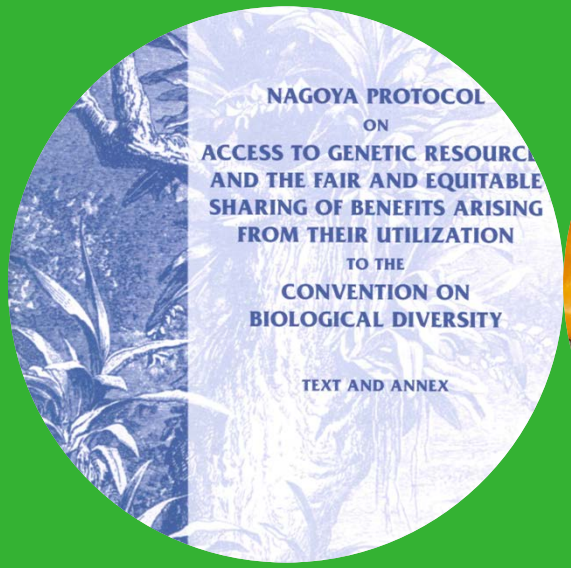
The Nagoya Protocol, its implementation in the EU, and the consequences for users of genetic resources.

Martin Brink

NVPW, 9 December 2016



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This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users
4. Conclusions

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Access and Benefit-Sharing

- 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)

Access and Benefit-Sharing

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

Convention on Biological Diversity (1)

- Negotiated in UNEP (United Nations Environment Programme).
- 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)

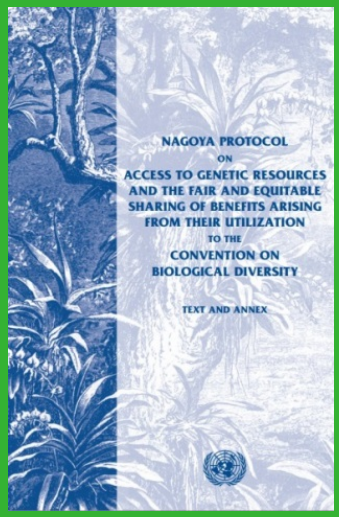
- Important elements
  - genetic resources no longer ‘heritage of mankind’; instead, states have sovereign rights over genetic resources
  - access to genetic resources for their utilization is subject to Prior Informed Consent (PIC) of the Party providing such resources, unless otherwise determined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

Convention on Biological Diversity (3)

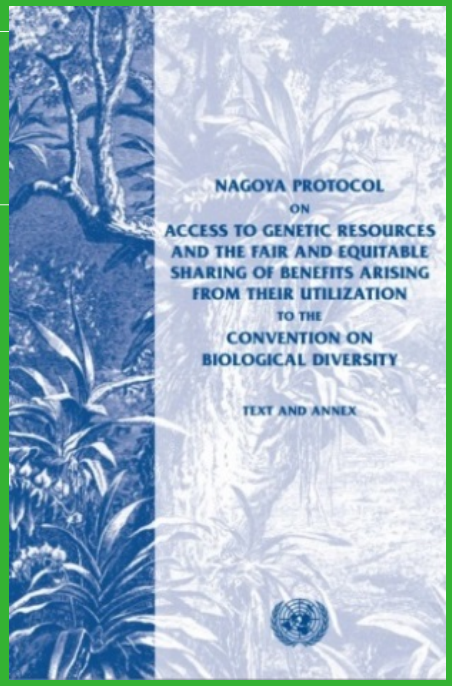
- Important terms
  - genetic material
    - any material of plant, animal, microbial or other origin containing functional units of heredity
  - genetic resources
    - genetic material of actual or potential value
  - Prior Informed Consent (PIC)
    - approval, by the authorities of the providing 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
  - 84 parties (83 countries + EU)

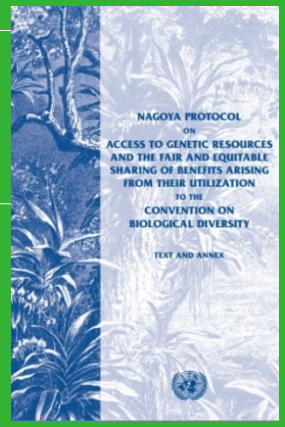


Nagoya Protocol (2)



- 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.)

