



The Nagoya Protocol: background, principles, and implementation

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The Nagoya Protocol: background, principles, and implementation

1. Background
2. The Nagoya Protocol
3. Implementation
4. Key points



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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 utilize genetic resources anymore, but may need permission from a government
- What forms of benefit sharing do exist?
 - monetary (e.g. royalties, up-front payments)
 - non-monetary (e.g. scientific co-operation, technology transfer)



ABS is relatively new

- For thousands of years, genetic resources were taken and exchanged freely
 - *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
 - *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*



ABS Example South Africa

- Product
 - extract of kanna (*Sceletium tortosium*) used as a basis for an antidepressant (Zembrin)
- Partners
 - HGH Pharmaceuticals
 - South African San Council (SASC)
 - local communities
- Access
 - HGH gets permit for bioprospecting and export to conduct research and commercialize products
- Benefit-sharing
 - up-front payments and royalties for SASC and local communities
 - employment creation for local communities through cultivation of kanna



Convention on Biological Diversity (CBD)

- Negotiated in UNEP (United Nations Environment Programme)
- In force since 29 December 1993
- 196 Parties
- Objectives
 1. conservation of biological diversity
 2. sustainable use of its components
 3. fair and equitable sharing of the benefits arising out of the utilization of genetic resources



Convention on Biological Diversity (CBD)

- Important elements
 1. covers all genetic resources (except human material)
 2. affirms that states have sovereign rights over their genetic resources
 3. access on the basis of bilateral negotiations between the provider country and the user
 4. concept of Access and Benefit Sharing (ABS) firmly embedded in the CBD.



From CBD to Nagoya Protocol

- Convention on Biological Diversity (CBD, 1993)

- genetic resources no longer considered 'common heritage of mankind'
- instead, all states have national sovereign rights over their genetic resources



- National ABS legislation established, e.g. Philippines (1995), Costa Rica (1998), Brazil (2001)

- rules often unclear and complex
- enforcement difficult

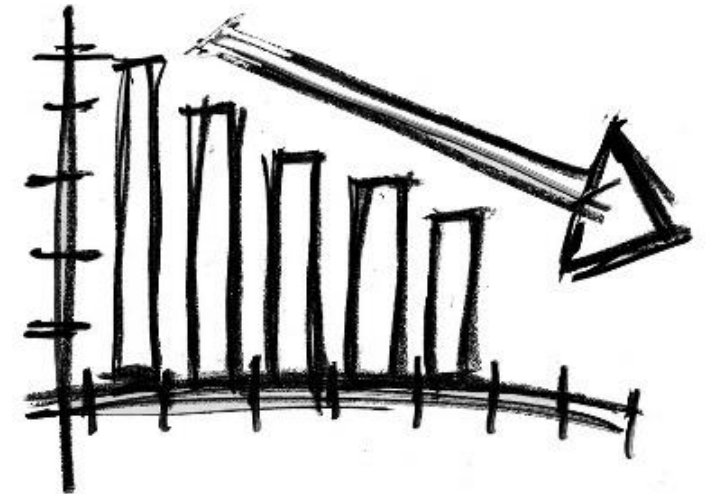


- Implications

- access to genetic resources limited
- little benefit-sharing



- Nagoya Protocol (2014)



