# The Nagoya Protocol: what you need to know

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# The Nagoya Protocol

- What is it about?
- What does it prescribe?
- How is it implemented in the EU?
- What does it mean for users?

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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 is relatively new

- Genetic resources (e.g. seeds) taken and exchanged freely for thousands of years
  - *genetic resources considered '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 from developing countries were transformed in market products in developed countries
  - concept of Access and Benefit Sharing (ABS) developed
- Convention on Biological Diversity (1993)
  - *genetic resources no longer 'heritage of mankind'*: instead, all states have sovereign rights over their genetic resources

# 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

- 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

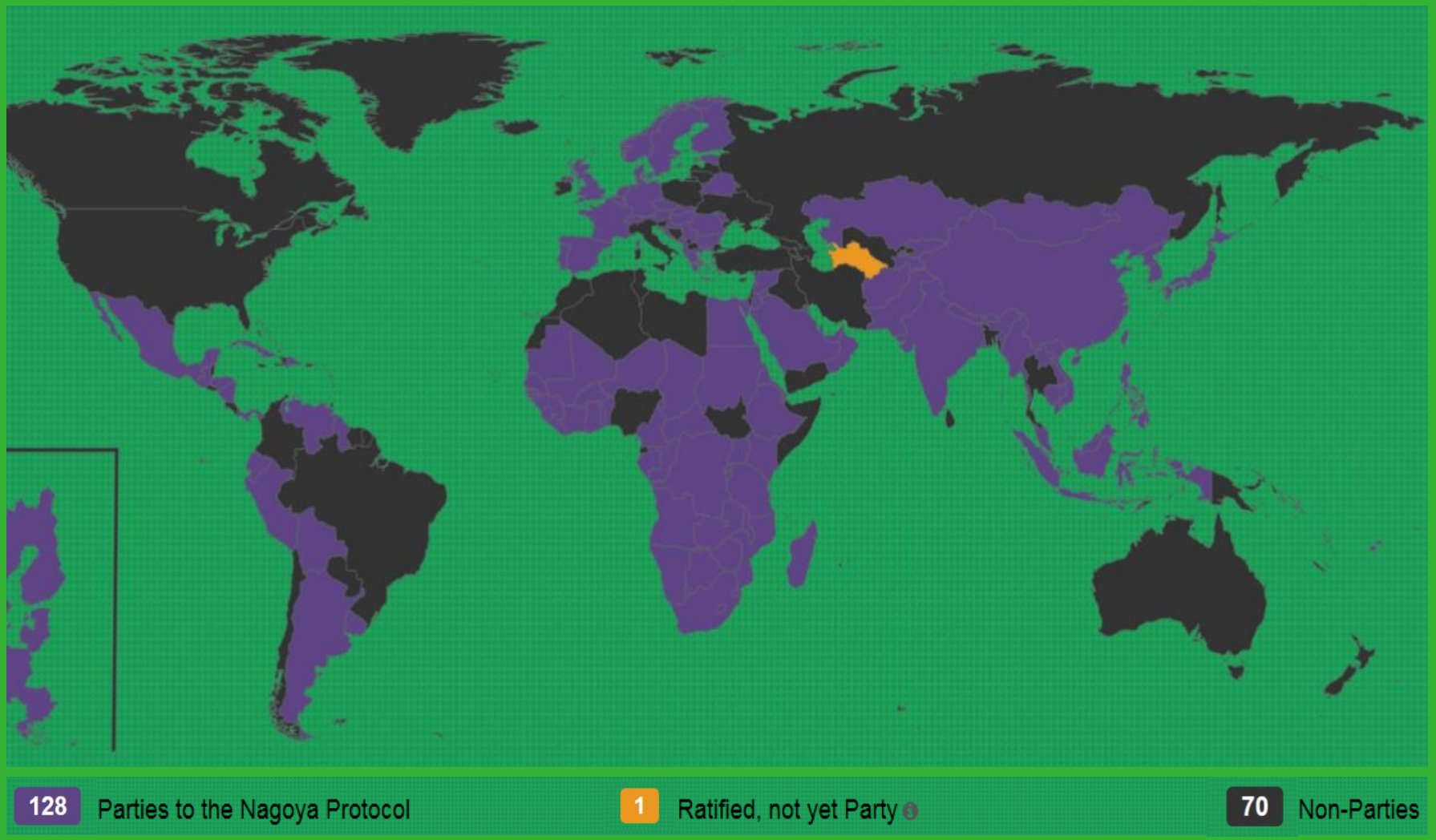
- Principles
  - Provider countries to ensure clear and transparent procedures
  - compliance to ABS rules in provider countries to be monitored by the countries where the genetic resources are utilized
- Access to genetic resources on the basis of
  - Prior Informed Consent (PIC): permission by authorities 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 (24 November 2020)



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# EU Regulation 511/2014

- 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
- 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

# 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"

# EU Guidance Document (2016)

- Not legally binding; explains 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'*
- 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
  - genetic modification

# EU Guidance Document (2016)

- Examples of '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

# Revised EU Guidance document (2020)

- More clarity provided on ‘utilisation’
- Important issues
  - Identification/Taxonomy
  - Human microbiome
  - Large scale screening
  - Laboratory strains
  - Derivatives (continuum, chemical modification)
  - Subcontractors
- Created in close consultation with EU Member States and users
- Probably published this year

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# What to do as a user?

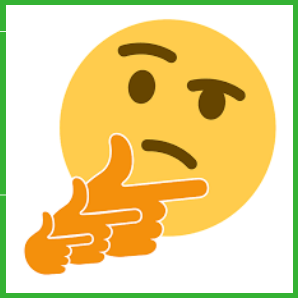
- If you utilise genetic resources within the EU:

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

# 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
  - recognized 'best practices'
- website National Focal Point NL: www.absfocalpoint.nl
  - maintained by National Focal Point NL
  - information on rules and what to do