International Treaty on Plant Genetic Resources for Food and Agriculture (1)

- Negotiated in FAO
- Objectives
  - conservation of biological diversity
  - sustainable use of its components
  - fair and equitable sharing of the benefits
- Entry into force
  - 29 June 2004
- Membership
  - 141 parties

International Treaty on Plant Genetic Resources for Food and Agriculture (2)

- Important elements
  - ABS goals to be achieved through a multilateral system (MLS) of exchange of genetic resources
  - 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 purposes
  - Access to MLS material with a Standard Material Transfer Agreement (SMTA)
  - Part of the monetary benefits must be placed into an International Benefit-Sharing Fund

ABS landscape

- 1993: CBD
  - ‘national sovereignty’ instead of ‘common heritage’
- 2014: Nagoya Protocol
  - compliance rests with member states
  - providing countries: simple and transparent procedures

- 2004: ITPGRFA
  - genetic resources available in multilateral system (MLS)
  - access on basis of Standard Material Transfer Agreement (SMTA)

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EU ABS Regulation

- Entry into force: 12 October 2014
- 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
  - relevant documentation to be kept for 20 years after end of utilisation
  - not applicable to exchanges of material from the multilateral system (MLS) of the ITPGRFA
  - does NOT regulate access in EU countries

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)

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 (2)

- 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
  - 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 (3)

- 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)

EU Guidance Document (4)

- Unresolved issues
  - ➢ 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 beverage industry sector
  7. biotechnology industry sector
- Additional sectors (start 2017)
  8. public research institutions
  9. collection holders

EU Sectorial Guidance Documents (2)

- Important issues currently discussed
  - how to determine the country of origin?
  - 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?
  - when does utilisation end (‘cut-off point’)?
  - are commercial plant varieties included?
  - derivatives: when do ABS rules apply?
  - activities to fulfil regulatory requirements?

National law

- National implementation in NL: ‘Wet implementatie Nagoya Protocol’ (+ Explanatory Memorandum)
  - into force per 22 April 2016 through ‘Besluit WJZ/15163191’)
  - Competent National Authority: Ministry of Economic Affairs
  - monitoring agency: NVWA
  - National Focal Point: CGN
  - Sanctions and penalties:

    “In the case of a serious offence, a prison sentence of a maximum of six years, a community service order, or a fine of the fifth category can be imposed. This is EUR 81,000 for persons and EUR 810,000 for legal entities. In the case of a lesser offence, a prison sentence of a maximum of one year, a community service order, or a fine of the fourth category can be imposed. This is then EUR 20,250 for persons and EUR 81,000 for legal entities.”
  - Access not regulated in NL

ABS landscape

- CBD
- Nagoya Protocol
- EU legislation
- National law

Regulation 511/2014
Implementing Act 2015/1866
EU Guidance
Sector-specific guidance

- ITPGRFA

Users of GR in NL

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What are my obligations?

- If you perform R&D on genetic resources obtained from 12 October 2014 onwards:
  - where required, seek permission (PIC) from Competent National Authority (CNA) of the provider country (if possible through/with local counterpart)
  - negotiate conditions with provider, and lay these down in a contract (MAT)
  - document how you use new materials for R&D
  - keep all documentation for 20 years
  - make ‘due diligence declaration’ at NVWA in case of submitting proposals for grants and of marketing products
  - pass on obligations to further users

What to document?

