ESFRI European Strategy Forum on Research Infrastructures

MIRRI MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

Impact on culture collections of the EU Regulation on ABS

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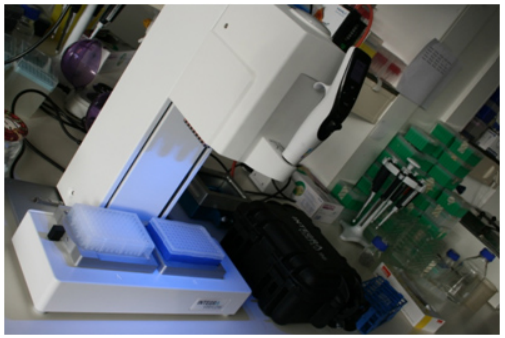
CAPACITIES

Culture collections generate benefits for society

Contributing to the biodiversity knowledge base, and applied and fundamental research for food safety, and human and plant health

- mBRCs invest in the long-term preservation of microbial genetic resources according to high quality standards which ensure authenticity and up-to-date identification
- mBRCs worldwide supply over 500 000 samples of microbial resources annually (CCINFO WFCC)
- mBRCs add value to the resources through research and release of associated data in databases
- mBRCs provide specialised training courses for student in microbiology
- mBRCs provide support to initiatives for the establishment of new *ex situ* collections in developing countries through sharing expertise and collaborative research programs



World Federation of Culture Collections (WFCC)

WDCM WFCC-MIRCEN World Data Centre for Microorganisms

www.wdcm.org

HISTORY NEWS WORKSHOP DATABASES RESOURCES CONTACT U

"

The WFCC-MIRCEN W
Microorganisms (WDCM
of the World Federation
The WDCM is a vehicle
centers of various types
information resource for
resource centers.

Registered in WDCM CCINFO database:

Culture collections: 692

Countries: 71

Numbers of strains :

Micro-organisms: 2.472.464

Bacteria: 1.051.258

Fungi: 727.014

Viruses: 37.933

DATABASES More

CCINFO

Culture Collections Information Worldwide is a database management system for culture collections in the world.

Enter

Analyzer of Bio-resource Citations

ABC is a platform that could support the researchers on the citations among papers, patent, genome, nucleotide sequences.

Enter

Global Catalogue of Microorganisms

GCM is expected to be a robust, reliable and user-friendly system to help culture collections to manage, disseminate and share the information related to their holdings.

Enter

Reference Strain Catalogue

This catalogue was produced to enable broader and easier access to the reference strains listed by the ISO Working Groups.

Enter

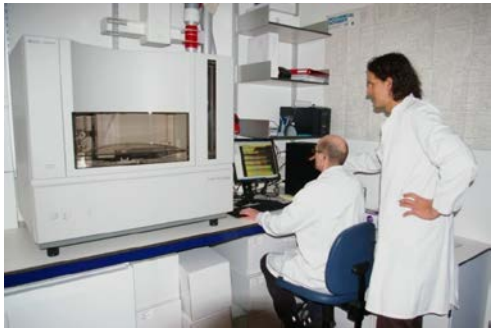
Where ABS and EU regulation impact on mBRCS

The Nagoya Protocol and EU Regulation 511/2014 affect...

- all biological materials (including genetic resources) in the mBRC *and* in research collections falling under the same legal entity, that are within scope

- all staff, authorized visitors and other associates working in the mBRC or in the same legal entity as mBRC staff, who are:
  (a) collecting biological material in a Party to the Nagoya Protocol
  (b) utilising genetic resources for their research

- the daily work in the culture collection, especially operational procedures for:
  (a) acquisition of material (new deposits)
  (b) supply of material to customers ("third parties") and exchange between collections
  (c) delivery of other services.



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

YES

Collecting can start

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

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 before 12 Oct 2014, NOT a year later!!!

applies to genetic resources over which States exercise sovereign rights … **that are accessed after the entry into force of the Nagoya Protocol for the Union**. It also applies to the benefits arising from the utilisation of such genetic resources and Traditional Knowledge associated with genetic resources.

