BlueRemediomics

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Executive Summary

The Access and Benefit Sharing (ABS) training guide is a translation of the in-person training session delivered to the consortium members during the BlueRemediomics General Assembly held on 4 April 2023 at the Anton Dohrn Zoological Station in Naples, Italy. The training session was conducted by Beneficiary ABSint (Dr Thomas Vanagt) who co-leads Work Package 5, which is aimed at Improving access, protection and sharing: ABS and IP of Marine Genetic Resources. This session was coupled with the presentation of an ABS management case study, which was delivered by Beneficiary EMBRC-ERIC (Arnaud Laroquette) . The key highlights from the training are summarised below:

- All members of the BlueRemediomics consortium received essential ABS training at the project onset to ensure that they fully understood their obligations and responsibilities when it comes to sharing samples and data (T7.2 and T5.1). A subsequent Q&A session aimed to clarify further queries from the consortium.
- EMBRC-ERIC presented a comprehensive case study on ABS management, highlighting their approach and experiences. The case study delivered valuable insights into the management of ABS within the EMBRC-ERIC framework.

This training will play a vital role in equipping the consortium members with the necessary knowledge and understanding to navigate Access and Benefit Sharing practices effectively and responsibly within the project.

Access and Benefit Sharing (ABS): An Introduction - Training Guide

Introduction

This training guide introduces Access and Benefit Sharing (ABS), focusing on the key principles and obligations outlined in international agreements, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol. The guide aims to enhance awareness and knowledge regarding ABS and its implications for research and development activities involving genetic resources. During the training session, participants gained an understanding of ABS concepts, legal frameworks, and compliance requirements.

Training Objectives

- Introduce participants to the concept of ABS and its importance in biodiversity conservation and equitable resource utilisation.
- Explore the key principles and obligations outlined in the CBD and the Nagoya Protocol.
- Understand the legal framework governing ABS, including national laws and international regulations.
- Familiarise participants with the components of an ABS compliance system and their roles and responsibilities.
- Provide guidance on conducting due diligence and ensuring compliance with ABS requirements.

Training Outline

Introduction to ABS

- Definition and significance of ABS
- Overview of the CBD and the Nagoya Protocol
- Importance of ABS in promoting equitable benefit sharing and conservation

ABS Legal Framework

- Key provisions of Article 15 of the CBD
- Principles and Objectives of the Nagoya Protocol
- Status and implementation of ABS at national and international levels

ABS Obligations: Access and Benefit Sharing

Access: Prior Informed Consent (PIC)

- Definition and purpose of PIC
- PIC requirements and conditions
- Role of Indigenous People in PIC

Benefit Sharing: Mutually Agreed Terms (MAT)

- Definition and scope of MAT
- Types of Benefits and benefit-sharing mechanisms
- Negotiation and establishment of MAT

ABS Compliance System

- Components of a corporate ABS compliance system
- Roles and responsibilities of staff in ABS implementation
- Documentation and track & trace procedures
- Due diligence declarations and compliance monitoring

Ensuring ABS Compliance in Research and Development

- ABS obligations throughout the R&D process
- Assessing ABS status and requirements for specific activities
- Material management and transfer procedures
- Compliance with benefit-sharing obligations

Audits, Inspections, and Best Practices

- Importance of audit and inspection in ABS compliance
- Awareness-raising and training for ABS implementation
- Contract drafting, negotiation, and legal considerations
- Track and trace systems for monitoring genetic resources

Summary of the training

Access and Benefit Sharing (ABS) is a crucial framework that has been established to address the equitable sharing of benefits derived from the utilisation of genetic resources. Under the Convention on Biological Diversity (CBD) and the Nagoya Protocol (Article 15), countries are granted sovereign rights over their natural resources within their jurisdiction. This means that they have the authority to determine access to genetic resources and are responsible for taking appropriate measures to ensure the fair distribution of the benefits arising from their use. This framework aims to strike a balance between the rights of countries as providers of genetic resources and the interests of users seeking to utilise these resources for research and development purposes.

Adopted in 2010 and in force since 2014, the Nagoya Protocol builds upon the principles set forth in the CBD and provides a more refined and detailed approach to ABS. ***At the international level***, the Nagoya Protocol has played a crucial role in promoting ABS implementation. The Protocol encourages countries to ratify and implement its provisions, creating a global framework for ABS practices. It sets forth principles and procedures for obtaining Prior Informed Consent (PIC) and establishing Mutually Agreed Terms (MAT) for benefit sharing. The Nagoya Protocol also establishes the Access and Benefit Sharing Clearing-House (ABSCH), an online platform that facilitates the exchange of information on ABS measures, permits, and checkpoints.

