While we are **focusing on the return to and strengthening of domestic**

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<sup>30</sup> Based on the definitions in the Intellectual Property Basic Act, genetic resources may be included in intellectual property. They are listed separately here due to their importance in the bio-strategy.

<sup>31</sup> See section 3.2

**production for the time being** in consideration of the short-term decline in global distribution and economic security as a result of the impact of COVID-19, we should **steadily promote what we can do to build a global supply chain** with a view to penetrating overseas markets on a mid- to long-term basis.

- In order to achieve **self-sustainability and decentralisation in consideration of securing energy, resources, etc.**, efforts should be made to figure out the amount of biomass at home and abroad, and **networking should be furthered with a balance between economic efficiency and flexibility**<sup>3233</sup>.

### 3.2 Overall objective and social vision for 2030

- The overall objective is “achieving the world’s state-of-the-art bioeconomy society by 2030”.
- The “world’s state-of-the-art bioeconomy society” is based on the premise of a **bio-first mindset**<sup>34</sup>, **the formation of a bio-community**<sup>35</sup>, and a **bio-data-driven society**<sup>36</sup>, and realisation of the following four social visions is assumed.

#### **(1) Society with an environmentally sound material cycle in which all industries are linked together**

- Going beyond the conventional concept of simple treatment to purify waste and wastewater generated from agricultural and industrial production activities, we should aim to develop a recycling-oriented social system in which waste is converted into substances and materials with added value, such as composting.
- While substantiating such a system in Japan, we should expand a model of production, utilisation, and recycling in cities, regions, and overseas countries by removing barriers between industries.

#### **(2) Society with sustainable primary production that satisfies diversified needs**

- Enhancement of productivity to cope with the decline in the labour force, adaptation to climate change, and sustainable primary production that enables conversion of wastewater and waste into useful materials so as not to harm the environment are issues that must be addressed both in Japan and overseas.
- Furthermore, as Asia and Africa continue to experience rapid economic growth, they will demand more delicious, healthier food, and there will be a wide variety of needs.
- In coping with these issues, we should utilise biotechnology such as data-driven breeding and AI-based soil production, rather than rely solely on craftsmanship and intuition.

#### **(3) Society that bio-engineers substances and materials with sustainable**

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<sup>32</sup> Ability to adapt to changes

<sup>33</sup> When studying the roadmap for each market region, consider programs related to all types of biofuels including waste biomass, non-edible parts of agricultural produce, forest scraps and algae.

<sup>34</sup> This is a mindset which encourages consideration of what can be accomplished with biotechnology and then takes action in an environment where the ethical, legal and social problems associated with biotechnology can be discussed, aiming to achieve Society 5.0 through sustainable production and recycling.

<sup>35</sup> These are communities where the bio-first mindset has taken root at all levels from company management and other leaders of society to ordinary citizens, and which are based on international cooperation, integration of different disciplines and open innovation. Appealing international communities and a network of local regions have been constructed, and these act as a catalyst for global data, personnel, investment, and research, producing a positive cycle of people, goods, and funds. The use of various types of distinct biotechnologies allows the creation of sustainable and recycling-oriented communities, and communities where people can live healthy lives, generating both domestic and international support.

<sup>36</sup> This refers to a country where a fusion of biotechnology and digital technology has been used to construct data infrastructure that includes the creation of data for biological activities, where international standard measurement methods and measurement instruments have been incorporated into production systems, and where it is possible to create the most data for biological activities in the world.

### **manufacturing methods**

- Based on the 3Rs, we should establish a carbon cycle in which products derived from renewable biological resources that achieve both reduction of greenhouse gas emissions and economic efficiency based on scientific evaluation are accepted by society, and in which environmental problems such as marine pollution caused by wastewater, waste, and plastic waste are also overcome.
- By utilising biotechnology and renewable biological resources, we should also try to develop high-performance materials that are lighter and more durable than ever before.

### **(4) Society in which medical care and healthcare work in tandem to allow social participation over the long term**

- A social system should be established that seamlessly enables self-care and early detection in the healthy and non-diseased stages, prevention of metabolic abnormalities, and treatment of organ disorders, as well as the prevention of aggravation thereof so that both medical care and the healthcare industry can evolve together.
- With this social system at the core, data from each individual can be compiled appropriately, and the data will be used to build evidence at the level necessary for the medical, drug discovery, and healthcare industries, leading to the development of stratified and personalised services.
- In countries where health insurance systems are still in their infancy with limited access to medical services, our country's biotechnology should be applied to promote health through self-care based on evidence-based diet, etc.

## **3.3 Positioning and structure of the strategy**

### **3.3.1 Positioning the strategy**

- The bio-strategy will be updated every year for the time being in order to respond promptly to the domestic and international situation, starting with the items that have been agreed upon by the parties involved in the implementation of the strategy.
- As pointed out in Section 2 "Background", the scale and impact of COVID-19 is enormous, even compared with the other recent global pandemic of infectious diseases, and the promotion of bioeconomy through the use of biotechnology and the utilisation of renewable biological resources, etc., is becoming increasingly important, both in terms of containing the pandemic and in terms of quick economic recovery once the pandemic is contained. We should not stop moving ahead, accordingly.
- Therefore, Bio-Strategy 2020 (basic measures) as formulated herein sets forth the following as temporary measures.
  - Immediate measures for research and development, etc. in order to contain the current pandemic
  - Fundamental measures that should be taken without delay in accordance with Bio-Strategy 2019 with a view to ensuring quick economic recovery after containment of the pandemic (related to data, formation of bio-communities, etc., system improvement, etc., and enhancement of the command function)
- With further actions taken to address COVID-19 and changes in circumstances such as economic downturn taken into account, market area roadmaps will continue to be discussed and will be drawn up around this winter.
- As for measures based on the market area roadmap, etc., Bio-Strategy 2020 (with a finalised market area policy) will be worked out sometime around this winter, and actions will be taken accordingly.
- With respect to the "immediate measures for research and development, etc. in order to contain the current pandemic" presented in this Bio-Strategy 2020 (basic

measures), measures related to health and medical care strategies, etc. as promoted under the Novel Coronavirus Response Headquarters are mainly presented.

### 3.3.2 Structure of the strategy

- First, the “immediate measures for research and development, etc. in order to contain the current pandemic” are presented as a special chapter as part of the bio-strategy (Chapter 4).
- This is followed by the main chapter of the bio-strategy, laying out the “fundamental measures that should be taken without delay in accordance with Bio-Strategy 2019 with a view to ensuring quick economic recovery after containment of the pandemic”.
  - Efforts in the market area that are related to data, formation of bio-communities, etc., and system improvement, etc. (Chapter 5)
  - Cross-functional efforts related to data, formation of bio-communities, etc., and system improvement, etc. (Chapter 6)
  - Enhancing the strategic command function (Chapter 7)

## 4 Research and development, etc. pertaining to countermeasures against COVID-19

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- Based on the policy set out by the government, we should promptly promote the necessary measures such as research and development while enhancing cooperation both at home and abroad. In doing so, we should also mull over necessary measures, keeping in mind issues such as how regulations on medical care should be handled in emergency situations. [OHP, OPINIDPR, COMEID, ONCDC, MEXT, MHLW]
- Measures should be taken expeditiously to develop diagnostic and therapeutic methods, vaccines, devices, and systems for emerging infectious diseases including COVID-19 by using the adjustment funds for medical research and development, reserve funds, the first supplementary budget for fiscal 2020, the second supplementary budget for fiscal 2020, etc. [OHP, DGSTI, OAMED, MOFA, MEXT, MHLW, METI]<sup>37</sup>

