The Nagoya Protocol and its implementation

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The Nagoya Protocol

1. Why was it established?
2. What does it entail?
3. How is it implemented?
4. What does it mean for you?
5. Conclusions

Nagoya Basics




- The Nagoya Protocol is about access to genetic resources and the sharing of benefits arising from their utilisation (in short: "Access and Benefit-Sharing" or ABS)
  - 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*
    - exception: human genetic resources (but pathogens and human microbiota may be in scope)
  - 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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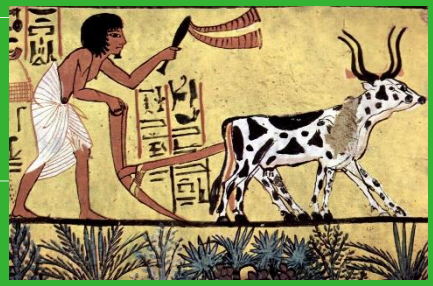
The Nagoya Protocol is about Access and Benefit Sharing (ABS)

- What is Access and Benefit Sharing?
  - regulation of access to genetic resources and associated information
  - sharing of benefits from the use of these between providers and users
- What does it mean?
  - you cannot always freely take and utilise ("access") 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 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 the local communities through cultivation of kanna

ABS is relatively new



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

First international ABS agreement: Convention on Biological Diversity (CBD)

- Entry into force:
  - 29 December 1993
- 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
- Membership
  - 196 parties (= almost the whole world)

Convention on Biological Diversity (CBD)

- Important elements
  - Genetic resources no longer 'heritage of mankind'
    - ➢ *instead, all states have sovereign rights over their genetic resources*
  - ABS to be regulated through bilateral contacts and on a case-by-case basis
  - For access to genetic resources, permission (Prior Informed Consent, PIC) needed from the government of the country providing the resources
    - ➢ *unless otherwise determined by that government*
  - Access shall be on Mutually Agreed Terms (MAT), agreed upon by provider and user

ABS: from CBD to Nagoya Protocol

- Convention on Biological Diversity (CBD, 1993)
  - genetic resources no longer seen as 'heritage of mankind'
    - *instead, states have sovereign rights over their genetic resources*

- National ABS legislations introduced
  - e.g. Philippines (1995), Costa Rica (1998), Brazil (2001)
  - but:
    - rules often unclear and complex
    - enforcement difficult

- Effects
  - access to genetic resources restricted
  - little benefit-sharing

- Nagoya Protocol (2014)

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The Nagoya Protocol

- Entry into force:
  - 12 October 2014
- Objective
  - *"the fair and equitable sharing of the benefits arising from the utilization of genetic resources (...), thereby contributing to the conservation of biological diversity and the sustainable use of its components."*
- Protocol to the *Convention on Biological Diversity* (CBD)
  - CBD: all countries have sovereign rights over their genetic resources
  - Nagoya Protocol: elaboration of the ABS provisions of the CBD (1993)

