Points to Consider for ABS Agreements

The Model Agreement of the EU funded MicroB3 Project

ABS informal EU Expert Meeting
Advancing together on Nagoya Protocol implementation
and preparing the COP/MOP1 (13-17 PyeongChang)
Roma, 4-5 September 2014

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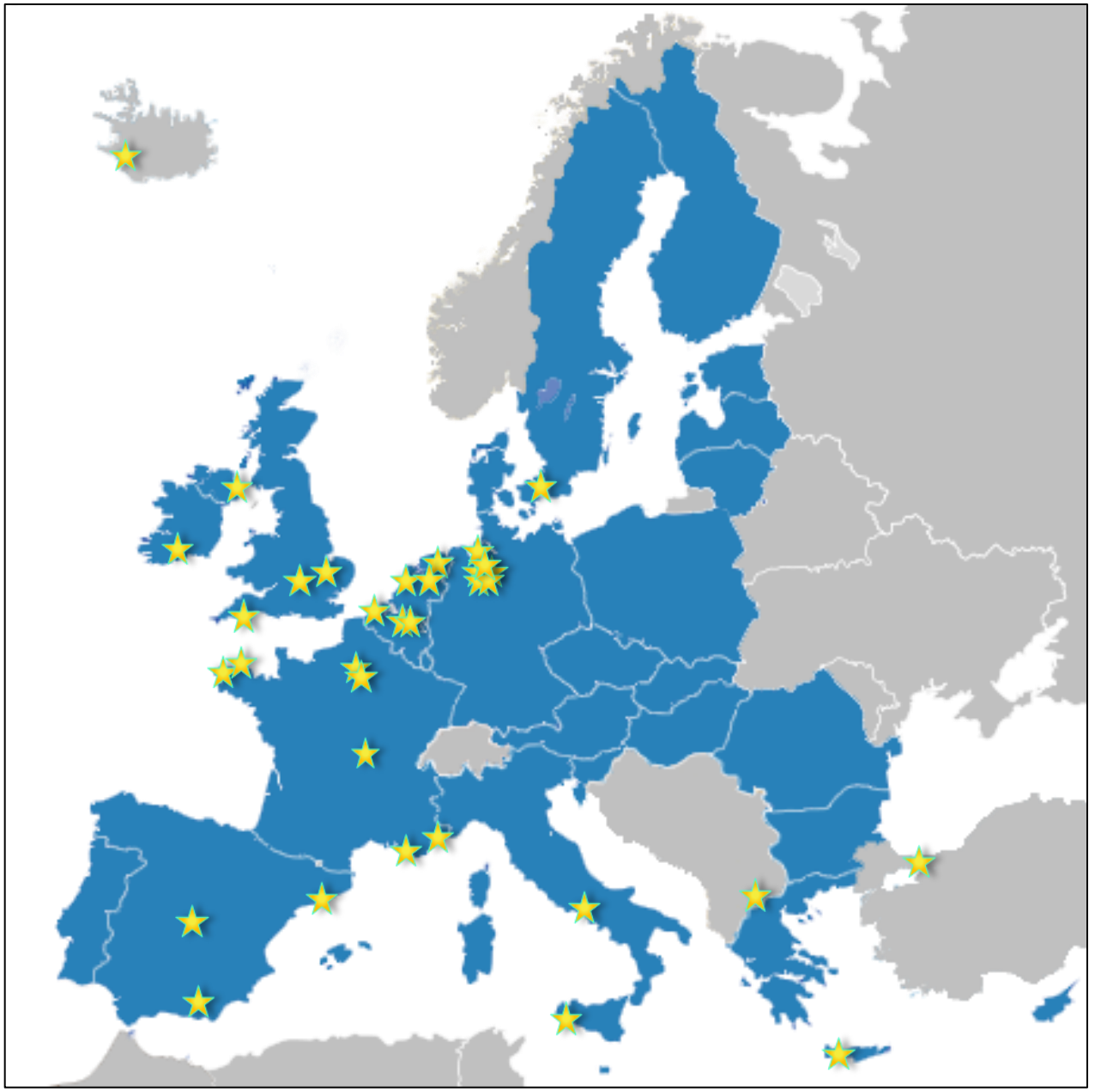
MicroB3 Project

