

(Tentative Translation)

Report from the Government of Japan

Concerning the Recommendations of
the Japan-EU Business Round Table (BRT)

July 2024

Note: The information in this report is based on the situation as of 30 June 2024.

This Progress Report is made in Japanese and translated into English. The Japanese text is the original and the English text is for reference purposes. If there is any conflict or inconsistency between these two texts, the Japanese text shall prevail.

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Working Party 1: Trade Relations; Investment and Regulatory Cooperation; Financial Services, Accounting and Taxation

WP-1 / #01* / EJ to EJ: Strengthening the EU-Japan Economic Relationship Post-EPA

Enhancing Regulatory cooperation

The Government of Japan and the European Commission held the fifth meeting of the Specialised Committee on Regulatory Cooperation in February 2024 to exchange views on cooperation on offshore wind power and on new EU regulations such as the Ecodesign Regulation, the Carbon Border Adjustment Mechanism (CBAM) and the F-Gas Regulation and confirmed they would continue promoting regulatory cooperation between Japan and the EU.

On 1 July 2024, the ‘Protocol Amending the Agreement between Japan and the European Union for an Economic Partnership’ on the inclusion of ‘provisions on the free flow of data’ into the Japan-EU EPA will enter into force. This is expected to ensure predictability regarding cross-border data flow and contribute to the promotion of data flow between Japan and the EU and thus strengthen economic relations.

The Government of Japan and the European Commission will continue to promote discussions on regulatory cooperation under the Japan-EU EPA.

Encouraging the use of EU-Japan EPA, particularly by SMEs

The Ministry of Economy, Trade and Industry (METI) and the Japan External Trade Organization (JETRO) are promoting the utilisation of the Japan-EU EPA by using their official websites to provide relevant information, including information provided from the EU side. To this end, METI and JETRO also hold briefing seminars and workshops in Japan and abroad as well as online, set up consultation centres, publish and distribute brochures and handbooks, and publicise through YouTube, web ads and SNS (Social Networking Service). The website of the Ministry of Foreign Affairs (MOFA) provides a list of useful information with Internet links dubbed as ‘Related Information on SMEs (Japan-EU EPA Chapter 20)’ to encourage SMEs to utilise the EPA.

To promote greater convenience through digitalisation, METI developed a free Excel tool, which has been offered through JETRO to assist with certificates of origin and other documents for trade agreements including the Japan-EU EPA, while conducting demonstration of a digital platform to provide SMEs with simple low-cost access to the EPA.

Joint investment in 3rd countries

The Government of Japan has stated that it aims to mobilise more than USD 65 billion for infrastructure support and private finance by 2027 under the G7 Partnership for Global Infrastructure and Investment (PGII) that the EU also participates in and will continue to promote quality infrastructure investment in cooperation with the EU.

The EU's Global Gateway is also an important contribution to the PGII, as it is an initiative to

mobilise actively private investment for sustainable development across the world. As reaffirmed at the Japan-EU Summit in July 2023, the Government of Japan will continue to work closely with the EU in this area under the ‘Japan-EU Partnership on Sustainable Connectivity and Quality Infrastructure’.

Promoting the free flow of data

On 1 July 2024, the ‘Protocol Amending the Agreement between Japan and the European Union for an Economic Partnership’ on the inclusion of ‘provisions on the free flow of data’ into the Japan-EU EPA will enter into force. It is expected to ensure predictability regarding cross-border data flow and contribute to the promotion of data flow between Japan and the EU and thus strengthen their economic relations.

It is also expected to contribute to the realisation of ‘Data Free Flow with Trust (DFFT)’ advocated by Japan as a model for advanced digital trade rules that promote the healthy development of the digital sector, a growth engine of the 21st century.

WP-1 / #02* / EJ to EJ: Recommendations for an ambitious multilateral trade agenda toward the next WTO Ministerial Conference

The Government of Japan is working on maintaining and strengthening the WTO regime through the reforms of all its functions, including the dispute settlement system (DS), negotiation function and deliberation function. At MC13, WTO Members reaffirmed the need to realise the restoration of the DS function by this year. With regard to the Joint Statement Initiatives (JSIs), progress was made, with the announcement of the substantial conclusion of 13 articles on e-commerce in December 2023, the declaration of the conclusion of negotiations on Investment Facilitation for Development, and the completion of the certification procedure of disciplines on the services domestic regulations for Japan, both in February 2024. An extension of the moratorium on the imposition of customs duties on electronic transmissions was decided at MC13. Based on these efforts and achievements, and with a view to MC14, the Government of Japan will continue to work on maintaining and strengthening a multilateral trading system, with the WTO at its core, including through utilising forums such as the G7 Trade Ministers' Meeting.

WP-1 / #03* / EJ to EJ Application of international standards and enhanced regulatory cooperation

1. Create a common chemicals regulation

The EU and Japanese regulatory authorities exchange views and information on regulatory cooperation at meetings of the Japan-EU Industrial Policy Dialogue Working Group on Chemicals. Most recently, in February 2024, the two sides held an update and exchange information and views on chemical management regulations. Both sides will continue sharing information and exchanging opinions on chemicals management. Japan will also seek to boost cooperation with the EU based on

international schemes such as the OECD Test Guidelines, OECD Principles of Good Laboratory Practice (GLP), Mutual Acceptance of Data (MAD), the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and the Stockholm Convention on Persistent Organic Pollutants.