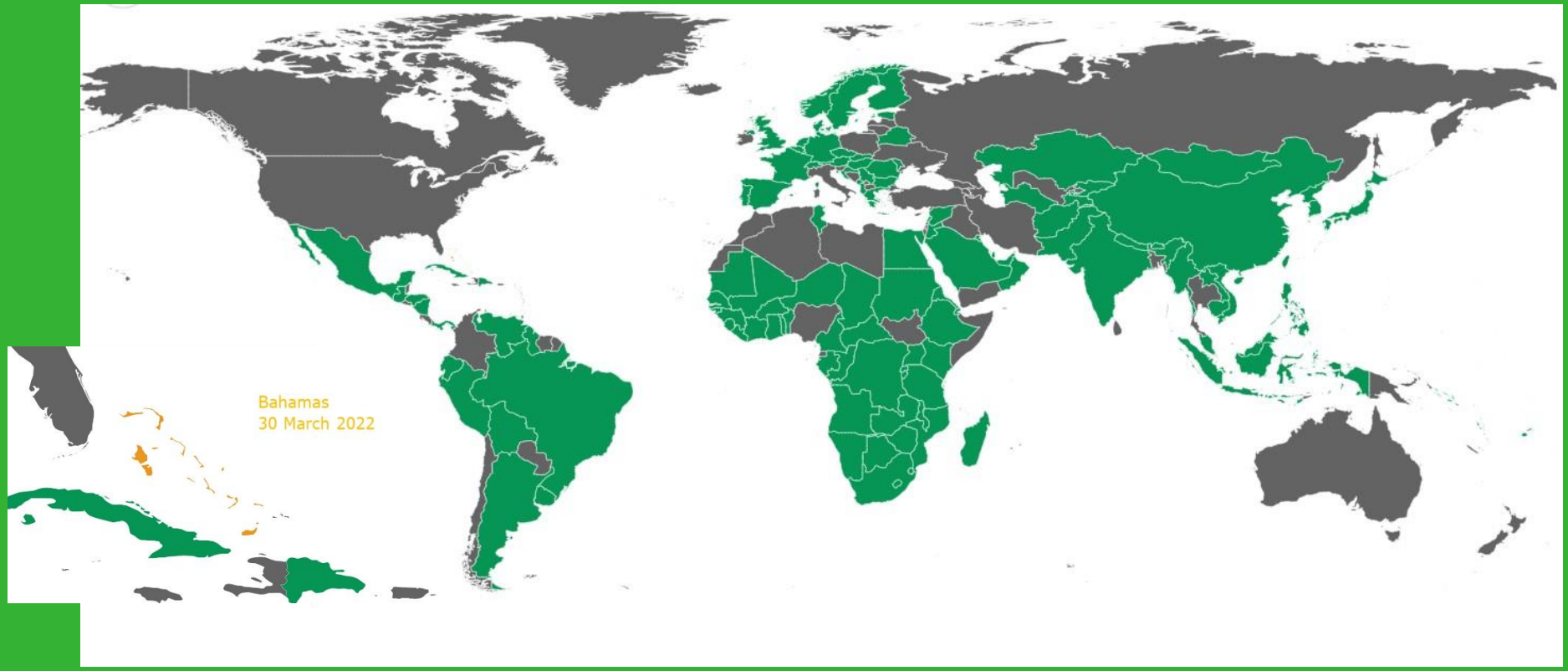
The Nagoya Protocol

- Principles
  - Provider countries to ensure clear and transparent procedures
  - compliance to ABS rules in provider countries 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 between provider and user

The Nagoya Protocol

- 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*
    - exception: 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*
- Also provisions on access traditional knowledge; opinions on Digital Sequence Information (DSI) differ

Parties to the Nagoya Protocol (10 February 2022)



133 Parties to the Nagoya Protocol

1 Ratified, not yet Party

65 Non-Parties

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Implementation Nagoya Protocol in NL

- EU
  - The EU ABS Regulation
    - *published in 2014*
  - Implementing Regulation
    - *published in 2015*
  - Guidance document
    - *published in 2016; revised version 2021*
- NL
  - Nagoya Protocol (Implementation) Act
    - *published in 2015*

The EU ABS Regulation

- Entry into force: **12 October 2014**
  - same date as entry into force of Nagoya Protocol
- Official name: Regulation (EU) 511/2014
- Regulation = Legally binding
- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, NOT with access*
- Contains obligations for
  - users of genetic resources and associated traditional knowledge in the EU
  - EU Member States

The EU ABS Regulation

Obligations of users of genetic resources and associated traditional knowledge in the EU (Art. 4)

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

The EU ABS Regulation

Obligations of EU Member States (Art. 7, 9, 11)

- 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
- carry out checks to monitor compliance of users
- lay down rules on penalties in case of non-compliance
  - "effective, proportionate and dissuasive"

