



Deliverable D5.1

White paper on ethical and regulatory aspects

Work package number and title	<i>WP5 Legal and ethical framework for microbiome biobanking</i>
Work package leader	<i>DSMZ</i>
Relevant Task	<i>T5.1 Developing a legally compliant consortium framework</i>
Lead contributor to Deliverable	<i>DSMZ</i>
Other contributors to Deliverable	<i>AIT, CABI, INRAE, HMGU, EMBL, MUG, SU</i>
Due date (month)	<i>M30</i>
Version	<i>1</i>



1. Background

Kickstarted with the workshop on the Nagoya Protocol held on December 11, 2023, WP5 began addressing Access and Benefit Sharing (ABS) compliance within the consortium. Significantly, the wide resonance and involvement of external participants in the workshop is testimony to the interest in compliance that extends beyond the MICROBE community of microbiologists.

Building on this initial experience, which revealed strong demand within the microbiology community for a deeper understanding of compliance frameworks related to microbiological resources and biobanking, WP5 mobilised all MICROBE project members to encourage broader reflection. The goal was to use the experience and compliance challenges of MICROBE's members as a foundation for gathering insights on ABS compliance from other stakeholders in microbiology and microbiome research, aiming to create a more comprehensive and impactful analysis.

2. White paper

This effort resulted in the manuscript "How to "do" the Nagoya Protocol: common misconceptions, challenges and best practices for access and benefit-sharing compliance". The manuscript, was coordinated under WP5 by the Leibniz Institute DSMZ of MICROBE and summarises the real-world experience on ABS of three Horizon Europe consortia in the field of microbiology: MICROBE, Microbes-4-Climate (M4C), and European Viral Outbreak Response Alliance (EVORA), as well as two human microbiome alliances, Afribiota and Global Microbiome Conservancy. This broad consortium addressed the challenges and opportunities presented by the UN Convention on Biological Diversity's Nagoya Protocol in developing ABS-compliant research in microbiology. In particular, it highlighted the paucity of practical information available to the scientific community and low awareness of the Nagoya Protocol among practitioners in the life sciences. It is therefore our intention that D 5.1., emerging from reflections on MICROBE's internal ABS compliance, will become a support tool to help a wider audience of microbiologists and researchers in the life sciences.

Currently submitted for consideration to Nature Microbiology for the "Best Practices in Microbiology" series, the preprint is available Open Access on Zenodo:

Faggionato, D., Muñoz García, M., Kostic, T., Ferrari, M. L., Vonaesch, P., Poyet, M., Portier, P., Ryan, M., Djeddour, D., Stumptner, C., Varese, G. C., Zuzuarregui, A., Groussin, M., Schloter, M., Finn, R. D., Haas, A. S., Probert, I., Verkley, G., Overmann, J., & Scholz, A. (2025). How to "do" the Nagoya Protocol: common misconceptions, challenges and best practices for access and benefit-sharing compliance.

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