CETAF

CONSORTIUM OF EUROPEAN TAXONOMIC FACILITIES

Practical Implementation in a Nutshell

CETAF Legislation and Regulations Liaison Group

Compliance in Scientific Collections in a nutshell

All following slides take an *EUROPEAN PERSPECTIVE*, i.e. they relate to *REGULATION (EU) NO 511/2014* and

HTTP://EUR-LEX.EUROPA.EU/LEGAL-CONTENT/RO/ALL/?URI=CELEX:32014R0511

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

Compliance in Scientific Collections in a nutshell

- Typical activities in collections include:
  - collection of material in the field (= in-situ access)
  - acceptance of material (= ex-situ access)
  - research (= ABS relevant utilisation)
  - transfer of material to Third Parties

Compliance in Scientific Collections in a nutshell

- Applicability of the Nagoya Protocol and European laws:
  - For all acquisitions *SINCE* *12 October 2014* *(= effective date)*

Compliance in Scientific Collections in a nutshell

- Applicability of the Nagoya Protocol and European laws:
  - For all acquisitions *SINCE* *12 October 2014* *(= effective date)*

- Criteria for applicability (applies for EU and non-EU researchers):
  1. Accession from a *STATE EXERCISING SOVEREIGN RIGHTS* on GR
  2. Accession from a *NP PARTY*
  3. The NP Party has established *ACCESS LAWS*
  4. Utilisation *INSIDE THE EU*

Compliance in Scientific Collections in a nutshell

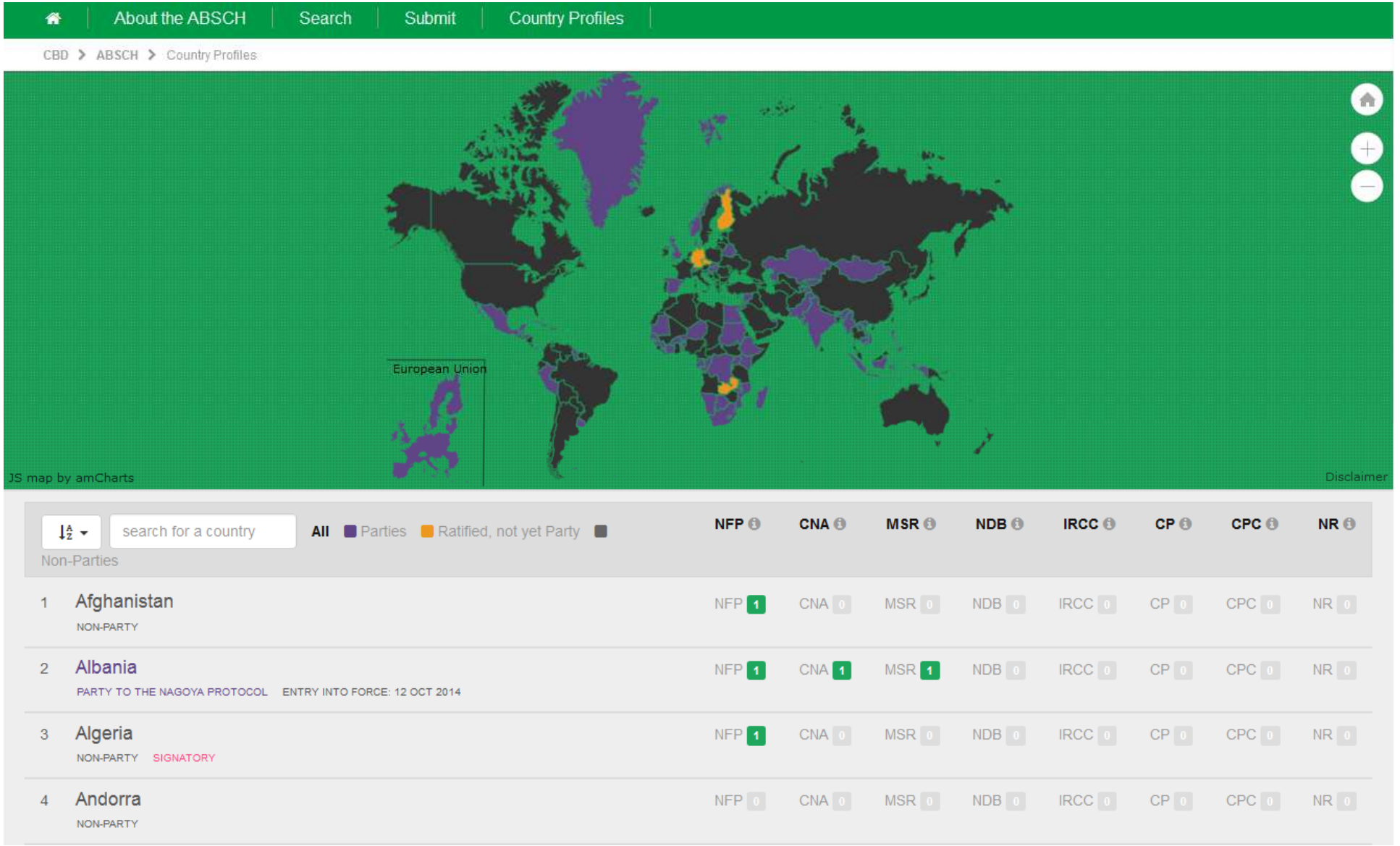
- European ABS laws are not applicable for:
  - biological material accessed before 12 Oct 2014
  - accepting and keeping of collections (including GR)
    - N.B.: check for relevant permits
  - traditional (e.g. morphological) comparison, identification and description
    - N.B.: it does not make sense to have two collections
  - utilisation outside of the EU