- ‘internationally-recognised certificate of compliance’
  - = document posted by the provider country on the ABS Clearing House website (http://www.cbd.int/abs/)

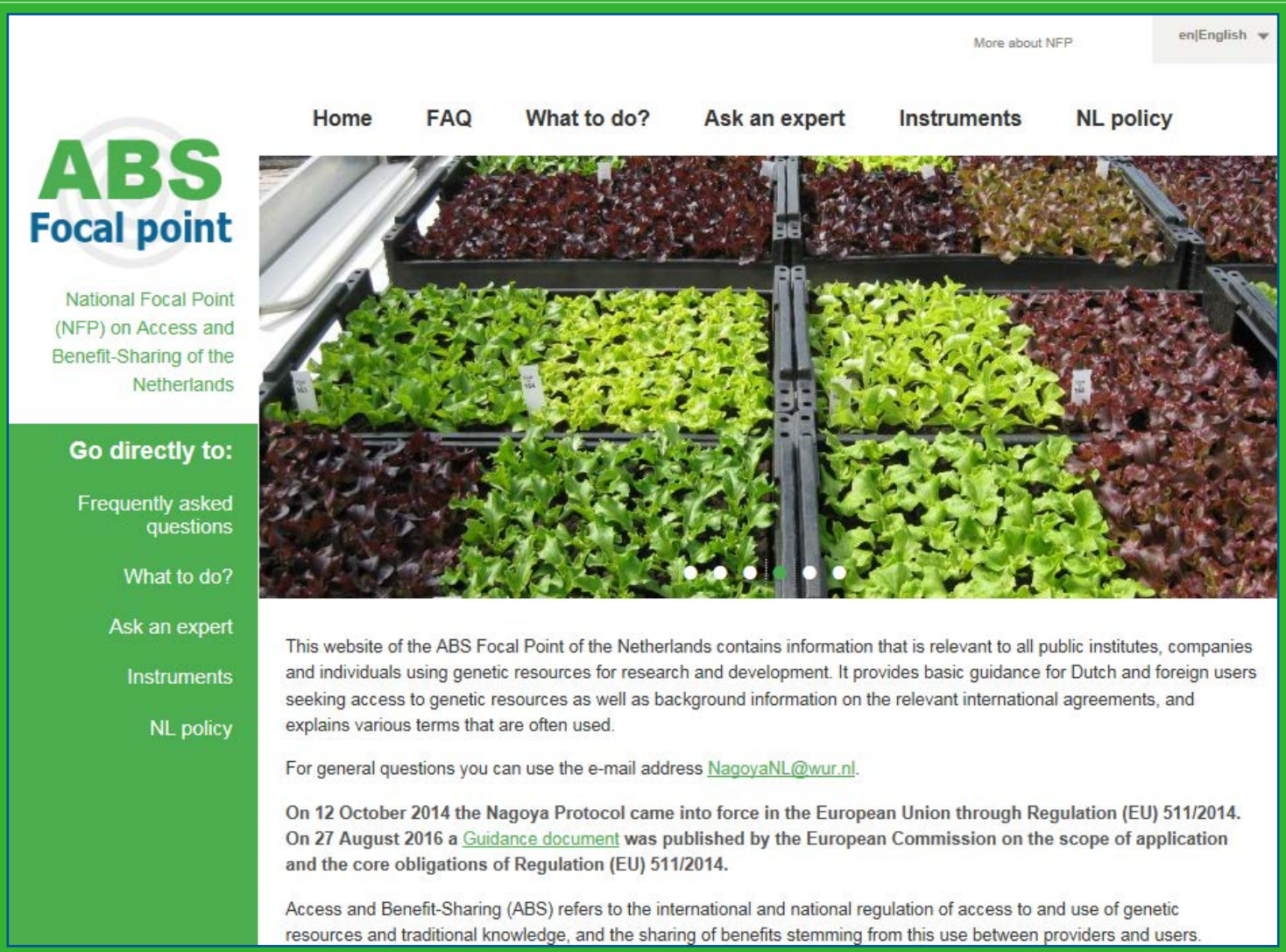
or:

- 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

What more can I do?