### 4.1 Promotion of research and development, etc.

#### 4.1.1 Research and development of diagnostic and therapeutic methods, vaccines, etc. [DGSTI, OAMED, MEXT, MHLW, METI]

##### (1) Development, etc. of diagnostic and therapeutic methods and vaccines

- Verification of the equivalence of test reagents
- Basic research and development of a rapid diagnostic kit and development of a serum antibody diagnostic system
- Production, etc. of antibodies for rapid diagnostic kits in cooperation with companies
- Selection of therapeutic drug candidates by in silico analysis<sup>38</sup> and development of antiviral drugs
- Examination of therapeutic effects and safety of treatment drugs
- Support for vaccine development

##### (2) Development of devices and systems

- Development of rapid testing devices
- Social empirical research on new rapid detection methods
- Development of technology to prevent viral and other infectious diseases
- Emergency response for emerging infectious diseases using AI and data infrastructure

##### (3) Cyclic Innovation for Clinical Empowerment

- Promoting research and development of innovative pharmaceutical products and medical devices, including measures against COVID-19, through collaboration among the industry, academia, and government

##### (4) Basic technology development, etc.

- Collection of data on COVID-19 in Asian countries
- Securing and analysing specimens from Japan and overseas
  - Analysis of immune responses, such as blood samples from infected patients, for development and research of vaccines, etc.
  - Promotion of research utilising specimens and information obtained at overseas research hubs

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<sup>37</sup> Existing programs include the following. (1) Stage 1 (13 February 2020): Based on knowledge concerning viruses such as SARS and MERS, quickly begin development of diagnostic methods, treatments, vaccines, and other necessary measures. (2) Stage 2 (10 March 2020): Accelerate clinical studies for the use of existing medicines with COVID-19, as well as the development of rapid test kits, and construct an R&D platform that can respond immediately to new infectious disease outbreaks. (3) First supplementary budget for fiscal 2020 (7 April 2020): In order to defeat the infectious disease and put the economy back on a path to growth, further accelerate the development of new devices and systems in addition to new treatment methods and vaccines for the infectious disease. (4) 2020 first adjustment funds for medical research and development (17 April 2020): Based on an understanding that the global spread of COVID-19 infections has made the development of therapeutic drugs, vaccines, medical devices, and other innovations an issue of great urgency, conduct top-down allocation of funds and further accelerate and expand R&D related to COVID-19. (5) Second supplementary budget for fiscal 2020 (12 June 2020): Add further R&D funds for the development of treatments and vaccines so that it is possible to work for a recovery in socioeconomic activities while at the same time also preventing the spread of infections.

<sup>38</sup> Analysis performed by computer

- Development, etc. of diagnostic and therapeutic methods based on new research trends, etc., and research and study projects for addressing resurgence of the epidemic
- Genome analysis of infectious diseases, immune repertoire analysis<sup>39</sup>, and integrated data sharing
  - Genomic and immunological analyses of specimens from patients infected with COVID-19 will be performed to establish a basis that can be utilised by integrating clinical and epidemiological information.
- Development of a new technology basis for research and development pertaining to emerging infectious diseases
  - Seeds will be solicited publicly for new technological bases required for research and development such as drug discovery pertaining to emerging infectious diseases including COVID-19.

#### 4.1.2 Environmental arrangement, etc. [MEXT, MHLW]

- Development of analysis bases for pathogens, specimens of infected patients, etc., and enhancement of drug discovery bases in the field of infectious disease.
  - The testing system will be supported by the National Institute of Infectious Diseases. In addition, some existing BSL3 units will be renovated and upgraded in Japan, and the system will be improved to allow for research and development using animal models of infection.
- Strengthening and expanding drug target exploration function
  - A 300-keV, high-end cryoelectron microscope will be installed at the BSL3 facilities to enable more detailed structural analysis of viral proteins, thereby strengthening and expanding the function of searching for target factors of anti-infection drugs.<sup>40</sup>
- Strengthening and enhancing research bases for measures against COVID-19
  - Support for drug discovery research will be enhanced, and basic research at overseas research bases for infectious diseases will be promoted.
- Project to establish a system for the rapid development of therapeutic agents for COVID-19, etc.
  - Safety evaluation of therapeutic agents for COVID-19 will be advanced, and performance evaluation of in vitro diagnostics for COVID-19 will also be promoted.
- Project to develop a system to prevent the spread of infection through genome analysis of COVID-19, etc.
  - The analysis of viral mutations using genome analysis technology will be enhanced to construct a framework for accurately understanding the spread of mutant viruses, etc., and the establishment of a research system using technology to quickly measure antibody titres in serum samples<sup>41</sup> will also be promoted.
- Solid maintenance of bioresources under the influence of the spread of COVID-19
  - In order to solidly maintain and provide (a certain part of) bioresources that the government should strategically develop even under the influence of COVID-19, labour-saving measures that enable maintenance activities with the minimum human resources will be promoted, and remote sensing and response to emergencies such as abnormal conditions in the breeding environment or equipment failure will also be promoted.

#### 4.1.3 Matters related to other countries [MOFA, MHLW]

- Project to establish a clinical research and clinical trial network in Asia

<sup>39</sup> This is a method of analysing the genetic diversity of the T cell receptors (TCR) and B cell receptors (BCR) that are located on the surfaces of T cells and B cells (each a type of lymphocyte). The analysis is based on RNA that is extracted from blood cells or tumour cells.

<sup>40</sup> Such a microscope is capable of observing proteins and other biological samples on the molecular level.

<sup>41</sup> Example: Measuring the amount of antibodies that react to an antigen. This data is used to understand matters such as the status of infection and immunity.

- Countermeasures against COVID-19 will be accelerated on an Asia-wide basis involving industries by building a project for intangible factors (human resource development, data collection, evaluation methods, etc.) that enables joint development in Asia (clinical research and clinical trials) based on the capabilities and experience of Japanese clinical research bases, together with support for tangible factors such as medical equipment necessary for the bases.
  - Contributions to international organisations
    - Contributions to the CEPI and Gavi<sup>42</sup> are planned.
- 4.2 Development of a system for the early commercialisation of vaccines
- A production system will be developed in parallel with vaccine development so that the novel coronavirus vaccine, currently under development, can be manufactured rapidly. [MHLW]

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<sup>42</sup> Gavi, the Vaccine Alliance, is a public–private partnership that was established in 2000 with the goal of increasing access to immunisation in poor countries. Its primary activities include promoting the wider use of new and underutilised vaccines, and reinforcing public health systems in order to effectively provide immunisations.

## 5 Efforts in the market area (basic measures to be taken without delay)

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### 5.1 Market area

- The following nine market areas have been established as those necessary to realise the four social visions described in Section 3.2. These market areas are expected to attract large investments from within and outside of the country, based on Japan's characteristics (strengths) and overseas trends, with the growth potential of the market fully taken into consideration.<sup>43</sup>

- (1) High-performance bio-based materials<sup>44</sup> (lightweight, durable, and safe) [DGSTI, MEXT, MAFF, METI, MOE]**
- (2) Bioplastics (substitute for commodity plastics) [DGSTI, MEXT, METI, MOE]**
- (3) Sustainable primary production system [DGSTI, MAFF]**
- (4) Processing organic waste and wastewater [DGSTI, METI, MLIT, MOE]**
- (5) Healthcare for lifestyle improvement<sup>45</sup>, functional foods, and digital health<sup>46</sup> [IT, OHP, MS, DGSTI, CAA, MIC, MEXT, MHLW, MAFF, METI, MOE]**
- (6) Industries related to biopharmaceuticals, regenerative medicine, cell therapy, and gene therapy<sup>47</sup> [OHP, MEXT, MHLW, MAFF, METI, MOE]**
- (7) Bio-production systems <Industrial and food production-related (production using biological functions)> [MAFF, METI]**
- (8) Bio-related analysis, measurement, and experiment systems [OHP, MEXT, MHLW, MAFF, METI]**
- (9) Large-scale construction using wood and smart forestry [MAFF, MLIT]**

- The following sections describe the fundamental measures that should be taken without delay in accordance with Bio-Strategy 2019 with a view to ensuring quick economic recovery after containment of the pandemic (related to data, formation of bio-communities, etc., system improvement, etc.), together with related issues and policies. Measures based on the impact of the infectious disease will be reflected in Bio-Strategy 2020 (with a finalised market area policy).

