Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan

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

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List of Abbreviations

Abbreviation	Meaning
BRT	Business Round Table
CAS	Chemical Abstracts Service
CEA	Cost Effectiveness Analysis
CGP	Comprehensive Genomic Profiling
EIR	Environment Impact Reduction
EPA	Economic Partnership Agreement
EU	European Union
EUA	Emergency Use Authorisation
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GOJ	Government of Japan
HTA	Health Technology Assessment
ICER	Incremental Cost Effectiveness Ratio
IP	Intellectual Property
ISHL	Industrial Safety and Health Law
ISO	International Organization for Standardization
J-PMD Act	Japanese Pharmaceutical and Medical Device Act
MDD	Medical Device Directive
MDR	Medical Device Regulation
MDSAP	Medical Device Single Audit Program Pilot
METI	Ministry of Economy, Trade and Industry
MHLW	Ministry of Health Labour and Welfare
MRA	Mutual Recognition Agreement
NHI	National Health Insurance
PBT/vPvB	Persistent, Bioaccumulative and Toxic / very Persistent and very Bioaccumulative
PDSCL	Poisonous and Deleterious Substance Control Law
PHR	Personal Health Records
PMDA	Pharmaceutical and Medical Device Agency
PMP	Price Maintenance Premium
PRTR	Pollutant Release and Transfer Register
QALY	Quality-adjusted life years
QMS	Quality Management System
R&D	Research & Development
REACH	Registration, Evaluation, Authorisation, Restriction and Chemicals
RMP	Risk Management Plan
SME	Small-to-mid-sized enterprise
UK	United Kingdom
WP	Working Party

Introduction

Japan and the EU face many similar challenges, such as ageing populations, shifting demands for products and services, food security, and environmental protection. In addition, geopolitical issues have profoundly been affecting many parts of society. Life sciences and biotechnologies offer the possibility of technologies that will help address these challenges and achieve both economic growth and a sustainable recycling-oriented society or bioeconomy society.

Working Party 2 focuses on the following sectors:

- Life Science & Healthcare (pharmaceuticals and medical devices)
- Biotechnology (agriculture, food, and industry)
- Animal Health
- Industrial Chemicals

The recommendations of WP-2 have the clear aim to improve the innovation capabilities of both the EU and Japan through concrete action plans in healthcare and biotechnology. The focus is on measures that will enhance efficient healthcare practices, sustainable agriculture, food production and supply, and high-performance materials, eventually contributing to the establishment of a bioeconomy society.

The BRT welcomes the aims of both the EU and Japan to support competitiveness and innovation, improve access to medicines, and secure a stable medicine supply as provided in the EU Pharmaceutical Strategy for Europe and the “Basic Policy on Economic and Fiscal Management and Reform 2023”, respectively. While the EU and Japan share common challenges to regain the attractiveness for investment in innovation, the BRT expects that comprehensive and sustainable measures will be taken in the EU and Japan to retain their roles to lead innovation. The BRT hopes that the recommendations in this report would help develop solutions to remove barriers to innovation and enhance their innovation ecosystems and drive economic growth while strengthening our economic relationship.

An asterisk (*) identifies “priority” recommendations.

Recommendations from both European and Japanese industries

Life Science & Healthcare

WP-2 / # 01 / EJ to EJ Regulatory environment should be improved for infectious disease control

The BRT calls on the EU and Japanese Authorities to:

- Protect and respect intellectual property rights of vaccines, diagnostics, and therapeutics, and
- Continuously promote the research and development for infectious diseases, especially for antimicrobial resistance (AMR) by reinforcing incentives.

The BRT believes that:

- Respect of intellectual property rights is fundamental to stimulating research and development and ensuring supply. Waiving intellectual property rights on any vaccines and therapeutics would undermine the ability to innovate and respond to ongoing and future global health threats.
- The number of drug-resistant bacteria is increasing, and if this situation continues, it is predicted that the annual number of deaths worldwide by 2050 due to drug-resistant bacterial infections will rise to approximately 10 million.
- The European Commission's adoption of stepping up EU actions to combat AMR is expected to lead to effective measures, which should incentivise antimicrobial development and provide predictability in access, and
- It is necessary to secure resources for solving AMR problems. Support for the development of new anti-infectives, including support for small-to-mid-sized enterprises (SMEs) which play a critical role in developing innovative new medicines, is vital. Further enhancing public support is a way forward to help hedge the risk of the research and development for emerging AMR and other infectious diseases.

