The Nagoya Protocol: background, main features, implementation and consequences for users

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9 September 2021

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The Nagoya Protocol

1. Background
2. Main features
3. Implementation
4. Consequences for users
5. Conclusions

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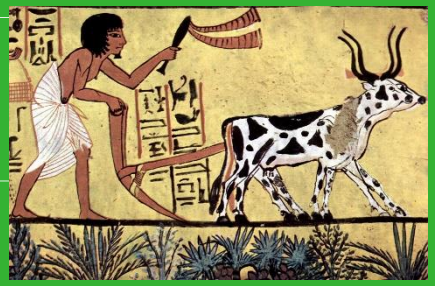
Access and Benefit Sharing (ABS)

- What is Access and Benefit Sharing?
  - regulation of access to genetic resources (GR) and associated information
  - sharing of benefits from the use of these GR 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)
- 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

Convention on Biological Diversity

- Negotiated in UNEP (United Nations Environment Programme)
- 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
- Entry into force
  - 29 December 1993
- Membership
  - 196 parties

Convention on Biological Diversity

- Important elements
  - Genetic resources no longer 'heritage of mankind'
    - ➢ *instead, all states have sovereign rights over their genetic resources*
  - ABS through bilateral contacts and on a case-by-case basis
  - For access to genetic resources, permission (Prior Informed Consent, PIC) needed from the Party providing such resources
    - ➢ *unless otherwise determined by that Party*
  - Access shall be on Mutually Agreed Terms (MAT)
  - Primarily focused on regulating access to genetic resources of wild flora and fauna species for chemical and pharmaceutical purposes

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)

The Nagoya Protocol

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The Nagoya Protocol

- 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."*
- Entry into force: ***12 October 2014***
- 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)

