BIG4
Biosystematics, Informatics, Genomics

BIG4 field workshop

June 5-11 2016, Havraníky, Czech Republic

This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 642241

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Legal aspects to consider before collecting

Dr. Ximo Mengual
Zoologisches Forschungsmuseum Alexander Koenig

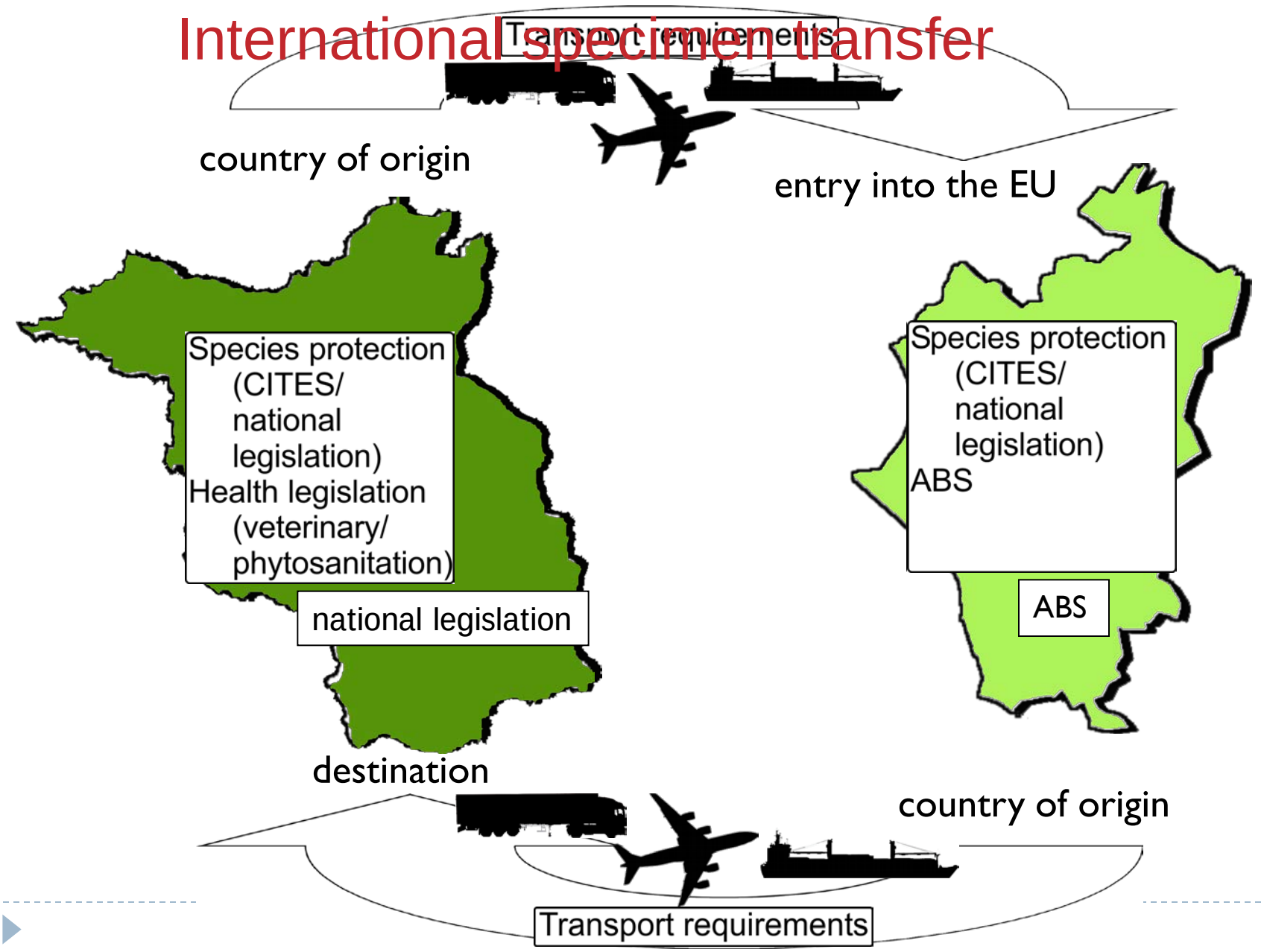
Scientific collections

- Collections are active entities where science is conducted.
- Their **raison d'être** are the specimens, and their use in different topics.