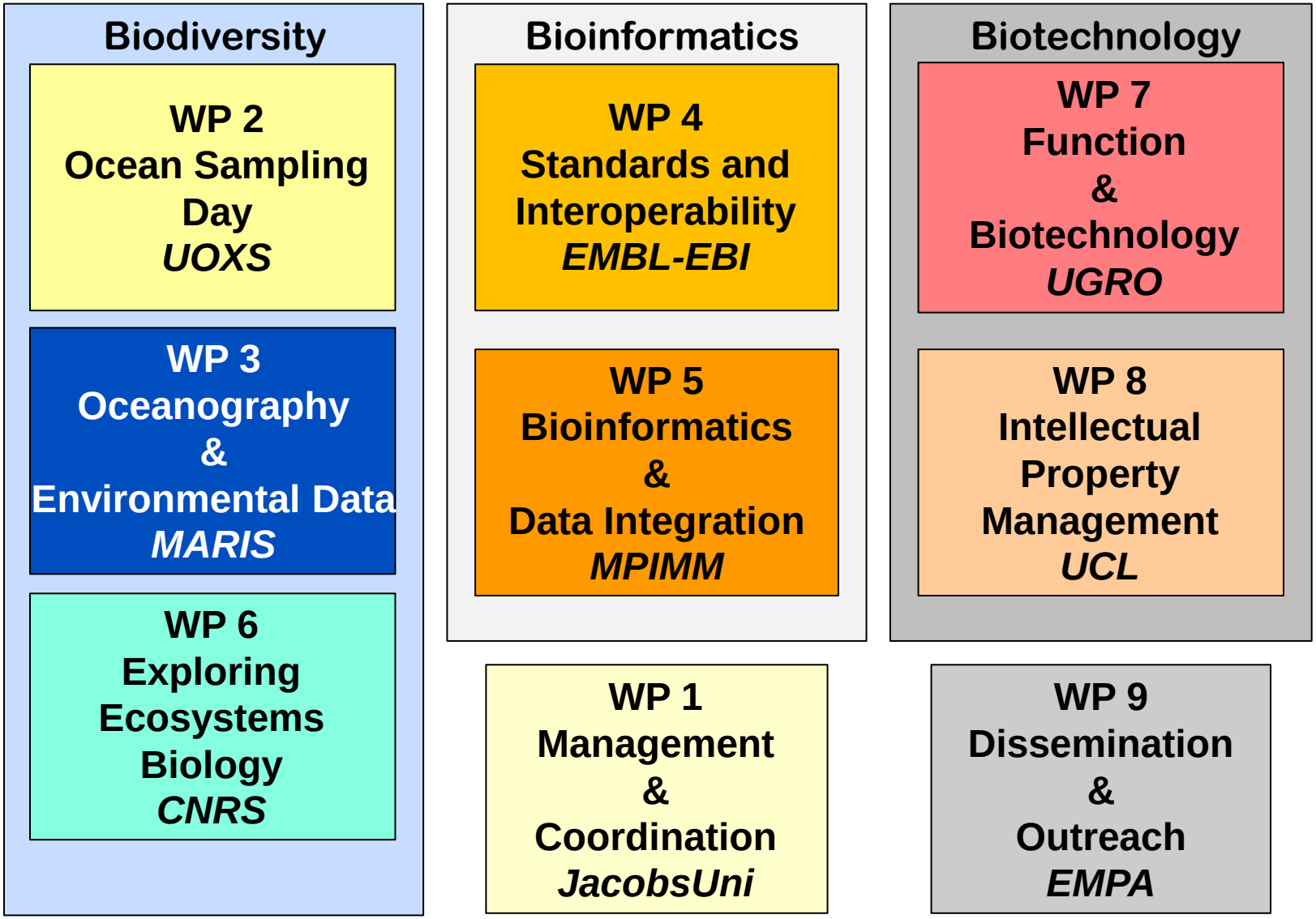
- Research on Marine Microbial Biodiversity, Bioinformatics, Biotechnology
- 32 European partner institutions, more associated world wide
- lead by Max Planck Institute for Marine Microbiology Bremen
- Scientists, information scientists, social scientists, lawyers