WP-2 / # 02 / EJ to EJ Mutual recognition should be improved for Medical Devices

Mutual recognition of quality management audit results for Medical Devices should be established between EU and Japan.

The BRT calls on the EU and Japanese Authorities to:

- Introduce a mutual recognition scheme for Quality Management System (QMS) audit results, preferably through EU accession to the Medical Device Single Audit Program Pilot, or through regulatory harmonisation between the EU and Japan.

- Harmonise submission-related formats and standards.
- Ensure post-approval QMS inspection dates coincide with the renewal of marketing authorisation rather than every 5 years in order to simplify and assure proper renewal operation.
- Introduce mutual recognition of Medical Devices products for lower risk classes as soon as possible.
- Harmonise the introduction schedule for new ISO standards, including a grace period, thereby ensuring they apply the same revision of a particular ISO standard, and
- Address the issues above through the next revision of the J-PMD Act.

The BRT believes that:

- The QMS inspection process remains complicated and burdensome despite Japan now accepting the ISO13485 audit report under the 2014 J-PMD Act.

There should be mutual recognition of Medical Devices product licenses.

The BRT calls on the EU and Japanese Authorities to:

- Mutually recognise Medical Devices product licenses. Existing similarities between EU and Japanese regulations on low-risk class II devices make mutual recognition of product licenses for this category of products possible.

The BRT calls on the Japanese Authorities to:

- Ensure PMDA and MHLW introduce mutual recognition, taking into account the difference in the classification of medical devices between Japan and the EU.

The BRT calls on the EU Authorities to:

- Improve their communication with the Government of Japan (GOJ) in relation to the new Medical Device Regulation (MDR) implementation, and
- Monitor whether the switch from the Medical Device Directive to MDR does indeed accelerate the mutual recognition of clinical trial results in Japan.

The BRT believes that:

- Harmonising QMS and classification should allow new products to be introduced in both the EU and Japan within the same time frame and in one process, and
- The EU Authorities are communicating insufficient information to Japan about the MDR.

There should be mutual recognition of clinical trial results for Medical Devices.

The BRT calls on the Japanese Authorities to:

- Accelerate mutual recognition of clinical trial results in actual operation, where the conformity is currently insufficient due to the existing strict conditions applied when accepting clinical evaluation reports originating outside of Japan.
- Provide early disclosure of clear guidance for judgment on the need for clinical studies, conditions for acceptance, etc. in order to make the actual operation of GCP smoother, and
- Develop guidelines for the effective utilisation of clinical evaluation reports soon. The EU industry side requests that the GOJ responds with specific timelines for this action as this has been a previously listed request with no practical progress.

The BRT believes that:

- Although foreign clinical trial data can be accepted in Japan as part of the application dossier under specific circumstances, additional data requirements were sometimes imposed on manufacturers without providing the rationale regarding such requests.
- The acceleration of mutual recognition of clinical trial results for the development of new Medical Devices would ensure access to new products for patients in Japan and the EU, both within the same timeframe and through one process. This would allow for further reducing the device lag, ensuring a high level of quality whilst minimising the administrative burden on manufacturers, and
- Early disclosure of clinical trial-related guidance would promote the entry of overseas companies into the Japanese market.

Biotechnology (Agriculture)

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**

There is an urgent need to achieve sustainable development of agriculture as well as environmental protection. Climate change has led to increases in the frequency and intensity of natural disasters and loss of biodiversity, which affects agricultural production and jeopardises food security. To reduce the environmental impact through agricultural production, both the EU and Japan have developed sustainable food production policies a reduction in the use and risk of chemical pesticides and an expansion of the land use for organic farming.

Innovation that enables the replacement of hazardous chemical pesticides with safer pesticides is a key driver to achieving such goals. It is critical to promote new technologies, including biopesticides, biostimulants, and RNA interferences, to reduce the use and risk of chemical pesticides and improve agricultural efficiency.

While many measures are being developed to achieve a sustainable agriculture system and environmental protection, BRT places a greater focus on the development of effective and safe technologies, including biopesticides, biostimulants and RNA interferences, and methods to improve agricultural productivity.

