The Nagoya Protocol and its implementation in the EU and the Netherlands

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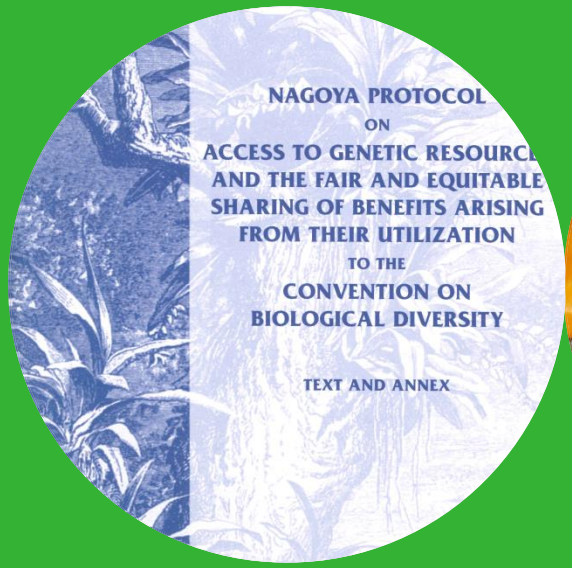
15 October 2018



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Centre for Genetic Resources, the Netherlands

This presentation

1. The Nagoya Protocol
2. Implementation in EU
3. Implementation in NL
4. Implementation by users
5. Conclusions

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Convention on Biological Diversity (CBD)

- Entry into force and membership
  - 29 December 1993
  - 196 parties (195 countries + EU)

- 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
- Important element
  - genetic resources no longer 'heritage of mankind'
    - ➢ *instead, states have sovereign rights over their genetic resources*
      - ➢ following the increasing role of IPR (patents) in the exploitation of genetic resources
      - ➢ provider countries would like a share of profits
      - ➢ would provide incentive for conservation

Convention on Biological Diversity (CBD)

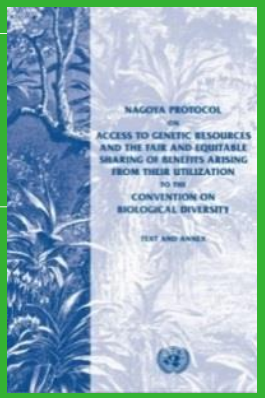
- CBD (1993)
  - genetic resources no longer 'heritage of mankind'
    - *instead, states have sovereign rights over their genetic resources*
- National ABS legislations introduced
  - e.g. Philippines (1995), Costa Rica (1998), Brazil (2001)
  - but:
    - rules often unclear and complex
    - enforcement difficult
- Effects
  - access to genetic resources restricted
  - little benefit-sharing
- Nagoya Protocol

Convention on Biological Diversity

Nagoya Protocol

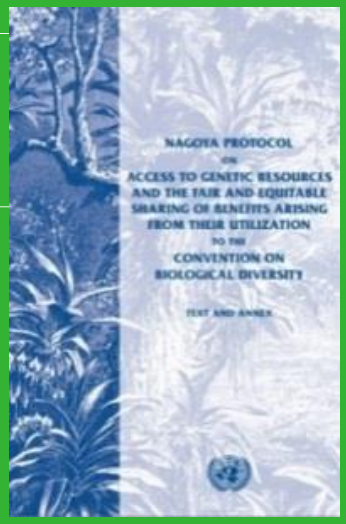
- Entry into force: 12 October 2014
- Objective
  - *the fair and equitable sharing of the benefits arising from the utilization of genetic resources*
    - = 3rd objective Convention on Biological Diversity (CBD)
- Protocol to the CBD
  - elaboration of the ABS provisions of the CBD
- Important elements
  - each Party must provide for legal certainty, clarity and transparency of their domestic ABS legislation
  - compliance to ABS rules in provider countries to be monitored by countries where GR are utilized

Nagoya Protocol



- Scope
  - applies to all genetic resources (like CBD)
    - *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
  - definition of 'utilization 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 GR
  - Digital Sequence Information (DSI)
    - currently heated debates on whether it is included or not

Nagoya Protocol



- Contains provisions on
  - access
  - benefit-sharing
  - compliance
- Each Party must designate
  - *Competent National Authorities* (CNA), responsible for providing access
  - *National Focal Point* (NFP), responsible for information supply
- ABS Clearing House website for information sharing
  - Each Party must make available relevant information

ABS Clearing House: https://absch.cbd.int/

ABS Clearing House: https://absch.cbd.int/

- Available information
  - 107 Parties (106 countries + EU)
  - National Focal Points (169 countries)
  - Competent National Authorities (63 countries)
  - Legislative, Administrative or Policy Measures (58 countries)
  - National Websites and Databases (31 countries)
  - Checkpoints (25 countries)
  - International Certificates of Compliance (229; 13 countries)
  - Interim National Reports on the Implementation of the Nagoya Protocol (86 countries)

