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**Guidance Document for Collection Holders**

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We would welcome any written comments (from participants and those who are not able to attend) **by 15 August 2017**. All written comments should be sent to [ABS.guidance@milieu.be](mailto:ABS.guidance@milieu.be), keeping Mr Martin Brink ([martin.brink@wur.nl](mailto:martin.brink@wur.nl)) in copy.

# Introduction

This Guidance document for collection holders is meant to help users, as well as competent national authorities, to establish whether activities carried out fall within the scope of the EU Access and Benefit Sharing (ABS) Regulation.[[1]](#footnote-2) It also aims to assist users in identifying their due diligence obligations and in concluding how these should be met.

The reader is advised to consult the general Guidance document before reading this guidance.[[2]](#footnote-3)

The EU ABS Regulation (hereafter referred to as “EU ABS Regulation” or the “Regulation”) is available at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>

The EU Commission Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 (hereafter referred to as “the EU general Guidance on ABS” is available at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC>

Other useful information can be found at:

<http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm>

As for all of the sectorial guidance documents, the aim of this document is to arrive at a shared interpretation for collection holders of the terms “utilisation” and “research and development” as contained in the EU ABS Regulation. It provides an overview of research and development activities, as well as a classification of activities as being within or outside scope of the EU ABS Regulation.

## Coverage

In the context of this Guidance document collection holders include genebanks, culture collection holders, biobanks, Biological Resource Centres (BRCs), botanic gardens, zoos and aquaria, and natural history museums. Their main activities include *ex situ* conservation of biodiversity, long-term national and international resources to support biological research (for instance in taxonomy, ecology, morphology, genomics, biochemistry, fisheries, agriculture, both in the private and public sectors), biodiversity management including under the implementation of the Convention on Biological Diversity, and commercial R&D. Collections may also be held *in situ* or on-farm. In some cases collection holders may not be involved directly in any research but exist for purely economic reasons as suppliers of genetic resources or extracts to others. Collection holders are primarily engaged in upstream activities in the user chain rather than in product development. Some types of collection holders (e.g. botanic gardens) are often integrated in universities or research institutes, while others (e.g. zoos) are usually independent entities.

Collections include, inter alia, dead specimens, sometimes preserved in such a fashion that no viable genetic material remains, frozen and cryopreserved collections, living collections and collections of extracted compounds or a combination thereof. Specimens may be identified to species or strain, or stored as mixed or environmental samples. Many collections also manage data relating to the specimens or their composition, including passport and provenance data, phenotypic (characterization and evaluation) data, and data on the legal status of the material (e.g. patents and ABS documents).

In some cases, traditional knowledge associated with the accessed genetic resources (aTK) may be held. “‘Traditional knowledge associated with genetic resources”’ means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources (See Article 3(7) of the EU ABS Regulation). Its use is also addressed in this document. This might, for instance, include knowledge with respect to traditional fermented food products, antibacterial properties of traditional medicinal plants and soil management in traditional agriculture.

Collections of biological resources may be held by public bodies (e.g. national museums, botanic gardens, national crop and crop-wild relative collections), the education sector (universities), private bodies, charities, companies, and private individuals. Zoos, for instance, are quite diverse in their legal entities. Around one third of the members of the European Association of Zoos and Aquaria (EAZA) are public bodies, one third have a company legal profile, and one third are charities.

## Collection Holders’ activities

**1.2.1 Types of collections and their activities**

There is no simple classification of collection types, and organisations may ‘overlap’ in their activities and the types of collection held. However, collection holders may self-identify as one or more of the main groups below:

1. Genebanks

Plant genebanks collect, characterize, evaluate, store, regenerate, multiply, and distribute genetic material. They may include seedbanks, tissue banks, cryobanks and field gene banks, the latter including living collections of crops (also including fruit trees and ornamentals), crop wild relatives, and forest tree species. Genebanks may closely cooperate with and distribute material to a range of commercial and non-commercial partners, including breeding companies, researchers, botanic gardens, NGOs, authorities and plant variety offices. Some, but not all, genebanks distribute to the general public and perhaps farmers. Basic and applied research activities may take place within genebanks. Documentation is also an important activity of genebanks, with data systems often being very well developed in the genebank world.

Livestock genebanks acquire and store semen, embryos, oocytes and tissues and provide them as needed. Co-operation with breeding companies to obtain biological material is quite common. So far, stored material has been distributed to a limited extent only, and mostly for use in conservation or breeding programmes.

For Plant Genetic Resources (PGR), *ex situ* conservation in genebanks has a long history and genebanks are widespread, while in case of Animal Genetic Resources (AnGR), the establishment of national genebanks started only at the end of the 20th century.

1. Culture collections

Culture collections contain micro-organisms, such as filamentous fungi and yeasts, bacteria and archaea, phages, plasmids, but also animal cells including human and hybridoma cell lines, animal and plant viruses, plant cells, algae and protozoa. These organisms and cell lines are kept alive and multiplied, and living material as well as DNA-extracts are exchanged with other collections and distributed to researchers both academic and commercial. Public culture collections are usually embedded in research institutes where basic and applied research is conducted on the holdings, often in collaboration with public bodies or companies. They may also fall under the heading of Biological Resource Centres. Most of larger culture collections also maintain databases with scientific (open access) data, and meet the Organisation for Economic Cooperation and Development (OECD) standards of Biological Resource Centres for quality of resources and associated data. Culture collections may carry out identification of specimens sent in by officials or private individuals.

1. Biobanks

Biobanks are generally focussed on collections of human tissues. However, these tissues might include pathogens and other associated organisms. There are also collections styling themselves as biobanks that deal explicitly with non-human tissues (for example the EAZA biobank), and some focus on human diseases. Geno (a Norwegian breeding organization) has established a biobank of animal tissues.

Biobanks may be associated with hospitals (and may source material from patients at these). Material is generally held frozen to preserve viability. The collections are maintained for research purposes, and biobanks make their samples and data derived from these samples available for researchers, in other institutions as well as in the collection-holding institution, e.g. for studies on diseases. The number of individuals from which samples are used in these studies may be very high (tens or hundreds of thousands).

1. Biological Resource Centres (BRCs)

BRCs have been defined in an OECD workshop as follows: “They consist of service providers and repositories of the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics.”[[3]](#footnote-4). BRCs thus include Culture Collections, Genebanks and Biobanks. BRCs supply to many actors, and include patent depositories.

The concept of Biological Resource Centres (BRC) was thought up as early as 1946, at UNESCO, on the set up of the Microbial Resources Centres Network (MIRCEN) programme, aimed at establishing microbial resource centres in developing countries and to strengthen threatened treasure houses of microbial diversity through mutual support within a network. In 1999, the Organization for Economic Co-operation and Development Working Group on BRC initiated the development of the concept into the 21st century, pointing out the crucial roles of BRCs for human life and the biosphere, underlining the necessity to provide the adequate support to enable the BRCs to meet the increasing challenges of biodiversity and genomics. While the emphasis was previously put on the biological resources conserved in specialized facilities, at present a BRC is conceived as a functional unit having all the necessary components to study, preserve and use biological diversity.

1. Botanic gardens and other living plant collections

Botanic gardens are usually open to the public and play a huge role in public education and awareness of conservation and biodiversity. Botanic gardens also focus on the collection, documentation and exchange with other collection holders of plant genetic resources. They provide genetic resources to universities and other research institutes for basic and/or applied research. Some botanic gardens may have specialised seed banks, holding seed as part of *ex situ* conservation programmes. Botanic gardens, especially those associated with universities, often carry out scientific research, either on their own or in collaboration with external parties. Material is distributed mainly to other botanic gardens, for the purpose of education and nature conservation.

Provenance trials are not considered plant collections, and are dealt with in the guidance document for the Plant Breeding sector. Dynamic genetic conservation units, i.e. forest stands or areas located in forests managed for multiple use or in protected areas, that have been established and maintained to conserve genetic diversity of European forest tree and shrub species in their natural habitat, are not considered collections either, just as natural reserves and parks.

1. Zoos and aquaria

The main aims of zoos and aquaria are *in situ* and *ex situ* biodiversity conservation, education and research. Zoos and aquaria predominantly maintain a variety of living animal species. In addition, several zoos also maintain a plant collection. Zoos and aquaria might also collect and bank genetic material (tissue, blood, serum, gametes).

Population management is often organised cross-institutional in population management (breeding) programmes run under the auspices of the European Association of Zoos and Aquaria (EAZA), the so called EAZA Ex-situ Programmes (EEPs). The objective of these programmes is to obtain sustainable genetically viable populations.

Zoos have a legal obligation to record data and the most common system used is ZIMS which is a global system and gives overviews on large amount of data to all member zoos. The aim of the EAZA Biobank, existing of hubs in different countries, is to store samples (tissue, blood or serum) of all EEP specimens that will be used to perform research to aid population management programmes.

Zoos and aquaria also carry out research including for the conservation of threatened species. Research might be coordinated institutionally or undertaken by the collective under the umbrella of EEPs, and will often involve cooperation with partners (e.g. universities, laboratories). Finally, zoos and aquaria may support authorities with the housing of confiscated animals and may carry out identification of specimens sent from other countries by both officials and private individuals.

