ESFRI European Strategy Forum on Research Infrastructures

MIRRI MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

Implementing the Nagoya Protocol in collections: the MIRRI approach

Gerard J. M. Verkley[1] and Paul de Vos [2]

[1]CBS Fungal Biodiversity Centre, Utrecht, the Netherlands

[2]BCCM/LMG, Ghent University, Belgium

CAPACITIES

Q Collect Workshop for Collections and users of biological material, Rome, September 8-9, 2015

Q-collect

Outline

1. Access and Benefit Sharing ABS – The legal basis and scope
2. Guidance for lawfully collecting and Studying Material
3. Depositing material in a public collection/ herbarium etc.
4. The MIRRI approach
5. Conclusions

Convention on Biological Diversity (CBD)

Entered into force on 29 December 1993 – State having signed up is called "Party"

Three objectives:

- conservation of biological diversity
- sustainable use of its components
- fair and equitable sharing of benefits arising from the utilisation of genetic resources

Key principles:

- States have **sovereign rights** over biological resources within their borders and shall **ensure conservation** of same (Art. 3);
- States shall endeavor to create conditions to **facilitate access** on **mutually agreed terms** and subject to **prior informed consent** **(MAT) (PIC)** (Art. 15(7));
- There should be **fair and equitable sharing of benefits** of use of genetic resources with the providing party (Art. 15(7));
- Any wider application of **traditional knowledge** (TK) shall be with the approval and involvement of TK holders (Art. 8(j)).

Convention on Biological Diversity

COP 10 MOP 5
Nagoya, Japan 2010
Life in Harmony, into the future
いのちの共生を、未来へ

MIRRI
MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

The Nagoya Protocol on Access and Benefit Sharing (ABS)

The legally binding instrument to implement the CBD

- Adopted by the 10th Conference of the Parties (COP10), on 29 October 2010, in Nagoya, Japan
- Entered into force 12 Oct 2014 (when 50 Parties had ratified it)

Access provided to genetic resources is subject to **Prior Informed Consent (PIC)** of the Country of Origin… = a permit stating *what* the applicant may collect *when* and *where*, issued by a Competent National Authority (CNA)

…and under **Mutually Agreed Terms (MAT)** by provider and user

= agreement that defines how you may use the collected material

Parties to the Protocol can choose to provide free access to the natural resources in their own territory → in that case, no PIC required

Parties are committed to enforcing within their own jurisdiction compliant use of resources originating from other Parties and sharing of benefits.

Regulation 511/2014 for ABS in the European Union

- The European Union is a Party to the CBD, as are the 28 Member States
- Regulation 511 **applies from 12 Oct 2014** (date of entry into force of the Nagoya Protocol)
- Regulation articles 4 (*user obligations*), 7 (*monitoring user compliance*) and 9 (*checks on user compliance*) **are applicable from 12 Oct 2015**
- Most EU Member States will grant free access to their genetic resources (probably not Croatia, Hungary, France, Norway and Spain) – harmonized EU access measures therefore not needed
- The implementing Acts are in an advanced stage but not yet finalized.

Temporal scope of relevant laws and regulations on ABS

29/XXII/1993 — 12/X/2014 — 12/X/2015

Convention on Biological Diversity (CBD) into force

National ABS law in an increasing number of Party-countries

Nagoya Protocol into force
..or later when country ratifies

EU Regulation 511/2014 applies

Art 4 - user obligations
Art 7 - monitoring user compliance
Art 9 - checks on user compliance

no "retro-activity" for new use of resources collected

BUT….it is not unlikely that some Parties will adopt a wider temporal scope, which then may also include "new use" of materials collected earlier in the country of origin, and (for example) deposited in *ex situ* collections.

