The Nagoya Protocol and its implications for the medical sector

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The Nagoya Protocol and the medical sector

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. New developments
6. Key messages

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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 genetic resources from developing countries were transformed in market products in developed countries
- Concept of Access and Benefit-Sharing developed

Key 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

- 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)*

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

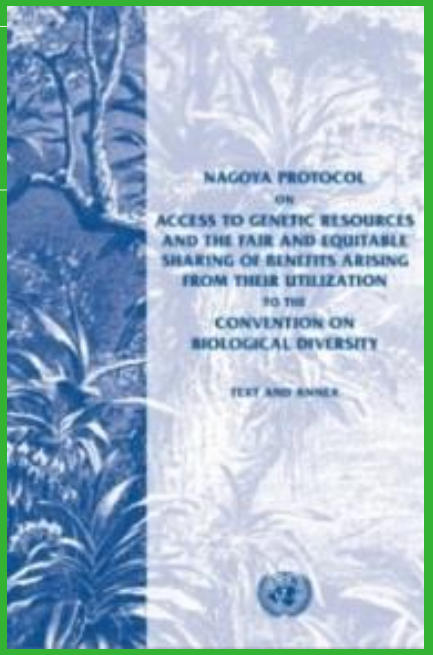
Convention on Biological Diversity (CBD)

- Important elements
  - 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)

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), but:
    - ➢ rules often unclear and complex
    - ➢ enforcement difficult
- Implications
  - access to genetic resources limited
  - little benefit-sharing
- Nagoya Protocol (2014)

Nagoya Protocol

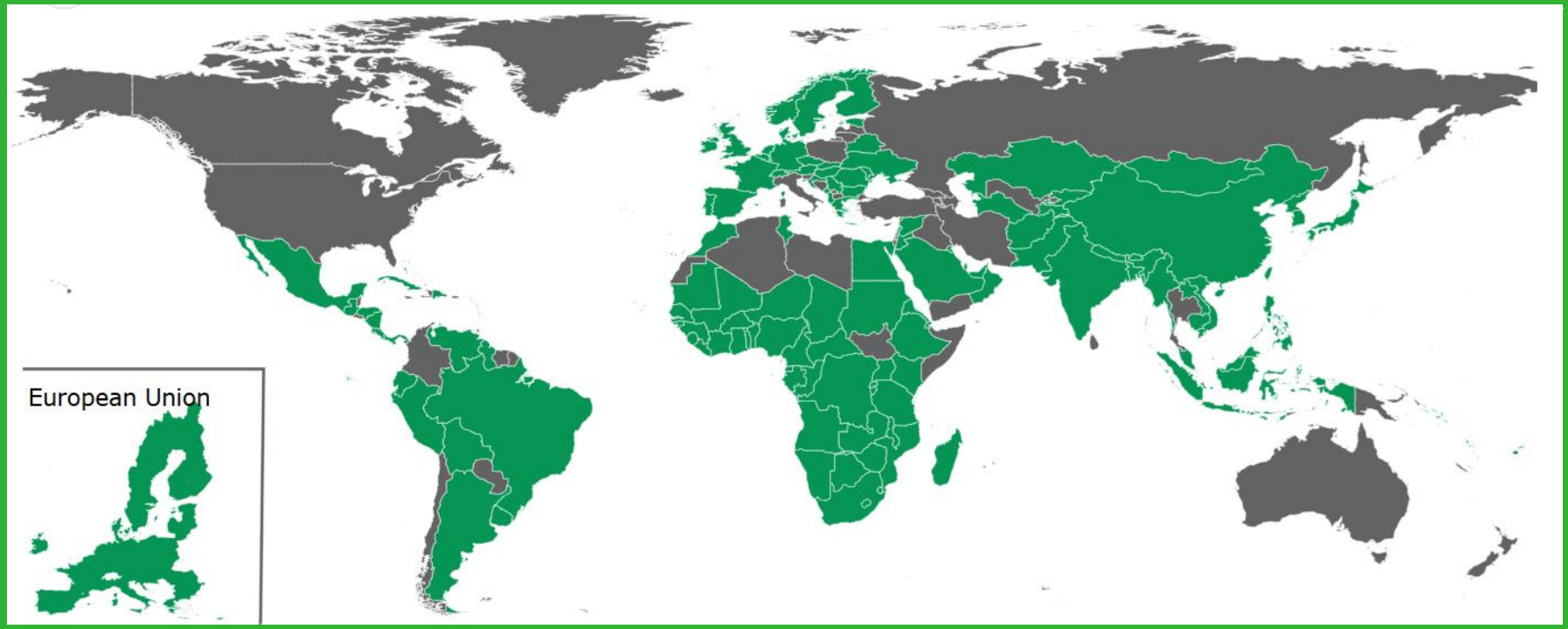


- Protocol to the CBD
- In force since 12 October 2014
- 142 Parties (as of March 2024)
- Objective
  - the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components
- Like the CBD, the Nagoya Protocol does <u>not</u> apply to human material

