Implementation of the Nagoya Protocol in the EU

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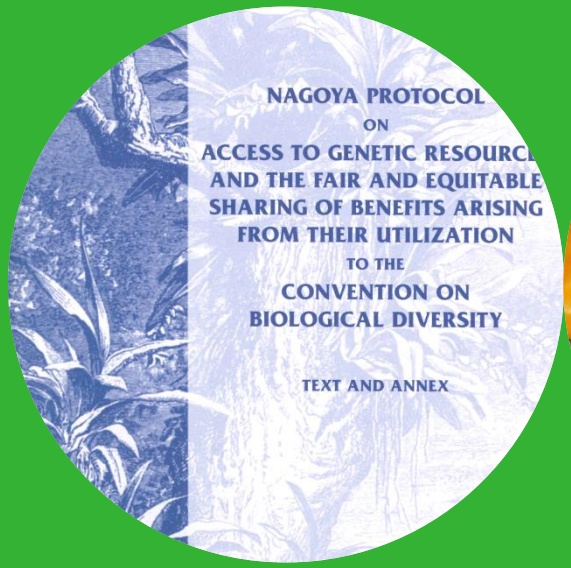

WAGENINGEN
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Centre for Genetic Resources, the Netherlands

This presentation

1. Background
2. Implementation Nagoya Protocol in the EU
3. Conclusions

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What is ABS?

- Access and Benefit Sharing (ABS)
  - 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)

ABS Example

- 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

Convention on Biological Diversity (1)

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

Convention on Biological Diversity (2)

- Important elements
  - Paradigm shift: genetic resources no longer 'heritage of mankind'; instead, states have sovereign rights over genetic resources
  - Access shall be 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)

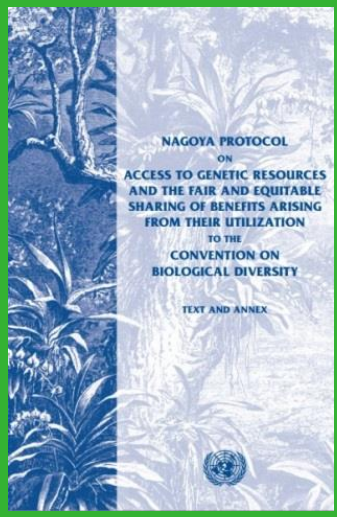
- Sovereign rights established by CBD (1993)

- National ABS legislations introduced: access restricted
  - Philippines (1995)
  - Costa Rica (1998)
  - Brazil (2001)
  - South Africa (2004)
  - Kenya (2006)

Convention on Biological Diversity

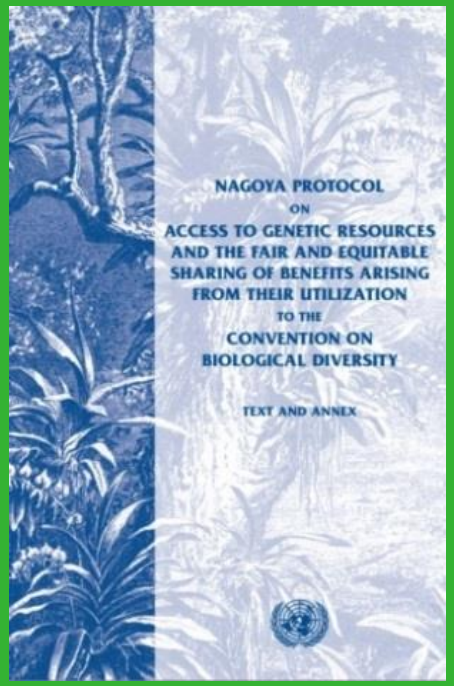
Nagoya Protocol (1)

- Entry into force
  - 12 October 2014
- Protocol to the CBD
  - elaboration of the ABS provisions of the CBD
- Objective
  - implementation of the third objective of the CBD: fair and equitable sharing of benefits arising from the utilisation of genetic resources
- Membership
  - 96 parties (95 countries + EU)



Nagoya Protocol (2)

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



ABS landscape

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

Convention on Biological Diversity

- 2014: Nagoya Protocol
  - user countries: monitoring of compliance
  - providing countries: simple and transparent procedures