2. Create a common resource efficiency policy

The Government of Japan will continue to contribute to international cooperation on energy efficiency through organisations that include working groups introducing best practices in energy efficiency policies and regulations under the framework of the Energy Efficiency Hub initiated by the International Energy Agency (IEA), and other programmes. In addition, efforts are being made in ISO/TC 323 for the international standardisation of the circular economy, and the Government of Japan will continue to collaborate with the European Commission on promoting international standardisation. The Government of Japan will also promote the development of standards and specifications both domestically and internationally in order to promote the use of recycled materials, renewable resources and other circular resources through the collaboration between arterial and venous industries.

3. Expand the benefits of AEOs

A relaxation of the handling of some collateral is scheduled to be implemented for authorised economic operator (AEO) importers from October this year. To further simplify customs procedures for AEOs, the Government of Japan will continue to explore feasible improved measures for specific issues facing the operators by collecting views and information exchanged between the public and private sectors.

4. Adoption of UN Regulations and promotion of regulatory cooperation in the automobile sector

The Government of Japan has cooperated with the European Commission in formulating international regulations in the World Forum for Harmonization of Vehicle Regulations (WP.29) under the United Nations Economic Commission for Europe. As Vice-Chair of WP.29 from 2023, Japan will cooperate with Italy, the current Chair of WP.29, to make further contributions on establishing globally harmonised technical regulation at WP.29. Toward realising carbon neutrality, Japan will work with the European Commission and the Japanese and European automobile industries to advance the discussions on developing a Life Cycle Assessment (LCA) in the automobile sector, taking carbon neutral fuels into consideration. The Government of Japan will continue to promote the international harmonisation of automobile regulations at WP.29 while working to ensure automobile safety and protect the environment in Japan.

5. Sanitary and phytosanitary regulation

Sanitary and phytosanitary measures are taken based on scientific evidence for the protection of human, animal or plant life or health in both Japan and the EU.

The Government of Japan and the European Commission confirmed their continued cooperation regarding sanitary and phytosanitary measures at expert level in the fifth meeting of the Specialised Committee on Sanitary and Phytosanitary Measures in December 2023.

Both sides will continue science-based discussions to achieve the objective of expanding food and beverage exports.

6. Electrical products

The Government of Japan recognises the importance of international harmonisation in this context, although it is difficult to achieve complete international harmonisation because of the existence of fundamental technological or infrastructural problems unique to Japan and the need to prevent harm and damage caused by electrical products. In considering the harmonisation of both systems through introducing international standards into the Japanese system as far as possible, the Government believes it is essential to deepen the discussion on the ‘goal’ pointed out by the BRT.

WP-1 / #05* / EJ to EJ Achieve climate neutrality

The Government of Japan has contributed to discussions on climate neutrality in the WTO Committee on Trade and Environment (CTE) and Trade and Environmental Sustainability Structured Discussions (TESSD) of the WTO Volunteer Groups. While there are also moves towards the introduction of Carbon Border Adjustment Mechanism (CBAM) outside the EU, the Government of Japan will continue to promote discussions at the WTO on the consistency of their measures with WTO rules and their impact on economic activities, including from the perspective of interoperability of multiple trade-related climate measures. The Government of Japan will also promote discussions on approaches to promote trade in goods manufactured in an environmentally friendly manner.

In addition, the way the measures should operate and the need for practical coordination for the upcoming CBAM secondary legislation to be announced will be discussed continuously and constructively under the Japan-EU Green Alliance.

Ensuring close communication on carbon pricing, including its treatment, will continue to be discussed with WTO member states, including the EU, at the WTO's CTE, TESSD and other relevant meetings.

The development of inter-regional grids and of interconnected grids within each area are important for the mass introduction of renewable energy and the strengthening of electricity resilience. In the future, measures will be taken for the systematic development of the inter-regional interconnected grids, based on the ‘master plan’ for the inter-regional interconnected grids and other relevant documents.

With respect to offshore wind power, the Government of Japan will work to develop next-generation technologies based on the domestic and international development of bottom-mounted and floating-type wind farms as well as Japan’s characteristics, strengths, and other conditions. The Government of Japan will encourage intergovernmental cooperation and collaboration between Japanese and

international corporations and proceed to establish a globally harmonised method for evaluating the safety of floating-type wind farms. In June 2024, the Government of Japan and the European Commission also held a Japan-EU Hydrogen Business Forum and confirmed they would establish a Japan-EU Clean Energy Industry Policy Dialogue. In the future, the Government of Japan and the European Commission will strengthen their cooperation on building a robust supply chain in the clean energy sector, including solar, wind and hydrogen. In addition to such bilateral cooperation, the Government of Japan will make maximum use of multilateral cooperation frameworks such as the International Partnership for Hydrogen and Fuel Cells in the Economy (IPHE), and actively work towards creating international standards to make new technologies easier to use across the world.

WP-1 / #06* / EJ to EJ Recommendations on the BEPS Action Plan and Other Tax Issues

BEPS Action Plan

Japan and the EU countries have played central roles in the Base Erosion and Profit Shifting (BEPS) Project to promote a level playing field and improve tax certainty. The BEPS Project is currently in its implementation phase, and the Government of Japan is contributing significantly to expanding the number of countries and jurisdictions joining the OECD/G20 ‘Inclusive Framework on BEPS’ (with more than 140 members joining the framework so far).