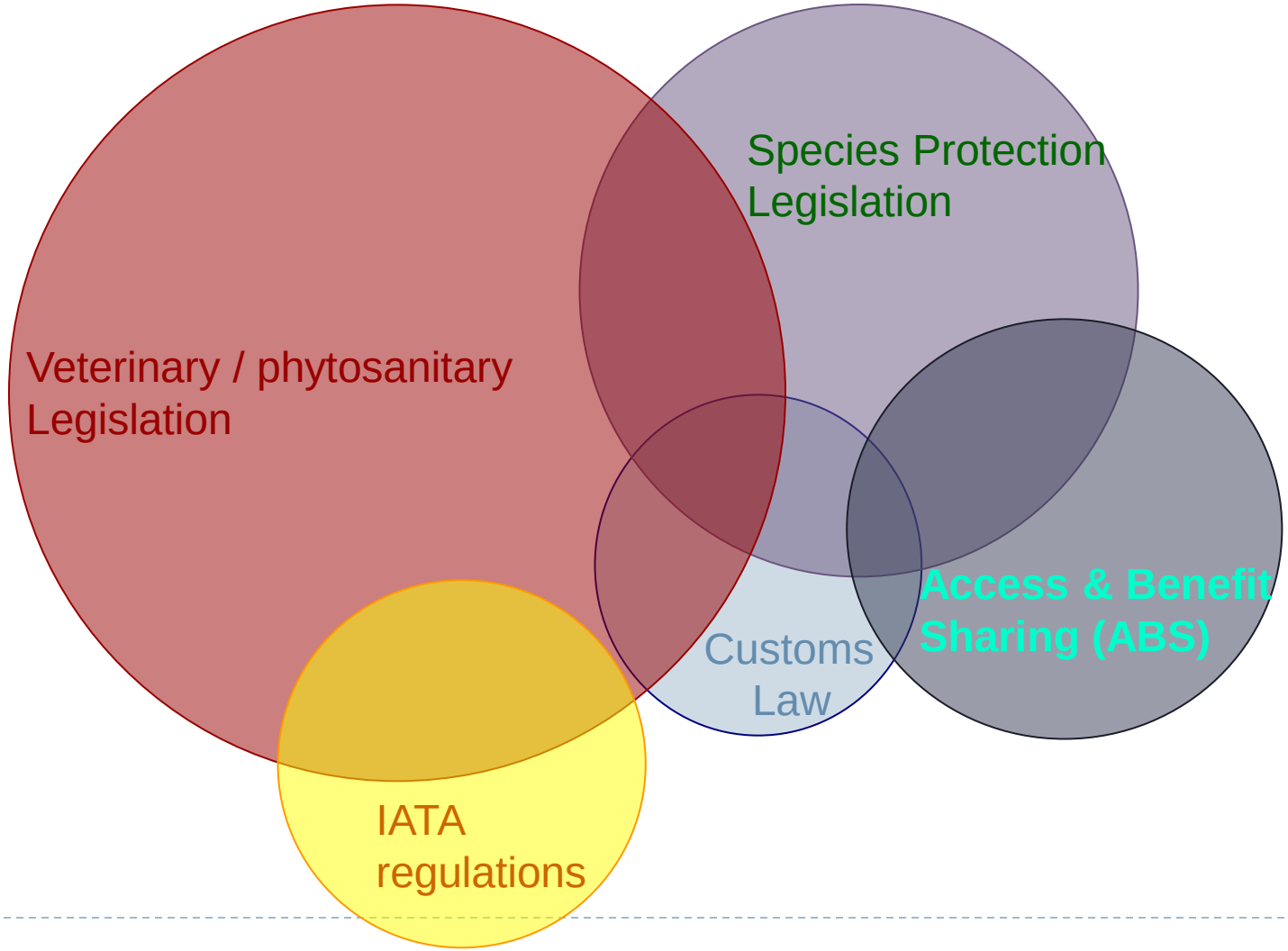
Scientific collections

- Acquisition of specimens:
  - collection of specimens
  - fixation
  - preparation
  - long term preservation
  - registration
  - labelling
  - place in collection
  - research
  - sending specimens to other institutions

International specimen transfer



Relevant legal areas



Before collecting

- **Collecting permit(s)**, normally issued by the pertinent local authority (local government, NP administration, others).
- **Export permit**; usually issued by the national government.
- '**DNA permit**'; again depending on national government.
- **National legislation**, i.e. each country has its different procedure.

After collecting

- **Import permit(s)**.
- **Vet (health) permit**.
- Plus all the previous permits.
- **National legislation**, i.e. each country has its different procedure.

October 12th 2014

Background

- **1992 Convention on Biological Diversity** (CBD, www.cbd.int) with 3 main objectives:
  1. conservation of biological diversity
  2. sustainable use of its components
  3. fair and equitable sharing of the benefits arising out of the utilization of genetic resources

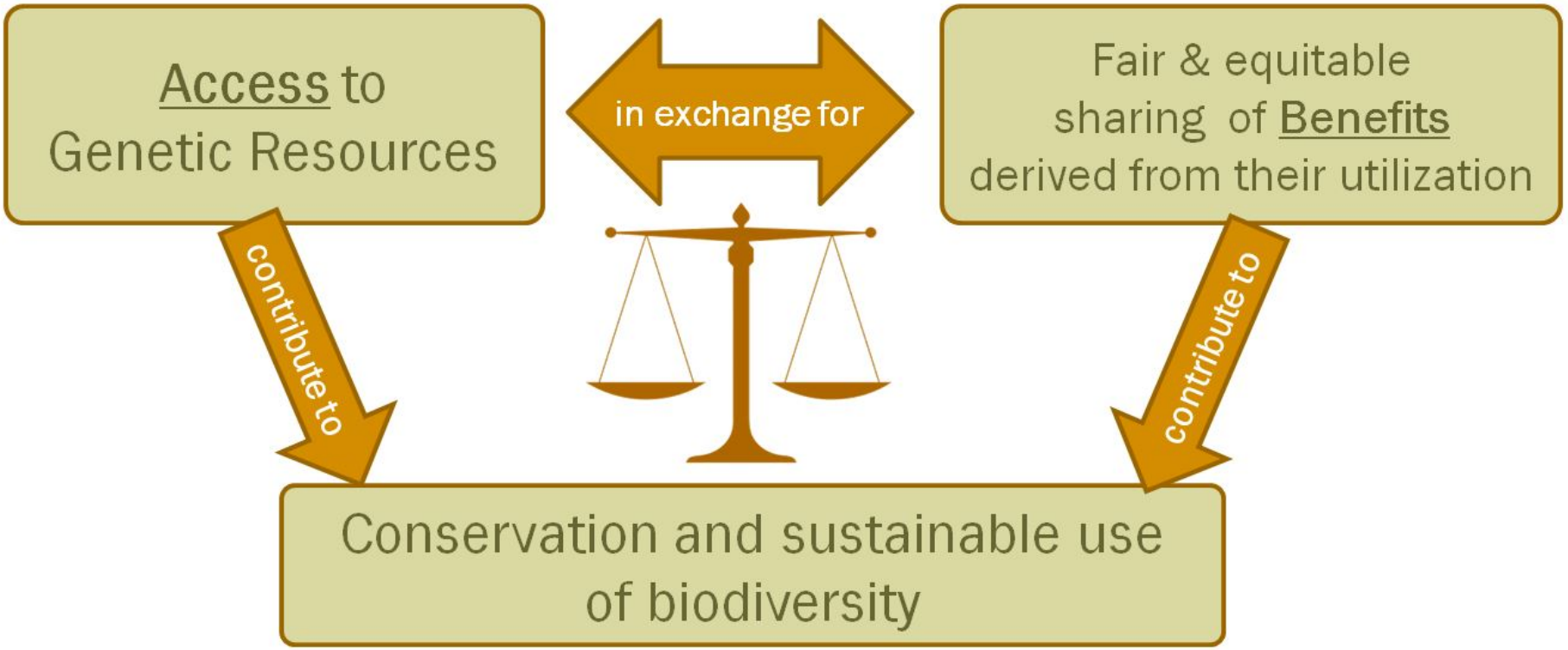
- **Paradigm change**: Genetic resources are no longer common heritage, but instead States have sovereign rights over their genetic resources and may regulate access and utilization

