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Multi-stakeholder expert workshop for validating the IP model agreements for pre-competitive access

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Summary

This report gives the context and key outcomes of a two-day Micro B3 multi-stakeholder workshop which considered the interface of open access-based data-management, access and benefit-sharing (ABS) under the Nagoya Protocol to the Convention on Biological Diversity (CBD), and the promotion of pre-competitive scientific research. During the workshop ABS policy-makers, representatives from research funding agencies and the scientific community discussed amongst others issues of data tracking and traceability; advantages and disadvantages of different public domain approaches; incentives and disincentives for data-sharing as well as necessary institutional infrastructures; or the idea of a potential exhaustion of benefit-sharing rights of provider states. The following workshop report presents a detailed discussion of these findings. It also indicates that ABS implementation in practice does not only pose great challenges for the scientific community, but also provides an opportunity to further promote research through enabling conditions for more open access to research results.

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Introduction

On 25 and 26 September 2014, the Micro B3 multi-stakeholder workshop titled *"At the Crossroads of Open Access to Data with Access and Benefit-Sharing Requirements – Promoting Pre-competitive Scientific Research"* was jointly organized at Fondation Universitaire in Brussels by the IUCN Environmental Law Centre, the Université catholique de Louvain, the University of Bremen, the Mediterranean Science Commission and the Environmental & Marine Project Management Agency (see the workshop program in Annex I).

The workshop took place in the context of Task 8.2 of the Micro B3 project, which deals with intellectual property (IP) model agreements for pre-competitive access to microbial research materials and microbial genomic research databases. During the preparations for this multi-stakeholder workshop (Task 8.2.3), Work Package 8 partners decided to approach this issue in combination with a consideration of the latest discussions on open access-based data-management under the access and benefit-sharing (ABS) regime of the Nagoya Protocol to the Convention on Biological Diversity (CBD). This broad approach to the issue of ABS was considered timely because

1. the Nagoya Protocol was about to enter into force in October 2014, thus shortly after the Micro B3 workshop;
2. large amounts of data, easy to be generated due to the revolution in high-throughput sequencing, are creating novel Omics databases whose legal status under the Nagoya Protocol has not yet been sufficiently discussed; and
3. wider access to gene synthesis enables the reverse path from data back to genetic material, an issue providing potential options in view of monitoring ABS compliance.

The Micro B3 multi-stakeholder workshop brought together 23 participants including ABS policy-makers, representatives from research funding agencies and the scientific community. Experts from three other research consortia were also attending: PharmaSea, MIRRI and Oceanomics (for a complete list of participants, see Annex II). The main objectives of the workshop were to inform and discuss

- different scenarios of data flow associated with genetic material that was accessed under the scope of the Nagoya Protocol;
- the importance of open access to marine, environmental and genomics data for pre-competitive research in order to facilitate dissemination and further analysis of such data and to fully unlock its scientific potential;
- the need for clear regulation of data access and transfer, as well as related benefit-sharing in ABS agreements at the point of access to genetic material; and

- possible options for managing data further downstream in the research and development chain in line with international obligations established by the Nagoya Protocol.

In this context, three Micro B3 ABS tools developed under Work Package 8 were presented and analysed:

- an Open Access Data Policy which covers the collection, storage, analysis and publication of data generated in relation with the Ocean Sampling Day (OSD);
- an ABS Model Agreement which aligns access agreements between provider states and collectors with the Open Access Data Policy; and
- a suggested ABS Disclaimer for databases storing and sharing the pre-competitive data derived from the Ocean Sampling Day.

These tools aim to provide a set of balanced and simple rules for fostering maximum utilization of research results and at the same time ensuring compliance with the Nagoya Protocol.

As an output of the workshop IUCN in collaboration with other Micro B3 partners, will deliver a policy brief on the crossroads of open access to data with ABS, as well as on ways to promote pre-competitive scientific research in line with Article 8(a) of the Nagoya Protocol. (Deliverable 8.5)

Workshop Proceedings

The workshop was organized over 1,5 days and structured in three different parts (see the agenda in Annex III):

Part I

Introduction to Micro B3

Part one (morning of day one) started with an introduction to the Micro B3 project. Being a part of Micro B3 the Ocean Sampling Day was presented as the world's first simultaneous mega-sequencing campaign with more than 180 sites around the globe. OSD is planned to deliver cumulative samples related in time, space and environmental parameters which shall provide insights into fundamental rules describing microbial diversity and function, as well as a reference data set for future experiments. It is expected to result in a huge amount (terabytes) of data comprising sequencing data as well as contextual data (metadata). The sequencing data will lead to the digitalization of the sampled material which allows their unlimited copying and sharing even when the physical material is gone. The OSD metadata contains different sets of environmental data which is a prerequisite for future research and analysis of the samples and their sequencing data; in other words, without the necessary environmental data sequencing data is more or less useless. Furthermore, it was noted that physical (sequencing) and contextual (environmental) data need to be differentiated from ABS data (i.e. information on necessary ABS permits). Having all permits such as ABS permits in place was mentioned as a requirement for OSD participation.