The Nagoya Protocol

- 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 provisions on traditional knowledge associated with genetic resources and derivatives

Parties to the Nagoya Protocol (18 March 2025)



142 Parties to the Nagoya Protocol **56** Non-Parties

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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
- National legislation in provider countries may go further than the EU ABS Regulation

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

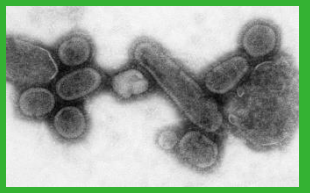
- To exercise 'due diligence' to ascertain that the genetic resources (and associated traditional knowledge) they utilise have been legally acquired, and that benefits are shared
- To utilise and transfer genetic resources in accordance with the MAT (Mutually Agreed Terms)
- Therefore:
  - seek relevant 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 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
- 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

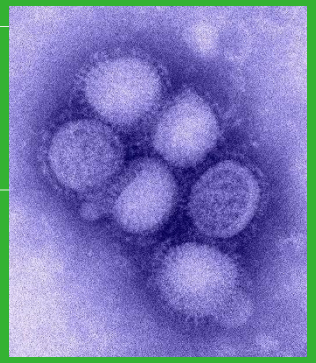
EU Guidance Document: Scope
EU ABS Regulation (cumulative)

- Geographic scope
  - applicable to GR 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 GR 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) includes basic research, applied research and product development
- Personal scope
  - applicable to all users of GR resources

EU Guidance Document: What is utilization?

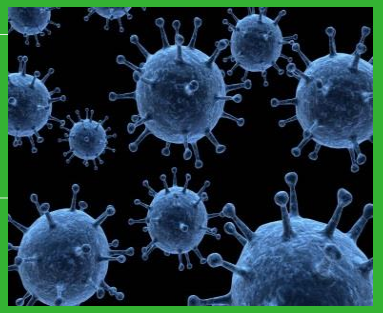
- Important element of the main text is about the question: *what is 'utilisation'?* (section 2.3.3)
- Examples of 'utilisation'
  - research to discover specific genetic and/or biochemical properties
  - creation and improvement of genetic resources to be used in production processes
  - genetic modification
- Examples of 'no utilisation'
  - identification
  - maintenance and management of a collection for conservation purposes
  - genetic resources as testing/reference tools

EU Guidance Document



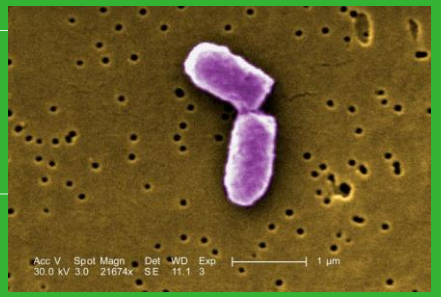
- Health as sector-specific issue (section 5.1)
  - pathogenic organisms generally within the scope of the EU ABS Regulation
    - except those covered by specialised ABS instruments, such as WHO Pandemic Influenza Preparedness (PIP) Framework
  - Parties required to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health
  - special status 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



- Unintentionally introduced pathogens (Section 2.3.1.5)
  - When pathogens present on a human 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 travellers who are unknowingly infected with a virus travel into an EU country
  - But: if the pathogens 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



- Human microbiota (Section 2.3.1.7)
  - Human microbiota: all microorganisms (such as bacteria, fungi, and viruses) residing on or in the human body
  - The human microbiota is considered separate from human genetic resources, since it comprises distinct and different organisms
  - Because of the symbiotic interaction between the microbiota and the human body, which results in a unique composition of microbiota in each individual, special conditions apply
    - ➢ 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 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

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: Genetic resources as tools

- Annex II, section 7.1: Using genetic resources as testing or reference tools
  - 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.

Case ‘Genetic resources as tools’

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.

Is this ‘utilization’ in the meaning of the EU ABS Regulation?

Case ‘Genetic resources as tools’

Investigation of function of genes: established introduced species

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.

