The Nagoya Protocol and the regulation of the utilisation of genetic resources

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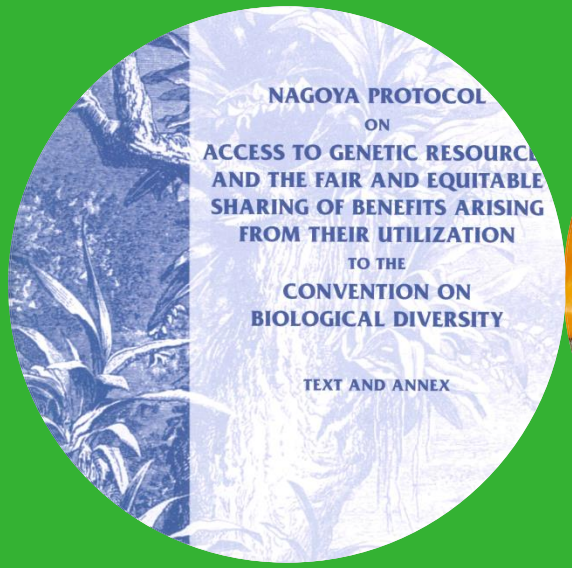

WAGENINGEN
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Access and Benefit Sharing (ABS)

- 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)

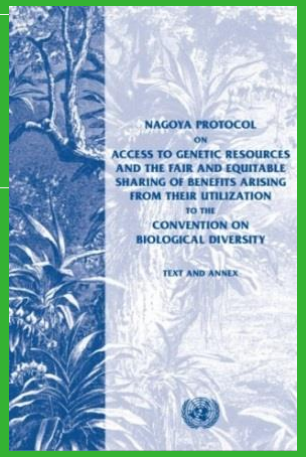
ABS Example South Africa

- 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 product
- Benefit-sharing
  - up-front payments and royalties for SASC and local communities
  - employment creation for the local communities through cultivation of kanna

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)
  - elaboration of the ABS provisions of the CBD (1993)

