Access and Benefit-Sharing (ABS): implications for researchers and collection holders

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Access and Benefit-Sharing (ABS): implications for researchers and collection holders

1. Access and Benefit-Sharing (ABS)
2. International ABS agreements
3. The Nagoya Protocol
4. Implementation of Nagoya Protocol in the EU and NL
5. Implications
6. New developments
7. Conclusions

But first some questions …

1. Who had heard about Access and Benefit-Sharing (ABS) before today?
2. Who had heard about the Nagoya Protocol before today?
3. Who had heard about the ABS Regulation of the European Union before today?
4. Who has made use of the EU Guidance documents explaining the EU ABS Regulation?
5. Who has practical experience with dealing with the Nagoya Protocol and the ABS Regulation of the European Union?
6. Who did attend the on line presentations that we gave for Naturalis in September and October 2021?

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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 for you?
  - you cannot freely take and utilise genetic resources anymore (from the wild, from fields, or from collections), but usually need permission from the country where you want to take it
- What forms of benefit sharing do exist?
  - monetary (e.g. royalties, up-front payments)
  - non-monetary (e.g. scientific co-operation, technology transfer)

ABS: 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*

ABS is relatively new

- Genetic resources (e.g. seeds) 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

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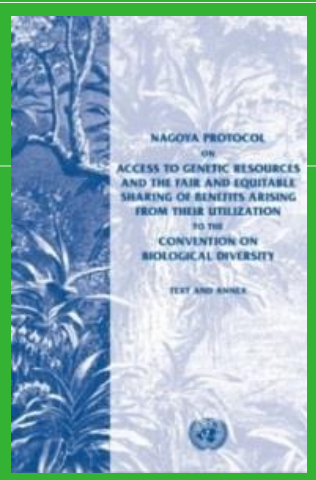
International ABS agreements

- Existing
  - Convention on Biological Diversity (CBD)
  - Nagoya Protocol (within CBD)
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
  - Pandemic Influenza Preparedness (PIP) Framework
- *Future*
  - *ABS instrument for Digital Sequence Information (within CBD)*
  - *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
  - 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)

Nagoya Protocol



- Protocol to the CBD
- In force since 12 October 2014
- 140 Parties (as of 1 October 2023)
- 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
  - user countries: monitoring of 'compliance' of their users
  - provider countries: clear and transparent access procedures
  - benefit-sharing agreed through bilateral negotiations between provider country and user

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
- 150 Parties (as of 1 October 2023)

- 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 agriculture
  - 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

- Negotiated in WHO (World Health Organization of the United Nations)
- In force since 24 May 2011
- 196 Parties
- Objectives
  - to improve pandemic influenza preparedness and response by establishing a system for 1) the global sharing of influenza viruses with human pandemic potential and 2) access to vaccines and sharing of other benefits
- Important elements
  - only covers influenza viruses with pandemic potential
  - access to genetic resources through a multilateral system, on the basis of standard contracts (SMTA1 and SMTA2)
  - benefit sharing: financial contributions of pharmaceutical companies to WHO en making available of vaccines and other countermeasures