The workflow of OSD was then described as follows: sampling, shipping of filters together with associated data, DNA release, sequencing, data integration and management. Furthermore, the OSD sample and data flows were explained: OSD samples go to a bio-archiving center (half of the sample goes to the Smithsonian for long-term archiving and future research); OSD oceanographic and biodiversity data goes to PANGAEA from where the oceanographic data is forwarded to SeaDataNet and the biodiversity data to EurOBIS; DNA goes to a sequencing center from where the sequence data is transmitted to ENA; all data is then integrated in the Micro B3 Information System.

Finally, an overview of different data analysis procedures at the Centre National de la Recherche Scientifique (CNRS), the European Bioinformatics Institute (EMBL-EBI), the Max-Planck-Institute for Marine Microbiology (MPI-MM) and Genoscope was given. Regarding the development of data it was highlighted that next generation sequencing is a game-changer. On the one hand costs and timing have dropped dramatically over the last three years and capacities therefore become more and more unlimited; on the other hand big data is now being developed which creates new opportunities but also challenges, such as appropriate data-management. As a response Micro B3 has focused on building appropriate bioinformatics tools.

Challenges and Opportunities of Data-Sharing

This introductory presentation was followed by two presentations highlighting the importance of data-sharing in scientific research. The presentation on *"Data-sharing: Challenges and Opportunities"* provided the context for data-sharing in microbiology and culture collections, as well as a technical and social perspective in this regard. It was explained that the World Federation for Culture Collections (WFCC) envisaged already in 1970 at its 10th International Congress for Microbiology the development of an international culture-data center, proving that data was early recognized as important for culture collections. The first directory of culture collections was then developed in 1972. It was further noted that in the same meeting in 1970 it was envisaged to distribute a world list of species held in culture collections in order to take stock of what was already held in the collections. The 1980s MINE project (Microbial Information Network Europe) was also mentioned which focused on structuring and computerizing strain data leading to the definition of minimum datasets and thereby building a basic link between microbiologic and ABS processes.

The presentation continued by explaining practical considerations around data-sharing which have to be taken into account when developing legal and policy frameworks. It was noted that a number of technical issues (machine factors) have to be considered, including communication (interface machine/human), compatibility (databases interoperability), as well as data storage and flow (cloud computing and big data). Regarding big data it was mentioned that in order to be usable big data must be reliable, accessible, comparable and exploitable. Mastering the overwhelming amount of data requires optimal data-material connection (error-free labelling), as well as sufficient data quality. Database curation was therefore recognized as a prerequisite.

In addition, social issues (human factors) were highlighted, such as the need for high quality input as a condition for high quality output (i.e. data quality starts at the bench, meaning the local level); capacity-building within the culture collection community regarding existing guidelines, best practices and standards; awareness-raising of microbiologists about the Nagoya Protocol. The importance of trust-building to facilitate cumulative research was raised requiring transparency and legal certainty (in ABS and IPR issues), "truth" (i.e. valid, reliable, true data), as well as lasting collaboration between partners. Finally, it was noted that technological costs have dropped while human costs have rather increased as the private sector is searching for bioinformatics experts.

Need for Openness and Informality

The following presentation on *"Openness and Informality"* commenced with an introduction to the chain of utilization noting that the value accumulates along this chain. The European Nucleotide Archive was presented as well as the terms of use of the EMBL-EBI. It was explained that the vast majority of datasets is freely available without restrictions. However, possible restrictions by a data provider (such as ABS obligations) are reflected, and tracking back the owner of data is possible.

The EMBL-EBI industry programme was then presented recognizing that open access to data could increase benefits. It was noted that pre-competitive innovation is early-stage research where competitors and partners share resources. The pre-competitive behavior in the pharma industry was explained highlighting that the costs for developing new drugs are increasing. Since financial resources are not infinite, the industry has adopted many pre-competitive initiatives.

The SNP Consortium (TSC) was mentioned as an example where an open access approach was taken, and the Pistoia Alliance as an example where pre-competitive data-sharing created enormous opportunities.

Finally it was distinguished between pre-publication and post-publication sharing of molecular data. Regarding the first case, the Bermuda, Fort Lauderdale and Toronto meetings and their voluntary codes of conduct were considered as very successful since their rules have mostly been followed. Regarding the latter, it was noted that all sequence-reporting journals state the need to report data to public repositories which provides informal, but strong social incentives.

Data under the Nagoya Protocol

The focus of the next presentations then shifted towards data-sharing and ABS compliance. First, the regulation of data-sharing under the Nagoya Protocol was briefly analyzed noting that the focus of the pre-Nagoya Protocol ABS negotiations was mainly on the genetic material and not on data. It was argued that while data and data-sharing are not specifically defined or regulated under the Nagoya Protocol it could be considered as utilization which is defined in Article 2 of the Nagoya Protocol. It was noted that for the same reason data and data-sharing could also fall under the scope of the EU ABS Regulation. Different data-rights at different points in the OSD workflow were indicated, and a link was made to the Micro B3 ABS tools which were introduced in the following.

The Micro B3 Model Agreement

The presentation *"Data Management as a Concern of ABS Agreements"* focused on the ABS Model Agreement of the Micro B3 project. It commenced with a more detailed explanation of the international legal requirements concerning data management, confirming that research and development on genetic resources can be considered as data production. Under the Nagoya Protocol, a provider state may therefore make its prior informed consent subject to data management requirements, and also determine data-sharing obligations through mutually agreed terms. The provider state's right to limit research and development is, however, qualified by its obligation to facilitate non-commercial research. It was further noted that a provider state may demand upstream tracking of data origins in order to ensure benefit-sharing, unless this is technically not possible. At the same time, ABS rights may also expire (i.e. such rights may have "exhausted" when there is no more causal link between the utilization of a genetic resource and the benefits). Finally, it was stated that researchers managing data associated with genetic resources can be considered as users under the EU

ABS Regulation. However, it is less clear whether databases also qualify as users under the same regulation.

