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**Guidance Document for Collection Holders**

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# Introduction

This Guidance document is meant to help holders of collections, as well as competent national authorities, to establish whether activities carried out fall within the scope 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 the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. It also aims to assist both collection holders and users of genetic resources obtained from collections in identifying their due diligence obligations and in concluding how these should be met.

The reader is advised to consult the general Guidance document[[1]](#footnote-2) before reading this guidance.

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 of the terms “utilisation” and “research and development (R&D)” 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 (including community seed banks), culture collection holders, biobanks, Biological Resource Centres (BRCs), botanic gardens, zoos and aquaria, natural history museums, and reference laboratories. The main activity of collection holders is the management of collections to ensure their availability for research and other purposes, including the long-term storage and provision of genetic resources under national or international governance. These genetic resources may be provided to support biological research (for instance in taxonomy, ecology, morphology, genomics, biochemistry, fisheries, agriculture, both in the private and public sectors), biodiversity monitoring and management, including under the implementation of the Convention on Biological Diversity, and commercial R&D. Collections may extend beyond the boundaries of the responsible institution, e.g. on-farm, whether in formal or informal networks. Collection holders such as botanic gardens, zoos and aquaria, farm parks as well as natural history museums also carry out extensive educational activities, and may provide entertainment. Collection holders are primarily engaged in upstream activities in the user chain rather than in product development, but some are developing new research models and modified organisms to support fundamental and applied research and development. 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, or alternatively for awareness raising. Some types of collection holders (e.g. botanic gardens) are frequently integrated in universities or research institutes, while others (e.g. zoos) are typically independent entities.

The definition of a ’collection’, as given in the EU ABS Regulation, is “a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private 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. In the livestock sector, the terms ‘*ex situ* *in vitro* conservation’ and ‘*ex situ* *in vivo* conservation’ are commonly used. *Ex situ* *in vitro* conservation refers to conservation external to the living animal in an artiﬁcial environment, under cryogenic conditions including, inter alia, the cryoconservation of embryos, semen, oocytes, somatic cells or tissues having the potential to reconstitute live animals at a later date; and ‘*ex situ* *in vivo* conservation’ refers to conservation through maintenance of live animal populations not kept under normal management conditions and/or outside of the area in which they evolved or are now normally found).

Specimens may be identified to species, subspecies, varieties or strains, or stored as mixed or environmental samples. Many collection holders 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 (associated TK, or aTK) may be held. This might, for instance, include knowledge with respect to traditional fermented food products, antibacterial properties of traditional medicinal plants and soil management practices in traditional agriculture. “‘Traditional knowledge associated with genetic resources”’ is defined in the EU ABS Regulation 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 (see Article 3(7) of the Regulation).

Collections of biological resources may be held by public bodies (e.g. universities, national, federal, regional or local museums, agencies, research institutes, botanic gardens, reference collections, and crop and crop-wild relative collections), private bodies, charities, companies, and private individuals. Collections may also be held by networks of public and/or private bodies or individuals. Zoos, for instance, are quite diverse in their legal status. 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 registered as charities.

## Collection Holders and their activities

**1.2.1 Types of collections**

There is no simple classification of collection types. Collection holders may self-identify as one or more of the main groups below, which, however, do show some ‘overlap’ in activities and types of collection involved:

1. Genebanks[[2]](#footnote-3)

Plant genebanks collect, characterize, evaluate, store, regenerate, multiply, and distribute genetic material. They may include seedbanks, tissue banks, cryobanks and field genebanks, 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 genebanks, including community seed banks, distribute to the general public, gardeners and 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. Conservation is often *ex situ*[[3]](#footnote-4), but there is a growing number of collection holders pursuing the *in situ* conservation[[4]](#footnote-5) of plant genetic diversity, and thus extending into locations outside the organisation itself.