Nationally, countries have taken various steps to incorporate ABS into their legal and policy frameworks. Many countries have developed specific ABS laws and regulations that outline the procedures and requirements for accessing genetic resources and sharing benefits. These national ABS frameworks aim to ensure the equitable sharing of benefits and promote the conservation and sustainable use of biological diversity within their territories. They often establish Competent National Authorities (CNAs) who are responsible for granting access permits, overseeing compliance, and facilitating benefit-sharing negotiations. The implementation of ABS at the national level varies among countries, depending on factors, such as legal frameworks, institutional capacity, and cultural contexts. Some countries have made significant progress in implementing ABS mechanisms, establishing functional ABS administrative systems, and successfully negotiating and implementing ABS agreements. These countries often have well-defined legislative frameworks, clear procedures for obtaining permits, and established benefit-sharing mechanisms that facilitate the fair and equitable distribution of benefits. Other countries may still be in the process of developing their ABS systems, addressing challenges related to legal harmonisation, institutional capacity-building, and stakeholder engagement.

Efforts have been made to enhance ***international cooperation and coordination in ABS implementation***. Regional and intergovernmental initiatives have been established to facilitate dialogue and knowledge-sharing among countries, supporting capacity-building and technical assistance. International organisations, such as the United Nations Environment Programme (UNEP) and the World Intellectual Property Organization (WIPO), have provided guidance and resources to assist countries in developing their ABS frameworks and building capacity. Despite progress, challenges remain in achieving full and effective implementation of ABS at both national and international levels. These challenges include inadequate financial and technical resources, limited awareness and understanding of ABS among stakeholders, the complexity of benefit-sharing negotiations, and the need for enhanced cooperation and coordination among countries. Ongoing efforts address these challenges through capacity-building initiatives, the development of best practices, and the promotion of synergies between ABS and related international agreements.

The ABS legal framework encompasses a broad range of materials and knowledge associated with genetic resources. It includes not only the genetic resources themselves, which can be of plant, animal, microbial, or other origin and contain functional units of heredity but also derivatives of these resources. Derivatives refer to naturally occurring biological compounds that are obtained from genetic resources, which may have valuable properties and applications in various industries. Additionally, traditional knowledge associated with genetic resources held by indigenous and local communities is also recognised and protected under the ABS framework. This recognition ensures that the contributions of these communities are respected and that they have a share in the benefits derived from the utilisation of their

traditional knowledge. Furthermore, the recent considerations revolving around ***Digital Sequence Information (DSI)*** in the scope of ABS could become an important aspect of the legal framework. DSI refers to the genetic information encoded in nucleotide or amino acid sequences that can be accessed and shared electronically. As advancements in technology enable the digital exchange of genetic information, it has become necessary to address the access and benefit-sharing implications of DSI. The inclusion of DSI in the ABS framework will ensure that the benefits derived from the utilisation of digital genetic information are shared in a fair and equitable manner.

ABS obligations are divided into two main categories, namely: (i) access and (ii) benefit sharing. ***Access obligations*** require users to obtain the necessary permits and fulfil the requirements specified in the national ABS laws of the provider country. ***Prior Informed Consent (PIC)*** is an essential element of access obligations, ensuring that the provider country has given its informed consent before the genetic resources are accessed or used. This consent serves as a safeguard to protect the rights and interests of the provider country. The definition of PIC revolves around the notion that access to genetic resources should only occur after the provider country has been duly informed about the purpose and scope of the intended use. The purpose of PIC is to ensure that the provider country is given the opportunity to evaluate and assess the potential impacts of granting access to its genetic resources. This evaluation process allows the provider country to make informed decisions, considering aspects, such as conservation, sustainable use, and the equitable sharing of benefits. PIC requirements and conditions outline the specific steps and considerations that users must undertake to obtain prior consent. These requirements typically vary among countries and are outlined in national ABS laws and regulations. Common elements include submitting a written request for access, providing detailed information on the intended use of the genetic resources, and demonstrating compliance with the relevant legal and regulatory frameworks of the provider country. Additionally, users may be required to demonstrate their capacity to handle genetic resources responsibly and share any derived benefits in a fair and equitable manner. ***The role of Indigenous Peoples in PIC*** is of particular importance due to their intimate connection with traditional knowledge and genetic resources. Indigenous Peoples have a unique relationship with their lands, territories, and resources, often holding valuable traditional knowledge associated with genetic resources. Recognising their rights and involvement in decision-making processes related to access and benefit sharing is crucial. Their participation in the PIC process ensures that their perspectives, concerns, and traditional knowledge are respected and considered. In many cases, the consent of Indigenous Peoples is a prerequisite for accessing genetic resources found within their territories.