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Implementation Nagoya Protocol in EU

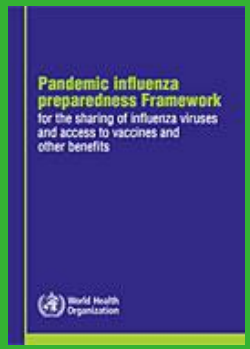
- EU rules
  - Regulation (EU) 511/2014
    - legally binding
  - Commission Implementing Regulation (EU) 2015/1866
    - legally binding
  - Guidance document
    - published, not legally binding
  - Sector-specific guidance documents
    - not yet published
- Rationale
  - EU wants to be a reliable international partner
  - proper regulation in EU will lead to good access for EU actors in other countries

EU Regulation 511/2014

- Implements the Nagoya Protocol in the EU
- Entry into force: 12 October 2014
  - same date as entry into force of Nagoya Protocol
- Applicable to GR and traditional knowledge associated with GR
  - accessed from 12 October 2014 onwards
  - accessed from countries which have ratified the Nagoya Protocol and established access measures
- Only deals with compliance, does NOT regulate access in EU countries

EU Regulation 511/2014

- Not applicable when ABS is governed by specialised international instrument
- Specialised international instruments recognised by EU
  - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
  - Pandemic Influenza Preparedness (PIP) framework



EU Regulation 511/2014

Obligations of EU Member States (Art. 7, 9, 11)

- request users to submit 'due diligence declaration'
  - when research funding is received for research project using GR and associated TK
  - at the stage of final development of a product developed via the use of GR or associated TK, e.g. when market approval/authorisation is sought
- carry out checks to monitor compliance
- lay down rules on penalties in case of non-compliance
  - "effective, proportionate and dissuasive"

EU Regulation 511/2014

Obligations of users in EU (Art. 4)

- to exercise 'due diligence' to ascertain that GR (and traditional knowledge associated with GR) they utilise have been accessed in accordance with ABS legislation of provider countries, and that benefits are shared
- To transfer and utilise GR (and associated TK) only in accordance with the MAT (Mutually Agreed Terms), if these are required
- Therefore:
  - seek, keep, and transfer relevant information to subsequent users
  - keep information for 20 years after end utilisation
- if GR are obtained from 'registered collection': 'due diligence' obligation considered fulfilled

What to document? (Art. 4)

- 'internationally-recognised certificate of compliance'
  - = document posted by the provider country on the ABS Clearing House website (https://absch.cbd.int/)

or:

- document(s) showing:
  - date and place of access of resources or traditional knowledge
  - description of the genetic resources or of traditional knowledge
  - source from which the genetic resources or traditional knowledge associated with genetic resources were obtained, as well as subsequent users (development chain)
  - rights and obligations relating to access and benefit-sharing including for subsequent applications and commercialisation
  - access permits, where applicable (from CNA)
  - MAT, including benefit-sharing arrangements, where applicable

Implementing Regulation (EU) 2015/1866

- Entry into force: 9 November 2015
- Lays down more 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

- Published: 27 August 2016
- Not legally binding
- More information/interpretation
  - scope of EU ABS Regulation
  - obligations of users
  - events triggering due diligence declarations
  - selected sector-specific issues

EU Guidance Document

Scope EU ABS Regulation

- Temporal
  - applicable to GR accessed from 12 Oct 2014 onwards
- Geographic
  - applicable to GR from countries which have ratified the Nagoya Protocol and established access measures
  - applicable to utilisation within EU territory
- Personal
  - applicable to all users of GR resources
- Material
  - applicable to the utilisation of genetic resources and of traditional knowledge associated with GR
  - utilisation (R&D) includes basic research, applied research and product development
  - examples of activities that are utilisation and activities that are not utilisation

EU Guidance Document

- Out of material scope (not 'utilisation')
  - mere planting and harvesting by a farmer
  - maintenance and management of a collection for conservation purposes, including storage, quality checks and verification upon acceptance
  - handling and storing of biological material and describing its phenotype
  - supply and processing of raw materials for subsequent incorporation in a product where the properties of the biochemical compound contained in the genetic resources are already known
  - genetic resources as testing/reference tools
  - application of biotechnology where genetic resources are not objects of R&D (e.g. use of yeasts in brewing beer)