1. Natural History Museums and herbaria

The core activities of Natural History Museums are the maintenance and exhibition of their collections, but many also perform research and education activities. According to the International Council of Museums (ICOM) Statutes, the common definition of a museum is a non-profit, permanent institution in the service of society and its development, open to the public, which acquires, conserves, researches, communicates and exhibits the tangible and intangible heritage of humanity and its environment for the purposes of education, study and enjoyment. Collections are considered and protected as Heritage. Collections of Natural History Museums may include specimens with no viable genetic material and frozen viable material. Some collections may hold confiscated material supplied by police, customs and quarantine authorities. By its nature, such material lacks appropriate documentation from the country of origin, which may not even be known. Research carried out may be basic or applied, sometimes in collaborative projects with universities or companies. Specimens are exchanged with or loaned to researchers globally, and many researchers from different countries visit the collections to carry out research. Most of larger museums and herbaria also maintain databases with scientific (open access) data; this may include aTK.

A herbarium is a collection of preserved plant specimens and associated data. The specimens may be whole plants or plant parts, which are dried and mounted on a sheet of paper and stored in boxes, or kept in alcohol or other preservative. The specimens in a herbarium are normally used for scientific study, and are often used as reference material in describing plant taxa. Herbaria may carry out identification of specimens sent from other countries by both officials and private individuals. A xylarium is a herbarium specialising in specimens of wood. A fungarium is collection of preserved specimens of fungi. Natural History Museums and herbaria are increasingly developing frozen tissue collections alongside their traditional preserved collections.

**1.2.2 Governance of collections**

A collection holding body or entity may be characterised as an institution (e.g. a national museum), a department within another institution (e.g. a university department), or even an individual within an institution (e.g. an individual researcher). This is important for collection holders to clarify, so that responsibilities for due diligence are understood an accepted by the appropriate entities. When considering characteristics influenced by governance and ownership, the following categories can be distinguished:

1. Public (governments, local authorities, universities, public institutes)

Collections under public ownership may have some activities, including acquisition and disposal, regulated by statutes or founding documents. Activities by staff may be strongly regulated or staff may operate more or less independently. National collections tend to be large and used by many researchers within and outside of the holding institution.

1. Commercial bodies

These include (i) collections held by companies primarily or exclusively for the use of their staff or staff of subsidiaries (nationally, regionally or globally); (ii) collections set up as commercial enterprises and serving many customers. Some of these are biobanks focussing on human tissues but even these will presumably include pathogens and other associated organisms.

1. Charities and foundations

Collections, e.g. botanic gardens, may also be managed and maintained by charities and foundations. An example is the Belmonte Arboretum in Wageningen, the Netherlands.

1. Researchers (independent or employed, but operating to some extent independently within their employment)

Collections held by, among others, individual or groups of researchers, or university or research institute departments, may be of any organism type. These collections may have been acquired for particular research projects with or without institutional oversight, and may include material collected both by employees and students. Specimens may be used by a variety of actors over time, although probably under the supervision of the original researcher. However, the collection may not be seen as a ‘collection’ per se, but simply as a research tool.

1. Private individuals

Particularly for organisms such as insects, molluscs and plants there is a large amateur (and professional) collection-holding population consisting of people not connected to institutions. They may access directly from providing countries, and large collections may ultimately be sold or bequeathed to major public collections and thus form part of the supply chain. Several of such private collections within the EU are listed on the Global Registry of Biodiversity repositories[[4]](#footnote-5).

**1.2.3 Classification of activities**

The following main groups of activities of collection holders can be recognised, in line with activities described in the other sectorial documents:

1. Acquisition

Biological material may be acquired from all over the world, or, especially by livestock genebanks, domestically. It may be acquired directly by collecting (including from the field or from local markets) by staff members and associates, or indirectly by donation or purchase, or though exchange with other collections. Material may be acquired for permanent custodianship or ownership, or it may be held in trust for others, including other countries. Material may also be added to the collection following research by staff of the collection-holding institution or others. Material when acquired may be of a single species or strain or a mixture of many different species or strains. Some entities may not have scientific names, being of unidentified or undescribed species or strains. Identification and separation may take place many years after acquisition, or never, in the case of environmental DNA samples. Material is usually gathered with information regarding its place of collection and other relevant information, which may include associated Traditional Knowledge. Appropriate documentation regarding collection may accompany the specimens; these documents include research permits, collecting permits, CITES permits, PIC and MAT, MoUs etc. These agreements will typically specify that the material covered can only be used for specific purposes (e.g. for most museums, herbaria and zoos that only non-commercial research is to be undertaken). Names on the permits (or PIC & MAT) may not include the name of the collection holding institution.

Material may also be deposited by third-party researchers, as reference material. In these cases, authorisation such as PIC or sampling authorisation and possible agreements are usually made before material enters a depository. So, these actions, often made independently from the depositories, and are out of control of depositories.

Material may be brought into the collection-holding institution by short-term visitors from the EU or elsewhere in the world as a part of their research, and subsequently removed. If the facilities are available in the collection-holding institution, the visitors may make use of the institution’s sequencing or other facilities.

Some specimens of unknown or known illegal provenance may be supplied by police or other authorities for the purposes of identification and storage.

1. Identification

Identification is an integral part of collection management. Even specimens or strains that have been supplied with a name may be re-identified subsequently, or the strain evaluated. Identification may be by means of morphological (phenotype) examination, or through the use of DNA, RNA or biochemistry (including barcoding technologies, which use short genetic markers in the DNA of organisms to identify them). DNA sequence data might be deposited in public databases, or compared with many other sequences held in these databases to carry out this identification. Identification may determine that the subject belongs to a species or strain already possessing a scientific name, or to a species or strain that does not possess a name (new to science). In the latter case the species may be given a name or merely recorded as ‘undescribed’. AnGR genebanks do not usually perform identification and evaluation, as the material is from known individual animals and is often kept as ‘insurance’.

Specimens or samples may be sent for identification purposes by private citizens, NGOs, government agencies including health, agriculture, forestry, fisheries and environmental management, often with rapid response requirement.

1. Taxonomic, biosystematic and other research

Description, inventory and clarification of relationships are characteristic of many collection holders, and may be undertaken as a part of collection management. As with identification, this may use phenotypic characters or DNA and RNA. DNA-analysis is an increasingly used tool in collection-based taxonomic work.

The use of DNA is an increasingly used tool in collections-based taxonomic work, including for the identification of taxa and determining relationships between them. In most cases genetic or biochemical properties are not examined. With the cost of genomic sequencing falling, increasing amounts of sequence information are being produced as a component of taxonomic and systematic work.

1. Breeding

Zoos and aquaria are involved in breeding programmes with the objective of obtaining sustainable genetically viable populations. Within zoo breeding programmes, the animals are managed as if being owned and managed by the collective, and management decisions in the context of EAZA Ex-situ Programmes (EEPs), e.g. on breeding or transfer of animals, lie with the collective of holders rather than with the legal owners of specimens. In many cases, zoos associations will sign the PIC and MATs and manage the programme, while the holding and breeding is done by individual member zoos. EEPs are non-commercial and animals (or parts thereof) are exchanged free of charge.

1. Documentation (Collection management and cataloguing)

Collection holders are increasingly managing data about their holdings and making this and other information about their holdings and their research public, where possible through open access systems. Collections will generally try to catalogue accessions to some level of detail to support collection management and access to collections. Typically this will involve adding specimen data to an institutional database and may include dissemination in publicly available scientific or cultural resources such as the Global Biodiversity information Facility or Europeana; such data may be used by many individuals worldwide. Collection managers use such data to help track specimen movements in and out of the institution or between separate collections managed by one institution, for example recording that a DNA sample has been taken from a particular sample. Such data capture also facilitates the recording of any restrictions placed on the use of a specimen by a provider.

1. Supply to third parties

In this case a ‘third party’ is understood as an individual or entity which is not a part of the collection-holding body. In the case of museums and herbaria, material is generally supplied in the form of loans to academics carrying out non-commercial research which is congruent with the work of the collection holder and with the terms and conditions attached to the material. Although supply is generally in the form of loans, for some institutions there is a proportion of tissue that might be consumed during genetic or biochemical analysis and hence not returned. In some cases specimens are exchanged with other collections. Microbial collections and genebanks do not usually supply material as loans, but transfer the material definitively. In the case of zoos and aquaria, animals that are part of breeding programmes are moved around between institutions.

## Types and sources of genetic resources used

Plant genebanks obtain genetic resources from all over the world through collection missions and exchange with other genebanks. They may also store material used in research projects, as well as material from plant varieties or animal breeds not available in the market anymore. Livestock genebanks mainly acquire material from endangered native breeds (from farmers etc.) and commercial breeds (often through breeding companies), from within the country. A few livestock genebanks collect material abroad but this is rather rare.

Culture collections (and Biological Resource Centres) obtain micro-organisms (fungi, yeasts, bacteria) from all over the world, through researchers who deposit cultures as reference material for their scientific publications (including type-strains for novel species), collecting by researchers of the collections, exchange and donation. Some may be deposited as a part of a patenting system. Often use is made of samples of soil, water, sediments or plants, which usually contain vast numbers of different microbes requiring significant lab work to obtain the genetic resource of interest (the entire microorganism or its genes).

