Access and benefit sharing according to the Nagoya protocol – what does it mean for marine biotech?

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Outline:

1.ABS: the CBD and the Nagoya Protocol
2.Practical guide
3.EU ABS Regulation
4. Novelties in Horizon2020

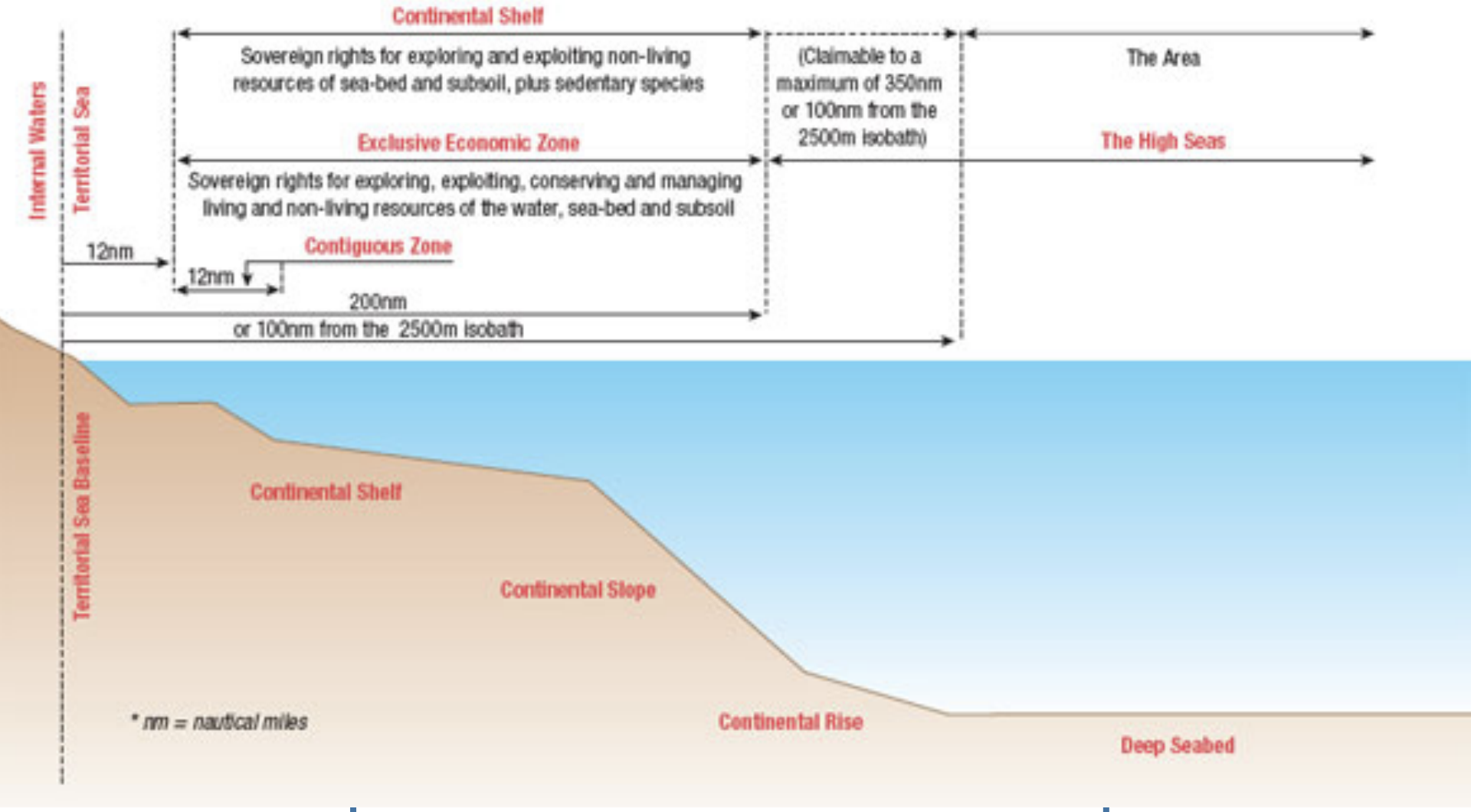
ABS - Sovereignty

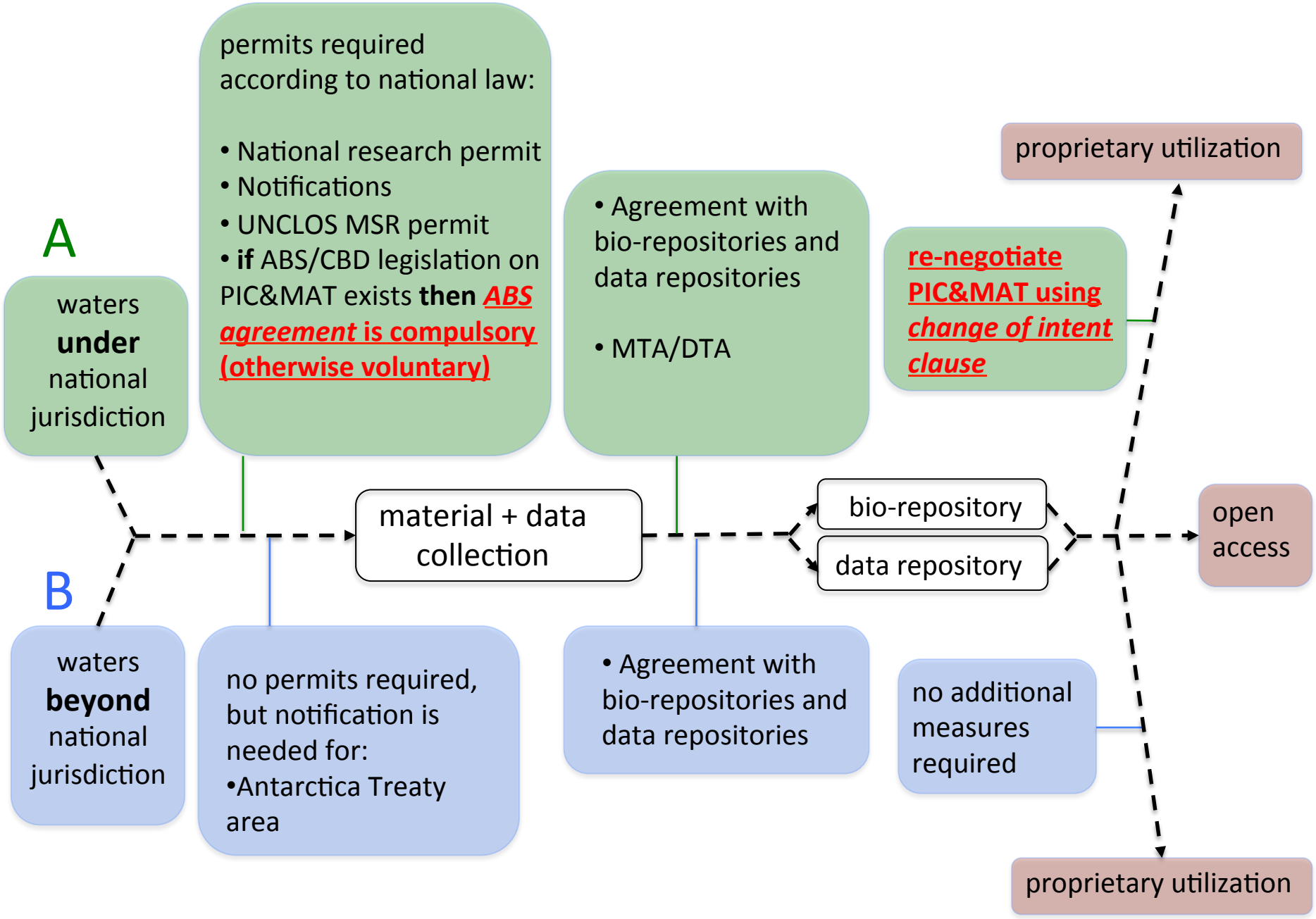
- ✓ States **sovereignty** over natural resources – right to determine access to them
- ✓ Convention on Biological Diversity 1992 – Nagoya Protocol 2010: **access** to genetic resources (GR) and **share of the benefits** coming from their utilization
- ✓ At the moment few states have ABS legislation in place: in the process of adopting them
- ✓ Nagoya Protocol in force: States have to take user measures to ensure compliance with ABS domestic legislation

Keys definitions

- ✓ Every activities of utilization of genetic resources trigger the application of the Nagoya Protocol and the EU ABS Regulation
- ✓ **Genetic material**: containing functional units of heredity
- ✓ **Genetic resources**: genetic material of actual or potential value
- ✓ **Utilization**: R&D on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology
- ✓ **User**: any natural or legal person utilizing GR or associated TK (EU Regulation)