The BRT calls on the EU and Japanese Authorities to:

- Mutually accept biostimulants and biopesticides that are authorised in the respective markets without requiring local risk assessments.
- Further establish and enhance definitions, rules, and guidelines for biopesticides to promote the development and use of biopesticides. Make the registration processes simple and efficient, similar to the comprehensive system provided by the US Environmental Protection Agency with clear definitions and guidelines, which enables the assessment and registration with a minimum data package.
- Develop scientifically sound data requirements and risk assessment processes for products based on new technologies, like RNA interferences.
- Develop a policy to encourage growers to adopt safer and more sustainable solutions in their farming practices, and
- Work with stakeholders to promote emerging technologies for sustainable and precision food production to lower the environmental load associated with agricultural production.

The BRT believes that:

- As there is no single solution that fits all, integrated solutions are needed to achieve sustainable food production and environment impact reduction with limited resources.
- Promotion of biopesticides, biostimulants, and RNA interferences is key to achieving environmental goals without impeding agricultural productivity.
- Enhancement and harmonisation of registration systems for biopesticides in the EU and Japan should support the achievement of their sustainable food production policies and reduction of the use and risk of chemical pesticides, and
- Incentives to growers are necessary to promote new technologies for environmental impact reduction (EIR) to enable growers to benefit from EIR initiatives.

WP-2 / # 04 / EJ to EJ **Legal clarity for and appropriate regulation for agricultural innovation, including genetically modified crops and genome-edited crops, should be established**

The BRT calls on the EU and Japanese Authorities to:

- Regulate agricultural technologies, including crop protection, genetically modified (GM) and genome-edited (GE) crops in a science-based and proportionate manner.
- Advance and adhere to global harmonisation of genetically modified organisms' risk assessments, and support the Global Low Level Presence Initiative.
- Provide legal clarity on the status of techniques such as genome editing and corresponding labelling requirements (e.g., for genome edited derived food), and
- Work with industry and other stakeholders to increase trust in the regulatory science and gain greater societal acceptance.

The BRT believes that:

- A fact-based platform for dialogue and sharing of information as well as a risk-proportionate, predictable, science-based treatment of new technologies is required.
- Taking a science-based and proportionate regulatory approach to agricultural technologies will aid in gaining societal acceptance and help weed out misinformation, and
- Ongoing regulations regarding data requirements for emerging technologies are not fully updated resulting in duplication of studies.

Biotechnology (Food Tech)

WP-2 / # 05*/ EJ to EJ **Emerging food technologies should be promoted to ensure food security while minimising the environmental impact**

The BRT calls on the EU and Japanese Authorities to:

- Promote emerging food technologies to secure food supply while reducing the environmental burden, and
- Establish and harmonise regulations that are necessary to advance food techs.

The BRT believes that:

- Reducing the environmental burden and achieving a sustainable food supply is an urgent issue and requires the development of new technologies and investment in new fields as the global food demand is estimated to increase to 1.7 times the 2010 level by 2050 while the environmental burden by agriculture, forestry, and fisheries is on the increase.

- Food techs, such as plant- or insect-based foods, genome-edited foods, cultured meat or cellular foods, and foods utilising microorganisms, are expected to provide alternative ways to meet the increasing demand for proteins, lipids, carbohydrates, etc.,
- Approvals for new food products are currently granted earlier in countries outside Europe and Japan, such as Singapore and the US, resulting in delays in rulemaking, market development, and investment for food techs. It is necessary to gain the trust and interest of investors and entrepreneurs by clarifying the process to launch such products, establishing rules and regulations and improving the business environment.
- International harmonisation and standardisation of regulations in the food tech field are necessary to activate imports and exports and promote technology transfer.
- Open innovation should be promoted through collaboration between established businesses and startups to apply innovative technologies from various fields to food techs, and
- It is vital to foster an understanding of new food products and acceptance among consumers, existing industry and agricultural producers, to promote use of alternatives through incentives, credits, etc., and to strengthen research on new technologies (food techs) and human resource development at universities.

Biotechnology (Industry)

WP-2 / # 06 / EJ to EJ **Utilisation of DSI (Digital Sequence Information on Genetic Resources) should be carefully discussed**

The BRT calls on the EU and Japanese Authorities to:

- Discuss carefully, the establishment of a benefit-sharing multilateral mechanism for the use of DSI, which will be considered for the next COP16, to ensure that the impact on industry and open innovation is kept within appropriate limits and that scientific progress is not negatively impacted, as adopted in the second part of the 15th Conference of the Parties (COP15) to the Convention on Biological Diversity in Montreal, Canada, in December 2022.

