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 Labor 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, Authorization, 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 aging populations, shifting demands for products and services, food security and environmental protection. In addition, the crisis caused by COVID-19 profoundly affected every part of society and has underlined the importance of science and technology. Life sciences and biotechnologies offer the possibility of technologies that will help address these challenges and achieve both economic growth and sustainable recycling-oriented society or bioeconomy society.

Working Party 2 focuses on the following sectors:

- Life Science & Healthcare (pharmaceuticals and medical devices)
- Biotechnology (agriculture 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 and that will eventually contribute to the establishment of a bioeconomy society.

In addition to the publication of the Pharmaceutical Industry Vision 2021 by the Ministry of Health, Labour and Welfare (MHLW) in Japan, which emphasizes the importance of continuous innovation to protect people's health and lives and thereby the need to promote pharmaceutical industry policy, the BRT welcomes "Basic Policy on Economic and Fiscal Management and Reform 2022" approved by the Cabinet of Japan in June 2022. The Basic Policy stipulates investment to ensure the quality and stable supply of pharmaceuticals, strengthen drug discovery capabilities, improve science and technology capabilities, and realize innovation. The BRT expects that public-private collaboration will be further enhanced to realize the MHLW Vision and improve the drug discovery, research and development systems as well as the international harmonization of regulations to achieve an innovation-conducive environment.

The conclusion of the Economic Partnership Agreement (EPA) was a major achievement for both sides and will bring mutual economic benefit.

Instead of an ending, the EPA should be seen as a beginning. It should be a launch pad: a chance to renew our commitment to removing barriers to business; a chance to find new energy for strengthening our economic relationship; a chance to deliver on the recommendations in this report. Let us take those chances.

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 COVID-19 and infectious disease control

The BRT calls on the EU and Japanese Authorities to:

- support the research, development, and manufacturing of diagnosis, treatments and vaccines for COVID-19 and coordinately promote collaborative actions of companies and/or academia to accelerate their developments, in alignment with the100 Days Mission proposed by G7, the ambition to make safe and effective vaccines, therapeutics and diagnostics available within 100 days of an epidemic or pandemic threat being identified,
- address the inequity in access to COVID-19 vaccines in collaboration with industry and non-governmental organizations by removing barriers hindering the equity,
- protect and respect intellectual property rights of COVID-19 vaccines and therapeutics, and
- continuously promote the research and development for other infectious diseases especially for AMR (Antimicrobial Resistance).

The BRT believes that:

- although collaborations among government, industry and academia have made COVID-19 vaccines available at an unprecedented speed, COVID-19 vaccines are not equally reaching all populations worldwide. Trade restrictions and regulatory barriers should be removed to facilitate the cross-border supply of COVID-19 vaccines and support should be given to enhance the infrastructure to deliver vaccination programs around the world,
- respect of intellectual property rights is fundamental to stimulating R&D and ensuring the scale up of supply. Waiving intellectual property rights on COVID-19 vaccines and therapeutics would not assist in improving vaccine equity but only undermine the ability to innovate and respond to ongoing and future global health threats, and
- overcoming the pandemic is the most important issue, but there are also significant challenges in the medium to long term. 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. At the same time, it is necessary to secure resources for solving such 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. The BRT welcomes the governments' recognition of the

need to foster SMEs. Building on some measures taken in response to the COVID-19 pandemic, 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 harmonization between the EU and Japan,
- harmonize submission-related formats and standards,
- ensure post-approval QMS inspection dates coincide with the renewal of marketing authorization 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,
- harmonize 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 recognize Medical Devices product licenses. Existing similarities between EU and Japanese regulations on low risk class II devices make mutual recognition on 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:

- harmonizing 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 utilization 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 minimizing the administrative burden on manufacturers, and
- early disclosure of clinical trial-related guidance would promote the entry of overseas companies to 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 environment protection. Climate change has led to increases in the frequency and intensity of natural disasters and loss of biodiversity, which affects agricultural production and jeopardizes food security. To reduce the environmental impact through agriculture production, both the EU and Japan have developed sustainable food production policies, including 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 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 authorized 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 a key to achieving environmental goals without impeding agricultural productivity,
- enhancement and harmonization 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 gene-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 gene-edited (GE) crops in a science-based and proportionate manner,
- advance and adhere to global harmonization 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 to weed out misinformation, and
- ongoing regulations regarding data requirements for emerging technologies are not fully updated resulting in duplication of studies.