Total:
32 partners

Start:
1 January 2012

Duration:
4 years

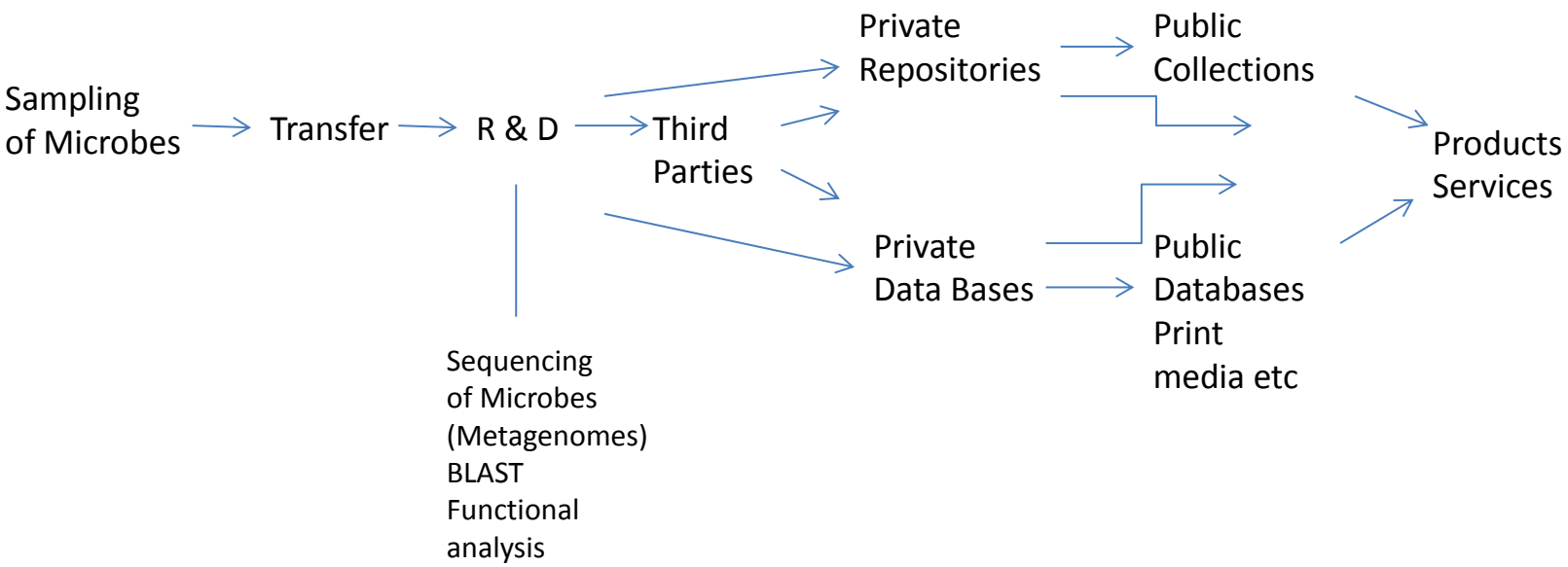




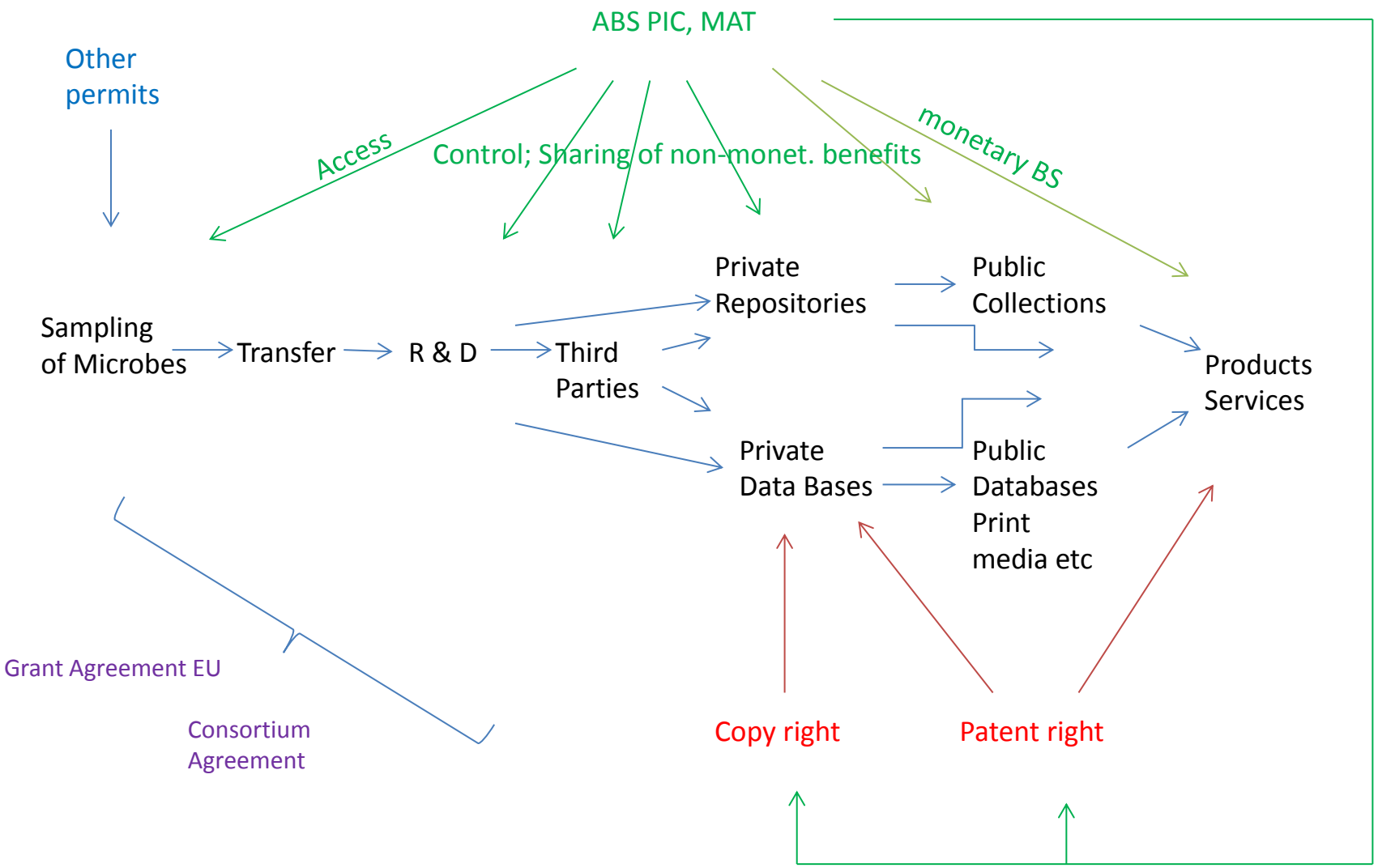
Involvement of stakeholders as partners, esp. companies