On the other hand, ***Benefit-sharing obligations*** involve reaching ***Mutually Agreed Terms (MAT)*** through written agreements between the provider country and the user. MAT establishes the terms and conditions under which benefits derived from the utilisation of genetic resources are shared between the provider country and the user. By establishing clear and mutually agreed-upon terms, benefit sharing ensures that the benefits derived from the utilisation of genetic resources are distributed in a fair and equitable manner. Compliance with ABS obligations is crucial for both the country of origin and the country of use. Every country of use is obligated to establish a compliance system to monitor the utilisation of genetic resources through designated checkpoints. The European Union has implemented a harmonised compliance system, which includes an information and material management system with due diligence obligations and designated checkpoints. Users are required to comply with ABS obligations not only in the country of origin but also in the country where the genetic resources are being used. The involvement of Indigenous Peoples in the PIC process goes beyond consent. It also includes their active participation in negotiations on MAT. Indigenous Peoples' participation ensures that their rights, interests, and contributions are acknowledged and that benefits are distributed in a fair and equitable manner, recognising their invaluable traditional knowledge and the role they play in the conservation and sustainable use of genetic resources.

The ABS compliance system plays a significant role in avoiding potential negative impacts and ensuring legal and ethical conduct within the realm of genetic resource utilisation. Allegations of ***"biopiracy"***, which refer to the unauthorised and unethical exploitation of genetic resources, can have severe consequences for companies, research institutions, and universities. Such allegations not only result in reputational damage but can also lead to legal actions and financial penalties. Compliance with ABS obligations is crucial to mitigate these risks and maintain a high standard of responsible and transparent behaviour. It entails adherence to a range of measures and practices that foster accountability and respect for the

principles of ABS. The compliance journey begins with raising awareness among users and stakeholders about the importance of ABS and the legal obligations it entails. This ensures that individuals and organisations are well-informed and can make informed decisions throughout the process of genetic resource utilisation. Within the compliance framework, ***contract drafting and negotiation*** play a vital role. Agreements between providers and users are meticulously crafted to establish clear and mutually agreed-upon terms and conditions for access and benefit sharing. These contracts serve as a safeguard, ensuring that all parties involved are aware of their rights, responsibilities, and entitlements in the utilisation of genetic resources. Through transparent and fair negotiations, the interests of both providers and users are taken into consideration, fostering a harmonious and equitable partnership.

ABS obligations are applicable at every stage of the R&D process, from the initial exploration and collection of genetic resources to the final development and commercialisation of products or technologies. ***Tracking and tracing materials*** is another crucial component of ABS compliance. It involves establishing robust systems and procedures to monitor the movement of genetic resources throughout the utilisation process. This includes accurately documenting the origin of genetic resources, their transfer between entities, and any subsequent transformations or derivatives that may arise. By implementing effective tracking and tracing mechanisms, stakeholders can ensure transparency and accountability, enabling the traceability of genetic resources and facilitating the enforcement of ABS obligations. ***Material transfer agreements (MTAs)*** play a vital role in establishing clear terms and conditions for the transfer of genetic materials, including any obligations related to ABS compliance. In addition, ***due diligence declarations*** form an integral part of ABS compliance. Users are required to exercise due diligence in their utilisation of genetic resources to ensure that they have taken all necessary measures to comply with ABS obligations. This involves conducting thorough assessments to determine the legal status of the genetic resources, verifying that appropriate permits and agreements are in place, and confirming that benefit-sharing arrangements are implemented as agreed upon. Due diligence declarations provide a means for users to demonstrate their compliance efforts and ensure that their actions align with the principles of ABS.

Awareness-raising and training initiatives are vital for effective ABS implementation. They help stakeholders, including researchers, developers, and relevant personnel, understand the importance of ABS compliance and the specific obligations that need to be fulfilled. Training programs provide valuable knowledge on topics, such as ABS principles, legal frameworks, permit requirements, and benefit-sharing arrangements. By raising awareness and providing training, organisations can foster a culture of compliance, minimise inadvertent violations, and promote responsible and ethical practices in the utilisation of genetic resources.

