ABSInt
Unlocking Genetic Resources

TOWARDS ACCESS & BENEFIT SHARING COMPLIANCE FOR ACADEMIC ORGANIZATIONS

A STEP-BY-STEP APPROACH

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Relevance of Access & Benefit Sharing rules

Are Access and Benefit-Sharing (ABS) rules relevant for your organisation? Have a quick look at these questions:

- ❑ Are your scientists returning from field trips, in your country or abroad, with genetic resources (plants, animals or microbes) or derivatives?
- ❑ Are your scientists receiving or transferring genetic resources from/to other research groups within your organisation or from/to other institutions/organizations?
- ❑ Are genetic resources deposited in your collections?
- ❑ Is your organization performing research using genetic resources?
- ❑ Is it possible that genetic resources maintained or used for research in your organization are further used in development in-house or by a third party?

If you answer yes to any of these questions then your organization must comply with international, European and national ABS rules.

These ABS rules r**equire that users of genetic resources**, and their host organizations, take several steps before obtaining the genetic resources as well as during and after the R&D process:

Obtain Prior Informed Consent (PIC) of the provider (State) of the genetic resources, if the provider's legislation requires so.

Negotiate with the provider **Mutually Agreed Terms** (MAT) for the conditions of access and utilization of the genetic resources and for the sharing of the benefits arising from their use.

Communicate at prescribed milestones to the national and international competent authorities certain ABS information and legal documents; provide ABS information to subsequent users and keep ABS records for 20 years after the last use.

The entering into force of the Nagoya Protocol and of the European Regulation on compliance measures for users from the Nagoya Protocol (EU ABS Regulation) creates **new challenges** for scientists, research managers, collection managers and database managers. Also funding agencies (e.g. EU research projects) require that all ABS requirements are met. **Improper handling** of genetic resources and lack of compliance with the applicable ABS requirements can **reduce the value of research** and development activities, and even **lead to criminal charges in certain countries**. It is therefore essential to take immediate action to ensure compliance for activities involving genetic resources within your organization.

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ABS-int's step-by-step approach

ABS-int is dedicated to helping organizations comply with ABS requirements. As a service provider our aim is to unlock the value of genetic resources for your research and development. We realize that research organizations are a unique environment with particular structures, in which academic freedom has high importance. In addition, academics already face a high administrative burden.

ABS-int has developed an offer of services which are essential to ensure full compliance with ABS requirements. These services can be complimentary to in-house efforts or can constitute the complete ABS compliance coordination. Understanding that each organization is unique, we will customize with you an approach that effectively and efficiently delivers the best results in line with your organization's structure and philosophy.

Why do you need this?	Where is it relevant?	How to put it in practice?	How to inform your organisation?	How effective is your organisation?
Presentation to the management	Assessment of utilization of genetic resources	Development of internal protocols & procedures	Staff Training	Auditing and assistance during an official inspection
	Audit of collections, database & documents	Database for track & trace	ABS help desk Q & A	Defence in case of legal or public challenge
		Contract drafting & negotiation		

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Why do you need this?

Understanding the ABS obligations

Presentation to the management

WHAT

The management of your organization is ultimately responsible for the ABS compliance of the organization. In addition, the management will decide on the priorities of an organization and its departments and personnel, and the allocation of resources related thereto. It is therefore crucial for the management of an organization to fully understand the repercussions of this new regulatory framework and the need to render every research activity ABS compliant.

ABS-int provides concise legal briefings and executive presentations on the main principles of ABS, and its legal requirements and operational consequences, highlighting the risks and potential liabilities for the organization in case of non-compliance.

WHO

Executive Board, heads of scientific departments.

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Where is it relevant?

Identifying the scope of ABS obligations in your organization

Assessment of utilization of genetic resources

WHAT

The ABS rules apply to "utilization of genetic resources" which means to "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology". Therefore it is important to map and identify all activities in your organization in which utilisation of genetic resources takes place.

ABS-int performs or assists with the mapping and identification of activities involving utilisation of genetic resources.

WHO

Executive Board, heads of scientific departments.

Audit of collections, database & documents

WHAT

Since the ABS rules impose a new regulatory framework upon the users of genetic resources, all instruments related thereto, including collections, databases and legal documents (including agreements) will need to be checked for compliance with ABS rules.

ABS-int assists your organization in conducting a detailed audit on the status of the collections, databases and legal documents taking into consideration the ABS rules.

WHO

Collection managers, database managers and legal counsel

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How to put it in practice?

Implementation

Development of Internal Protocols & Procedures

WHAT

Each laboratory and each collection needs to implement or adapt its own procedures to ensure compliance with ABS rules in relation to receiving, storing, using and transferring samples of genetic resources.

ABS-int assists in adapting existing and developing new procedures that will facilitate effective compliance

WHO

Heads of scientific departments, heads of laboratories, program leaders, and collection managers.