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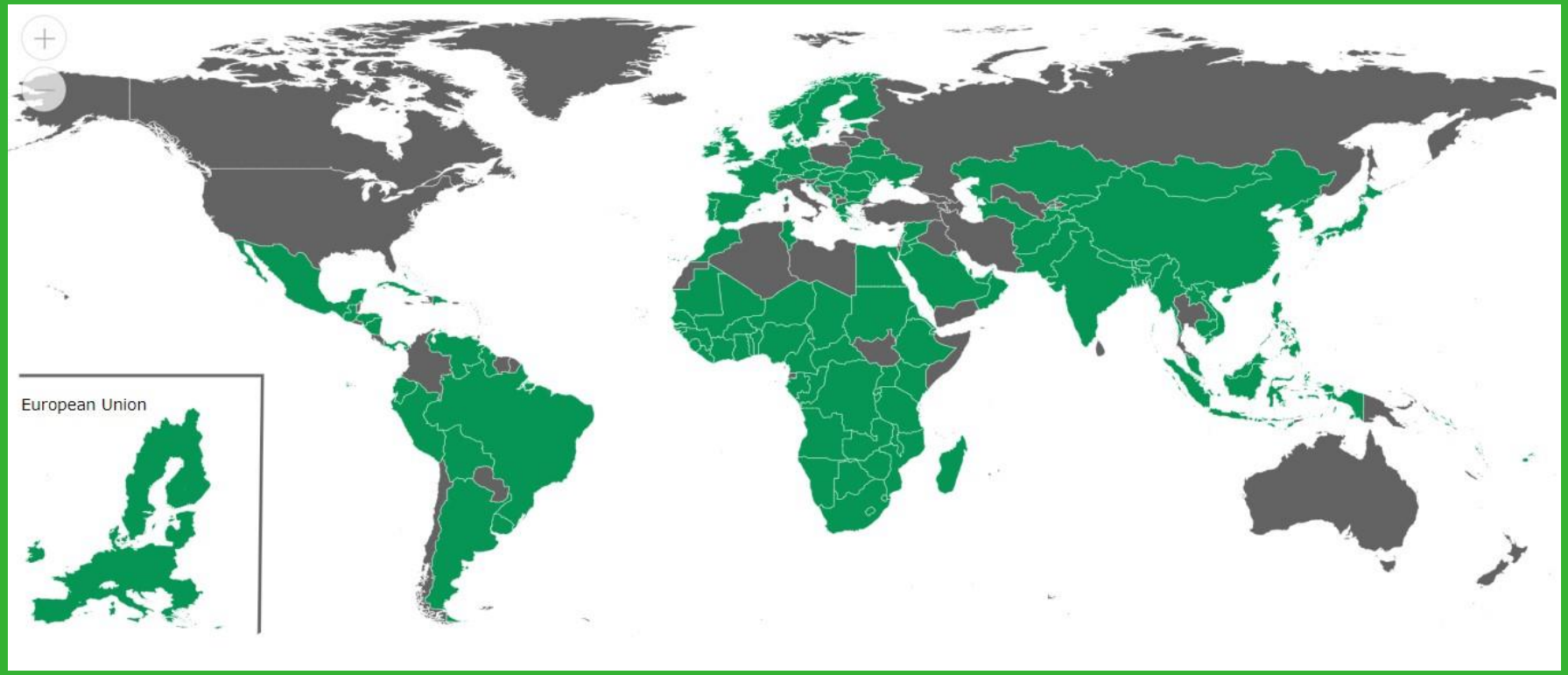
From CBD to Nagoya Protocol

- 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)

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; opinions on Digital Sequence Information (DSI) differ

Parties to the Nagoya Protocol (1 October 2022)



140 Parties to the Nagoya Protocol | 0 Ratified, not yet Party | 58 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*

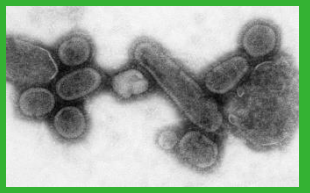
- NL
  - Nagoya Protocol (Implementation) Act
    - *published in 2015*

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: 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

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
- *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 '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: Register of trusted collections (Art. 5)

- Collections may request their government to include them in the EU Register of trusted collections
- Requirements for collection to be included
  - applies standardised procedures for exchanging and supplying samples and related information
  - supplies samples only with evidence that genetic resources and related information were legally accessed
  - keeps records of all samples of genetic resources and related information supplied for their use
  - uses unique identifiers for samples supplied,
  - uses tracking and monitoring tools for exchanges with other collections
- Register accessible on ABS website EU (currently 3 collections)
- Users of material from these collections are considered to have exercised due diligence as regards the seeking of information

The EU ABS Regulation: Best practices (Art. 8, 9)

- Associations of users or other interested parties may submit an application to the European Commission to have a combination of procedures, tools or mechanisms, developed and overseen by them, recognised as a best practice
- European Commission may grant recognition
- Users implementing a recognized best practice are considered by authorities to have a lower risk of non-compliance with EU ABS Regulation
- Currently one recognized best practice: Consortium of European Taxonomic Facilities (CETAF) *Code of Conduct and Best Practice for Access and Benefit-Sharing*
- Register of best practices accessible on ABS website EU

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'
  - exchange of genetic resources as commodities
  - genetic resources as testing/reference tools
  - *maintenance and management of a collection for conservation purposes (including te quality/phytopathology checks)*

