What you need to know about Access and Benefit-Sharing (ABS)

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What you need to know about Access and Benefit-Sharing (ABS)

1. Access and Benefit-sharing (ABS)
2. International ABS agreements
3. Implementation in the Netherlands
4. New developments
5. Key messages

But first some questions …

1. Who had heard about Access and Benefit-Sharing (ABS) before this course?
2. Who had heard about the Nagoya Protocol before this course?
3. Who had heard about the ABS Regulation of the European Union before this course?
4. Who has practical experience with dealing with the ABS, the Nagoya Protocol and/or the ABS Regulation of the European Union?

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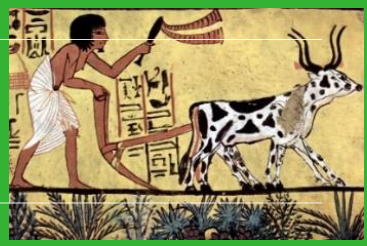
Access and Benefit Sharing (ABS)

- 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 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*

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

Key ABS definitions

- ABS is about access to genetic resources and the sharing of benefits arising from their utilisation
  - 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*
    - except for human genetic resources
  - what is utilisation of genetic resources?
    - *to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology*

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International ABS agreements

1. Convention on Biological Diversity (CBD, 1993)
2. International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2004) Existing international ABS agreements
3. Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework, 2011)
4. Nagoya Protocol (in CBD, 2014)
5. Multilateral Mechanism for Digital Sequence Information (MLM, 2024)
6. International instrument on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (BBNJ Treaty, 2026)

Convention on Biological Diversity (CBD)

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

- Important elements
  - covers all genetic resources (except human material)
  - affirms that states have sovereign rights over their genetic resources
  - access on the basis of bilateral negotiations between the provider country and the user (unless otherwise determined by that country)

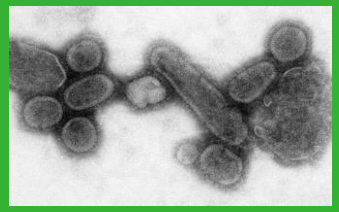
International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

- Negotiated in FAO (Food and Agriculture Organization of the United Nations)
- In force since 29 June 2004
- 155 Parties (as of 1 January 2026)

- Objective
  - the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use
- Important elements
  - focused on a limited number of agricultural crops
  - Provides facilitated access to a common pool of genetic resources (the Multilateral System or MLS), on the basis of a standard contract (the Standard Material Transfer Agreement or SMTA)
  - benefit-sharing through a multilateral fund to finance projects

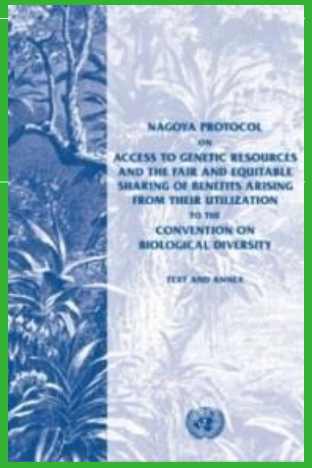
Pandemic Influenza Preparedness (PIP) Framework

- Agreed within WHO (World Health Organization)
- In force since 24 May 2011
- 196 Parties
- Objective
  - to improve pandemic influenza preparedness and response by establishing a system for the global sharing of influenza viruses with pandemic potential and access to vaccines and sharing of other benefits



- ABS aspects
  - only covers influenza viruses with human pandemic potential
  - access to influenza viruses on the basis of Standard Material Transfer Agreements (SMTA1 and SMTA2)
  - benefit-sharing: pharmaceutical companies make financial contributions to the WHO and make vaccines and other countermeasures available

Nagoya Protocol (1)

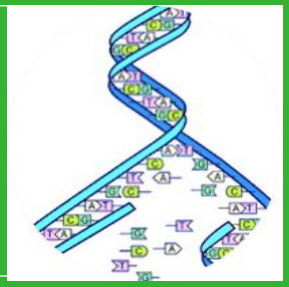


- Part of (Protocol to) the Convention on Biological Diversity (CBD, 1993)
- In force since 12 October 2014
- 142 Parties (as of 1 January 2026)
- Objective
  - the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components
- Important elements
  - covers all genetic resources (except human material)
  - access and benefit-sharing on the basis of bilateral negotiations between the provider country and the user (unless otherwise determined by that country)

Nagoya Protocol (2)

- 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
- Access to genetic resources 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
    - ➢ *including benefit-sharing arrangements*
- Also applying to traditional knowledge associated with genetic resources

Multilateral Mechanism for Digital Sequence Information (MLM) (1)



- Part of the Convention on Biological Diversity (CBD, 1993)
- 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, but used as 'placeholder'
  - ➢ primarily refers to information on the genetic composition of organisms

Multilateral Mechanism for Digital Sequence Information (MLM) (2)

- Main elements
  - scope: databases that make DSI publicly available
  - open access maintained
  - larger companies in sectors relying on DSI are encouraged to contribute to the benefit-sharing fund
  - indicative rates: 0.1% of revenues or 1% of profits
  - fund to be used for the conservation and sustainable use of biodiversity in developing countries
  - 50% of funds to go to Indigenous Peoples and Local Communities
- Other ABS instruments can use MLM but also create their own ABS system for DSI.