Biobanks obtain human tissues from hospitals and other medical centres. In the cases of disease the pathogens may have been acquired by patients in other countries.

Botanic gardens obtain new plant genetic resources through exchange with other botanic gardens and buying from commercial growers. Field collection missions are also carried out. The origin of the material is worldwide.

Zoos usually do not use animals from the wild in their breeding programmes, but offspring (2nd, 3rd or 4th generation) from breeding programmes. Exchange is mostly within Europe, but animals may also be obtained from zoos outside Europe. They have a digital registration system, which includes all their animals and their histories: the ZIMS (Zoological Information Management System) database.

Natural History museums and herbaria obtain plant, animal and microbial genetic resources from all over the world, through fieldwork, collection in source countries, exchange with other Natural History institutes, or donation, bequests and purchase from private individuals. Typically material enters in high volumes, comprising hundreds or thousands of different species, often unidentified. Acquisition, if from a third party, may take place many years after access, and a single acquisition may contain specimens from many different collecting events in different countries.

## Actors in the Collection Holders domain

The collection holders domain comprises many individual genebanks, culture collections, biobanks, Biological Resource Centres, botanical gardens, zoos and aquaria, Natural History Museums and herbaria.

Collection holders work together and they have created and agreed on a wide variety of best practices and other tools:

* Plant genebanks often use the Standard Material Transfer Agreement (SMTA), developed in the framework of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The use of the SMTA is obligatory for plant genetic resources included in the Multilateral System (MLS) of the ITPGRFA. The SMTA may also be used voluntarily for plant genetic resources that are not included in the MLS.
* Many European botanic gardens use the International Plant Exchange Network (IPEN) system, a registration system for botanic gardens which implement a common Code of Conduct with respect to access of genetic resources and benefit-sharing, in agreement with the Convention on Biological Diversity (CBD) and the Nagoya Protocol, and use a standardized Material Transfer Agreement (MTA) developed by IPEN. Some botanic gardens subscribe to the *Principles on Access to Genetic Resources and Benefit-Sharing[[5]](#footnote-6).*
* Members of the Consortium of European Taxonomic Facilities (CETAF) are implementing the CETAF Code of Conduct and Best Practices[[6]](#footnote-7), which is currently being considered for recognition by the European Commission under the EU ABS Regulation. The CETAF toolkit includes template Material Transfer Agreements (MTAs) and a Statement of use of biological material. CETAF members include Botanic Gardens, Herbaria and Natural History Museums.
* A number of EU Natural History Museums, Botanic Gardens and Culture Collections are members of the Global Genome Biodiversity Network (GGBN), which has developed a Code of Conduct and Best Practices for ABS[[7]](#footnote-8) based on an early version of the CETAF documents. The GGBN toolkit includes template MTAs, a Statement of use of biological material, and data management standards.
* Culture collections may use the Core Material Transfer Agreement (MTA) of the European Culture Collection’s Organization (ECCO)[[8]](#footnote-9), and have developed ABS-policies and best practices in the framework of the Microbial Resource Research Infrastructure (MIRRI)[[9]](#footnote-10). An earlier standard, MOSAICC, is now being replaced by TRUST (Transparent User-friendly System of Transfer, implementing the Nagoya Protocol in microbiology)[[10]](#footnote-11). TRUST is an internet-based system, built on the Global Catalogue of Microorganisms where data related to microbiological material stored in culture collections can be retrieved, including administrative data, which makes possible the monitoring of flows in the culture collections community at global scale. MIRRI may be connected to the global TRUST system when MIRRI- European Research Infrastructure Consortium (MIRRI-ERIC) infrastructure is set and has a data management system that enables processing of administrative data. The MTA may also be a Material Deposit Agreement (MDA), or what culture collections call a Material Accession Agreement (MAA).
* Biobanks may use the Best Practices for Repositories developed by the International Society of Biological and Environmental Repositories (ISBER)[[11]](#footnote-12); this is currently being revised with the inclusion of ABS requirements for non-human material. They are generally operating within a range of requirements linked to donor rights. Countries may have laws regulating ownership of samples held in biobanks.
* Biological Resource Centres have their best practices (although more focussed in biosecurity) from the OECD[[12]](#footnote-13); many are aware of the Nagoya Protocol and considering relevant best practices e.g. under MIRRI.
* One of the objectives of EUGENA is to facilitate a European approach for international cooperation and exchange of Animal Genetic Resources in the context of the Nagoya Protocol for Access and Benefit Sharing; the work is going on to develop voluntary model Material Acquisition Agreements (MAA) and Material Transfer Agreement (MTA) for livestock genetic resources.

# Classification of activities in relation to utilisation of genetic resources

## Introduction

This chapter explores the range of activities that may be carried out by collection holders, and relates these activities to the EU ABS legislation and, more specifically, to the obligations of users that may follow from the Regulation. It should be noted that collection holders often accept material under written agreements which may impose contractual conditions on collection use which may be additional to requirements under EU ABS regulations.

Article 3(5) of the EU ABS Regulation defines utilisation as “*to conduct research and development on the genetic or biochemical composition of genetic resources*, including through the use of biotechnology (…)”.

How the terms research and development (R&D) and utilisation should be understood in the context of the implementation of the Nagoya Protocol in the European Union can be derived from the OECD’s 2002 Frascati Manual. According to this manual[[13]](#footnote-14), “research and experimental development comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications”. The manual further distinguishes three types of R&D: basic research, applied research and experimental development. Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view. Applied research is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective. Experimental development is systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

Furthermore, it has been suggested by Morgera and Geelhoed to interpret the term research and (experimental) development as “two intimately related processes by which new products and new forms of old products are brought into being through technological innovation”.[[14]](#footnote-15)

Articles 5.4, 8(a) and 17 of the Nagoya Protocol and Article 7 of the EU ABS Regulation indicate and imply that each type of R&D is considered to constitute utilisation.

***Further considerations***

Chapter 2.3 below provides an overview of the cases analysed. Some activities typically precede actual R&D and others normally take place after finalisation of R&D. Yet other activities are undertaken that should be classified as R&D. Finally, certain activities may be distinguished that have no direct relation with R&D.

Chapter 2.3 refers to the main activities undertaken by collection holders, and lists whether the activities concerned are considered to fall inside or outside the scope of the EU ABS Regulation. It is intended to help the reader in assessing whether an activity falls within or outside scope, and explains what the due diligence obligations are.

The cases refer to the use of genetic resources mainly. In some cases, traditional knowledge associated with the genetic resource involved may be used in the research and development process, and in such cases all obligations under the EU ABS Regulation would also apply to the use of such associated knowledge.

Not all cases described below are specific for collection holders, as some cases may occur in various domains (see sector-specific guidances).

Qualifying a certain activity as to constitute R&D is a *necessary* but not a *sufficient* condition to determine whether such activity falls within the scope of the EU ABS Regulation. An activity only comes under the scope of the EU ABS Regulation if it involves the utilisation of genetic resources acquired from a country that is a Contracting Party to the Nagoya Protocol and the associated geographic, temporal, and material conditions as detailed in the general Guidance document have been met. In short, it means that (1) the providing state must exercise sovereign rights over genetic resources, must be a Party to the Protocol and established access measures on genetic resources, (2) genetic resources were obtained after the entering into force of the EU ABS Regulation, and (3) accessed genetic resources are utilised for the purpose of Research and Development within EU Territory. Users are referred to the general Guidance document[[15]](#footnote-16) for a more elaborate explanation of these conditions.

The EU ABS Regulation and laws of Contracting Parties to the Nagoya Protocol outside the EU may reflect a different interpretation of the obligations stemming from the implementation of the Nagoya Protocol. It is possible that ABS legislation and regulatory requirements in provider countries go beyond the scope of the EU ABS Regulation. Users in the EU are expected to respect such national legislation and requirements, as outlined in chapters 2.2 and 3.1 of the general Guidance document.

In the activities described and classified in Chapter 2.4, it is assumed that all other conditions (geographic, temporal, and material) have been met. Furthermore, it is assumed that any contractual obligations as well as any obligations stemming from other legislation will be respected and transferred to subsequent users, where applicable. These assumptions are not repeated in the discussion of the individual cases.

## Due diligence obligations

In addition to a mere classification this Guidance document also addresses in relevant cases what the user should do in order to fulfil his due diligence obligations. The EU ABS Regulation specifies and the Implementing Regulation further details when a due diligence declaration is required, i.e. in the research phase when receiving a grant and in the product development phase before the commercialisation of a product. For the purpose of demonstrating compliance with the due diligence obligation, Article 4(3) of the EU ABS Regulation requires users to seek, keep and transfer to subsequent users certain information, whereas Article 7 on the monitoring of user compliance regulates the following:

“1. The Member States and the Commission shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4.

2. At the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4, ....”

Although at each checkpoint (research or stage of final development of a product) the declaration is only required to be submitted once, it is possible that the same genetic resource will be subject to declarations at both checkpoints.

