

How to "do" the Nagoya Protocol: common misconceptions and practical advice for access and benefit-sharing compliance

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Europe Biobank Week 2025

3A: One Health: Non-human biobanking



Biodiversity loss 1970-2020 (Living Planet Index 2024)





Multilateral environmental agreements Under the UN Envirormental Programme





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Convention on Biological Diversity

196 Parties

Objectives:

- the conservation of biological diversity
- sustainable use of its components
- the fair and equitable sharing of the benefits arising from commercial and other utilization of genetic resources

Timothy Swanson, International Affairs, Volume 75, Issue 2, April 1999, Pages 307–331

The Nagoya Protocol (NP)



Adopted on 29 October 2010 Enterd into force on 12 October 2014

Provides the legally binding supplementary protocol to the CBD for the effective implementation of the third objective of the CBD:

• The fair and equitable sharing of benefits arising from of the utilization of genetic resources

Key principle:

 It provides a comprehensive international framework for Acces and Benefit Sharing (ABS) and compliance The Nagoya Protocol (NP)



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What is ABS about?

enefit-

haring



Access...

- Taking and using material for research and development AND
- asking for permission first

Benefit-sharing...

- is giving something back
- can be many things: sharing research results, joint research and publication, training, in-kind support....
- should contribute to conservation and sustainable use of biodiversity

ABCs of ABS – the pillars of the protocol





The Nagoya Protocol is relevant for you if you do research with genetic resources or derivatives

What is a genetic resource?

Biological material that contains DNA/RNA (alive or dead)

"any material of plant, animal, microbial or other **(non human)** origin containing functional units of heredity i.e. genes."





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"any material of plant, animal, microbial or other **(non human)** origin containing functional units of heredity i.e. genes."

Excludes:

- Human DNA/RNA (including pathogens & microorganisms on/in human bodies),
- Plant genetic resources under the ITPGRFA*
- Influenza strains under the Pandemic Influenza Preparedness (PIP) Framework*

*the material and use must be under the scope of these agreements (example rice)







The Nagoya Protocol is relevant for you if you do research with genetic resources or derivatives

What is a derivative?

Derivatives

"naturally occurring biochemical compounds resulting from the genetic expression or metabolism, even if it does not contain functional units of heredity".

Some examples are: proteins (including enzymes), lipids, organic compounds (e.g. essential oils or resins) and other products of metabolism.



MICROBE

Biobanking (RI)

Enabler

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Access and Benefit Sharing (ABS) measures ensure that research results **support provider countries** to:

- Make **informed decisions** on conservation, sustainable use and management of their biodiversity.
- Implement **innovative solutions** for productive activities, contributing to sustainable development.
- Build capacities for **local research** / to solve local problems
- Other monetary or non-monetary benefits as agreed.

The ABS principle is easy to understand but ABS compliance is complex





The ABS principle is easy to understand but ABS compliance is complex







- Legal complexity
- Diversity of regulatory frameworks and liability fragmentation
- Rules for retrospective ex situ access
- Governance and legal complexities affecting Indigenous People and Local Communities (IPLC) involvement in ABS
- Incompatibility of some ABS laws and the International Code of Nomenclature of Prokaryotes (ICNP)
- Insufficient Legal and Regulatory Training in Scientific Education





 August 2016 – Entry into force of the French law on ABS (simple declaration for non-commercial use vs. full authorization for commercial use)

Manuscript in preparation





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ABS legislation evolves!

ABS compliance intricacies There's more to that!





Vonaesch/Ferrari/Poyet/Groussin Made with Biorender

Let's correct some misconceptions about the Nagoya Protocol... the "DOs"!



- Researcher from countries that are not Party to the Nagoya Protocol <u>DO</u> have ABS obligations
- Non-commercial academic researchers **DO** have ABS obligations
- ABS legislations <u>DO</u> apply to national researchers of provider countries (in most cases)
- Provider countries **DO** refer to where the genetic resource were originally colleccted, not where it is cultivated, grown, or stored
- The inclusion of microorganisms belonging to the human microbiome under the scope of ABS regulations <u>DO</u> varies among countries

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How to **DO** the Nagoya protocol, some effective advices (Before you start your research)



Define the provider country: In-situ access/Ex-situ access

Understand Regulations:

- Check national laws & permits and Contact authorities
- Confirm if GR/aTK access is regulated

Permit Process:

- Each country has unique procedures
- Negotiate fair benefit-sharing agreements: don't make promises you can't keep
- Ensure application completeness and verify permit validity

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How to **DO** the Nagoya protocol, some effective advices (while you do your research and afterwards)



- Follow ABS permit terms
- Request modifications if project changes
- New permit may be needed for different sample use
- Stay compliant with national laws

After Research:

- Share benefits as agreed
- Cite IRCC or national permit number in publications



- Complex, but can be navigated
- Not always pleasant, but let us remember that the purpose is an ethical and fair benefit-sharing from the use of Genetic Resources
- An encouragement to bring people, providers and users of genetic resources together: input from new perspectives and ethical best practices can help improve its application



- Complex, but can be navigated
- Not always pleasant, but let us remember that the purpose is an ethical and fair use of Genetic Resources
- An encouragement to bring people, providers and users of genetic resources together, input from new perspectives and ethical best practices can help improve its application
- Nurture your Networks, use the resources provided by your institutions and extra and inter-institutional resources

Acknowledgements





Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures GmbH

Department of Science Policy & Internationalisation

Dr. Amber Hartman Scholz - Head of the Department Melania Muñoz Garcia

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WISSENSCHAFTSORGANISATIONEN



COP16 - A multilateral mechanism for Digital Sequence Information, decision 16/2





Adapted from Muñoz Garcia et al. 2025

You should think about ABS/Nagoya Protocol if you...



•do research on non-human biological material
•the material originally comes from outside of Germany
•ABS also applies to basic/non-commercial research

•The ABS world is bigger than the Nagoya Protocol



Platform(s) for exchanging information on access and benefit-sharing



CBD ABS Clearing-House https://absch.cbd.int/



National Records ABS National Focal Point 178 Competent National Authority Legislative, Administrative or Policy Measure 299 ABS Procedure National Model Contractual Clause Internationally Recognized Certificates of Compliance 5678 National Websites or Databases Checkpoint 98 Checkpoint Communiqué 1st National Reports on the Implementation of the Nagoya Protocol Interim National Reports on the Implementation of the Nagoya Protocol

...but also: www.nagoyaprotocol-hub.de

