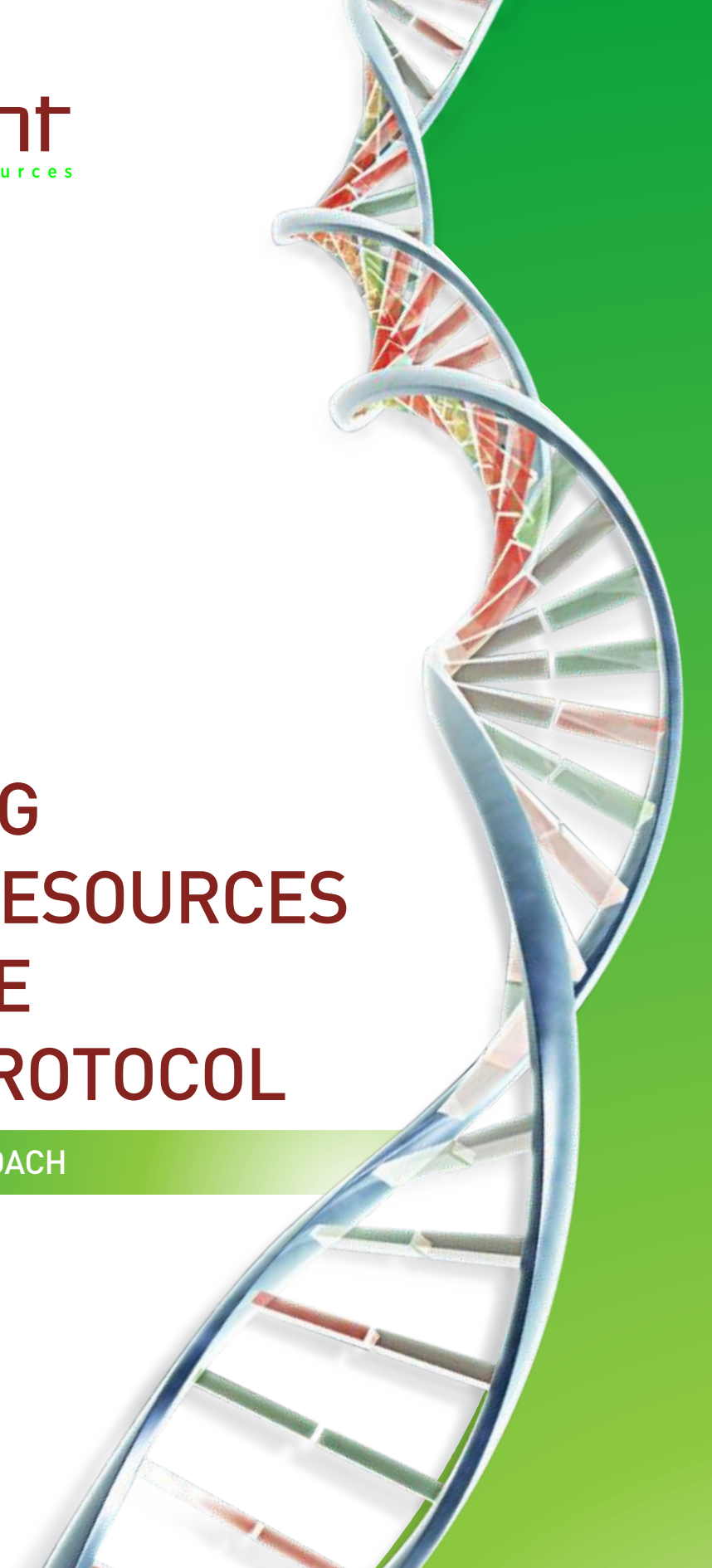
ABSInt
Unlocking Genetic Resources



UNLOCKING GENETIC RESOURCES UNDER THE NAGOYA PROTOCOL

A STEP-BY-STEP APPROACH

ABS int
Unlocking Genetic Resources

Relevance of Access & Benefit Sharing rules

Are Access and Benefit-Sharing (ABS) rules relevant for your company? 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 company or from/to other institutions/companies?
- ❑ Are genetic resources deposited in your collections?
- ❑ Is your company performing research and development, product development and commercialization using genetic resources?
- ❑ Is it possible that genetic resources maintained or used for research and development in your company are further used in development in-house or by a third party?

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

These ABS rules r**equire that users of genetic resources**, and their host companies, 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 companies active in natural product research, which inherently involves the use of genetic resources. Lack of compliance with the applicable ABS requirements can reduce the value of natural product research, and even lead to criminal charges in certain countries. It is therefore essential to take immediate action to ensure full compliance.

