

Recommendations to the Leaders of the EU and Japan

Working Party 2

Life Sciences & Biotechnology, Healthcare & Well-Being

Working Party Leaders:

Mr. Osamu NAGAYAMA Honorary Chairman Chugai Pharmaceutical Co., Ltd. Mr. Julio TRIANA

President, Representative Director & Senior Bayer Representative for Japan Bayer Holding Ltd.



Overview of WP-2 Recommendations

- WP-2 recommends taking action, to improve the innovation capabilities in the sectors below;
 - Life Science & Healthcare (9)
 - Biotechnology (6)
 - Industrial Chemicals (4)
 - Animal Health (1)

* () number of recommendations

- WP-2 strongly calls on the EU and Japan to foster a sustainable business ecosystem and accelerate the following actions:
 - Properly evaluate innovations
 - Expedite regulatory harmonization
 - Promote new technologies to achieve sustainable food production and environmental load reduction

 RESTRICTION



Prioritized WP-2 Recommendations

- Properly evaluate innovations
 - Properly reward innovations to fulfill patient unmet needs
 - Exclude innovative drugs from off-year drug price cuts in Japan
- Expedite regulatory harmonization
 - Promote regulatory reform to accelerate international regulatory harmonization
 - Utilize regulatory process more appropriately and effectively to promote evaluation and authorization of pharmaceuticals with high needs
 - Apply more flexible evaluation processes for breakthrough innovations
- Promote new technologies to achieve sustainable agriculture
 - Mutually accept biostimulants/biopesticides that are authorized in the respective market without requiring local risk assessments
 - Develop scientifically sound data requirements and risk assessment processes for new technologies



Bioeconomy for sustainable agriculture/food

- To overcome the major challenges presented by climate change combined with a growing global population, WP-2 places focus on new technologies to reduce environmental impact and improve agricultural productivity
- Innovation that enables the replacement of hazardous chemical pesticides with safer ones is a key driver to achieving sustainable food production policies
- Key enablers include:
 - promotion of biopesticides, biostimulants, and RNA interferences
 - enhancement and harmonization of registration systems and mutual acceptance of biopesticides/biostimulants
 - Incentives for growers to adopt safer and more sustainable solutions in farming