…ercise sovereign rights …
…e Nagoya Protocol for the
… the utilisation of such
…ciated with genetic

applies to resources and traditional knowledge **to which ABS legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable**

Scope of the Nagoya Protocol and EU Regulation

Utilisation of genetic resources – to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (definition in Article 2 of the CBD)

Genetic resources – genetic material of actual or potential value (definition from NP)

Genetic material – any material of plant, animal, microbial or other origin containing functional units of heredity (from CBD) = **living and dead material, and DNA extracts!**

Scope of the Nagoya Protocol and EU Regulation

Materials within scope:

- Genetic resources accessed in a country that is Party to the Nagoya Protocol (i.e., by ratification) – **access** not defined (in text CBD, NP), BUT in EU Reg. Art. 3: "*the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol*"

Outside scope:

- Human genetic resources (CBD Decision X/1), except the microbes isolated from human tissue, blood etc.
- Commodities (trade food, e.g., fruits), except the microbes isolated therefrom
- Plant genetic resources governed by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- Any material collected from areas beyond national jurisdiction (ABNJ), e.g., the deep waters, Antarctica, etc. (no Party can exercise sovereign rights over such material)

Activities within scope of the Nagoya Protocol and EU-regulation

"**Research and development** are cumulative requirements. This means that to be in the scope of 'utilisation', as defined in the ABS Regulation, the activity has to include an element of development.

Further interpretation of this term can be expected at the international level with the entry into force of the Nagoya Protocol and the beginning enforcement practice" (from EU Memo 14-411_EN of June 10, 2014)

Current understanding
Descriptive research without any element of development is outside the scope
For example: morphological analysis

DNA-extraction and sequencing for purely taxonomic work, quality control and identification **should** be outside scope

! More clarity should be provided in **Sector-specific guidance by the EC**

Guidance for collecting material *in situ* in a country that is Party to the Nagoya Protocol

START

Check the CBD ABS-Clearinghouse website (ABS-CH) or National Focal Point (NFP), and consider involving a local partner in the country of interest

Find the Competent National Authority (CNA)

Find the Access and Benefit Sharing (ABS) legislation

Is Prior Informed Consent (PIC) required? If uncertain, ask local partner or CNA!

NO

Collecting can start

YES

Work with CNA (and your local partners) in the country of interest to determine requirements

Permit

Prior Informed Consent (PIC)

Mutually Agreed Terms (MAT)

Acces now legal - Collecting can start

IRCC

CNA issues Internationally-recognized Certificate of Compliance in the ABS-CH

Keep on record important metadata and IRCC number
Keep permit and other documents relevant to ABS (MTA, PIC, MAT), and of correspondance with CNA as proof of DUE DILIGENCE for at least 20 years after end of period of use

In all **publications** acknowledge the country of origin and cite applicable IRCC- or permit-number

In all **transfers and deposits of material** provide country of origin and other important metadata, copies of all documents relevant to ABS, and refer to applicable IRCC- or permit-number

END

Q-collect

EU Regulation Implementing acts (under development)

Lay down detailed rules for

DRAFT

- **Register of collections for the EU**
- **Due diligence declaration*** to be made by users:
  - **recipients of funding for research** involving the utilisation of genetic resources and/or traditional knowledge
  - **users bringing a product to the EU market** developed involving the utilisation of genetic resources and/or traditional knowledge
- Associations of users requesting for recognition of **best practices**

** Only users who have not obtained genetic resources from registered collections, or do not have IRCC (or a standard MTA cf. ITPGRFA), should be required to provide detailed information (cf. Reg. art. 4(3)b) in their due diligence declaration.*

EU Regulation on ABS in the Union: Register of collections (art. 5)

Requirements for registered collections :

- Apply standardised procedures for exchanging genetic resources with other collections and supplying to third persons
- Supply GR and related information to third persons only with documentation providing evidence that they were legally accessed and, where relevant, with Mutually Agreed Terms (MAT)
- Keep records of all genetic resources and related information supplied to third persons
- Establish and use unique identifiers, where possible, for samples of genetic resources supplied to third persons
- Use appropriate tracking and monitoring tools for inter-collection exchange

Competent National Authority will decide if a collections can be included in the Register

- *An entire collection or part thereof can be registered*
- *Users obtaining a genetic resource from a registered collection shall be considered to have exercised due diligence (Art. 4, par. 7)*

EU Regulation on ABS in the Union: Register of collections (art. 5)