In response to the project’s recommendations, the Government of Japan has given due consideration to the potential compliance costs for businesses as well as predictability for compliant taxpayers through hearings with the business community and relevant authorities when designing its domestic tax systems and relevant procedures.

The Government of Japan will continue to explore a system for preventing aggressive tax planning by multinational enterprises, while seeking opinions from the business community in order to effectively implement the agreed measures.

The Government of Japan hopes to make continuous effort to resolve advance pricing agreement (APA) cases effectively and efficiently through bilateral and multilateral negotiations, thereby avoiding double taxation between Japan and the EU member states.

Japan will maintain cooperation with its international counterparts, including the EU, to fully implement the BEPS package in a timely, consistent, and comprehensive manner as it addresses the remaining challenges with a view to ensuring a level playing field.

Other tax issues

The Government of Japan recently lowered the statutory corporate income tax rate to its 20-percent target range following the FY2016 Tax Reform and will monitor the effects of the reduction. In the FY2020 Tax Reform, the Government of Japan established a ‘consolidated tax payment system’ after simplifying and revising the consolidated taxation system, from the perspective of reducing companies’ administrative workload and creating a business environment for companies to make group management more efficient and fully demonstrate their competitiveness.

The Government of Japan will also continue to actively expand its tax treaty network with the EU member states to further promote investments and economic exchanges between Japan and the EU by eliminating double taxation through the reduction of investment income taxation by the source countries and the introduction of arbitration proceedings.

To address the tax challenges arising from the digitalisation of the economy, an agreement on the Two-Pillar Solution was reached at the OECD/G20 ‘Inclusive Framework on BEPS’ in October 2021. The Government of Japan will continue to contribute to the ongoing international discussions as well as carrying out necessary considerations towards amending of domestic laws in accordance with the agreement.

WP-1 / #07* / EJ to EJ Economic security

On economic security, the Government of Japan attaches great importance to cooperation with like-minded countries, including the EU. At the Japan-EU High Level Economic Dialogue in October 2023, the two sides exchanged views on recent developments in dealing with economic coercion, building resilient supply chains, export controls, etc., and concurred to establish a technical-level ‘Working Group on international collaboration on policies for building more transparent, resilient and sustainable supply chains’ and have been exchanging views through this working group. At the Japan-EU High Level Economic Dialogue in May 2024, both sides exchanged views on their respective approaches to economic security and launched the ‘Transparent, Resilient and Sustainable Supply Chains Initiative’ to address strategic dependencies and structural vulnerabilities and to work together to ensure resilient and reliable global supply chains.

At the G7 Apulia Summit held from 13 to 15 June 2024, the G7, including the EU, also confirmed that they will continue to work together on issues related to overcapacity and non-market policies and practices, addressing economic coercion, enhancing supply chain resilience and the protection of critical and emerging technologies.

The Government of Japan will continue to work closely with the EU in the international fora, including the G7 and the WTO, as well as with like-minded partners, including the EU, to address economic security challenges through public and private sector cooperation.

WP-1 / #08* / E to J Human rights and supply chains

In October 2020, the Government of Japan formulated a five-year Action Plan on Business and Human Rights to ensure consistency in the policies of relevant ministries and agencies on business and human rights, to promote responsible corporate behaviour and to protect and promote the human rights of those adversely affected by corporate activities. In order to revise the said Action Plan, the Government of Japan will continue its dialogue with stakeholders and strengthen cooperation between relevant ministries and agencies, while striving to harmonise policies.

The Government of Japan formulated the ‘Guidelines on Respecting Human Rights in Responsible Supply Chains’ in 2022. The Guidelines provides concrete explanations of the initiatives required of

companies in line with the actual situation in the private sector, taking into account international standards, including the UN Guiding Principles on Business and Human Rights, the OECD Guidelines for Multinational Enterprises and the ILO Declaration on Multinational Enterprises. As a complement to the Guidelines, METI has also developed ‘Reference Material on Practical Approaches’ for business enterprises with no experience in full-scale initiatives. METI continues to work on improving the environment in which companies can actively engage in respect for human rights.

WP-1 / #09* / E to J Harmonization & mutual recognition of standards and product certifications; acceptance of international standards where applicable

Automobiles

A transitional period stipulated in Articles 5 to 9 of the Japan-EU EPA Annex 2-C (Motor Vehicles and Parts) was agreed upon after years of Japan-EU EPA negotiations. The Government of Japan has made steady progress, adopting the regulations listed in the EPA as domestic regulations earlier than initially planned.

In the fields of emissions and fuel consumption, the Government of Japan grants mutual recognition of approval under the 1958 agreement including the Worldwide Harmonized Light Vehicles Test Procedure (WLTP) and other measures.

In addition, the Government of Japan has served as Vice-Chair of WP.29 since 2023, and will cooperate with Italy, which was elected as Chair, to further contribute to the international standards harmonisation activities of WP.29. Furthermore, the Government of Japan will cooperate with the European Commission and Japanese and European industry in discussions on the development of a Life Cycle Assessment (LCA) methodology for vehicles that also takes carbon neutral fuels into account, with the aim of becoming carbon neutral.

