The Nagoya Protocol and its Implications for Research and Development

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19 May 2025

WAGENINGEN
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1. Background
2. The Nagoya Protocol and other international ABS agreements
3. Implementation of the Nagoya Protocol in the EU and NL
4. Implications for users
5. More information

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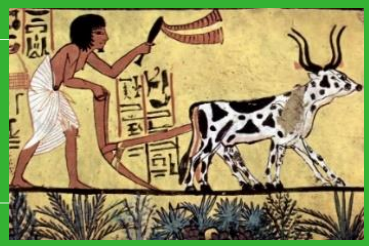
The Nagoya Protocol is about **Access and Benefit Sharing (ABS)**

- What is Access and Benefit Sharing?
  - regulation of access to genetic resources and traditional knowledge associated with genetic resources
  - sharing of benefits from the use of these between providers and users
- What does it mean?
  - you cannot always freely take and utilise genetic resources anymore, but may need permission from a government
- What forms of benefit sharing exist?
  - monetary (e.g. royalties, up-front payments)
  - non-monetary (e.g. scientific co-operation, technology transfer)

ABS is relatively new



- Genetic resources were taken and exchanged freely for thousands of years
  - ➢ *genetic resources were considered 'common heritage of mankind'*
- Second half 20th century: increasing role of Intellectual Property Rights for market products based on genetic resources (e.g. in medicine, cosmetics, plant breeding)
  - ➢ *products based on genetic resources were not considered 'common heritage of mankind'*
- Recognition that many freely available genetic resources from developing countries were transformed in not-freely available market products in developed countries
  - ➢ *concept of Access and Benefit-Sharing (ABS) developed*

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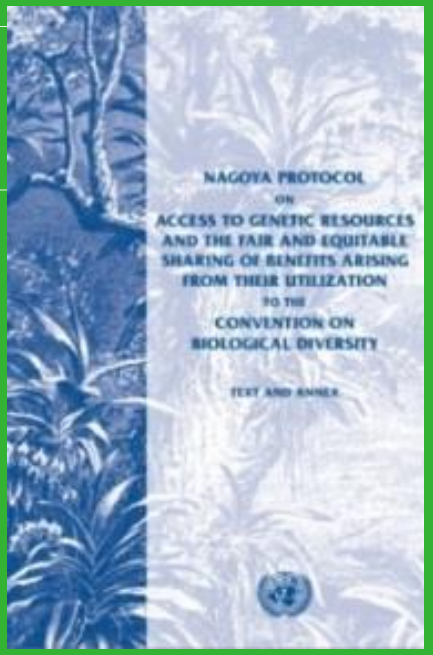
International ABS agreements

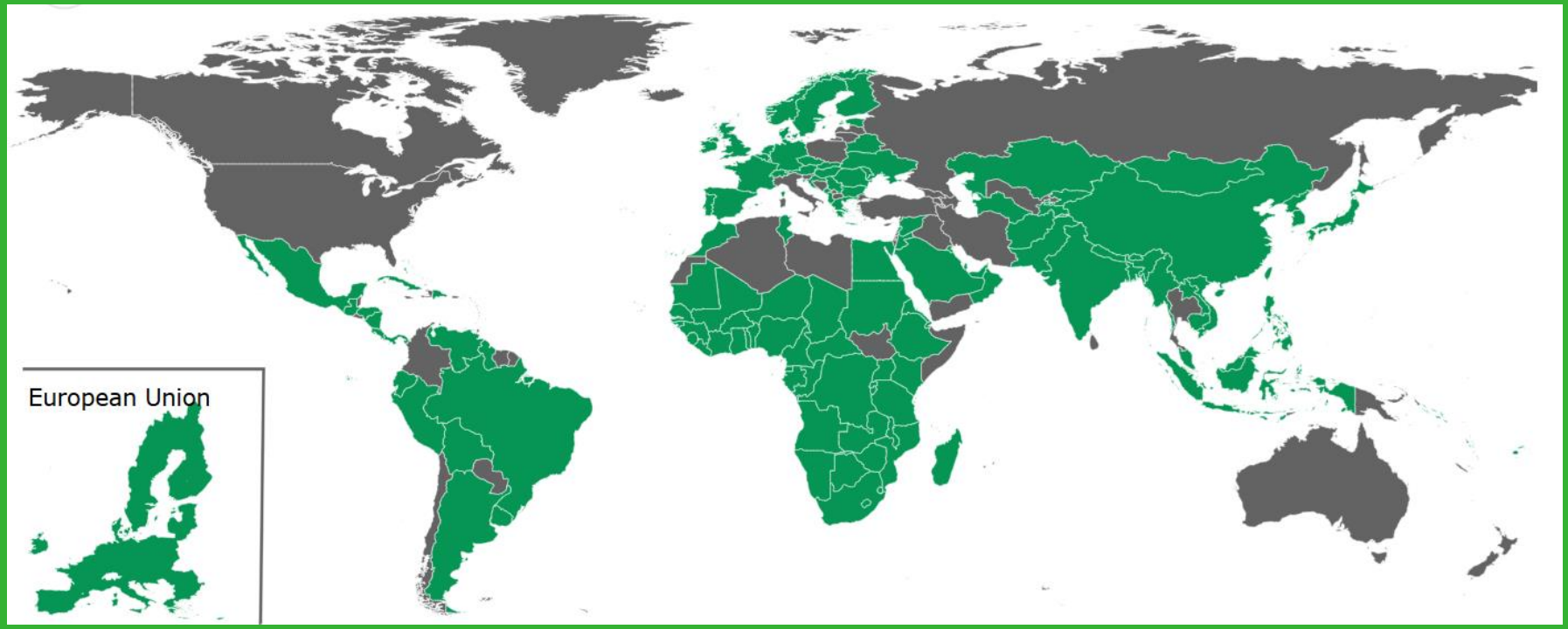
- Existing
  - Convention on Biological Diversity (CBD)
  - Nagoya Protocol (within CBD)
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA; in FAO)
  - Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits (in WHO)
  - ABS instrument for Digital Sequence Information (within CBD)
- *Future*
  - *International instrument on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (BBNJ Treaty or "Treaty of the High Seas")*
  - *Pathogen Access and Benefit-Sharing (PABS) System (in WHO)*

