

Recommendations to the Leaders of the EU and Japan

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

Working Party Leaders:

Mr. Osamu Nagayama
Honorary Chairman
Chugai Pharmaceutical Co., Ltd.

Mr. Christopher Thomas
Representative Director & President
Merck Ltd. Japan

Summary of the Recommendations

Advancing a Sustainable Future Through the Bioeconomy

Europe and Japan share common challenges like declining competitiveness, healthcare issues, climate change, and food security.

Advances in life sciences and biotechnology can help to address these challenges and promote sustainable economic growth towards a bioeconomy society.

Working Party 2 is focused on enhancing innovation in healthcare and biotechnology by:

- Improving efficient healthcare practices.
- Promoting sustainable agriculture and food production.
- Developing bio-based high-performance materials.

Highlighted Recommendations

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

- Establish clear and practical legislation that creates an easy-to-implement system for DSI utilization, balancing benefits and burdens across industries while ensuring legal certainty and consistency.
- Facilitate discussions with various industries to develop business incentives that promote industrial use of DSI, encouraging innovation and active participation in biodiversity conservation efforts.

WP-2/#11*/J Active support should be provided in order to achieve carbon neutrality at an early stage, such as securing biomass raw materials and establishing evaluation and certification systems, to strengthen material production through the utilization of biomass.

- Implement industrial support measures in Japan to secure domestic biomass raw materials, such as utilizing non-edible biomass and forest resources, and remove tariffs on biomass inputs used for products to promote utilization.
- Establish methods for evaluating the environmental value of biomass-derived products and create a certification system, allowing comparison with fossil fuel-derived products and considering greenhouse gas (GHG) reductions.

Highlighted Recommendations

WP-2/#16/EJ Harmonize regulations on Good Simulation Practice (GSP) for medical products

- Establish harmonized regulations on Good Simulation Practice (GSP) for medical products in collaboration with Japanese stakeholders and policymakers, aligning with international GxP guidelines to ensure consistency and efficacy.
- Recognize and promote in silico methodologies as valid alternatives to traditional experiments, reducing the need for animal and human testing while enhancing efficiency and patient relevance in medical product development.

WP-2/#17/EJ Re-establish industry leadership in BioSciences

- Implement comprehensive policies and targeted investments in the EU and Japan to strengthen the biosciences ecosystem, setting clear numerical targets for increases in R&D funding, startup formation, clinical trials, new therapy approvals, industry growth, employment, and exports.
- Foster EU-Japan collaboration by establishing shared biomanufacturing facilities for startups, incentivizing the use of allied CRO/CDMO facilities, and creating a working group to explore joint R&D, regulatory harmonization, and trade facilitation in biosciences and biotechnology.