- Based on changes in circumstances attributable to COVID-19, a market area roadmap for each market area, including the following, will be drawn up by this winter<sup>48</sup>, and actions will be taken accordingly.

- Ideal market in 2030 to aim for
- Issues
- Target market size
- Public and private sector efforts by category, including data, bio-community, start-up and investment environment, regulations, public procurement, standards, research and development, human resource development, intellectual property, genetic resources, international strategy, and ELSI

### 5.2 High-performance bio-based materials, bioplastics, organic waste and wastewater processing, bio-production systems, and bio-related analysis, measurement, and experiment systems

#### 5.2.1 Issues and policies

The commercialisation of bio-based materials, etc. requires the creation of genetically engineered organisms, etc. for production, as well as technological development from small-lot production to full scale, investment in plants and equipment, and human

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<sup>43</sup> For the reasons behind the establishment of the market areas, refer to Bio-Strategy 2019.

<sup>44</sup> Cellulose nanofibre, lignin, etc.

<sup>45</sup> In addition to food, this also includes products and services that promote lifestyle improvements such as exercise and sleep.

<sup>46</sup> Including non-invasive or minimally invasive medical devices such as wearable devices

<sup>47</sup> Bio-production system for culture, transportation, and contract manufacturing, as well as contract development of pharmaceutical products etc.

<sup>48</sup> It may be possible to conduct a centralised study covering multiple market areas.

resource development. However, these are difficult for individual companies to handle, and data linkage has not progressed enough.

- For marine biodegradable plastics to gain popularity, evaluation of their biodegradability and identification labelling thereof are necessary, but an evaluation method for international standardisation and for proposing ISO standards has not yet been established.<sup>49</sup>
- Stimulating and expanding initial demand is necessary for the spread of bio-derived products
- Based on these, the following measures will be implemented.
  - Examining how the data linkage should be established to contribute to the development of market areas
  - Integrating research and development functions, etc. related to bio-derived products into global bio-communities
  - Promoting measures to stimulate demand, international standardisation, etc.
  - Promoting the development, safety assurance, etc. of biological resources, which are the basis for the development of market areas

### 5.2.2 Efforts

- The following basic measures will be promoted in order to capture domestic and overseas markets for bio-derived products that contribute to the reduction of environmental load and for bio-related analytical, measurement, and experiment systems, which form the foundation of the entire biotechnology industry<sup>50</sup>. [DGSTI, MAFF, METI, MOE]
  - (1) Data-related matters
    - The needs of the industry will be gathered, and a platform will be developed to collect domestic and overseas data and utilise big data with the aim of realising a society with an environmentally sound material cycle. [DGSTI, METI]
  - (2) Formation of a bio-community, etc.
    - Full-fledged support will begin in fiscal 2021 for the establishment of a base for substantiation of bio-production and human resource development in the global bio-community candidate regions so that gene modification technologies and innovative bio-production technologies can be developed in an integrated fashion on the initiative of private sector along with industry-academia collaboration. [METI]<sup>51</sup>
    - In order to promote the shift to bio-derived products contributing to the reduction of environmental load associated with manufacturing, support will be provided for the procurement of funds such as green bonds and for investment in plant and equipment. [METI, MOE]
    - Deliberation on the formation of a consortium of bio-related analytical, measurement, and experiment systems is scheduled to begin by the end of fiscal 2020, with the development base being clearly specified. [METI]
    - In order to promote the full domestic production of bio-derived products, integrated research and development from raw material supply to manufacturing processes to commercialisation will be promoted. [MAFF, METI]
  - (3) System improvement, etc.
    - The criteria, etc. for judging the proportion of biomass materials in specified procurement products under the Act on Promoting Green Purchasing will be strengthened based on market conditions, etc. [MOE]
    - Deliberation will be carried out with the aim of introducing labelling of bio-

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<sup>49</sup> International standard established by the International Organization for Standardization

<sup>50</sup> To be carried out in coordination with the roadmap for introduction of bioplastics that is will be formulated based on the strategy for recycling of plastic resources.

<sup>51</sup> See section 6.2

based products<sup>52</sup> that reduce environmental load in the mid-2020s, and measures to stimulate demand for bio-derived products<sup>53</sup> will also be considered with reference to the Act on Promotion of Procurement of Eco-Friendly Goods and Services by the State and Other Entities, etc. [MAFF, METI, MOE]

- With a view to expanding the use of bioplastics in bags for combustible waste, guidelines will be formulated to encourage municipalities to introduce bioplastics, and information related to bioplastics will be added to the Guide for Charging for General Waste Disposal around fiscal 2020. [MOE]
- The development of an evaluation method will be supported with the aim of proposing international standardisation of the evaluation of marine biodegradable plastics in the early 2020s. [METI]
- The development and expansion of biological resources in Japan, as well as the development of a safety management structure for contaminating microorganisms during product manufacturing and the improvement of safety management technologies, will be promoted in cooperation with the intellectual infrastructure development plan. [METI]

### 5.3 Sustainable primary production system

#### 5.3.1 Issues and policies

- Japan is the world's sixth richest country in terms of genetic resources, but the environment for using these resources for breeding development is insufficient.
- In the midst of the demand for both more efficient agricultural production and less environmental load, it is necessary to optimise the use of fertiliser, water, etc. and to recycle waste and wastewater for composting, etc.
- To develop a highly profitable and sustainable aquaculture industry against the backdrop of increased demand for marine products due to the increase in the world population, etc., it is necessary to resolve bottlenecks related to feed, seeds and seedlings, and fishing grounds, which are the three elements of aquaculture production.
- Development of a system in which universities, related organisations, etc. work hand in hand to develop technologies is inadequate.
- Japanese beef is a unique property of the country, and any illegal outflow of domestic animal genetic resources to foreign countries may have serious repercussions on the promotion of livestock farming in our country. It is therefore necessary to thoroughly control the distribution of domestic animal genetic resources and step up the protection of such resources as intellectual property.
- Under the current variety registration system, the export of high-quality new plant varieties to foreign countries cannot be restricted, and even if the breeder's rights are infringed, it is difficult to prove. Accordingly, enhanced protection is necessary.
- Based on these, the following measures will be implemented.
  - Development of a data infrastructure for breeding, soil, and fisheries, which are the basis for the development of market areas
  - Development of a system in which universities, related organisations, etc. work hand in hand to develop technologies
  - Development of a system for the protection of intellectual property and genetic resources

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<sup>52</sup> Considering LCA assessments (a method of quantifying the environmental impact of a product or service over its entire life cycle (resource extraction, raw material production, product production, distribution and consumption, scrapping, and recycling) or at any particular stage of its life cycle), as well as matters such as environmental issues, ethical and moral issues, degradable functions, and suitability for recycling

<sup>53</sup> For example in Europe, products which contain a certain percentage of bio-derived plastic are exempt from regulations on disposable plastic. In the United States, The BioPreferred Program has been introduced to stimulate demand by certifying bio-derived products and requiring that the federal government and other entities engaged in public procurement purchase product that have received this certification.