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

Temporal scope of relevant laws and regulations on ABS

29/XXII/1993

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

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

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.

xercise sovereign rights …
e Nagoya Protocol for the
the utilisation of such
ociated with genetic

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

Temporal scope issues

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/

Acquisition of material

- Routine check for **exercising due diligence** in all cases (by curator or responsible researcher)

- Check **at the moment of entry** of the material (at any entry point, be it mBRC 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

Acquisition of material

- For deposit into the public collection, the mBRC normally uses an **accession form**, where fields should be included for all necessary information.

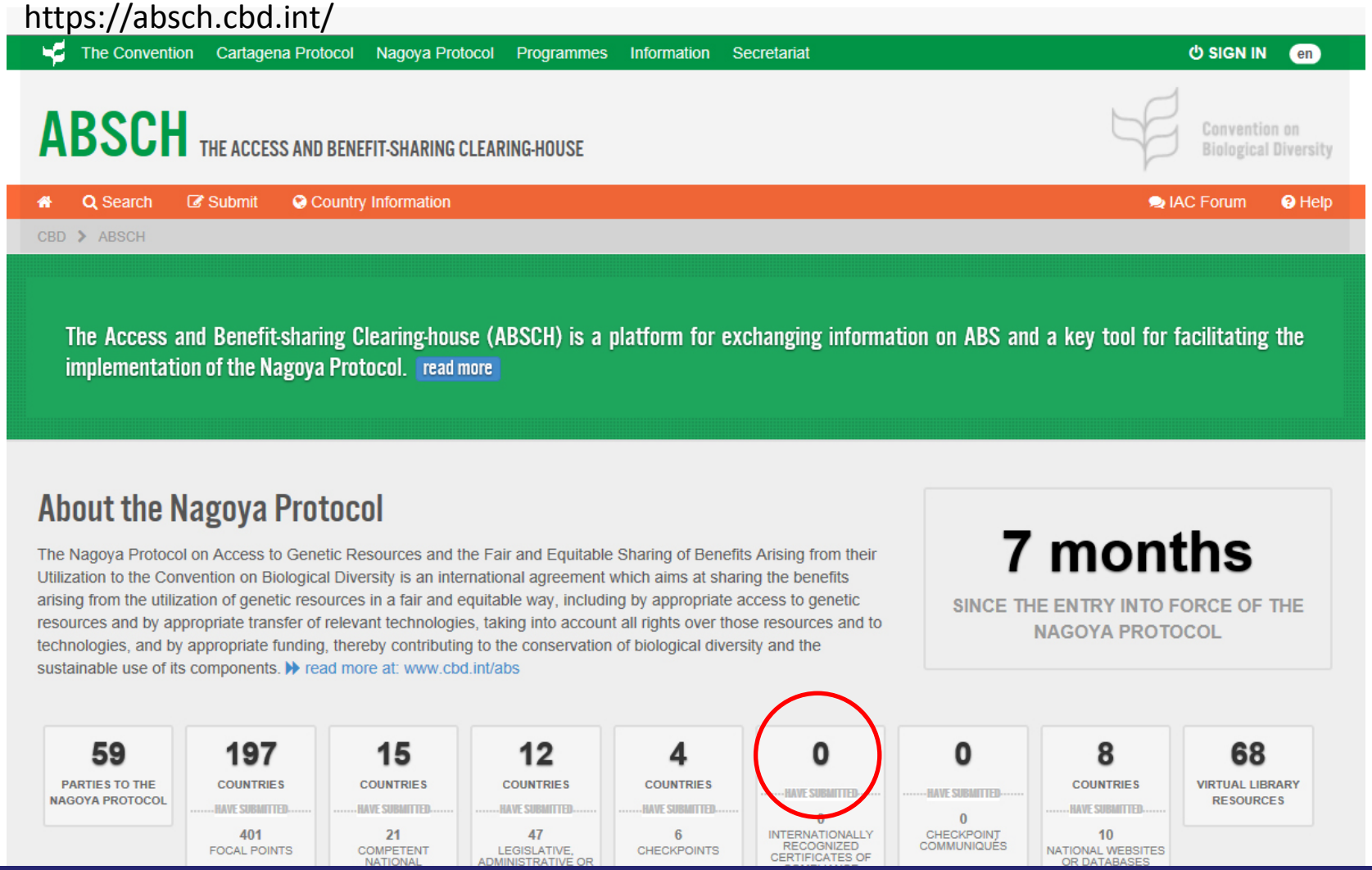
- ! If the information provided remains insufficient to exercise due diligence, the material should not be accepted for deposit and not be retained by the legal entity.