PharmaMar, MATIS, BIO-Iliberis, Bio-Prodict, Interworks; IUCN, CIESM

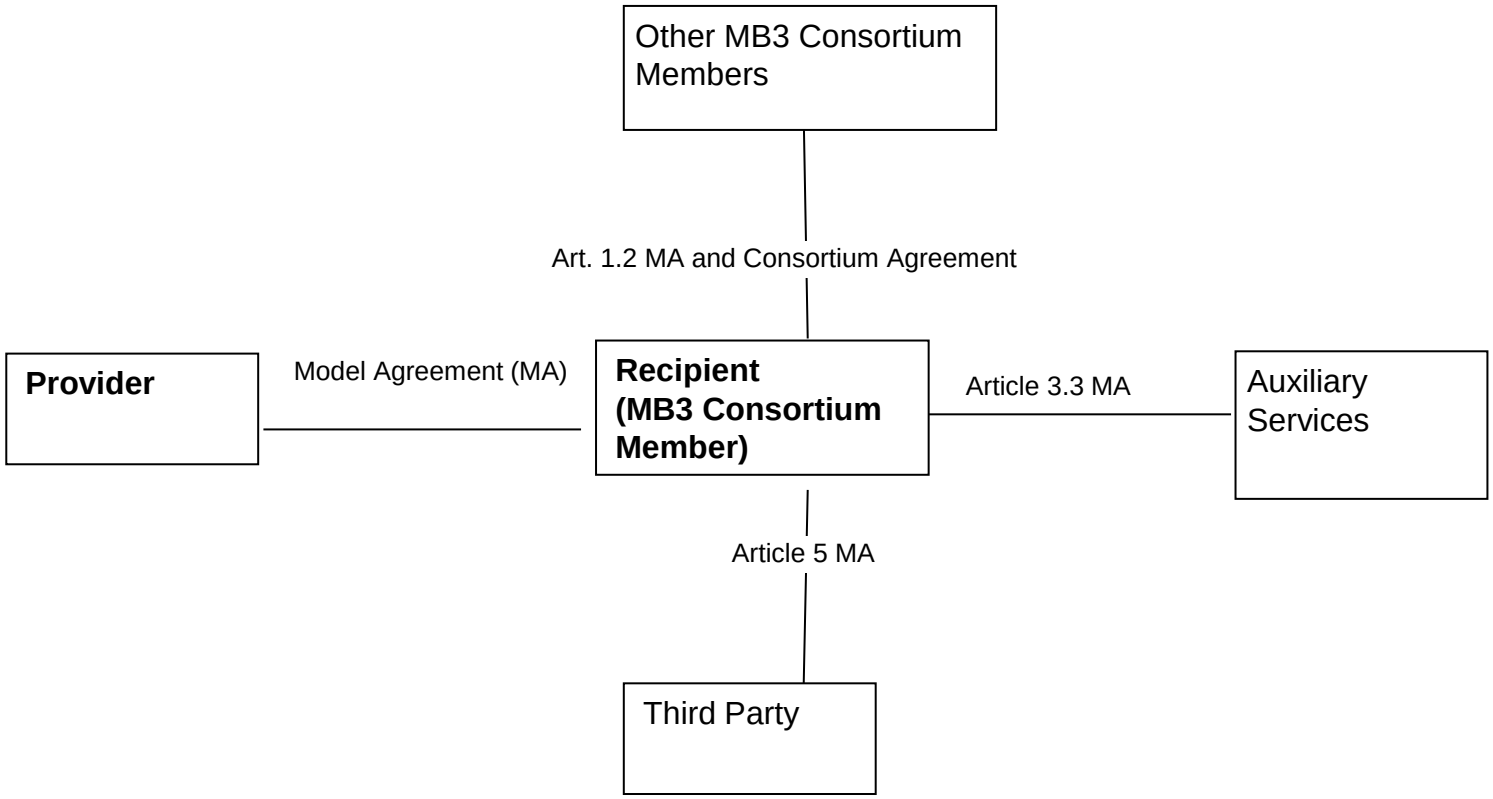
MicroB3 R&D Process



Legal instruments framing the project



Multiple actors
example MicroB3 project



Scope of the model agreement

- Genetic resources – microbes, not eg traditional knowledge
- Sampling – not eg purchase, taking from collection
- Access for utilisation (= R&D on GR) – not for consumption or bulk use
- Territorial Sea and EEZ => provider is the coastal state
- Provider having established access regime => many EU states have not (yet?)
- Not captured by exemption clauses, such as
  - Local/traditional uses
  - Education
  - ITGRFA
  - Emergencies
  - Basic taxonomic research

Form of access agreements

- Contract
  - = MAT, if including export of GR: MTA
  - along with permit (= PIC)
  - PIC contained in contract
- To be concluded between organisation of researcher and competent authority
- Possibly alongside with other permits/contracts required by legislation on research, environment, export etc; landowner‘s consent

  => problem of streamlining (one stop shop, removal of consent requirements) due to obligation of provider state
    - to facilitate access for non-commercial research
    - to ensure legal certainty (clarity, transparency of conditions)

