Update on Nagoya Protocol and ABS in the EU

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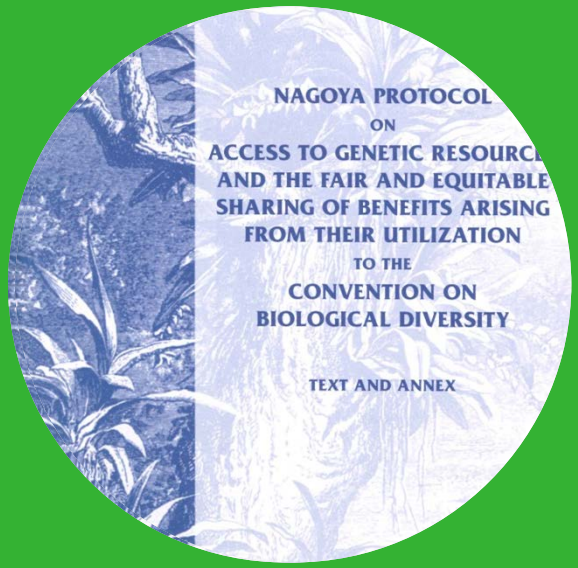
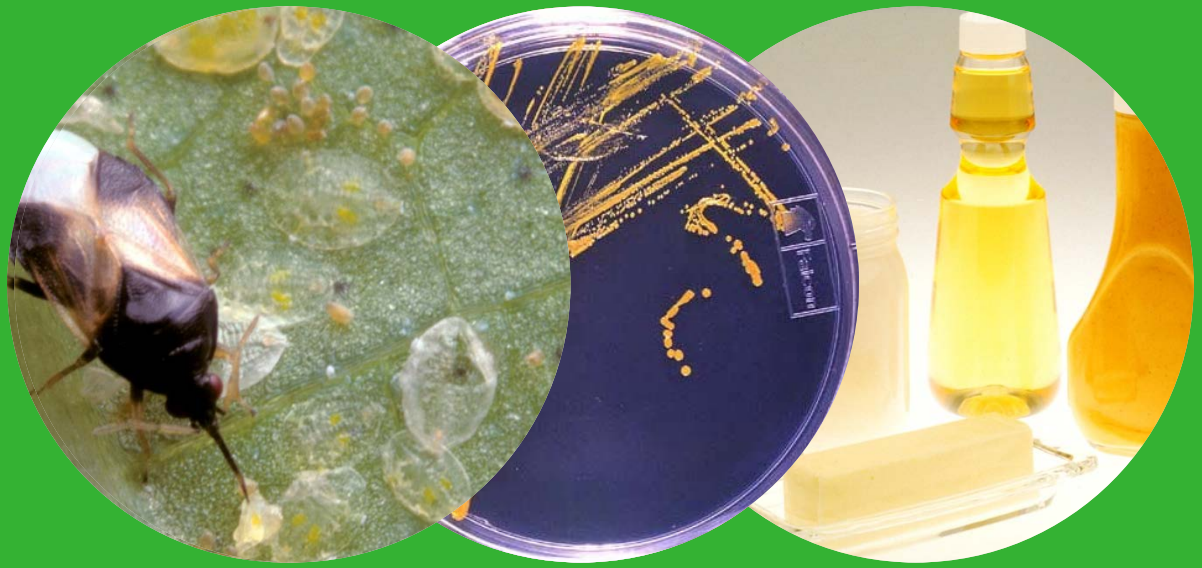
ABIM, 25 October 2016





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Centre for Genetic Resources, the Netherlands

This presentation

- What is ABS?
- International ABS agreements
  - Convention on Biological Diversity
  - Nagoya Protocol
- Implementation of Nagoya Protocol in the EU
  - EU ABS Regulation
  - EU Implementing Regulation
  - EU Guidance Document
  - EU Sectorial Guidance Documents
- Conclusions

What is ABS?

- ABS: 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

- Possible benefits
  - monetary (e.g. royalties, funding for research)
  - non-monetary (e.g. scientific co-operation, technology transfer)

What is ABS?