Background

- Reason for this paradigm change = **‘biopiracy’**

Background

- Basic idea: Equity relationship between Access and Benefit-Sharing



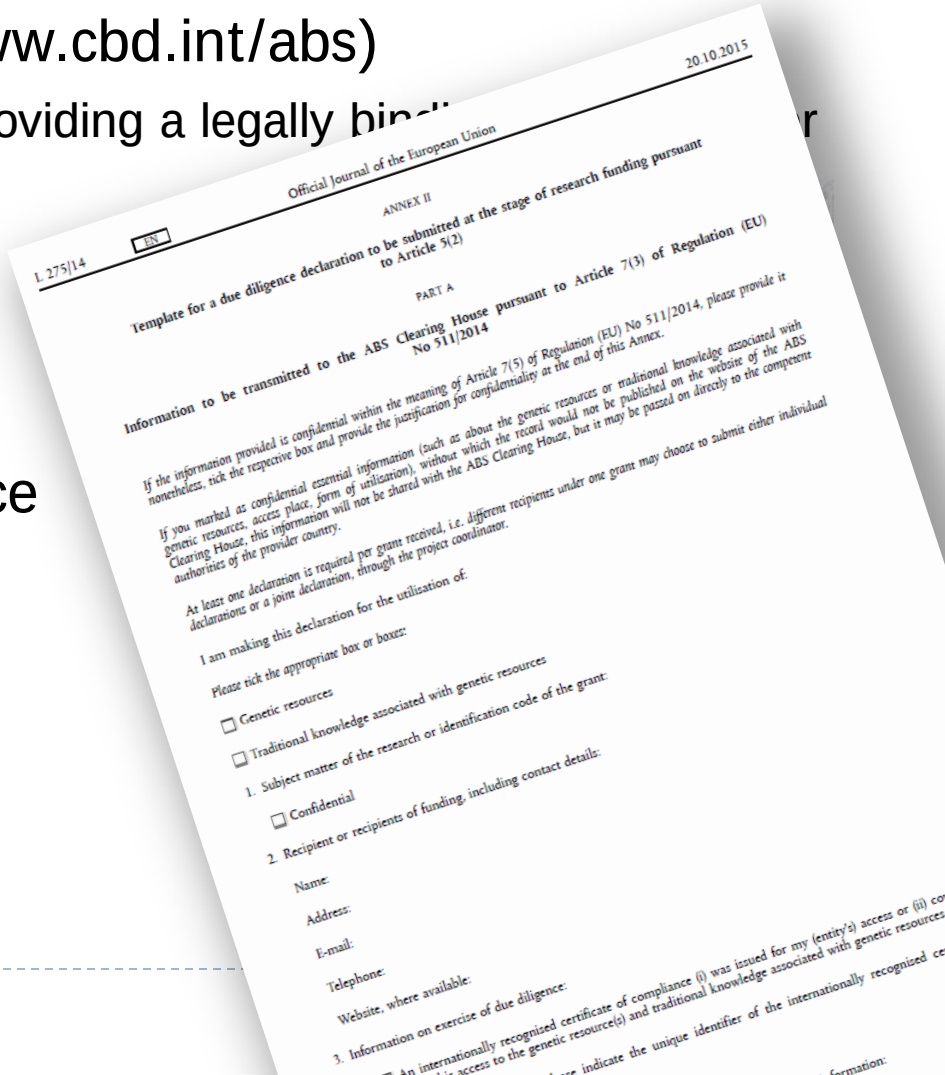
Background

- 2010 (CBD COP10): **Nagoya Protocol on Access and Benefit Sharing** adopted (www.cbd.int/abs)
- Supplementary agreement to CBD, providing a legally bi… …r the implementation of objective 3

- **12 October 2014**:

  Nagoya Protocol came into force

  (EU Regulation No. 511/2014)



L 275/14 EN Official Journal of the European Union 20.10.2015

ANNEX II

Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 5(2)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation), without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:

☐ Confidential

2. Recipient or recipients of funding, including contact details:

Name:

Address:

E-mail:

Telephone:

Website, where available:

3. Information on exercise of due diligence:

an internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) co…

…access to the genetic resource(s) and traditional knowledge associated with genetic resources

…indicate the unique identifier of the internationally recognized ce…

…formation:

Access & Benefit-Sharing (ABS)

- …a complex topic …with a complex terminology.

  - **CBD** = Convention on Biological Diversity
  - **NP** = Nagoya Protocol
  - **ABS** = Access & Benefit Sharing
  - **GR** = Genetic Resources
  - **TK** = Traditional Knowledge associated with genetic resources
  - ***In situ*** = field work, samples for identification
  - ***Ex situ*** = Material in collections, biobanks or botanical gardens

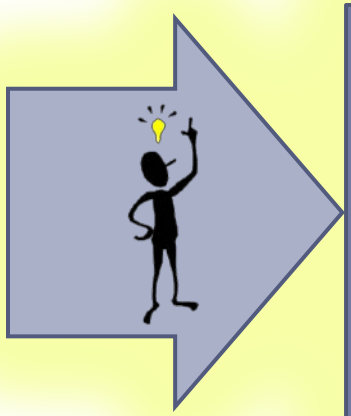
Access & Benefit-Sharing (ABS)

- …a complex topic …with a complex terminology.

  - **PIC** = *Prior Informed Consent* = permission of the Provider Country to a user to access GR
  - **MAT** = *Mutually Agreed Terms* = agreement between provider and user of GR on conditions of access, use and (monetary / non-monetary) benefit sharing between both parties
  - **MTA** = Material Transfer Agreement = a contract that governs the transfer of tangible research materials between two organizations.

Access & Benefit-Sharing (ABS)

- **Genetic resources** = any material of plant, animal, microbial or other origin containing functional units of heredity and of actual or potential value.



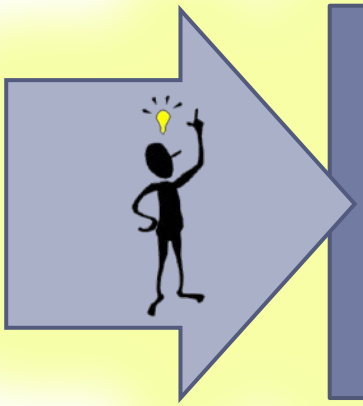
The term „Genetic Resources" comprises:

- *Everything that contains DNA*
- *Living or dead plant material*
- *Wild species as well as breeding varieties*
- *material from in situ and ex situ sources*

Access & Benefit-Sharing (ABS)

- **Access** = Acquisition of a genetic resource (no matter whether from in situ or ex situ sources).

- **Utilization** = Research and development on the genetic and/or biochemical composition of genetic resources.



- *No differentiation between commercial and non-commercial (ABS provisions applicable also to basic research)*
- *The definition of „utilization" might be interpreted differently from country to country*

Access & Benefit-Sharing (ABS)
Article 15 of the CBD

1) Recognizing the souvereign rights of States over their natural resources, the authority to determine access to genetic resources rests within the national governments and is subject to legislation
2) Each contracting party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses [...]
3) [...]
4) Access, where granted, shall be on Mutually Agreed Terms [...]
5) Access to GR shall be subject to Prior Informed Consent of the contracting party providing such resources [...]

Access & Benefit-Sharing (ABS)
Article 15 of the CBD

6) Each contracting party shall endeavour to develop and carry out scientific research based on GR provided by other contracting parties with the full participation of, and, where possible, in such contracting parties.

➡ **CALL FOR COLLABORATIONS**

7) Each contracting party shall take legislative, administrative or policy measures [...] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of GR with the contracting party providing such resources.
Such sharing shall be on Mutually Agreed Terms.

➡ **EU REGULATION AND NATIONAL COMPLIANCE LAWS**

The ABC of ABS
… and challenges for basic research

Access

States (also within EU) may regulate access to their genetic resources

→ *National Legislation*

Get permission (PIC, prior informed consent) from the competent national authority

