The Nagoya Protocol: look before you leap

Martin Brink

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WAGENINGEN
UNIVERSITY & RESEARCH

Centre for Genetic Resources, the Netherlands

The Nagoya Protocol

1. What is it about?
2. What does it entail?
3. How is it implemented in the EU?
4. What to do as a user?
5. “Digital Sequence Information” (DSI)
6. Key messages

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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 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

ABS: from CBD to Nagoya Protocol

- Convention on Biological Diversity (CBD, 1993)
  - *genetic resources no longer considered 'heritage of mankind'*
  - *instead, all states have sovereign rights over their genetic resources*
  - *widely accepted (CBD has now 196 Parties)*

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

- Nagoya Protocol (2014)
  - elaboration of the ABS provisions of the CBD
    - *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*

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- Additional Protocol to the *Convention on Biological Diversity* (CBD, 1993)
  - elaboration of the ABS provisions of the CBD
- 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***
- Legally binding for countries that are Parties to the Protocol

The Nagoya Protocol

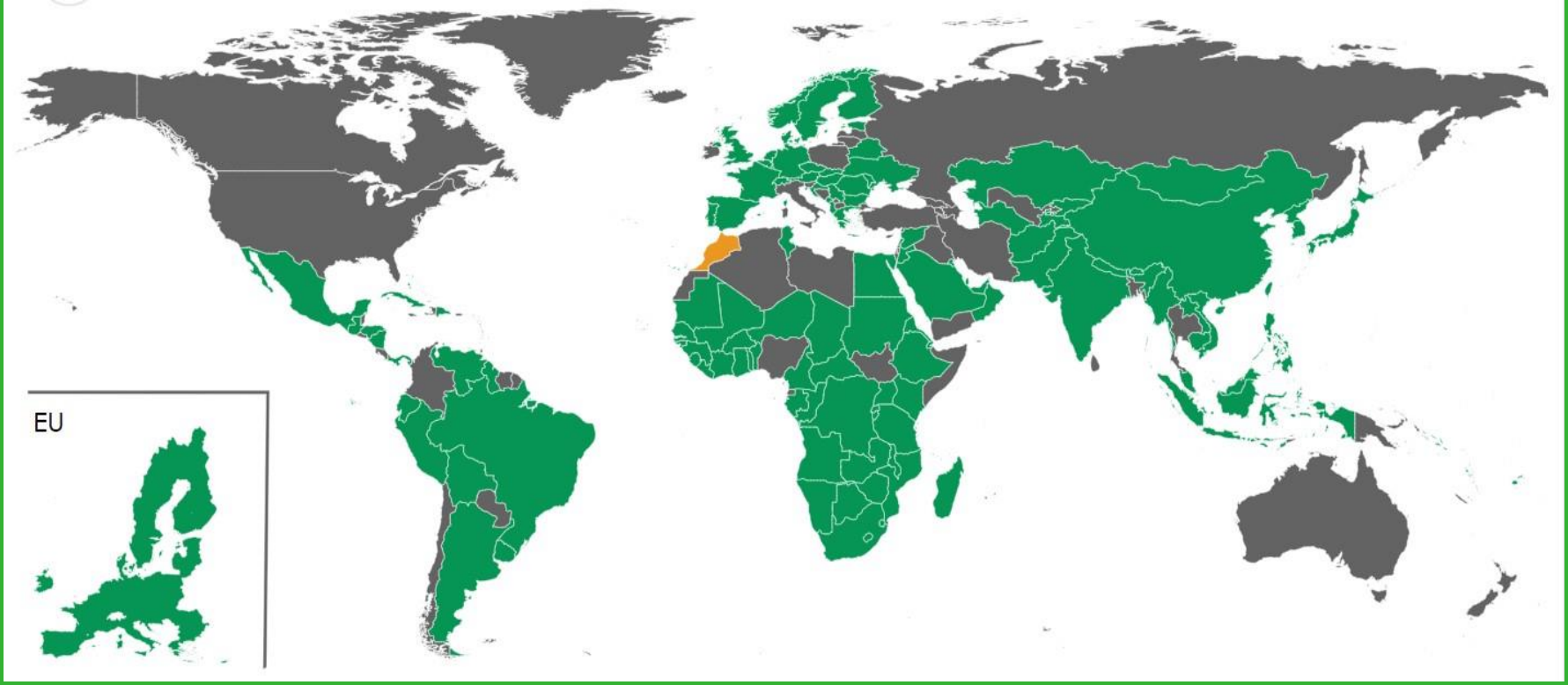
- Principles
  - Provider countries are to ensure clear and transparent procedures
  - compliance to ABS rules in provider countries is to be monitored by the countries where the genetic resources are utilized
- Access to genetic resources on the basis of
  - Prior Informed Consent (PIC): permission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

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 traditional knowledge associated with genetic resources and derivatives; opinions on Digital Sequence Information (DSI) differ

Parties to the Nagoya Protocol (20 May 2022)



134 Parties to the Nagoya Protocol

3 Ratified, not yet Party

64 Non-Parties

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The EU ABS Regulation

- Official name: Regulation (EU) 511/2014
- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, NOT with access*
  - *access regulated at national level, not at EU level*