Implementing regulation laid down in art. 2-5 DRAFT

Art. 4: Frequency and nature of checks

- Once every 3 years by competent authority
- Additional verification when reason for doubt of meeting criteria
- The (additional) verification shall include, as appropriate:
  - On-the-spot checks
  - Examination of documentation and records of the collection demonstrating compliance to the critera in art 5(3) of the Regulation
  - Genetic resource sample documentation
  - Interviews with the collection staff, "external verifiers" and (!) recipients of genetic resources
  - Access to genetic resources in the collection granted in line with mutually agreed terms

Art 5: Remedial actions

- Revision of measures taken by the collection in order to comply, additional reporting
- The competent authority may also take immediate measures

EU Regulation Implementing acts: detailed procedures for Register of Collections, due diligence declarations (user obligations) and best practices

- **Collections can apply for admittance to a Register of collections for the EU (Art. 5)** - Users obtaining a genetic resource from a registered collection will be considered to have exercised due diligence
- **Recipients of funding for research** involving the utilization of genetic resources and/or traditional knowledge must make **due diligence declaration** to the Competent National Authority (where recipient is established), and to the Commission
- ..and similar declarations for **users at the final stages of bringing a product to the EU market**
- Associations of users can request for recognition of **best practices**

Register of collections (Article 5)

Art.5.3 Criteria to be registered into the EU register: "*a collection shall demonstrate its capacity to:*"

c) keep records of all samples of genetic resources and related information supplied to third persons for their utilisation **MTA +customer list + delivery notes**

d) establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; **Catalogue + MAA**

e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections. **MAA & MTA**

Taken from the TRUST document: (http://www.wdcm.org/workshop2014/one_one.pdf)

MIRRI Best Practice for ABS
for *microbial collections* (mBRCs)

Developed in response to Nagoya Protocol art. 20 and EU Regulation 511/2014 art. 8 .

- Applies to all materials (including genetic resources) in the mBRC *and* in research collections falling under the same legal entity;
- Applies to all staff, authorized visitors and other associates working within or on behalf of the same legal entity as mBRC staff.

The package will include:

(i) a **policy statement** on how MIRRI Member mBRCs commit themselves to contributing to reaching the main objectives of the CBD while operating in compliance with all applicable national and international laws on ABS and regulatory requirements;

(ii) sets of **minimal requirements** MIRRI regards necessary for compliant operation of the member mBRCs;

(iii) MIRRI Best Practice to provide guidance for the mBRCs in implementing their ABS institutional policies and working procedures for

(a) acquisition of material;
(b) supply of material (including exchange);
(c) delivery of other services;
(d) research by the mBRCs on their own holdings and lawful utilization of the genetic resources

Important elements for a best practice for ABS

Acquisition of materials

- For deposit into the public collection, the BRC should implement accession forms and (optional) Material Accession Agreements (MAA) according to agreed minimal requirements.
- Due diligence in all cases and preferably at the moment of entry (at any entry point, be it BRC or other department in the legal entity)
- Identify any requirements under applicable ABS legislation and regulations, for which the following info is needed:
  - ✓ Geographic origin (country of origin, or ABNJ), or reasonable explanation why this is indeterminable (e.g., old lab-strain)
  - ✓ Date of collection (*in situ*, in the habitat)
  - ✓ Person who collected the source sample, and his/her affiliation (institute, company, etc.)

  And if such is required:

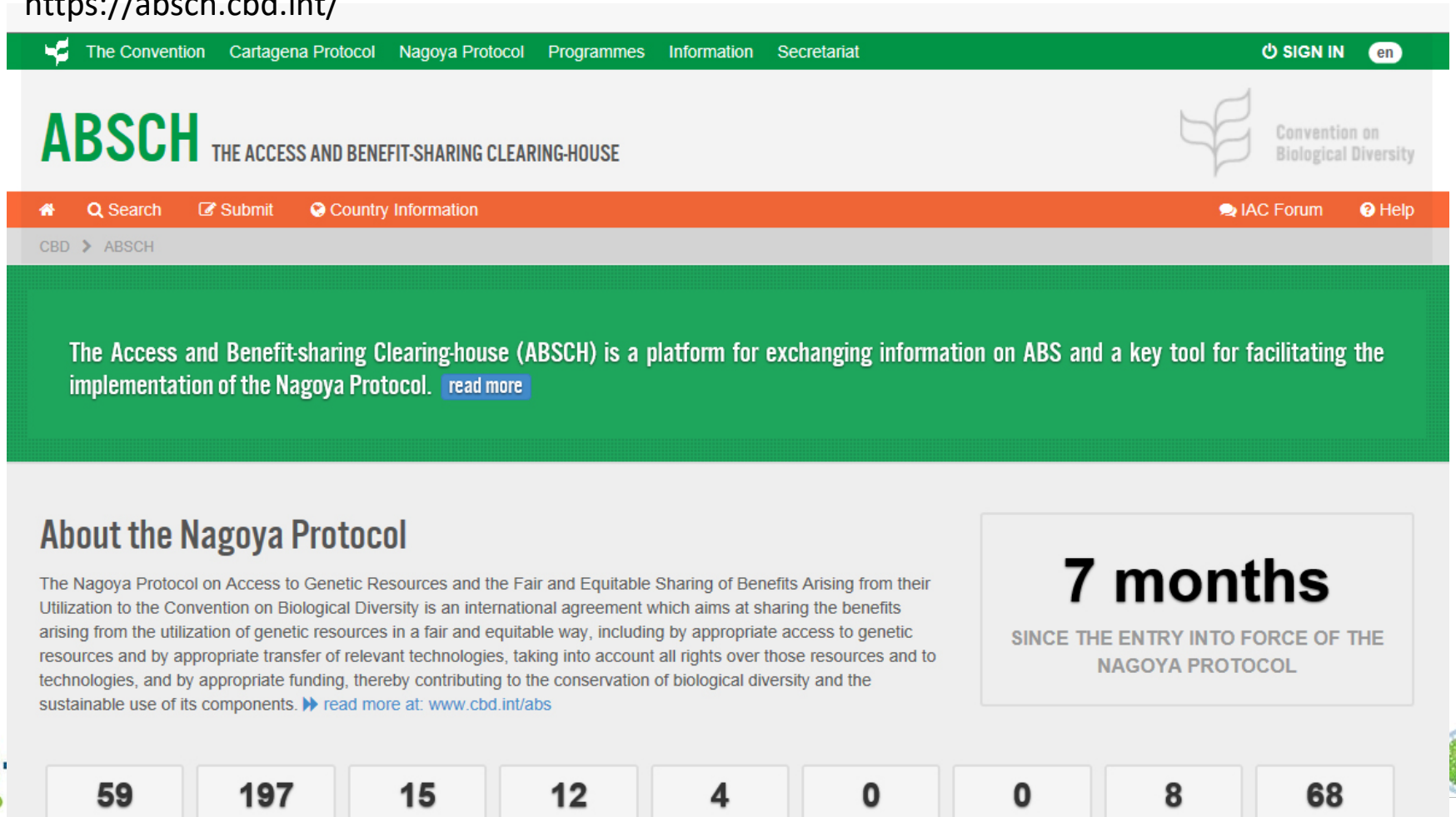
  - ✓ IRCC number (if available), PIC, or other collecting permit, and MAT, and any relevant MTA(s), if applicable
- ! If the information provided remains insufficient to exercise due diligence, the material should not be accepted for deposit and not be retained by the legal entity.

Best practice for ABS

Acquisition of materials

If available, the IRCC should be checked on its content in the ABS Clearing House

https://absch.cbd.int/



Best practice for ABS

Accession form

- set of standard questions and/or (optional) terms so the depositor will understand what can or cannot be done with the material once accessioned into the public collection.
- The form should at least be signed by the depositor.
- Incompatibilities between the depositor's proposed terms and those in standard MTA of the BRC should be resolved, or a special MTA for supply set up.

Material Accession Agreement (MAA) could also be used, if appropriate.

→ National ABS law in certain Parties to the CBD may demand that a model MTA of the competent authorities (in the country of origin) is signed between the authority or the depositor and the receiving BRC.