Benefit-Sharing

Users must agree with providers about Benefit-Sharing

→ *Mutually agreed terms (MAT)*

Document and abide by the provisions of the MAT, and share benefits

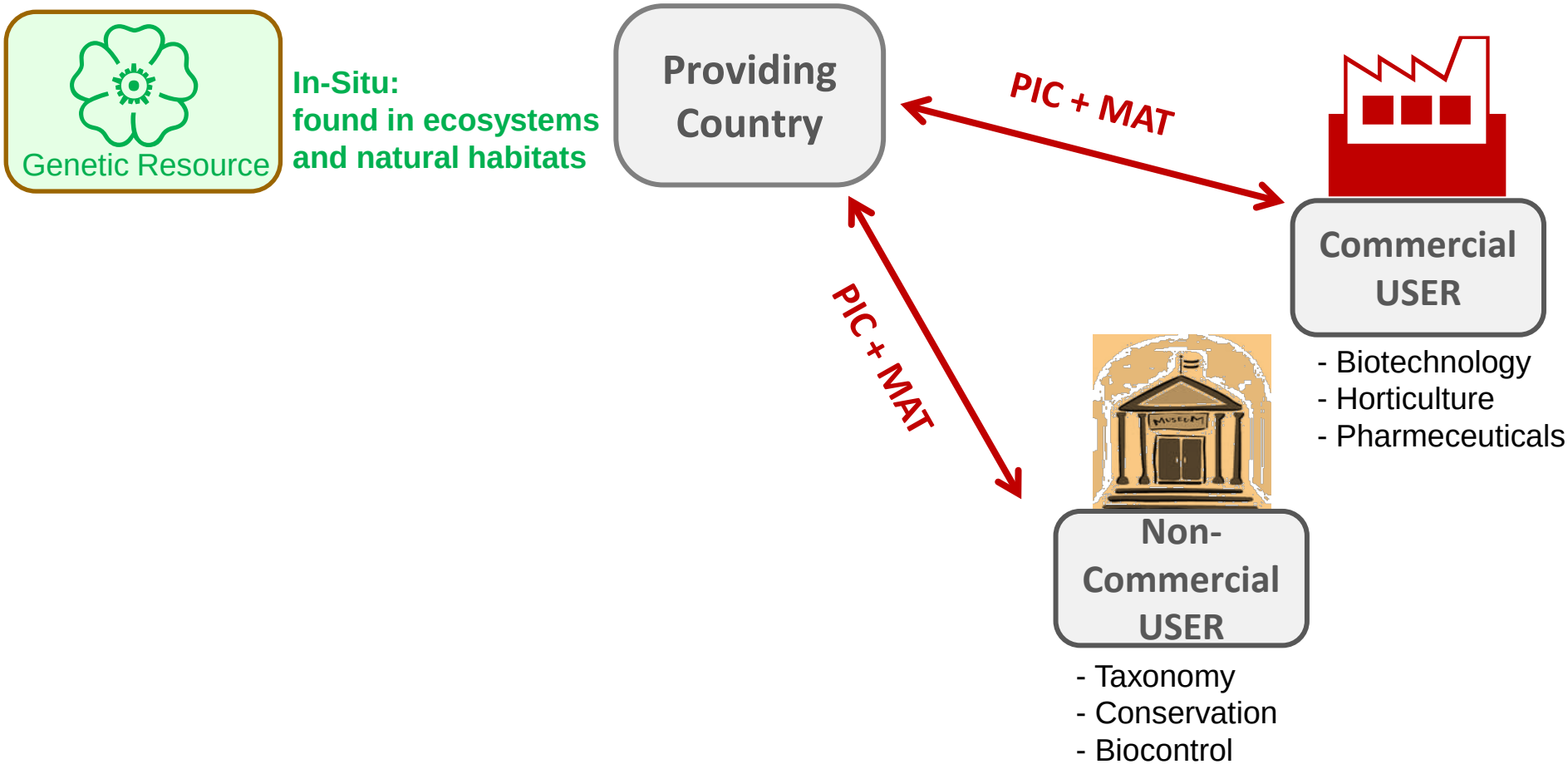
Compliance

States must ensure that users comply with the Nagoya Protocol

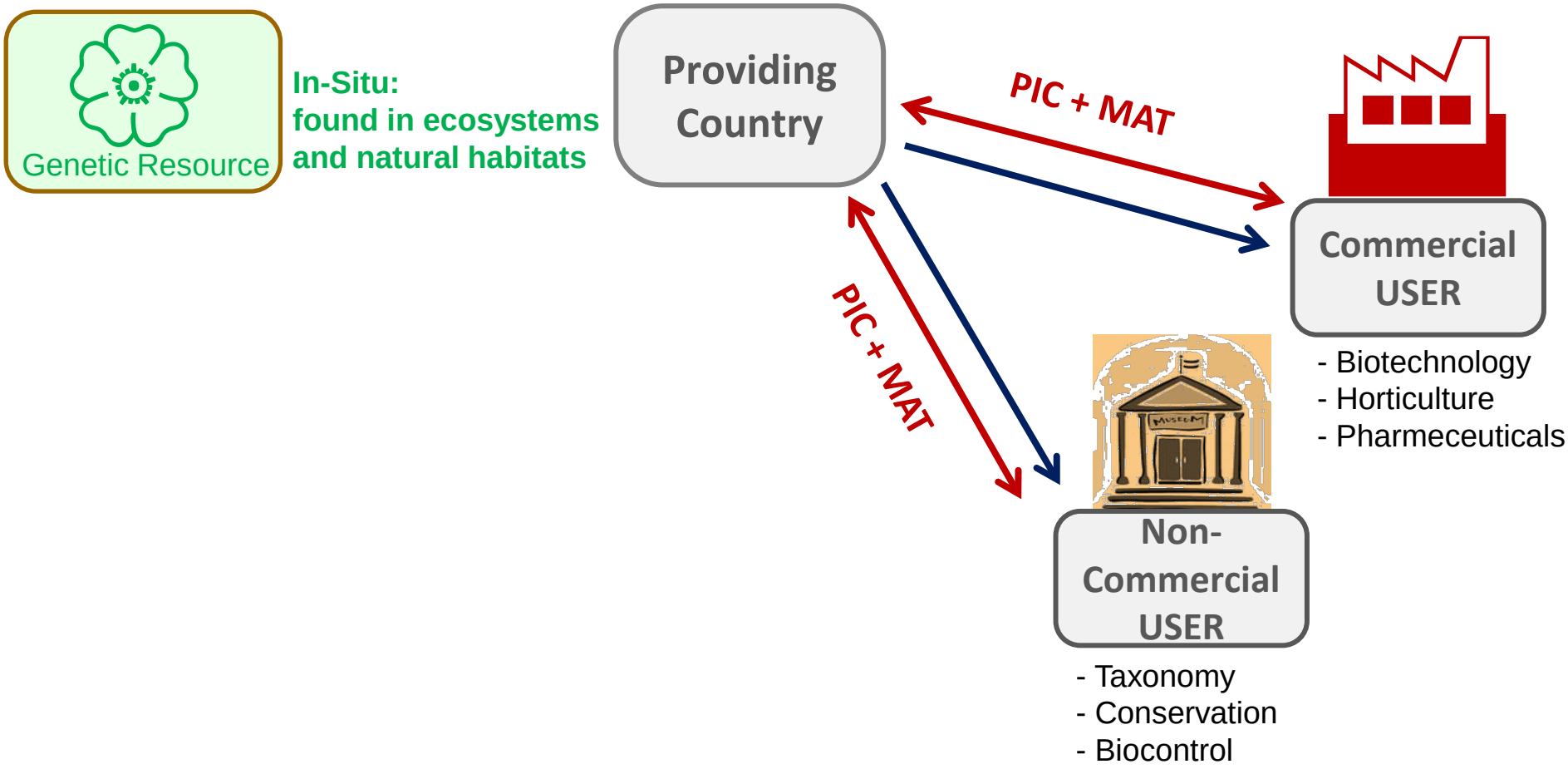
→ *EU Regulation*

Fulfill obligations of the EU Regulation (e.g. reporting)