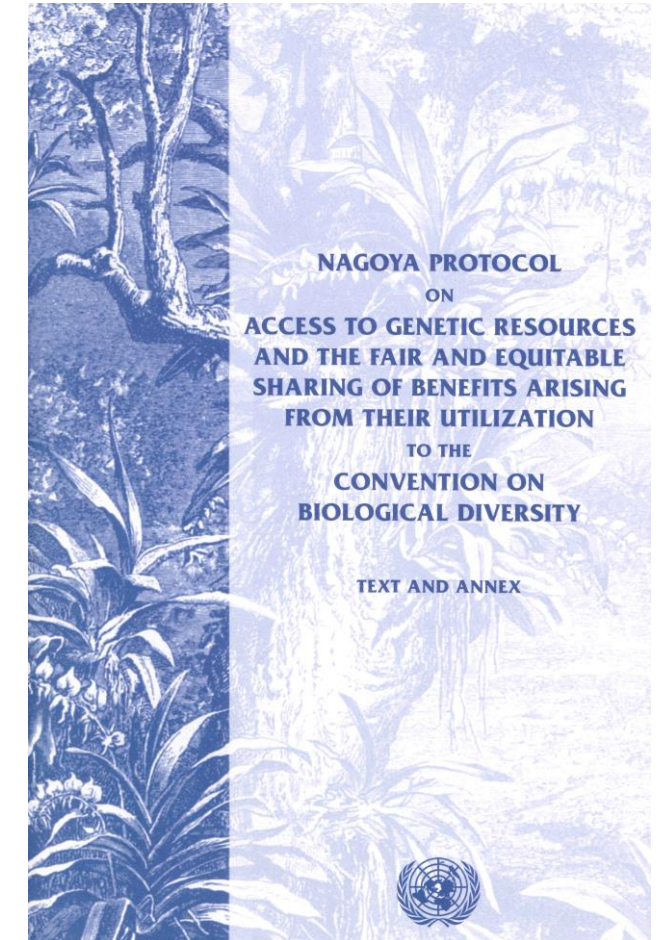
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Nagoya Protocol

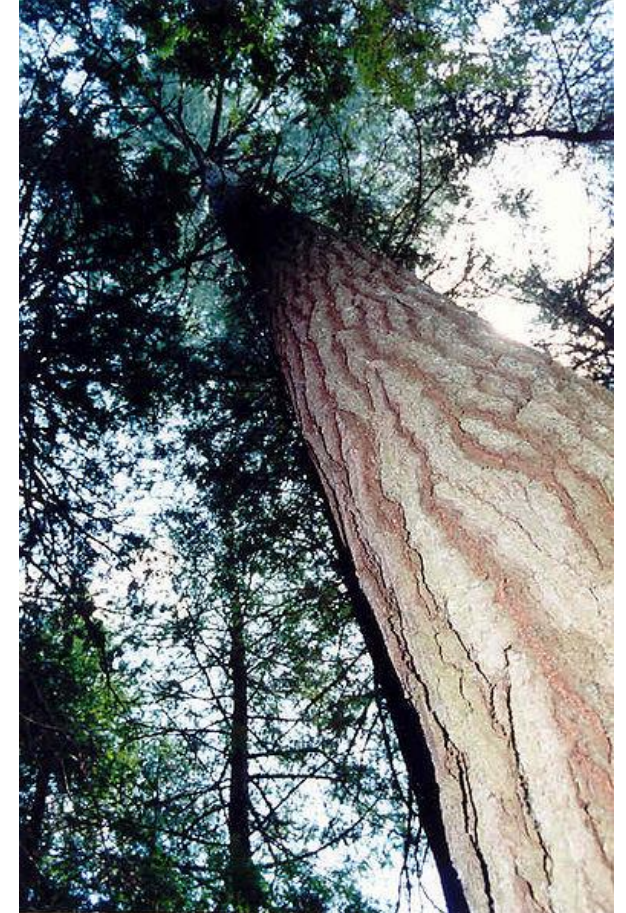
- Part of (Protocol to) the Convention on Biological Diversity (CBD, 1993)
- In force since 12 October 2014
- 143 Parties (as of 1 October 2026)
- Objective
 - the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components



Nagoya Protocol

- Important elements

1. covers all genetic resources (except human material)
2. access and benefit-sharing on the basis of bilateral, case-by-case negotiations between the provider country and the user
3. provider countries are to ensure clear and transparent procedures
4. compliance to ABS rules of provider countries is to be monitored by the countries where the genetic resources are utilized



Nagoya Protocol

- The Nagoya Protocol is about **access** to **genetic resources** and the sharing of benefits arising from their **utilization**
 - what is **access**?
 - the term 'access' is not defined
 - what are **genetic resources**?
 - any material of plant, animal, microbial or other origin containing functional units of heredity, that is of actual or potential value
 - what is **utilization** of genetic resources?
 - to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology



Nagoya Protocol

- Access to genetic resources on the basis of
 1. **Prior Informed Consent** (PIC): permission by authorities of the country providing genetic resources
 - *unless otherwise determined by that country*
 2. **Mutually Agreed Terms** (MAT): contract with provider
 - including agreements on e.g., use, benefit-sharing and transfer to third parties
- Also applies to traditional knowledge associated with genetic resources



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Implementation of the Nagoya Protocol

■ European Union level

- EU ABS Regulation (Regulation 511/2014)
 - published in 2014; legally binding
 - implements the compliance aspects of the Nagoya Protocol in EU
- ~~Implementing Regulation 2015/1866~~
 - published in 2015; legally binding
 - ~~gives more details on some provisions EU ABS Regulation, including templates~~
- Guidance document
 - published in 2016; revised 2021; not legally binding
 - gives explanations



■ National level the Netherlands

- Nagoya Protocol (Implementation) Act
 - published in 2015; legally binding
 - national implementation of the Nagoya Protocol in NL
 - compliance to EU ABS Regulation to be monitored by Netherlands Food and Product Safety Authority (NVWA); information supply by ABS National Focal Point at CGN



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

- Implements the compliance aspects of the Nagoya Protocol in the EU
 - is only about compliance, not about access (access rules established by individual countries)
- Entry into force: 12 October 2014
- Legally binding for all companies, institutions and individuals within the EU
- Applies to genetic resources and associated traditional knowledge
 - 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)
- Does not apply to 'digital sequence information'
- *National legislation in provider countries may go further than the EU ABS Regulation (but the NVWA only monitors compliance to the EU ABS Regulation)*



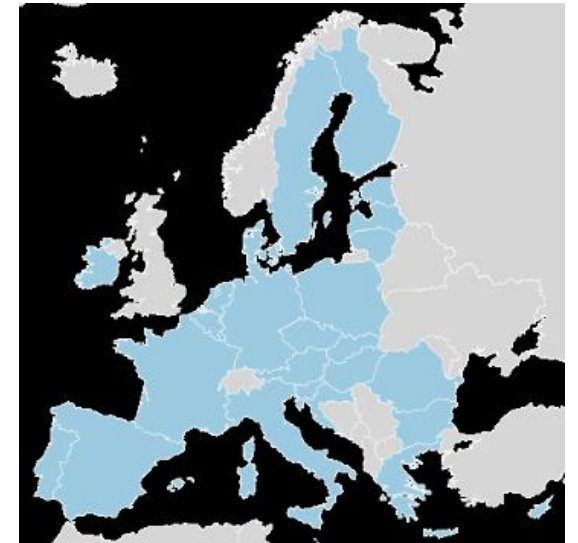
The EU ABS Regulation: User obligations (Art. 4)

- 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 possible subsequent users
- Users of material from a collection included in the EU Register of trusted collections are considered to have exercised due diligence regarding the seeking of information



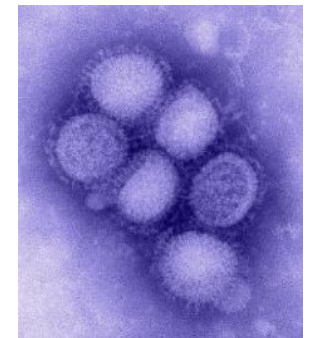
The EU ABS Regulation: Member State obligations (Art. 7, 9, 11)

- 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'
- Specialised International Instruments recognised by the EU
 - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2004)
 - *covers plant genetic resources for food and agriculture*
 - Pandemic Influenza Preparedness Framework (PIP-framework, 2011)
 - *covers influenza viruses with human pandemic potential*
- In the future more specialised international instruments may be recognised



EU Guidance Document

- First version 2016; revised version 2021
- Not legally binding; explains EU ABS Regulation
- EU interpretation of 'utilisation': can be basic research, applied research and/or product development
- 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, Chapter 2: Scope of the EU ABS Regulation (cumulative)