DUE DILIGENCE before collecting

1. What is the effective date of access (do I receive samples during the field trip that have been collected before 12 Oct 2014)?
2. Is the country party to the NP?
3. Does the country have national access legislation?
   (This may entail additional requirements or permits)
4. Who is the contact person?

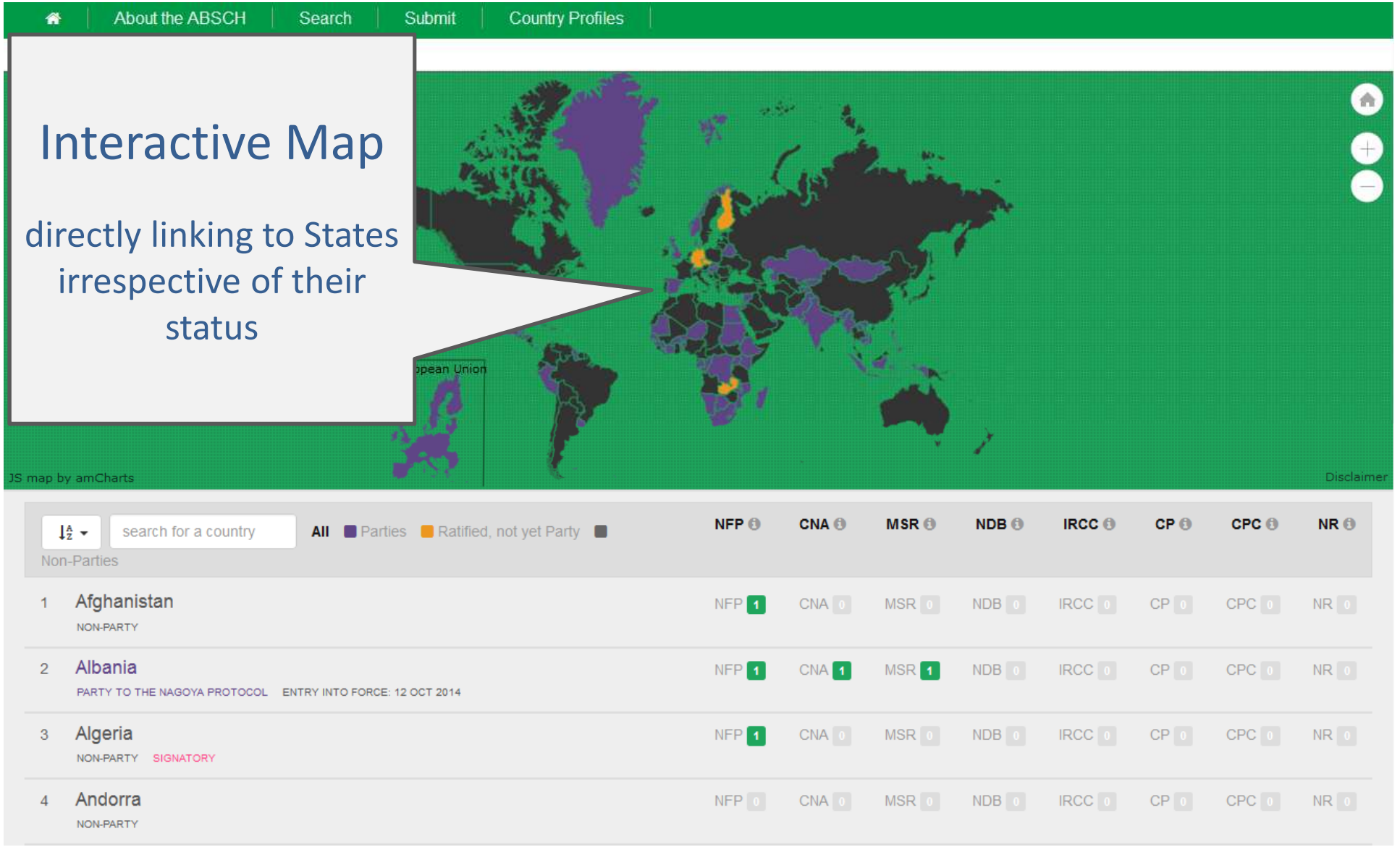
Finding relevant contacts using the ABS Clearing House