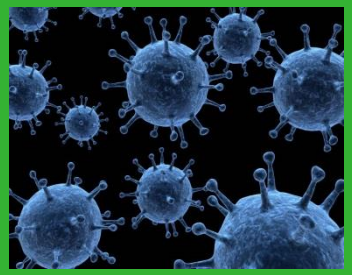
EU Guidance Document

- 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 the activity creates new insight into characteristics of the genetic resources which is of (potential) benefit to the further process of product development, it is 'utilisation'*
  - research on genetic resources leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a cosmetic product
  - breeding to create a new plant variety based on landraces or naturally occurring plants
  - genetic modification
  - creation and improvement of genetic resources applied in biotechnology (e.g. of yeasts to be used in brewing process)

EU Sector-specific guidance documents

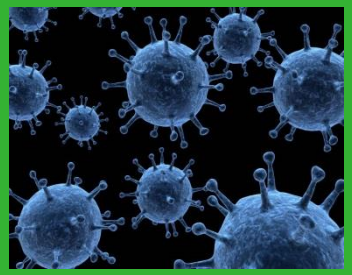
- start 2016, finish December 2017
- 9 sectors/domains
    1. animal breeding sector
    2. plant breeding sector
    3. biocontrol/biostimulants sector
    4. cosmetics sector
    5. pharmaceutical sector
    6. food and beverage industry sector
    7. biotechnology industry sector
    8. public research institutions
    9. collection holders



EU Sectorial Guidance Documents

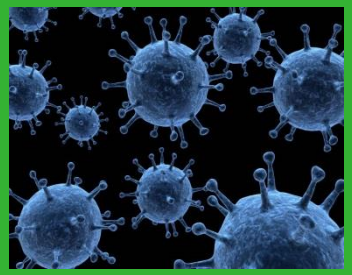
- 'Unresolved issues' currently discussed by EU Member States
- Some examples
  - large scale screening: permits needed for every accession?
  - does the regulation apply to commercial plant varieties?
  - derivatives: when does regulation apply?
  - human biome in scope?
  - phylogenetic research
  - laboratory strains



EU Sectorial Guidance Documents

- Decisions on unsolved issues to be taken by EU Member States
- Sectorial guidance documents will be combined into 1 document for official publication
- *Provider countries may have different interpretations than EU!*



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National law

- *Nagoya Protocol (Implementation) Act* (with Explanatory Memorandum, Regulation and Decrees)
  - implements Nagoya Protocol in NL
  - into force: 23 April 2016
  - Competent National Authority (CNA): Ministry of Economic Affairs (now: Ministry of Agriculture, Nature and Food Quality)
    - ➢ overall responsibility
  - monitoring agency: Netherlands Food and Consumer Product Safety Authority (NVWA)
    - ➢ monitoring
  - National Focal Point (NFP): Centre for Genetic Resources, the Netherlands (CGN)
    - ➢ information supply

National law

- Access to *in situ* genetic resources not regulated in NL
  - ➢ *Prior Informed Consent (PIC) not needed*

- Access to plant genetic resources for food and agriculture held in public *ex situ* collections
  - ➢ usually on the basis of the Standard Material Transfer Agreement (SMTA) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

Sanctions and penalties

- Light infringements (information lacking, no timely due diligence declaration): provisions of administrative law
  - Notice of remedial action or measures to be taken by the user
  - standard: 3 months to restore
  - if not resolved, Minister can:
    - take products into custody, commission a fine
    - take immediate interim measures (costs to be charged to the infringer)
- Serious violations: criminal law
  - fines up to 81,000 for persons and EUR 810,000 for legal entities
  - max 6 years imprisonment

Monitoring: Netherlands Food and Consumer Product Safety Authority (NVWA)

- Inspections
  - On-site
    - from 2016 onwards
  - Digital inspections
    - will start in 2018
  - Sector-wise
    - 2016/2017: Plant Breeding sector
    - 2018/2019: Public Research; Food and Feed sector
  - Preceded by information activities for the sector
    - presentations by NFP and NVWA
    - information in journals and on websites
    - where possible together with sector associations

Netherlands Food and Consumer Product Safety Authority
Ministry of Agriculture, Nature and Food Quality

Monitoring: Netherlands Food and Consumer Product Safety Authority (NVWA)

Netherlands Food and Consumer Product Safety Authority
Ministry of Agriculture, Nature and Food Quality