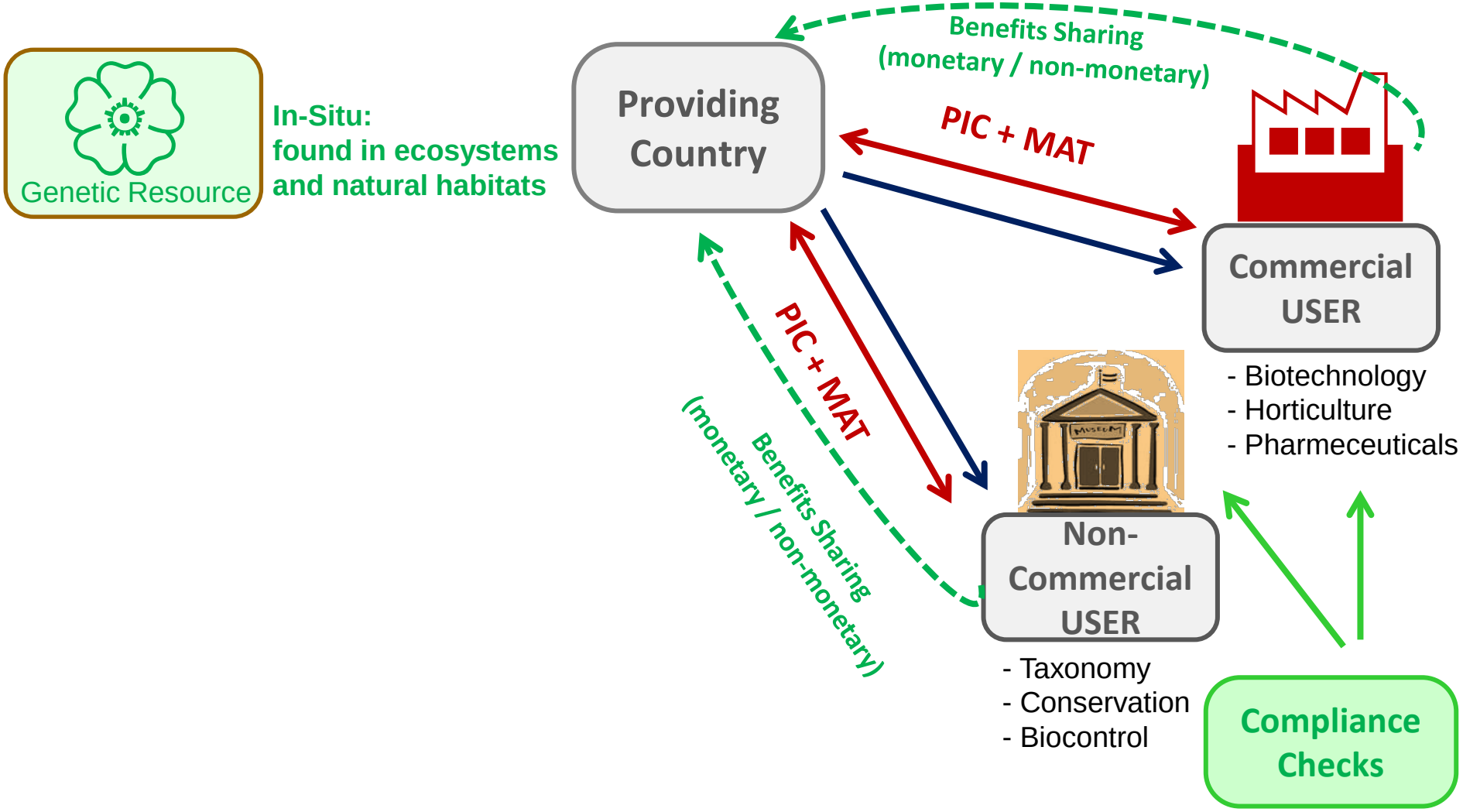
ABS – in theory



ABS – in theory



ABS – in theory



ABS – in theory

Genetic Resource

Ex-Situ accessioned after 12/10/14:
Found in Botanical Gardens
Natural History / University or
Commercial Collections