BBNJ Treaty ("Treaty of the High Seas")

- BBNJ Treaty: "*International instrument on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction*"
  - is about activities with marine biological diversity in areas beyond national jurisdiction
  - adopted on 19 June 2023
  - entered into force on 17 January 2026

- Includes ABS provisions for marine genetic resources in areas beyond national jurisdiction and associated DSI
  - ➢ notification of activities mandatory
  - ➢ benefit-Sharing through a financial mechanism, decoupled from access
  - ➢ benefit-Sharing Fund initially filled through contributions by countries; future modalities will be further discussed

NEW!

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Implementation in the Netherlands

- The compliance aspects of the Nagoya Protocol are implemented through the EU ABS Regulation, a European law,
- Further details in the Dutch Nagoya Protocol (Implementation) Act
- There is no EU or Dutch legislation to implement the ITPGRFA, the PIP Framework and the Multilateral Mechanism for Digital Sequence Information (MLM, 2024).
- The EU ABS Regulation does not cover access rules of EU member states, these are decided upon by countries themselves.
- Access to genetic resources from the Netherlands and other Northwest-European countries is not regulated.

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

- Implements compliance aspects of the Nagoya Protocol
- 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 data from gene sequencing
- National legislation in provider countries may go further than the EU ABS Regulation

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

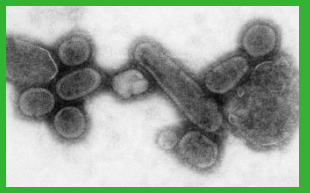
- To exercise 'due diligence' to ascertain that the genetic resources (and associated traditional knowledge) they utilise have been legally acquired, and that benefits are shared
- To utilise and transfer genetic resources in accordance with the MAT (Mutually Agreed Terms)
- Therefore:
  - seek relevant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

EU Guidance Document

- First version 2016; revised version 2021
- Not legally binding; explains EU ABS Regulation
- Explanation 'utilisation' = basic research, applied research and/or product development
  - *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: Annex II

- Provides specific guidance on when genetic resources are considered to be utilised in the meaning of the EU ABS Regulation (assuming they fall in the geographical, temporal and material scopes)
- 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

Case (1)

Using eDNA to screen for target organism

Water samples are taken from a river to determine if an invasive species of fish is present, using environmental DNA (eDNA). The water samples are tested with a DNA marker specific to the invasive species, which will determine if the DNA of the fish is in the water or not.

This type of screening is similar to identification, does not involve study of the properties of genes, and is not in scope of the EU ABS Regulation.

Case (2)

Investigation of gene function discovered through taxonomic analysis

A research institute carries out DNA sequencing of an organism for taxonomic identification. Subsequent analysis of the genetic sequence and functionality encoded by these genes by the same organisation reveals novel and potentially useful antibody gene structures. This subsequent line of research results in the use of immune cells from the organism to develop novel antibody products.

The taxonomic identification is not considered to constitute utilisation in the meaning of the EU ABS Regulation. However, subsequent to the initial taxonomic identification, the genetic resource is used for the purpose of product development, making use of the gene function. The research and development involved in this process constitutes utilisation in the meaning of the EU ABS Regulation.

Case (3)

Optimising a cloning vector

The DNA sequence of a cloning vector consisting of a plasmid is optimised, so that the expression level of a gene-of-interest can be improved. For example, Agrobacterium species contain plasmids that can transfer DNA into plant cells, resulting in crown galls. Scientists have removed the crown gall inducing genes of Agrobacterium strains and replaced these by regulatory sequences and expressed genes so that the strains can be used for the purpose of introduction of useful genes in many agricultural crops.

The activity of optimising a cloning vector qualifies as utilisation of the Agrobacterium plasmid in the meaning of the EU ABS Regulation.

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Pathogen Access and Benefit-Sharing (PABS) System

- A multilateral system for access and benefit sharing for pathogens with pandemic potential
- Addressing physical samples as well as sequence information
- Coordinated and convened by the World Health Organization (WHO)
- Originally planned to be adopted during the last WHO World Health Assembly in May-June 2024
- Negotiations were extended, with a view for adoption in December 2024, with a final deadline for May 2025
- However, Member States did not succeed in adopting the PABS System in 2025 and decided to establish a PABS system within the broader Pandemic Agreement, but to defer its development and operationalization to a future process