### 5.3.2 Efforts

- With regard to the sustainable primary production system that contribute to a stable food supply and reduced environmental load, the following basic measures will be taken to capture markets at home and abroad. [DGSTI, MAFF]
  - (1) Data-related matters
    - A smart breeding platform that utilises a big data infrastructure for breeding and AI will be developed, with the aim of operating the platform on a trial basis around 2023. [DGSTI, MAFF]
    - Soil-related databases will be enhanced and research on soil microorganisms will be promoted, with the aim of rolling out soil-related data through a data linkage base around 2023. [DGSTI, MAFF]
    - Development of high value-added aquaculture varieties will be accelerated, and smart aquaculture and innovative aquaculture feed development will be promoted through the promotion of data linkage in the fisheries sector. [MAFF]
  - (2) Formation of a bio-community, etc.
    - An agri-bio base will be constructed as a hub for the development of a sustainable primary production system, etc. with concerted efforts of the private and public sectors. [MAFF]
  - (3) System improvement, etc.
    - Protection of intellectual property and genetic resources will be promoted through measures to prevent the illegal outflow of genetic resources to foreign countries based on the amendment to the Plant Variety Protection and Seed Act and the post-amendment Act on Improvement and Increased Production of Livestock, as well as the Act for Prevention of Unfair Competition Using Livestock Genetic Resources. [MAFF]

## 5.4 Healthcare for lifestyle improvement, functional foods, digital health, and industries related to biopharmaceuticals, regenerative medicine, cell therapy, and gene therapy

### 5.4.1 Issues and policies

- It is necessary to develop a data infrastructure that will serve as a foundation for Japan's growth (both research and innovation) in all health and medical fields based on efforts in the medical field yet including non-medical fields.
- In order to promote the commercialisation of biopharmaceuticals, regenerative medicine, and their related industries, it is necessary to establish a system to work seamlessly from research and development to commercialisation while cooperating with clinical sites such as hospitals.
- For further expansion of the sound market for functional foods, it is necessary to accumulate scientific knowledge and to aim for the realisation of new labelling for health use, such as improvement of immune function, while taking into account the international situation.
- Based on these, the following measures will be implemented.
  - Promoting coordination and utilisation of data pertaining to cohort biobanks and establishing technical standards, such as the development of rules necessary to promote PHR, which is the basis for the development of market areas
  - Consolidating functions, etc. with the aim of developing relevant industries that support the supply chain, such as development and manufacturing
  - Preparing guidelines necessary for the sound development of market area 5 "Healthcare for lifestyle improvement, functional foods, and digital health"
  - Taking measures, etc. to stimulate demand based on scientific knowledge

### 5.4.2 Efforts

- The following efforts will be made as basic measures to capture domestic and

overseas markets for industries related to biopharmaceuticals and regenerative medicine, such as healthcare for lifestyle improvement. [IT, OHP, MS, DGSTI, CAA, MIC, MEXT, MHLW, MAFF, METI, MOE]

(1) Data-related matters

- In order to promote PHR, deliberation on matters such as digitisation of data pertaining to health check ups and medical examinations will be carried out in expert meetings, and cooperation of API and ideal rules for private businesses, etc. will be discussed. [IT, OHP, MS, MIC, MEXT, MHLW, METI]
- Building a large-scale cohort biobank of healthy individuals is set as the target that should be achieved through a step-by-step approach while reviewing the sufficient scale, etc. of the cohort as a basis for supporting global competitiveness through cooperation among the implementing entities such as a cohort of healthy individuals.<sup>54</sup> With regard to disease cohorts, efforts will be accelerated and intensified by incorporating genome-wide analysis, etc. while considering the use of a control group, and comparative analysis, etc. with the healthy subject cohort will be promoted. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
- The results of the Tohoku Medical Megabank Project, which is the foundation of a genome data infrastructure, an important infrastructure for personalised healthcare, will be advanced. [MEXT]
- By utilising the SIP and PRISM, examples of achievement through data linkage will be substantiated by fiscal 2021. [DGSTI, MEXT, MHLW, METI, MOE]

(2) Formation of a bio-community, etc.

- In collaboration among industry, academia, and government, the necessary efforts will be considered and carried out, such as the development of an international base for substantiation of development and manufacturing, involving related industries including CROs and CDMOs from within and outside of the country that support the supply chain, such as development and manufacturing, as well as the development of a data utilisation infrastructure for research and development. [OHP, DGSTI, MEXT, MHLW, MAFF, METI]

(3) System improvement, etc.

- For consumer genetic testing businesses, guidance on matters to be observed by companies providing consumer services will be prepared from fiscal 2020. [METI]
- Necessary efforts will be carried out, such as technology development and standard infrastructure that contribute to the realisation of treatment and healthcare using the microbiome. [METI]
- For foods with functional claims, scientific knowledge will be accumulated, and new labelling for health use through improvement of immune function, etc. will be realised. [CAA, MHLW, MAFF, METI]

## 5.5 Large-scale construction using wood and smart forestry

### 5.5.1 Issues and policies

- It is necessary to digitalise resources and boundary information for efficient forest administration and cost reduction, to utilise ICT for production management, and to increase productivity and safety by automating felling and transportation.
- For large-scale construction using wood to gain popularity, it is necessary to develop wooden building materials with high strength, to improve design and

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<sup>54</sup> In terms of scale, as Japan works towards a proposed million person genome cohort study, it was decided (Science Council of Japan, 26 July 2013) that “based on the current rate of disease occurrence in Japan, a number of one million persons will be set as a number which will make it possible to identify the causes of many critical illnesses”. The United States announced that it was aiming for one million or more participants, and in May 2018 the U.K. announced genome analysis for five million persons over five years.

construction techniques, etc., and to arrange the environment including human resource development.

- It is also necessary to respond to the regulations and specifications in the export destination countries, as well as the quality and other performance requirements of consumers.
- Based on these, the following measures will be implemented.
  - Developing a data infrastructure related to smart forestry, which is the basis for the development of the market area
  - Substantiating large-scale construction using wood, developing and popularising wood building materials, training designers, etc., developing standard methods, etc. for design and construction, etc.
  - Gathering the information necessary to acquire markets, including overseas markets

#### 5.5.2 Efforts

- The following efforts will be carried out as basic measures to acquire domestic and overseas markets for large-scale construction using wood and smart forestry. [MAFF, MLIT]
  - (1) Data-related matters
    - Smart forestry will be furthered by promoting the introduction of forest clouds complying with the standards, as well as ICT production control systems. [MAFF]
  - (2) System improvement, etc.
    - Substantiation of construction through leading construction using CLT, etc., human resource development, etc. will be promoted towards popularisation of large-scale construction using wood. [MAFF, MLIT]
    - A system to provide a stable supply of wood building materials with reliable quality and performance will be developed, as well as standard design and construction methods, by 2024. [MAFF]
    - The development of design and construction technologies for mixed structure buildings and the development of design standards for mid-to-high-rise buildings with a glued laminated timber structure will be promoted. [MLIT]
    - Wooden fire-retardant materials, high-strength and durable materials, etc. will be developed and popularised. [MAFF]
    - Information on laws, regulations, specifications, etc. of export destination countries will be gathered. [MAFF]

## 6 Cross-functional efforts

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### 6.1 Development of a data infrastructure for the integration of bio- and digital technologies<sup>55</sup>