So, this activity is no ‘utilization’ in the meaning of the EU ABS Regulation

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)

Internationally recognised certificate of compliance (IRCC)

UN environment

Convention on Biological Diversity

Access and Benefit-Sharing Clearing-House (ABSCH)

ABSCH-IRCC-FR-248769-1
Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

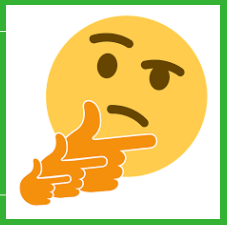
What to document?

- 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*
- USA is not foreseen to join the Nagoya Protocol
  - *EU ABS Regulation rules do not apply to US genetic resources (but only if they are really from USA)*
- *National legislation in provider countries may go further than the EU ABS Regulation*

Some recommendations

- Seek advice and help from local counterparts
- Find out if the genetic resource can be obtained
  - under a specialised international instrument (ITPGRFA, PIP-Framework)
  - from a collection included in the EU Register
- Try to conclude a framework agreement between your organisation and the provider country
- Keep documentation on genetic resources that do not fall under the EU ABS Regulation, to make plausible that these were legally accessed
- *Take ABS aspects into account from the very start of the project*

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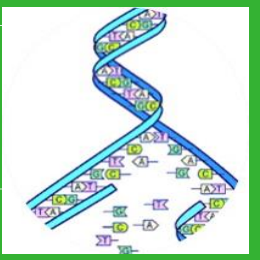
New developments

1. International instrument for Digital Sequence Information (DSI) on genetic resources
2. International instrument on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (BBNJ)
3. Enhancement of the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
4. Pathogen Access and Benefit-Sharing (PABS) System

Digital Sequence Information (DSI)

- Term "DSI" not defined, but used as 'placeholder'
  - primarily refers to information on the genetic composition of organisms
- Discussed in a variety of international organizations since 2016
  - CBD leading
- CBD meeting Canada, December 2022
  - agreement that Multilateral Mechanism (MLM) for DSI would be established, with a global benefit-sharing fund

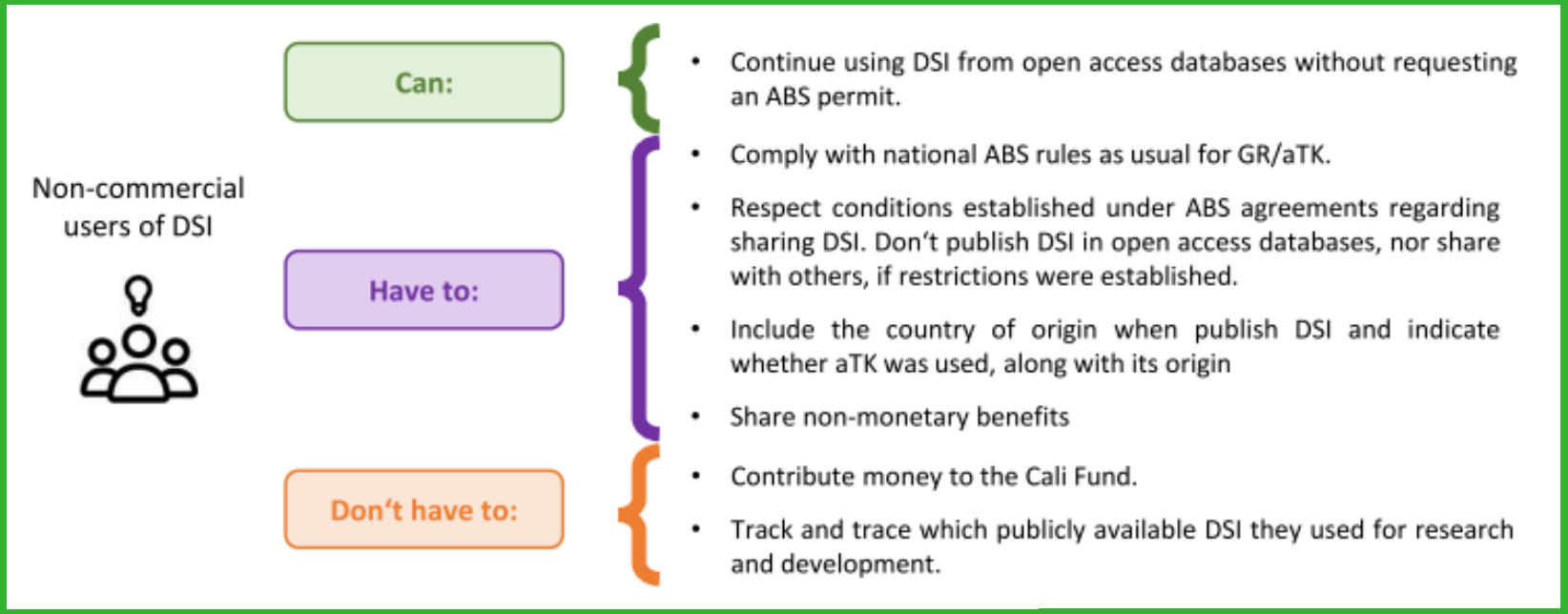
Digital Sequence Information (DSI)