Nagoya Protocol



- Negotiated in UNEP (United Nations Environment Programme)
- Part of (Protocol to) the Convention on Biological Diversity (CBD, 1993)
- In force since 12 October 2014
- Objective
  - *the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components*
- 142 Parties (May 2025)

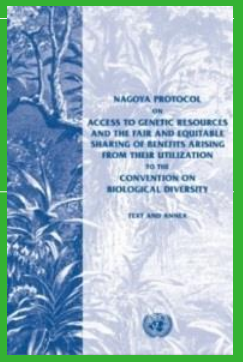
Nagoya Protocol (May 2025)



142 Parties to the Nagoya Protocol

56 Non-Parties

The Nagoya Protocol



- Scope
  - Genetic Resources
    - *any material of plant, animal, microbial or other origin containing functional units of heredity, that is of actual or potential value*
    - *except for human genetic resources*
  - Also provisions on traditional knowledge associated with genetic resources and derivatives
- Principles
  - Provider countries are to ensure clear and transparent procedures
  - Compliance to ABS rules in provider countries is to be monitored by the countries where the genetic resources are utilized

The Nagoya Protocol

- Access on the basis of
  - Prior Informed Consent (PIC): permission by authorities of the country providing genetic resources
    - ➢ *unless otherwise determined by that country*
  - Mutually Agreed Terms (MAT): contract with provider
    - ➢ *so, bilateral negotiations are necessary*
- Benefit-sharing
  - benefits can be monetary (e.g. royalties, up-front payments) and non-monetary (e.g. co-operation, technology transfer)
  - to be bilaterally agreed (in Mutually Agreed Terms)

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Implementation Nagoya Protocol in EU and NL

- EU
  - The EU ABS Regulation (Regulation (EU) 511/2014)
    - *published in 2014; legally binding*
  - Implementing Regulation (EU) 2015/1866
    - *published in 2015; legally binding*
  - Guidance document
    - *published in 2016; revised 2021; gives explanations, not legally binding*

- NL
  - Nagoya Protocol (Implementation) Act
    - *published in 2015*

The EU ABS Regulation (Regulation (EU) 511/2014)

- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, NOT with access*
  - *access regulated by individual countries, not at EU level*
- Entry into force: **12 October 2014**
- Applies to genetic resources
  - accessed from 12 October 2014 onwards
  - accessed from a country that is a Party to the Nagoya Protocol and has established access measures
  - utilised in R&D within the EU (commercial and non-commercial)
- Legally binding for all companies, institutions and individuals within the EU

The EU ABS Regulation: User obligations (Art. 4)