- 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 (commercial and non-commercial)
- Legally binding for all companies, institutions and individuals within the EU

The EU ABS Regulation

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

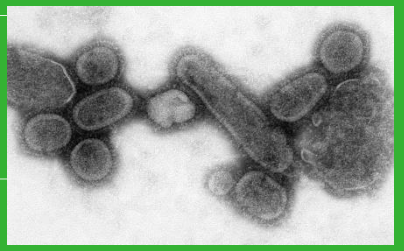
- to exercise 'due diligence' to ascertain that the genetic resources they utilise have been legally acquired, and that benefits are shared
- to utilise and transfer genetic resources in accordance with the MAT (Mutually Agreed Terms)
- therefore:
  - seek relevant ABS information (including permits 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)

- 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



- The EU ABS Regulation does not apply when ABS of genetic resources is covered by a '*Specialised International Instrument*' (Art. 2)
  - 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*
- Users of material from a collection included in the EU Register of collections are considered to have exercised due diligence as regards the seeking of information (Art. 4)

The EU ABS Regulation

- Important supporting documents
  - Commission 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
      - *due diligence declarations*
      - *register of collections*
      - *best practices*
    - legally binding
  - EU Guidance document
    - published in 2016, revised version published in 2021
    - provides more detailed information and practical examples on the scope and user obligations of the EU ABS Regulation
      - *e.g. collection management and taxonomy not in scope*
    - not legally binding; explains the EU ABS Regulation

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What to do as a user?

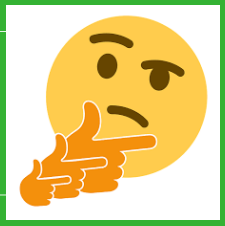
- If you (want to) utilise genetic resources within the EU:

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 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*

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’ (through https://webgate.ec.europa.eu/declare/) when you
   - *receive external research funding, or*
   - *bring a product on the market*
8. pass on information to further users of the genetic resources

Some 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*
- If genetic resources for R&D are bought abroad from a local market, the EU ABS Regulation may apply
- Some European countries have access legislation
  - *the obligations of the EU ABS Regulation may also apply to imports of genetic resources for R&D 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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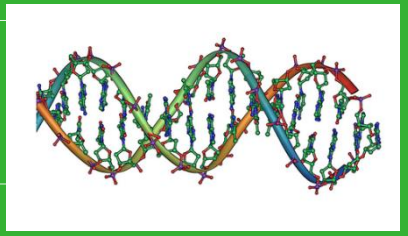
"DSI" - background

- Recognition that 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
  - *"Digital Sequence Information" ("DSI") is undefined term (genomic information or wider?)*
- Research sector has made it clear 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

"DSI" – where do we stand?



- "DSI" is discussed in various international fora, e.g.
  - Convention on Biological Diversity (CBD) / Nagoya Protocol
  - World Health Organization (WHO)
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- *Main discussion forum is the CBD, with other fora mostly awaiting the outcomes there*
- Countries disagree thoroughly on how to deal with "DSI"
  - *EU insists that open access to DSI in databases is preserved and favours multilateral options*
- Various 'policy options' have been defined, including maintaining the status quo, various bilateral and multilateral options, capacity building, and no benefit sharing

"DSI" - where do we go?

Convention on Biological Diversity

- Criteria have been defined to assess the proposed policy options
  - 'Performance matrix'
  - Assessment done by independent expert
- Further CBD discussions in June; decisions probably taken during CBD meeting in August-September
- What can you do?
  - participate in discussions
  - advise your governments on their position
  - interact with international colleagues and collaborators
- More information:
  https://www.cbd.int/doc/c/1081/7ad0/05a4577d6c756e8d2f6cb22f/wg2020-03-04-add1-en.pdf

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Key messages

1. Concept of Access and Benefit Sharing (ABS) was firmly established by the Convention on Biological Diversity (CBD) in 1993
    - *all states have sovereign rights over their genetic resources*
    - *ABS is widely accepted (CBD has now 196 Parties)*
2. Nagoya Protocol in force since 12 October 2014
    - *compliance to national access laws of provider countries must be monitored by countries where genetic resources are used*
    - *provider countries are to ensure clear and transparent procedures*
    - *access to genetic resources usually on the basis of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT)*

Key messages

3. EU ABS Regulation also in force since 12 October 2014
   - *only deals with compliance; access regulated at national level*
   - *applies to genetic resources*
     - *accessed from 12 October 2014 onwards*
     - *accessed from a country that is a Party to the Nagoya Protocol and has applicable access measures*
     - *used in R&D within the EU*
   - *users in the EU must exercise 'due diligence' to make sure access is in accordance with national laws of provider countries*

4. On access to and benefit-sharing from "Digital Sequence Information ("DSI") various options have been identified
   - *options will be assessed and possibly a decision will be taken during the CBD meeting in August/September this year*
   - *EU insists that open access to "DSI" in databases is preserved and favours multilateral options*
   - *it may be a good idea for you to participate in the discussion*

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

Thank you!

www.absfocalpoint.nl

martin.brink@wur.nl

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