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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

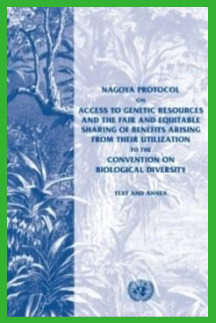
- Implements the Nagoya Protocol in EU
- Binding and applicable from 12 October 2014 in EU
  - some articles only apply from 12 October 2015
- Major elements
  - EU users have to exercise 'due diligence' to ascertain that GR utilised have been accessed in accordance with ABS legislation of providing 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’
  - basis of national legislation

Convention on Biological Diversity

- 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

Implementing Regulation (EU) 2015/1866

- Entry into force: 9 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
  - templates

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 to genetic resources accessed from a provider country on or later than 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 of 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 of GR used in biotechnology (e.g. of 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
    - exercise ‘due diligence’ to ascertain that GR have been accessed in accordance with ABS legislation of provider country
    - determine if Regulation is applicable and material falls within scope
    - if Regulation is applicable, demonstrate due diligence: seek, keep, and transfer information to subsequent users
    - 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)

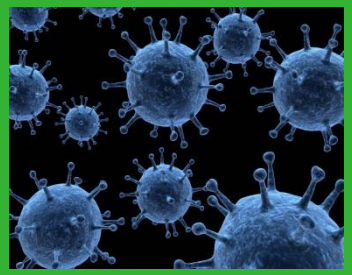
EU Guidance Document (7)

- Clarity still insufficient
  - ➢ mainly: what is utilisation? (material scope)

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

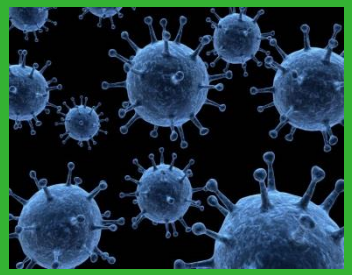
EU Sectorial Guidance Documents (1)

- Initial sectors (start 2016, finish 2017)
  1. animal breeding sector
  2. plant breeding sector
  3. biocontrol/biostimulants sector
  4. cosmetics sector
  5. pharmaceutical sector
  6. food and feed sector
  7. biotechnology sector
- Additional sectors (2017)
  8. public research institutions
  9. collection holders



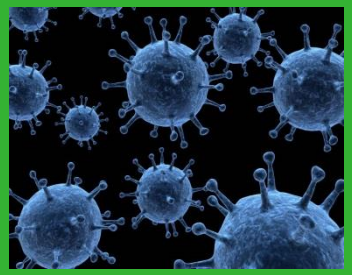
EU Sectorial Guidance Documents (3)

- Methodology
  1. Guidance Development Group (GDG) with 6-10 members established for each sector: makes draft 1.0; meets once
  2. Workshop with representatives from sector and ABS authorities EU countries: discussion of draft 1.0
  3. Invitation of written comments: draft 2.0
  4. Draft 2.0 discussed in ABS Consultation Forum
  5. Draft 3.0 submitted to EC
  6. EC discusses draft with EU Member states
  7. EC publishes final sector-specific guidance documents
- Work in progress!



EU Sectorial Guidance Documents (4)

- Important 'unresolved issues' currently discussed
  - large scale screening: PIC and MAT needed for every accession?
  - commercial plant varieties in scope?
  - derivatives and their modification
  - human biome
  - subcontractors and service providers
  - when does utilisation end ('cut-off point')?



Guidance Document Food and Feed sector

- Chapter 1: Introduction
  - Coverage
  - Food and feed activities
  - Types and sources of genetic resources used
  - Actors in the food and feed sector
- Chapter 2: Classification of activities
  - Introduction
  - Due diligence obligations
  - Specific cases for the food and feed sector
- Chapter 3: Unresolved issues
- Annexes: background information
  - General principles
  - Short description of the sector (additional information)
  - Sources and major exchange practices

Guidance Document Food and Feed sector

- Case A

Title	Transport, storage and classification after access from a culture collection
Description	Company purchases microbial strains of unknown identity from a culture collection. It imports the strains, performs whole-genome sequencing for taxonomic classification of the strains, and deposits the strains in its internal culture collection, for possible later utilisation.
Analysis	Access, transport and storage do not constitute utilisation in the meaning of the EU ABS Regulation. Similarly, proper identification of the acquired genetic resource forms a prerequisite for subsequent R&D. Taxonomic identification of genetic material, in the form of verification of received material by morphological or molecular analysis is not considered to constitute utilisation in the meaning of the EU ABS Regulation.