The Micro B3 ABS Model Agreement was then presented as an attempt to live up to these international legal requirements in case a provider state has enacted ABS legislation. It was mentioned that during OSD the agreement was only used twice (in Ireland as a precautionary measure and in Norway as attachment to the prior informed consent - PIC). It was also noted that the agreement could serve as a model for those states (including EU member states) that prepare ABS legislation.

Afterwards, the content of the Micro B3 Model Agreement was introduced to the workshop participants. In particular, the agreement's approach on how to differentiate between non-commercial vs. commercial research was clarified. This is based on the intent of the research: Commercial research is considered as research and development for proprietary purposes (i.e. aiming to protect, keep secret, etc. the associated knowledge/products/processes developed from the accessed genetic resources, and/or to bring the products/processes on the market); non-commercial research is considered as research and development for the public domain (i.e. aiming to make the associated knowledge/products/processes publicly available at no more than incremental costs for dissemination, and without protection or restriction by IP rights). Furthermore, a number of "features" of the Model Agreement were explained, such as its hybrid character (i.e. its adaptability to both non-commercial as well as commercial research), its comeback clause (i.e. an obligation to go back to the provider and seek PIC and renegotiate MAT in case the intent changes from non-commercial to commercial research), and its viral clause (i.e. the transfer of not yet published data to third parties is allowed if they agree to apply the same conditions as set out in the original access agreement).

Regarding database management it was noted that public databases need to ensure traceability of their data allowing a provider state to monitor and control the potential use of data associated with its genetic resources for proprietary purposes. Such traceability is guaranteed in the Micro B3 Information System. It was further highlighted that databases are not parties to access agreements, but only researchers. Consequently, the Model Agreement foresees a due diligence obligation for the researcher (recipient) to make reasonable efforts to ensure that the release of data will be organized in a way that data users are bound not to use the data for proprietary purposes unless PIC was obtained from the provider.

Finally it was mentioned that access agreements which aim to control the entire research and development process may be counterproductive. It was concluded that such agreements would be too bureaucratic creating hurdles particularly for non-commercial research, and forcing commercial research to avoid the use of *in situ* genetic resources. They would also be not very realistic leading in the end to frustration on the provider side as they cannot control the entire process. Public databases could even refuse to manage and control such data input. It was therefore suggested not to establish access regimes except as leverage for sharing non-monetary benefits to support domestic research, and for monetary benefits only if short term substantial revenues are visible. As an alternative a multilateral

agreement introducing a biodiversity tax on products and services based on genetic resources was proposed.

The Micro B3 Data Policy and ABS Disclaimer for Databases

The last presentation of the first day's morning session focused on two other Micro B3 ABS tools, the OSD Data Policy and a suggested ABS disclaimer for databases. Upfront the importance of rapid access to data in the innovation process was highlighted leading to a number of data policy initiatives to promote early release and sharing of data in large-scale biological and genomic research projects. An overview of data-sharing principles was provided, including the Bermuda Principles from 1996 (applicable to all human genomic sequence data), the Fort Lauderdale Principles from 2003 (extending the principle of rapid pre-publication release to other types of data and safeguarding the right of researchers to publish first the analysis of their own data), and the Toronto Statement from 2009 (expressly obliging data users to respect a one year embargo period in favor of data producers). The EC Recommendation C/2008/1329 and the OECD Guidelines for Access to Research Data from Public Funding (2007) were also mentioned as promoting open access to and sharing of publicly funded research data with certain restrictions linked to commercial exploitation. Furthermore, a reference was made to Article 244 of the United Nations Convention on the Law of the Sea (UNCLOS) which provides an obligation to disseminate the knowledge resulting from marine scientific research and to promote the flow of scientific data and information.

Afterwards the Micro B3 Data Policy was presented as an effort to integrate these principles on data-sharing with ABS rules. While the Data Policy is non-binding, its signature was mandatory for participation in OSD. The policy covers the collection, dissemination, analysis and publication of OSD data, and aims to standardize such data and to harmonize its management. Accordingly, all OSD data has to be collected legally (responsibility is on the individual collectors) and released to the public domain as soon as the sequencing has taken place and the quality has been checked. It will be made freely available according to the Fort Lauderdale Principles which grant data producers the right to make the first presentation and publish the first data analysis. It was further highlighted that the authorship of the global analysis of all OSD datasets will belong to the OSD consortium with case-by-case decisions on the authorship of individual specialist publications.

An ABS Disclaimer for databases was then suggested as a tool to support public repositories which need to ensure the implementation of provider state restrictions on the use of data derived from their genetic resources. Such a disclaimer could request the data submitter to declare (possibly through a click) if the use of the data is not restricted by any provider state requirement, or if it is restricted to non-commercial uses by provider state requirement. In the latter case, the data user would then need to declare (possibly again through a click) that the data will only be used for non-commercial/public domain purposes, and in the case of change of intent the provider state will be contacted to negotiate new use conditions. Finally the OSD experiences were explained. Here only two countries limited the use of data to non-commercial purposes. Consequently, public repositories have been advised not to release such data for the moment while waiting for the implementation of an ABS disclaimer.