Livestock genebanks acquire and store semen, embryos, oocytes, germ cells 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), substantial progress towards establishment of national genebanks was observed 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[[5]](#footnote-6) 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 in public and private institutions and industry. 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 in the groups of Biological Resource Centres (BRCs) or Reference Laboratories. Most of the 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 phenotypic and/or genotypic identification of specimens sent in by officials or private individuals, and store in a confidential manner biological resources belonging to private companies. They may provide patent deposit services under the auspices of the Budapest Treaty or safe deposit services sometimes required by a depositor’s contractual obligations. For example, in the case of bacteria and fungi, new species cannot be described, i.e. are not recognized, without deposit in two public collections in two different countries. Plant viruses kept in living hosts are considered to form an *in situ* culture collection.

1. Biobanks

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

There are also collections that deal explicitly with non-human tissues, for example the biobank of the European Association of Zoos and Aquaria (EAZA), and the biobank of Geno (a Norwegian breeding organization). Livestock biobanks conserve DNA samples. Plant biobanks maintain and distribute collections of DNA libraries of plant species.

Environmental Specimen Banks (ESBs) are engaged in the long-term preservation of specimens, or parts of specimens (organs, tissues, cells) to allow in the future retrospective analysis on intrinsic characteristics of the environment where they are obtained from. In many cases, these banks aim to analyse the accumulation of chemicals, but the genetic material can also be used for other purposes, for instance a retrospective analysis of subpopulation dynamics in a commercially relevant species. ESBs usually obtain their resources by systematic samplings.

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.”[[6]](#footnote-7). BRCs thus include Culture Collections, Genebanks and Biobanks. BRCs supply to many actors, and include patent depositories. The concept of BRC also applies to the preservation of environmental samples such as soil samples, since these samples include biological material (bacteria, mycorrhiza, microfauna) which are not easily defined taxonomically and may not always be culturable, but may represent a critical resource for agriculture.

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 OECD 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 adequate support to enable the BRCs to meet the increasing challenges of biodiversity management 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 facilities to study, preserve, use and develop (by creating new model organisms) biological diversity, including research activities aimed at improving preservation procedures. BRCs are now considered as a category of research infrastructures.

1. Botanic gardens and other living plant collections

While botanic gardens typically include collections of living plants, they may also hold collections of seeds and collections of preserved plant samples, such as herbaria (with dry material of plants, lichen and fungi), alcohol collections (e.g. for plants or algae) and frozen collections. Their collections may also include material confiscated by the authorities, e.g. CITES listed species. Some botanic gardens may have specialised seed banks, holding seed as part of the network of botanic gardens and of *ex situ* conservation programmes. Botanic gardens are usually open to the public and play a major 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. Botanic gardens often carry out scientific research, either on their own or in collaboration with universities or external parties. Material is distributed mainly to other botanic gardens, for the purpose of education and nature conservation. Furthermore, botanic gardens provide genetic resources to universities and other research institutes for basic and/or applied research. Botanic Gardens also act as repositories for national authorities or governmental agencies, identifying and storing confiscated plants supplied by police, customs and quarantine authorities.

Orchards, cultivated fields and experimental forest stands maintained by research institutions may also be used for the preservation and the distribution of genetic resources. Field collections (*in situ* or on-farm) may be held by institutes, NGOs, networks (formal or informal) or individuals. Examples of these collections are cultivated orchards, fields to maintain rare genotypes, managed forest stands, and animal herds with rare genotypes. Provenance trials (trials of different tree populations of the same species, to observe their performance under different environmental conditions) are not considered plant collections, and are dealt with in the guidance document for the Plant Breeding sector. Dynamic genetic conservation units, such as 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, aquaria and other living animal collections

The main aims of zoos and aquaria are *in situ* and *ex situ* *in vivo* biodiversity conservation, education and research. Zoos and aquaria predominantly maintain a variety of living animal species in *ex situ* conditions. In addition, zoos may also maintain plant collections. 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, consisting 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 related to 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.