Content of access agreements

- General strategy for negotiations:
  - Find a way between becoming too specific and too general
  - Understand the provider state‘s concerns
    - biopiracy, non-monetary benefits, etc
  - MicroB3 approach: intended to be balanced, even addressing issues that provider states have as yet not asked for, eg re data management
- Determination of sample, location, time
  - determination of organisms after sampling => two-step procedure (**see example**)

Stepwise identification of GR (MicroB3)

Art. 3

3.2 The Recipient shall within … [weeks] after collection of the samples notify to the Provider the kinds of genetic resources the Recipient intends to utilize. The Provider may, within … [weeks], raise objections in which case the Parties will seek agreement on the kinds of genetic resources allowed to be utilized.

Content of access agreements

- General strategy for negotiations:
  - Find a way between becoming too specific and too general
  - Understand the provider state‘s concerns
    - biopiracy, non-monetary benefits, etc
  - MicroB3 approach: intended to be balanced, even addressing issues that provider states have as yet not asked for, eg re data management
- Determination of sample, location, time
  - determination of organisms after sampling => two-step procedure (see example)
- Determination of allowed R&D:
  - Location (in-country, transfer to other user country)
  - kinds of R&D
  - non-commercial/commercial (**see example)**
  - change of R&D intent from non-commercial to commercial by user or provider (see example)

Definition of R&D for non-commercial/ commercial purposes (MicroB3)

Art. 2

J) Utilization for proprietary purposes means research and development that aims at protecting the associated knowledge, including products and processes developed, by patent rights, keeping the resulting knowledge secret, making the resulting knowledge accessible at more than incremental costs for dissemination and/or bringing the products and processes developed from the accessed genetic resources on the market.

k) Utilization for the Public Domain means research and development that aims at making the associated knowledge, including products and processes developed, publicly available at no more than incremental costs for dissemination, and without being protected by patent rights or further restricted by other intellectual property rights.

Commercial/non-commercial intent (MicroB3)

4.2 The utilization of the accessed genetic resources shall be for the public domain.

Specifications, if deemed necessary

_____

(to be crossed out if not applicable)

4.3 The Recipient shall be entitled to utilize part/all (please cross out) of the accessed genetic resources for proprietary purposes:

Specifications, if deemed necessary:

_____

(to be crossed out if not applicable)

Content of access agreements

- General strategy for negotiations:
  - Find a way between becoming too specific and too general
  - Understand the provider state‘s concerns
    - biopiracy, non-monetary benefits, etc
  - MicroB3 approach: intended to be balanced, even addressing issues that provider states have as yet not asked for, eg re data management
- Determination of sample, location, time
  - determination of organisms after sampling => two-step procedure (see example)
- Determination of allowed R&D:
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  - kinds of R&D
  - non-commercial/commercial (see example)
  - change of R&D intent from non-commercial to commercial by user and/or provider (**see example**)

Change of intent (MicroB3)

4.4 Should the Recipient, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Recipient shall seek the consent of the Provider.

Specifications of the consent procedure, if deemed necessary:

_____

_____

4.5 Should the Provider, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Provider shall enter into amicable negotiations with the Recipient on the modification or termination of this agreement.

Content of access agreements

- Cooperation in R&D (= non-monetary benefit)
  - MA/PhD candidates
  - Joint authorship
- Transfer of material to third parties; „viral clause“ (**see example**)

Transfer of material to third parties (MicroB3)

5.1 The Recipient may transfer to a third party the accessed genetic resources, or parts of them, provided that the third party agrees with the Recipient, to apply to the transferred genetic resources Articles 4 to 16 of this agreement.

Content of access agreements

- Transfer of material to third parties; „viral clause“ (see example)
- Data management
  - If R&D results are for proprietary purposes and researcher wants to transfer it to third parties: „viral clause“ (**see example**)

Transfer of data to third parties (MicroB3)

5.2 If the Recipient intends to transfer to a third party the associated genetic knowledge which is not yet or shall not be submitted to the public domain according to Article 6, the third party shall agree with the Recipient, to apply to the transferred knowledge Articles 4 to 16 of this agreement.

Content of access agreements

- Transfer of material to third parties; „viral clause“ (see example)
- Data management
  - If R&D results are for proprietary purposes and researcher wants to transfer it to third parties: „viral clause
  - If R&D results are for the public domain; esp. data submitted to public data bases => possibility that users of data bases utilize the data for proprietary purposes => provider may want to control this with aim of benefit sharing => challenge for public data bases
    - Traceability of origin in data bases => ensured in MicroB3 data base, but not in global data bases (eg Gene Bank)
    - Come back clause for commercial uses (**see example**)

Knowledge for the public domain (MicroB3)

6.3 The Recipient shall make reasonable efforts to ensure that the release of associated genetic knowledge through online media, print media or delivery upon request will be organized such that users are bound not to use the associated genetic knowledge taken from the portals for proprietary purposes unless they have obtained prior informed consent of the Provider.