Best practice for ABS

Exchange between BRCs

- MTA for a specific exchange may or may not be required (depending on national legislation)
- Transfer in agreement with terms under which the material was acquired by the supplying BRC
- Distribution by the receiving BRC is under MTA conditions equivalent and compatible to those in place at the supplying BRC
- The exchanging BRCs inform each other about all relevant ABS documentation associated with the exchanged material and properly file these in their records

Simplified mechanisms: checking compatibility of the BRCs standard MTA for supply, and resolve any issues.

- Reference collections should use highly compatible MTA for distributing to third parties
  → compliant also under the BRCs own "standard" MTA
- Exchange with non-European BRCs may become more complicated than before

Best practice for ABS

Supply of biological material from the public collection

- No supply without MTA
- Terms in agreement with those under which the material was received by the BRC
- If required by applicable ABS law or regulatory requirements, copies (electronic or paper) of the relevant documents are supplied to the recipient:
  - Internationally-recognized Certificate of Compliance (IRCC) and information on the content of mutually agreed terms (Reg. art. 4 (3) a) *or,* if no IRCC is available,
  - Original PIC and MAT, *or*
  - Any other legally valid documentation, providing proof that the material was legally accessed in the country of origin

  ….and as far as the information is not confidential

Best practice for ABS

MTA for supply of material by the BRC to the users

Generally: **third party transfer not allowed**.
However, for MIRRI sharing of material would be acceptable in these cases:
(i) the recipient can share the material with colleagues (employed by the same legal entity) under the condition that the MTA and annexes should always be transferred along with the material;
(ii) the recipient can also share the material with scientists working in the same consortium, where in a consortium agreement the control of access to material is clearly defined to meet the terms in applicable MTAs;
(iii) in situations where scientists employed by different legal entities (for example, a research institute or a university) work in permanently shared laboratory facilities and collaborate, it is allowed to make an arrangement that these scientists can also share material.

"Legitimate exchange" will only include the above and exchange between mBRCs. In the ECCO-Core MTA the term also includes exchange between researchers collaborating in "a joint defined project", but MIRRI advices against such practice.

Material collected post-CBD *and* pre-Nagoya

- Is not subject to the Regulation 511/2014
- ! Could be subject to ABS national legislation in country of origin (based on CBD) that was in force at time of collecting
- If so, and permits or other documents required are actually missing, distribution of that material by the BRC may harm its reputation, especially when supplied from a registered collection
- Practical solution could be to (continue to) only distribute the material under condition as worded in art. 7 of the ECCO Core MTA*: *"If the RECIPIENT desires to use the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSE(S), it is the responsibility of the RECIPIENT, in advance of such use, to negotiate in good faith the terms of any benefit sharing with the appropriate authority in the country of origin of the MATERIAL, as indicated by the COLLECTION's documentation."*

* Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. The MTA text is available here: http://www.eccosite.org/

Best practice for ABS

Research by the BRC staff or others in the same legal entity

The BRC should keep record of all supplies to “internal users” and inform these recipients about the conditions for use of the material and all obligations per MTA.

The BRC or its institute should implement an ABS compliance policy for collecting and research, clarifying:

- ✓ conditions and terms for utilization of genetic resources in research by staff, visiting scientists and other authorized visitors for their research;
- ✓ how inappropriate utilization is handled

Staff wanting to utilize (“research and development”) a genetic resource for which PIC and MAT are not available but ABS legislation or regulatory requirements (likely) apply, should first contact the relevant authorities in the country of origin of the genetic resource and/or other appropriate stakeholders to obtain PIC and negotiate MAT.