The Government of Japan will continue to promote globally harmonised automobile regulations at WP.29, while working to ensure automobile safety and protecting the environment in Japan.

Railways

Railway safety standards are developed and maintained in each country based on its own transportation conditions and lessons learned from past accidents, and collateral policies are accordingly different between Japan and the EU. In Japan, the Government of Japan conducts conformity assessments of technical regulations and has not established regulations that ensure product safety through third-party certification and other forms, as in Europe. Japanese suppliers are required to undergo the EU’s conformity assessment for exported products, despite their products conforming to Japan’s standards. In addition, the Government of Japan understands that both Japan and the EU allow railway operators to test whether products meet their own requirements.

The Government of Japan has established a ministerial ordinance on ‘Technical Regulatory Standards’ and the nonbinding interpretation on ‘Approved Model Specifications’ which provides standard and specific numerical value. The English translation of these standards is available on this

website: (http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/index.html)

In terms of standardisation activities, Japan contributes to consensus building at the standards council meetings on ISO/IEC and other international standards, with the Railway International Standards Center playing a central role in participating in regular meetings with European organisations, including the JISC-CEN/CENELEC discussion sessions, and exchanging views on activities related to the development of international standards.

The Government of Japan understands that railway operators should determine their own unique solutions based on the challenges, needs and current conditions of their railway lines while taking costs and other factors into account.

Some Japanese railway operators publish a list of planned procurements. The Government of Japan understands that Japanese railway operators constantly seek safe and reliable products, and that they are willing to actively procure superior European products.

The Government of Japan has drawn up comparison tables between Japan's Technical Regularly Standards and the EU's Technical Specifications for Interoperability (TSI) and has instructed the relevant railway operators to equally treat tests and experiments required of suppliers and disclose the appropriate and applicable part of their implementation standards to European suppliers with a firm interest. The Government of Japan understands that Japanese railway operators will take concrete measures and expects European suppliers to make specific approaches to Japanese operators.

Processed food

In Japan, the use of food additives is prohibited, except when the Prime Minister designates harm to human health as unlikely under the Food Sanitation Act. The designation procedures for food additives (including enzymes) are, in principle, based on requests from business operators and other entities. The Government of Japan understands that the EU also takes a similar approach.

The data necessary for the designation of food additives (including enzymes) are derived from publications as well as evaluations by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and other bodies. Japan's standards and criteria for additives are established in harmony with international standards by referring to the regulations of the EU and other regions as well as the Codex Alimentarius.

Furthermore, since 2002, the Government of Japan has been in the process of designating 45 food additives (excluding flavouring agents) proven safe and used internationally, with 41 items having completed the procedures. Three of the remaining items were cancelled because they were no longer considered as falling under the category of internationally used additives after re-examination for exporters to Japan, and the last one item is under review by the expert committee of the Food Safety Commission of Japan.

In light of the nuclear power plant accident in the former Soviet Union, the Government of Japan continues to give guidance on conducting instruction-based inspection for radioactive substances in foods to importers of berries, berry products, mushrooms, and other related items from some EU

countries when submitting import notifications. This is because violations exceeding Japan's standard values continue to be found during inspections at the time of importation.

WP-1 / #10* / E to J: Self-verification and risk assessment

Japan's framework for RF technical standards conformity certification now permits the self-verification of the conformity to technical standards by manufacturers and other entities with regard to wireless devices that are less likely to disrupt other radio stations. Authorities continue ramping up the categories of wireless devices that can be self-verified as far as not disrupting other radio stations or adversely affecting human health. Careful consideration must be given to the concerns that non-conforming base station equipment with high antenna power could cause disruption/interference in other radio stations and excess over safety limits for human exposure.

In Japan, the Food Sanitation Act does not require government or third-party approval for food apparatus, containers or packaging.

Under Japan's current system, medical devices including non-invasive medical devices are classified based on their risk levels in a way that conforms to international standards, and different procedures are required for each classification. Devices considered extremely low-risk to the human body even if failures occur, are classified as general medical devices (Class I), and are permitted to be marketed by submitting notification (i.e., self-verification of conformity) to the Pharmaceuticals and Medical Devices Agency (PMDA).

WP-1 / #11* / E to J: Wind power

The currently planned offshore wind projects are at the stage of being assessed by a registered conformity assessment body to confirm conformity with the technical standards, and the assessment after the operation of the current system has not yet been completed for any of the projects. Once the results of the assessments by the registered conformity assessment body have been accumulated, issues such as the assessment period, assessment methods and working languages will be confirmed through the verification of the outcome.

In addition to Noshiro Port, Akita Port, Kashima Port, and Kitakyushu Port, Niigata Port (in April 2023) and Aomori Port and Sakata Port (in April 2024) were newly designated as the base ports essential for the installation and maintenance of offshore wind power facilities. These ports are now undergoing necessary improvements that include strengthening the geo-resilience of quay walls. The Government of Japan will continue to maximise its use of designated base ports while proceeding with planned port upgrades in light of the development of offshore wind power.