Content of access agreements

- Transfer of material to third parties; „viral clause“ (see example)
- Data management
  - insufficiently addressed by model agreements
  - Keeping R&D results private between researcher and provider? (= non-monetary benefit)
  - Obligation to feed into public domain? (= non-monetary benefit)
    - Tracing origin of GR/TK
      - Notice in publication
      - Traceability in data bases => challenge for public data bases?
    - Control of commercialising utilisation of data
      - Disclaimer for data input
      - Come back clause for commercial uses => challenge for public data bases (see example)
- Management of final products/ services (see example)
  - Duty of sharing of monetary benefits from patents, products, services
  - Definition of causality GR – products: Share in product? „Exhaustion“ ?
  - Fixing percentage of return? Upfront payment?
  - Come back clause (**see example**)

Sharing of monetary benefits (MicroB3)

11.2 If the Recipient utilizes the accessed genetic resources or uses the associated knowledge for proprietary purposes according to Articles 4.3 and 4.4, it must fairly and equitably share with the Provider any monetary benefit obtained.

11.3 The share shall be determined by further negotiations between the Parties to this agreement.

11.4. (Alternatively to 11.3) The share shall be _____percent of the revenue from sales of the product or process based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the Provider or an authority designated by the same at the end of any year of any revenue generation to the account designated by the same.

Conclusion

Sceptical note:

- Access agreements aiming to control the entire R&D process may have counterproductive effects
  - Retrenchment of non-commercial R&D process through bureaucratic hurdles, limitations, reporting duties, preconditions for publication
  - Frustration of provider states because of impossibility to in fact control the process
  - Commercial R&D may avoid to use natural GR => impoverishment of gene pool
  - Public data bases may refuse to control input as to conditions, ensure traceability of data to origin, and prevent commercialisation of output
- Luckily, most MicroB3 partners have no access regime in place; the model agreement only used by a few (Ireland, Norway): a desirable disappointment
- My suggestion:
  - No access regime except
    - as a leverage for sharing of non-monetary benefits, but only if support of domestic research necessary
    - as a leverage for sharing of monetary benefits only concerning highly valuable GR promising short term and substantial revenue
  - Otherwise: no access regime; preferable: multilateral agreement introducing biodiversity tax on products and services based on GR or TK

MicroB3 model agreement accessible at
http://www.microb3.eu/news/commentary-micro-b3-abs-model-agreement

Coauthors: Caroline von Kries, Arianna Broggiato, Tom Dedeurwaerdere

Further reading

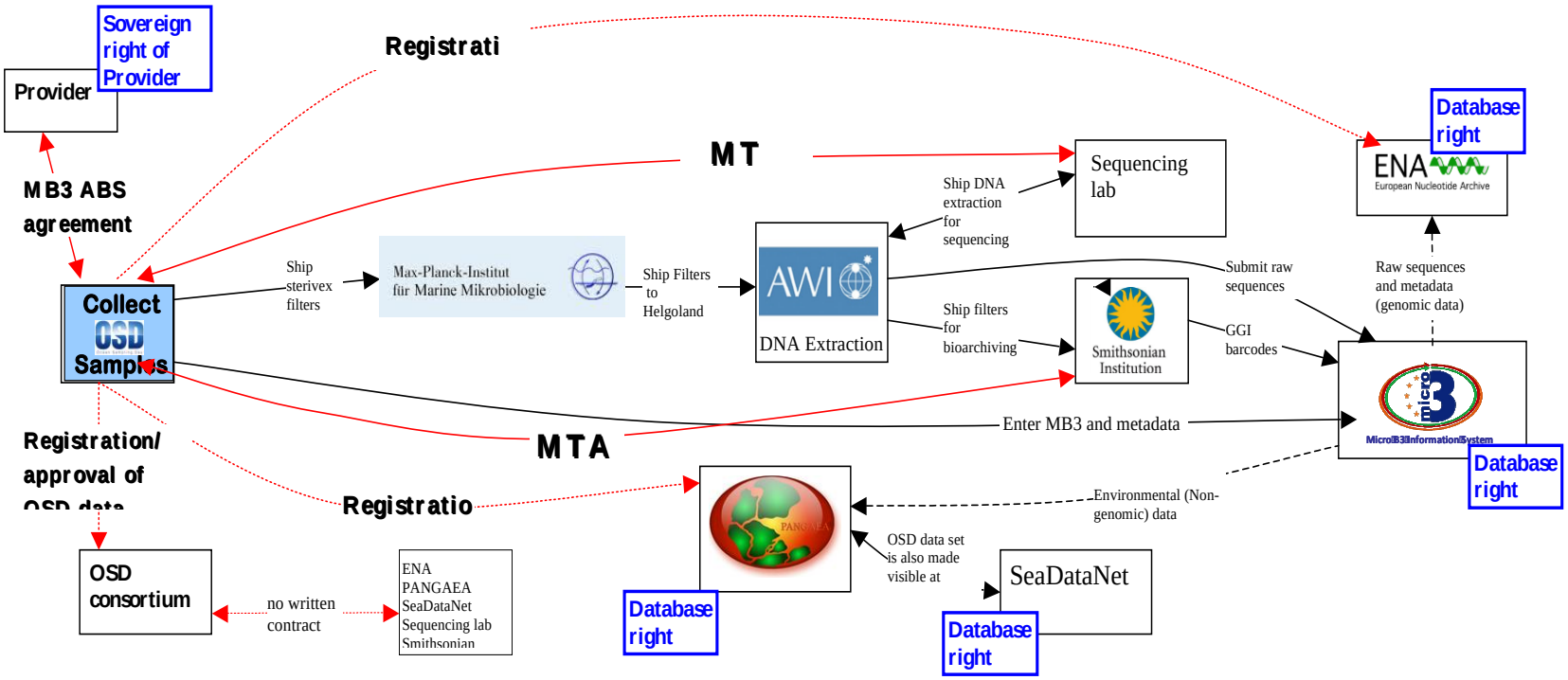
Evanson Chege Kamau, Gerd Winter (eds) Common Pools of Genetic Resources, Routledge 2013