Guidance Document Food and Feed sector

- Case B

Title	Use of whole-genome sequencing to identify new products
Description	1.Company purchases microbial strains of unknown identity from a culture collection in a country that is Party to the Nagoya Protocol. It imports the strains into the EU, performs whole-genome sequencing for the purpose of taxonomic classification, and deposits the strains in its culture collection. 2. A few years later, the genome sequence of one of the strains is analysed for potential lipase genes, and one of the candidate lipase genes is used to generate a commercial production strain for this particular lipase.
Analysis	1. Whole-genome sequencing for taxonomic classification is not utilisation in the meaning of the EU ABS Regulation. 2. Analysis of the genome sequence for candidate genes for commercial production, and construction of a production organism for such a candidate enzyme, does involve R&D on a genetic resource, and therefore these activities fall within the scope of the EU ABS Regulation.

Guidance Document Food and Feed sector

- Case C

Title	Improvement of product characteristics
Description	Company accesses a fungal strain from a Party to the Nagoya Protocol for its known phospholipase activity. However, in application tests, the phospholipase turns out not to be sufficiently temperature stable. Protein engineering is applied to make the phospholipase more temperature stable, and a recombinant production strain is subsequently generated for the commercial-scale production of the protein-engineered phospholipase.
Analysis	Generation of more temperature-stable variants of the phospholipase, and construction of recombinant production strains for such phospholipase variants, are both considered to represent utilisation of the genetic resource in the meaning of the EU ABS Regulation.

Guidance Document Food and Feed sector

- Case D

Title	Physical processing of foods
Description	Company accesses a particular variety of tomatoes in a Party to the Nagoya Protocol and applies physical techniques that are routinely used in food preparation and that do not intentionally alter the biochemical composition of the genetic resource to produce a purée or a juice.
Analysis	This activity involves the use of the tomatoes as a commodity for food production, and no research and development is carried out on the genetic resource. Therefore, the activity does not constitute utilisation in the meaning of the EU ABS Regulation.

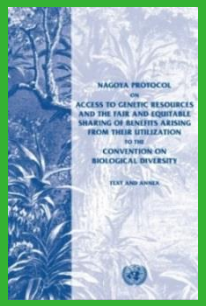
Guidance Document Food and Feed sector

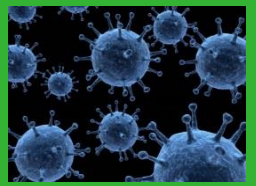
- Case E

Title	Accessing and testing plants from EU based nurseries
Description	Company collects Yuzu plants from three nurseries in France, Belgium and the Netherlands to perform R&D towards new citrus flavours. The acquired plants had been accessed and imported from an East Asian country into the European Union before 12 October 2014. They have been kept and replicated in nurseries since.
Analysis	Utilisation from all these nurseries is outside the scope of the EU ABS Regulation, since the genetic resource was accessed from the provider country before 12 October 2014. While the user may be under national law obligations of the provider country at the time of access, this would not trigger obligations under the EU ABS Regulation.

ABS landscape EU

- CBD
- Nagoya Protocol
- EU legislation





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

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Conclusions

1. 29 December 1993: CBD in force
   - national sovereignty over genetic resources
   - national access legislation may apply
2. 12 October 2014: Nagoya Protocol and EU ABS Regulation in force
   - users must exercise 'due diligence' to make sure GR are accessed in accordance with national legislation of providing countries
   - compliance monitored by EU countries
   - access not regulated at EU level
3. Geographical, temporal and personal scope of EU ABS Regulation clear, but material scope ('what is utilisation') still under discussion
4. Seeking, keeping and transferring information to subsequent users has become essential