EU Guidance Document: specific situations

- Examples of specific situations
  - Pathogens and pests (section 2.3.1.5)
    - normally in scope of the EU ABS Regulation
    - *but not in scope when they were introduced unintentionally into the EU*
  - Human microbiota (microorganisms residing on or in the human body) (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
  - Derivatives (biochemical compounds) (section 2.3.4)
    - only in scope when there is an ascertainable level of continuity between a derivative and the genetic resource from which it was obtained

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, through storage, collection management, identification and characterisation, 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: Identification

- Identification and characterization of organisms and other activities at the beginning of the value chain (Annex II, chapter 6)
  - Taxonomic identification, characterization or description of genetic resources: no utilisation in the meaning of the EU ABS Regulation
    - *When, however, combined with research on its specific genetic and/or biochemical composition, specifically the function of the genes: utilisation*
  - Phylogenetic analysis: no utilization, as long as it does not entail research and development of the genes, and the function of the genes or DNA sequences is not investigated

Case ‘Identification’

Environmental DNA metabarcode analysis of water samples to discover the numbers of fish species present

Water samples are taken from a river to discover the number of different fish species present. It makes use of DNA released into the water by organisms. To obtain a biodiversity inventory the DNA is purified from the water samples, DNA markers are targeted and sequenced, and the sequences discovered are taxonomically assigned by comparison with reference sequences in a database. The function of the genes is not investigated.

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

Case ‘Identification’

Environmental DNA metabarcode analysis of water samples to discover the numbers of fish species present

Because only the sequence is used, and the functions are not studied or considered, such inventory studies do not constitute utilisation under the EU ABS Regulation.

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

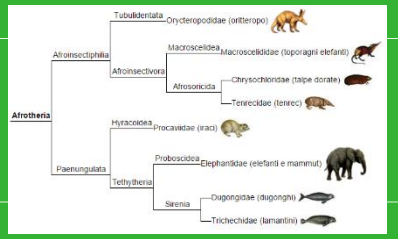
Case ‘Phylogenetic analysis’

Phylogenetic analyses without consideration of function of genes

A taxonomist studies a group of organisms in preparation of a floristic treatment or taxonomic monograph. As a part of the descriptive process, the taxonomist creates a phylogeny of the taxa involved, using morphological and DNA sequence information obtained from specimens in a collection. This is done without additional research on the genetic resource to discover specific genetic functions of the genes analysed. The morphological and sequence information is used in a descriptive manner and to recognise taxa at strain, species, or higher levels.

Is this phylogenetic analysis to be considered ‘utilization’ in the meaning of the EU ABS Regulation?

Case ‘Phylogenetic analysis’



Phylogenetic analysis without consideration of function of genes

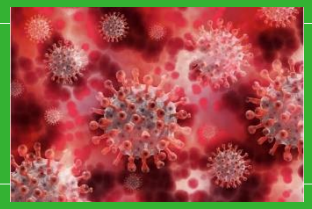
The phylogeny is used to provide a classification. This does not qualify as utilisation in the meaning of the EU ABS Regulation. If the taxonomist would make use of the function of the genes in the phylogenetic analysis, this activity would qualify as utilisation in the meaning of the EU ABS Regulation.

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

EU Guidance Document: Storing

- Annex II, chapter 3: Storing and collection management
  - Storing genetic resources in a public or private collection does **not** constitute utilisation in the sense of the EU ABS Regulation
  - Verification the identity of genetic resources and assessing their health status and the presence of pathogens form an integral part of collection management and are not considered to be utilisation in the meaning of the EU ABS Regulation
  - General good practice of collection holders upon receiving material is to check if the original permits for collecting genetic resources allow supply to third-party users
    - ➢ *if so: make the information on the permits available for potential users and to supply it together with any material to the potential users*

Case 'Storing and collection management'

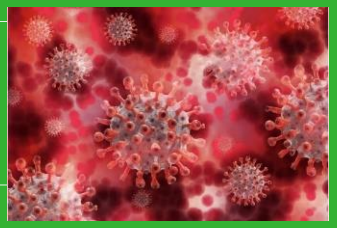


Storage of pathogens pending a decision on their use in a vaccine

Different pathogens are isolated from hosts in various countries as part of global surveillance systems and considered from epidemiological analysis to be a potential public health threat. Initial analysis does not make it clear which, if any, of the isolates will be needed for vaccine development. However, the threat is considered sufficiently great that preparation of vaccines and diagnostics is requested by WHO and by individual governments around the world. Therefore, these pathogens are collected and stored in an already existing collection, as well as exchanged with other collections.