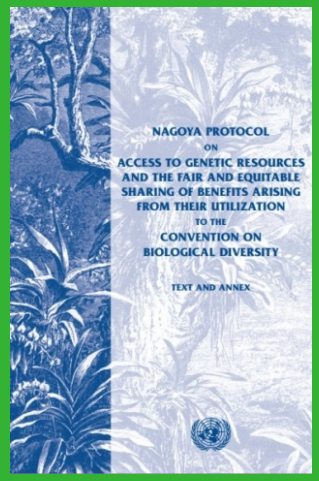
Example (South Africa)

- 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 (before commercialization) and royalties for SASC and local communities
  - employment creation through cultivation of kanna

International ABS agreements

- Convention on Biological Diversity (CBD)

- The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (Nagoya Protocol)



Convention on Biological Diversity (1)

- Objectives
  - conservation of biological diversity
  - sustainable use of its components
  - fair and equitable sharing of the benefits
- Entry into force
  - 29 December 1993
- Membership
  - 196 parties

Convention on Biological Diversity (2)

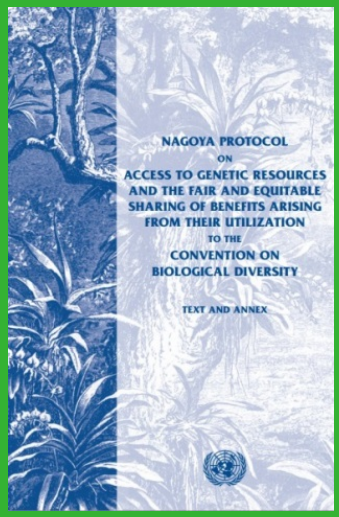
- Important elements
  - genetic resources no longer ‘heritage of mankind’; instead, states have sovereign rights over genetic resources
  - access to genetic resources for their utilization is subject to Prior Informed Consent (PIC) of the Party providing such resources, unless otherwise determined by that Party
  - access shall be on Mutually Agreed Terms (MAT)

Convention on Biological Diversity (3)

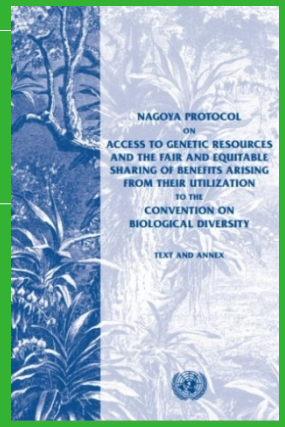
- Important terms
  - genetic material
    - any material of plant, animal, microbial or other origin containing functional units of heredity
  - genetic resources
    - genetic material of actual or potential value
  - Prior Informed Consent (PIC)
    - approval, by the authorities of the providing country, of access to and utilization of genetic resources
  - ‘Mutually Agreed Terms’ (MAT)
    - agreement between two private parties under civil law contract; defining the conditions governing the use of genetic resources and benefit-sharing

Nagoya Protocol (1)

- Protocol to the CBD
  - elaboration of the ABS provisions of the CBD
- Objectives
  - implementation of the third objective of the CBD: fair and equitable sharing of benefits arising from the utilisation of genetic resources
- Entry into force
  - 12 October 2014
- Membership
  - 78 parties (countries + EU)

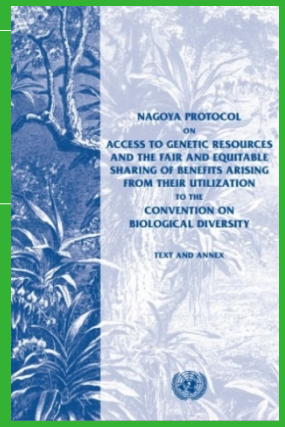


Nagoya Protocol (2)



- Important elements
  - compliance to be monitored by Parties to the NP (= member states)
  - providing countries: simple and transparent procedures
  - provisions on access to traditional knowledge related to genetic resources

Nagoya Protocol (3)



- Important terms
  - utilization of genetic resources
    - to conduct research and development (R&D) on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology
  - derivative
    - a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity
    - So: no DNA has to be present in a product for the Nagoya Protocol to apply