- Besides applicable ABS legislation, it remains important to stay alert on other laws, e.g. those prohibiting collecting without permits in protected areas, national parks, etc.

Acquisition of material

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

https://absch.cbd.int/



CBD website http://www.cbd.int/countries/?country=no

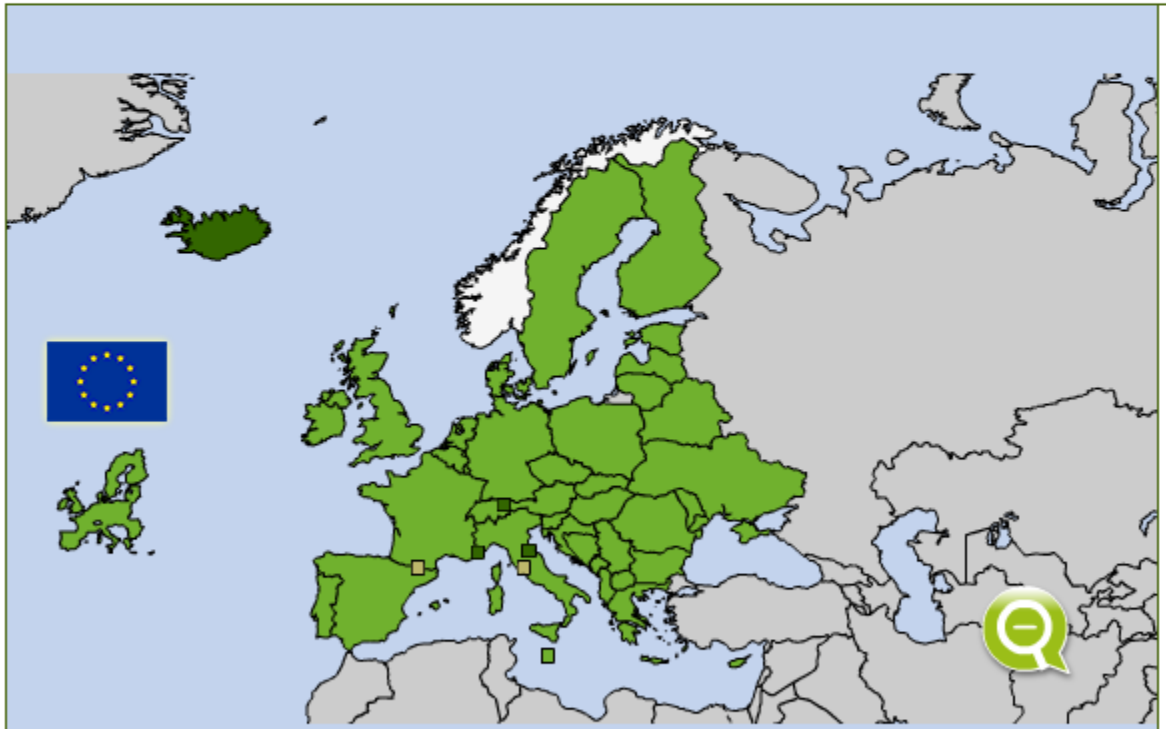
The Convention | Cartagena Protocol | Nagoya Protocol | Programmes | Information | Secretariat