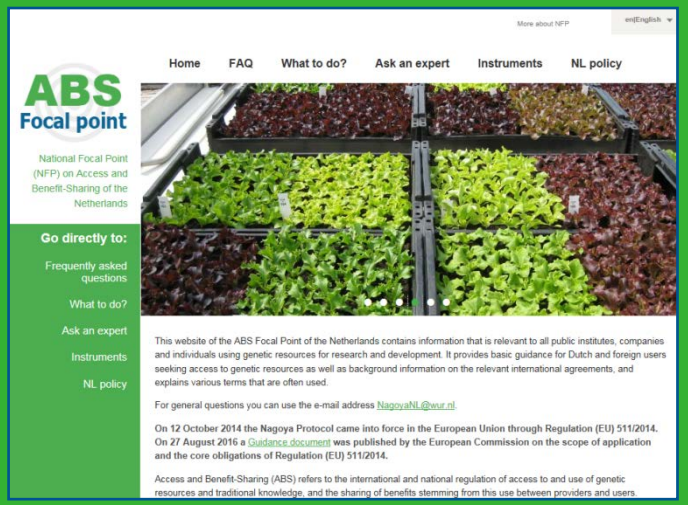
- Document what you had already in possession before 12 October 2014
  - not a legal obligation but a precaution to avoid future conflicts
- Be prepared for questions on the legal status of acquired genetic resources
  - e.g. publication policies journals
- Consider your options in accessing genetic resources
  - worth the effort?
  - from a collection, or from nature or farmers' fields?
  - from which country (track record)?
  - access possible through ITPGRFA?

ABS National Focal Point (absfocalpoint.nl)



ABS National Focal Point

- See website (www.absfocalpoint.nl) for:
  - guidance (“What to do as a user of genetic resources”)
  - Frequently Asked Questions
  - asking your own questions
  - info on international instruments
  - info on NL policy and legislation
  - any new developments
- Website in English and Dutch



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Conclusions

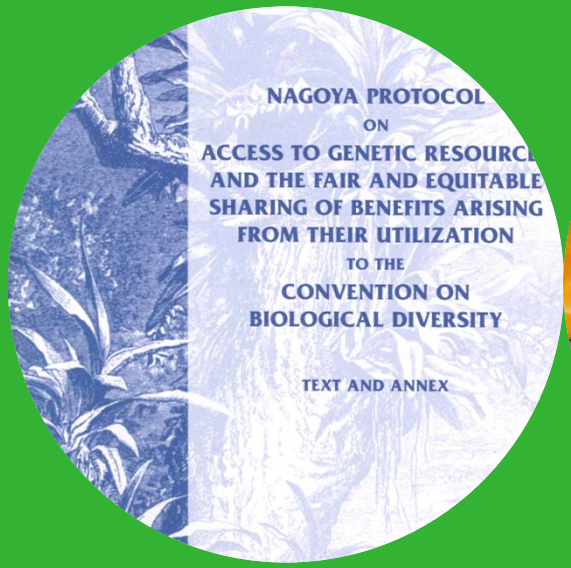
1. Since 29 December 1993 (CBD): national sovereignty over genetic resources
    - ➢ national access legislation may apply
2. Since 12 October 2014: Nagoya Protocol and EU ABS Regulation in force
    - ➢ users must exercise ‘due diligence’ to make sure GR are accessed in accordance with national legislation 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

Conclusions

4. EU Regulation not applicable to exchanges for which the ITPGRFA applies
5. Seeking, keeping and transferring information on access conditions and benefit-sharing agreements has become essential
6. What to do?
    - document what you have in stock
    - secure legal status of new materials at access
    - document how you use new materials for R&D
    - make ‘due diligence declarations’
    - pass on obligations to further users
    - regularly check www.absfocalpoint.nl

Thank you!

(more information: www.absfocalpoint.nl)



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