Part II

In Part two of the workshop (afternoon of day one) the first "World Café" session was held. Here the focus was on access to data and third party transfer at the point of access to genetic material.

Participants were first informed about the main questions to address, and then given some time to reflect individually before breaking into parallel working groups to discuss in more detail. At the end of Part two, both groups met again in plenary to share their findings (see Main Findings below).

Discussions concentrated on the following points:

1. The scientific point of view: I.e. different scenarios of data flow, their impact on ABS, as well as monitoring practices regarding open access in these scenarios. Distinctions were needed between
   - data flowing only to members of a consortium (i.e. known third parties which could be bound through a consortium agreement) vs. data going into the public domain (i.e. fully shared, a consortium agreement is not an option);
   - data used for proprietary vs. non-proprietary purposes (important in view of simplified access measures under Article 8(a) of the Nagoya Protocol); and
   - data without any use restrictions vs. data with a restriction to use only for non-commercial purposes vs. data usable for both commercial and non-commercial purposes but still with some obligations attached (e.g. reporting requirements, or a right of first access/embargo period to the benefit of a provider state).

2. The regulatory point of view: I.e. regulation of ABS at the point of access to genetic material. Possible options for regulating data-sharing and promoting benefit-sharing had to be envisaged, such as
   - embargo periods,
   - viral clauses,
   - reporting requirements,
   - direct sharing of data with providers, and
   - giving preferential treatment to provider states.

3. Institutional point of view: I.e. what are the main organizations to involve in order to make the system work and to have the model agreement/open access principles adopted in practice, such as
   - funding agencies, and
   - databases.

4. Technical point of view:
   - Is tracking feasible?
   - Should ABS rights exhaust?
   - Should databases be considered as users in the ABS context?

Part III

The third and last part of the workshop (morning of day two) started with a quick summary of the conclusions from day one. Afterwards, the focus of discussion was shifted to the regulation of data-management, i.e. regulation of access to data and third party transfer at the point of databases.

As an introduction to this session different examples were given where databases exist within the chain of utilization: sequence databases (e.g. ENA); oceanographic databases (e.g. PANGAEA, SeaDataNet and EurOBIS); and also culture collections with databases behind (however, the purpose of these databases is not to serve data to 3rd parties). It was highlighted that when regulating data-management possible consequences for research and sampling need to be considered, in particular whether such regulation will hamper making data publicly available in databases due to complicated ABS compliance regimes and submission procedures. Such consequences should also be taken into account for databases and their management, as well as for stakeholders/users of databases. In this regard a reference was made to "trusted collections" which are envisaged under the EU ABS Regulation, and which might solve the ABS compliance problem of data users.

Afterwards, participants were introduced to the main questions to address in this session and given once more time to reflect individually, before parallel working groups were established which finally reported back to plenary (see Main Findings below). Discussions concentrated on issues of storage and providing access to large scale genomic data in a scientific and legal sound way, in particular:

1. Scientific/organizational points of view: I.e. key incentives/disincentives that need to be considered in order to foster genomic data deposit on open access digital platforms.

2. Legal points of view:

   - Meaning and practical implementation of typical ABS contract obligations to provide information feedback (about research results, etc.) to provider states; problems of provider states in enforcing such feedback requirements; possibility of requesting deposits to be reimbursed by provider states after feedback submission; checkpoints in user states (e.g. funding agencies) which have necessary information about types of research undertaken.
   - Possible requirements that organizations hosting databases need to require from data submitters and users; such as PIC and MAT (if existing) from data submitters (considering also linkages to the ABS Clearing House); ABS disclaimer from data users

recognizing ABS restrictions (if existing); duty to monitor vs. user liability; trusted collections (providing only data which is a. legal, and b. not restricted) as a possible solution.

Main Findings

Regarding access to data and third party transfer at the point of access to genetic material

Scenarios of data flow

Data tracking and traceability: Knowledge about the origin of a genetic resource (and related data), as well as potential conditions on their utilization is critical in view of benefit-sharing obligations. Data tracking and traceability are thus important for monitoring ABS compliance.

- All parties involved in a chain of utilization (including the provider state) carry responsibilities for monitoring data flows.
- The possibility of tracking data has been confirmed.
    - Through unique identifiers provider states can track data and therefore ensure that ABS feedback is provided and research and development results are accessible.
    - The ABS Clearing House together with a unique identifier functioning worldwide could facilitate the development of a database in which data related to ABS requirements are stored.
- Furthermore, traceability has been confirmed.
    - Tracing back data samples to GPS coordinates of their origin as well as related legal arrangements is also possible (as shown by the Micro B3 experiences).
    - However, traceability requires minimum reporting criteria as well as diligence in collecting and providing such information.
    - Here the human factor is usually a problem that needs to be considered.

Possible options for regulating data-sharing and promoting benefit-sharing at the point of access

Commercial vs. non-commercial utilization: Instead of distinguishing between commercial and non-commercial utilization, a distinction between proprietary and non-proprietary utilization is recommended.