A due diligence declaration is only one element of the due diligence obligations established in the EU ABS Regulation. Other obligations include the requirement for users to seek, keep and transfer to subsequent users certain information. In its Chapter 3.3, the general Guidance document provides further information on how these obligations should be fulfilled.

Collection holders do not always perform R&D themselves, but may simply transfer material to others, so the question is raised as to whether collection holders have the obligation to seek, keep and transfer information to other users. General good practice for collection holders is to act as users in this respect, and to seek, keep and transfer the necessary information. Also, upon receiving material, it is good practice for collection holders to always check if the original permit for collecting GR allows supply to third-party users.

***Due diligence obligations for holders of registered collections***

Collection holders have the possibility to include their collection, or part of it, in an EU Register of Collections (Article 5 of the EU ABS Regulation). When a user obtains genetic resources from such a collection, the user is considered to have exercised due diligence as regards the seeking of information for these genetic resources (see Article 4(7) of the EU ABS Regulation)).

The procedures for inclusion of a collection in the EU Register of Collections are set out in the Implementing Regulation 2015/1866 (Article 3). With respect to the due diligence obligations of holders of collections included in the EU Register of Collections, they have the obligation to supply the genetic resources together with all the relevant information. However, the duty to keep and transfer this information rests with the user who has received the material from the collection. The obligation to make a due diligence declaration (in the research phase when receiving a grant and in the product development phase before product commercialisation) also rests with the user, making use of the information provided by the collection.

*Example*

A scientist may want to deposit a fungal strain for deposit in a public collection that is listed in the EU Register of Collections, and not want to disclose the country of origin of that strain, because all information on the provenance is company confidential. In this case, the strain could pose a considerable liability risk for the collection, as there is no information on the terms and conditions under which it may have been accessed, while users obtaining this strain from the collection would be considered to have exercised due diligence as regards the seeking of information for these genetic resources. Therefore, the manager of the collection should check if the original permit for collecting GR allows supply to third-party users, and, if so, under which conditions.

## Specific case analysis for Collection Holders

This chapter presents activities discussed in Chapter 1.

***2.3.1. Acquisition***

*Case 1*

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| *Title* | ***Specimens held in a collection without PIC and MAT*** |
| *Description* | Specimens of organisms are present in a collection. No PIC and MAT are present, and there are no records of whether or not PIC and MAT were ever obtained. |
| *Analysis* | If the material is not to be utilised in the context of the EU Regulation, the Regulation does not apply and no due diligence is required under the Regulation (although other factors may require action by the collection holder). However, if the specimens are later selected for utilisation, due diligence should be applied to determine whether this is within scope of the Regulation and, if so, PIC and MAT should be sought from the country where the material was obtained. |

*Case 2*

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| --- | --- |
| *Title* | ***Collecting from in situ conditions*** |
| *Description* | Specimens of organisms are collected from *in situ* conditions in a provider country. |
| *Analysis* | Any organism collected in *in situ* conditions falls under sovereign rights of the country where it is collected. In the CBD, the ‘country of origin of genetic resources’ has been defined as ‘the country which possesses those genetic resources in *in situ* conditions’, and ‘in situ conditions’ as ‘conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties’.  Incorporation into a collection itself does not involve R&D on the genetic or biochemical composition of the genetic resource. Therefore, this activity does not constitute ‘utilisation’ in the sense of the EU ABS Regulation. However, acquisition of these genetic resources should be done in line with the requirements of the country of collection, with Prior Informed Consent (PIC)[[16]](#footnote-17) and Mutually Agreed Terms (MAT)[[17]](#footnote-18) on intended use being negotiated if required by the country where the material is collected. |

*Case 3*

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| --- | --- |
| *Title* | ***Collecting from a market or shop*** |
| *Description* | Specimens of organisms are acquired from a market or shop in the country of origin and incorporated in a collection. |
| *Analysis* | Incorporation into a collection itself does not involve R&D on the genetic or biochemical composition of the genetic resource. Therefore, this activity does not constitute ‘utilisation’ in the sense of the EU ABS Regulation. However, acquisition of these genetic resources should be done in line with the requirements of the country of collection, with Prior Informed Consent (PIC)[[18]](#footnote-19) and Mutually Agreed Terms (MAT)[[19]](#footnote-20) on intended use being negotiated if required by the country where the material is collected.  If the specimens are later selected for utilisation in the sense of the EU ABS Regulation, due diligence should be applied and PIC and MAT should be sought from the country where the material was obtained, if required by that country. |

*Case 4*

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| --- | --- |
| *Title* | ***Accessing micro-organisms from commodities*** |
| *Description* | Plant material is imported into the EU as a commodity. At border inspection, some material showing disease symptoms is intercepted and sent to an institute providing an identification service and maintaining a public collection. Together with strains of the agent (a fungal pathogen), several strains of other fungal species are also isolated, which are not known to cause disease on these plants, and were most likely present as endophytes. Out of scientific interest, the institute decides to place all strains (the pathogen and non-pathogens) in the public collection without any restrictions on use, recording the non-EU country as the country of origin. |
| *Analysis* | Unintentional access of a pathogenic organism or pest does not trigger any compliance obligations under the EU ABS Regulation (Chapter 5.1.1 of the general Guidance document). For non-pathogens, however, no such guidance exists, and, before making the non-pathogens available without any restrictions on use, the collection holder should check the requirements of the country of origin, with PIC and MAT being negotiated if required by that country. |

*Case 5*

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| *Title* | ***Collecting associated organisms from a specimen in an ex situ collection*** |
| *Description* | Specimens of associated organisms are collected from a specimen of the host in an *ex situ* collection outside the country of origin. |
| *Analysis* | If there are original PIC and MAT covering the collecting of the host organism, these original PIC and MAT should be checked if they also cover associated organisms. If not, or if there is no PIC and MAT, it should be checked if the country of origin requires PIC and MAT, and this country should be approached to provide PIC and MAT if the organisms are utilized within the meaning of the EU Regulation. |

*Case 6*

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| --- | --- |
| *Title* | ***Collecting associated organisms from a human host*** |
| *Description* | Specimens of associated organisms are collected from a human host |
| *Analysis* | The human biome (i.e. the populations of microbiota inhabiting the intestinal tract, the breast, skin and other bodily surfaces as part of normal human physiology) consists of independent organisms, which are not human genetic resources. Hence there is no legal argument for exclusion of such type of genetic resources from the scope of the EU ABS Regulation or the Nagoya Protocol. However, it is considered that the Regulation does not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such are introduced unintentionally to a place in the EU territory, be it from a third country or from a Member State with access legislation in place (Chapter 5.1.1 of the general Guidance document). |

*Case 7*

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| --- | --- |
| *Title* | ***Collecting for genetic conservation*** |
| *Description* | A tree species is very rare in country A where its populations are considered to be endangered. Individuals from the remnant populations are vegetatively propagated and planted in a genetic conservation collection in country B. A PIC from country A was obtained before establishing the collection, but no MAT was negotiated or needed at the time. A decade later a joint European project wishes to make DNA-analysis of the collection and use the results for improving the genetic conservation programme of the species in question in Europe. By then no natural populations remain in country A. |
| *Analysis* | DNA-analysis with the aim of using the results for improving a genetic conservation programme constitutes ‘utilisation’ in the meaning of the EU ABS Regulation. If only PIC was obtained for the initial transfer from country A to country B and no MAT was negotiated, the terms of the original PIC should be checked. If the PIC does not contain any terms on future transfer and use, the European project needs to get new PIC and MAT on intended use from the authorities of country A, if required by this country. |

*Case 8*

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| --- | --- |
| *Title* | ***Isolating from foods processed with recorded or unrecorded traditional methods*** |
| *Description* | Specimens of micro-organisms are acquired from traditionally processed foods whose methods of production and use a) have been recorded by researchers in the field and been published previously or b) have not been recorded by researchers in the field and have not been published previously. |
| *Analysis* | If the specimens will be incorporated into a collection for subsequent use in R&D, this is a change in use from a commodity. Acquisition of these genetic resources should be done in line with the requirements of the country of origin, with PIC and MAT on intended use being negotiated if required by the country.  In both cases, the use of traditional knowledge in the preparation of the foods should be declared when seeking PIC, as publication does not automatically invalidate the rights of the holders of traditional knowledge. PIC and MAT will need to be obtained for the aTK if required by the country. If the use of the aTK is relevant for the utilisation of genetic resources and as such is described in the MAT applying to the utilisation of genetic resources the aTK falls within scope of the EU Regulation. |

*Case 9*

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| --- | --- |
| *Title* | ***Accessing genetic resources and associated traditional knowledge in the field*** |
| *Description* | A researcher collects plants and proceeds to conduct phytochemical analyses to study their pest control potential based on surveys of traditional knowledge kept by indigenous peoples identifying de-infecting traditional practices. |
| *Analysis* | The use of the plants as well as the associated knowledge to study their pest potential constitutes ‘utilisation’ in the meaning of the EU ABS Regulation, because it creates new and useful insights into the potential use of the genetic resource. In addition to the conditions for access to the plant, the usage of the associated TK has to be incorporated in the mutually agreed terms covering the utilisation of the accessed genetic resources.  If the access to the genetic resources on the one hand and the access to the traditional knowledge, e.g. maintained in one or more public databases, on the other hand constitute two different activities and involve different sources, then the use of the traditional knowledge still constitutes utilisation in the meaning of the EU regulation if this use is described in MAT; users are advised to check the ABS requirements for PIC and MAT of the providing country. |