- Geographic scope
 - *applicable to genetic resources from countries which are a Party to the Nagoya Protocol and have established access measures*
 - *applicable to utilisation within EU territory*
- Temporal scope
 - *applicable to genetic resources accessed from 12 Oct 2014 onwards*
- Material scope
 - *applicable to the utilisation of genetic resources and of traditional knowledge associated with GR*
 - *utilisation (R&D) may include basic research, applied research and/or product development*
- Personal scope
 - *applicable to all users of genetic resources*



EU Guidance Document, section 2.3.2:

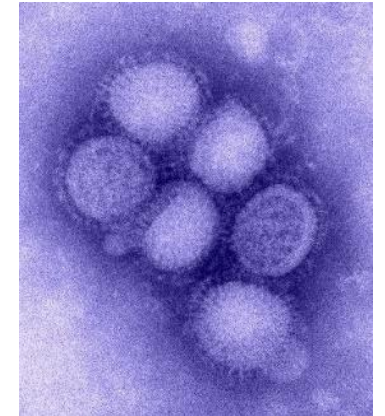
What is utilisation?

- 'utilisation' can be: basic research, applied research and/or product development
 - *if an activity creates new insight into characteristics of the genetic resource which may be of (potential) benefit to the further process of product development, it falls under the term 'utilisation'*
- 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



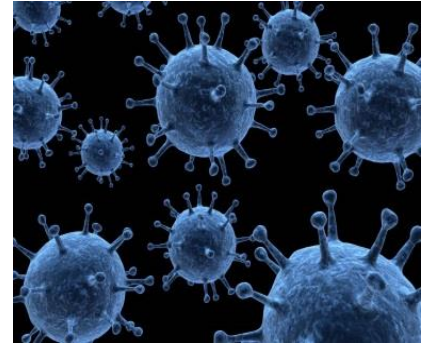
EU Guidance Document, section 5.1: Health as sector-specific issue

- pathogenic organisms that pose a threat to human, animal or plant health fall generally within the scope of the EU ABS Regulation
 - *except those covered by specialised ABS instruments, such as the WHO Pandemic Influenza Preparedness (PIP) Framework*
- Parties are required to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health
- special status given to pathogenic organisms (likely) causing a present or imminent public health emergency of international concern or a serious cross-border threat to health
 - *extended deadline for compliance with the due diligence obligations*



EU Guidance Document, section 2.3.1.5: Unintentionally introduced pathogenic genetic resources and pests

- When pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material are introduced unintentionally into the EU, they fall outside the scope of the EU ABS Regulation, as there was/is no intention of introducing the pathogens as genetic resources
 - *e.g. when travelers who are unknowingly infected with a virus travel into an EU country*
- But: if the pathogenic organisms or pests are established in situ in an EU country following introduction, utilisation of these genetic resources may be in scope of that country's ABS legislation



EU Guidance Document: Annex 2

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



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



EU Guidance Document: Annex II, section 7.1: genetic resources as testing or reference tools

- Guidance

- The application of genetic resources as testing or reference tools is not considered to constitute utilisation in the meaning of the EU ABS Regulation.
- This is because at that stage the material is not the object of the research in itself but only serves to confirm or verify the desired features of other products developed or under development.



EU Guidance Document: Annex II, section 7.1: genetic resources as testing or reference tools

- Case

Use of animals in animal test models

The efficacy of a chemically synthesised compound is tested in an animal test model in an EU country. The animal test model involves rats that show a certain type of cancer.

The rats are used as tools for research and development. Research and development is not carried out on the rats.

Therefore, the use of the rats to test the compound does not constitute utilisation of genetic resources in the meaning of the EU ABS Regulation.



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Key points

1. The concept of Access and Benefit Sharing (ABS) was already firmly embedded in the Convention on Biological Diversity (CBD) in 1993.
2. The main ABS instrument for genetic resources is the Nagoya Protocol, in force since 2014; it obliges countries where genetic resources are used to monitor compliance to ABS rules.
3. The EU ABS Regulation, in force since 2014, is a European law that implements the compliance aspects of the Nagoya Protocol in the EU.
4. The EU ABS Regulation contains obligations for all users in the EU and governments of EU Member States. It does not apply to the access rules of EU Member States.