Public domain approach: Following a public domain approach provider states have two options to regulate data in mutually agreed terms.

- A narrow public domain option which means that only non-commercial use of data is allowed.
    - Advantage: more acceptable for provider states.

  - Disadvantages: difficult to monitor; not practical as innovation might depend on more than a few genes and their sequences accessed from various databases leading to the question with whom to negotiate benefit-sharing in practice.
- A wide public domain option which means that the data will never be "behind a fence".
  - Advantage: allows commercial use of data as long as data stays in the public domain; provides already a sort of benefit-sharing; no tracking needed.
  - Disadvantage: more difficult to get provider state's consent as there are less chances for ex-post monetary returns; this disadvantage needs to be "compensated" by other, more direct benefits such as intensive collaboration, technology transfer, funding of research tools, training, etc.
- However, a problem may arise in case an innovation is based on 100s of parts of sequences from different origins which makes it difficult to negotiate benefit-sharing. This problem is not to be solved through access agreements but can be solved through the issue of exhaustion of rights of provider states (*see findings under 2.b. below*).

Viral license clause: A viral license clause is an interesting approach to ensure ABS compliance.

- As an ABS agreement is between a provider and a recipient, it cannot directly bind databases which are not parties to the agreement. However, a viral license clause can ensure that ABS conditions travel from user to user, including also users of databases.
- Such conditions may include for example
  - Reporting duties: A provider needs to be informed where the data is stored. However, databases cannot communicate to providers every time their data is used; instead reporting can be made upon request.
  - Submission duties: Users can be obliged to submit data only to those databases which will be persistent (so that data will not get lost), and to make submissions only to databases with minimum information (in order to ensure interoperability).
- A viral license clause is probably a more practical/less burdensome approach than a legal provision (envisaged in certain countries) requesting a specific declaration for non-commercial use, allowing only one-time utilization, and requesting permission for each transfer to a third party, new utilization, etc.

Main organizations to involve

Pyramid of institutional infrastructure: International and regional facilities (e.g. the European Marine Biological Resource Centre (EMBRC) ELIXIR, MIRRI, and others) as well as organizations at different levels are needed to provide various services, such as establishing and maintaining databases, clearing data-related rights, monitoring and tracking, etc.

- Challenges:
    - Funding, i.e. countries have to sign up and pay for these services.
    - Non-parties, i.e. shall researchers from non-signatory countries be granted access and if so under the same conditions?
    - Industry's role.
- Requirements:
    - Setting up a whole pyramid of infrastructure: facilities/service providers hosted by international and regional institutions supported by their research associations.
    - Funding agencies to avoid duplication.

Technical considerations

Industry's/application perspective: Application aspects are gaining more and more importance in fundraising.

- In the context of microorganisms "everything seems to be everywhere", in which case industry will probably access those sites where the least restrictions exist (this is not the same for botany where endemic species exist).
- Prioritization of research funding in view of potential commercial application can be counterproductive for the sharing of research results as it can increase competition (unless data are provided to the public domain in a reasonable timeframe).

Regarding access to data and third party transfer at the point of databases

Scientific and organizational issues

Interoperability of databases: There is an overall need to improve the interoperability of genomic and environmental databases for which ABS can provide a trigger/opportunity.

- Opportunities:
    - ABS can be seen as an opportunity to promote/improve the creation of database infrastructure and interoperability.
    - The ABS Clearing House could promote such interoperability.
- Challenges:
    - The human factor.

Incentives: A number of incentives for data-sharing through databases already exist, or could be envisaged.

- General visibility of the data: Scientists have an interest to show their interesting work/data.
- Networking: Visibility of data can inform about who sampled where and what, and thereby stimulate scientific collaboration.
- Credits: Higher visibility also creates higher chances that data is transferred into knowledge and credits are received (e.g. through citations or short articles describing the data).
- Relation with publishers: There is an emerging interest also on the publishers' side to publish all relevant data together with a publication.
- Safety reasons: Storing data in different databases ensures that the data does not get lost in case an individual server breaks down.
- Facilitated vs. restricted access: A further incentive could be created if access to data was restricted to those who share their data, and/or to those from parties to the Nagoya Protocol.
- Funding opportunities: Project budgets may foresee funding for data management (up to 10-15% of overall budget). Some donors already provide specific/additional funding for data management (which is sometimes underused).

Disincentives: At the same time different obstacles for sharing data through databases exist.

- Organizational and financial responsibility: Facilities/institutions have to take care of setting up, managing and also financing databases and their services. This means the institutions need to explore revenue streams from their service while at the same time costs for users must remain low.
- Legal responsibility: Providers of data have an interest to ensure that they cannot be held liable for downstream utilization by others. Sharing data may lead to increased documentation and reporting duties, or even loss of control over the use of shared data.

Legal issues

Database disclaimer: As databases hold data which is associated with genetic material from provider states, database policies must be in place regulating how to deal with such data when providing it to 3rd parties.

- Database disclaimers can be an instrument to solve downstream ABS problems.
- A database disclaimer in form of a waiver is already implemented by EBI:
    - It is stating that all contributors to the EBI database have to ensure ABS compliance of their data before submission.
    - It is a rather weak waiver which probably needs to be strengthened.

Definition of raw data vs. source data: Raw data and source data have to be differentiated depending on whether it provides information or knowledge.