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

Norway

> Information > Country Profiles > National Focal Points

Norway - National Focal Points

Show map

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Norway

Convention
Party since: 1993-12-29
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

CBD Information
Overview
Main Details
National Focal Points
PoWPA Action Plan
ABS Information
BCH Information
UNDB 2011-2020

COUNTRY INFORMATION

Map | List

Nagoya Protocol Party status

- Party ()
- Inbetween party ()
- Signatory ()
- Non-Party (0)
- All ()

Select a country

Qatar
Republic of Korea
Republic of Moldova
Romania
Russian Federation
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
San Marino
Sao Tome and Principe

Norway

Party since 01 Oct 2013

National Contacts and Information

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Legislative, administrative or policy measures on access and benefit-sharing (MSR)

NAME	TYPE	STATUS

NO LEGISLATIVE, ADMINISTRATIVE OR POLICY MEASURES ON ACCESS AND BENEFIT-SHARING (MSR) AVAILABLE

Norway

Party since 01 Oct 2013

National Contacts and Information

Nagoya Protocol ICNP Focal Point

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Legislative, administrative or policy measures on access and benefit-sharing (MSR)

NAME	TYPE	STATUS	JURISDICTION
NO LEGISLATIVE, ADMINISTRATIVE OR POLICY MEASURES ON ACCESS AND BENEFIT-SHARING (MSR) AVAILABLE			

Internationally Recognized Certificates of Compliance (IRCC)

NAME	ISSUED TO	SUBJECT MATTER	USE
NO INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)			

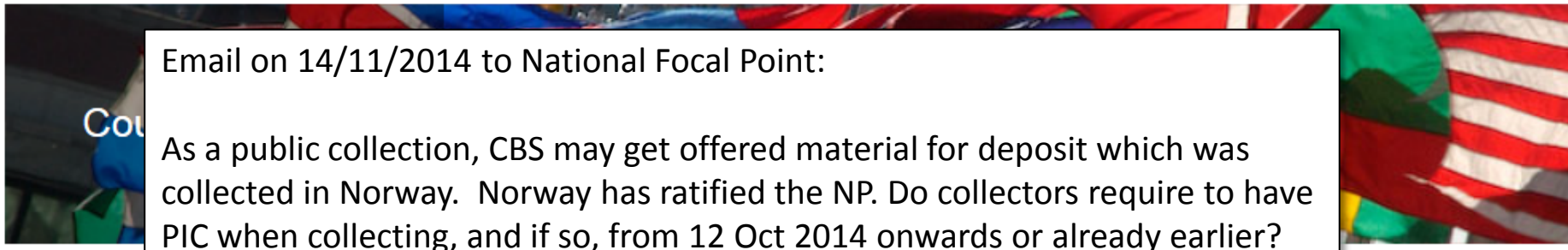
Checkpoint Communiqués (CPC) SENT

CHECKPOINT	TITLE	SOURCE COUNTRY	USER	SUBJECT MATTER	IRCC
NO CHECKPOINT COMMUNIQUÉS (CPC) SENT					

Checkpoint Communiqués (CPC) RECEIVED

ISSUING COUNTRY	CHECKPOINT	TITLE	USER	SUBJECT MATTER	IRCC

The Convention | Cartagena Protocol | Nagoya Protocol | Programmes | Info



Email on 14/11/2014 to National Focal Point:

As a public collection, CBS may get offered material for deposit which was collected in Norway. Norway has ratified the NP. Do collectors require to have PIC when collecting, and if so, from 12 Oct 2014 onwards or already earlier?

Norway

> Information > Country Profiles > National Focal Points

Answer on 14/11/2014 (from Clearing House manager)

Norway is working on the issue of access regulations under the Marine Resources Act and the Nature Diversity Act. Regulations are not in place.

Therefore there are no PIC or Benefit-sharing obligations for the access of Genitic Resources in Norway. Special rules apply for Spitsbergen(Svalbard).