Best practices for ABS: other initiatives

- Culture collections already (since the CBD entered into force) worked to reach compliance and harmonise practices

- Two important initiatives:
  - MOSAICC (http://bccm.belspo.be/projects/mosaicc
  first voluntary code of conduct providing a set of clauses for PIC and MAT
  - ECCO organisation (http://www.eccosite.org/ with the ECCO-core MTA

- A recent initiative by the WDCM: Trust (Transparent User-friendly System of Transfer) document:
  (http://www.wdcm.org/workshop2014/one_one.pdf)

Conclusions

- The information provided here is based on current understanding of the ABS legislation.
- Definitions of some terms and how some provisions should be interpreted are at present not fully clear to the user community
- Before collecting, or at moment of acceptance of material for research or as a new deposit for the public collection, is the right time to check any obligations under applicable ABS legislations or regulation for legal security
- Research Institutes and Collections are in a vulnerable position (many publications, public collection), and all staff should be aware of their responsibility to protect reputation
- Therefore it is recommended to develop an ABS policy for the institute

Conclusions

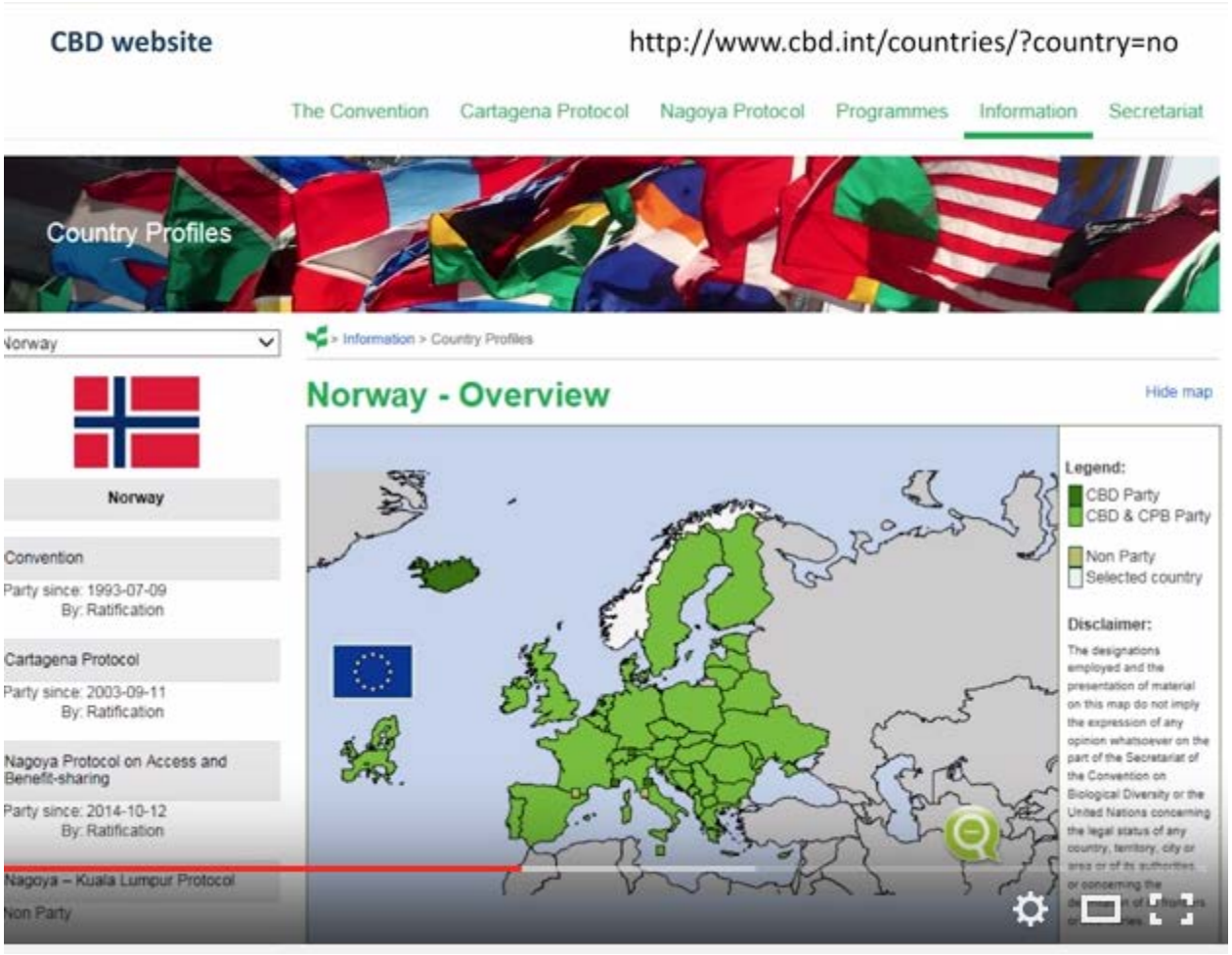
- The Microbial Resource Research Infrastructure (MIRRI) collection network and other stakeholders continue discussions with the legislators and will propose best practices for implementing ABS in a feasible way.
- International harmonization of legal governance and best practices is essential
- MIRRI international workshop on ABS in the microbial domain 15 September 2015 in Amsterdam – global focus, planned sessions:
  - EU Regulation 511/2014 and national ABS implementation
  - Round Table Discussion: the EU Register of Collections
  - ABS Best Practices and Codes of Conduct for microbial BRCs
  - Database-systems to support ABS implementation