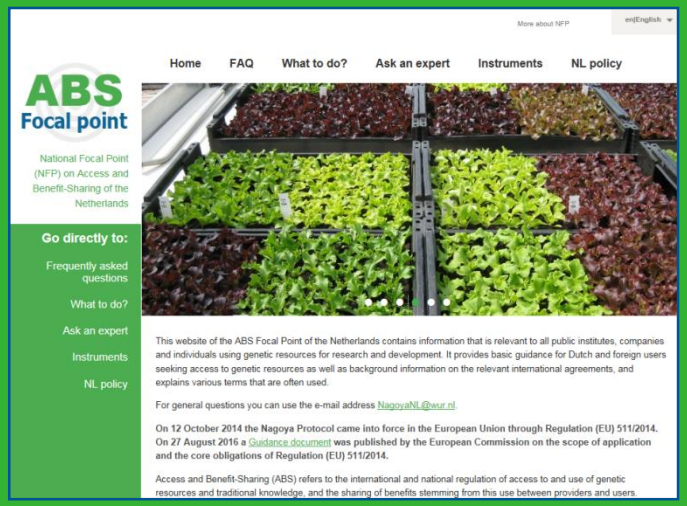
- Handling 'Due diligence declarations'
  - 2 checkpoints:
    - when receiving external funding for research
    - at final stage of product development
  - submitted through European website 'Declare' (https://webgate.ec.europa.eu/declare/)
  - published on ABS Clearing House website

Information supply: National Focal Point on ABS

- website
- brochures
- articles in journals and on websites
- presentations
- meetings
- answering of questions
- information on ABS Clearing House website

Information supply: NFP website

- www.absfocalpoint.nl
- bilingual: English and Dutch
- contents
  - guidance ("What to do as a user of genetic resources")
  - Frequently Asked Questions (FAQ)
  - asking your own questions
  - info on international instruments
  - info on NL policy and legislation
  - any new developments
- ±5000 page views per year
- regularly updated



Initiatives towards researchers

- Meetings with sector organizations
  - Vereniging van Universiteiten (VSNU)
  - Vereniging Hogescholen (VH)
  - Koninklijke Nederlandse Academie van Wetenschappen
- Individual organizations informed by sector organizations
- Presentations during symposia, workshops, thematic days etc.
- Consultation with main funding agencies
  - e.g. information published on website NWO

Initiatives towards researchers

- Direct contacts with research groups and individual researchers at universities and research institutes
  - Presentations on-site
  - Answering of questions/cases
- Digital inspections pre-tested with research institute

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Measures taken by users

- Embedding in the organisation
  - who is responsible for compliance to the rules?
- Document what already in possession before 12 October 2014
  - no legal obligation but a precaution to avoid future conflicts
- Install/upgrade documentation system(s) with information on
  - date and place of access of genetic resources
  - conditions of access, utilization and transfer (with supporting documents)
  - utilization
  - transfer to third parties (with supporting documents)

Measures taken by users

- Also keep documentation on genetic resources which do not fall under the EU ABS Regulation
  - to make plausible that these genetic resources were indeed accessed legally
- Think about where to access genetic resources
  - from which country?
  - from a collection, or from nature or farmers' fields?
  - worth the effort?
- Seek information and advice
  - from National Focal Point
  - from sector associations

Measures taken by Wageningen University and Research (WUR)

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- *Code for obtaining and using genetic materials of foreign origin at Wageningen University & Research*
  - What are Nagoya Protocol and EU ABS Regulation about?
  - When does the EU Regulation apply?
  - Which obligations should I comply with as a user?
  - How do I obtain Prior Informed Consent (PIC)?
  - How are the Mutually Agreed Terms (MAT) realised?
  - What could happen if I am not in compliance with the obligations?
  - Who is responsible within the organisation?
  - what exactly should users of genetic resources with foreign origins do?
  - How is this checked in the Netherlands?
  - Where can I find more information?

Measures taken by Wageningen University and Research (WUR)

- Responsible within the organisation:
  - chair holders
  - business unit managers
- Legal department to be consulted for advice and signing of contracts
- No centralized administration/documentation system

Measures taken by users

- Experiences:
  - users generally support idea of benefit-sharing, but find administrative burden too high
  - large differences in awareness
    - between and within sectors
    - often thought that rules do not apply to research or non-commercial research
  - responsibilities often unclear
    - some universities: managers
    - others: Biological Safety officers
    - contracts through Legal Department

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Conclusions

1. Since 12 October 2014: Nagoya Protocol in force
   - compliance to national access legislation of provider countries to be monitored by countries where GR are used
   - provider countries must provide for legal certainty, clarity and transparency of their ABS legislation
2. Since 12 October 2014: EU ABS Regulation in force
   - EU users must exercise 'due diligence' to make sure GR are accessed in accordance with national legislation of provider countries
   - compliance monitored by EU countries
   - access not regulated at EU level
   - geographical, temporal and personal scope of EU ABS Regulation clear, but material scope ('what is utilisation') still under discussion

Conclusions

4. Implementation in NL
   - Law into force on 23 April 2016
   - tasks (overall responsibility; monitoring; information supply) divided over different organizations
   - inspections started in 2016
   - access to in situ genetic resources not regulated in
5. Implementation by users
   - embedding in organization
   - documentation
   - where to access genetic resources?
   - Information
6. Experiences
   - support for benefit-sharing, but administrative burden found too high
   - differences in awareness
   - responsibilities often unclear