- CBD meeting, Colombia, October-November 2024
  - Operationalization of the Multilateral Mechanism for DSI:
    - scope: databases that make DSI publicly available
    - open access retained
    - fund ('Cali Fund') established for benefit-sharing from the use of DSI
    - larger companies in sectors dependent on DSI are expected to contribute to the fund
    - indicative rates: 0.1% of revenue or 1% of profit
    - contributors receive a certificate as a "license to operate," which provides legal certainty
    - money from fund intended for conservation and sustainable use of biodiversity in developing countries
    - public research and academic institutions are <u>not</u> expected to make monetary contributions to the global fund
    - but: all users of digital sequence information on genetic resources should share non-monetary benefits

Digital Sequence Information (DSI)

- Consequences DSI decision for academic research



From Munoz-Garcia et al. (2025)

- non-monetary benefit-sharing to support self-identified capacity and technical development needs and priorities, including capacity-building for the generation of, access to and use and storage of DSI
- be aware in public-private research partnerships

Pathogen Access and Benefit-Sharing (PABS) System

- A multilateral system for access and benefit sharing for pathogens with pandemic potential, as part of a broader 'Pandemic Agreement' in the World Health Organization (WHO)
- Addressing physical samples as well as digital sequence information
- Originally planned to be adopted during the last WHO World Health Assembly in May-June 2024; deadline extended to May 2025
- However, so far Member States did not succeed in agreeing on PABS
- WHO Member States decided the PABS System cannot be fully developed within the Pandemic Agreement, but do want it to be part of the agreement.
- Decided to establish PABS system within the Pandemic Agreement (article 12), but defer its development and operationalization to a future process

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Key messages

1. The concept of Access and Benefit Sharing (ABS) was already established by the Convention on Biological Diversity (CBD) in 1993.
2. The Nagoya Protocol, in force since 2014, 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. It contains obligations for users and for governments in the EU.
4. According to the interpretation of the EU ABS Regulation, ‘utilization' may include basic research, applied research and/or product development.
5. The EU Guidance document gives detailed explanations and examples related to the EU ABS Regulation.

Key messages

6. The ABS Regulation does not cover access rules of EU member states; these are decided upon by countries themselves.
7. Access to Dutch genetic resources is not regulated: Prior Informed Consent (PIC) is not needed.
8. National legislation in non-EU provider countries may go further than the EU ABS Regulation.
9. "Digital Sequence Information" ("DSI") does not fall under the Nagoya Protocol and the EU ABS regulation, but a multilateral ABS-system for DSI has been established under the CBD.
10. Negotiations on a multilateral Pathogen Access and Benefit-Sharing (PABS) system under the WHO, addressing physical samples as well as sequence information of pathogens with pandemic potential, are still ongoing.

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)
- ABS website of the EU (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'

More information

- WHO website (www.who.int)
  - Information on Pandemic Influenza Preparedness (PIP) Framework (www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord)
  - Information on the future Pathogen Access and Benefit-Sharing (PABS) System (www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord)
- 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
  - FAQ

Thank you for your attention!

www.absfocalpoint.nl

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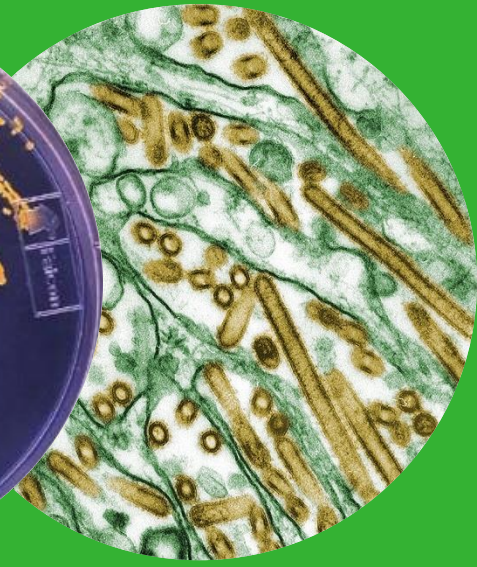