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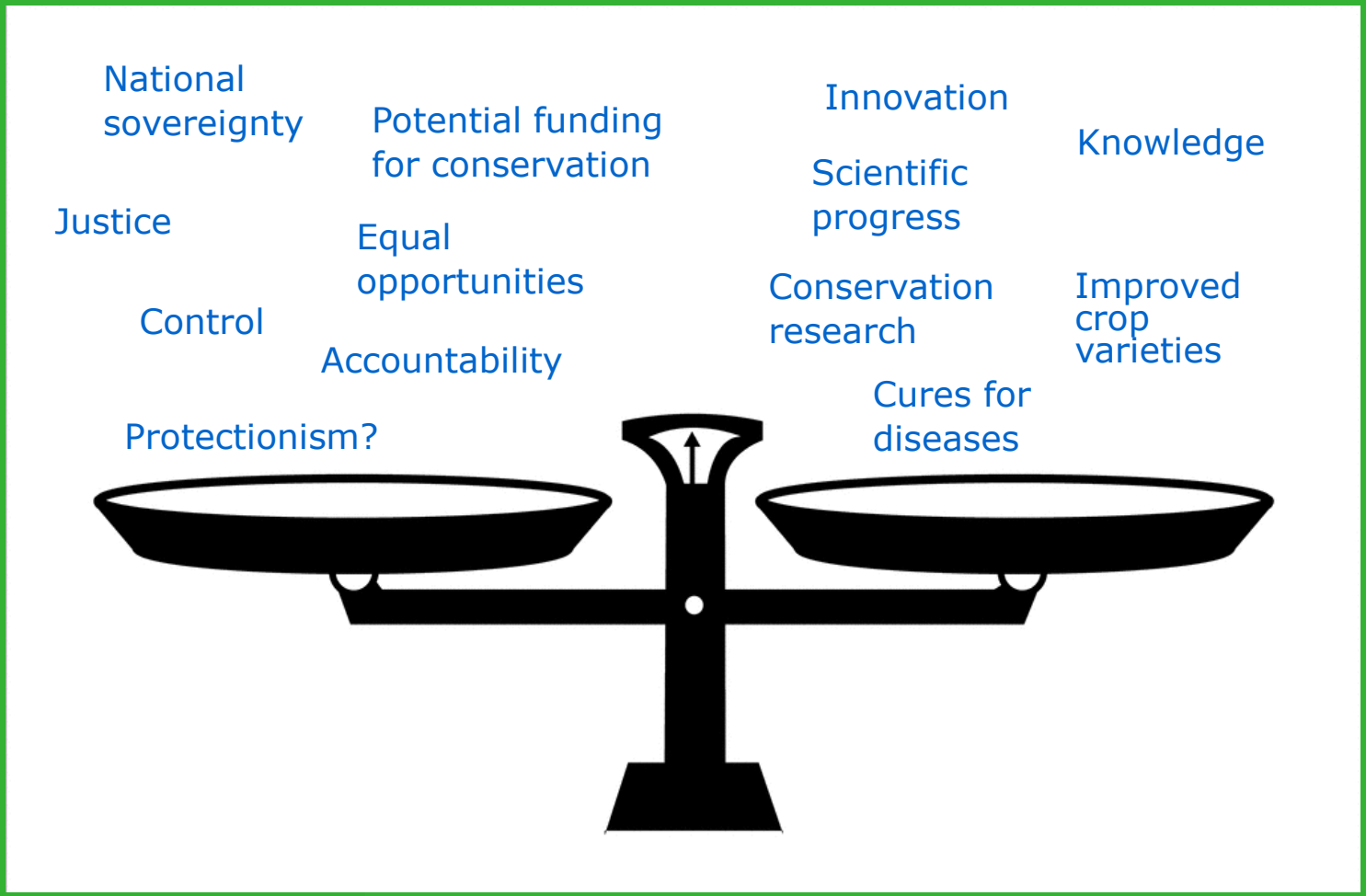
Key messages (1)

1. The concept of Access and Benefit Sharing (ABS) was already firmly established by the Convention on Biological Diversity (CBD) in 1993.
2. There are various international ABS agreements in force, all different in character.
3. The main 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.
4. "Digital Sequence Information" ("DSI") does not fall under the Nagoya Protocol, but a multilateral ABS-system for DSI has been established under the CBD.
5. There are additional specialized instruments for agricultural crops, for influenza viruses with pandemic potential, and for marine genetic resources and DSI from areas beyond national jurisdiction.

Key messages (2)

6. The EU ABS Regulation, in force since 2014, is a European law that implements the compliance aspects of the Nagoya Protocol in the EU, with obligations for users and governments.
7. The EU ABS Regulation does not cover access rules of EU member states, these are decided upon by countries themselves.
8. Access to genetic resources from the Netherlands and other Northwest-European countries is not regulated.
9. Another international ABS instrument will involve pathogens with pandemic potential and their sequences.
10. The ABS landscape is becoming more and more complex, with different international instruments and each country having its own interpretation and legislation.

Access and Benefit-Sharing: How to find the right balance?



More information

- Website CBD / Nagoya Protocol (www.cbd.int)
  - maintained by CBD/NP
  - lists of Parties to CBD and NP and contact points
  - Information on meetings and processes
- ABS Clearing House (absch.cbd.int/)
  - maintained by CBD/NP
  - country information (contact persons, laws)
- 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
  - subscription to ABS newsletter
  - FAQ

Thank you for your attention!

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