https://absch.cbd.int/countries



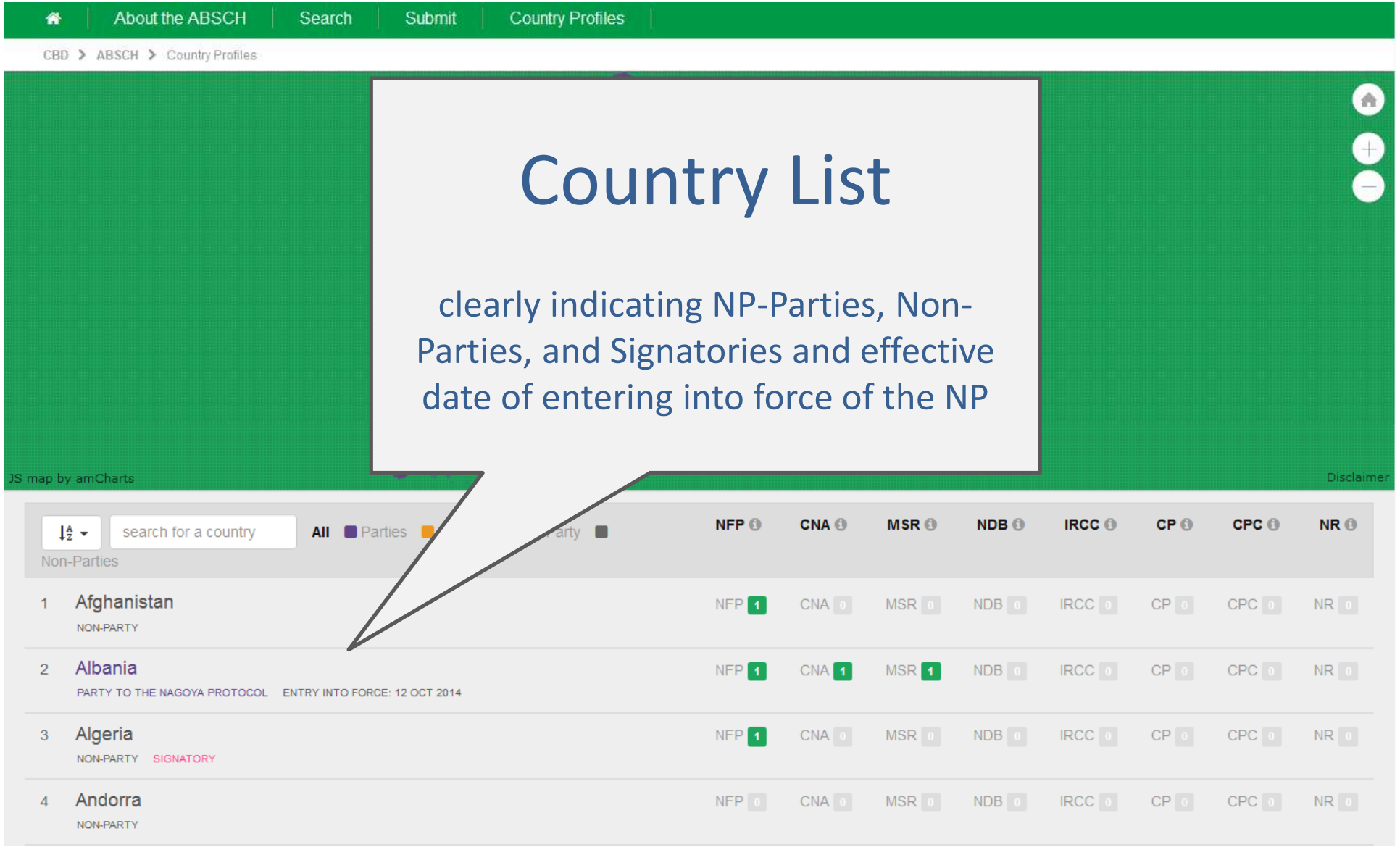
Finding relevant contacts using the ABS Clearing House