Other living animal collections include experimental populations maintained by research institutions or conservatory herds of native breeds. Experimental flocks may be held to maintain rare genotypes of domestic animals with well-characterised phenotypes and to distribute DNA tissue of these genotypes to researchers. Farm Parks focus on educational activities and the conservation of breeds of animals. They are open to the general public.

1. Natural History Museums and botanical collections

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. Stored specimens serve as reference objects for the description of species and documentation of the world’s biodiversity. Collections of Natural History Museums may include not only preserved specimens with viable genetic material, but also specimens with no viable genetic material, frozen material, and extracts. 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. Many institutions also offer identification services to individuals, public and private bodies or governmental agencies. Most of the larger collections also maintain databases with scientific (open access) data; this may include aTK.

Botanical Collections store preserved specimens of plants, lichens and fungi and associated data. The specimens may be whole plants, lichens or fungi, or parts thereof, which are dried and mounted on a sheet of paper and stored in boxes, or kept in alcohol or other preservative. The specimens are normally used for scientific study, and are often used as reference material in describing plant taxa. Botanical collections may carry out identification of specimens sent from other countries by both officials and private individuals. Sometimes botanical collections include special collections, such as a xylarium (which focuses on specimens of wood). Natural History Museums and botanical collections are increasingly developing frozen tissue and DNA collections alongside their traditional preserved collections.

1. Reference Laboratories

Reference laboratories are focal points for the detection and identification of organisms, for instance plant pests or food contaminants, and for risk assessment. This type of collection holder includes National Reference Laboratories, European Union Reference Laboratories and other Official Laboratories.

Although collection management is not a primary task of Reference Laboratories, collections are vital for their daily work. They develop, validate and perform diagnostic methods for known and ‘new’ (harmful) organisms for which collections of target and related non-target organisms are essential. Furthermore, collections are required for research on biology and epidemiology of these organisms. Reference material is used for the organisation of ring tests (proficiency testing and test performance studies) and is available for third parties on request.

Collections maintained by reference laboratories include culture collections, frozen collections (of organisms, plant material, DNA, RNA), *in situ* collections, microscope slide collections, collections of pinned insects, living invasive plant species and/or dried materials.

**1.2.2 Types of activities of collection holders**

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

1. Acquisition and storing

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 through 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 an individual specimen belonging to a single species, variety/breed or strain or a mixture of many individuals belonging to a single or different species, varieties/breeds or strains. Acquired material may also contain organisms that were accessed unintentionally, such as pathogens or symbionts. Some entities may not have scientific names, being unidentified or undescribed species or strains. Identification and separation may take place many years after acquisition, for instance 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 usually accompanies the specimens; these documents include research permits, collecting permits, CITES permits, Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), Material Acquisition Agreements (MAA), Material Transfer Agreements (MTA), including the Standard Material Transfer Agreement (SMTA) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and Memoranda of Understanding (MoU). These agreements will typically specify that the material covered can only be used for specific purposes (e.g. that only non-commercial research is to be undertaken). Names on the permits (or other documents) may not include the name of the collection holding institution that eventually will receive and hold the material.

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. These actions are often made independently from the depositories, and are out of the 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 (e.g. for sequencing or for biochemical analyses) are available in the collection-holding institution, the visitors may make use of these facilities.

Specimens of unknown or known illegal provenance may be transferred to collections by the police or other authorities for the purposes of identification, documentation and storage. Material of unknown origin may also be submitted for identification as pests or pathogens, for food safety or environmental monitoring or screening.

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 or evaluated subsequently. Identification may be by means of morphological (phenotype) examination, and/or through the use of genomics and other omics techniques (including barcoding technologies, which use short genetic markers in the DNA of organisms to identify them) or biochemistry. DNA sequence data might be deposited in public databases, and/or compared with many other sequences held in these databases to carry out this identification. Identification may determine that the specimen or strain belongs to a species already possessing a scientific name, or to a species 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’.