*Case 10*

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| *Title* | ***Accessing traditional knowledge from a traditional source even though publicly available*** |
| *Description* | Use is made of a genetic resource covered in a catalogue of uses of Indian plants published in 1890, so publically available (but perhaps hard to find). A researcher revisits the same area of India and collects similar information from IPLCs (Indigenous Peoples & Local Communities) with the intention of adding it to the collection database. |
| *Analysis* | If the aTK refers to known plant species, and if it is included in the MAT, utilisation of the aTK falls within scope of the EU ABS Regulation, and the researcher should seek PIC and MAT according to the legal requirements of India. |

*Case 11*

|  |  |
| --- | --- |
| *Title* | ***Accessing genetic resources and associated traditional knowledge from a collection*** |
| *Description* | A research centre keeps a herbarium of nearly 500 local plants sheets made during the 1990s, associated with ethnobotanical survey records compiling traditional medical virtues, local names, data on informants and modes of preparation. A researcher requires a consultation of four herbarium sheets and corresponding records. |
| *Analysis* | If the country where the herbarium is located has chosen to exert its sovereign rights over GR and aTK originating in its country and held ex situ within its borders, the date of access will be the date when the GR and aTK are taken from the collection, not when it entered that collection. |

*Case 12*

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| --- | --- |
| *Title* | ***Depositing genetic resources in a collection*** |
| *Description* | A public collection acquires living biological material through collaboration with a taxonomist from a University in the country of origin (that is a Party to the Nagoya Protocol and has established access measures). The collection staff has expertise in the organisms of interest and is able to perform the necessary characterization of phenotype and genotype, to compare the results with types present in its collection, and to store the organisms in the living state (which is not possible in the country of origin). The taxonomist in the country of origin collected the biological material under a permit of their University, according to which sharing of biological resources with foreign researchers (such as the collection staff) is allowed, but further supply of the material to third parties is not. Several new species are discovered by the collaborators but in order to fulfil the requirement of valid publication under rules of nomenclature, the type material of the new species will not only have to be deposited in a public collection but also be available for non-commercial research by third-party users. |
| *Analysis* | The taxonomist in the country of origin needs to contact the Competent National Authority (CNA)[[20]](#footnote-21) of that country to settle on a new agreement which will allow deposit of the material in the public collection and settles the terms for the Material Transfer Agreement (MTA)[[21]](#footnote-22) for supply to third-party users. If the taxonomist fails to acquire a new agreement, the material cannot be supplied to third-party users, and should not be deposited in the public collection, as the deposit in the public collection would make any user ordering the strain later a third party from the view-point of the country of origin. Only if third-party transfer is allowed, the collection can distribute without further necessity to make a new agreement with the country of origin. General good practice for collection holders upon receiving material is to always check if the original permit for collecting GR allows supply to third-party users. |

*Case 13*

|  |  |
| --- | --- |
| *Title* | ***Storing genetic resources as a safe deposit*** |
| *Description* | A culture collection provides a confidential service of safe deposit against a fee. Companies and other bodies can deposit biological material in a secured part of the collection through a contract, where all rights and obligations over the material remain exclusively with the depositor and material is never transferred to third parties or used for research or development by the collection itself. The complete stock to be stored is either sent by the depositor to the collection, or stock is created by the collection itself by multiplying material received from the depositor. If the collection extracts DNA and performs sequencing, it does so purely for identification or verification. |
| *Analysis* | The service the collection provides does not involve research and development. The handling, storage and quality checks (including verification by DNA extraction and sequencing upon acceptance) under the service are not considered ’utilisation’ in the meaning of the EU ABS Regulation. There is no obligation for the depositor to transfer documents providing evidence of legality of the material; since the collection is not considered as a user it has no due diligence obligations under the EU ABS Regulation with regard to accepting the material as safe deposit. |

*Case 14*

|  |  |
| --- | --- |
| *Title* | ***Deposition of material with an IRCC number*** |
| *Description* | A scientist sends a strain to a public collection in the EU for deposit. The depositor provides an IRCC number, and detailed information on date and locality of collection and the persons who collected the source material in situ. The curator checks the information, but is not able to find all information in the ABS Clearing House database as it is partly confidential. The curator sees no reason to doubt the legality of access, and accepts the strain in the part of the collection that is registered under Art. 5 of the Regulation. Subsequently the strain is supplied along with the IRCC number to multiple researchers. One of these researchers conducts R&D on it and publishes a scientific paper. Then, he is informed by an authority in the country of origin that he has violated the conditions in PIC and MAT covering the genetic resource, and that he will be facing charges. |
| *Analysis* | This case raises the questions which information is essential for collection holders if someone wants to deposit material, and what is to be expected of collection holders if they are to accept material. In this case, the collection holder has fulfilled all requirements under Articles 4 and 5 of the EU Regulation. However, to avoid reputational or other risks, additional actions may be advisable. In this case, collection holders should transfer the IRCC when transferring the strain third parties, and refer these third parties to the CNA of country of origin for the confidential parts. |

*Case 15*

|  |  |
| --- | --- |
| *Title* | ***Deposition of a contaminant*** |
| *Description* | A strain is deposited by a scientist that has worked with the strain in his laboratory outside the country of origin of the strain. The IRCC number is provided by the depositor. While checking the material received, the collection staff discovers a contaminant which it subsequently isolates from the original strain. The depositor is not aware of the presence of the contaminant. Out of scientific interest, the collection may decide to deposit the contaminant strain in the public collection and record the country of origin as “unknown”. |
| *Analysis* | The contaminant organism could have originated from the country of origin of the primary strain, or from the country where the depositor works. It is considered that the Regulation does not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such are introduced unintentionally to a place in the EU territory, be it from a third country or from a Member State with access legislation in place. (Chapter 5.1.1 of the general Guidance document). If the contaminant is not a pathogen, and the country of origin can really not be traced, the collection should not deposit the strain in its public collection. |

*Case 16*

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| --- | --- |
| *Title* | ***Assessment of health status of acquired genetic resources (quality control)*** |
| *Description* | Genetic resources acquired by a collection are checked for their health status and the presence of pathogens. |
| *Analysis* | Quality and phytopathology checks are not considered ‘utilisation’ in the meaning of the EU ABS Regulation (Chapter 2.3.3 of the general Guidance document). |

***2.3.2. Identification***

*Case 17*

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| --- | --- |
| *Title* | ***Identification on the basis of phenotype*** |
| *Description* | Specimens are identified using phenotypic characters that do not involve DNA sequencing or biochemical analysis (e.g. by means of comparing with herbarium sheets). During the identification process, undescribed species may be recognised. |
| *Analysis* | According to the general guidance document (Chapter 2.3.3), the mere description of a genetic resource in phenotype-based research such as morphological analysis normally would also not amount to utilisation. Therefore, the identification on the basis of phenotype is not considered ‘utilisation’ in the meaning of the EU ABS Regulation. |

*Case 18*

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| *Title* | ***Identification on the basis of phenotype and genotype*** |
| *Description* | In the accession and maintenance of strains within a culture collection it is important to carry out phenotypic as well as genotypic tests to ensure the correct strain has been preserved. |
| *Analysis* | Taxonomic identification of genetic material, in the form of verification of received material by morphological and molecular analysis is not considered to constitute ‘utilisation’ in the meaning of the EU ABS Regulation. |

*Case 19*

|  |  |
| --- | --- |
| *Title* | ***DNA extraction and sequencing for identification and/or identity checks*** |
| *Description* | Specimens are identified using characters that involve DNA sequencing or biochemical analysis. Undescribed species may be recognised. |
| *Analysis* | Identification of specimens using DNA sequences is not considered ‘utilisation’ in the meaning of the EU ABS Regulation, as it does not involve the discovery of specific genetic and/or biochemical properties. As such it does not “create new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development”, and thus ‘fails’ the litmus test as set out in the general guidance Document. While there is clarity that identification of a specimen or sample to a previously named species or strain is not utilisation, there is less clarity regarding the situation if the species has not previously been given a scientific name. Under the litmus test criterion, there is no difference between the process if the result points to a previously named entity, an entity which is represented on a public sequence database but not given a name (undescribed/unnamed species are present), or not named and not recorded on a database. |

*Case 20*

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| --- | --- |
| *Title* | ***Identification for quality control and verification*** |
| *Description* | A collection of microorganisms is working under a quality management system that includes the standard extracting of DNA and sequencing ribosomal RNA genes to identify all newly accessioned strains for quality control and verification. Furthermore, new batches of stored materials are analysed with MALDI-TOF mass spectrometry for quality control. Sequence and mass-spec data are stored in a central database. |
| *Analysis* | Identification and quality checks are not considered ‘utilisation’ in the meaning of the EU ABS Regulation (Chapter 2.3.3 of the general Guidance document). |