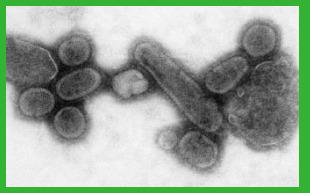
- To exercise 'due diligence' to ascertain that the genetic resources (and associated traditional knowledge) they utilise have been legally acquired, and that benefits are shared
- To utilise and transfer genetic resources in accordance with the MAT (Mutually Agreed Terms)
- Therefore:
  - seek relevant ABS information
  - obtain required permits and contracts
  - keep ABS information for 20 years after end utilisation
  - transfer relevant ABS information to subsequent users

The EU ABS Regulation: Member State obligations (Art. 7, 9, 11)

- Lay down rules on penalties in case of non-compliance
  - ➢ "effective, proportionate and dissuasive"
- Carry out checks to monitor compliance of users
- Request users to submit a 'due diligence declaration'
  - ➢ when external funding is received for research project using genetic resources
  - ➢ at the stage of final development of a product developed via the utilisation of genetic resources

The EU ABS Regulation: Specialised International Instruments (Art. 2)

- The EU ABS Regulation does not apply when ABS of genetic resources is covered by a '*Specialised International Instrument*' (Art. 2)
- Instruments recognized by the EU:
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
    - ➢ *plant genetic resources for food and agriculture*
  - Pandemic Influenza Preparedness Framework (PIP-framework)
    - ➢ *influenza viruses with human pandemic potential*



- In the future probably more specialised international instruments will be recognized

Implementing Regulation (EU) 2015/1866

- Entry into force: 9 November 2015
- Legally binding
- Lays down more detailed rules on the implementation of certain articles of the EU ABS Regulation
  - due diligence declarations
  - EU register of trusted collections
  - Best practices
- Annexes:
  - information to be provided
  - templates

EU Guidance Document

- First version 2016; revised version 2021
- Not legally binding; explains EU ABS Regulation
  - *if an activity creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development, it falls under the term 'utilisation'*
- Two main parts
  - main text
  - Annex 2

EU Guidance Document: Main text

1. Introduction
2. Scope of the EU ABS Regulation
3. Obligations of users
    - due diligence obligation
    - specific situations
4. Events triggering due diligence declarations
    - external research funding
    - final development of product
5. Sector specific issues
    - health
    - food and agriculture

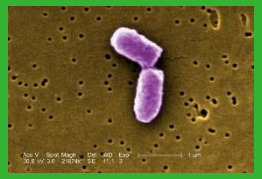
EU Guidance Document: What is utilisation?

- Important element of the main text is about the question: *what is 'utilisation'?* (section 2.3.3)
  - ➢ comprises basic research, applied research and/or product development
- Examples of 'utilisation'
  - research to discover specific genetic and/or biochemical properties
  - creation and improvement of genetic resources to be used in production processes
  - genetic modification

- Examples of 'no utilisation'
  - identification
  - maintenance and management of a collection for conservation purposes
  - genetic resources as testing/reference tools

EU Guidance Document: Specific situations

- Derivatives
  - only in scope if they are naturally occurring compounds
  - only in scope if there is a "verifiable level of continuity" between a derivative and the genetic source from which it was obtained
- Human microbiota (Section 2.3.1.7)
  - studies focusing on the microbiota from an individual human as a whole, and not on individual taxa, are out of scope of the EU ABS Regulation
  - studies focusing on individual taxa isolated from the human microbiota are in scope of the EU ABS Regulation (as the isolate no longer represents the unique microbial composition characteristic of an individual human)



EU Guidance Document: Annex II

- Provides more specific guidance on when genetic resources are considered to be utilised in the meaning of the EU ABS Regulation
- Follows logic of the value chain, starting from acquisition to placing of a product on a market
- Contains many examples (cases) drawn from different sectors, often based on feedback from stakeholders

EU Guidance Document: Annex 2

1. Introduction
2. Acquisition
3. Storage and collection management
4. Rearing and multiplication
5. Exchange and transfer
6. Identification of organisms and other activities at the beginning of the value chain
7. Genetic resources as tools
8. Breeding
9. Product development, processing and product formulation
10. Product testing
11. Marketing and application

Case 1: 'In-depth analysis of amylase enzymes'

In-depth analysis of amylase enzymes

Microorganisms in which alpha-amylase has been detected are studied for their value in baking, by testing of the candidate alpha-amylases under real-life conditions in baking applications (using different doughs, different baking conditions, etc.), and their stability (both shelf-life stability and stability in the dough).

Such activities examine the biochemical composition and activity of a derivative extracted from a genetic resource in detail and are within scope of the EU ABS Regulation (all other conditions fulfilled).