- Raw data (much broader information) is the sequencing data plus metadata which is not yet subject to analysis.
    - Such raw data/information is produced without much intellectual contribution (can be done e.g. by hiring a ship, technicians, and a company to do sequencing).
- Once analysis is done with the raw data it becomes source data/knowledge.
    - Source data/knowledge is different as its generation requires intellectual input.
- Copyrights are not possible for raw data; only knowledge/source data can be subject to copyright.
    - Raw data is thus in the public domain.
    - However, the question is also whether the source data is publicly available or not.

Ownership of/rights over data: The question of ownership of data is in fact a question of proprietary rights over data.

- Proprietary rights may allow excluding others from the utilization of the data. At the same time, such rights also create responsibilities.
- At a psychological level labor theory supports the assumption of a researcher that the one who puts labor into data development also owns the data.
- However, the question of ownership/proprietary rights depends on different factors, such as: the permission/rights granted by a provider state; if significant input was made to the creation of a database; or even who submitted data (which may create problems for broker institutions).
- Therefore, rights over data can be held by provider states, but also other parties in the chain of utilization may have rights over data (e.g. copyrights, a right to refuse data-transfer if the infrastructure is not appropriate, etc.).

Potential exhaustion of benefit-sharing rights of provider states: New data/innovation may be based on the utilization of different genetic resources from different countries throughout a research and development chain. This may raise the question with whom to negotiate terms of benefit-sharing, as negotiation with all provider states may be practically impossible if the number of provider states is high (can be easily 50-100 countries). Options are:

- If data/innovation is given back to the public domain, there should be no obligation to negotiate benefit-sharing.
- If data/innovation is used for commercial application, the contribution of a genetic resource from a provider state could be considered as disappearing in the chain of research and development so that benefits cannot anymore be considered to “arise from” it (as envisaged in Article 5 of the Nagoya Protocol).

- Such disappearance/exhaustion could be considered in five cases:[1]
  - "Comparator": a genetic resource is used as a comparator to identify functions of another genetic resource, and only the other gene is used as the basis for further research and development.
  - "De minimis": the presence of a genetic resource in the final product is not characteristic.
  - "Recurrence": genes of the genetic resource code for basic function reappear in many other genetic resources.
  - "Ubiquity": a genetic resource is spread globally (e.g. E. coli).
  - "Time": the provider states should, in analogy to patent and copy rights, let expire their rights after some time (post-market), say after 25 years (~ one human generation).
- Acknowledging such disappearance/exhaustion of benefit-sharing rights would help
  - to create a "realistic" understanding of the right to benefit-sharing,
  - to avoid futile negotiation and litigation, and
  - to reduce transaction costs.

[1] Note: Full list provided by Gerd Winter, University of Bremen, after the workshop.

Annex I: Workshop Programme

Micro B3

Stakeholder Workshop

At the Crossroads of Open Access to Data with Access and Benefit-Sharing Requirements –

Promoting Pre-competitive Scientific Research

Programme

Brussels, 25 – 26 September 2014

Aims of the Micro B3 Project and Workshop Rationale:

The EU FP7 project Micro B3 (Marine Microbial Biodiversity, Bioinformatics, Biotechnology) aims at

- studying marine microorganisms through genomics and metagenomics in different oceans and seas,
- producing information to be shared through several open-source and open-access databases, easily accessible through one Micro B3 Information System and
- fostering, in the medium to long-term, biotechnological product and process development.

For this, Micro B3 offers improved, mostly bioinformatic but also legal tools to achieve facilitated access to research results, including genomic and environmental data, and to integrate data from different marine scientific projects.

Micro B3 is now organizing a stakeholder workshop which will approach the issue of access and benefit-sharing (ABS) under the Convention on Biological Diversity (CBD) and its Nagoya Protocol from an open access-based data-management view point. This broader approach to the issue of ABS is timely because

- the Nagoya Protocol will enter into force in autumn 2014,
- large amounts of data, easy to be generated due to the revolution in high-throughput sequencing, are creating novel Omics databases, and
- wider access to gene synthesis enables the reverse path from data back to genetic material.

Workshop Output:

Based on the results of this stakeholder workshop, IUCN, in collaboration with other Micro B3 partners, will prepare a policy brief on the crossroads of open access to data with ABS, as well as on ways to promote pre-competitive scientific research in line with Article 8(a) of the Nagoya Protocol.

Background:

As research planned under Micro B3 (like many other projects dealing with marine genetic resources) is based on the taking of samples within internal waters, the territorial sea and the exclusive economic zone of coastal states, the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization apply.

Accordingly the coastal state may, by national legislation, require its prior consent to the sampling and utilization of its marine genetic resources and ask for the sharing of benefits

derived from these resources. Such access and benefit-sharing (ABS) conditions are normally determined through a contract concluded between the sampling research institution and the coastal state.

At the same time, Article 8(a) of the Nagoya Protocol foresees that states have an obligation to create special conditions in order to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, including through simplified measures on access for non-commercial research purposes.

So far, ABS policies and contracts often concentrate on conditions for the access to and utilization of genetic material, only, thereby neglecting the importance of addressing also associated data, i.e. data which is pertinent to or derived from research and development on the genetic material. To realize the full potential of large-scale collaborative research initiatives, however, rapid and continued (open) access is needed not only to genetic research materials but also to a multitude of data associated with such collected materials in order to create information and knowledge.