The Nagoya Protocol

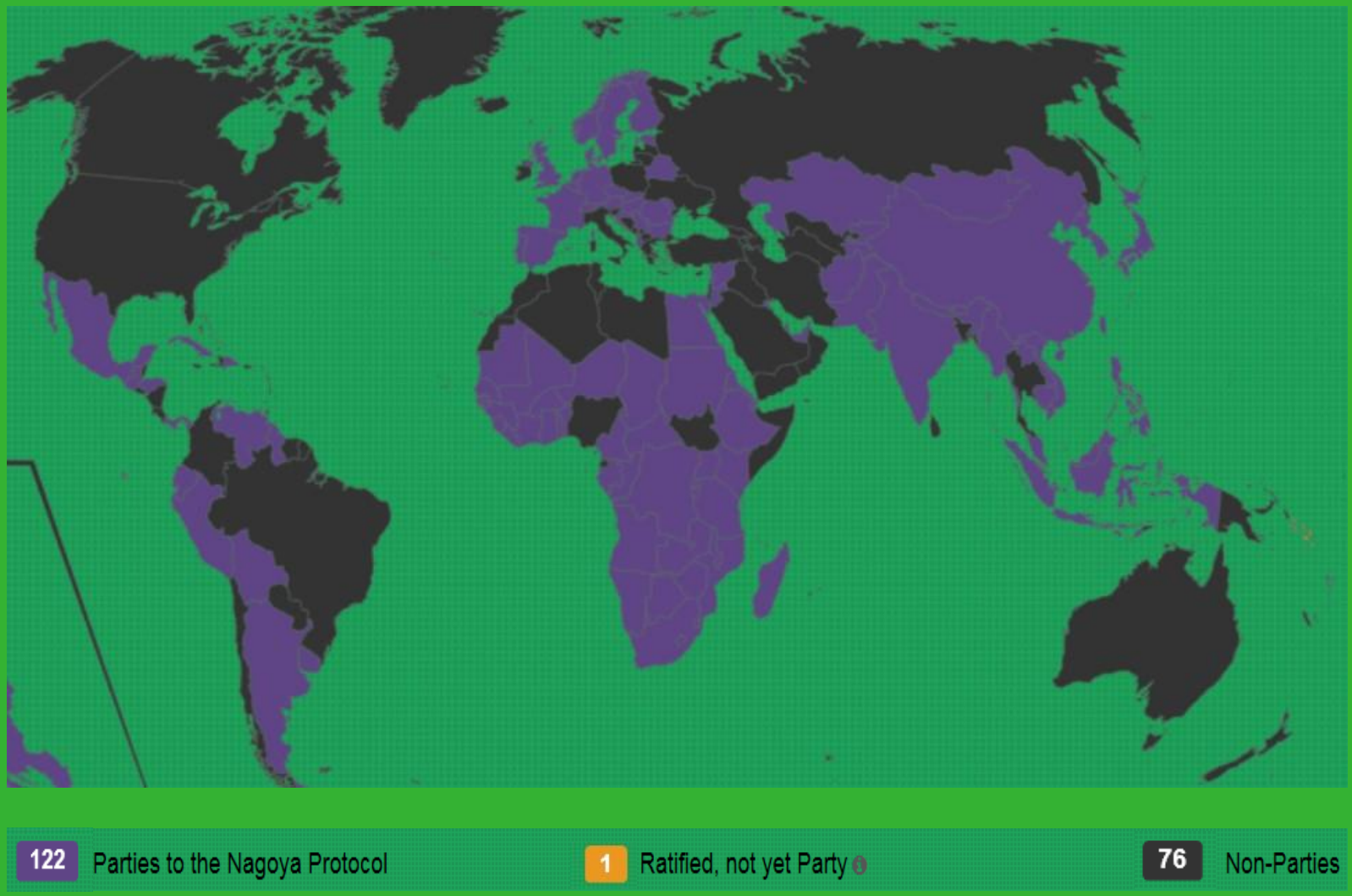


- Principles
  - compliance to ABS rules in provider countries to be monitored by countries where the genetic resources are utilized
  - Provider countries to ensure clear and transparent procedures
- Access to genetic resources on the basis of
  - Prior Informed Consent (PIC): permission by government authorities
  - Mutually Agreed Terms (MAT): contract with provider
  - ➢ *unless otherwise determined by the provider country*

The Nagoya Protocol

- Is about access to genetic resources and the sharing of benefits arising from their utilisation
  - '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
  - '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



Implementation Nagoya Protocol in EU and NL

- EU
  - Regulation (EU) 511/2014
    - *published in 2014; legally binding*
  - Implementing Regulation (EU) 2015/1866
    - *published in 2015; legally binding*
  - Guidance document
    - *published in 2016; currently revised*
  - Specific guidance document
    - *not yet published*

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

EU Regulation 511/2014

- 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
- 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
- Does not apply when ABS is covered by a 'specialised international instrument' (ITPGRFA, PIP-framework)

EU Regulation 511/2014

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

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

EU Regulation 511/2014

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 (2016)

- ‘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’*
- examples of ‘utilisation’
  - research to discover specific genetic and/or biochemical properties
  - creation and improvement of genetic resources (e.g. yeasts) to be used in production processes
  - breeding programme to create a new plant variety based on landraces or naturally occurring plants
  - genetic modification

EU Guidance Document (2016)

- No 'utilisation'
  - maintenance and management of a collection for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance
  - exchange of genetic resources as commodities, whether for direct consumption or as ingredients, e.g. in food and drink products
    - ➢ *but when R&D is carried out on genetic resources which originally entered the EU as commodities, such new use falls within the scope of the EU ABS Regulation*
  - genetic resources as testing/reference tools
  - planting and harvesting by a farmer

Revised Guidance and new Specific Guidance document (2020)

- To provide more clarity on ‘utilisation’
- Important issues
  - Large scale screening
  - Subcontractors
  - Laboratory strains
  - Commercial plant varieties
  - Taxonomy
  - Derivatives (continuum, chemical modification)
  - Intentionality of access
  - Invasive species
  - Human microbiome
- Crated in close consultation with EU Member States and users

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

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*')

What to do as a user?

4. use the GR only in accordance with the conditions agreed with the provider

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 considerations

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

More 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
- website National Focal Point NL: www.absfocalpoint.nl
  - maintained by National Focal Point NL
  - information on rules and what to do