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Digital Sequence Information (DSI)

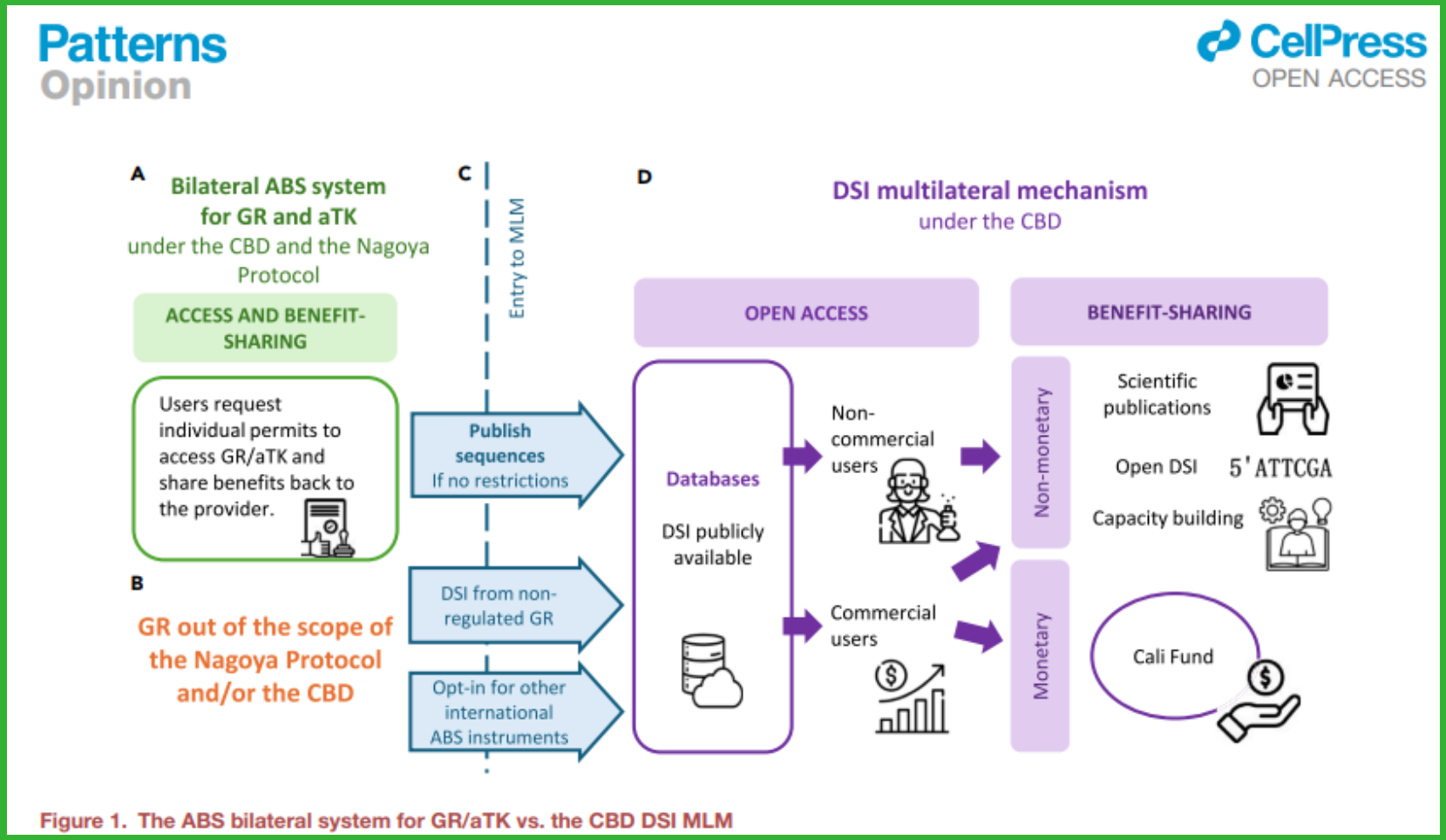

Figure 1. The ABS bilateral system for GR/aTK vs. the CBD DSI MLM

From Munoz-Garcia et al. (2025)