Database for track & trace

WHAT

In order to ensure compliance, effective data management of all ABS related information is key. In addition, information on access to genetic resources, on the conditions of accessing them and the conditions of their utilization, and information on the different users needs to be stored for 20 years after the end of utilization. Compliance with these obligations requires an effective database. Organizations often have their own database management systems, but these might need to be revised and updated to ensure an effective tracing and tracking of genetic resources.

ABS-int assists your organization in assessing your existing database and is cooperating with IT companies in developing updated or new databases for an effective track and trace of ABS related information at organization level.

WHO

Database managers. ICT Department.

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How to put it in practice?

Implementation

Contract drafting & negotiation

WHAT

Genetic resources are usually accessed by scientists through an expedition or via a scientific collaboration. Scientists usually do not have the legal background to negotiate with a provider the conditions of access and utilization of these resources. Once negotiated these conditions stay attached to the material, unless a re-negotiation with the provider takes place, therefore subsequent Material Transfer Agreement conditions depend upon the initial ABS contracts/agreement.

ABS-int works with scientists and legal counsel to revise and draft agreements and other legal documents (including PIC and MAT); as well as to develop model agreements. ABS-int is supported by a strong network in many provider countries.

WHO

Scientists, legal counsel.

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How to inform your organisation?

Training & support

Staff training

WHAT

ABS obligations affect many facets of the R&D process. All scientists using genetic resources and all staff mandated to negotiate agreements related thereto need to have an in depth knowledge of ABS obligations. Scientists need to ensure they have the necessary permits before any in situ collection takes place and to use proper Material Transfer Agreements (MTA) when transferring and receiving genetic materials.

ABS-int performs targeted training workshops explaining all ABS obligations and the practical repercussions for the different steps of the R&D process, as well as the tools to facilitate compliance organization

WHO

Heads of scientific departments, database managers, collections managers, all scientists using genetic resources, technology transfer officers

ABS help desk Q & A

WHAT

Management of genetic resources within the different R&D activities of an academic organisation is complex in terms of ABS compliance. Scientists may face uncertainty in relation to management of genetic resources and necessary paper work. This is complicated further by the fact that the legal framework is in constant evolution.

Because in most cases, the workload linked to ABS is fluctuating and because of the specialist knowledge required, managing information or service requests related to ABS compliance is difficult to handle.

ABS-int has developed an ABS Help Desk, which is available at any given moment in time to provide the right assistance. The helpdesk agreement is set up in such a way that full confidentiality can be guaranteed.

WHO

All staff dealing with genetic resources.

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How effective is your organisation?

Checking implementation

Auditing and assistance during an official inspection

WHAT

As ABS imposes a new set of obligations, it is important to measure how your organization is implementing the necessary actions. Audits provide a critical, constructive external view that will help you improve on achieving compliance.

ABS-int conducts different audit types: compliance audits ("is the management of genetic resources in compliance with ABS requirements?"), performance audits ("is the way ABS requirements are managed efficacious and efficient?") and system audits ("is everything in place to ensure future compliance?"). ABS-int may also perform an audit in preparation of an inspection by the authorities aiming to check compliance with all technical and procedural requirements. ABS-int can also assist you during an inspection or investigation and interact with the authorities.

WHO

Executive Board, heads of scientific departments, legal counsel

Defence in case of legal or public challenge

WHAT

Every organization which is using genetic resources can face legal or public challenges, which might eventually lead to a legal case.

ABS-int can provide you with legal advice and cooperates with other specialised attorneys on a global level to ensure effective representation in a legal case. ABS-int can also assist you in drafting talking points and communication documents in case of a public challenge.

WHO

Executive Board, heads of scientific departments, legal counsel

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Who are we?

ABS-int is a service provider dedicated to helping organizations comply with ABS requirements. Our aim is to unlock the utilization of genetic resources for your research and development in a cost effective way.

Connected through our network of professionals, we can cover the international dimension that is inherent to the ABS framework.

Our multi-disciplinary team consists of professionals with different backgrounds, including science, law and regulatory. These professionals have years of experience in providing advice to national and international companies and institutions, including in the fields of ABS, sustainable resources management, biodiscovery, biosafety regulations, stewardship, environmental law and intellectual property law.

Our previous work?

ABS-int's multi-disciplinary team has a strong experience in ABS related matters. It has acquired the necessary skills through:

- Raising awareness of scientists within several EU funded projects on biotechnology (e.g. MicroB3 – PharmaSea – MaCuMBA)
- ABS Help Desk for several organizations and projects
- Training workshops in nine European countries for users of genetic resources in academic and research organization, commissioned by the European Commission
- The draft of the first ABS model Agreement to access Marine Microorganisms within the FP/ Project Micro B3
- Assistance to culture collections within the World Federation of Culture Collections
- Active participation in the discussions for the drafting of an Implementing Agreement to the United Nations Convention on the Law of the Sea at the United Nations, including by providing presentations to the relevant UN bodies
- Academic research on ABS, including publishing several scientific papers on the topic
- Assistance in ABS awareness raising and setting up compliance tools for a range of research organizations, SME's and large companies

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