Overall, the ABS compliance system is a multi-faceted approach that encompasses various components and practices aimed at upholding legal and ethical conduct in the utilisation of genetic resources. By raising awareness, drafting fair contracts, implementing robust tracking systems, and exercising due diligence, users can navigate the complex landscape of ABS with integrity and accountability. This not only mitigates the risks of reputational damage and legal actions but also fosters a culture of responsible and transparent utilisation of genetic resources, contributing to the conservation of biodiversity and the equitable sharing of benefits for all stakeholders involved.

The ABS compliance system in BlueRemediomics assists the consortium and project management members in ensuring compliance with ABS requirements, promoting responsible and ethical utilisation of genetic resources. The system includes various measures, such as consortium training, publication of guidelines, availability of tools like the ABS wizard, creation of an ABS consortium database, sharing experiences, and capacity-building training.

ABS Management in EMBRC: A Case Study of a European Research Infrastructure

Introduction

The case study explores the management of Access and Benefit Sharing (ABS) within the context of EMBRC-ERIC (European Marine Biological Resource Centre – European Research Infrastructure Consortium). EMBRC aims to support and facilitate marine biological research and innovation while providing access to ecosystems, biological resources, and research facilities.

Overview

EMBRC, an organisation spanning ten countries and operating across 70 research and experimentation sites, stands as an ERIC committed to overcoming bottlenecks, fostering technological advancements, and advocating for the marine biological research community. With access granted to a diverse range of marine ecosystems stretching from the Arctic to tropical regions, EMBRC facilitates scientific exploration by providing state-of-the-art research facilities, platforms, and tools.

In order to empower researchers and enable marine research advancements, EMBRC offers an array of services encompassing ecosystem access, access to biological resources, experimental facilities, technology platforms, e-services, training, and library services. These services allow scientists to conduct experiments in close proximity to the marine resources they seek to study, thereby facilitating the development of innovative tools and techniques in the field.

To ensure responsible and compliant utilisation of resources, EMBRC has developed a meticulous approach to ABS management. This approach encompasses the comprehensive management of bioresources from sampling to maintenance, informative training webinars on ABS, meticulous record keeping of origin countries and their respective ABS restrictions, and the provision of a transparent catalogue showcasing available bioresources. Additionally, EMBRC issues bioresource passports to institutions and users, along with comprehensive guides on ABS compliance.

Within the organisation, a well-defined six-step iterative process guides users in planning research projects involving resources. By understanding the nature and origin of resources, assessing the project's impact on ABS, gathering information about ABS requirements, negotiating ABS permits when necessary, demonstrating ABS compliance, and effectively managing ABS documentation, users are equipped to fulfil their ABS obligations diligently.

EMBRC places significant emphasis on the importance of collecting and securely storing information regarding the resources used in projects. This includes meticulous documentation of details such as sampling locations, resource descriptions, sources, and associated ABS permits or contracts. Through secure data storage practices, EMBRC ensures traceability and compliance with ABS requirements.

The EMO BON project is a shining example of ABS integration within the EMBRC framework. By employing various sampling techniques, centralising DNA extraction and sequencing processes, and publishing data and metadata in relevant databases, EMO BON ensures compliance with ABS and other legal requirements. Each country involved adheres to specific procedures and regulations, exemplifying the commitment to responsible and ethical research practices.

Conclusion

By completing this training, participants gained a solid understanding of ABS, including its legal framework, obligations, and compliance requirements. They are now equipped with the knowledge and tools necessary to navigate the complexities of accessing genetic resources, establishing mutually agreed terms, and ensuring compliance with ABS regulations and can access this guide, which represents the foundation for this training. Importantly, by delivering this training at the project outset, the BlueRemediomics consortium highlights its commitment to promoting responsible and ethical practices in utilising biodiversity resources while fostering equitable benefit-sharing and conservation efforts.

In addition, EMBRC offered valuable insights on managing ABS in research projects. Key recommendations include designating an ABS managing person, ensuring rights to access and use bioresources, managing sampling campaigns effectively, maintaining traceability and FAIR principles in databases, documenting collected bioresources, using persistent unique identifiers, and archiving ABS documents. These measures promote compliance, traceability, and responsible use of biological resources. By implementing effective ABS management practices, research infrastructures like EMBRC contribute to the conservation of biodiversity and the fair and equitable sharing of benefits derived from genetic resources.