Article 3 of the Ship Law stipulates that, in principle, maritime transportation between domestic ports should be conducted by Japanese-flagged vessels. Even for transportation incidental to the construction work for offshore wind power, foreign-flagged vessels cannot be used for this purpose. A foreign-flagged vessel can be used for domestic transportation by reflagging to a Japanese-flagged vessel.

WP-1 / #12* / E to J: Automobiles

Tax incentives for Kei cars have been introduced as a social policy, taking into consideration Japan's specific circumstances such as its higher population density relative to land mass, and the rationale behind such incentives remains valid. In addition, these incentives make it easier for residents living in rural areas who need automobiles for their daily lives to purchase Kei cars and deliver substantial social benefits.

The Government of Japan is of the view that the taxation system is an issue to be discussed through domestic tax reform process in each country. As regards the Mini-Vehicle Ownership Tax, the tax rate was raised by the 2014 Tax Reform Outline that took effect in April 2015. In addition, following the increase in the consumption tax rate to 10% from October 2019, the tax was lowered on passenger cars newly registered on/after 1 October 2019. With these measures, the tax gap between passenger cars and Kei cars was narrowed.

WP-1 / #13* / E to J: Freight and logistics

Imported goods such as foodstuffs that require notification under the Food Sanitation Act are temporarily stored in bonded warehouses, and the quarantine station of the Ministry of Health, Labour and Welfare (MHLW) at the seaport or airport where the goods clear customs examine import notifications. MHLW does not specify the location of the bonded warehouse and import notification can be made at any bonded warehouse.

To prevent the spread of pests that damage Japanese agricultural products through plants imported from overseas, plant quarantine inspection in Japan is conducted in principle at the port or airport where the plants are imported and is not allowed at the bonded warehouses. As an exception, postal items handled by international postal service operators are allowed to be inspected after being transported from airports, etc. to the facilities of international post offices that conduct customs clearance procedures. This is because inspections are conducted indoors in urban areas, where the risk of spread of pests is low, and because each package is individually packed and the risk of dispersion of pests during transportation is low, etc. International courier service, which is transported in the same manner as postal items, is also allowed to be inspected after being transported by land from the airport where it was imported to another port or airport, because the risk of dispersal of pests is low.

The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has been operating Cyber port (Port Logistics) since April 2021, a platform for improving productivity in port logistics by computerising logistics procedures between private operators, including Delivery Orders. MLIT will continue to promote the expansion of use of the system by improving functions that contribute to increased user-friendliness.

To promote digitalisation in the logistics industry, the public and private sectors will exchange views and gather information on specific cases faced by operators and continue to discuss possible improvement measures. Thermometers, etc. transported with a container and used principally for that

type of container have already been included in the container as ‘normal accessories and fixtures’. However, the handling of each ‘smart box’ should be considered based on whether it falls under this category and whether there are needs of the business operator.

Currently, the number of input fields in the Import Declaration Items Registration (IDA operations) of the Nippon Automated Cargo and Port Consolidated System (NACCS) is set at a maximum of 99 according to the operational specifications. Expanding the number of input fields to 100 or more fields is difficult at present because the number of columns changes from 2 to 3 digits, resulting in a large system load and an impact on NACCS users’ own systems. Also, the 7th NACCS, which will be released in October 2025, is to achieve the expansion because the detailed specifications have been finalised and development is ongoing already. On the other hand, it is possible to consider the pros and cons as one of the requests for additional functions after the 7th NACCS upgrade, taking into account the above issues and the opinions of NACCS users.

Working Party 2 Life Sciences and Biotechnologies, Healthcare and Well-being

WP-2 / #03* / EJ to EJ: New technologies including biopesticides should be further promoted to achieve a paradoxical agenda of feeding population without starving the planet

The Government of Japan has been working to reduce the risks associated with the use of chemical pesticides based on the ‘Strategy for sustainable Food Systems, MIDORI’ that aims to enhance both productivity potential and sustainability in the agriculture, forestry and fisheries industries with innovation.

As alternatives to traditional chemical pesticides, the Government of Japan will consider what rules to adopt for using biopesticides, biostimulants, RNA-based pesticides, and other materials, referring to the discussions at the OECD. Japanese authorities are of the view that mutual authorisation would be difficult because data obtained solely from other countries with different natural conditions cannot determine the impact on non-target organisms. However, authorities will continue to discuss such rules based on the latest scientific knowledge and harmonised with the trends of international discussions.

WP-2 / #05* / EJ to EJ: Promoting new food technologies (food tech) that reduce environmental impact and ensure food security

With the rapid expansion of food tech businesses worldwide, the Foodtech Public-Private Council, which was launched in 2020 and comprises private companies, research institutions and the government, has formulated a vision to foster and promote food tech businesses from Japan in 2023. Also, the ‘Ministry of Agriculture, Forestry and Fisheries’ SMEs Innovation Creation Promotion Project’ is being implemented to promote the social implementation of cutting-edge technologies possessed by start-up companies, etc. The Government of Japan will continue to support the initiatives of food tech companies. In addition, the Basic Law on Food, Agriculture and Rural Areas was passed in May 2024. The law includes basic measures such as the promotion of reducing the environmental impact of agricultural production activities and food industry business activities, and the promotion of new businesses related to the food industry and related industries that utilise advanced technologies.

Food experience plays a crucial role in food safety. For those food products using food techs for which there is a lack of food experience, scientific knowledge on their safety is currently being collected and, if necessary, the need for regulation is being considered.