Case 2: ‘Screening of amylase enzymes’

Screening of amylase enzymes

In standardized conditions various microorganisms are screened to check which ones contain alpha-amylases.

This process will only provide information that alpha-amylase is present in some microorganisms and enable the microorganism samples that do not contain alpha-amylases to be excluded from further examination. It does not provide information on how such amylase performs in the baking process.

Such screening to eliminate unwanted microorganisms prior to any analysis is considered screening and out of scope of the EU ABS Regulation.

Case 3: 'Improvement of product characteristics'

Improvement of product characteristics

A company accesses a fungal strain for its known phospholipase activity. However, in application tests the phospholipase turns out not to be sufficiently temperature stable.

Therefore, the strain is genetically engineered to produce more temperature-stable phospholipase, and a recombinant production strain is subsequently generated for commercial-scale production.

Construction of recombinant production strains for more temperature-stable phospholipase variants involves research and development on the genetic and/or biochemical composition of the fungal strain. Therefore, it is in scope of the EU ABS Regulation (all other conditions fulfilled).

National legislation NL

- Nagoya Protocol (Implementation) Act (with Explanatory Memorandum, Regulation and Decrees)
  - implements Nagoya Protocol in NL
  - into force: 23 April 2016
  - Competent National Authority (CNA): Ministry of Economic Affairs (now: Ministry of Agriculture, Fisheries, Food Security and Nature)
  - monitoring agency: Netherlands Food and Consumer Product Safety Authority (NVWA)
  - National Focal Point (NFP): Centre for Genetic Resources, the Netherlands (CGN)
  - *Access to Dutch genetic resources not regulated: Prior Informed Consent (PIC) not needed*

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What to do as a user?

1. Check the access rules of the provider country
   - ABS Clearing House (https://absch.cbd.int/)
   - National Focal Point (NFP) of the provider country
2. Check if the material can be obtained through a specialised international ABS instrument (ITPGRFA; PIP Framework).
   1. *If yes, sign a Standard Material Transfer agreement (SMTA)*
   2. *If no, continue with 3-8*
3. If required, seek permission from the Competent National Authority (CNA) of the provider country (PIC: '*Prior Informed Consent*')
4. Negotiate conditions with provider, and lay these down in a contract (MAT: '*Mutually Agreed Terms*')

What to do as a user?

5. Use the genetic resources only in accordance with the conditions agreed with the provider and laid down in the MAT
    - *if the intended use changes, new PIC and MAT may need to be obtained*
6. Carefully document the use
7. Keep all documentation for 20 years after the end of utilisation
8. Submit a 'due diligence declaration' (through https://webgate.ec.europa.eu/declare/) when you
    - *receive external research funding, or*
    - *bring a product on the market*
9. Pass on information to further users of the genetic resources

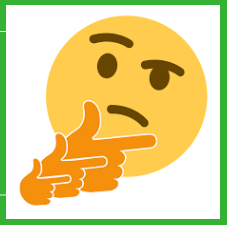
What to document?

- Internationally-recognised certificate of compliance (placed by provider country on the ABS Clearing House website)

OR

- Information/documents on:
  - date and place of access of resources or traditional knowledge;
  - description of the genetic resources or of traditional knowledge;
  - source from which the genetic resources or traditional knowledge associated with genetic resources were obtained, as well as subsequent users (development chain);
  - rights and obligations relating to access and benefit-sharing including for subsequent applications and commercialisation;
  - access permits, where applicable (Competent National Authority);
  - mutually agreed terms, including benefit-sharing arrangements, where applicable

Some further points of attention



- In the EU ABS Regulation, the user is responsible for compliance, not the supplier
  - *if genetic resources for R&D are bought from a trader, request access documentation*
- The utilisation in R&D of genetic resources bought abroad from a local market may also fall under the EU ABS Regulation
- Some EU countries have access legislation
  - *the obligations of the EU ABS Regulation may also apply to material from these EU countries*
- National legislation in provider countries may go further than the EU ABS Regulation
- *Take ABS aspects into account from the very start of the project*

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More information

- ABS Clearing House (absch.cbd.int/)
  - maintained by CBD/NP
  - country information (contact persons, laws)
- ABS website of the European Union (http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)
  - maintained by European Commission
  - information on EU rules
  - EU registers of collections and recognized 'best practices'
- Website of National Focal Point NL (www.absfocalpoint.nl)
  - bilingual (Dutch/English)
  - information on rules and what to do
  - interactive help tool
  - news articles on new developments (e.g. DSI)
  - subscription to ABS newsletter

Thank you for your attention!

www.absfocalpoint.nl

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