UNCLOS: Maritime Zones based on sovereignty and jurisdiction




A
waters **under** national jurisdiction
permits required according to national law:
• National research permit
• Notifications
• UNCLOS MSR permit
• **if** ABS/CBD legislation on PIC&MAT exists **then** ***ABS agreement* is compulsory (otherwise voluntary)**
• Agreement with bio-repositories and data repositories
• MTA/DTA
re-negotiate PIC&MAT using *change of intent clause*
proprietary utilization
material + data collection
bio-repository
data repository
open access
B
waters **beyond** national jurisdiction
no permits required, but notification is needed for:
•Antarctica Treaty area
• Agreement with bio-repositories and data repositories
no additional measures required
proprietary utilization

National ABS legislations: ACCESS *IN SITU*

A

No ABS legilation in place: No regulation – no permit required

B

ABS legislation: no permit required (Denmark and the Netherlands for example)

C

ABS legislation: ABS requirements – Negotiation of PIC and MAT

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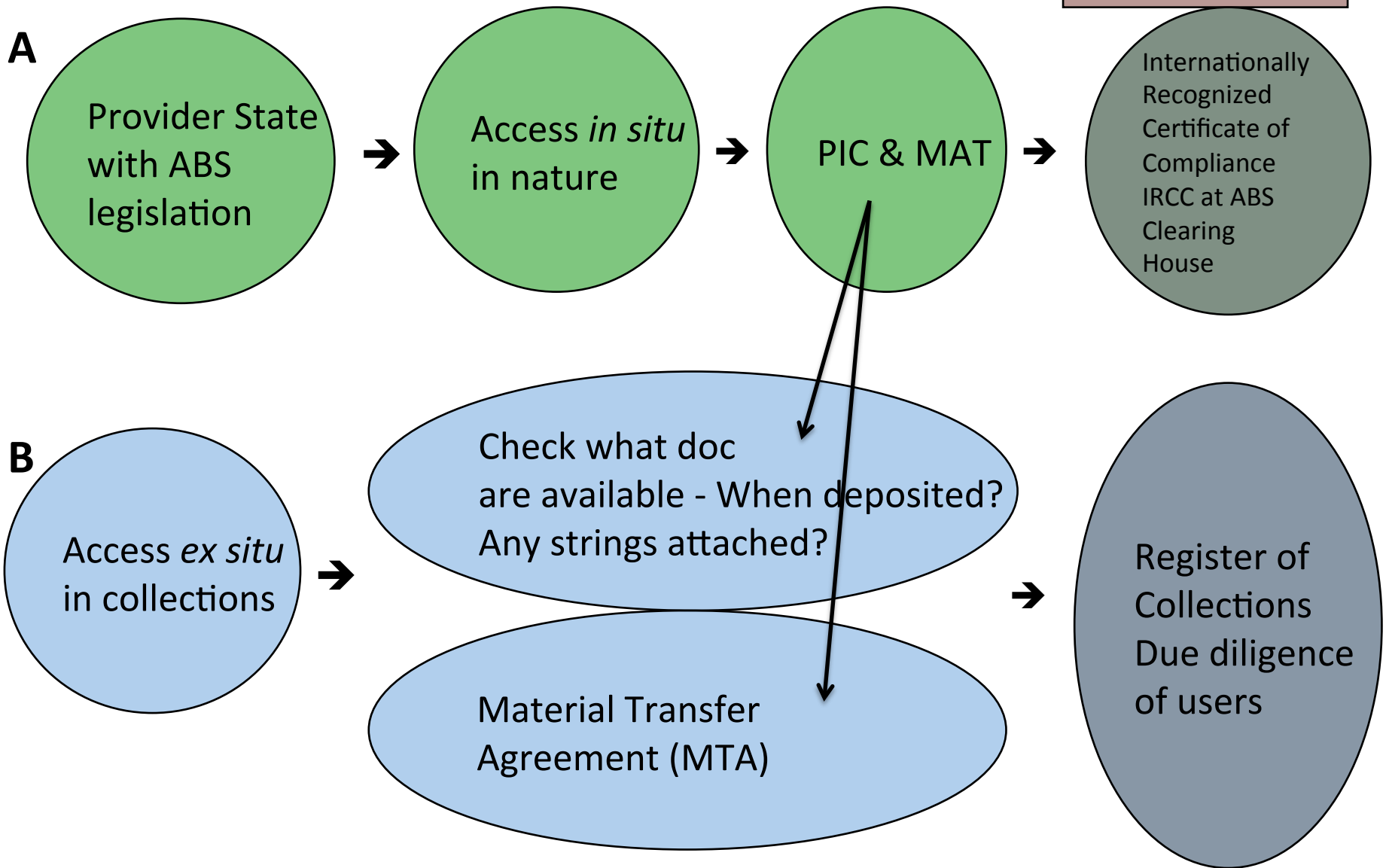
Nagoya Protocol: International Recognised Certificate of Compliance At ABS Clearing House