ABS-int
Unlocking Genetic Resources

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 company?	How compliant is your company?
Presentation to the management	Assessment of utilization of genetic resources	Development of internal protocols & procedures	Staff Training	Auditing & assistance during an official inspection
	Audit of collections, databases & documents	Database for track & trace	ABS help desk Q & A	Defence in case of legal or public challenge
	Mapping of value chain & audit of relevant contractual arrangements	Contract drafting & negotiation		

ABS-int
Unlocking Genetic Resources

Why do you need this?

Understanding the ABS obligations

Presentation to the management

WHAT

The management of your company is ultimately responsible for the ABS compliance. In addition, the management will decide on the priorities of a company and its departments and personnel, and the allocation of resources related thereto. It is therefore crucial for the management of a company to fully understand the repercussions of this new regulatory framework and the need to render every R&D 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 company in case of non-compliance.

WHO

Executive Board, heads of R&D, regulatory and IP departments

ABS-int
Unlocking Genetic Resources

Where is it relevant?

Identifying the scope of ABS obligations in your company

Assessment of utilization of genetic resources

WHAT

ABS-int assists your company in conducting a detailed audit on the status of the collections, databases, R&D activities and legal documents (including pending and existing IP rights) taking into consideration the ABS rules.

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

WHO

Collection managers, database managers, legal, regulatory and IP departments

Audit of collections, database & documents

WHAT

Since the development of a product based upon natural product research involves a complex value chain with many different players, it is key to ensure and enable full ABS compliance by all different parties of the value chain by mapping all parties involved and auditing the contractual arrangements between them. This enables the integrity of the whole value chain to be safeguarded.

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

Mapping of value chain & audit of relevant contractual arrangements

WHAT

Since the development of a product based upon natural product research involves a complex value chain with many different players, it is key to ensure and enable full compliance by all different parties of the value chain. It is therefore essential to map all parties involved and audit the contractual arrangements between all players to safeguard all rights and obligations related to compliance with ABS rules. By doing so, the integrity of the whole value chain is safeguarded.

ABS-int assists your company in mapping the value chain in detail and auditing contractual arrangements in the light of ABS rules. In a next step the value chain can be optimized by inclusion of specific clauses in the relevant contractual arrangements.

WHO

Purchase managers, stewardship managers, legal, regulatory and IP departments

ABS-int
Unlocking Genetic Resources

How to put it in practice?

Implementation

Development of Internal Protocols & Procedures

WHAT

Each R&D department 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 R&D departments, project managers 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. Companies 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 company 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 the company level.

WHO

Database managers. ICT Department.

ABS-int
Unlocking Genetic Resources

How to put it in practice?

Implementation

Contract drafting & negotiation

WHAT

Genetic resources are usually accessed by scientists within the R&D department 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 agreements.

ABS-int works together with the R&D, legal and regulatory department 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, R&D, legal and regulatory departments

ABS-int
Unlocking Genetic Resources

How effective is your company?

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 and use proper Material Transfer Agreements (MTAs) when transferring and receiving genetic resources.

ABS-int performs 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 company compliance. Moreover, ABS-int develops dedicated e-learning modules that can be used to train staff and to test their competence.

WHO

Heads of scientific departments, database managers, collection managers, all scientists using genetic resources, legal, regulatory and IP departments

ABS help desk Q & A

WHAT

Management of genetic resources within the different R&D activities of a company is complex in terms of ABS compliance, which causes administrative burden. This is further complicated 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.

WHO

All staff dealing with genetic resources.

ABS int
Unlocking Genetic Resources

How effective is your company?

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 company is performing 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 R&D, legal and regulatory departments

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 R&D, legal, regulatory and IP departments

ABS-int
Unlocking Genetic Resources

Who are we?

ABS-int is a service provider dedicated to helping companies comply with ABS requirements. Our aim is to unlock the potential of genetic resources for your R&D activities in an effective and efficient manner.

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

Our multi-disciplinary team consists of experts with different backgrounds, including science, law and regulatory, who have years of experience in providing advice to national and international companies and institutions, including in the field of ABS, sustainable resource 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:

- Country specific ABS assistance
- Standard Operation Procedure for large companies and SMEs
- ABS training for various biotech industries
- ABS Help Desk for several companies and projects
- Raising awareness of scientists within several EU funded projects on biotechnology (e.g. MicroB3 – PharmaSea – MaCuMBA)
- Assistance in ABS awareness raising and setting up compliance tools for a range of research organizations, SMEs and large companies
- The draft of the first ABS model Agreement to access Marine Microorganisms within the Fp7
- 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

Kortrijksesteenweg 127, B-9830 Sint Martens Latem, Belgium
+32 475 45 72 04
info@**abs-int**.eu
www.**abs-int**.eu

ABSint

Unlocking Genetic Resources