Implementation of Nagoya Protocol in the EU

- Nagoya Protocol is an agreement between states
  - binding between “Contracting Parties”
- Needs further legislation to become binding to citizens
  - Regulation (EU) No 511/2014 (‘EU ABS Regulation’)

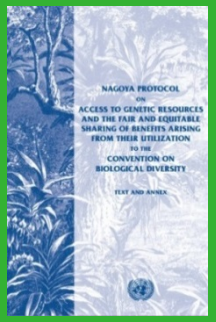
EU ABS Regulation

- Implementing the Nagoya Protocol in EU
- Binding and applicable from 12 October 2014 in EU
  - some provisions only operational from 12 October 2015
- Major elements
  - EU users have to exercise ‘due diligence’ to ascertain that GR utilised have been accessed in accordance with ABS legislation of providing countries, and that benefits are shared
  - EU governments have to check compliance
  - in case of non-compliance: prosecution possible in your own country
  - does NOT regulate access in EU countries

ABS landscape EU

- 1993: CBD
  - ‘national sovereignty’ instead of ‘common heritage’

- 2014: Nagoya Protocol
  - compliance rests with member states
  - providing countries: simple and transparent procedures



- 2014: EU ABS Regulation
  - EU users have to exercise ‘due diligence’
  - EU governments have to check compliance

EU Implementing Regulation

- Commission Implementing Regulation (EU) 2015/1866
- Entry into force: 2 November 2015
- Lays down detailed rules on the implementation of Articles 5, 7 and 8 of the EU ABS Regulation
  - register of collections
  - due diligence declarations
  - best practices
- Annexes: Information to be provided

EU Guidance Document (1)

- Published: August 2016

- Contents

1. Scope of EU ABS Regulation (when does it affect me?)
2. Obligations of users (what do I have to do?)
3. When to make a declaration?
4. Selected sector-specific issues

EU Guidance Document (2)

1. Scope of EU ABS Regulation

Temporal scope

- applicable from 12 October 2014

Geographic scope

- applicable to GR from countries which have ratified the Nagoya Protocol and established access measures
- applicable to utilisation within EU territory

Personal scope

- applicable to all users of genetic resources

Material scope

- applicable to the utilisation of genetic resources and of traditional knowledge associated with genetic resources

EU Guidance Document (3)

- Out of material scope (no ‘utilisation’)
  - mere planting and harvesting
  - maintenance and management of a collection for conservation purposes, including storage, quality checks and verification
  - handling and storing of biological material and describing its phenotype
  - trade and exchange of GR as commodities
  - supply or processing of raw materials for incorporation in a product, where properties of the biochemical compound of the GR are already known
  - GR as testing/reference tools
  - use of biotechnology where GR are no object of R&D (e.g. use yeasts in brewing beer)

EU Guidance Document (4)

- In material scope ('utilisation')
  - description of a GR combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties
  - 'litmus test': if your activity with GR creates new insight into characteristics of the GR which is of (potential) benefit to the further process of product development, it is 'utilisation'
  - breeding
  - genetic modification
  - creation and improvement GR used in biotechnology (e.g. yeasts to be used in brewing process)
  - R&D on derivative when access to derivative is combined with access to GR from which the derivative was/is obtained

EU Guidance Document (5)

2. Obligations of users

- take reasonable measures in the seeking, keeping, transfer and analysis of information (‘due diligence’)
- determine if Regulation is applicable and material falls within scope
- if Regulation is applicable: seek, keep and transfer information (demonstrate ‘due diligence’)
- if GR obtained from indigenous and local communities: reflect views of communities in the Mutually Agreed terms (MAT)
- if GR from ‘registered collections’: ‘due diligence’ obligation considered fulfilled

EU Guidance Document (6)

3. When to make a due diligence declaration?
    - 2 checkpoints
        - ➢ when public or private funding is received for research project using GR
        - ➢ at the stage of final development of a product, e.g. when market approval/authorisation is sought
4. Selected sector-specific issues
    - health
    - food and agriculture (mainly plants)

EU Guidance Document (7)

- Unresolved issues
  - ➢ mainly: what is utilisation? (material scope)

- Further sector-specific guidance documents under development in 2016/2017

EU Sectorial Guidance Documents (1)