Key points

5. According to the interpretation of the EU ABS Regulation, 'utilisation' may include basic research, applied research and/or product development.
6. Some activities, such as storing genetic resources in a collection, determining the identity of genetic resources, and using genetic resources as testing and reference tools are not in scope of the EU ABS Regulation.
7. The EU Guidance document provides a wealth of information on what is and what is not considered 'utilisation' in the meaning of the EU ABS Regulation.
8. National legislation in provider countries may go further than the EU ABS Regulation (but the NVWA only monitors compliance to the EU ABS Regulation).

Thank you for your attention!

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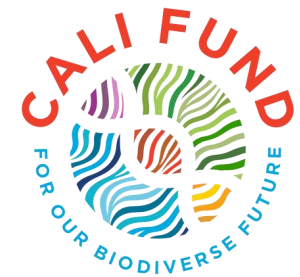
Annex: Beyond the Nagoya Protocol

- Other international ABS instruments
- Multilateral Mechanism for Digital Sequence Information (MLM)
- ABS implementation in the Netherlands



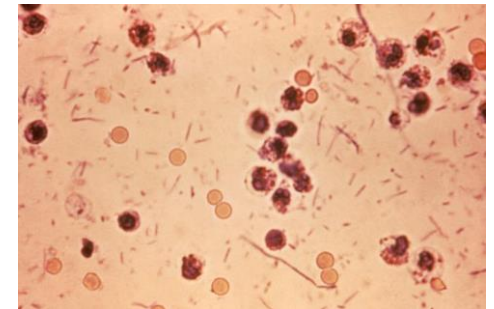
Other international ABS instruments

1. International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2004)
 - covers plant genetic resources for food and agriculture
2. Pandemic Influenza Preparedness Framework (PIP Framework, 2011)
 - covers potentially pandemic influenza viruses
3. Multilateral Mechanism for the sharing of benefits from the use of digital sequence information on genetic resources (MLM, 2024)
 - part of CBD
 - covers Digital Sequence Information (DSI)
 - monetary benefit-sharing through Cali fund



Other international ABS instruments

4. Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ Agreement, 2026)
 - covers marine genetic resources from areas beyond national jurisdiction and related DSI
5. Pathogen Access and Benefit-Sharing System (PABS, under negotiations)
 - covers pathogens with pandemic potential as well as sequence information



Multilateral Mechanism for the sharing of benefits from the use of digital sequence information on genetic resources (MLM)

- Part of the Convention on Biological Diversity (CBD)
- Operationalized in 2024
- Objective
 - the fair and equitable sharing of the benefits arising from the utilization of Digital Sequence Information (DSI) on genetic resources
- Term “Digital Sequence Information” (“DSI”) not defined
 - refers to information on the genetic composition of organisms (only DNA and RNA? metabolites? proteins? other information?)



Multilateral Mechanism for the sharing of benefits from the use of digital sequence information on genetic resources (MLM)

- Important elements
 - open access to DSI in publicly available databases largely maintained
 - no case-by-case benefit-sharing with individual countries, but larger companies in sectors relying on DSI should contribute to a multilateral benefit-sharing fund (the 'Cali fund')
 - indicative rates: 0.1% of revenues or 1% of profits
 - fund to be used for the conservation and sustainable use
 - 50% of funds to go to Indigenous Peoples and Local Communities in developing and developed countries
 - *all users of DSI are expected to engage in non-monetary benefit-sharing*
 - not (yet) a mandatory system
- Other ABS frameworks can use the MLM but can also create their own ABS system for DSI



ABS implementation in the Netherlands

- Access to genetic resources from the Netherlands not regulated
- Compliance aspects of the **Nagoya Protocol** implemented through EU ABS Regulation, a European law, with obligations for users of genetic resources and governments of EU Member States
 - *Inspections of users have been carried out since 2016*
- No legislation considered needed for the implementation of the **ITPGRFA** and the **PIP Framework**
- No legislation (yet) for the implementation of the **Multilateral Mechanism for Digital Sequence Information**
- Law for implementation **BBNJ Agreement** in preparation