#### 6.1.1 Issues and policies

- Various studies have been conducted based on past bio-strategies, and databases are scattered without coordination. Attempts to consolidate databases were made. However, without an integrated strategy with clear objectives, big data were scarcely built for innovation. As information from the industry and academia has not been gathered, we have not been able to participate in major international collaborations.
- The key to overcoming this situation is to visualise the value that is to be produced with the goal of market acquisition so that motivation to get over the cost of data linkage can be maintained.
- In line with the government's studies on standards and technologies for data linkage, the procedures specified below will be followed to visualise the value to be created by data utilisation and to explore methods for data utilisation to solve problems.
  - Clarifying the value to be created for market acquisition
  - Designing mechanisms (regulations, certifications, labelling, standards, joint development, etc.) to create value
  - Extracting issues that constitute obstacles to the realisation of mechanisms and that should be solved by using data
  - Substantiating data linkage and utilisation to solve these issues

#### 6.1.2 Efforts

- Interim compilation of the Guidelines for Linkage and Utilisation of Bio-Data (provisional title)<sup>56</sup> will be completed by the middle of 2021, and the Guidelines will be formulated by the end of fiscal 2022 based on the interim results along with substantiation. In the process of developing the Guidelines, an environment will be established that enables broad and flexible data linkage involving different sectors, while also utilising the SIP, PRISM, the life science database integration project, etc., based on the premise of common efforts for data infrastructure development and data linkage in the entire government, as set out below. [IT, OHP, DGSTI, IPSH, MEXT, MHLW, MAFF, METI, MOE]
  - Efforts of the Task Force on Digital Society<sup>57</sup>
  - Efforts of “development and international expansion of research data infrastructure” in the integrated innovation strategy
- The development of new data infrastructures and the verification and improvement of existing databases will be implemented in light of the Guidelines for Linkage and Utilisation of Bio-Data (provisional title), and this process will be based on the study of market area roadmaps, with sustainability, standardisation, international interoperability, etc. taken into account. [IT, OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]

### 6.2 Formation of bio-communities

#### 6.2.1 Issues and policies

- In the previous policy for forming regional bases, the ideal form of regional bases

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<sup>55</sup> Development of a data infrastructure refers to programs that link together various bio-related databases.

<sup>56</sup> These Guidelines establish standard procedures and other matters when conducting studies for the market area roadmaps and for data linkage and utilisation between different market areas.

<sup>57</sup> This is an organisation composed of related government ministries and agencies and established based on the framework of the Council for Integrated Innovation Strategy. It studies the optimisation of system design based on system links and data circulation spanning multiple fields for the IT programs that are carried out by each government ministry to accelerate social innovations through digitization.

and related issues were not fully discussed, all initiatives were devised only within the limited resources (human resources, financial resources, etc.) of an individual city or research institution, resulting in inadequate collaboration. Consequently, diverse resources were not combined, internationally competitive initiatives were not carried out to a sufficient extent, and excellent efforts were not demonstrated for companies and investors, making it impossible to carry on investment in the biotechnology field.

- Key challenges for the formation of a global bio-community have been identified as follows:
  - Research and development organisations: Due to the small scale of research and development organisations, securing internationally competitive human resources, maintaining the research environment, developing research support systems, and securing positions for young researchers are not sufficient, and the integration of different disciplines is not progressing either. Only a limited number of persons have expertise in contracts and intellectual property in the biotechnology field, and the ability to make investment proposals to investment funds and companies is low.
  - Incubation agencies: With limited liquidity in tenants, support for ventures is insufficient. Still in their infancy, incubation agencies have much room for improvement when viewed with an experienced eye. It is necessary to shore up cooperation between incubation agencies and their overseas counterparts.
  - Investment fund institutions: Only a few biotech investment funds have earned credibility with institutional investors. There is a paucity of human resources capable of evaluating the scientific aspects of the biotechnology field. While priority is given to starting up a business in a short period of time, the development of the seeds necessary for the biotechnology field can take a long time and establishment of exit strategies is insufficient. Moreover, experience raising funds in overseas countries is lacking.
  - Companies: The ability to discern seeds in the biotechnology field should be improved further.
  - Agencies substantiating bio-production: Facilities undertaking substantiation in the biotechnology field are lacking, and no adequate human resources have been fostered for bio-production.
  - Networking agencies: Apart from research and development organisations, incubation agencies, investment fund institutions, companies, ventures, and agencies substantiating bio-production, no other organisations exist that play a coordinating role to create communities, including local governments that support community planning, etc.
- With regard to the formation of medium- and small-scale bio-communities, there are still many issues to be addressed, such as promoting collaboration between local research and development organisations and local companies, and it is necessary to clarify the market areas that each region should focus upon in the future.
- Based on these, the following measures will be implemented.
  - Presenting the ideal picture of the bio-community in 2030
  - Recognising the achievements, etc. of local communities engaged in the formation of bio-communities towards the ideal picture
  - Promoting collaboration within and between bio-communities and proactively offering information at home and abroad to create a brand for each bio-community
  - Assessing and accrediting the maturity of individual organisations within each bio-community, and implementing mutual cooperation within each bio-community to facilitate growth

## 6.2.2 Ideal picture of the bio-community in 2030

- In the ideal picture of the bio-community, the bio-first mindset should be ingrained in citizens, and each market area should be developed as each bio-community functions effectively, with successful networking among global bio-communities and local bio-communities as described below. With our country playing a part in the global market, the bioeconomy will expand, and a sustainable “Society 5.0” will become a reality.

### (1) Global bio-communities:

- Seeds will be smoothly commercialised through collaboration between world-state-of-the-art research and development organisations and other organisations and companies with development functions such as bio-production systems. Acting as a catalyst for access to global data, human resources, investment, and research, global bio-communities will be recognised by the world as one of the bio-innovation hubs.
- This should be the world’s most advanced development base for bio-production systems and bio-related analysis, measurement, and experiment systems, which are fundamental market areas in the biotechnology field. Internal and external markets will be expanded by developing several other markets.
- There should be core hospitals that can provide specimens, cells, and medical information essential for research and development in the healthcare field and form a network with surrounding research and development organisations.
- The organisations that make up the global bio-communities will be as follows:
  - Research and development organisations: There should be large, world-state-of-the-art research and development organisations, including those with an international competitive edge.
  - Incubation agencies: Incubation agencies should provide experimental equipment, research support personnel, etc. to help smoothly turn ideas into reality.

A system will be established to provide commercialisation support, regulatory consultation, etc. A venue for people who form the bioeconomy to meet and form a community will be provided, as well as a function to cultivate the human resources necessary for the commercialisation of bioeconomy. The ability to discern seeds should function effectively, with a healthy turnover of tenants.
  - Investment fund institutions: There should be persons who understand the science of each field (healthcare, industry, agriculture, environment, etc.) and who can raise funds from domestic and overseas institutional investors to play an active role.
  - Companies: Markets will be expanded at home and abroad by promoting market areas, open innovation, and ESG investment. There will also be an increase in employment.
  - Ventures: The goal is not to increase market capitalisation or to go public; there should be a substantial increase in total sales and investment in venture businesses, together with a constant turnover of stakeholders.
  - Agencies substantiating bio-production: A sustainable business model will be established, and by conducting research and development in tandem with research and development organisations, agencies substantiating bio-production will provide the data and technology bases necessary for bio-production, thereby producing results that contribute to market expansion. Agencies substantiating bio-production will also develop human resources for data-driven bio-production.

- Networking agencies: Networking agencies will take on the role of coordination within the bio-community, promote cooperation between organisations, and formulate initiatives to develop the region and enhance the branding capability of the region. Being recognised as a contact point for building relationships including overseas, networking agencies will function effectively.

