The Nagoya Protocol & its implementation in the EU - What does it mean for biodiscovery?

Greifswald, 23/08/2018
The Origins of ABS

Since entry into force of CBD (1993):

- Access and Benefit-sharing (ABS) as 3\textsuperscript{rd} CBD objective

  "… fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding." (Art. 1 CBD)

- Clarification: states have sovereign rights over their (biological & genetic) resources (Art. 3 CBD)
- ABS as innovative instrument for biodiv conservation
The Origins of ABS: Article 15 CBD

ABS principles according to CBD:

Art. 15(1) • Sovereign rights of states over their (biological) resources, incl. right to regulate access to GR

Art. 15(2) • Create conditions to facilitate access to GR

Art. 15(4) • Access based on mutually agreed terms (MAT)

Art. 15(5) • Access subject to prior informed consent (PIC), unless otherwise determined

Art. 15(7) • Take measures with the aim of fair & equitable sharing of benefits from utilization
From CBD to Nagoya Protocol

1993: CBD enters into force


2002: COP 6 adopts the voluntary Bonn Guidelines

2002: Rio+10 calls for negotiation of an internat. ABS regime

2004-2010: Negotiations on the Nagoya Protocol

October 2010: COP 10 adopts the legally binding Nagoya Protocol

June 2004: FAO ITPGRFA enters into force

May 2011: WHO adopts PIP Framework

12 October 2014: Nagoya Protocol enters into force

2018-2020: UNCLOS negotiations on BBNJ
Nagoya Protocol – Status Quo

105 NP Parties
(4 ratifications)

+ 26 NP signatories

Further info on ABS CH:
https://absch.cbd.int/

White = Non CBD Parties
Beige = CBD Parties
Lime green = NP Signatories
Dark green = NP Parties

Credits:
Valerie Normand - SCBD
The **ABC** of ABS

- **A**ccess: internat. „standards“ / criteria for domestic access measures (Art. 6(3), 8 NP)
- **B**enefit-sharing: based on MAT (incl. IPLCs) (Art. 5 NP)
- **C**ompliance measures (Art. 15-17 & 18-20 NP)

**Institutional provisions:**

- **ABS National Focal Point** (Art. 13(1) NP):
  - Information on ABS rules & procedures in provider state
- **Competent National Authority(ies)** (Art. 13(2) NP):
  - Responsible for implementation of ABS rules & procedures
Nagoya Protocol

Article 36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
Which countries are Parties to the NP?
ABS Clearing-House

Country profiles:

India

- Party Status: Party to the Nagoya Protocol
- Entered into force on: 12 Oct 2014
- Ratification on: 09 Oct 2012
- Signatory: Signed on 11 May 2011
- CBD Country Profile: www.cbd.int/countries/?country=in

+ ABS National Focal Point (NFP)
+ Competent National Authorities (CNA)
Legal Framework in Germany

**Access**
- Regulated by EU MS themselves
- In Germany, generally free (no PIC)

**Benefit Sharing**
- Regulated by EU MS themselves
- In Germany, not required (no MAT)

**Compliance**
- Based on EU legislation

Regulation (EU) No 511/2014:
Entry into force on 12.10.2014

Impl. Regulation (EU) 2015/1866:
Entry into force on 9.11.2015

EU Guidance Document (EC) 2016/C 313/01: Published on 27.08.2016

Implementing Act adopted on 25.11.2015
Entry into force on 1.7.2016
Scope of Regulation (EU) No 511/2014

All prerequisites must be fulfilled

If one is not fulfilled
EU Reg. & Impl. Act not applicable

However, existing ABS legislation of provider country must still be upheld!
Scope of Regulation (EU) No 511/2014

Geographic scope + Personal scope + Material scope + Temporal scope = EU Reg applicable

Geographic scope + Personal scope + Material scope + Temporal scope = EU Reg applicable

Regs of provider state applicable + Regs of provider state applicable
Due Diligence System

Art. 4 EU Reg.: General DD obligation

- User to ascertain that
  - GR/TK accessed in accordance with applicable ABS legislation
  - Benefits fairly & equitably shared upon MAT