The BRT believes that:

- The definition and scope of DSI, the multilateral system for DSI benefit sharing, the objective and manner of benefit sharing, the point in time when benefit sharing becomes effective, etc., should be discussed and determined in a fair and equitable manner in a public forum to find solutions that meet the following criteria:
  - Efficient, feasible, and practical; generate more benefits; provide certainty and legal clarity; not hinder research and innovation; and be consistent with open access to data,
- It is also essential that an appropriate, fair, and equitable collection and distribution system be established so that there is no bias toward either developed or developing countries, and

- It is critical that the EU and Japan show leadership in this area in order to address many of the biodiversity issues and to defend the line that industry must uphold.

Life Science & Healthcare

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

The BRT calls on Japanese Authorities to:

- Support the pharmaceutical industry to innovate in and accelerate new drug development and bring new drugs rapidly to meet the needs of patients in Japan without any delay from other countries and to eliminate “drug lag” and “drug loss”.
- Vitalise the drug discovery and development capabilities in Japan in line with the MHLW’s Pharmaceutical Industry Vision by improving the current pricing system to strengthen the reward for innovation and maintain an incentive for companies.
- Optimise the reimbursement and payment systems for emerging technologies, including cell and gene therapies, so that patients and society can reap the transformative benefits of innovations.
- Determine a drug price that properly reflects evaluation which includes a wide range of elements such as clinical efficacy to patients and doctors and patient-reported outcomes, and is carried out under a transparent and highly predictable process.
- Limit the scope of off-cycle price revisions. Since drug expenditure has been well controlled by the current pricing system, the scope of off-cycle price revisions must be limited to exceptional cases with huge discounts. Drug prices of innovative patented products should be protected and should not be subject to off-cycle price cuts.
- Avoid frequent revisions of the pharmaceutical pricing system and secure sufficient lead time before the enforcement of any pricing rule changes to ensure long-term business predictability and facilitate investment decisions.
- Expand the scope of pricing policy reforms beyond annual drug costs, as drug costs are only one part of the overall and long-term healthcare costs, and
- Increase opportunities and time for constructive and meaningful dialogues between the authorities and industry to allow the industry to provide input and ensure transparency of policy decisions.

The BRT believes that:

- The repeated revisions to the pharmaceutical pricing system introduced in 2018 with as short as three-month notice, created significant issues with business predictability for the Japanese market resulting in delayed access to the latest treatments for patients in Japan. Market predictability is essential as the development of innovative drugs requires long-term, substantial investment, unless innovation is properly evaluated, it becomes increasingly challenging for the industry to continuously create innovative drugs to fulfil unmet medical needs. This will not be beneficial for the patients nor for society.

- A paradigm shift in the reimbursement and payment systems is needed for transformative cell and gene therapies with the potential to cure diseases, which is not contemplated in the current systems.
- Among key developed markets in the world, Japan is the only country with pricing rules that provide mandatory annual price reductions for new drugs during the patent period, and
- Annual drug costs are only one part of the overall and long-term healthcare costs: a holistic view is needed, and a fundamental reform should not be limited to managing drug prices only. Thus, to ensure long-term healthcare system sustainability while securing rewards for innovation, future reforms should include a review of all healthcare costs and revenue sources, including medical fees, medical procedures, hospital stays, patient co-payments, etc.

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

The BRT calls on the Japanese Authorities to:

- Promote regulatory reform to enable flexible regulatory decision-making and accelerate international regulatory harmonisation to ensure fast access to innovations for the people in Japan without any delay from EU and other countries.
- Utilise regulatory processes, including priority review system, pioneering drug designation system, exceptional approval system, and emergency approval system, more appropriately and effectively to promote evaluation and authorisation of pharmaceuticals with high needs, as the criteria for designation are excessively stringent and the number of designations is much smaller in Japan than in other key countries, and
- Apply more flexible evaluation processes for breakthrough innovations rather than the conventional one-size-fits-all processes in order to adapt to rapidly evolving healthcare innovations and to ensure that patients in need have fast access to them.

The BRT believes that:

- While new scientific and medical capabilities are bringing more precision and personalised medicine, with the potential to overcome diseases where there are currently no treatments available or where treatments have limitations, it is necessary to promote pro-innovation policies as well as regulatory harmonisation and convergence in Japan with more flexibility and adaptability in regulatory and health insurance systems to ensure that patients in Japan can benefit from the latest innovations in the world.
- Minimising Japan-specific standards and accepting more international data will accelerate the authorisation and availability of healthcare innovations in Japan, and more flexibility in accepting international data is vital to ensure that patients in Japan have fast access to innovations.