Providing Country

negotiate
PIC + MAT

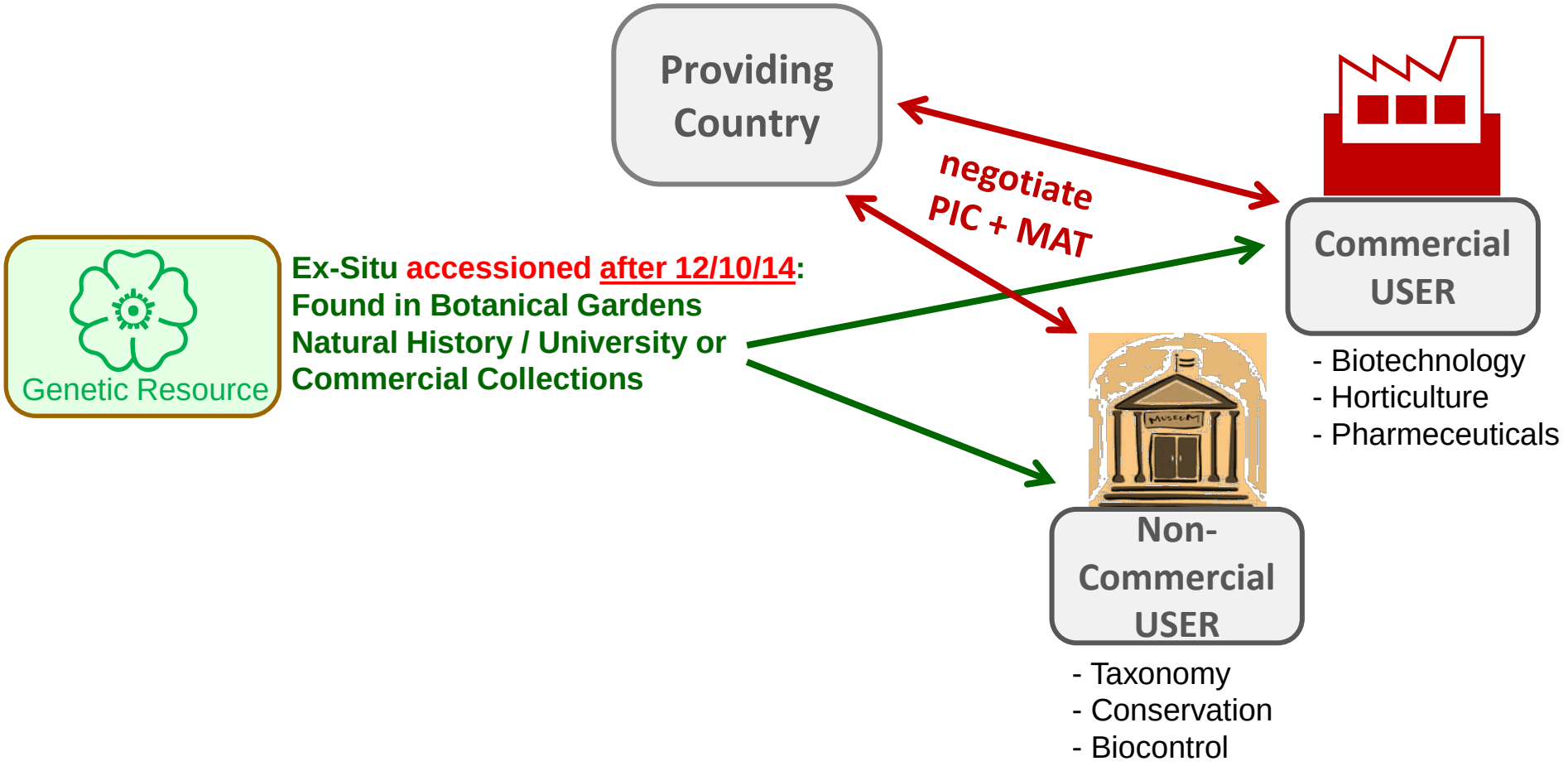
Commercial USER

- Biotechnology
- Horticulture
- Pharmeceuticals

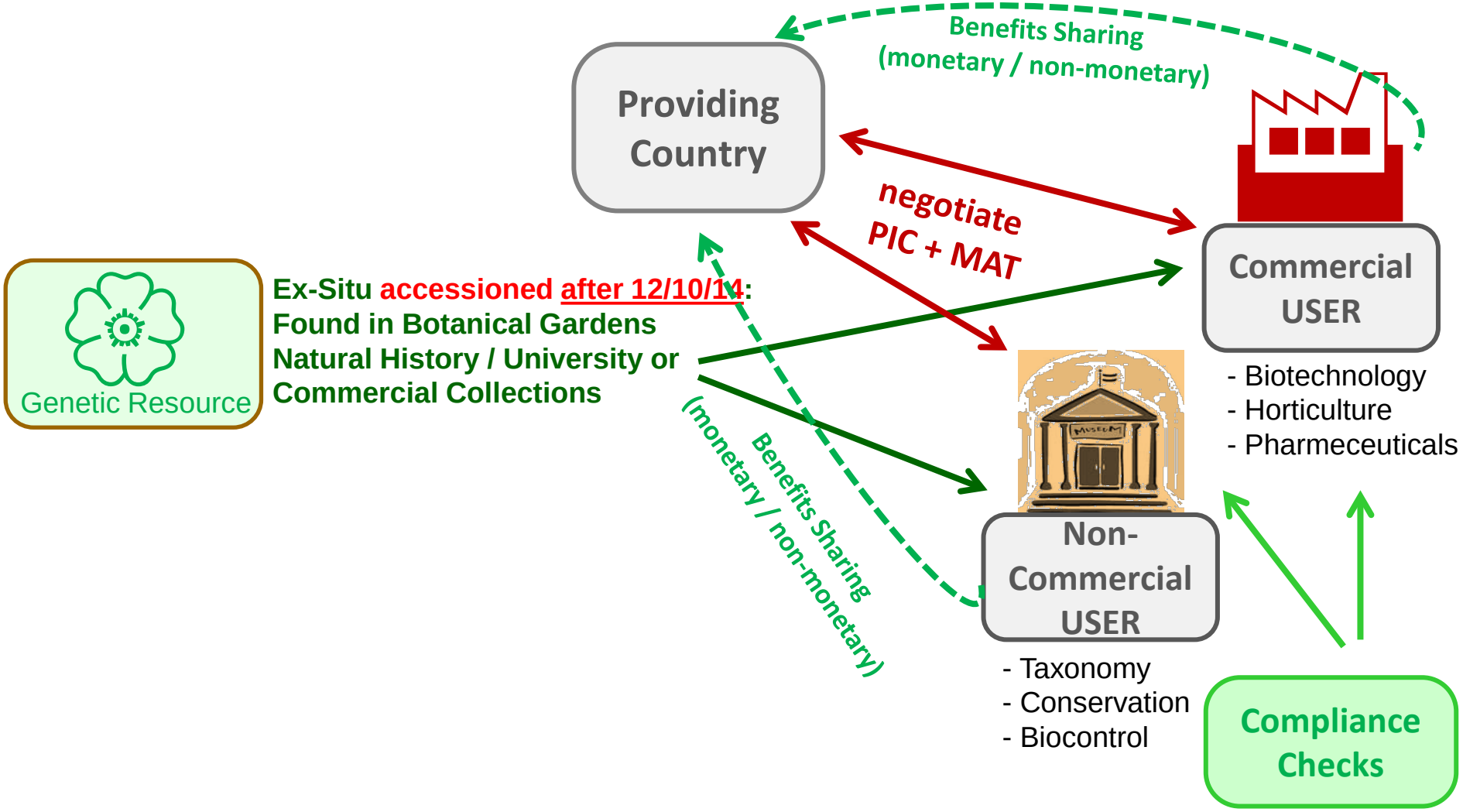
Non-Commercial USER

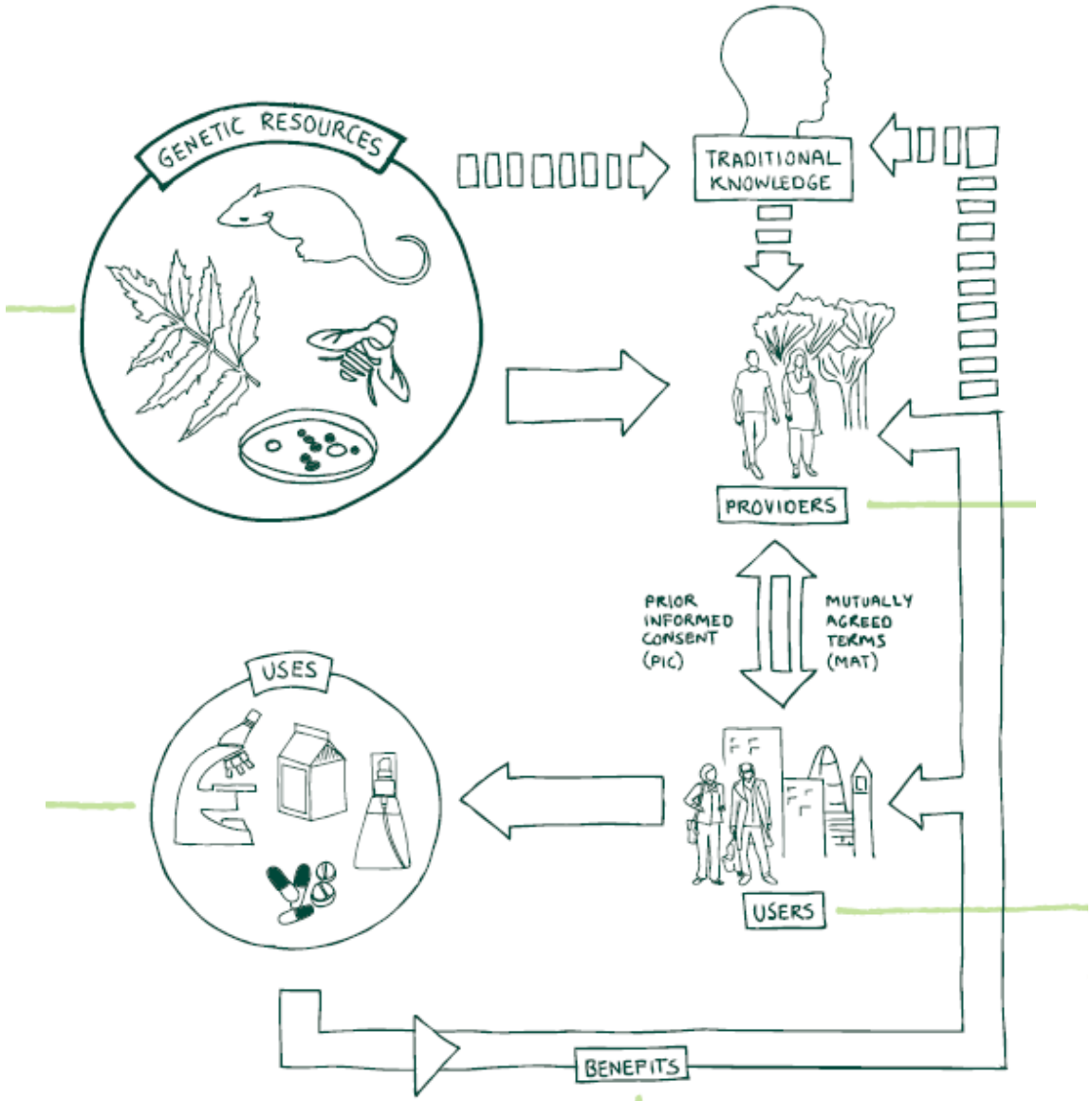
- Taxonomy
- Conservation
- Biocontrol

ABS – in theory



ABS – in theory





Source: Access & Benefit-Sharing Information Kit
(http://www.cbd.int/abs/information-kit-en/)