Furthermore, many ABS policies and contracts still take a rather restrictive approach, without special exceptions for non-commercial pre-competitive research. Indeed, access to genetic materials and associated data for pre-competitive research is often treated under the same conditions and procedures as materials and data of known commercial value. Such restrictive ABS approaches ignore that the vast majority of research data and research materials are pre-competitive, that is of unknown and/or unlikely commercial potential.

Conversely, awareness of the need to ensure compliance with ABS obligations is relatively low amongst researchers when they are sharing and utilizing associated data downstream throughout the research and development chain. The development of compliance measures for databases is also still at a very early stage.

Micro B3 Legal Tools:

University of Bremen, Germany, and Université catholique de Louvain, Belgium, with support from other Micro B3 partners have developed different tools under its Work Package dedicated to legal issues. These tools respond to Articles 19 and 20 of the Nagoya Protocol which encourage the development of sectoral and cross-sectoral model contractual clauses for mutually agreed terms, as well as the development of codes of conduct, guidelines and best practices and/or standards in relation to ABS.

In the spirit of the European Commission's open data policy, the EU Regulation on ABS Compliance Measures, and Article 8(a) of the Nagoya Protocol, a set of balanced and simple rules for fostering maximum utilization of research results and at the same time ensuring compliance with the Nagoya Protocol have been produced. They comprise:

- the Micro B3 Open Access Data Policy which covers the collection, storage, analysis and publication of data generated in relation with the Ocean Sampling Day2,

[2] The Ocean Sampling Day (OSD) is a simultaneous sampling campaign of the world's oceans which took place on the summer solstice

- the Micro B3 ABS Model Agreement which aligns access agreements between provider states and collectors with this Policy, and
- the Micro B3 ABS Disclaimer for databases storing and sharing the pre-competitive data derived from the Ocean Sampling Day.

These tools link exceptions for non-commercial research to a duty of users to keep information in the public domain without any downstream restrictions attached.

The workshop will discuss whether they could provide templates to be adopted by other research consortia. In particular, research funders and ABS policy-makers could adjust these approaches in order to open up a wealth of scientific data to the global research community, including researchers from developing and transition countries.

Workshop Objectives:

The objectives of this Micro B3 stakeholder workshop are to inform and discuss:

- different scenarios of data flow associated with genetic material that was accessed under the scope of the Nagoya Protocol,
- the importance of open access to marine, environmental and genomics data for pre-competitive research in order to facilitate dissemination and further analysis of such data and to fully unlock its scientific potential,
- the need for clear regulation of data access and transfer, as well as related benefit-sharing in ABS agreements at the point of access to genetic material, as well as
- possible options for managing data further downstream in the research and development chain in line with international obligations established by the Nagoya Protocol.

Date and Location:

The stakeholder workshop will be held over 1,5 days from 25 – 26 September, 2014, at Fondation Universitaire in Brussels, Belgium.

It will be co-organized by the IUCN Environmental Law Centre in collaboration with Université catholique de Louvain, University of Bremen, and CIESM, the Mediterranean Science Commission.

(June 21st) in the year 2014.

Participants:

Participation in the workshop is upon invitation by the organizers, only. The target audience comprises ABS policy-makers, as well as representatives from research funding agencies and the scientific community, including from marine and genomic databases and microbial culture collections.

Workshop Approach:

The workshop will be structured in three different parts:

- Part I – Introduction to Micro B3 and the importance of data sharing in scientific research: approaches and experiences from Micro B3 and other marine scientific research initiatives.
- Part II – Parallel and plenary sessions on regulating data management (access to data and third party transfer) at the point of access to genetic material.
- Part III – Parallel and plenary sessions on managing data throughout research and development in line with ABS obligations introduced by the Nagoya Protocol.

Annex II: List of Participants (in Alphabetical Order)

Name	Contact Information
Ana Rachel Teixeira Cavalcante	Legal Advisor at Fondation pour la Recherche sur la Biodiversité Project partner in Oceanomics
Anne-Emmanuelle Kervella	Station Biologique de Roscoff Coordinator for Legal and Governance Issues in the Preparatory Phase of the European Marin Biological Resource Centre (EMBRC) Project partner in Oceanomics
Arianna Broggiato	Research Fellow at the Université catholique de Louvain Project partner in Micro B3
Astroza Alessandro Andrès Tovik	Ministry of Trade, Industry and Fisheries Norway
Dagmar Meyer	European Research Council Executive Agency (ERCEA)
Dermot Hurst	Marine Institute, Ireland
Frank-Oliver Glöckner	Head of the Microbial Genomics and Bioinformatics Research Group Max Planck Institute for Marine Microbiology Jacobs University Bremen gGmbH Project partner in Micro B3
Gerard J. M. Verkleij	CBS-KNAW Fungal Biodiversity Centre, Centraalbureau voor Schimmelcultures (CBS) Project partner in Microbial Resource Research Infrastructure (MIRRI)
Gerd Winter	Professor at the Department of Law, University of Bremen Project partner in Micro B3
Guy Cochrane	Team Leader, European Nucleotide Archive - European Bioinformatics Institute Project partner in Micro B3