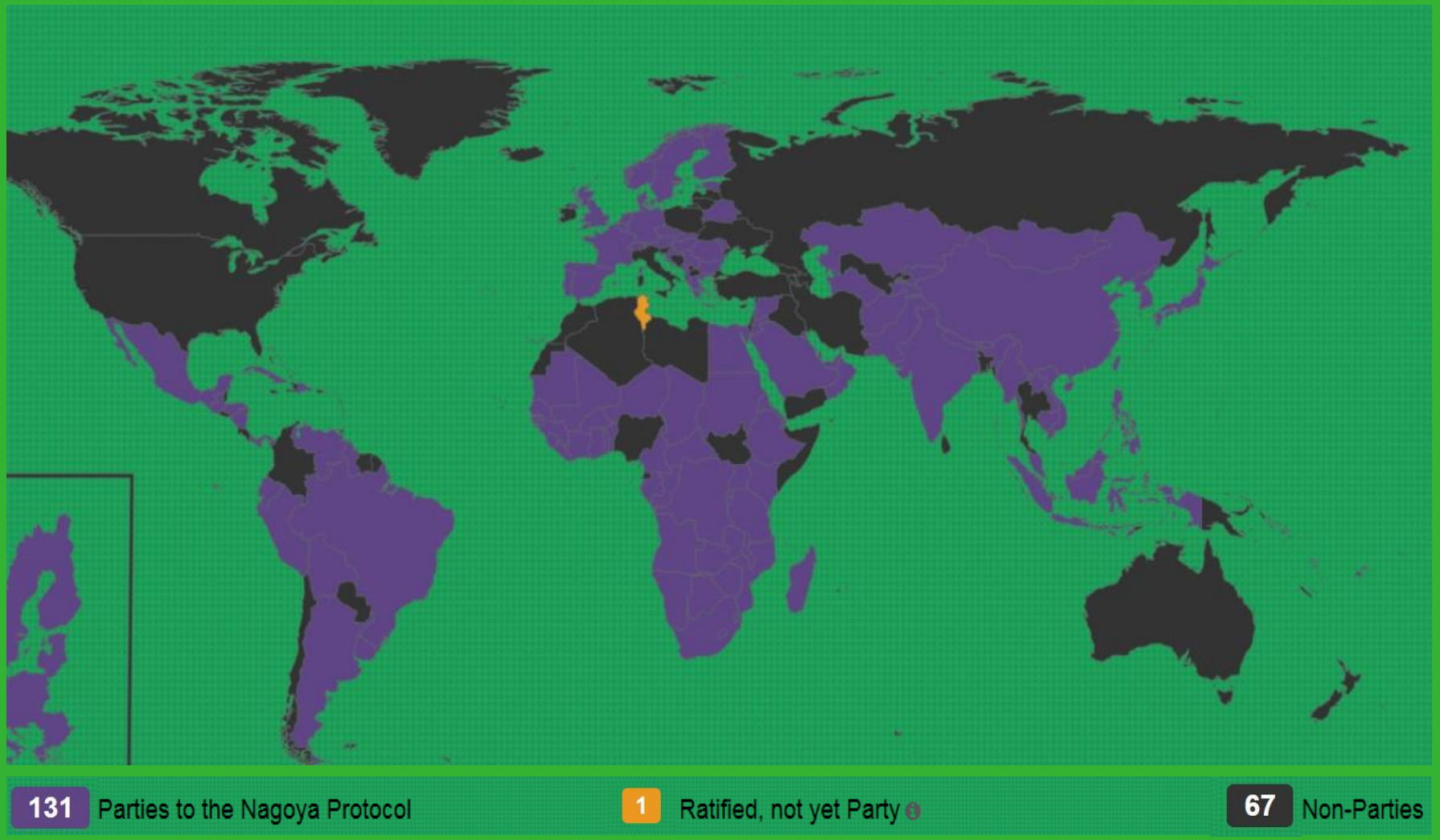
The Nagoya Protocol

- 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 with provider

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*
    - 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*
- Also provisions on access to derivates and traditional knowledge; opinions on Digital Sequence Information (DSI) differ

Nagoya Protocol (9 September 2021)



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

The EU ABS Regulation

- Official name: REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
- Regulation = Legally binding
- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, NOT with access*
- Entry into force: **12 October 2014**
  - same date as entry into force of Nagoya Protocol
- Does not apply when ABS is covered by a 'specialised international instrument' (ITPGRFA, PIP-framework)

The EU ABS Regulation

Obligations of users in 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
- users of material from collections included in the EU Register of collections are considered to have exercised due diligence as regards the seeking of information

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 (EU) 2015/1866

- Entry into force: 9 November 2015
- Lays down more detailed rules on the implementation of certain articles of the EU ABS Regulation
  - register of collections
  - due diligence declarations
  - 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

- 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

- Product testing (Annex 2, chapter 10)
  - *Many if not all products which are developed via utilisation of genetic resources and are to be placed on the market, are subjected to various tests regarding their identity, purity, quality, efficacy or safety, in order to establish whether such products meet expected product standards or market standards.*
  - *Confirmatory tests on individual product lots to verify whether they meet product standards are not considered to constitute utilisation in the meaning of the EU ABS Regulation, since they do not involve research and development on the genetic or biochemical composition of the genetic resource and do not deliver additional insights into the characteristics of the genetic resource for development of the product.*
  - *However, if the product test results are used to modify the product or its production process through research and development on the genetic resource, such tests are regarded to contribute to further research and development of the product and hence to be in scope of the EU ABS Regulation.*

EU Guidance Document

- Example/Case Product testing (Annex 2, chapter 10)

(Food and feed sector) Detecting and correcting off-notes

Tests of a flavour formulation are carried out. If the test detects an off-note (unpalatable flavour), the results may either lead to

(i) a redefinition of the specifications of the raw materials but no alteration of the product development process, in which case the use of the results does not fall within the scope of the EU ABS Regulation; or lead to

(ii) a change in the product development process, in which case the analysis would contribute to the qualities of the new and altered product and hence fall within the scope 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

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What to do as a user?

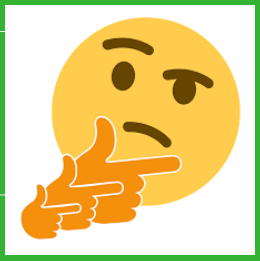
- If you utilise genetic resources within the EU:

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 as a user?

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

Some more 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*

Considerations for users

- Take ABS rules into account from the very start of the project
- From which country do you obtain your genetic resources?
- From which source (farmer, nature, collection)?
- Under which ABS-instrument (Nagoya Protocol, ITPGRFA, PIP)?
- Possibility for framework agreement?

Seek information!

- ABS Clearing House website: https://absch.cbd.int/
  - maintained by CBD/NP
  - country information (contacts, legislation)
- ABS website EU: http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
  - maintained by EU
  - information on European rules
  - EU register of collections
  - recognized 'best practices'
- website National Focal Point NL: www.absfocalpoint.nl
  - maintained by National Focal Point NL
  - information on rules and what to do

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Conclusions

1. Since 1993: CBD
   - national sovereignty over genetic resources
   - resulting in countries regulating access to GR in *national* legislation

2. Since 2014: Nagoya Protocol
   - compliance to national access legislation of provider countries to be monitored by countries where GR are used
   - provider countries must provide for legal certainty, clarity and transparency of their ABS legislation

3. Since 2014: EU ABS Regulation
   - EU users must exercise 'due diligence' to make sure GR are accessed in accordance with national legislation of provider countries
   - compliance monitored by EU countries
   - access not regulated at EU level

Conclusions

4. 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!

www.absfocalpoint.nl

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