https://absch.cbd.int/countries



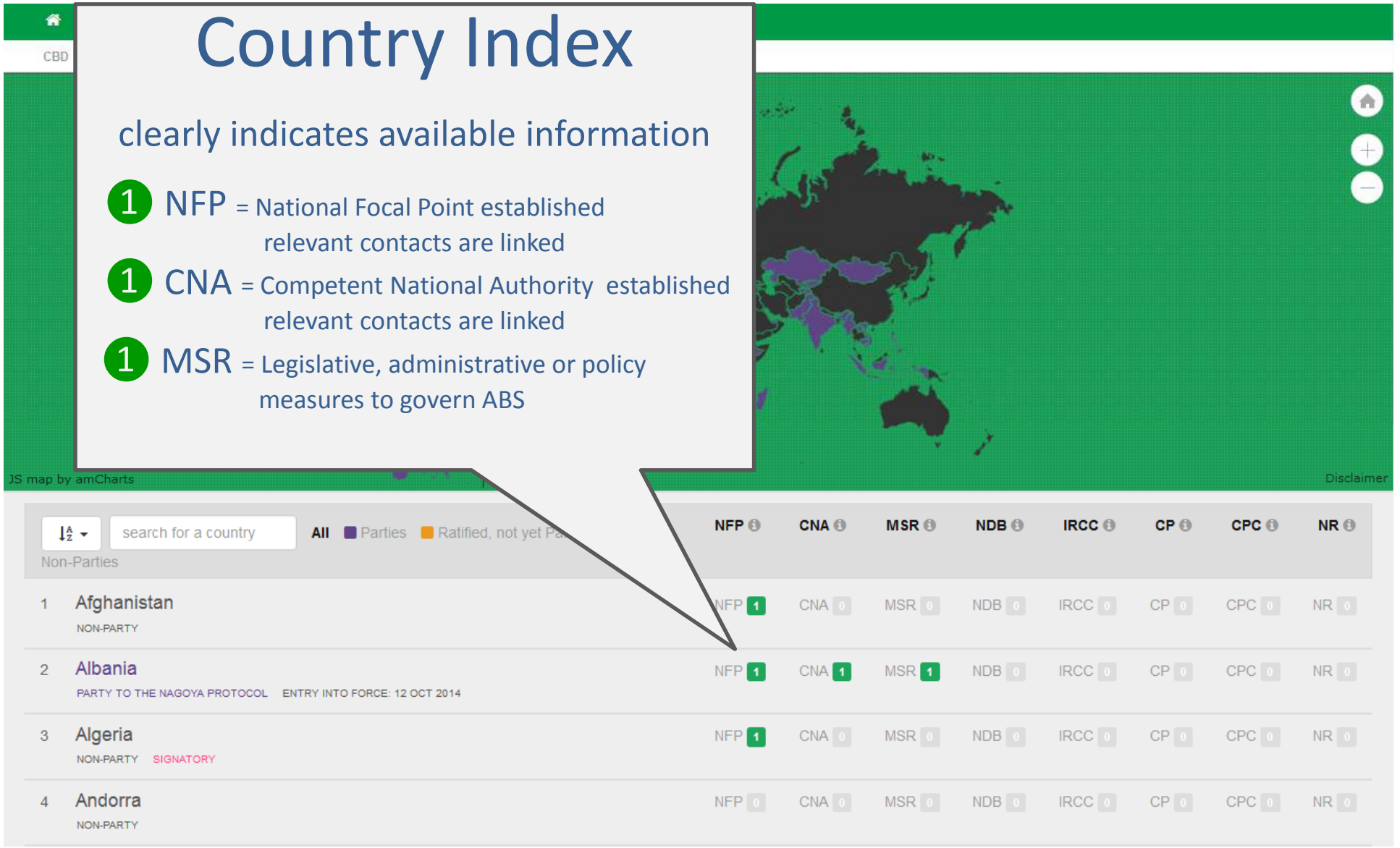
Finding relevant contacts using the ABS Clearing House

https://absch.cbd.int/countries



Finding relevant contacts using the ABS Clearing House

https://absch.cbd.int/countries



DUE DILIGENCE before collecting

IMPORTANT:

KEEP ALL CORRESPONDENCE with authorities of providing country

TO DOCUMENT DUE DILLIGENCE of any subsequent accession in the respective country.

DUE DILIGENCE before collecting

1. What is the effective date of access?
2. Is the country party to the NP?
3. Does the country have national access legislation?
4. Who is the contact person?

DUE DILIGENCE before collecting

1. What is the effective date of access?
2. Is the country party to the NP?
3. Does the country have national access legislation?
4. Who is the contact person?
5. Seek PIC[1] (Prior Informed Consent)
   with authority of country of origin
6. Negotiate MAT[1] (Mutually Agreed Terms) [other forms of permit?]
   on legal future utilization with Competent National Authority
7. Retain copy of PIC und MAT[1] for 20 years after end of utilization

[1]Note: only applicable to material from NP member states with access legislation.

DUE DILIGENCE before collecting

IMPORTANT:

Negotiating MAT & PIC may require

additional time to establish and

additional travel funds for signing these agreements

DUE DILIGENCE before collecting

Fine Print for later reference

→ Clarify who is entitled to handle / sign relevant legal matters
(MoCs, MoUs, MATs & PIC agreements) in your institution

→ Consider additional cooperation partners based outside your institution
or third-party users (e.g. for external barcoding/sequencing) in negotiations

→ Consider whether any (oral or other) traditional knowledge
might be associated with the GR (TKaGR)

→ Consider to which extent existing specimens should be covered
(GR inside your collection that are currently not utilised but might be utilised in the future).