Implementing Regulation

- Entry into force: 9 November 2015
- Official name: Commission Implementing Regulation (EU) 2015/1866
- Lays down more detailed rules on the implementation of certain articles of the EU ABS Regulation
  - due diligence declarations
  - register of 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
- '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

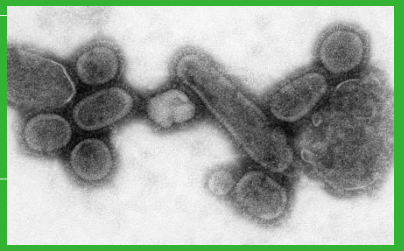
- Main text
  - Scope of the regulation
    - geographic scope
    - temporal scope
    - material scope
    - personal scope
  - Obligations of users
    - due diligence obligation
    - specific situations
  - Events triggering due diligence declarations
    - external research funding
    - final development of product
  - 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
  - not applicable to material covered by specialised international instruments (ITPGRFA and PIP Framework)
- Personal scope
  - applicable to all users of GR resources

EU Guidance Document



- The EU ABS Regulation does not apply when ABS of genetic resources is covered by a '*Specialised International Instrument*' (Section 2.3.1)
  - 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*

EU Guidance Document

- 'Utilisation' (Section 2.3.3.1)
  - *"Researchers involved in basic research may not necessarily be aware of it at that stage, but their findings may still turn out to have commercial relevance at a later stage. Depending on the specific activity undertaken, both basic and applied research may be considered as 'utilisation' in the sense of the Protocol and Regulation."*
  - *"There are nonetheless certain upstream activities which are related to (or carried out in support of) research but should not as such be considered 'utilisation' in the meaning of the Regulation – e.g. the maintenance and management of a collection for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance."*

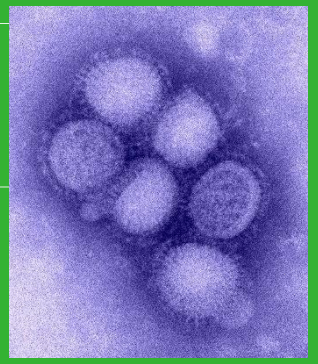
EU Guidance Document

- Annex 2
  - 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 and storing of genetic resources 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

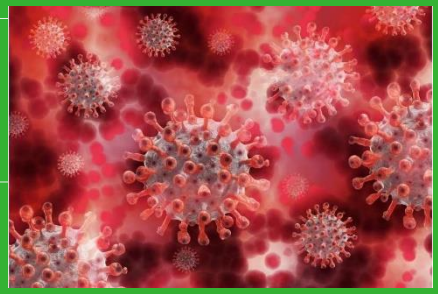
- Annex 2
  - Acquisition of genetic resources
  - Storage and collection management
  - Rearing and multiplication
  - Exchange and transfer of genetic resources
  - Identification of organisms and other activities at the beginning of the value chain, including large-scale screening
  - Genetic resources as tools, including testing or reference tools and laboratory strains
  - Breeding of genetic resources
  - Product development, processing and product formulation
  - Product testing
  - Marketing and application

EU Guidance Document



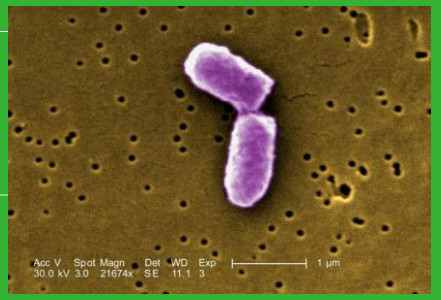
- Health as sector-specific issue (section 5.1)
  - pathogenic organisms generally within the scope of the EU ABS Regulation
    - except those covered by specialised ABS instruments, such as WHO Pandemic Influenza Preparedness (PIP) Framework
  - Parties required to pay due regard to cases of present 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)

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

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What to do?