Evanson Chege Kamau, Peter-Tobias Stoll, Gerd Winter (eds) Genetic Resources and Biodiversity Research Cooperation: Public Domain Approaches in Implementing the Nagoya Protocol, Routledge, forthcoming

Thank you for attention

Micro B3 / OSD Research Pipeline (1)

(Caroline von Kries, Micro B3, WP 8, 13 02 14)

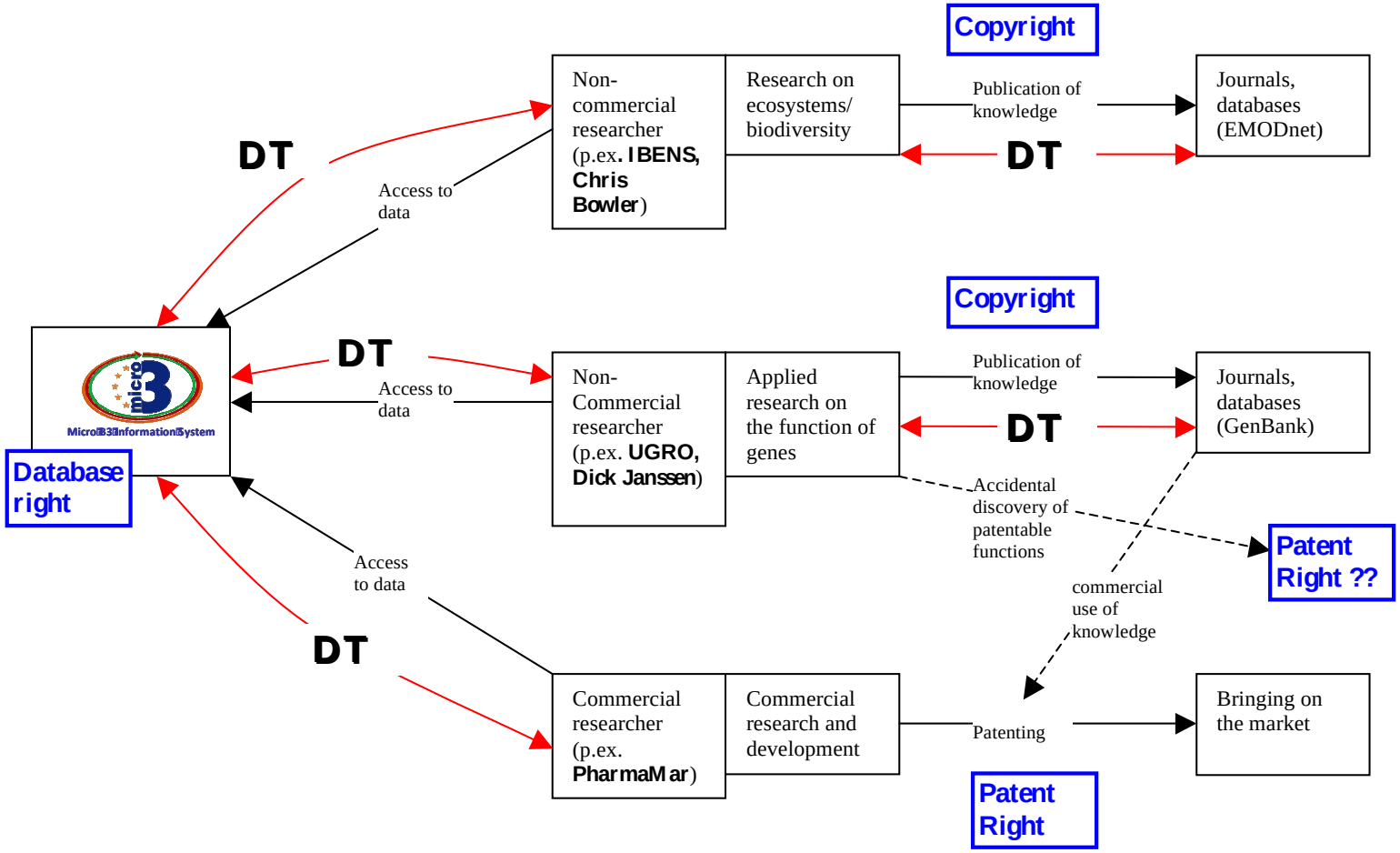


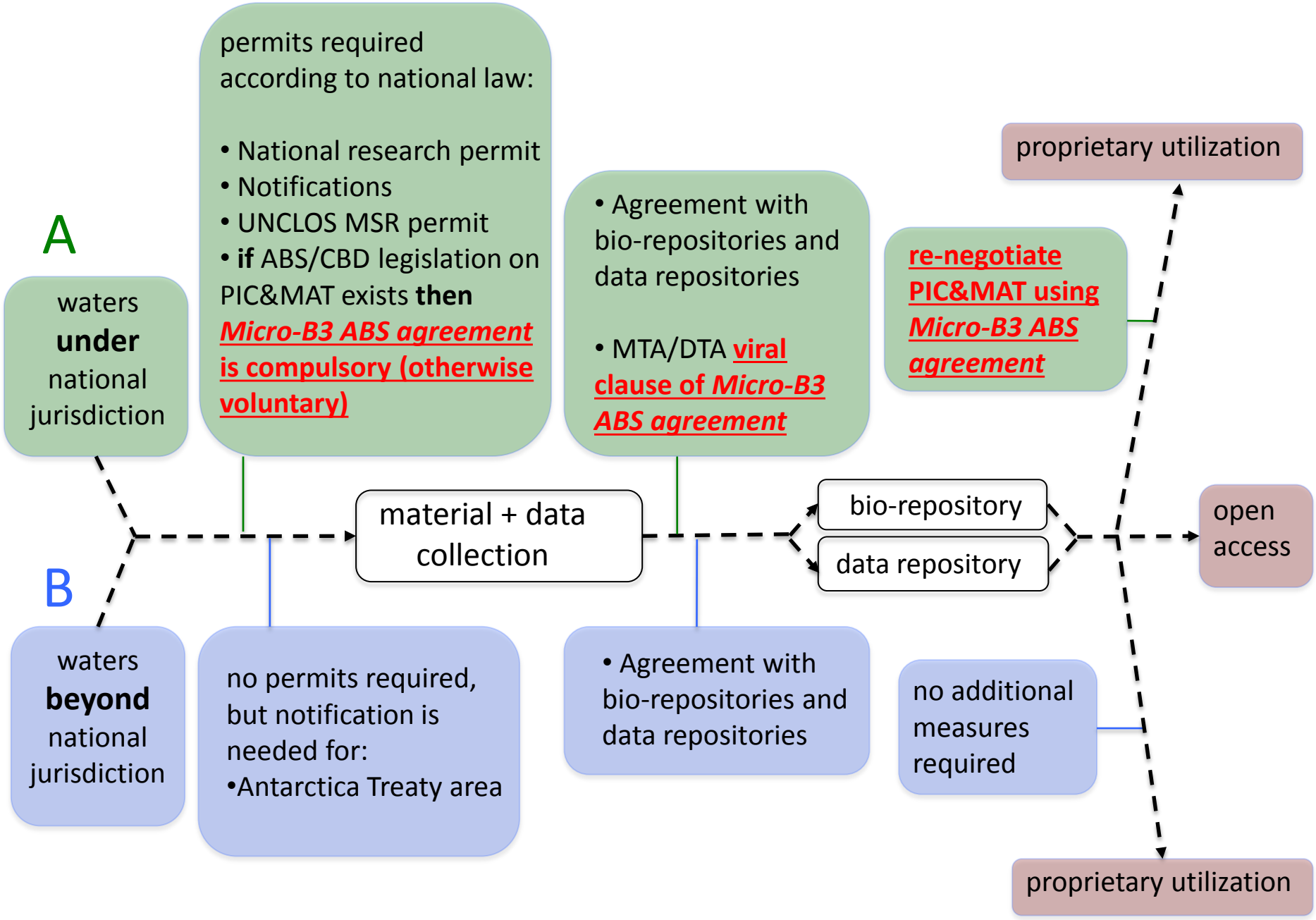
Legend:

MB3-IS: *Micro B3 Information System* (megx.net ist a web site for specialized *georeferenced databases and tools* for the analysis of marine bacterial, archaeal, and phage genomes and metagenomes)
AWI: Alfed-Wegener-Institut
SI NMNH: Smithsonian Institution for the National Museum of Natural History
ENA: European Nucleotide Archive ("third party")
PANGAEA: Data publisher for Earth and Environmental Science, Open access library ("Third party")
SeaDataNet: Pan-European Infrastructure for ocean&marine data management
OSD: Ocean Sampling Day

Micro B3 / OSD Research Pipeline (2)

(Caroline von Kries, Micro B3, WP 8, 13 02 14)




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** ***Micro-B3 ABS agreement*** **is compulsory (otherwise voluntary)**
• Agreement with bio-repositories and data repositories
• MTA/DTA **viral clause of *Micro-B3 ABS agreement***
re-negotiate PIC&MAT using *Micro-B3 ABS agreement*
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
ABS
INTERESTS
MICRO B3 AGREEMENT
IPRs