- Sectors to be covered (start 2016)
  1. animal breeding sector
  2. plant breeding sector
  3. biocontrol/biostimulants sector
  4. cosmetics sector
  5. pharmaceutical sector
  6. food and beverage industry sector
  7. biotechnology industry sector
- Additional sectors (start 2017)
  8. public research institutions
  9. collection holders

EU Sectorial Guidance Documents (2)

- Methodology
  1. Guidance Development Group (GDG) with 6-10 members established for each sector
     - ➢ makes draft document
     - ➢ meets once
  2. Workshop with representatives from sector and ABS authorities EU countries
     - ➢ discussion of draft document
  3. Invitation of written comments
  4. Draft document submitted to EC
  5. EC discusses draft document with EU Member states
  6. EC publishes final sector-specific guidance documents

- Work in progress! (final versions in 2017)

EU Sectorial Guidance Documents (3)

- Important issues
  - where does identification/description stop and R&D start? (e.g. genome sequencing)
  - in case of mass screening: PIC and MAT needed for every accession?
  - determining the country of origin
  - when does utilisation end? (‘cut-off point’)
  - commercial plant varieties to be included?
  - derivatives: when do ABS rules apply?
  - activities to fulfil regulatory requirements
  - providing countries may have different interpretations than EU

Guidance Document Biocontrol/Biostimulants

- Chapter 1: Introduction
  - Delineation of the sector
  - Sector activities
  - Types of genetic resources used
  - Actors
  - Origin of genetic resources used
- Chapter 2: Classification of activities
- Annex
  - Background information on sector

Guidance Document Biocontrol/Biostimulants

- Case A

Title	Multiplication of biocontrol or biostimulant agents
Description	Many activities in the biocontrol sector are mainly focusing on, and based on, the multiplication of organisms.
Analysis	No research is being done on the genetic or biochemical composition of the genetic resources. Therefore this activity does not constitute utilisation in the context of the EU ABS Regulation

Guidance Document Biocontrol/Biostimulants

- Case B

Title	Taxonomic identification of organisms
Description	Biological control programmes require identification, and sometimes formal description, of pests and biological control agents, initially based on morphological analysis.
Analysis	The taxonomic identification of organisms and the mere description of a genetic resource by morphological analysis does not amount to utilisation in terms of the EU ABS Regulation. However, if the identification of a genetic resource is combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties, this would qualify as utilisation in terms of the EU ABS Regulation.

Guidance Document Biocontrol/Biostimulants

- Case C

Title	Conscious and targeted crossing and/or selection within populations of organisms
Description	Conscious and targeted crossing and/or selection of biological control agents is done in the framework of a breeding programme, which may be modest or complex.
Analysis	Research is being done on the genetic and/or biochemical composition of the genetic resources with the aim to change this composition. Therefore this activity does constitute utilisation in the context of the EU ABS Regulation.

Guidance Document Biocontrol/Biostimulants

- Case D

Title	Evaluation of the mode of action of identified active substances obtained from genetic resources for use as a biological control agent or biostimulant
Description	This activity involves studying how an identified active substance is effective and how this can be explained from its chemical composition.
Analysis	This activity creates new insight into characteristics of the GR which is of (potential) benefit to the further process of product development. Therefore this activity does constitute utilisation in the context of the EU ABS Regulation.

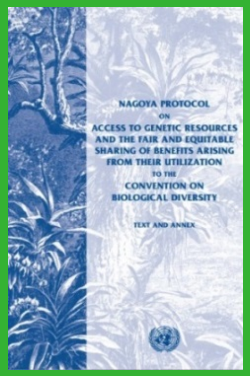
Guidance Document Biocontrol/Biostimulants

- Case E

Title	Trading biocontrol agents/products and biostimulants
Description	Biocontrol agents/products and biostimulants may be purchased or sold to customers in the same and other countries.
Analysis	Trading does not constitute utilisation in the context of the EU ABS Regulation, and hence does not fall within the scope of the EU Regulation. However, the transaction might trigger contractual benefit-sharing obligations towards the initial provider of the genetic resources used to develop the traded product.