In order to maintain the balance between free trade and food safety, the Government of Japan will continue to work on this issue in cooperation with relevant industries and with reference to the measures taken in other countries.

WP-2 / #07* / EJ to EJ: Reform of the pharmaceutical pricing system should provide a stable, predictable environment that rewards innovation

The Government of Japan considers it important for the pharmaceutical industry to develop new drugs through ceaseless innovation as well as creating an environment that encourages global competition. Based on this view, MHLW will constantly review the pharmaceutical pricing system at the Central Social Insurance Medical Council on the basis of balancing ‘promotion of innovation’ with ‘sustainability of the universal health insurance system’, taking the industry’s opinions into full account.

WP-2 / #08* / EJ to J: Regulatory environment should be improved to ensure fast access to ground-breaking innovations

The Government of Japan together with the US and EU, established the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to work towards international harmonisation of pharmaceutical regulations, and has actively incorporated the internationally harmonised guidelines established by the ICH into Japanese pharmaceutical regulations.

Regarding the evaluation and authorisation of pharmaceuticals with high clinical needs, Japanese authorities have worked on operational improvements, including, for example, setting up a consultation service for innovative drugs, which has resulted in increasing the number of designations from zero in 2020 to seven in 2023. The Government of Japan will continue to consider additional initiatives through opinion exchanges with industry organisations.

With respect to Software as a Medical Device (SaMD), the Government of Japan has introduced a two-step approval scheme involving the first-step approval at an early stage when a certain efficacy or effectiveness can be validated, and the second-step approval after clinical significance is determined at post-marketing phase.

Working Party 3: Digital Innovation and Mobility

WP-3 / #01* / EJ to EJ: Strengthening EU-Japan Cooperation to realise DFFT

A) Cooperation in Rulemaking on Global Digital Trade

Regarding the Moratorium on Customs Duties on Electronic Transmissions, which was extended at the 13th WTO Ministerial Conference (MC13), the importance of a permanent prohibition of customs duties on electronic transmissions was confirmed in the outcome documents of the G7 Trade Ministers' Meetings held in October 2023 and February 2024, and the Government of Japan will continue to cooperate with WTO members.

As a co-convenor, the Government of Japan has led the negotiations of the WTO Joint Statement Initiative (JSI) on E-commerce and substantially concluded the negotiation on 13 articles including personal information protection and cybersecurity by the end of 2023. The Government of Japan continues to make an effort to an early conclusion of the negotiation.

In June 2023, the Personal Information Protection Commission (PPC) hosted the 3rd G7 Data Protection and Privacy Authorities Roundtable (in Tokyo). The Commission clearly stated its support for the work on Government Access in the OECD in its deliverables, the Communiqué and the G7 DPAs' Action Plan. The PPC will continue our discussions and work on this and keep making efforts to disseminate the 'OECD Declaration on Government Access to Personal Data Held by Private Sector Entities' to non-OECD member countries.

In December 2023, the G7 Digital and Technology Ministers welcomed the discussions on establishing an Institutional Arrangement for Partnership (IAP) at the OECD. In the same month, the establishment of the DFFT Expert Community as part of the IAP was endorsed. The Joint Statement of the second meeting of the Japan-EU Digital Partnership Council held in April 2024 and the Memorandum of Cooperation on Digital Identity signed on 30 April 2024 confirmed cooperation between Japan and the EU on strengthening the organisation of the IAP.

WP-3 / #01* / EJ to EJ: Strengthening EU-Japan Cooperation to Realise DFFT

B) Cooperation through EPA and Digital Partnership between Japan and the EU

On 1 July 2024, the 'Protocol Amending the Agreement between Japan and the European Union for an Economic Partnership' on the inclusion of 'provisions on the free flow of data' into the Japan-EU EPA will enter into force. This is expected to ensure predictability regarding cross-border data flow and contribute to the promotion of data flow between Japan and the EU and thus strengthen their economic relations. It is also expected to contribute to the realisation of 'Data Free Flow with Trust (DFFT)' advocated by the Government of Japan as a model for advanced digital trade rules that promote the healthy development of the digital sector, a growth engine of the 21st century.

At the second meeting of the Japan-EU Digital Partnership Council held in April 2024, the Digital Agency, METI and Ministry of Internal Affairs and Communications (MIC) and the European Commission reaffirmed the importance of their ever-closer strategic partnership. The meeting

welcomed the launch of the IAP, including the establishment of the DFFT Expert Community at the OECD, with a view to operationalising the DFFT through the promotion of concrete solutions to specific issues, such as the use of digital technologies, between European data spaces and Japanese data spaces (including DATA-EX and the Ouranos Ecosystem), and confirmed continued cooperation to promote interoperability, as well as cooperation in a wide range of areas such as semiconductors, submarine cables, high-performance computing (HPC), quantum, security conformity assessment schemes for IoT products, networks such as 6G, and AI.

It will also promote international cooperation, including between Japan and the EU, to ensure interoperability of digital identities, based on the Memorandum of Cooperation on Digital Identities in the Japan-EU Digital Partnership signed in the same month.