→ Consider any material from ex-situ sources such as unsolicited samples
which might be sent in to your institution for identification at a later point from any person or party inside or outside of the Providing Country

DUE DILIGENCE before collecting

More Fine Print for later reference

→ MAT & PIC ***may not include*** Collecting Permits, and Collecting Permits ***may not replace*** MAT & PIC (contacts for authorities?)

→ Who owns the GR I want to access? PIC+MAT should be phrased accordingly for legal acquisition

→ Change in ownership does not necessarily include transfer of intellectual property rights (IPR) other than for scientific publications (e.g. in the public domain)

→ Which benefits can realistically be offered and be included in an agreement?

→ Are GR associated with collected objects (irrespective of the original purpose or intention, e.g. gut contents) covered in the permit or not?

→ Try to consider and cover any potential future form of utilization (e.g. Genome Sequencing)

→ Consider external sequencing and DNA analysis (especially NextGen and Genomic Sequencing)

→ Consider sharing of raw data (e.g. cloud based DNA analysis) and sharing of analysis results with external colleagues or third parties (contracted sequencing)

→ Consider publication of DNA sequence and other information (e.g. TKaGR) resulting from your utilisation

→ Be clear about what the accessed biological material will be or could be used for

→ Be clear if GR resources are exclusively accessed for non-commercial purpose or if commercial requests (e.g. of Third Parties) need be included in the agreement

→ Be clear whether freelancers/amateurs/hobbyists associated with your institutions should be included and covered, or not

CETAF Code of Conduct & Best Practice

Use Statement of Use of Biological Material

- Helps when seeking PIC
- Helps to decide if a permit is silent on some uses (How do we decide?)
- Helps to obtain certainty (Can we sequence?)
- Helps to give clarity to provider and user on what can be done and what not (and is ideally annexed as additional document to permits)

CETAF Code of Conduct & Best Practice

Use Statement of Use of Biological Material

- Research
  - what and by whom; includes broad range of methods (e.g sequencing)
- Research results
  - publication
  - sequences deposited in public databases
- Information and images (to be freely available)
- Supply to Third Parties
  - Loans and Permanent supply
- Propagation (botanic gardens)
- Public displays
- TKaGR
- Commercialisation
  - is mentioned even if rarely undertaken, addresses renegotiation if potential discovered
- Benefit-sharing

Compliance in Scientific Collections

Typical workflow:

- Acquisition
  of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to
  other institutions

Compliance in Scientific Collections

Typical workflow:

- Acquisition of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to other institutions

Access

Utilization

Compliance in Scientific Collections

NP established → Due Diligence Obligation

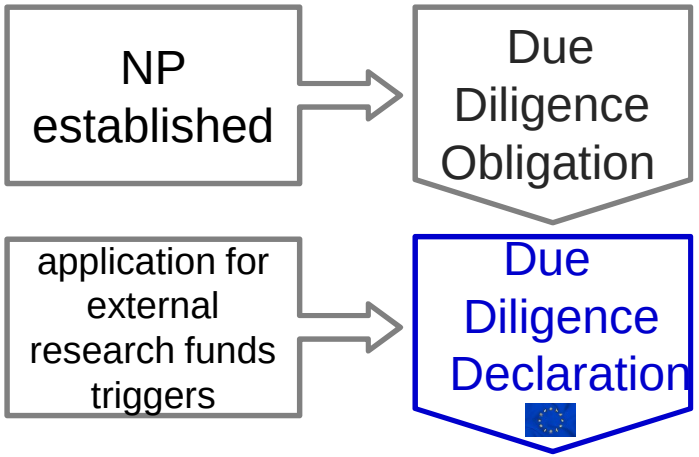
Typical workflow:

- Acquisition of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to other institutions

Access

Utilization

Compliance in Scientific Collections



Typical workflow:

- Acquisition of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to other institutions