## (2) Local bio-communities

- The market area of the bio-strategy will be expanded through cooperation between local companies, agriculture, forestry, and fishery businesses and research and development organisations such as local universities, which will lead to forays into the global market. The regional economy will also be revitalised by job creation, etc.
- In regions targeting the development of market area <sup>58</sup> or <sup>60</sup>, there should be core hospitals that can provide essential specimens, cells, and medical information for research and development in the healthcare field and form a network with surrounding research and development organisations.
- The organisations that make up the local bio-communities will be as follows:
  - Research and development organisations: Research and development organisations with a global competitive edge will help local companies to enter the global market by furnishing seeds, human resources, etc.
  - Incubation agencies: Incubation agencies should provide experimental equipment, research support personnel, etc. to help smoothly turn ideas into reality. Through networking with global bio-communities, a system will be established to provide commercialisation support, regulatory consultation, etc. A venue for people who form the bioeconomy to meet and form a community will be provided, as well as a function to cultivate the human resources necessary for the commercialisation of bioeconomy.
  - Companies, etc.: Local companies and agriculture, forestry, and fishery businesses, etc. will actively cooperate with research and development organisations to make forays into the global market. An increase in employment in the region will result.
  - Ventures: In the presence of research and development bases or substantiating bases in the region, the network with global bio-communities will be utilised for the full-scale commercialisation, and ventures will advance into the world market and play an active role. Ventures will also contribute to local employment growth.
  - Networking agencies: Networking agencies will take on the role of coordination within the bio-community, promote cooperation between organisations, and formulate initiatives to develop the region and enhance the branding capability of the region. Being recognised as a contact point for building relationships including overseas, networking agencies will function effectively and promote collaboration with networking agencies in the global bio-community to connect with global markets.

### 6.2.3 Efforts

- A preliminary survey<sup>60</sup> will be conducted to assess the future plan of the bio-community with a clearly defined market area to work on, the structure of

<sup>58</sup>Healthcare for lifestyle improvement, functional foods, digital health

<sup>59</sup>Industries related to biopharmaceuticals, regenerative medicine, cell therapy, and gene therapy

<sup>60</sup> As one part of this investigation, a feasibility study will be conducted on candidates for the International Bio-community that was presented in Bio-Strategy 2019. The study will cover the research and development organisations, incubation agencies, investment fund institutions, companies, etc., venture enterprises, agencies substantiating bio-production, industry associations, local governments and other entities necessary for the formation of a bio-community.

networking organisations, and the status of the accumulation and performance of the necessary organisations such as companies, etc. (including infrastructure development and human resource development), and then global bio-communities (two regions or so)<sup>61</sup> and local bio-communities (several cities) will be designated (executed on a trial basis in 2021, followed by full-scale operation in 2022)<sup>62</sup>. Until fiscal 2030, we will provide the necessary comprehensive support to attract private investment while shoring up cooperation among the relevant government entities, including financial support (e.g., loans and investments), regulatory reform, commercialisation support, and the dissemination of information in Japan and overseas<sup>63</sup>. The implementation status will be summarised and disclosed. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]

- A committee (hereinafter, “the Committee”) undertaking designation review and the formulation of designation requirements for global and local bio-communities will be organised by economic organisations, industry associations, academia, members of the advisory council, etc., and will be run in cooperation with relevant government entities. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
- The preliminary survey, designation, and support will be implemented in accordance with the following particulars, in coordination with the study and promotion of the market area roadmap and the efforts of startup ecosystem core cities (global core cities and promotional core cities).

(1) Global bio-communities:

- Preliminary survey
  - The survey will be conducted using a comparison with foreign counterparts by targeting the Tokyo and Kansai regions, which are assumed to be candidate regions for global bio-community designation (hereinafter, “global bio-community candidate regions”) where the world’s most advanced research organisations in the biotechnology field are concentrated, where there are many university-led ventures in the biotechnology field, and where the largest impact of the collaborative efforts can be expected at present. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
- Designation
  - After regional applications and subsequent review by the Committee, global bio-communities will be designated from among regions that include a startup ecosystem (global core city), have a considerable number of world-class research organisations in the biotechnology field, and have many university-led ventures in the biotechnology field<sup>64</sup>. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
- Support
  - The right to use a logo will be granted to the designated regions, and the visibility of the global bio-community’s activities will be increased by the dissemination of information by the government, etc. in Japan and overseas. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
  - Growth will be supported on an ongoing basis through opinion exchanges between the government and the global bio-community. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
  - Support for the formation of an independent base for industry-academia co-creation in the biotechnology field will be started this fiscal year so that results can be produced constantly in the global bio-community candidate regions. [MEXT]

<sup>61</sup> This refers to the International Bio-community in Bio-Strategy 2019

<sup>62</sup> Regular assessment and designation

<sup>63</sup> To be carried out while reinforcing collaboration with existing related programs.

<sup>64</sup> 3 stages are expected: system construction, presentation of results, and international designation.

- Full-fledged support will begin in fiscal 2021 for the establishment of a base for substantiation of bio-production and human resource development in the global bio-community candidate regions so that gene modification technologies and innovative bio-production technologies can be developed in an integrated fashion on the initiative of the private sector along with industry-academia collaboration. [METI]
  - Based on the study of the market area roadmap, etc. for industries related to biopharmaceuticals and regenerative medicine such as healthcare for lifestyle improvement, the development of an international base for substantiation of development and manufacturing will be considered and carried out, involving related industries including CROs and CDMOs from within and outside of the country that support the supply chain, such as research and development, in collaboration among industry, academia, and government. [OHP, DGSTI, MEXT, MHLW, MAFF, METI]
  - An agri-bio base will be constructed as a hub for the development of a sustainable primary production system, etc. with concerted efforts of the private and public sectors. [MAFF]
- (2) Local bio-communities
- Preliminary survey
    - The survey will be conducted by inviting applicants from cities, etc. that have a willingness to collaborate with industries, local companies, agriculture, forestry, and fishery businesses, etc. related to the market area of the bio-strategy and research and development organisations such as local universities, and to acquire and expand overseas markets, and are expected to benefit from efforts related to collaboration. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
  - Designation
    - Local bio-communities will be designated after filing of applications from cities, followed by review by the Committee<sup>65</sup>. With regard to requirements for designation, emphasis will be placed upon collaboration between local companies, agriculture, forestry, and fishery businesses, etc. and research and development organisations such as local universities, acquisition and expansion of overseas markets, effective utilisation of various government policies, etc. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
  - Support
    - The right to use a logo will be granted to the designated cities, and the visibility of the local bio-community's activities will be increased by the dissemination of information by the government, etc. in Japan and overseas [DGSTI]
    - Growth will be supported on an ongoing basis through opinion exchanges between the government and local bio-community. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
    - An agri-bio base will be constructed as a hub for the development of a sustainable primary production system, etc. with concerted efforts of the private and public sectors. [MAFF]
    - Relevant government entities will work together to promote measures that contribute to the formation of local bio-communities (sharing good examples of efforts based on the Basic Plan for Promotion of Practical Use of Biomass, a venue for accumulating and utilising knowledge, the formation of a regional recycling and symbiotic community, a cohort of

<sup>65</sup> 3 stages are expected: system construction, presentation of results, and entry into overseas markets.