EU Regulation: user has to exercise due diligence

Different types of ACCESS

CBD implementation

Nagoya Protocol and EU Regulation



EU ABS Regulation

- ✓ To ratify the Nagoya Protocol, then MS have to ratify
- ✓ It applies only to GR and TK to which the Nagaya Protocol applies: **no retroactivity**
- ✓ But check for previously adopted legislations: CBD and national legislations apply
- ✓ **It does not regulate access to GR within the EU but Member States might do it** (France for example)
- ✓ It prescribe **user measures**
- ✓ Safeguards for **confidentiality** and essential interests of security

User measures within the EU ABS Regulation (art.4)

- ✓ Exercise **DUE DILIGENCE**: seek, keep (for 20 years) and transfer to subsequent user the IRCC and info on MAT
- ✓ If it is not available seek, keep and transfer minimum dataset of information:
  - Date and place of access
  - Description of GR and TK
  - The source and subsequent users
  - Rights and obligations
  - Access permits – MAT
- ✓ In cases of uncertainty/insufficient info the user has to obtain a permit **or discontinue utilization**

User measures within the EU ABS Regulation

- ✓ Users have two checkpoints: recipients of research funding + at **the stage of final development of a product** – due diligence declaration to the Competent Authorities + IRCC has to be produced (art.7)
- ✓ Competent authorities can do "effective, proportionate and dissuasive **checks**" (art.9): in case of concerns provided by third parties or provider country – interim measures, **penalties** (national)
- ✓ Safeguard for **confidentiality**
- ✓ The Regulation is in force but the core obligations (user measures – monitoring and check compliance) will be in force after a year of entry into force of the NP for the EU

Register of collections and Associations of Users

- ✓ **Register of collections**: MS applies and the EC decide
- ✓ Criteria: apply standards procedures – keep records – transfer permits – use unique identifiers – track and monitor
- ✓ Consequence: users obtaining from these collections are considered to have exercised due diligence
- ✓ **Associations of Users**: recognition of best practices reduces users' risk of non-compliance, less likely to be checked

Codes of conducts: research and industrial

- ✓ Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), Transparent User Friendly System of Transfer for Science and Technology (TRUST) Project;
- ✓ International Plant Exchange Network (IPEN);
- ✓ Consortium of European Taxonomic Facilities (CETAF)
- ✓ Global Genome Biodiversity Network (GGBN);
- ✓ Guidelines by the Members of the Biotechnology Industry Organization;
- ✓ Guidelines for International Federation of Pharmaceutical Manufacturers and Associations Members (IFPMA);
- ✓ Association of European Self-Medication Industry (AESGP).

Steps for collectors

0. Involve your boss/director of the institution where you work:
1. Check in which maritime zone you are going to sample

In areas within national jurisdiction:

2. Contact the CBD National Focal point and/or the NP CNA and ask what are the requirements of the legislation (if any is in place)
www.cbd.int/information/nfp.shtml
3. If the legislation requires for PIC and MAT start negotiation
4. Negotiate on the basis of a widely accepted standards agreement (Micro B3?!)
5. Communicate to the
6. Access, use and transfer the material only **in accordance with the requirements set out in the permit and/or the ABS agreement**

- **OTHERWISE**: go back to the relevant authorities of the Provider State and **renegotiate**.

EU funded projects: HORIZON2020

- Ethics issues checklist – Session 3 – Third parties

  If animals, plants, micro-organisms and associated traditional knowledge are involved, documentation demonstrating compliance with the Convention on Biodiversity (e.g. access permit and benefit sharing agreement)

  As above (use of local resources) and narrative document describing benefit sharing, responsiveness to local research needs and capacity building.

- **"Commentary to Micro B3 ABS Model Agreement"** Von Kries, C.; Broggiato, A., Dedeurwaerdere, T.; Winter, G. available at http://microb3.eu/news/commentary-micro-b3-abs-model-agreement
- **"A Model Agreement for ABS of Non-commercial and Commercial Research concerning Marine Microorganisms: the MicroB3 Experience."** Von Kries, C.; Broggiato, A., Dedeurwaerdere, T.; Winter, G. – in Genetic Resources and Traditional Knowledge: Research Cooperation and Facilitated Access. Chege Kamau, E.; Stoll, PT.; Winter, G.; forthcoming, 2014.

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THANK YOU