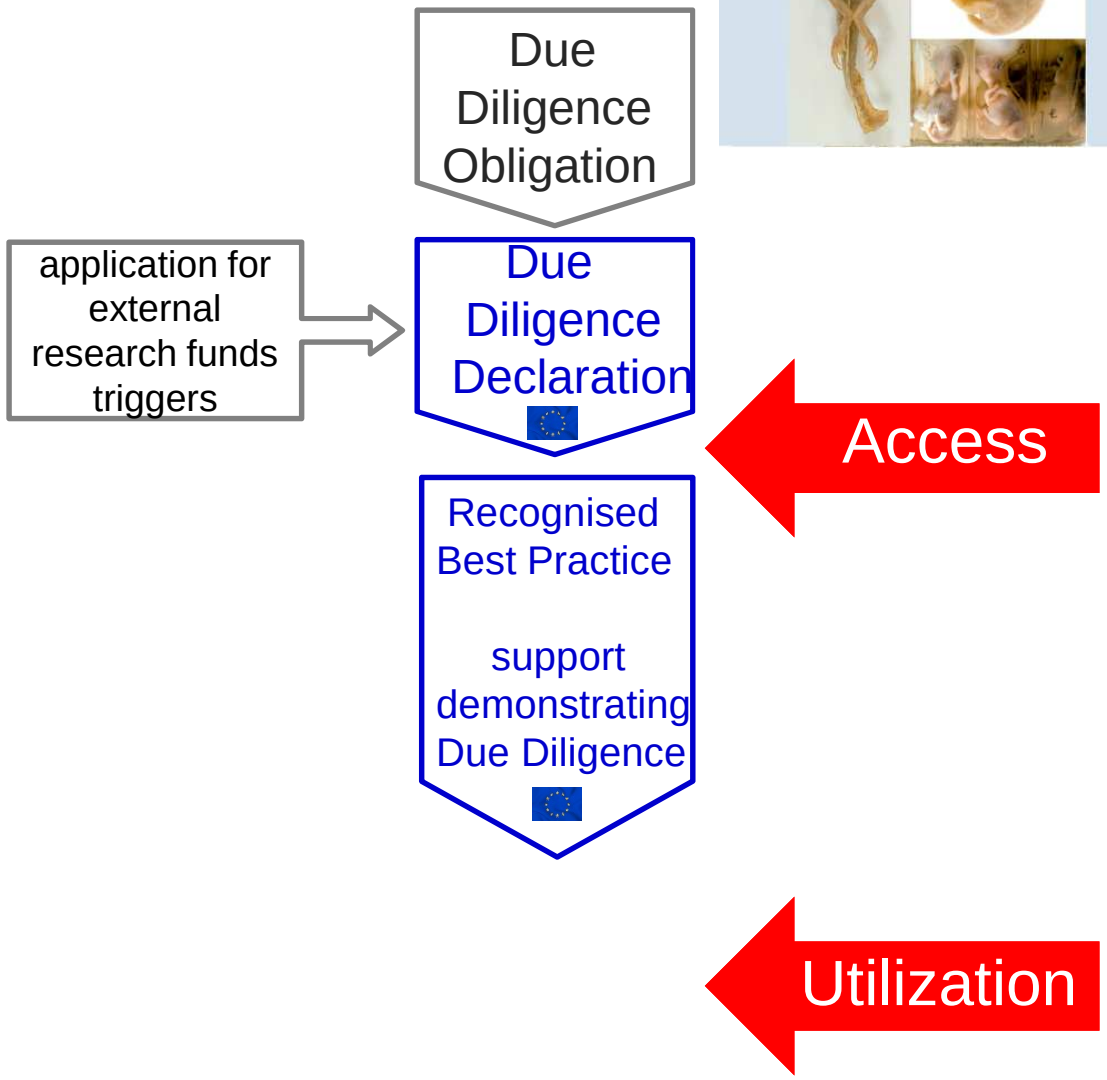
Access

Utilization

Compliance in Scientific Collections

Typical workflow:

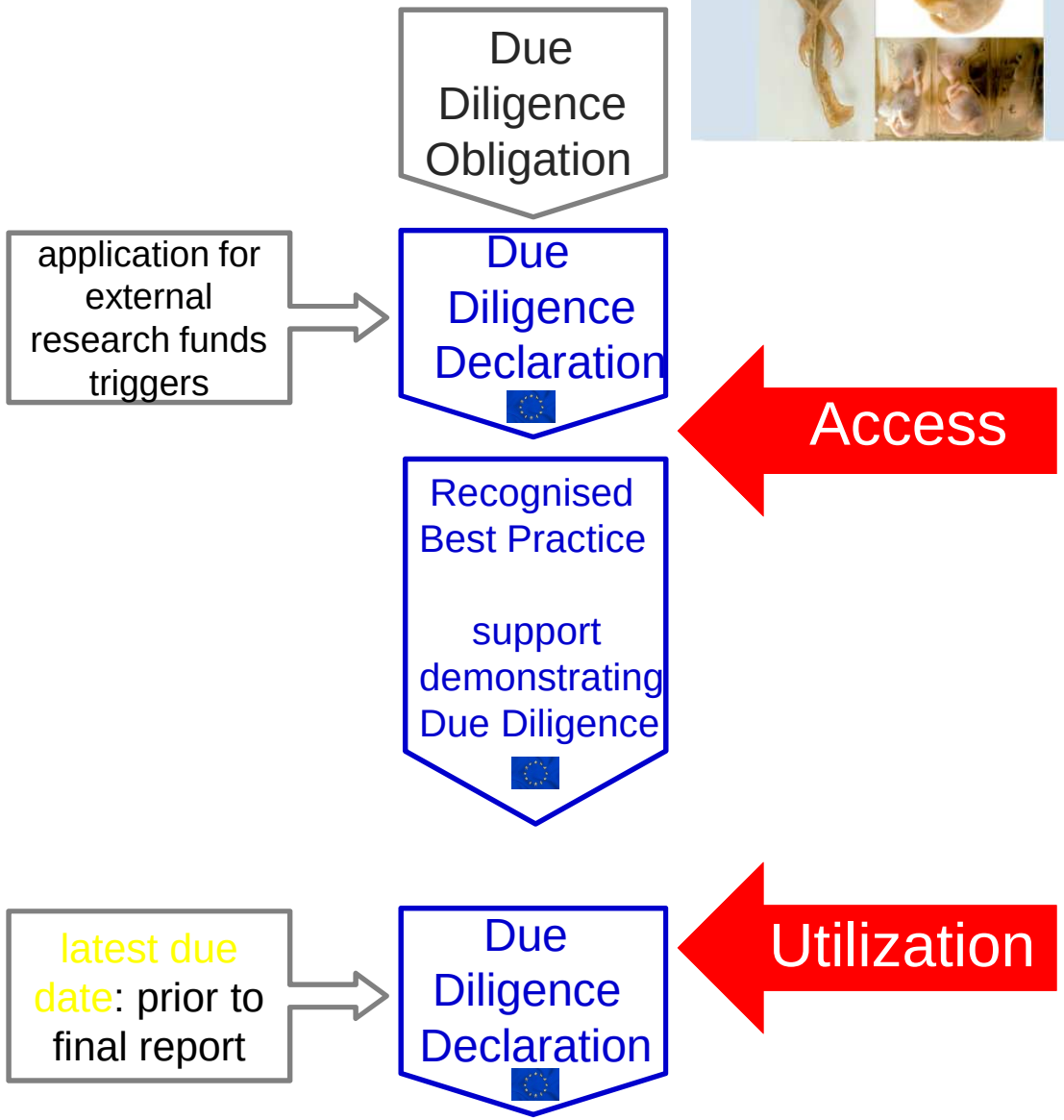
- Acquisition of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to other institutions



Compliance in Scientific Collections

Typical workflow:

- Acquisition of new specimens
- Fixation
- (Preparation)
- Preservation
- Registration
- Labelling
- Storage in collection
- Research (genetic)
- Transfer to other institutions

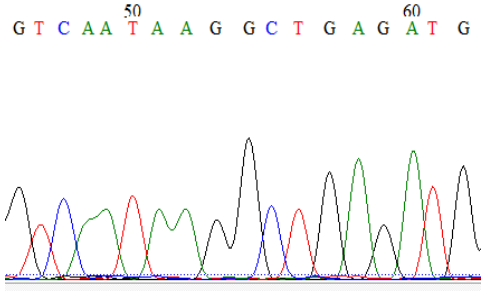


Compliance when accepting material

1. Consider existing Due diligence obligations!
2. Obtain PIC and MAT[1] from donor and document transfer
   (must be retained 20 years after end of utilization)
3. Intended utilization (research) must be covered by MAT[1]
   re-negotiate MAT if this is not the case
4. Transfer of material must be allowed (MAT) and accompanied by a copy of PIC and MAT[1]
5. Benefits with country of origin must be shared as laid down in MAT[1]
   e.g. by co-authorship, capacity building etc.

[1]Note: only applicable to material from NP member states with access legislation.

Compliance when doing research



1. Consider existing Due diligence obligations!
2. Utilization of material from NP member states is only allowed if accompanied by PIC and MAT[1]
3. Utilization (research) has to comply with MAT[1]
   re-negotiate MAT if this is not the case
4. Transfer of material must be allowed (MAT) and accompanied by a copy of PIC and MAT[1]
5. All utilization must be recorded (who, how – needed for optional subsequent transfer)
6. Benefits with country of origin must be shared as laid down in MAT[1]
   e.g. by co-authorship, capacity building etc.

[1]Note: only applicable to material from NP member states with access legislation.

Compliance in transfer to Third Parties

1. Determine whether the transfer is allowed under original permit (e.g. MAT[1])
2. Check whether transfer of TKaGR is covered by permits (e.g. MAT[1])
3. Communicate existing restrictions or requirements (original access / collecting permits, e.g. MAT)
4. determine if objects are to be transferred permanently (change in ownership), or not [what if, what if not?]
5. include copies of relevant documentation (copies of permits & internal recording of transfer)

[1] Note: only applicable to material from NP member states with access legislation.