WP-3 / #02* / EJ to EJ: Support for Social Implementation of Digital technologies

In December 2023, the G7 Digital and Technology Ministers welcomed the discussions to establish an Institutional Arrangement for Partnership (IAP) at the OECD. In the same month, the establishment of the DFFT Expert Community as part of the IAP was endorsed. The Joint Statement of the second meeting of the Japan-EU Digital Partnership Council held in April 2024 and the Memorandum of Cooperation on Digital Identity signed on April 30 confirmed the cooperation between Japan and the EU on strengthening the organisation of the IAP.

The Government of Japan will continue to work on the priority areas, including initiatives to share and utilise data across companies, industries and national borders (the Ouranos Ecosystem, an initiative originating in Japan).

WP-3 / #03* / EJ to EJ: Cybersecurity for Safe, Secure and Trusted Society

The Ministry of Internal Affairs and Communications (MIC) will use the quantum cryptography testbed to clarify issues for social implementation and promote its use to early adopters regarding quantum key distribution (QKD) based on the Promotion Measures for the ‘Creation and Development of the Quantum Industry’ announced in April this year. International organisations such as the ITU are promoting international standardisation of interconnection of QKD equipment so that superior QKD equipment can be used globally.

In March of this year, the METI formulated a draft policy for a security conformity assessment system for IoT products. The final policy for the system is currently being compiled based on the results of public comments, with the aim of partially launching the system by March 2025. At the second meeting of the Japan-EU Digital Partnership Council, held in April 2024, the Government of Japan and the European Commission confirmed the continuation of ‘efforts to promote compatibility of the two systems and to cooperate in strengthening cooperation between experts in developing standards for both systems’.

The Government of Japan will coordinate with other countries towards interoperability between the EU's Cyber Resilience Act and other foreign systems.

WP-3 / #04* / EJ to EJ: Social Implementation of human-centred AI Technology

Considering the various risks posed by AI and international governance trends in both soft law approaches, such as guidelines, and hard law approaches, such as legal instruments, a desirable AI governance system will be explored. In addition, the Government of Japan will continue to lead the international efforts to advance safe, secure and trustworthy AI through the Hiroshima AI Process and other initiatives and continue to promote innovation opportunities created by AI in cooperation with Asian countries and the Global South. Furthermore, Japan will build an international networks between the AI Safety Institute (AIS) of Japan and AISs in other countries, etc., and examine measures to ensure the safety of AI.

WP-3 / #06* / EJ to EJ: Updating Connectivity for Digital Transformation for All

In 2022, under the Japan-EU Digital Partnership, launched by the leaders of Japan and the EU, both sides concurred on promoting the development and deployment of 5G and Beyond 5G/6G technologies through research and development cooperation. In response, the MIC, in cooperation with the EU authorities, issued a public call, from March to May 2024, for joint Japan-EU research projects. Following an adoption review, the selected research projects will be launched in 2025.

The MIC is considering establishing an environment such as a testbed where various parties can develop use cases for Beyond 5G/6G.

The Japan-EU ICT Policy Dialogue held in February 2024 and the Japan-EU Digital Partnership Ministerial Meeting held in April 2024 confirmed the importance of open, secure, innovative and resilient networks, including Open RAN. Discussions will continue on the promotion of open networks through intergovernmental dialogues and other forms.

WP-3 / #08* / EJ to EJ: Cooperation on Supply Chain Resilience

Semiconductor

In July 2023, the METI and the European Commission made a Memorandum of Cooperation on Semiconductors. Based on this, the METI and the European Commission signed a Memorandum of Cooperation on a Joint Early Warning Mechanism on Semiconductor Supply Chain in October 2023 and on a Semiconductor Public Support Transparency Mechanism in May 2024. In addition, a Japan-EU Semiconductors Workshop was held in January 2024 to promote cooperation between Japan and the EU on semiconductors, including the theme of human resource development. The Government of Japan will cooperate with the EU under the Early Warning Mechanism and the Public Support Transparency Mechanism and will further deepen discussions toward the realisation of Japan-EU cooperation, including human resource development.

Critical Raw Materials

The Government of Japan has announced that it will also focus on securing upstream resources necessary for battery manufacturing and other purposes with the aim of achieving net-zero GHG emissions by 2050. A budget of 215.8 billion yen has been set aside to support investment by Japanese

companies in mine development, etc. The Government of Japan is prepared to provide financial support for investment by Japanese companies and will actively consider new projects for joint investment between Japan and the EU.

WP-3 / #09* / EJ to EJ: Developing skills for Digital Economy

The Government of Japan supports the establishment of industry-academia collaboration systems, research and development, and human resource development related to the design, development and operation of AI semiconductors and other key devices. In addition, the Government of Japan will work to enrich and disseminate educational content to improve AI skills and AI literacy. Young researchers and doctoral students who would develop next-generation AI will be further supported.

WP-3 / #11* / EJ to EJ: R&D cooperation

The Government of Japan and the European Commission discussed researcher exchanges and ways to strengthen strategic research and development. Japan will continue to deepen its understanding of Horizon Europe and explore opportunities for collaboration with the EU side through various channels, including Horizon Europe.

Startup businesses are key players in the transformation of social issues into growth engines and the achievement of a sustainable economy and society. Japan is now providing support for the construction and development of a startup ecosystem while promoting international cooperation to attract domestic and foreign businesses and help startups enter the global market.

