EU Regulation implementing the Nagoya Protocol in the Union

User obligations

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For quality of life

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This presentation

- Convention on Biological Diversity
- Nagoya Protocol
- EU Regulation 511/2014
- National law
- Consequences for NL users

Convention on Biological Diversity

- CBD = international agreement = international law
  - needs national implementation
- Objectives
  - conservation of biological diversity
  - sustainable use of its components
  - fair and equitable sharing of the benefits
- Entry into force
  - 28 December 1993
- New principle and concept
  - sovereign rights of states; access and benefit-sharing (ABS)

Nagoya Protocol (NP)

- Protocol to the CBD
  - elaboration of the ABS provisions of the CBD
- What is new?
  - ABS concept operationalised
  - Compliance rests with Parties to the NP (= member states)
- Entry into force
  - 12 October 2014

EU Regulation 511/2014

- Implementing the Nagoya Protocol
- Binding and applicable from 12 October 2014 in NL
- Major principles
  - Due diligence
    - Show that you did your best to follow the law
  - Registered collections
    - Safe providers, no further user obligations
  - Best practices
    - Associations of users with "quality scheme"
    - Tracking and tracing demonstrable

National law

- To fill in national level implementation in NL
  - NVWA monitoring agency
  - CGN national focal point
  - sanctions and penalties
    - not determined yet, but may be as high as years of imprisonment and above € 100.000 penalties for conscious and consistent offenders

What is relevant for whom?

- The EU Regulation applies to all users of genetic resources in all EU Member states

- The EU Regulation does not apply to exchanges for which the International Treaty and Standard MTA apply
    - = most genetic resources obtained from plant genebanks

Important terms

- 'Genetic resources' means genetic material of actual or potential value of plant, animal, microbial or other origin containing functional units of heredity
- 'Utilisation of genetic resources' means to conduct *research and development on the genetic and/or biochemical composition* of genetic resources, including through the application of biotechnology

Important terms

- 'Prior Informed Consent' (PIC) means approval, by the authorities of the country where access is sought, of access to and utilization of genetic resources
- 'Mutually Agreed Terms' (MAT) are reached between two private parties under civil law contract. MTA may be used.

What are my obligations?

- If you perform research and development on genetic resources obtained from 12 October 2014 onwards:
  - seek documented permission from Competent National Authority (normally delegated in case of collections) (http://www.cbd.int/doc/lists/nfp-abs-cna.pdf)
  - proceed to negotiate conditions with provider and document in the form of contract (a local counterpart helps!)
  - document further R&D (tracking and tracing)
  - show documentation in case of submitting proposals for grants and of marketing products (obligation under EU Regulation)
  - pass on obligations to further users

What to document?

- internationally-recognised certificate, 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 (Competent National Authority);
  - mutually agreed terms, including benefit-sharing arrangements, where applicable.

What is an internationally-recognised certificate?

- Only documents posted on the CBD website by the providing country
  - See in future http://www.cbd.int/abs/ (not operational yet)
- In case you obtain genetic resources from a collection holder, check if signing regular MTA is sufficient
  - Always the case for EU registered collections

What more can I do?

- Document what you had already obtained before 12 October 2014 by printing passport data on CD-ROM
  - 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)?

Basic guidance

- Rules do not apply if you only provide a service (e.g. sequencing) for a third party
- If you buy abroad from a local market, Regulation applies
- If you buy from a trader, request access documentation
- Still to be decided: your obligations when using a UPOV-protected variety
- Obligations also apply to imports from other EU countries
- USA will not join Nagoya Protocol: rules do not apply to imports from USA
- In doubt, do not proceed

ABS National focal point

- See www.absfocalpoint.nl for
  - more background information
  - frequently asked questions
  - any new developments
  - asking your own questions

Recommendations

- Document what you have in stock
- Secure legal status of new materials at access
- Document how you use new materials for R&D
- Pass on obligations to further users
- Be aware of sanctions