Compliance in transfer to Third Parties

Documenting requirements of EU Regulation 511/2014:
(users shall seek, keep and transfer to subsequent users)

1. the internationally-recognised certificate of compliance (if available)
   [not mentioned before…]
2. description of the GR / TKaGR utilised
3. direct source and all subsequent users of the GR or TKaGR
4. presence or absence of rights and obligations relating to ABS, including rights and obligations on subsequent application and commercialisation
5. access permits, where applicable
6. MAT including ABS arrangements were applicable

CETAF Code of Conduct & Best Practice

Supply to Third Parties

Important to consider:

- Some of the information listed is required within the EU by national checkpoints
- Point (iii) [all subsequent users] implies to keep a record of users
- Information on transfer to Third Parties should be retained
- Be clear on terms for transfer of objects containing GR

  (with or without change in ownership)

CETAF Code of Conduct & Best Practice

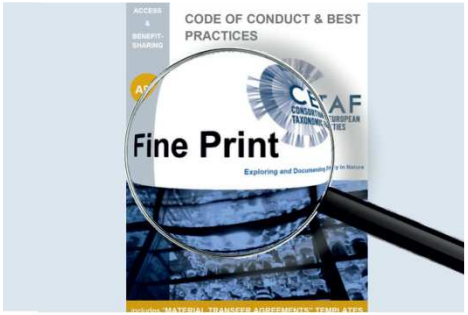
Supply to Third Parties

CETAF Templates for Material Transfer Agreements:

- MTA 1 for Transfer of Material with Change in Ownership
- MTA 2 for Transfer of Material with no Change in Ownership
- MTA 3 for Receipt of Material with Change in Ownership
- MTA 4 for Researchers bringing material to an institution

CETAF Code of Conduct & Best Practice

Supply to Third Parties



Institutional Policy Section of CETAF Best Practice assists to:

- develop institutional policies and internal procedures
- identify points in workflows, where decisions have to be taken
- make explicit who is obliged to follow which procedures

(please refer to section 6 in CETAF Best Practice for further details)

Note that:

- commissioned sequencing needs clear contracts that respect existing user obligations
- publication and data release of any information or analysis results should be covered and agreed in MAT
- inadvertent non-compliance with ABS agreements may occur at different levels

CETAF Code of Conduct & Best Practice

Curation and Management

Apply 'Due Diligence' during all steps of:

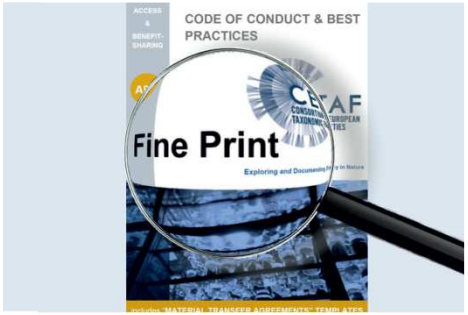
- acquisition
- utilisation

Harmonise procedures & policies with:

- all departments or research groups of your institution
- "special collections", e.g. any living collections, public exhibit collections or frozen tissue and DNA collection (if operated under different or separate policies)

CETAF Code of Conduct & Best Practice

Curation and Management



Procedures and policies should cover:

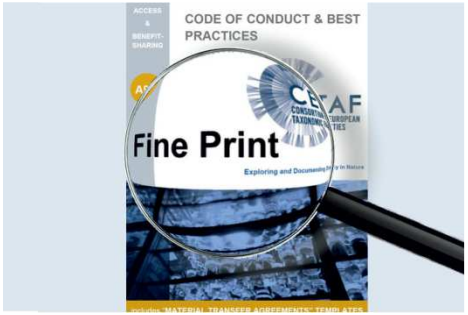
- any aspects of the Institution's acquisition, documenting, digitization, archiving
- Databasing, image and document management, digital linkage of data records, objects, subsamples
- conditions for the publication or release of any data or associated TKaGR to the public domain

Publication of data

- data should be released to the public domain only with a data use statement
- any form of publication and data release should acknowledge original providing country and existing benefits sharing arrangements

CETAF Code of Conduct & Best Practice

Benefit Sharing



Institutions and researchers should consider:

- use the CETAF Use statement and Code of Conduct when negotiating benefit sharing (see Annex 4 of the CoC)
- Strive to include share benefits arising from new utilisation of pre-NP GR were reasonably possible to raise trust

Institutions and researchers are strongly advised to:

- to keep records of any shared benefits
- to determine relevant and agreed benefits that have been shared already prior to accessioning of GR (e.g. during field work) and to keep this information accessible for documenting and reporting

Further Information:

CETAF CoC / Best Practice / MTAs, etc.:
http://cetaf.org/taxonomy/publications

IUCN explanatory guide:
http://www.iucn.org/about/work/programmes/environmental_law/elp_resources/elp_res_publications/?uPubsID=4763

Further Reading:

Neumann et al. 2014. http://www.spnhc.org/media/assets/ABS-GlobalImplications_SPNHC-Sep2014Vol28.pdf

Lyal CHC (2014) Can we keep it? Managing the impact of the Nagoya protocol on insect collections and research. *Antenna*, **38** : 226 - 228.

Myrna Watanabe. 2015.
http://bioscience.oxfordjournals.org/content/early/2015/05/05/biosci.biv056.short?rss=1

Thank you very much for your attention!

BGCI learning tool:

www.bgci.org/policy/abs/