The Access and Benefit Sharing (ABS) Landscape for Genebanks

Martin Brink

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Centre for Genetic Resources, the Netherlands

This presentation

1. Access and Benefit Sharing (ABS)
2. International ABS Agreements
3. Implementation of ABS in the European Union (EU)
4. Conclusions

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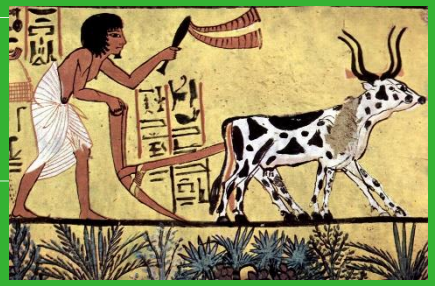
Access and Benefit Sharing (ABS)

- 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 freely 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

ABS essentials




- ABS 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*

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Convention on Biological Diversity (CBD)

- Entry into force: *29 December 1993*
- 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
- Membership
  - 196 Parties

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 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)

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

- 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)
- Membership: 132 Parties (as of December 2021)

The Nagoya Protocol

- Principles
  - provider countries to ensure clear and transparent procedures
  - compliance to ABS rules of 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*
    - 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 to derivates and traditional knowledge; opinions on Digital Sequence Information (DSI) differ

ABS landscape

- Convention on Biological Diversity (CBD, 1993)
  - 'national sovereignty' instead of 'common heritage'
  - ABS through bilateral contacts and on a case-by-case basis

- Nagoya Protocol (2014)
  - additional protocol to CBD
  - provider countries to ensure clear and transparent procedures
  - compliance to ABS rules to be monitored by the countries where the genetic resources are utilized

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

- Entry into force: *29 June 2004*
- Negotiated in FAO
- Objective
  - the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security
- Membership: 148 parties

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

- Important elements
  - ABS goals to be achieved through a Multilateral System (MLS) of exchange of genetic resources
  - Recognition that facilitated access to plant genetic resources for food and agriculture (PGRFA) through the MLS is in itself a major benefit
  - Annex 1: list of crops (35 crop and 29 forage genera) covered under the MLS
  - Genetic resources in the MLS available for research, breeding and training for food and agriculture
  - Access to MLS material with a Standard Material Transfer Agreement (SMTA)
  - Monetary benefits placed into an International Benefit-Sharing Fund

ABS landscape

- Convention on Biological Diversity (CBD, 1993)
  - 'national sovereignty' instead of 'common heritage'
  - ABS through bilateral contacts and on a case-by-case basis

- Nagoya Protocol (2014)
  - additional protocol to CBD
  - provider countries to ensure clear and transparent procedures
  - compliance to ABS rules to be monitored by the countries where the genetic resources are utilized

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2014)
  - ABS through a multilateral system (MLS) of exchange of genetic resources
  - access to MLS on basis of Standard Material Transfer Agreement (SMTA)
  - monetary benefits placed into an International Benefit-Sharing Fund

The International Treaty
ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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Implementation of the Nagoya Protocol in the European Union (EU)

- Compliance
  - Legislation at EU level
    - fine-tuning at national level (authorities, penalties)
- Access
  - Legislation individual countries; no EU legislation
    - some EU Member States have established access legislation (Bulgaria, Croatia, France, Malta and Spain; Finland for traditional knowledge only)
    - other EU Member States (including the Netherlands) do not regulate access to their genetic resources and associated traditional knowledge

EU ABS Regulation

- Entry into force: *12 October 2014*
  - same date as entry into force of Nagoya Protocol
- 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 throughout the EU
- Implements compliance aspects of the Nagoya Protocol in the EU
  - *only deals with compliance, NOT with access*

EU ABS Regulation

Scope (cumulative)

- Geographic scope
  - applicable to genetic resources 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 genetic resources accessed from 12 Oct 2014 onwards
- Material scope
  - applicable to the utilisation of genetic resources and of associated traditional knowledge
  - utilisation includes basic research, applied research and product development
- Personal scope
  - applicable to all users of genetic resources

EU ABS Regulation

Obligations of users in EU

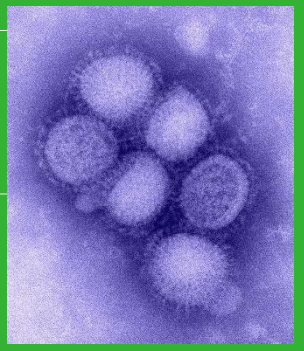
- to exercise ‘due diligence’ to ascertain that the genetic resources they utilise have been legally acquired, and that benefits are shared
- to utilise and transfer genetic resources only in accordance with the Mutually Agreed Terms (MAT)
- therefore:
  - seek relevant ABS information (including permits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

EU ABS Regulation

Obligations of governments EU Member States

- carry out checks to monitor compliance of users
- follow up on concerns of provider countries
- lay down rules on penalties in case of non-compliance
  - "effective, proportionate and dissuasive"
- request users to submit a 'Due Diligence Declaration'
  - when external funding is received for research projects using genetic resources
  - at the stage of final development of a product developed via the utilisation of genetic resources
- transmit information of Due Diligence Declarations to ABS Clearing House as 'Checkpoint Communiqués'

EU ABS Regulation



- Does not apply when ABS of genetic resources is covered by a '*Specialised International Instrument*'
  - 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*

ABS landscape

- Convention on Biological Diversity (CBD, 1994)

- Nagoya Protocol (2014)

- EU ABS Regulation (2014)

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, 2004)

The International Treaty
ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Genebanks in the European Union

What does this mean for genebanks?

- ABS rules apply to *utilisation* of genetic resources, not to having them in *possession*
- However, genebanks want to supply genetic resources which can be utilised
  - ➢ *therefore, they must take into account ABS rules*
- For plant genetic resources, genebanks can use the bilateral route (CBD/Nagoya Protocol) or the multilateral route (ITPGRFA)
- More on the consequences of ABS for genebank management in the next presentation by my colleague Theo van Hintum

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Conclusions (1)

1. Since 1993: Convention on Biological Diversity (CBD) in force
    - national sovereignty over genetic resources
    - national access legislation may apply
2. Since 2004: International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in force
    - selected plant genetic resources available in multilateral system (MLS)
    - access to MLS on basis of Standard Material Transfer Agreement (SMTA)

Conclusions (2)

3. Since 2014: Nagoya Protocol in force
   - forms part of CBD
   - compliance monitored by member states
   - simple and transparent access procedures

4. Since 2014: EU ABS Regulation in force
   - users must exercise 'due diligence' to make sure genetic resources are accessed in accordance with national legislation of provider countries
   - compliance monitored by EU countries
   - access not regulated at EU level
   - EU ABS Regulation not applicable to exchanges for which the ITPGRFA applies

Thank you!

martin.brink@wur.nl

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