Documentation obligation

- Seek
- Keep (20 years after utilization)
- Transfer
- Relevant documentation (Art. 4.3 a) or b)

Risk assessment obligation

- If insufficient information or uncertainties about legality of access & utilization
- PIC & MAT or equivalent to be obtained or
- Utilization to be discontinued (Art. 4.5)

Options for mitigating risks

- Acquisition of GR from registered collection (Art. 5)
- Recognized best practice (Art 8.2 EU Reg. or Art 20.2 NP)

Art. 7 EU Reg.: Obligations to file DD declarations

- Seek
- Keep (20 years after utilization)
- Transfer
- Relevant documentation (Art. 4.3 a) or b)

- If insufficient information or uncertainties about legality of access & utilization
- PIC & MAT or equivalent to be obtained or
- Utilization to be discontinued (Art. 4.5)

- Acquisition of GR from registered collection (Art. 5)
- Recognized best practice (Art 8.2 EU Reg. or Art 20.2 NP)
At stage of research funding (Art. 7.1)

Content: Annex II of Implementing Reg.

Submission by recipient of funding

Projects funded by commercial or non-commercial sources

Not internal budgetary resources

Submission after 1st instalment of funding & GR/TX obtained

But no later than time of final report or project end

In Germany, DDD under Art. 7.1 mandatory since 10.05.2018
At stage of final product development (Art. 7.2)

Content: Annex II of Implementing Reg.

Only made once
Prior to first of following events

Market approval; notification prior to placing on Union market for first time; placing on Union market for first time; sale or transfer of result of utilization within Union; end of utilization in Union & sale or transfer of outcomes outside Union

4 weeks before end of utilization
Declaration of DDD

Welcome to DECLARE

DECLARE is the entry point of the Environment Data Submission Portal, supporting collection, validation, analysis, and dissemination of the statistical information submitted per domain.

Please choose a policy domain to work on.

ALURES - Animals used for scientific purposes
Since 1998, the EU has had in place specific legislation covering the use of animals for scientific purposes. On 22 September 2012, the EU adopted Directive 2010/63/EU which updates and replaces the 86/609/EEC on the protection of animals used for scientific purposes. The aim of the new Directive is to promote the use of alternative methods and to control the use of animals as defined by the Directive. The new Directive also allows flexibility as regards the use of different methods of pain relief to be used, as well as to fully implement the principles of the Three Rs to Reduce and Replace the use of animals in EU legislation. Directive 2010/63/EU took full effect on 1 January 2013.

ETS - The EU Emissions Trading System
The EU emissions trading system (EU ETS) is a cornerstone of the European Union’s policy to combat climate change and is a key tool for reducing industrial greenhouse gas emissions cost-effectively. The tool - and still by far the biggest - international system for trading greenhouse gas emissions, it includes more than 10,000 power stations and industrial plants in 31 countries, as well as airlines.

NAGOYA - Protocol on Access and Benefit Sharing
The Nagoya Protocol on Access and Benefit Sharing under the Convention on Biological Diversity (CBD) or Nagoya Protocol, was adopted by parties to the convention in order to ensure the fair and equitable sharing of benefits arising from the use of genetic resources. In 2010, Parties to the CBD adopted the Nagoya Protocol on Access and Benefit Sharing under the Convention on Biological Diversity (CBD). The Protocol has since been adopted by almost all the countries that are Parties to the CBD, and it provides a legal framework for ensuring that the fair and equitable sharing of benefits arising from genetic resources is achieved. The Protocol entered into force on 12 October 2014.

User

Commission

CNA

ABS CH
Submission of DDD

How to use DECLARE:

• Registration of user institution through ECAS
  https://webgate.ec.europa.eu/cas

• Login with ECAS-ID in DECLARE
  https://webgate.ec.europa.eu/declare/

• Automated notification of BfN as CNA & activation of user institution

• Automated notification of user institution after activation
Submission of DDD

- User institution may navigate in DECLARE system
  - Adding further users of same or partnering institution
  - Drafting & submitting DDDs

- Automated notification of BfN after submission of DDD

- Reply to user or DDD forwarded to ABS CH

- Automated conversion into checkpoint communiqué published on ABS CH & notification of provider state

Register of Collections

Art. 5 EU Reg.:

- Register established & maintained by Commission
- Application to & recognition by Member States
- Criteria to register collection or part of it:
  - Standardized procedures for exchanging samples of GR
  - Supply of GR only with appropriate documentation
  - Keep records of all samples of GR supplied to 3rd persons
  - Establish or use unique identifiers where possible
  - Use appropriate tracking & monitoring tools
- Content of application: Annex I of Implementing Reg.