Livestock genebanks do not need to perform identification and evaluation, as the biological material is obtained from individual animals with known pedigree and, to a variable degree, known phenotype, genotype, and performance or breeding value. However, characterisation of obtained genetic resources may be undertaken. Livestock genebanks may store material of endangered and commercial breeds mainly as ‘insurance’ for the future needs of animal breeding, to support *in situ* conservation activities as well as for research purposes.

Identification can also be offered as a service (for charge). Specimens or samples may be sent for identification purposes by scientists, private citizens, NGOs, government agencies including health, customs, law enforcement, agriculture, forestry, fisheries, and environmental management, often with rapid response requirement. Samples may be consumed during or destroyed after identification, while others may be returned to the sender or retained by the collection (for example for referencing purposes).

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 characteristics or DNA and RNA sequence information.

DNA analysis is an increasingly used tool in collections-based taxonomic work, including for the identification of taxa and determining relationships between them. It is also increasingly used to determine whether the specimens in the collection adequately represent the natural genetic diversity of the species in question. DNA analysis may be carried out for identification only or for also examining genetic or biochemical/physiological properties. With the costs of genomic sequencing falling, increasing amounts of sequence information are being produced as a component of taxonomic and systematic work.

Collection holders may also carry out research on conservation technologies. Genebanks, for instance, test cryopreservation media and freezing protocols. Reference laboratories develop, validate and perform diagnostic methods for known and new organisms.

1. Collection maintenance and 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. Agreements with countries of origin are commonly signed by individual zoos, even if the programme is managed by the zoo association, but the association is now also starting to sign agreements. However, even if zoo associations sign the PIC and MATs and manage the programme, the holding and breeding is usually done by individual member zoos. EEPs are non-commercial and animals (or parts thereof) are exchanged free of charge.

Holders of farm parks, experimental orchards, forest stands and experimental flocks may also be involved in breeding programmes aimed at producing new genotypes, avoiding inbreeding, and the evaluation of expression of traits and behaviour of animals. At present exchanges are mainly regulated by veterinary and phytosanitary rules.

Plant genebanks maintain the viability of their collections through regeneration of accessions by growing plants from their seeds.

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 publicly available. 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 it may include dissemination in publicly available scientific or cultural resources such as the Global Biodiversity Information Facility (GBIF) or Europeana; such data may be used by many individuals worldwide. Collection managers have the option to 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 biological specimen. 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 that is not a part of the collection-holding body. In the case of museums and botanical collections, material is generally supplied in the form of loans to scientists carrying out non-commercial research that 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. Culture collections, genebanks, botanic gardens, biobanks and BRCs do not usually supply material as loans, but transfer the material definitively, although often the distribution is limited only to the receiving individual and cannot be further distributed (e.g. see guidelines established in the ECCO Core MTA). In the case of zoos and aquaria, animals that are part of breeding programmes are moved around between institutions.

Reference laboratories provide reference material to third parties to be used as positive controls in diagnostic tests. In addition, samples of reference material may be sent to third parties in the framework of ring tests to assure the diagnostic performance of tests and/or laboratories. Furthermore, NRLs may provide isolates of pests to breeders to assist selection of resistant lines.

## Types and sources of genetic resources used

Plant genebanks obtain genetic resources (including wild material, landraces and advanced cultivars) from all over the world through collection missions and exchange with other genebanks, networks and other custodians conserving plant genetic resources (such as amateurs, farmers and breeders). They may also store material used in research projects, breeding lines and old varieties 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. Some livestock genebanks collect material abroad but this is rather limited.

Culture collections and Biological Resource Centres obtain micro-organisms (fungi, yeasts, bacteria, viruses) and macro-organisms (invertebrates and vertebrates) from all over the world, through researchers who deposit cultures, organisms or tissue samples as (mandatory) reference material for their scientific publications (including type-strains for novel species), collecting by researchers of the collections, exchanges with other collections and donation. Some may be deposited to fulfil patent requirements. Often use is made of environmental samples of soil, water, sediments or plants, which usually contain vast numbers of different microbes requiring significant laboratory work to obtain the genetic resource of interest (frequently including partial or complete DNA sequencing for identification purposes).