Norway

Convention

Party since: 1993-12-29
By: Ratification

Cartagena Protocol

Party since: 2003-09-11
By: Ratification

Nagoya Protocol on Access and Benefit-sharing

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Nagoya – Kuala Lumpur Protocol

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Acquisition of material

Accession form

- Should be reviewed to ensure compliance with the EU Regulation – support of the legal specialists will be needed
- A set of standard questions and/or (optional) terms to assure that 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 (requirements may vary from country to country).
- Incompatibilities between the depositor's proposed terms and those in standard MTA of the mBRC 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 mBRC.

Curation of information and documentation

- Data management policy to assure that all data and documents relevant to ABS for all holdings are properly filed, and readily accessible to authorized staff
- Add essential fields to the mBRC strain database and synchronize fields with other internal databases (e.g., working collections in other departments of the same institute)
- Whenever possible, legal documents should be digitized and saved in a central storage facility. Where possible, electronic files of document should be linked to the main record of the material
- Documents must be screened to prevent breaches of confidentiality
- IRCC number and other important non-confidential information could be made available in the online strain catalogue

Transfers - Exchange between mBRCs

- 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 mBRC
- Distribution by the receiving mBRC is under MTA conditions equivalent and compatible to those in place at the supplying mBRC
- The exchanging mBRCs 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 mBRCs standard MTA for supply, and resolve any issues.

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

Transfers – supply to customers

Supply of material from the public collection

- No supply without MTA
- Terms in MTA in agreement with those under which the material was received by the mBRC
- Transfer by recipient to a third party not allowed
- 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

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)

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

Are collections users or non-users?

When do staff in the mBRC utilise the genetic resources (or traditional knowledge associated with genetic resources) within scope of the EU Regulation?

Collection management activities

(a) Handling material for purpose of accession, preservation, preparing for the supply of samples, quality control, and for pursuing correct and up-to-date identification → **outside scope**

Research proper, viz.:

(b 1) activities generating data which add value to the material, and will be made available in the public domain → **outside scope**

(b 2) activities that can be seen as conducting 'research and development' on the genetic resource, for various purposes including, but not limited to, commercial purposes → **within scope**

Measures to assure compliance throughout the mBRC's legal entity

The mBRC 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 mBRC 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.

Unexpected opportunities for commercialization: If the mBRC wishes to explore further, it should immediately inform the country of origin of the genetic resource and other rightful stakeholders to negotiate the terms for benefit sharing, at least if such is required per terms under which the resource was acquired by the mBRC.

Other mBRC services

These following services are typically outside scope of the EU Regulation:

Material acquired temporarily (unsolicited)

- For performing identification service, and not used by the mBRC for research purposes
- Destroyed or returned to sender at end of work

Deposits under the Budapest Treaty

- The IDA activities fall outside the scope of the EU Regulation

Safe deposits

- Material deposited in the secured collection through a signed contract, where all rights over the material remain exclusively with the depositor, is confidential, and is never transferred to third parties by the mBRC or used for research by the mBRC. Outside the scope of the EU regulation;
- If transfer to third parties should be possible, then the depositor will have to provide at the time of deposit all information needed to assess ABS status.

Issues

- ABS awareness among depositors is (very) low to date; mBRCs can advise, and provide info on their websites and refer to CBD information resources and ABSCH
- Where there are issues concerning legality of material for deposit, it is best that the depositors themselves contact the authorities in the country of origin
- Information on responses by competent authorities (to the depositor) need to be properly filed at the mBRC (for due diligence)
- Relation between material offered and permits provided by depositor is often not verifiable
- PIC and mutually agreed terms of material may complicate and slow down normal procedures for supply to customers – this is not what MIRRI would like to see – how to avoid this and still assure that the provider countries will trust us and our customers with their materials?
- Administrative work for the curators is increasing rapidly
- ABSCH does not contain IRCC records at this time

Conclusions

- 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
- 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

Thank you for your attention !