First (and so far only) registered collection in EU
Best Practices

Art. 8 EU Reg.:
- Recognized by Commission
- Who can apply?
  - Association of users &
  - Other interested parties
- Criteria defined in EU Reg.
  - Combination of procedures, tools & mechanisms
  - Enabling user to comply with obligations under Art. 4 & 7
- Content of application: Annex IV of Implementing Reg.
Compliance Checks

Art. 9 EU Reg. & Art. 5.4 EU Reg.: 

- Compliance checks carried out by competent national authorities
- On the basis of
  - Periodically reviewed control plans using risk-based approach
  - Substantiated concerns
- Subject matter:
  - Due diligence obligation
  - DDDs
  - Criteria of registration
Competencies in Germany

NFP: Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)

CNA: Federal Agency for Nature Conservation (BfN)

Cooperation on human pathogens

Information on patent applications

Declarations & applications, checks & sanctions, information & advice

Cooperation on GR for food & agriculture

Division 1.3 "Competent National Authority for the Nagoya Protocol"

User
... Depending on the specific activity undertaken, both basic and applied research may be considered as “utilization” in the sense of the NP and EU Regulation. (EU Guidance Doc (EC) 2016/C 313/01; 2.3.3.)

Litmus test: Users should ask themselves whether what they are doing with the GR creates new insight into characteristics of the GR which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term “utilization”. (EU Guidance Doc (EC) 2016/C 313/01; 2.3.3.)
Utilization under Regulation (EU) No 511/2014

- Quality checks, verification
- Mere description of GR in phenotype-based research
- Use of GR as testing/reference tools

Research on GR but not utilization

EU Reg not applicable

ABS Reg of provider states might be applicable
Utilization under Regulation (EU) No 511/2014

Identification through DNA sequencing, if no new knowledge on genetic and/or biochemical compositions is developed (e.g. no new species is being described)

Discovery, description and publication of a new species as long as it does not involve research on genetic and/or biochemical compositions of GR

Research on GR
but not utilization

EU Reg not applicable
ABS Reg of provider states might be applicable
Utilization under Regulation (EU) No 511/2014

- Research on GR leading to isolation of biochemical compound used as new ingredient (active or not) incorporated in product
- Breeding program to create new plant variety based on naturally occurring plants
- Genetic modification – creation of genetically modified animal, plant or microorganism containing a gene from another species

EU Reg applicable
ABS Reg of provider states applicable
Digital Sequence Information

- Call by developing countries to include DSI within scope of NP
- CBD COP Decision XIII/16 & NP MOP Decision 2/14:
  - Consider (by COP XIV / MOP 3) any potential implications of use of DSI on GR for the 3 objectives of CBD & objective of NP
- Open process comprising following steps:
  - 04-12/2017 Scoping study on terminology & concepts
  - 09/2017 Submission of views & information
  - 02/2018 Meeting of AHTEG
  - 07/2018 SBSTTA to make recommendations
  - 11/2018 Negotiations at COP XIV / MOP 3
Digital Sequence Information

Other fora where DSI is being discussed:

World Health Organization

Food and Agriculture Organization of the United Nations

Oceans & Law of the Sea United Nations
Thank You Very Much!

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Credits

Slide 2  "Logo Convention on Biological Diversity", https://www.cbd.int/
Slide 7  "Annex of the Nagoya Protocol", www.cbd.int/abs
Slide 16  Graphics by the European Commission
Slide 19  "Logo of DSMZ", https://www.dsmz.de/
Slide 29  Сергей_Хакимуллин_iStockphoto.com