Glossary

- **ABS compliance system:** A system of measures and practices aimed at ensuring compliance with ABS obligations, including obtaining permits, conducting due diligence, and tracking and tracing genetic resources (https://www.cbd.int/abs/compliance.shtml).
- **Access and Benefit Sharing (ABS):** A framework established to address the equitable sharing of benefits derived from the utilisation of genetic resources (https://www.cbd.int/abs/information-kit-en/; https://www.cbd.int/abs/infokit/revised/web/factsheet-nagoya-en.pdf).
- **ABSCH (Access and Benefit Sharing Clearing-House):** An online platform established by the Nagoya Protocol to facilitate the exchange of information on ABS measures, permits, and checkpoints (https://absch.cbd.int/en/).
- **ABS wizard:** A tool/software developed by ABSint (Beneficiary 13, Work package 5 Co-Lead) that assists users in navigating and understanding ABS requirements and obligations.
- **Benefit-sharing negotiations:** Discussions and agreements between provider countries and users regarding the distribution of benefits derived from the use of genetic resources.
- **Biopiracy:** The unauthorised and unethical exploitation of genetic resources.
- **Capacity-building training:** Training programs aimed at enhancing the knowledge, skills, and capacity of stakeholders in ABS (https://www.cbd.int/abs/key-capacitybuilding.shtml).
- **Competent National Authorities (CNAs):** National authorities responsible for granting access permits, overseeing compliance, and facilitating benefit-sharing negotiations (https://absch.cbd.int/en/about/guides/CNA; https://www.cbd.int/doc/programmes/abs/factsheets/abs-factsheet-faqs-en.pdf).
- **Convention on Biological Diversity (CBD):** An international agreement that aims to conserve biological diversity, promote sustainable use of its components, and ensure fair and equitable sharing of benefits arising from the use of genetic resources (https://www.cbd.int).
- **Digital Sequence Information (DSI):** Genetic information encoded in nucleotide or amino acid sequences that can be accessed and shared electronically (https://www.cbd.int/dsi-gr/).
- **Due diligence:** The process of conducting thorough assessments to ensure compliance with ABS obligations, including verifying legal status, obtaining necessary permits and agreements, and implementing benefit-sharing arrangements.
- **Equitable benefit sharing:** The fair and just distribution of benefits derived from the utilization of genetic resources, ensuring that all stakeholders involved receive a fair share of the benefits.
- **Genetic resources:** Biological materials of plant, animal, microbial, or other origin that contain functional units of heredity.
- **Indigenous Peoples:** Communities with a unique connection to their lands, territories, and resources, often possessing valuable traditional knowledge associated with genetic resources.
- **Legal harmonization:** The process of aligning national laws and regulations with international agreements and frameworks related to ABS.
- **Material transfer agreements (MTAs):** Agreements that establish terms and conditions for the transfer of genetic materials, including obligations related to ABS compliance.
- **Mutually Agreed Terms (MAT):** Terms and conditions established through written agreements between the provider country and the user for the sharing of benefits derived from the utilisation of genetic resources (https://www.cbd.int/doc/programmes/abs/factsheets/abs-factsheet-faqs-en.pdf).
- **Nagoya Protocol:** An international treaty that provides a more refined and detailed approach to ABS, building upon the principles of the CBD. It sets forth principles and procedures for obtaining Prior Informed Consent (PIC) and establishing Mutually Agreed Terms (MAT) for benefit sharing (https://www.cbd.int/abs/).
- **Prior Informed Consent (PIC):** Consent obtained from the provider country before accessing or using genetic resources, ensuring the provider country's informed decision-making (https://www.cbd.int/doc/programmes/abs/factsheets/abs-factsheet-faqs-en.pdf).
- **R&D process:** Research and development process, including the exploration, collection, and commercialization of genetic resources.

- **Stakeholder engagement:** Involving and consulting relevant stakeholders, including local communities and indigenous peoples, in ABS processes and decision-making.
- **Tracking and tracing:** Monitoring and documenting the movement of genetic resources throughout the utilisation process.
- **Traditional knowledge:** Knowledge and practices of indigenous and local communities associated with genetic resources.
- **United Nations Environment Programme (UNEP):** An international organisation that provides guidance and resources to assist countries in developing their ABS frameworks and building capacity (https://www.unep.org).
- **World Intellectual Property Organization (WIPO):** An international organisation that provides guidance and support on intellectual property matters, including ABS (https://www.wipo.int/portal/en/index.html).