*Case 21*

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| --- | --- |
| *Title* | ***Identification of microorganisms in tattoo inks*** |
| *Description* | The national health agency of an EU country investigates the presence of microorganisms in tattoo inks imported into the EU, because these may pose health risks. Fungal strains isolated from ink samples are sent to an expert institute in the EU for identification, and subsequently deposited in the public collection of that institute. The institute publishes the results in a scientific paper. The ingredients of the inks come from multiple and untraceable origins. |
| *Analysis* | If it is possible to trace the country of origin, it should be checked if the country of origin requires PIC and MAT, and, if so, this country should be approached to negotiate PIC and MAT on intended use. If the contaminant is not a pathogen, and the country of origin can really not be traced, the strains should not be deposited in the public collection of the institute. |

***2.3.3. Taxonomic, biosystematic and other research***

*Case 22*

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| *Title* | ***Taxonomic research*** |
| *Description* | Mushrooms are collected in situ by a local scientist in a provider country, strains are isolated from them, and all this is subjected to morphological study. The scientist prepares a manuscript in which a new species will be described. The dried fruit bodies are lodged in the national herbarium in the country of origin, and because the country lacks a culture collection, the ex-type strains are deposited in a culture collection in the EU with the PIC and MAT documents. The collection does DNA-extraction and sequencing of ribosomal genes to fulfil its quality control standards. The sequences are lodged in the collections’ database, and in consultation with the depositing researcher will be placed online. |
| *Analysis* | The scientist needs to ascertain that his activities are allowed under national ABS legislation in the country of origin, if any further requirements have to be met before the strains can be sent abroad, and if third party transfer will be allowed. The culture collection needs to ascertain which requirements it has to meet in order to legally distribute the strains to third party users. In the EU, extraction and sequencing for quality control are considered not to constitute ‘utilisation’ in the sense of the EU ABS Regulation, but national law in the country of origin may be applicable and should be respected. The requirements have to be taken into account in the MTA for supply by the collection. |

*Case 23*

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| --- | --- |
| *Title* | ***Screening large numbers of samples to identify genetic resources of interest*** |
| *Description* | 1. An EU consortium of research institutes and companies is preparing to start a screening program for discovering novel antimicrobials. The intent is to target ex-situ microbial biodiversity preserved in European culture collections. Except for accessions not available for screening or commercial use per terms of covering agreements, the collections involved are considering the following options: to include in the screening all accessions, or to exclude all available accessions dating after December 1993, or to exclude only those dating after October 2014 (except those originating from areas beyond national jurisdiction and non-signatory states of the CBD).  2. A culture collection customer purchases an entire collection (several 1000 strains) for screening purposes. |
| *Analysis* | No consensus exists yet on the question whether such activities involve research and development on the entire set of such accessions or not, and hence consensus is lacking on the question whether the described screening of all such accessions falls within or outside the scope of the EU ABS Regulation. This unresolved issue (see Chapter 3.1) is currently under discussion in the EU.  Regardless of a position on whether large-scale screening of genetic resources is to be considered ‘utilisation’ in the meaning of the EU ABS Regulation or not, the use of genetic resources for the purpose of large-scale screening requires PIC and MAT of a providing country, in case such genetic resources are accessed from such country. |

*Case 24*

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| *Title* | ***Preparation of a taxonomic monograph using morphological and sequence information*** |
| *Description* | A taxonomist prepares a monographic taxonomic treatment of a group of organisms. As a part of the descriptive process, the taxonomist creates a phylogeny of the taxa involved, using morphological and sequence information. The properties of the genes are not identified or used. |
| *Analysis* | The sequence information is used in a descriptive manner and to recognise taxa at strain, species or higher levels. The phylogeny is used to provide a classification. This is done without additional research on the genetic resource to discover specific genetic and/or biochemical properties. In line with the general guidance document, this would not qualify as utilization in the meaning of the EU ABS Regulation. |

***2.3.4. Breeding***

*Case 25*

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| *Title* | ***Breeding for a sustainable genetic viable population*** |
| *Description* | The objective of zoo breeding programmes is to obtain a sustainable genetically viable population, which could thus be considered an end product. Article 7(2) of the EU ABS Regulation states that “At the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 (...)”. |
| *Analysis* | Breeding qualifies as ‘utilisation’ in the meaning of the EU ABS Regulation, and thus triggers due diligence obligations. The genetically viable population as such is not an end product, until the moment the population or its progeny is subject to one of the actions set out in Implementing Regulation Article 6, at which point the zoo breeding programme should submit a due diligence declaration. However, a due diligence declaration is only one element of the due diligence obligations established in the EU ABS Regulation. Other obligations include the requirement for users to seek, keep and transfer to subsequent users information, as set out in Article 4 of the EU ABS Regulation. |

***2.3.5. Documentation (Collection management and cataloguing)***

*Case 26*

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| *Title* | ***Publishing of information on accessions*** |
| *Description* | Collection holders are increasingly managing data about their holdings and making this and other information about their holdings and their research public, where possible through open access systems. This may involve adding specimen data to an institutional database and may include dissemination in publicly available scientific or cultural resources such as the Global Biodiversity information Facility or Europeana. |
| *Analysis* | Publication of data associated with genetic resources is not covered in the EU ABS Regulation.  The general guidance document states that the use or publication of data might be covered by conditions set in the MAT, which should be respected, and that in particular those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it. |

*Case 27*

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| --- | --- |
| *Title* | ***Use of Digital information*** |
| *Description* | The curator of a collection is asked by a company to advise on which strains to order, based on their affinities and properties. The curator compares sequence data in the private collection database as well as in a public database to prepare the advice. Sequence data that are not in the public domain are not shared with the company. |
| *Analysis* | The general Guidance document (chapter 2.3.3) states that: “It could be argued that the Nagoya Protocol deals with access to and utilisation of genetic resources as such and therefore does not regulate issues concerning digital information obtained from genetic resources. However, the implications of this distinction are still to be considered by the Parties to the Protocol, in the light of recent technological developments. Without prejudice to the outcome of that consideration, the use of publicly available genetic sequencing data could be considered to be out of scope of the ABS Regulation.” |

***2.3.6. Supply to third parties***

*Case 28*

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| *Title* | ***Exchange with other collection holders*** |
| *Description* | Chytrid strains highly pathogenic to salamanders are isolated from wild host populations in Spain in 2017 and deposited in a public collection in another EU Member State. In accordance with access rules of Spain, the strains can be supplied to third parties under an MTA which only allows use in taxonomic research. As an exchange, the collection then sends the strains to a collection in the United States which collaborates with US partners including industry to develop a conservation action plan for threatened amphibian populations. |
| *Analysis* | Although it is for good purposes, this use by the US Partners is not covered in the MTA and thus not allowed. Under Article 4 of the EU ABS Regulation, if the collection holder decides to send material to the US collection, it must also supply the conditions specified in the MTA to third parties along with the strains. |

*Case 29*

|  |  |
| --- | --- |
| *Title* | ***Exchange between zoos and aquaria which are partners in a breeding programme*** |
| *Description* | Within zoo breeding programmes, animals are managed as if being owned and managed by the collective, and management decisions (e.g. on the breeding or transfer of animals) are taken by the breeding programme coordinator in cooperation with the collective of holders rather than with the legal owners of specimens. In many cases, a zoo will sign the PIC and MAT and the programme is managed by the Zoo association, while the holding and breeding is done by individual member zoos. In the framework of such a breeding programme, a zoo in the EU obtains an animal from a zoo in another country. Both zoos are official partners in the breeding programme. |
| *Analysis* | Breeding qualifies as ‘utilisation’ in the meaning of the EU ABS Regulation. It should be checked if the country of origin requires PIC and MAT, and, if so, this country should be approached to negotiate PIC and MAT on intended use. PIC and MAT can either be negotiated by the overarching programme, or by the individual zoo. |

# Unresolved issues

This chapter lists issues on which no consensus has been reached until now. In particular, it deals with activities which so far could not unequivocally be qualified as falling within or outside the scope of the EU ABS Regulation, as well as with the question whether certain limitations to due diligence obligations should be understood to exist.

**3.1 Large scale screening of genetic resources**

It is common practice to screen a large number of genetic resources, for example accessions obtained from a collection holder, in order to find a trait that may eventually be identified in only one or two of such accessions. Furthermore, based on the outcome of a large scale screening, genetic resources may be subjected to further analysis for the presence and features of wanted and unwanted traits. Such analysis would serve to decide whether or not to integrate a genetic resource in further R&D activities or not. Such activities are typically part of the early phases of a R&D programme. No consensus exists on the question whether such activities involve research and development on the entire set of such accessions or not, and hence consensus is lacking on the question whether the described screening of all such accessions falls within or outside the scope of the EU ABS Regulation.

Various alternative and opposing considerations can be applied.

• Large-scale screening is an activity by which genetic resources that can be usefully incorporated into further research activities can be identified. The very large majority of such screened samples will normally not contain the desired traits or properties and hence not be incorporated into breeding activities. Such discarded samples are therefore considered not to have been the subject of research and development. Moreover, few samples may be selected for a further assessment of the presence or absence of wanted or unwanted traits. Such activity can be regarded as part of the large-scale screening programme and does not yet constitute research and development in the meaning of the EU ABS Regulation. Whereas the large-scale screening of genetic resources could be considered as to only select useful samples and to precede research and development, it could be argued that in contrast, the subsequent use of any samples (normally very few) identified as potentially useful and subsequently incorporated into breeding programmes will qualify as utilisation in the context of the EU ABS Regulation.