- healthy individuals in the region, etc., and promoting collaboration)<sup>66</sup>. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
    - In response to requests from local governments, support will be provided through the participation of local governments in the study of market area roadmaps, and advice on the formulation of a regional revitalisation plan<sup>67</sup>. [OHP, DGSTI, MEXT, MHLW, MAFF, METI, MOE]
- Within each bio-community, the particulars set out below will be followed to carry out assessment, accreditation, etc. of individual organisations, thereby promoting branding and development hand in hand.
  - Networking agencies will assess and accredit the maturity of individual organisations in each bio-community on a scale of three or so, and growth will be supported through mutual cooperation within each bio-community.
  - The assessment and accreditation of individual organisations by networking agencies will be carried out periodically on the basis of the guidelines specified by the Committee and the requirements set by each bio-community from the perspective of contribution to the market area, open innovation based on the characteristics of the biotechnology field, community-forming activities, ESG investments and activities, etc.
  - Support will be provided to the organisations that have been accredited by the networking agencies by granting the right to use a logo, disseminating information in Japan and overseas, and requesting that the private sector promotes investments.
- A green finance system will be examined and established for ESG investment, etc. in the biotechnology field in order to improve the funding environment based on the characteristics of this field. [METI]
- A guidebook will be prepared to provide guidance for drug discovery bioventures to go ahead with the disclosure of non-financial information needed from the standpoint of investors. [METI]
- A forum for the industry, academia, government to discuss the handling of intellectual property in industry-academia collaboration based on the characteristics of the biotechnology field will be established by the end of fiscal 2020. [DGSTI, IPSH, MEXT, METI]
- A system to cultivate bio-related data scientists taking on the integration of bio- and digital technologies at a base for substantiation of bio-production and human resource development, etc. will be established by fiscal 2021, by defining the character of the persons sought and setting a development goal<sup>68</sup> according to the character. [DGSTI, MEXT, METI]

## 6.3 Other cross-functional efforts

### 6.3.1 Issues and policies

- Cross-functional efforts have been made steadily in line with Bio-Strategy 2019.

### 6.3.2 Efforts

- The efforts laid out in Sections 4.4 and 4.6 to 4.9 of Bio-Strategy 2019 will be further promoted<sup>69</sup>. [All relevant ministries and agencies]

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<sup>66</sup>The support measures of related government entities vary depending on the efforts of individual local bio-communities and include not only carrying out projects but also promoting collaboration, providing advice and other actions achieved by utilising the results from past projects.

<sup>67</sup> This is a plan aimed at achieving the regional revitalisation described in Article 5 of the Local Revitalization Act (Act No. 24 of 2005).

<sup>68</sup> The number of required persons will be decided for each category of human resources after first identifying and considering the expected supply-demand balance for human resources.

<sup>69</sup> These are the efforts in Sections 4.4 (Enhancing the start-up and investment environment), 4.6 (Improvement of research and development and human resource development), 4.7 (Protection of intellectual property and genetic resources), 4.8 (Improving international strategies), and 4.9 (Addressing Ethical, Legal, and Social Issues (ELSI)).



## 7 Enhancing the strategic command function

### 7.1 Policy

- The bio-strategy will continue to be implemented until at least 2030.
- To step up the strategic command function of the Council for Integrated Innovation Strategy, the Bio-Strategy Task Force<sup>70</sup> and the Bio-Strategy Advisory Council will be established as permanent bodies under the framework of the Council for Integrated Innovation Strategy.
- The promotion and follow-up of the strategy will be discussed utilising domestic<sup>71</sup> and overseas information<sup>72</sup> provided by relevant organisations, as well as information obtained from international organisations.
- The health and medical care strategy, AI strategy, quantum technology innovation strategy, and progressive environmental innovation strategy will be promoted in tandem with the bio-strategy.
- The bio-strategy will be pushed forward through evaluation of the overall objectives, promotion and updating of the market area roadmap, designation of bio-communities, and formulation of various guidelines in a mutually coordinated fashion, as shown in the figure.

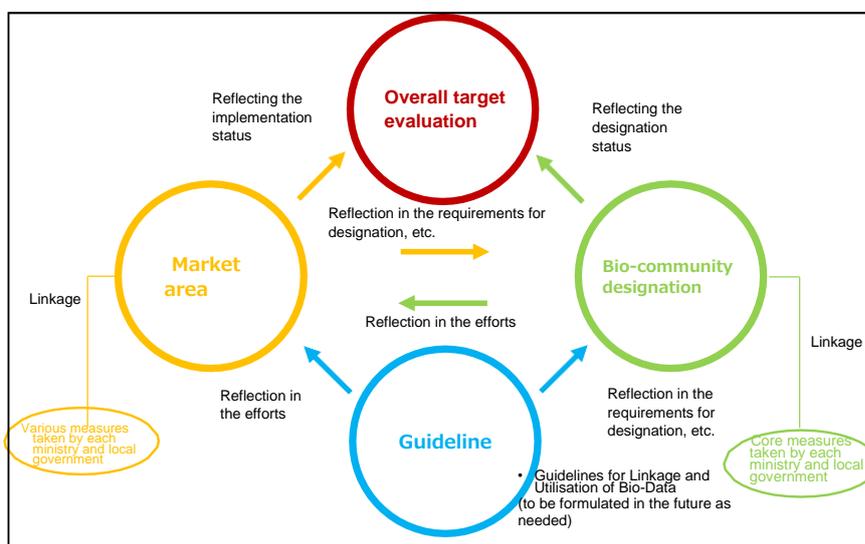


Figure. Schema of bio-strategy promotion

### 7.2 Evaluation of overall objectives

#### (1) Overview

- Evaluation of the overall objectives will be carried out from quantitative and qualitative aspects at the advisory council. [DGST]
- A schedule for evaluating the overall objectives will be worked out by mid-fiscal year 2021. [DGST]

#### (2) Quantitative evaluation

- With the participation of industry associations, etc., the Bio-Strategy Task Force will deliberate on specific evaluation methods, including a system, method, and frequency of identification of the indices to be used for quantitative evaluation, and the advisory council will make decisions on specific evaluation methods by mid-fiscal year 2021. [OHP, DGST, MAFF,

<sup>70</sup> This organisation is responsible for formulating, implementing and conducting follow-up of bio-strategies that were established based on the framework of the Council for Integrated Innovation Strategy. It is composed of the innovation-related command headquarters offices and related government entities.

<sup>71</sup> Information regarding domestic and overseas policy trends, market trends, regulatory trends and related matters is provided by the JST Center for Research and Development Strategy, NEDO Technology Strategy Center, NITE, AMED, NARO, JETRO, JICA and other organisations.

<sup>72</sup> OECD, WHO, FAO, etc.

METI]

<Examples of the indices>

- Size of Japan's bioeconomy market (estimated domestic production equivalent [including exports] and overseas production equivalent of Japanese companies)
- Market size of each market area<sup>73</sup>
- Amount of investments in the biotechnology field
- Number of persons employed in the biotechnology field
- International collaboration (number of companies participating in major biotechnology trade shows abroad)
- Corporate awareness of the bio-strategy (number of companies taking part in the global and local bio-communities)

### (3) Qualitative evaluation

- With the participation of industry associations, etc., the Bio-Strategy Task Force will deliberate on specific evaluation methods, including a system, method, and frequency of identification of the information to be used for qualitative evaluation, and the advisory council will make decisions on specific evaluation methods<sup>74</sup> by mid-fiscal year 2021. [OHP, DGSTI, MAFF, METI]

<Examples of the information>

- Status of assessment and accreditation of each organisation by the networking agencies for global and local bio-communities
- Progress of the market area roadmap

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<sup>73</sup> Use of data used for follow-up of each market area roadmap

<sup>74</sup> This is expected to be an assessment from the perspectives of a bio-first mindset, formation of a bio-community, and a bio-data-driven society.