- While MHLW intends to expedite the regulatory processes for emergency cases and the BRT welcomes the recent improvement in the number of the designation of pioneering products, further regulatory harmonisation and flexibility are needed not only for emergency cases, and
- A paradigm shift is required in the evaluation and reimbursement systems to bring breakthrough innovations, such as cell and gene therapies, to patients.

WP-2 / # 09 / EJ to J **The environment for innovative Medical Devices should be improved in Japan**

Japan should further sub-divide the current functional classification for Medical Devices

The BRT calls on the Japanese Authorities to:

- Revise the reimbursement pricing scheme bringing it closer to a product-oriented system.
- Improve the reward for innovation by sub-dividing current functional classifications, and
- Set the reimbursement price for old products separately from the reimbursement price for new products.

The BRT believes that:

- It would be sensible to allow a certain period of time prior to conclusive assessment, because it often takes time for the effectiveness of new products to become apparent and for safety and efficacy to be adequately addressed.

The health insurance system for cancer genome profiling (CGP) testing should be improved to ensure early access for patients to indicated testing

The BRT calls on the Japanese Authorities to:

- Enable patients to conduct CGP testing and receive their results at optimal timings and types of samples using the public insurance system.

The BRT believes that:

- Tissue-based CGP testing and blood-based CGP testing which comprehensively detect cancer-related genes have been covered by national health insurance and reimbursed as a medical device since June 2019 and August 2021 respectively, but there is a restriction that they are reimbursed only if CGP testing is performed either by tissue or blood at the end of the standard of care when patients already get drug resistance or are in worse general status. An environment is socially demanded where each patient can get access to CGP testing at early and optimal timings and types of samples. Enhanced accessibility to CGP testing is expected to improve access to safer and more effective treatments tailored to individual patient needs, and treatment approaches developed based on genetic information will lead to further improvement in the quality of healthcare.

WP-2 / # 10 / EJ to J **Health Technology Assessment (HTA) should be carefully applied**

Health Technology Assessment (HTA) for Pharmaceuticals should not become a barrier to patient access

The BRT calls on the Japanese Authorities to:

- Keep refining the system of using HTA and Cost Effectiveness Analysis (CEA) for Pharmaceuticals, and
- Refrain from using CEA in making reimbursement decisions.

The BRT believes that:

- Use of CEA for reimbursement decisions would possibly lead to a recurrence of drug lag and fully agrees with the government's decision not to use CEA to decide reimbursement. CEA/HTA should be positioned as being supplemental to the current drug pricing system and a scientific approach should be ensured in the process,
- significant additional values that new medicines bring about need to be assessed comprehensively and transparently, involving multiple stakeholders including patients. Disease severity, unmet need, and ethical, and societal considerations should be considered as additional factors in evaluating the true value of drugs. Through this approach, Japan should establish a more balanced HTA system.
- Careful use and interpretation of the estimated ICER values are required as ICERs calculated from models based on various data and assumptions inevitably contain uncertainties, and
- All stakeholders, including clinical experts from both the public analysis team and industry, should fully participate in the discussion of refining the newly introduced system to ensure that the experiences and failures of other countries are duly evaluated and considered.

HTA for Medical Devices should be introduced with caution

The BRT calls on the Japanese Authorities to:

- Be prudent in the introduction of HTA (Health Technology Assessment) systems for Medical Devices taking into account the following factors:
    - QALY, an indicator often used in HTA evaluation for pharmaceutical products is difficult to be applied for the evaluation of medical device,
    - Users' skills and techniques of each medical device can affect the evaluation,
    - Medical devices have a shorter improvement cycle than pharmaceuticals.

The BRT believes that:

- It is important that HTA systems do not hinder the creation of innovative products, delay the listing for medical insurance reimbursement, or impose an excessive burden on the industry (e.g., development of databases or adding human resources). Such outcomes would delay patient access to cutting-edge medical technologies. To avoid this, there should be a clear distinction and balance between assessment and appraisal. There should be no inappropriate use of the ICER measure.