ABS landscape EU

- CBD
- Nagoya Protocol
- EU legislation



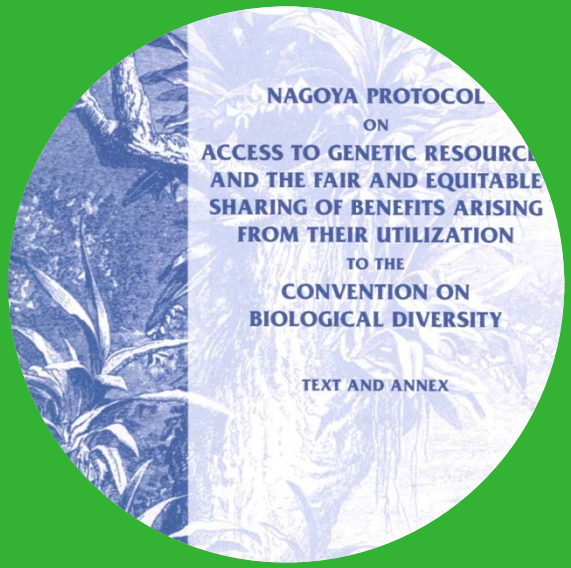
EU ABS Regulation
EU Implementing Regulation
EU Guidance Document EU
EU Sectorial Guidance Documents

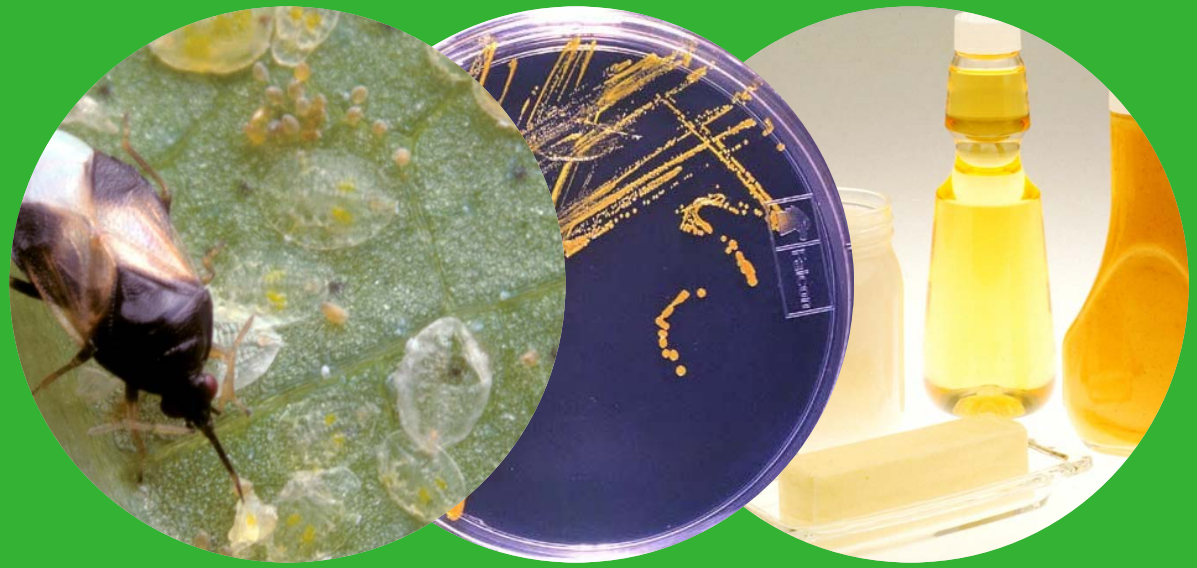
Conclusions

1. Since 29 December 1993 (CBD): national sovereignty over genetic resources
    - ➢ national access legislation may apply
2. Since 12 October 2014: Nagoya Protocol and EU ABS Regulation in force
    - ➢ monitoring of compliance in EU
    - ➢ access not regulated at EU level
3. Geographical, temporal and personal scope of EU ABS Regulation clear
4. Material scope (‘what is utilisation’) still under discussion
5. Providing countries may have other interpretations than EU
6. Seeking, keeping and transferring information on access conditions and benefit-sharing agreements has become essential

Thank you!

(more information: www.absfocalpoint.nl)





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