Working Party 4: Environment and Sustainable Development

WP-4 / #01* / EJ to EJ: Measures and policies of both authorities against climate change

The Government of Japan has decided the ‘GX Promotion Strategy’ by the Cabinet meeting based on the GX Promotion Act enacted in May 2023 in order to simultaneously realise the three goals of decarbonisation, stable energy supply and economic growth under the target of net-zero GHG emissions by 2050 and the medium-term target which is aligned with the 2050 target. At the end of 2023, the Government of Japan also compiled a ‘sector-specific investment strategy’ with the aim of turning the 20 trillion yen-scale GX Economic Transition Bond into a concrete investment promotion measure.

Aiming to break away from excessive dependence on fossil fuels, the Government of Japan will promote conversion to highly decarbonised power sources such as renewable energy and nuclear power in addition to thorough energy conservation. Under the ‘Pro-Growth Carbon Pricing Concept’, the Government of Japan seeks to realise public and private GX investment of more than 150 trillion yen over 10 years. In addition, a ‘GX 2040 Vision’ from a longer-term perspective will be presented by the end of the FY2024 by comprehensively examining industrial structure, industrial location, and energy supply. In addition, through the Trade and Environmental Sustainability Structured Discussions (TESSD) and the OECD Trade Committee, the Government of Japan will continue to discuss the design and operation of the Carbon Border Adjustment Mechanism (CBAM) and the need for practical coordination.

WP-4 / #02* / EJ to EJ: Promotion of resource efficiency and the circular economy

The Government of Japan is expanding policy support, strengthening industry-government-academia collaboration initiatives and developing regulations and rules to realise the circular economy. With regard to the expansion of policy support, the Government of Japan will provide 30 billion yen over the next 3 years with the aim of expanding investment in resource recycling.

To strengthen industry-government-academia collaboration initiatives, in September 2023, the Government of Japan launched the Circular Partners, which brings together relevant parties ambitious for the circular economy. It is working to strengthen collaboration across the entire life cycle, including in the arterial and veinous industries. Under the Circular Partners, parties are considering measures necessary for the realisation of a circular economy, such as the construction of information sharing platforms to visualise information on products and materials required for recycling and the actual state of recycling. In addition, the 5th Fundamental Plan for Establishing a Sound Material-Cycle Society will be formulated this summer as a national strategy to compile measures. The Government of Japan will encourage local authorities and companies to make good use of local circular resources and renewable resources such as biomass to promote advanced initiatives, thereby utilising the high technological capabilities of the manufacturing and waste treatment and recycling industries and promoting the use of circular and renewable resources that are characteristic of each region.

In developing regulations and rules, it is necessary to lead and participate in international rulemaking such as international standardisation. Cooperation between Japan and the EU will be promoted through the use of multilateral frameworks such as the G7 and the G20, as well as bilateral frameworks such as the Japan-EU Green Alliance and the Japan-EU EPA. Furthermore, the circular economy and resource efficiency principles (CEREP) will be promoted in cooperation with the G7, B7 and other business communities, including the EU.

WP-4 / #04* / EJ to EJ: Realisation of a resilient and comfortable life

In recent years, there have been increasing expectations for the functions of green spaces to address issues such as climate change countermeasures, securing biodiversity, and improving well-being. Against this background, the Government of Japan is also striving to realise a good urban environment by strongly promoting the securing of green spaces in urban areas in both quality and quantity, the introduction of renewable energy, and the efficient use of energy. Specifically, the Urban Green Space Law was partially revised to formulate the basic policy of the national government and to establish a system that MLIT certifies private companies' efforts to secure high-quality green spaces. The Government of Japan is leading efforts to conserve green spaces and improve the environment for investment in green spaces.

With regard to the development of energy-saving measures, METI will promote the introduction of energy-saving equipment through support for the replacement of energy-saving equipment and support for energy-saving housing. In implementing these support measures, METI will strive to ensure consistency with the standards required by the Top Runner System based on the Rational Use of Energy (Energy Conservation Act) and simplify the procedures.

With regard to the Digital Garden City Nation Plan, for which the BRT expressed support, the Government of Japan will promote four initiatives under the Digital Rural City State Concept: (1) creating jobs in rural areas, (2) creating a flow of people, (3) fulfilling hopes for marriage, childbirth and childcare, and (4) creating attractive regions, while utilising digital technology. In addition, the following three initiatives, which are prerequisites for digital implementation, will be strongly promoted: (1) development of a digital infrastructure of hardware and software, (2) development and securing of digital human resources, and (3) efforts to ensure that no one is left behind. Through these efforts, the Government of Japan will aim to realise “a society where everyone can live conveniently and comfortably anywhere in the country”, to redress the excessive concentration of population in the Tokyo area and to revitalise the regions.

In addition, based on the ‘Digital Garden City National Infrastructure Development Plan (Revised Version)’, the MIC will promote the development of digital infrastructure toward the realisation of the ‘Digital Garden City National Plan’, such as eliminating areas where optical fibre has not yet been developed, further developing 5G, etc., promoting the development of data centre regional centres and submarine cables, etc., and promoting the early development of NTN (Non-Terrestrial Network) in Japan, as well as establishing technology related to the next-generation information and communications infrastructure Beyond 5G.