WP-2 / # 11 / EJ to J **A harmonised approach for integration of health-related data and construction of data health infrastructures should be established**

The BRT calls on the Japanese Authorities to:

- Foster a harmonised approach for the integration of health-related data in order to accelerate digital transformation and strongly promote the construction of data health infrastructures in the medical field of Japan, and
- Accelerate the integration according to the grand design under cross- ministerial guidance.

The BRT believes that:

- Personal health records (PHR) will directly contribute to individual patients' choice of personalised treatments.
- The integrated health data will be fundamental to accelerate digital transformation in the medical field of Japan and promote evidence-based policymaking in health areas to improve the efficiency of healthcare, medical services, and nursing care.
- Utilisation of big data by academia and industries will lead to new products and services, and
- Acceleration of the digital transformation is therefore much expected while the BRT welcomes the initiatives led by the Cabinet Office on the healthcare digital transformation.

WP-2 / # 12 / EJ to J **Infectious disease control and vaccine policies should be reinforced**

The BRT calls on the Japanese Authorities to:

- Accelerate international harmonisation of vaccine regulations and minimise Japan-specific standards to offer access to vaccines to people in Japan without delay.
- Promote regulatory reform to enable flexible regulatory decision-making depending on the evidence level and urgency, including improvement of the Emergency Use Authorization (EUA) system and expansion of the use of the conditional approval system, and

- Reinforce infectious disease control, preventive medicine, and vaccine policies, including the national immunisation program, using learnings from the COVID-19 pandemic.

The BRT believes that:

- The people in Japan suffer a disadvantage from delayed access to COVID-19 vaccines, largely resulting from a lack of international regulatory harmonisation and limited agility in regulatory systems to respond to the public health emergency. The BRT welcomes MHLW's plan to expedite the regulatory processes for emergency cases. Japan-specific standards should be minimised and fast access to vaccines and therapeutics should be ensured for the people in Japan, and
- Investing in preventive medicine and infectious disease control is one of the important pillars for our healthcare system to ensure a healthy and safe society. It requires a robust national strategy and upfront investment to promote vaccine development and infectious disease control

Biotechnology (Industry)

WP-2 / # 13 / EJ to J **Fostering bioeconomy by encouraging small-to-mid-sized enterprises, such as start-up companies should be promoted**

The BRT calls on the Japanese Authorities to:

- Accelerate the project to promote the drug discovery venture ecosystem by the Japan Agency for Medical Research and Development, enhance support for the development of the business environment, and promote innovations driven by small-to-mid-sized enterprises, such as start-up companies under the Pharmaceutical Industry Vision and the action plans in Bio Strategy 2020, authorised by the GOJ.

The BRT believes that:

- Supporting start-up companies, from every aspect of their business activities, such as research, development, human resources, funding, etc., is important for innovation in the healthcare sector,
- Enhancing the project to promote the drug discovery venture ecosystem should help to secure investment in drug development and commercialisation in Japan and ensure the availability of breakthrough innovations, including gene and cell therapies, without delay from other countries, and
- Planning and implementation of specific measures for this bio-strategy allow for an early opportunity to cooperate and collaborate with European stakeholders engaged in the bioeconomy promotion in the EU and Japan, to aim at sustainable development of the economy in both EU and Japan.

Biotechnology (Agriculture)

WP-2 / # 14 / EJ to J **New technologies, including biopesticides and biostimulants, should be further promoted to achieve both environment protection and sustainable agriculture**

The BRT calls on the Japanese Authorities to:

- Encourage a reduction in the use of antibiotics in agriculture production to reduce the risk to the well-being of humans, and
- Promote the development of new technologies to reduce the use of soil fumigants which would represent about 50% of chemical inputs.

The BRT believes that:

- Key technologies include newer and safer chemicals with higher selectivity or farming practice, such as crop rotation or improved soil health with improved soil diagnosis.

WP-2 / # 15/ EJ to J **Reviewing period for genetically modified crops should be shortened**

The BRT calls on the Japanese Authorities to:

- Further shorten reviewing period through harmonisation in data requirement for genetically modified crops as well as dossier on human & environment safety, and through acceptance of summaries in English, as well as
- Take advantage of the evaluation results from foreign countries in order to reduce the resource burden on the Japanese authorities, and
- Expand the scope of the genetically modified crops for which local confined field testing may be excluded to other crops and traits based on accumulated evidence and scientific justification by leveraging confined field-testing data from foreign countries.