Tips on ABS

- Ensure that only legally acquired GR are used.
- Collect information relevant for compliance (Check points).
- Visit the Access and Benefit-Sharing Clearing House: https://absch.cbd.int/
- Mind existing access laws (also outside NP or CBD).
- Read ‘Code of Conduct and Best Practices’ by CETAF.

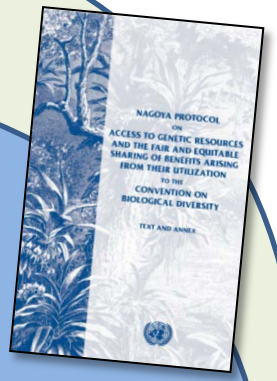
The ethical framework

The legal framework

Basic Principles of Access & Benefit Sharing

National
ABS Legislation

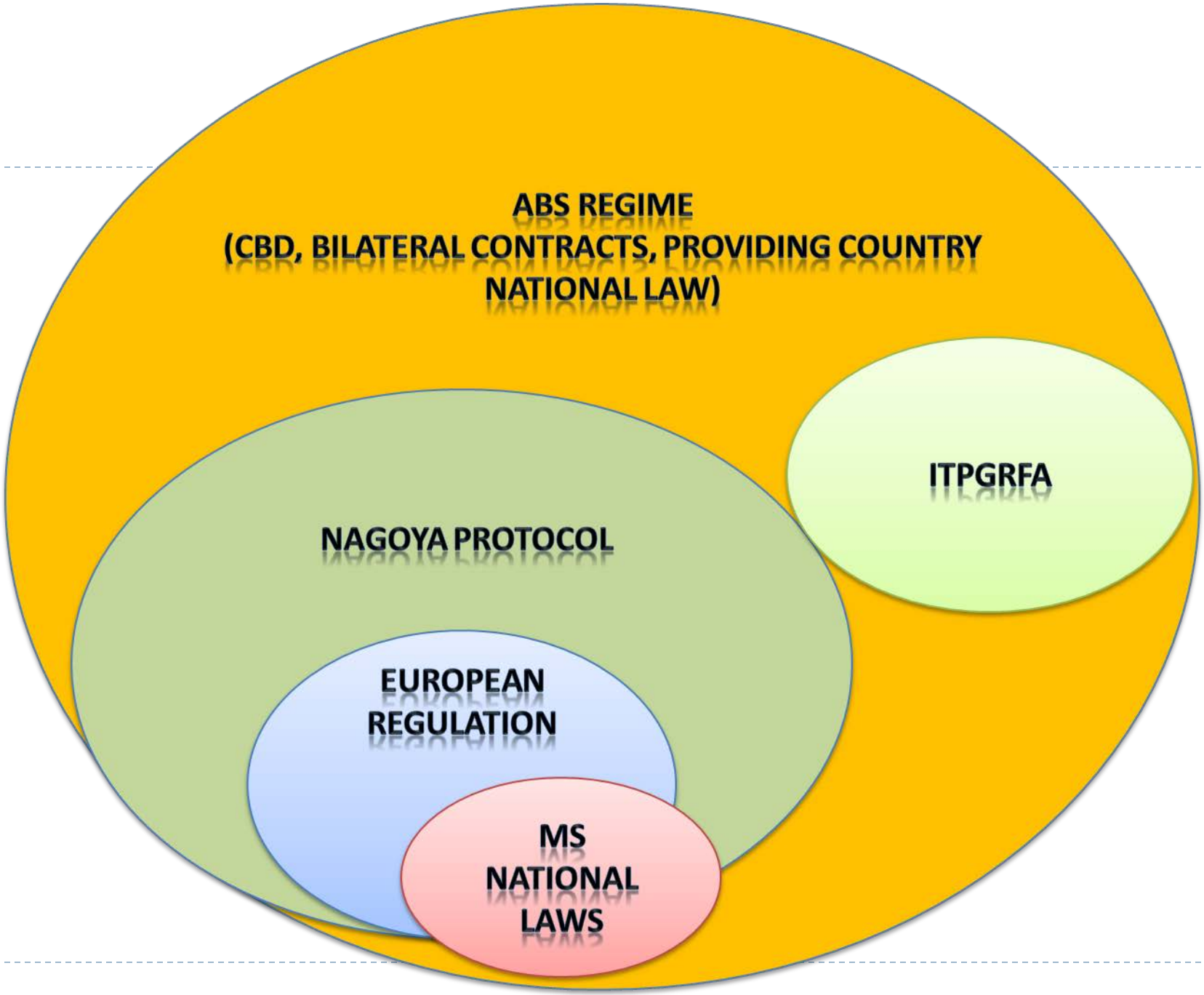
Nagoya Protocol



- EU Regulation 511/2014
- Implementing Regulation 2015/1866

Tips on ABS

- NP does **NOT** apply to:
  - human genetic resources
  - Areas beyond national jurisdiction are not covered (e.g. Open Sea or Antarctica)
  - import of raw materials
  - for GR covered by other international agreements (ITPGRFA)
- But does cover human pathogens, parasites and other associated organisms carrying genetic material.


ABS REGIME
(CBD, BILATERAL CONTRACTS, PROVIDING COUNTRY NATIONAL LAW)
ITPGRFA
NAGOYA PROTOCOL
EUROPEAN REGULATION
MS NATIONAL LAWS

Tips on ABS

1. Due diligence!
2. Was the material accessed after 12 Oct 2014?
3. Is the country party to the NP?
4. Does the country have national access legislation?
5. Who is the contact person?
6. negotiate PIC (Prior Informed Consent) with authority of country of origin.
7. negotiate MAT (Mutually Agreed Terms) on legal future utilization with Competent National Authority.
8. retain copy of PIC und MAT for 20 years after end of utilization.
9. only utilization (Research) that is covered by the MAT is allowed, otherwise re-negotiations.
10. if allowed (MAT) transfer of material must be accompanied by a copy of PIC and MAT.
11. if utilized: "Benefit Sharing" – sharing of benefits with country of origin, e.g. by co-authorship, capacity building etc.

(3) Tutorial

Example 1: Own research project, involving field work and collection of new specimens in country A

Questions to ask (and answer):

1) Does Country A have **national legislation on access** to its genetic resources?