1. ***Is the storage of pathogens 'utilization' in the meaning of the EU ABS Regulation?***
2. ***Is the development of vaccines on the basis of these stored pathogens 'utilization' in the meaning of the EU ABS Regulation?***

Case 'Storing and collection management'



Storage of pathogens pending a decision on their use in a vaccine

Building up a collection of pathogens with the aim to use them in case of further needs is not considered to constitute utilisation in the meaning of the EU ABS Regulation. However, if at a later stage the vaccine candidates are used to develop a vaccine, this is research and development on the genetic or biochemical composition of the genetic resource and such activity would fall within the scope of the EU ABS Regulation.

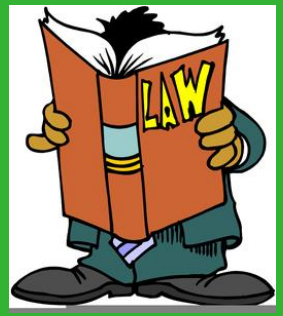
1. ***So, the storage of pathogens is no 'utilization' in the meaning of the EU ABS Regulation***
2. ***The development of vaccines on the basis of these stored pathogens, on the other hand, is 'utilization' in the meaning of the EU ABS Regulation***

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, Nature and Food Quality)
  - 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*

National legislation NL: Sanctions

- Nagoya Protocol (Implementation) Act
  - Art.6: Minister may take immediate interim measures, e.g.
    - *confiscation of genetic resources or products developed*
    - *prohibiting further use*
    - *return of genetic resources to the provider country*
  - Art.8: actions contrary to the law seen as an 'economic offence'
- Both criminal and administrative law possible
  - administrative law: fine
  - criminal law: fine, community service, detention (according to Economic Offences Act)
- Intervention policy NVWA
  - lesser offence (unconscious and easily correctable)
    - *warning with re-check after a few months*
  - serious offence (conscious and/or unrecoverable)
    - *corrective intervention and/or official report*



Overview ABS rules NL

Genetic resources

CBD

Nagoya Protocol

EU ABS Regulation

Nagoya Protocol
(Implementation) Act

ITPGRFA

PIP
Framework

Users in the Netherlands

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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 in the EU?

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

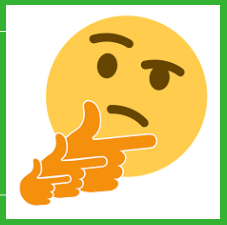
What to document?

- 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*
- 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
- *Look before you leap: take ABS aspects into account from the very start of the project*

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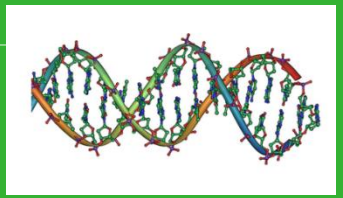
New developments

1. Digital Sequence Information (DSI)
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)

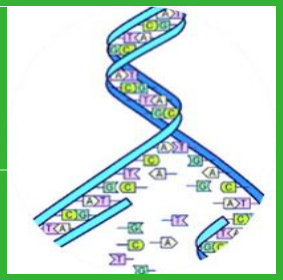
- Genomic information is increasingly used in R&D, in addition to or even instead of genetic resources
  - ➢ *some countries fear that this will lead to decreased benefit-sharing from the use of genetic resources*
- International discussion arose on the question if the use of so-called *Digital Sequence Information" ("DSI")* should also be subject to ABS obligations, similar to the use of genetic resources
- Research sector stresses that the bilateral Nagoya system is not suitable for "DSI", because the use of "DSI" is very different from the use of genetic resources
- Some developing countries have already included "DSI" in their domestic ABS legislation

Digital Sequence Information (DSI)



- "DSI" is discussed in various international fora, e.g.
  - Convention on Biological Diversity (CBD) / Nagoya Protocol
  - International instrument on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (BBNJ)
  - World Health Organization (WHO)
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- Main discussion forum: CBD
- Term 'DSI' not defined, but used as 'placeholder'
  - primarily refers to information on the genetic composition of organisms