List of abbreviations

Abbreviation	Full term
3R	Reduce, Reuse, Recycle (Reduce, Reuse, Recycle)
AI	Artificial Intelligence (Artificial Intelligence)
AMED	Japan Agency for Medical Research and Development (Japan Agency for Medical Research and Development)
API	Application Programming Interface (Application Programming Interface)
BSL	Bio Safety Level (Bio Safety Level)
CDC	Centers for Disease Control and Prevention (Centers for Disease Control and Prevention)
CDMO	Contract Development and Manufacturing Organisation (Contract Development Manufacturing Organization)
CEPI	Coalition for Epidemic Preparedness Innovations (Coalition for Epidemic Preparedness Innovations)
CLT	Cross Laminated Timber (Cross Laminated Timber)
CRO	Contract Research Organisation (Contract Research Organization)
ELSI	Ethical, Legal, and Social Issues (Ethical, Legal and Social Issues)
FAO	Food and Agriculture Organisation of the United Nations (Food and Agriculture Organization of the United Nations)
GDPR	General Data Protection Regulation (General Data Protection Regulation)
ICT	Information and Communication Technology (Information and Communication Technology)
IT	Information Technology (Information Technology)
JETRO	Japan External Trade Organisation (Japan External Trade Organization)
JST	Japan Science and Technology Agency (Japan Science and Technology Agency)
KPI	Key Performance Indicator (Key Performance Indicator)
NARO	National Agriculture and Food Research Organisation (National Agriculture and Food Research Organization)
NEDO	New Energy and Industrial Technology Development Organisation (New Energy and Industrial Technology Development Organization)
NITE	National Institute of Technology and Evaluation (National Institute of Technology and Evaluation)
PHR	Personal Health Record (Personal Health Record)
PRISM	Public/Private R&D Investment Strategic Expansion Program (Public/Private R&D Investment Strategic Expansion Program)
SDGs	Sustainable Development Goals (Sustainable Development Goals)
SIP	Cross-ministerial Strategic Innovation Promotion Program (Cross-ministerial Strategic Innovation Promotion Program)

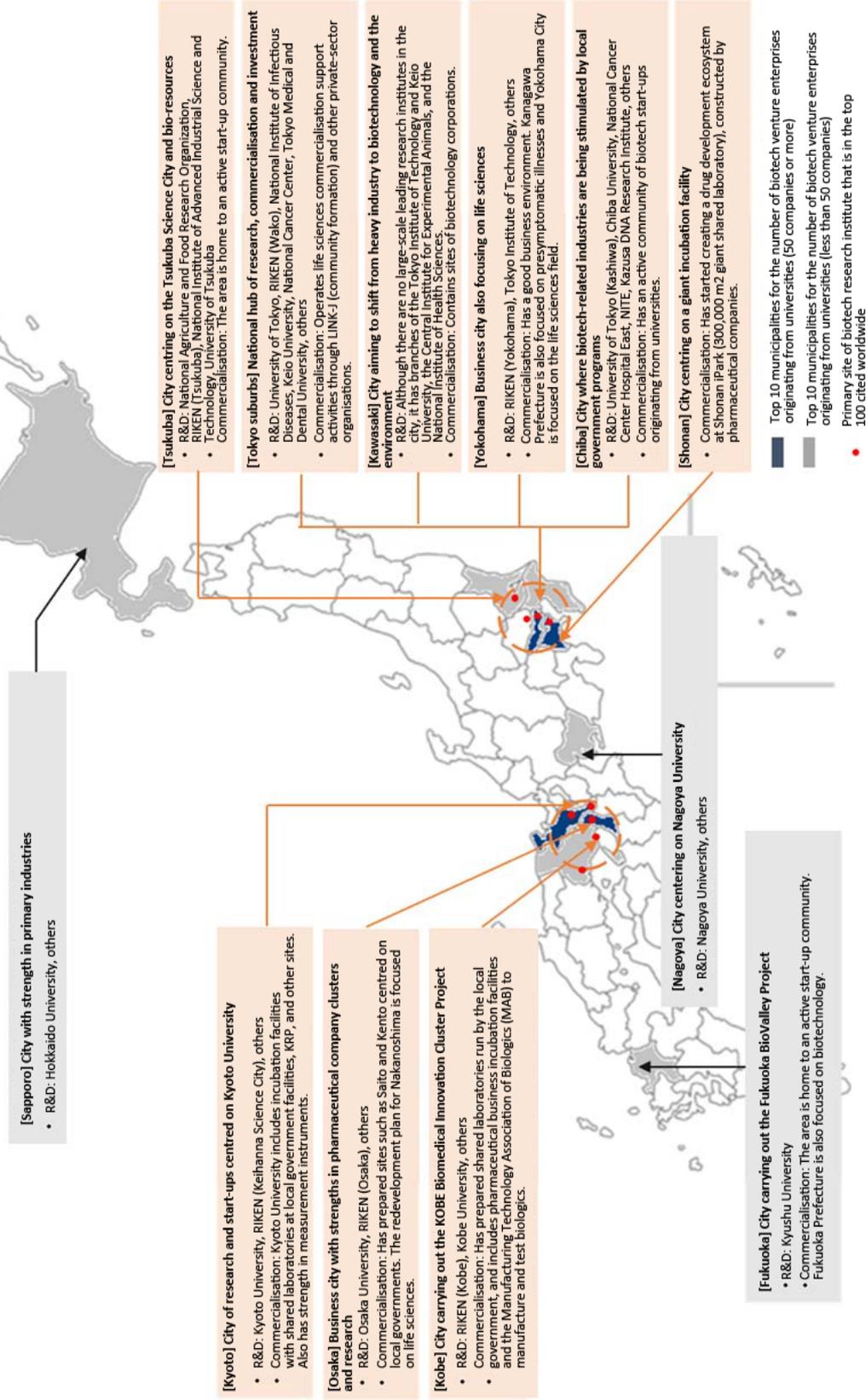
TLO	Technology Licencing Organisation (Technology Licensing Organization)
WHO	World Health Organisation (World Health Organization)

The abbreviated names of ministries and agencies used in the square brackets in Chapters 4 to 7 are as follows (underlined are the ministries and agencies responsible for compiling and following up market area roadmaps, linkage and utilisation of bio-data, formation of bio-communities, or evaluation of overall objectives).

Abbreviation	Name of ministry or agency	
IT	Cabinet Secretariat	National Strategy Office of Information and Communication Technology
OPINIDPR		Office for Pandemic Influenza and New Infection Diseases Preparedness and Response
OHP		Office of Healthcare Policy
COMEID		Coordination Office of Measures on Emerging Infectious Diseases
ONCDC		Office for Novel Coronavirus Disease Control
MS	Cabinet Office	Minister's Secretariat
DGSTI		Director General for Science, Technology, and Innovation
IPSH		Intellectual Property Strategy Headquarters
CAA		Consumer Affairs Agency
OAMED		Office for Japan Agency for Medical Research and Development (AMED) and Medical Information Infrastructure
MIC	Ministry of Internal Affairs and Communications	
MOFA	Ministry of Foreign Affairs	
MEXT	Ministry of Education, Culture, Sports, Science and Technology	
MHLW	Ministry of Health, Labour and Welfare	
MAFF	Ministry of Agriculture, Forestry and Fisheries	
METI	Ministry of Economy, Trade and Industry	
MLIT	Ministry of Land, Infrastructure, Transport and Tourism	
MOE	Ministry of the Environment	

# [Reference] Examples of data for global bio-community candidate sites

The two possible city area that have potential for collecting the necessary functions within a 100 km area are the Tokyo Metropolitan Area and Kansai Metropolitan Area.



Created using data from Reference Material – 288 Benchmarking Research Capability of Universities in Japan, the United Kingdom and Germany 2019 (National Institute of Science and Technology Policy, Ministry of Education, Culture, Sports, Science and Technology), and data from the Report of the FY 2019 Survey on Industrial Technology (Investigation of Venture Enterprises Originating from Universities) (Ministry of Economy, Trade and Industry).