• Large-scale screening creates new knowledge on the presence and/or absence of specific traits, or the level of certain biochemical activity. The creation of such knowledge should be seen as the result of utilisation and therefore qualifies as within the scope of the EU ABS Regulation.

Regardless of a position on whether large-scale screening of genetic resources is to be considered within or outside the scope of the EU ABS Regulation, the use of genetic resources for the purpose of large-scale screening might require PIC and MAT of a providing country, in case such genetic resources are accessed from such country.

**3.2 Intentionality of access**

Section 5.1.1. of the Horizontal Guidance Document states that “It is … considered that the Regulation does not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such are introduced unintentionally to a place in the EU territory, be it from a third country or from a Member State with access legislation in place.” However, Section 5.1. states that “Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol” and “The Regulation gives special status to a pathogenic organism that is determined to be (or is determined likely to be) the causing pathogen of a present or imminent public health emergency of international concern or a serious cross-border threat to health. To these genetic resources an extended deadline for compliance with the due diligence obligation applies (see Article 4(8) of the Regulation).” This leads to opposite interpretations, i.e. that pathogens and pests if isolated from a human, plant, animal or microorganism host out of its host country that was not acquired with the intention of pathogen study would be in scope under 5.1., but out of scope according to 5.1.1.

From the point of view of collection holders this leads to conflicting understanding of responsibilities. For example, if border interception of material showing disease symptoms results in the material being sent to an institute providing an identification service and maintaining a public collection, and the strains of a pathogenic agent and several strains of other fungal species are also isolated, the isolation and identification are out of scope under section 5.1.1. Under a broad interpretation of section 5.1.1. the collection holder may incorporate the pathogenic strain in the collection (including for future utilisation) without seeking PIC and MAT, but would need to seek PIC and MAT for the non-pathogenic strains. Given that economically pathogenic strains are likely to be more interesting than non-pathogens this is not an appropriate action under the Protocol. Note also that there is no legal definition of ‘pathogen’ or ‘pest’ to enable clarity on what organisms are included under these terms, and an organism may be said to be pathogenic or non-pathogenic depending on the context. A user could decide to class something as a pathogen in order to avoid due diligence responsibilities. There is no legal certainty generated in the context of adding to collections.

The text in section 5.1.1. was to give freedom to operate in the context of interception of pathogens or pests, as is the intent of Article 4(8) of the Regulation. However, to take it to exclude all pathogens from the provisions of the Regulation for subsequent users and for collections if they were unintentionally accessed seems against the intent of both the Protocol and the Regulation and, indeed, against the Article 4(8) of the Regulation. The guidance should be amended to identify under what conditions unintended access allows the material to be out of scope of the Regulation.

*This issue affects Cases 4, 6 and 15 above*.

**3.3. Traditional Knowledge associated with genetic resources (aTK).**

The wording of the Nagoya Protocol and of the Regulation is ambiguous on the meaning of aTK. There are two alternatives: (i) that the TK is accessed at the same time and place as the GR, or (ii) that when TK refers to GR that can be identified the TK is associated with that GR. In the second case the TK does not have to be accessed with a GR but is associated anyway. These alternatives carry very different implications for collection management and for research. The EU Regulation described traditional knowledge associated with genetic resources as “traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources”. This does not demand that the aTK is accessed with the GR, merely that the TK and the utilisation of the GR are described in the MAT.

The publication of TK does not invalidate the rights of the originators; the mere fact that information is publicly available (not necessarily the same as in the public domain) does not automatically invalidate the rights of the Indigenous Peoples & Local Communities (IPLCs) concerned.

In general, if TK is to be used in the context of utilisation of GR the users should consider what the national legislation of the provider country states and, as required, include this in PIC. Failure to mention this when seeking PIC may well invalidate the PIC. If the use of the aTK is then in included in the MAT, the provisions of the EU Regulation apply. There are additional sources of assistance for users available, including the International Society for Ethnobotany guidelines and the UNDRIP provisions.

*This issue affects cases 8, 9 and 10 above.*

**3.4 Laboratory strains**

A laboratory strain is biological material which has been kept alive for research in the laboratory based on one or more particular properties which make it unique for research areas. Properties of the strain could be considered to have developed naturally, or may have been introduced as a result of activities in the laboratory for which other biological material could also have been used. A laboratory strain has often been used and transferred between laboratories over a long period of time. Depending on information that has been documented about its provenance the country of origin of such a strain may be determinable or not. It could be argued that laboratory strains are not natural resources in the sense of Article 15(1) of the CBD and therefore they do not fall under the scope of the CBD, the Nagoya Protocol and the EU ABS Regulation.

On the other hand, it can be argued that laboratory strains are at least partly based on genetic resources obtained from outside the laboratory. Their distinguishing properties may even have been obtained from these genetic resources. Therefore, the use and transfer of these strains should be in agreement with the conditions set in the original PIC and MAT under which the genetic resources were obtained. If no PIC and MAT are available, due diligence should be applied to determine whether PIC and MAT should be sought from the country where the material was obtained. If somebody wants to deposit a laboratory strain in a culture collection, the culture collection holder needs to ascertain which requirements it has to meet in order to legally distribute the strains to third party users. If, however, no information on its provenance exist, and the collection holders are unable to find any information in the literature that could proof that the strain is in or out of scope (for instance out of the temporal or geographic scope), the matter would remain unresolved.

# Annex. Background information

## General principles

The European Commission has developed a general Guidance document[[22]](#footnote-23) that is intended to provide general guidance on the provisions and implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union ("the EU ABS Regulation" or "the Regulation"). Regulation 511/2014 implements in the EU the international rules established in the Nagoya Protocol governing user compliance measures – i.e. what users of genetic resources have to do in order to comply with the domestic/national rules on access and benefit-sharing (ABS) and how this will be overseen by the competent national authorities.

Following the definition in the Convention on Biological Diversity (CBD), "genetic resources" are defined in the EU ABS Regulation as "genetic material of actual or potential value" (Art. 3), where "genetic material" means "any material of plant, animal, microbial or other origin containing functional units of heredity", i.e. containing genes (Art. 2 CBD).

"Utilisation of genetic resources" is defined as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology, as defined in Article 2 of the Convention" (Article 3(5) of the Regulation). According to the general Guidance document, the definition of “utilisation” is quite broad and covers many activities relevant for many sectors, without providing for a list of specific activities to be covered. Any person, including legal person, conducting utilisation in the meaning above is considered a “user”. Users need to assess themselves whether the specific activities they (plan to) undertake should be considered as “utilisation” in the meaning of the Protocol and the Regulation, or not, keeping in mind they are the ones having to apply for *prior informed consent* and negotiate *mutually agreed terms,* if applicable. The term "research and development" is not defined in the Nagoya Protocol nor in the EU ABS Regulation.

The general Guidance document contains elements that bear directly on the question whether a certain activity or actor falls within the scope of the Regulation. It addresses, *inter alia,* the use of (1) genetic resources isolated from commodities imported in the EU, (2) privately held genetic resources, and of (3) traditional knowledge associated with genetic resources, as well as (4) the nature of the research, (5) the activities of collection holders, (6) the coverage of derivatives, and (7) the status of the user.

## Short description of the collections and its activities

Natural History Museums, Herbaria and Botanic Gardens store large collections of organisms with a global coverage. Many of the specimens were collected long before the Nagoya Protocol, CBD or UN Resolution 1803 (XVIII) in 1962 (Permanent Sovereignty over Natural Resources). Collections are still being enhanced, and best practices emphasise the need to obtain the appropriate legal permissions from provider countries. Most of the institutions carry out taxonomic research on the collection. They also host scientific visitors from other institutions and countries, including often the countries where the specimens were collected, and send material on loan to scientists around the world. The taxonomic basis of their work has been identified as a priority by the CBD under the cross-cutting issue ‘Global Taxonomy Initiative’, and increasing the availability of taxonomic information made the basis of a Global Taxonomic Information System called for under the GTI Programme of Work. These institutions typically share non-monetary benefits in terms of information and capacity building. They are almost or completely non-commercial in terms of their output, and consequently access biological material on that basis. Supply to industry is a very low level of activity and unknown in many institutions.

As mentioned above, taxonomic work carried out by collection holders, including classification of species and other taxa, is necessary to facilitate identification and monitoring under Art 7 of the CBD. Such work has been recognised under the Nagoya Protocol in Article 8a, which states that “In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: ... (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research”. In furtherance of this aim, and in line with the Horizontal Guidance Document, several case studies address this, noting in all cases that all genetic resources should be acquired with PIC and MAT where the provider country exercises sovereign rights over its genetic resources, and that studies are carried out only if permitted under PIC and MAT.

## Economic features

Most benefits shared by collection holders are mon-monetary, and often involve cooperation with partners.

## More on the organisation of collections

Apart from a wide variety of individual genebanks, culture collections, biobanks, Biological Resource Centres, botanic gardens, zoos and aquaria, Natural History Museums and herbaria, various international organizations play important roles.