Digital Sequence Information (DSI)



- CBD meeting Montreal, December 2022
  - ABS-system for DSI will fall under CBD and not under Nagoya Protocol; will *not* follow the bilateral approach of the Nagoya Protocol, but basically a multilateral approach
    - benefit-sharing decoupled from access
    - global fund for benefit-sharing
  - Some principles agreed upon, including:
    - consistent with open access to data
    - effective, efficient, feasible and practical, more benefits than costs
    - certainty and legal clarity for providers and users
    - not hinder research and innovation
  - Follow-up process for the development of a system

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
  - will enter into force after ratification by 60 Parties

- Includes ABS provisions for these marine genetic resources and associated DSI
  - notification of activities mandatory
  - Benefit-Sharing through a financial mechanism, decoupled from access
    - Initially filled through contributions by countries
    - later modalities further discussed

Access and Benefit-Sharing (ABS): implications for researchers and collection holders

1. Access and Benefit-Sharing (ABS)
2. International ABS agreements
3. The Nagoya Protocol
4. Implementation of Nagoya Protocol in the EU and NL
5. Implications
6. New developments
7. Conclusions

To conclude, a few more questions …

1. Did Access and Benefit-Sharing (ABS) start with the coming into force of the Nagoya Protocol in 2014?
2. Is it mandatory to comply to the ABS Regulation of the European Union?
3. Can there be ABS requirements if the ABS Regulation of the European Union does not apply?
4. Is collection management 'utilization' in the meaning of the ABS Regulation of the European Union?
5. Is identification of organisms during which the functions of genes are investigated 'utilization' in the meaning of the ABS Regulation of the European Union?
6. Do published genome sequences fall under the ABS Regulation of the European Union?

Key messages

1. The concept of Access and Benefit Sharing (ABS) was already firmly 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 of ABS rules.
3. The ABS Regulation of the European Union is a European law that implements the compliance aspects of the Nagoya Protocol in the EU. It contains obligations for all users in the EU and for governments of EU member states. It does not cover access rules of EU member states.
4. According to the interpretation of the EU ABS Regulation, ‘utilization' may include basic research, applied research and/or product development.

Key messages

5. Storing genetic resources in collection, verification the identity of genetic resources and assessing their health status and the presence of pathogens are not considered to be ‘utilization’ in the meaning of the EU ABS Regulation.
6. Collection holders can help a customer to meet its ABS obligations by collecting, storing and passing on relevant ABS information.
7. National legislation in provider countries may go further than the EU ABS Regulation.
8. “Digital Sequence Information” (“DSI”) does not fall under the Nagoya Protocol and the EU ABS regulation, but a multilateral ABS-system for DSI will be established under the CBD.

More information

- Website CBD / Nagoya Protocol (www.cbd.int)
  - 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)
  - information on EU rules
  - EU registers of collections and recognized 'best practices'
- Website National Focal Point NL (www.absfocalpoint.nl)
  - Bilingual (Dutch/English)
  - information on rules and what to do
  - interactive help tool
  - FAQ

ABS Focal Point website

- www.absfocalpoint.nl
- Interactive help tool, newsletter
- Articles on:
  - Derivates (for example non-synthetic vectors, proteins, antibodies, plasmids)
  - Large-scale screening
  - Laboratory strains
  - Human microbiota/pathogens
  - Service providers
  - Testing and reference tools
  - and more

Thank you for your attention!

www.absfocalpoint.nl

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WAGENINGEN
UNIVERSITY & RESEARCH

Centre for Genetic Resources, the Netherlands

Some questions from your side

1. Do we need to comply with anything (or have any responsibility) if other parties use our samples?
2. Do we need to comply with anything (or have any responsibility) if other parties use data derived from our samples?
3. How do we ensure the provenance of samples? And how do we record the origin of the materials and objects, linked to this documentation?
4. How to record all agreements and documents?
5. Is there any difference between generating barcodes vs genomic data?

Some questions from your side

6. What are the consequences (legal, financial, academic) if we don't comply with the regulations?
7. What to do when we have problems contacting NFPs or other relevant people that can authorize us?
8. What do we need to take into consideration when working with international partners?
9. Could you please clarify the purpose of the DECLARE platform?
10. Is the use of the DECLARE platform mandatory during the research funding application process, including Horizon Europe funding?