LIFE SCIENCE & HEALTHCARE
WP-2 / # 05* / 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 in line with the Cabinet's Basic Policy on Economic and Fiscal Management and Reform 2022, in order for it 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,
- vitalize the drug discovery and development capabilities in Japan in line with the MHLW's Pharmaceutical Industry Vision 2021 by improving the current pricing system to strengthen the reward for innovation and maintain an incentive for companies,
- determine a drug price that properly reflects evaluation which includes a wide range of elements such as clinical efficacy to patients and doctors, 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,
- 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 administrative labour and costs involved in drug price surveys and drug price revisions, which are required to implement annual revisions are a considerable cost driver and in consequence hinder a sustainable reduction in medical costs. Therefore, in order to improve the return on investment and policy implications of the off-cycle price revision, it is necessary to limit the revision's scope,
- the repeated revisions to the pharmaceutical pricing system introduced since 2018 with as short as three-month notice, created significant issues with business predictability for the Japanese market and could result in delayed access to the latest treatments for Japanese patients. Market predictability is essential as the development of innovative drugs requires long-term, substantial investment,

- the MHLW's Pharmaceutical Industry Vision 2021 should be leveraged to encourage the industry to generate innovations in Japan. 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,
- 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 reward 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., and
- opportunities for the industry to provide input on healthcare and pricing reform are currently limited, with which meaningful discussions cannot be made. Opportunities should be enhanced for more constructive dialogues and working level discussions.

WP-2 / #06* / 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 harmonization, including removal of Japan-specific regulatory standards and requirements, especially for regenerative medicine, to ensure fast access to innovations for the people in Japan without any delay from EU and other countries,
- utilize 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 personalized 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 harmonization and convergence in Japan with more flexibility and adaptability

in regulatory and health insurance systems to ensure that patients in Japan can benefit from latest innovations in the world,
- minimizing Japan-specific standards and accepting more international data will accelerate the authorization 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, further regulatory harmonization and flexibility is 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 / # 07 / 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 / # 08 / EJ to J
Health Technology Assessment (HTA) should be carefully applied

Health Technology Assessment (HTA) for Pharmaceuticals should not become a barrier for 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, 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 is 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 devices;
  - 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 / # 09 / EJ to J
A harmonized 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 harmonized 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, and
- utilization of big data by academia and industries will lead to new products and services.

WP-2 / # 10 / EJ to J
Infectious disease control and vaccine policies should be reinforced

The BRT calls on the Japanese Authorities to:

- accelerate international harmonization of vaccine regulations and minimize 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,
- oppose a waiver on intellectual property rights on COVID-19 vaccines and therapeutics by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), and
- reinforce infectious disease control, preventive medicine and vaccine policies, including the national immunization 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 harmonization 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 minimized and fast access to vaccines and therapeutics should be ensured for the people in Japan,
- waiving patents on COVID-19 vaccines would not assist the capacity expansion of COVID-19 vaccines but only induce the risk of counterfeit vaccines and negate any innovation-based response to future pandemics, 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 / # 11/ 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:

- enhance support for the development of business environment and promote innovations driven by small-to-mid-sized enterprises, such as start-up

companies under the Pharmaceutical Industry Vision 2021 and the action plans in Bio Strategy 2020, authorized 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, and
- planning and implementation of specific measures for this bio-strategy allows 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 / # 12 / 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 of 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 / # 13 / 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 harmonization 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 genetically modified soybean and other crops 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 new active substance of crop protection products, and
- harmonizing 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 and Taiwan etc. leverage the field data collected in cultivation countries for safety assessment.

WP-2 / # 14 / 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

LIFE SCIENCE & HEALTHCARE

WP-2 / # 15 / E to J
Requirements for Japanese versions of the clinical trial protocol and investigator's brochure should be relaxed

The BRT calls on the Japanese Authorities to:

- accept clinical trial protocols and investigator's brochures as well as applications, which are written only in English.

The BRT believes that:

- acceptance of English-only protocols and investigator's brochures would reduce costs and make innovative drugs available to patients in Japan more quickly, and
- the requirement for translation of the original English version of a clinical trial notification is delaying the start of patients' enrolment in Japan.

INDUSTRIAL CHEMICALS

WP-2 / # 16 / 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 / # 17/ 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 / # 18 / 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 harmonization 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 / # 19 / 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 authorizations 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.

INDUSTRIAL CHEMICALS

WP-2 / # 20 / J to E
The draft regulations on microplastics for cosmetics in EU under REACH (regulation for chemicals) should be reconsidered

The BRT calls on the EU Authorities to:

- derogate all wiped-off cosmetic products (make-up, lip and nail products) from the restriction of microplastics.

The BRT believes that:

- microplastic emission from make-up, lip and nail cosmetic products to the aquatic environment is insignificant, because they are wiped-off after their use and, in addition, they are trapped in sewage treatment systems. Restriction of make-up, lip and nail cosmetic products does not contribute to reducing the environmental impact.

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