The European Culture Collections' Organisation (ECCO) aims to promote collaboration and exchange of ideas and information about all aspects of culture collection activity. The Federation of European Microbiological Societies (FEMS) aims to serve the microbiology community through providing resources, building capacity, and stimulating collaboration.

The World Federation of Culture Collections (WFCC) is concerned with the collection, authentication, maintenance and distribution of cultures of microorganisms and cultured cells. Its aim is to promote and support the establishment of culture collections and related services, to provide liaison and set up an information network between the collections and their users, to organise workshops and conferences, publications and newsletters and work to ensure the long term perpetuation of important collections[[23]](#footnote-24).

Many botanic gardens are members of the International Plant Exchange Network (IPEN), which facilitates the exchange of plant genetic resources among its members, respecting the provisions of the Convention on Biological Diversity (CBD). Botanic Gardens may also be members of Botanic Gardens Conservation International (BGCI), which was established to link the botanic gardens of the world in a global network for plant conservation. BGCI’s membership includes more than 500 botanic gardens in 96 countries. It supports the development and implementation of the Global Strategy for Plant Conservation (GSPC) at a global, regional, national, and local level.

Many zoos and aquaria in the EU are members of the European Association of Zoos and Aquaria (EAZA). EAZA members cooperate in breeding programmes and exchange knowledge, experiences and information. Annual EAZA campaigns focusing on particular (threatened) animal species or ecosystems to raise awareness of and money for nature conservation projects.

Natural history museums as well as other collection holders including botanic gardens may be members of the Consortium for European Taxonomic Facilities (CETAF). CETAF promotes training, research and understanding in systematic biology and palaeobiology, and facilitates access to information (collections) and the expertise of its member institutions across Europe. It has produced a Code of Conduct, Best Practices and tools to manage ABS requirements and a number of its members are now implementing these. The same organisations may be members of the Global Genome Biodiversity Network (GGBN), GGBN provides a platform for biodiversity biobanks from across the world to collaborate to ensure consistent quality standards for DNA and tissue collections, improve best, harmonize exchange and use of material in accordance with national and international legislation and conventions and making their DNA and tissue collections discoverable for research through a networked community of biodiversity biobanks. It has produced Best Practices, a Code of Conduct, template MoUs based on the CETAF model.

The European Cooperative Programme for Plant Genetic Resources (ECPGR) is a collaborative programme among most European countries aimed at ensuring the long-term conservation and facilitating the increased utilization of plant genetic resources in Europe. The members of ECPGR have established the European Genebank Integrated System (AEGIS) which constitutes a European Collection which operates as a virtual genebank. The aim of AEGIS is to conserve genetically unique and important accessions for Europe and make them available for breeding and research. The germplasm accessions and their related information registered in the European Collection are freely available in accordance with the terms and conditions set out in the International Treaty on Plant Genetic Resources for Food and Agriculture.

In 2013, first steps have been taken to officially establish the European Genebank Network for Animal Genetic Resources (EUGENA). EUGENA is the network of gene banks in the European countries with the objective to support the *ex situ* conservation and sustainable use of AnGR in Europe under common terms of agreement. EUGENA is the platform of national gene banks operating under the umbrella of the European Regional Focal Point for Animal genetic resources (ERFP) at the regional level of Europe. In this context, a national gene bank for AnGR is defined as a repository for *ex situ* conservation and sustainable use of AnGR held by a host institution authorized and/or recognized by a national authority to fulfil these tasks. A gene bank may be constituted by one or more repositories collaborating as a network at the national level[[24]](#footnote-25).

The European Forest Genetic Resources Programme (EUFORGEN)[[25]](#footnote-26) is an international networking programme that promotes the conservation and sustainable use of forest genetic resources in Europe. EUFORGEN contributes to the implementation of Forest Europe commitments on forest genetic resources and to decisions of the Convention on Biological Diversity. EUFORGEN also contributes to the implementation of regional strategic priorities of the Global Plan of Action for the Conservation, Sustainable Use and Development of Forest Genetic Resources. Several members of EUFORGEN have established core collections on European black and white poplars which contain typical genetic material for these two species from several countries and is maintained by the Poplar Research Institute in Casale Monferrato, Italy and to some extent also duplicated in some of the other countries that participate to the EUFORGEN programme. Furthermore a database is created containing all the collections of European black and white poplars that are held in European countries. This database is located and managed by the Poplar Research Institute in Casale Monferrato, Italy[[26]](#footnote-27).

## Recent and expected trends

## Relation to business sectors

*Biocontrol and Biostimulants sector*

Collection holders, public institutions and commercial companies active in the biocontrol and biostimulants sector collaborate and exchange materials.

*Plant breeding sector*

Traditionally, plant genebanks have distributed genetic resources to actors in the plant breeding sector. Many plant breeding companies, NGOs and farmer-breeder networks collaborate with collection holders. Typically, collaboration involves the genotypic and phenotypic evaluation of collection stocks for the presence of useful traits, the organisation of collecting missions, and in some cases also the regeneration of genebank accessions.

## Other relevant legislation impacting on GR access and transfer

Natural History Museums and genebanks are often designated as public depositories for national collections that may include and preserve genetic resources and traditional knowledge associated with genetic resources. These collections may fall under the scope of cultural and heritage legislations, depending on the legal status of their owner or custodianship.

1. Regulation (EU) No 511/2014 [↑](#footnote-ref-2)
2. Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01). [↑](#footnote-ref-3)
3. OECD, Biological Resource Centres. Underpinning the future of Life Sciences and Biotechnology http://www.oecd.org/sti/biotech/2487422.pdf [↑](#footnote-ref-4)
4. <http://grbio.org/> [↑](#footnote-ref-5)
5. https://www.bgci.org/policy/abs\_principles/ [↑](#footnote-ref-6)
6. http://cetaf.org/sites/default/files/final\_cetaf\_abs\_coc.pdf [↑](#footnote-ref-7)
7. http://www.ggbn.org/docs/ABS\_Guidance/GGBN%20Guidance%20\_Best\_Practice\_June\_2015-Final.pdf [↑](#footnote-ref-8)
8. Janssens D, Tindal B, Green P, Garay E, Fritze D, Stalpers J, Smith D, Bimet F, Desmeth P (2009). The ECCO core Material Transfer Agreement for the supply of samples of biological material from the public collection. The MTA text is available here: http://www.eccosite.org/. [↑](#footnote-ref-9)
9. Microbial Resources Research Infrastructure (MIRRI). 2016. Best practice manual on access and benefit sharing. http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI\_ABS\_Manual\_web.pdf. [↑](#footnote-ref-10)
10. http://bccm.belspo.be/projects/trust [↑](#footnote-ref-11)
11. http://www.isber.org/?page=BPR [↑](#footnote-ref-12)
12. http://www.oecd.org/sti/biotech/oecdbestpracticeguidelinesforbiologicalresourcecentres.htm [↑](#footnote-ref-13)
13. Section 2.1. p.30 [↑](#footnote-ref-14)
14. Morgera E, and Geelhoed M. 2016. Consultancy on the notion of “utilisation” in the Nagoya Protocol and the EU ABS Regulation for the upstream actors. University of Edinburgh. [↑](#footnote-ref-15)
15. EC, 2016. Guidance on the EU ABS Regulation implementing the Nagoya Protocol. Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Guidance on the scope of application and core obligations. [↑](#footnote-ref-16)
16. In the present context, Prior Informed Consent (PIC) means approval for access to and utilisation of genetic resources by the authorities of the country where access is sought (www.absfocalpoint.nl). [↑](#footnote-ref-17)
17. Mutually Agreed Terms (MAT) define the conditions governing the use of genetic resources and benefit-sharing. MAT are reached between the two parties to a contract under private law (even if one of them is a government institution) (www.absfocalpoint.nl). [↑](#footnote-ref-18)
18. In the present context, Prior Informed Consent (PIC) means approval for access to and utilisation of genetic resources by the authorities of the country where access is sought (www.absfocalpoint.nl). [↑](#footnote-ref-19)
19. Mutually Agreed Terms (MAT) define the conditions governing the use of genetic resources and benefit-sharing. MAT are reached between the two parties to a contract under private law (even if one of them is a government institution) (www.absfocalpoint.nl). [↑](#footnote-ref-20)
20. The Competent National Authority (CNA) of a country is responsible for granting access, advising on applicable procedures and requirements for obtaining PIC and entering into MAT (www.absfocalpoint.nl). [↑](#footnote-ref-21)
21. A Material Transfer Agreement (MTA) is a contract between a provider and a recipient of genetic material, specifying the terms and conditions of the transfer of such material (www.absfocalpoint.nl). [↑](#footnote-ref-22)
22. Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01). [↑](#footnote-ref-23)
23. http://www.wfcc.info [↑](#footnote-ref-24)
24. https://asas.org/docs/default-source/wcgalp-posters/437\_paper\_8691\_manuscript\_289\_0.pdf?sfvrsn=2 ) [↑](#footnote-ref-25)
25. www.euforgen.org [↑](#footnote-ref-26)
26. www.euforgen.org/forest-genetic-resources/poplars-clones-database [↑](#footnote-ref-27)