Han De Koeijer	CHM Partnership Assistant, Belgium Royal Belgian Institute of Natural Sciences
Johanna Wesnigk	Environmental & Marine Project Management Agency, Bremen Project partner in Micro B3
Julian Jackson	ABS and Agricultural Plant Genetic Resources Department for Environment, Food & Rural Affairs (Defra), UK
Laura Lallier	Legal Adviser at eCoast Marine Research Project partner in PharmaSea
Lily O. Rodriguez	German Research Foundation (DfG) ILR - Institut für Lebensmittel und Ressourcenökonomik University of Bonn
Marianne Schlesser	Executive secretary of the CBD National Focal Point Operational Directorate Natural Environment - OD Nature Royal Belgian Institute of Natural Sciences
Michèle Barbier	The Mediterranean Science Commission (CIESM) Project partner in Micro B3
Philippe Desmeth	President of the World Federation of Culture Collections
Sarah Aubertie	Fondation pour la Recherche sur la Biodiversité Project partner in Oceanomics
Stefan Schröder	Head of Division - Information and Coordination Centre for Biological Diversity (IBV) German Federal Office for Agriculture and Food (BLE)
Steinar Bergseth	The Research Council of Norway
Thomas Greiber	Senior Legal Officer at the IUCN Environmental Law Centre Project partner in Micro B3
Thomas Vanagt	Managing Director at eCoast Marine Research Project partner in PharmaSea

Tom Dedeurwaerdere	Professor at the Université catholique de Louvain Director of the BIOGOV Unit Centre for Philosophy of Law Project partner in Micro B3

Annex III: Workshop Agenda

Day 1

25 September 2014

	Day 1	
10:00 – 10:20	**Welcome – Introduction to the Meeting** ➢ Introduction to Micro B3 ➢ Objective of the workshop ➢ Tour de table	Frank Oliver Glöckner, *Head of Microbial Genomics and Bioinformatics Research Group - Max Planck Institute for Marine Microbiology, Jacobs University Bremen gGmbH*
10:20 – 11:00	**Importance of Open Access to Data for Research** ➢ Data-sharing and its opportunities for precompetitive scientific research ➢ Views and experiences of the World Federation of Culture Collections and the European Bioinformatics Institute ➢ Q&A	Philippe Desmeth, *President of the World Federation of Culture Collections* Guy Cochrane, *Team Leader, European Nucleotide Archive - European Bioinformatics Institute*
11:00 – 11:15	**COFFEE BREAK**	
11:15 – 11:40	**Data-sharing and ABS Compliance** ➢ The Micro B3 workflow ➢ Challenges in view of compliance with the Nagoya Protocol ➢ Q&A	Thomas Greiber, *IUCN Environmental Law Centre*
11:40 – 13:00	**Micro B3 Tools to Promote Data-sharing and ABS Compliance** ➢ Key aspects of the Micro B3 ABS Model Agreement ➢ Overview of the Micro B3 Open Data Policy ➢ A suggested ABS disclaimer for databases ➢ Q&A	Gerd Winter, *University of Bremen* Arianna Broggiato, *Centre for Philosophy of Law, Université catholique de Louvain*

13:00 – 14:00	**LUNCH**	
14:00 – 14:20	**Parallel Session I: Data Management at Point of Access to Genetic Material** ➢ Introduction ➢ Showcase of different flows of data, using the Ocean Sampling Day Initiative as a practical example	Tom Dedeurwaerdere, *Centre for Philosophy of Law, Université catholique de Louvain*
14:20 – 16:00	**Parallel Session I: Group Work** ➢ Breakout in smaller groups ➢ Groups to identify different approaches to and opportunities and challenges in o regulating data-sharing in ABS agreements o monitoring and enforcement	
16:00 – 16:15	**COFFEE BREAK**	
16:15 – 17:15	**Parallel Session I: Plenary** ➢ Breakout groups to present their findings in plenary ➢ Groups to comment on each other's findings ➢ Conclusions in view of Article 19 of the Nagoya Protocol (Model Contractual Clauses)	
17:15 – 17:30	**Wrap Up Day 1**	
19:00	**JOINT DINNER**	**Restaurant Taverne du Passage Galerie de la Reine, 30 1000 Bruxelles**

Day 2

26 September 2014

	Day 2	
9:00 – 9:15	**Welcome Back** ➢ Reporting back from day 1	Tom Dedeurwaerdere
9:15 – 9:35	**Parallel Session II: Data Management at Point of Data Storage and Sharing** ➢ Showcase of different data storage and sharing scenarios ➢ Introduction to the group work	Frank Oliver Glöckner Tom Dedeurwaerdere
9:35 – 11:15	**Parallel Session II: Group Work** ➢ Breakout in smaller groups ➢ Groups to identify different approaches to and opportunities and challenges in o ensuring ABS compliance of databases o monitoring and enforcement	
11:15 – 11:30	**COFFEE BREAK**	
11:30 – 12:30	**Parallel Session II: Plenary** ➢ Breakout groups to present their findings in plenary ➢ Groups to comment on each other's findings ➢ Conclusions in view of Article 20 of the Nagoya Protocol (Codes of Conduct, Guidelines, and Best Practices and/or Standards)	
12:30 – 13:00	**Wrap Up Day 2 and Closing of Workshop**	
13:00 – 14:00	**LUNCH (optional)**	