The BRT believes that:

- Along with the unstable international situation and rising food prices, concerns are growing over stable food supply in Japan. Delivering novel and safe seeds is vital for addressing such concerns by increasing food production, saving labour and energy in agriculture, and reducing environmental impact.
- While R&D-intensive companies are continuously and heavily investing in new technologies, the innovation will not contribute to food production without their governmental approval. Hence, early market access to novel genetically modified crops is crucially important.

- Delayed market access to novel genetically modified crops will cause technology gaps, resulting in unnecessary disadvantages for farmers due to limited access to innovative products.
- Further progress in shortening the reviewing period would bring Japan much closer to international best practice standards, while the BRT acknowledges the shortened time to market for the new active substance of crop protection products, and
- Harmonising international data requirements will enable the industry to avoid duplicated investment for market access in the respective area. Currently, only China and Japan request local confined field testing for GMO crops for import use, while other import countries like the EU, Korea, Taiwan, etc. leverage the field data collected in cultivation countries for safety assessment.

WP-2 / # 16 / EJ to E **Measures should be established to secure a stable supply of agricultural chemicals to importing countries**

The BRT calls on the EU Authorities to:

- Not to immediately stop production and exportation of the pesticidal active substances banned in the EU as they are critically important for stable food production in the countries that import them from the EU.

The BRT believes that:

- Pesticides are essential materials for the stable and sustainable production of affordable foods.
- The EU policy not to produce and export the pesticidal active substances banned in the EU under the Chemicals Strategy for Sustainability in the EU New Green Deal will affect the stable and sustainable production of affordable foods globally, while the BRT respects the EU decision,
- Because of their intrinsic hazardous properties of pesticidal active substances, the quality and use of pesticides are highly regulated, and they are only used after intensive risk assessments in respective countries. Any addition or change in the sourcing of pesticidal active substances is strictly controlled and requires demonstration of the equivalence, and thereby stable production and supply of high-quality active substances is critically important, and
- Pesticides are highly regulated in the destination countries and the use of such pesticides in the destination countries is different from that in the EU and thereby the outcomes of the pesticide use are different.

Recommendations from European industries

Industrial Chemicals

WP-2 / # 17 / E to J **English translations for issued regulations should be provided**

The BRT calls on the Japanese Authorities to:

- Provide English translations of all issued regulations from METI (Ministry of Economy, Trade, and Industry) and MHLW at the same time as, or shortly after, the announcement in Japanese.

The BRT believes that:

- Japan's regulating authorities should provide English translations of issued regulations, adapting to global practice and thereby enhancing Japan's presence in the world market.

WP-2 / # 18/ E to J **Reference to CAS numbers in regulations for chemical substances should be provided**

The BRT calls on the Japanese Authorities to:

- Indicate CAS (Chemical Abstract Services) numbers in addition to chemical compound names in regulations issued by authorities, as has become a global practice.

The BRT believes that:

- If METI and MHLW regulations would refer to Chemical Abstracts Service (CAS) numbers in addition to chemical compound names, risks of differing interpretations and varying degrees of regulatory compliance can be avoided. In addition, swift and accurate internal alignment of concerned companies could be ensured.

WP-2 / # 19 / E to J **Naming requirements for product labels of chemicals with the names used in Japanese law should be aligned**

The BRT calls on the Japanese Authorities to:

- Revise the labelling requirement of the Poisonous and Deleterious Substance Control Law (PDSCL) to indicate chemicals in accordance with the naming used in Japanese law instead of stating the specific names of the included substance.

The BRT believes that:

- A harmonisation of the labelling requirement regulations (PDSCL, ISHL, and PRTR) to list the contained chemical “as regulated by the Japanese law” on the label would allow users to quickly assess the toxicity and regulatory relevance of the materials they handle, and
- The discrepancies between naming in Japanese regulations and product labelling requirements pose a risk that substances are used without a clear understanding of the regulations they relate to. This should be avoided.

Recommendations from Japanese industries

Animal Health

WP-2 / # 20 / J to EJ **Mutual recognition of GMP for Animal Health products should be ensured**

The BRT calls on the EU and Japanese Authorities to:

- Agree on the mutual recognition of European and Japanese marketing authorisations for veterinary products, starting with mutual recognition of GMP certification of veterinary medicines, and
- Include veterinary products within the scope of the MRA (Mutual Recognition Agreement).

The BRT believes that:

- Mutual recognition of GMP certification for veterinary products between the EU and Japan will provide for faster access to new useful products.