NO → nothing to consider under ABS, but you still might need other permits (e.g. for research, collection, export, CITES etc) ✓

YES →
1. contact national authority, explain your intentions, get PIC (and MAT, if required)
2. read small print, check authorization before signing contracts
3. document your activities and keep all permits, contracts and other documents (preferably attach to accession data base)
4. abide by PIC and MAT

2) Is Country A party to the Nagoya Protocol?

NO → No further obligations under the EU regulation (but see question 1)

YES → EU Regulation applicable
(i.e. potential checks by BfN, due diligence declaration)

(3) Tutorial

Example 2: Joint research project, involving field work and lab analyses, but partners collect specimens (pt. 1)

Questions to ask (and answer):

0) Do you **utilize genetic resources**, i.e., do you conduct research on the genetic and/or biochemical composition of the material?

- **NO →** nothing to consider under ABS
- **YES →** As a **user** of genetic resources, **you** have to conduct due diligence → therefore, check questions 1 and 2

1) Does the country have **national legislation on access** to its genetic resources?

- **NO →** nothing to consider under ABS,
  but you still might need other papers (e.g. for CITES etc.)
- **YES →**
  1. make sure that your partners contact national authority and obtain a PIC (and MAT, if required) that includes you
  2. document your activities and keep all permits, contracts and other documents (preferably attach to accession data base)
  4. abide by PIC and MAT

(3) Tutorial

Example 2: Joint research project, involving field work and lab analyses, but partners collect specimens (pt. 2)

Questions to ask (and answer):

0) Do you **utilize genetic resources**, i.e., do you conduct research on the genetic and/or biochemical composition of the material?

1) Does the country have **national legislation on access** to its genetic resources?

2) Is the country **party to the Nagoya Protocol**?

NO → No further obligations under the EU regulation (but see question 1)

YES → EU Regulation applicable
(i.e. potential checks by BfN, due diligence declaration)

(3) Tutorial

Example 3: Unsolicited material, e.g. sent by partners for identification or analysis

Questions to ask (and answer):

0) Do you intend to **utilize genetic resources**, i.e., do you conduct research on the genetic and/or biochemical composition of the material?

- **NO →** nothing to consider under ABS
- **YES →** check questions 1 and 2

1) Does the country have **national legislation on access** to its genetic resources?

- **NO →** nothing to consider under ABS
- **YES →** 1. contact national authority, explain your intentions, get PIC (& MAT)
  2. read small print, check authorization before signing contracts
  3. document your activities and keep all permits, contracts and other documents (preferably attach to accession data base)
  4. abide by PIC and MAT

2) Is the country **party to the Nagoya Protocol**?

- **NO →** No further obligations under the EU regulation
- **YES →** EU Regulation applicable
  (i.e. potential checks by BfN, due diligence declaration)

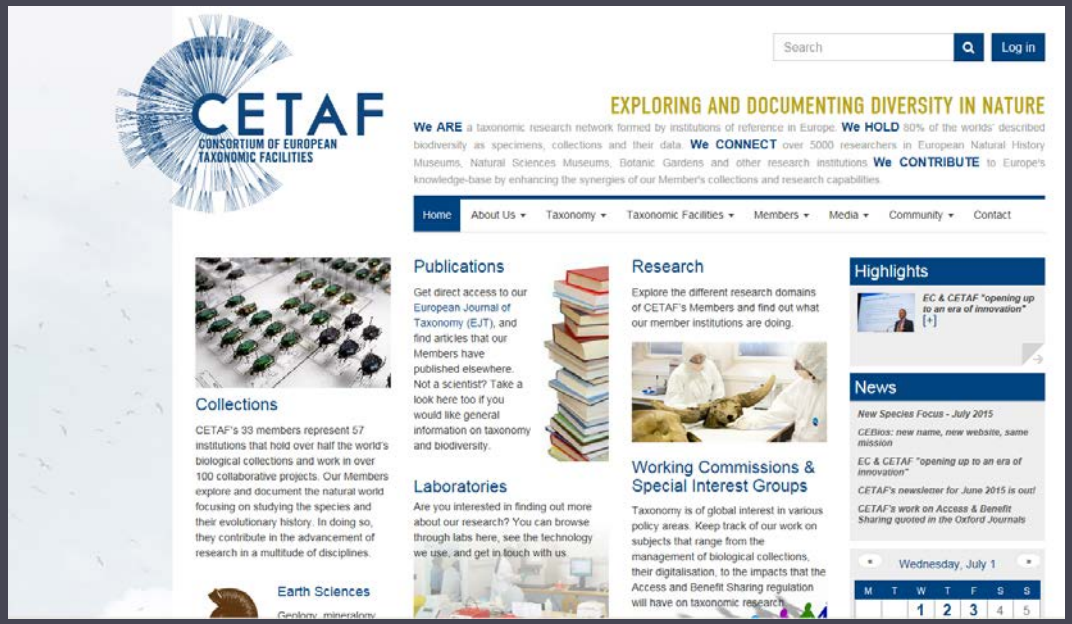
More information

- Nagoya Protocol, official webpage http://www.cbd.int/abs
- European Commission‘s webpage: http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm
- IUCN „An explanatory guide to the Nagoya Protocol on access and benefit-sharing” http://www.iucn.org/news_homepage/events/cbd/work/the_nagoya_protocol/?uPubsID=4763
- Information Portal of the Swiss Academy of Sciences, especially for non-commercial academic researchers http://abs.scnat.ch/
- for German speakers:
  - Federal Agency for Nature Conservation (BfN): http://abs.bfn.de
  - Our Project Homepage: www.globalnature.org/ABS-Deutschland

Acknowledgements

Thanks to

- Conny Löhne (ZFMK)
- ABS Core Group of CETAF
- All other members of CETAF who shared information and material on ABS



Links to legislation and official info:

- Nagoya Protocol - official webpage including full text: http://www.cbd.int/abs
- EU Regulation on ABS – European Commission‘s info page: http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm
- ABS Clearing House: https://absch.cbd.int/ (official info portal on the Nagoya Protocol, unfortunately not fully up-to-date)

Further reading on ABS:

- IUCN „An explanatory guide to the Nagoya Protocol on access and benefit-sharing” http://www.iucn.org/news_homepage/events/cbd/work/the_nagoya_protocol/?uPubsID=4763
- Cabrera Medaglia, Perron-Welch & Philipps (2014): Overview of National and Regional Measures on Access and Benefit-Sharing – Challenges and Opportunities in Implementing the Nagoya Protocol. Third Edition. CISDL Biodiversity & Biosafety Law Research Programme. 125 pages [http://www.cisdl.org/aichilex/files/Global Overview of ABS Measures_FINAL_SBSTTA18.pdf]

Guidelines / Codes of Conduct for Researchers

- CETAF Code of Conduct and Best Practice on ABS: http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf (CETAF = Consortium of European Taxonomic Facilities, the umbrella organisation of natural history museums and similar research institutions)
- GGBN Code of Conduct and Best Practice on ABS: http://www.ggbn.org/docs/ABS_Guidance/GGBN Guidance _Best_Practice_June_2015-Final.pdf (GGBN = Global Genome Biodiversity Network, an umbrella organisation for biobanks and similar facilities)
- Information Portal of the Swiss Academy of Sciences, especially for non-commercial academic researchers http://abs.scnat.ch/