Where can info be found concerning

- ABS regulation 511/2014/ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511
- Implementation guidelines: not yet available
- CBD: https://www.cbd.int/convention/text/
- Parties that have rattified the CBD and Nagoya:
- National authorities: https://www.cbd.int/abs/text/articles/?sec=abs-13
- National focal points: https://www.cbd.int/information/nfp.shtml
- Clearing Houses: https://absch.cbd.int/

CBD website http://www.cbd.int/

	CBD Party	Nagoya Protocol Signed	Nagoya Prot. Ratified	Nagoya Prot. Party
Australia	1993-12-29	2012-01-20		
Austria	1994-11-16	2011-06-23		
Brazil	1994-05-29	2011-02-02		
Canada	1993-12-29			
China	1993-12-29			
Czech Rep.	1994-03-03	2011-06-23		
Denmark	1994-03-21	2011-06-23	2014-05-01	2014-10-12
Egypt	1994-08-31	2012-01-25	2013-10-28	2014-10-12
Estonia	1994-10-25			
Finland	1994-10-25	2011-06-23		
France	1994-09-29	2011-09-20		
Germany	1994-03-21	2011-06-23		
Israel	1995-11-05			
Italy	1994-07-14	2011-06-23		
Japan	1993-12-29	2011-05-11		
Netherlands	1994-10-10	2011-06-23		
New Zealand	1993-12-29			
Norway	1993-12-29	2011-05-11	2013-10-01	2014-10-12
Pakistan	1994-10-24			
Slovakia	1994-11-23			
South-Africa	1996-01-31	2011-05-11	2013-01-10	2014-10-12
Sweden	1994-03-16	2011-06-23		
Thailand	2004-01-29	2012-01-31		
UK	1994-09-01	2011-06-23		
USA				
Venezuela	1994-12-12			


CBD website
http://www.cbd.int/countries/?country=no
The Convention
Cartagena Protocol
Nagoya Protocol
Programmes
Information
Secretariat
Country Profiles
Norway
> Information > Country Profiles
Norway - Overview
Hide map
Norway
Convention
Party since: 1993-07-09
By: Ratification
Cartagena Protocol
Party since: 2003-09-11
By: Ratification
Nagoya Protocol on Access and Benefit-sharing
Party since: 2014-10-12
By: Ratification
Nagoya – Kuala Lumpur Protocol
Non Party
Legend:
CBD Party
CBD & CPB Party
Non Party
Selected country
Disclaimer:
The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the Secretariat of the Convention on Biological Diversity or the United Nations concerning the legal status of any country, territory, city or area or of its authorities

Procedures for deposit in a public collection or fungarium

Minimal* information needed for assessing ABS requirements by the curators:

- Geographic origin (country of origin, or ABNJ), or reasonable explanation why this is indeterminable (e.g., old lab-strain)
- Date of collection (*in situ*, in the habitat)
- Person who collected the source sample, and his/her affiliation (institute, company, etc.)
- And if such is required: IRCC number (if available), PIC, or other collecting permit

*** Check your national ABS law for possible additional information required**

Thank you for your attention !