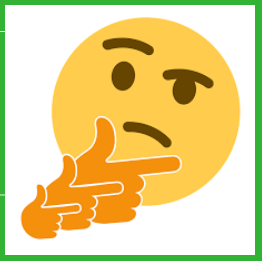
- If you utilise genetic resources within the EU:

1. check access rules of the provider country
   - ABS Clearing House (https://absch.cbd.int/)
   - National Focal Point (NFP) of the provider country
2. where required, seek permission from the Competent National Authority (CNA) of the provider country (PIC: '*Prior Informed Consent*')
3. negotiate conditions with provider, and lay these down in a contract (MAT: '*Mutually Agreed Terms*')
4. use the GR only in accordance with the conditions agreed with the provider

What to do?

5. carefully document the use
6. keep all documentation for 20 years after the end of utilisation
7. submit a ‘due diligence declaration’ when you receive external research funding or bring a product on the market (through https://webgate.ec.europa.eu/declare/)
8. pass on information to further users of the genetic resources

Points of attention



- If you buy abroad from a local market, the EU ABS Regulation may apply
- If you buy from a trader, request access documentation
- The obligations of the EU ABS Regulation may also apply to imports from other EU countries
- USA will not join Nagoya Protocol: rules do not apply to US genetic resources
- Recommended to also keep documentation on genetic resources that do not fall under the EU ABS Regulation, to make plausible that these were legally accessed
- *National legislation in provider countries may go further than the EU Regulation*

Further considerations for users

- Take ABS rules into account from the very start of the project
- Think about the country from which to obtain the genetic resources
- Can local counterparts provide advice and help?
- Think about the source (wild? collection?)
- Is acquisition under specialised international instrument (ITPGRFA, PIP-Framework) possible?
- Is a framework agreement between your organisation and the provider country possible?

Seek information!

- ABS Clearing House (absch.cbd.int/)
  - maintained by CBD/NP
  - country information (contact persons, laws)
- ABS website of the EU (ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)
  - information on European rules
  - EU register of collections and recognized 'best practices'
- National Focal Point NL (www.absfocalpoint.nl)
  - information on rules and what to do
  - interactive help tool
  - FAQ
  - newsletters

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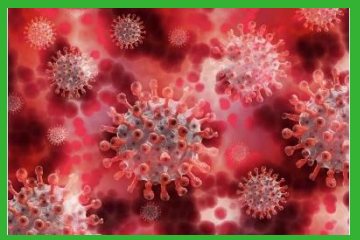
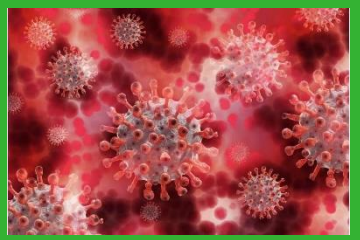
Conclusions

1. Since 1993: Convention on Biological Diversity (CBD)
   - Access and Benefit-Sharing (ABS) accepted
   - national sovereignty over genetic resources
   - resulting in countries regulating access to genetic resources in national laws
2. Since 2014: Nagoya Protocol
   - compliance to national access laws of provider countries must be monitored by countries where genetic resources are used
   - provider countries must provide for legal certainty, clarity and transparency of their ABS legislation
3. Since 2014: EU ABS Regulation
   - users in EU must exercise 'due diligence' to make sure access is in accordance with national laws of provider countries
   - compliance must be monitored by EU countries
   - access not regulated at EU level



Conclusions

4. Since 2016: Nagoya Protocol (Implementation) Act
   - division of tasks NL: LNV/NVWA/CGN
   - access to Dutch (in situ) genetic resources not regulated
5. How to deal with it?
   - secure and document legal status of genetic resources you acquire(d)
   - document how you use genetic resources in R&D
   - keep all documentation for 20 years
   - pass on information to further users
   - make 'due diligence declarations' when required
6. Where to find information?
   - ABS Clearing House
   - ABS website EU
   - website National Focal Point NL



Thank you!

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