Biobanks obtain tissues from hospitals and other medical centres, or sampled in wild populations. In the case of infectious diseases, the pathogens may have been acquired by patients in other countries. Plant and livestock biobanks conserve DNA samples collected from all over the world.

Botanic gardens obtain new plant genetic resources through *in situ* collecting, exchange with other botanic gardens or (very rarely) buying from commercial growers. The origin of the material may be from anywhere in the world.

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 botanical collections obtain plant, animal, and microbial genetic resources from all over the world, through fieldwork in source countries, exchange with other Natural History institutes, or donation, bequests and purchase from private individuals. Material may enter in high volumes, comprising hundreds or thousands of different species, often unidentified. Acquisition, if from a third party, may take place many years after this third party has accessed the genetic resource in the provider country, and a single acquisition may contain specimens from many different collecting events in different countries.

Reference laboratories obtain material (micro-organisms, viruses, nematodes, arthropods) primarily from imported plants and plant products and from national surveys and outbreaks. Alternatively, material is acquired from other collection holders.

## Actors in the Collection Holders domain and good practices

**1.4.1 Actors in the Collection Holders domain**

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 and accepted by the appropriate entities. In general, governance and funding structures of collection holders are quite heterogeneous among the different institutions. While most collection holders are governed at the national or regional level, some may be operated at an international level, for instance the collections in the Consultative Group on International Agricultural Research (CGIAR) system. However, the following simplified categories can be distinguished:

1. Public (national, regional or 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 the holding institution. Collections may also be partially publicly funded and/or partially or completely funded by sales of samples from the collection. They can also take the form of different legal entities including non-profit corporations (e.g., a non-profit GmbH in Germany). Public collections might also have very limited or no public funding and, therefore, recover full costs through their activities. This heterogeneity can lead to a divergence in business models.

1. Commercial bodies

These include (i) collections held by companies primarily or exclusively for the use by 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 they may 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 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 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 genetic resources directly from providing countries, and large collections may ultimately be sold or bequeathed to major public collections and thus become available for others.

**1.4.2 Good practices in Collection Holders domain**

Collection holders work together and they have created and agreed on a wide variety of good practices and other tools with respect to ABS. The list below is not exhaustive, but provides an overview of the main good ABS practices and tools available.

* European Genebanks follow the “Genebank Standards for Plant Genetic Resources for Food and Agriculture”[[7]](#footnote-8). Plant genebanks and other actors/networks active in the field of plant genetic resources for food and agriculture (PGRFA) 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[[8]](#footnote-9), a worldwide registration system for botanic gardens for the exchange of plants and seeds, which implements 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[[9]](#footnote-10).*
* Members of the Consortium of European Taxonomic Facilities (CETAF) are implementing the CETAF Code of Conduct and Best Practices[[10]](#footnote-11) as management tool to monitor user compliance which is currently being considered for recognition by the European Commission under Article 8 of 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, botanical collections 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)[[11]](#footnote-12), which has developed a Code of Conduct and Best Practices for ABS[[12]](#footnote-13) based on an early version of the CETAF documents. The GGBN toolkit for the transfer of genetic resources 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)[[13]](#footnote-14), and have developed ABS-policies and best practices in the framework of the Microbial Resource Research Infrastructure (MIRRI)[[14]](#footnote-15). An earlier standard, MOSAICC, is now being replaced by TRUST (Transparent User-friendly System of Transfer, implementing the Nagoya Protocol in microbiology)[[15]](#footnote-16). 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 and if the MIRRI- European Research Infrastructure Consortium (MIRRI-ERIC) infrastructure is set up 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)[[16]](#footnote-17); 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. Animal biobanks for DNA samples use MTAs or bilateral agreements with providers of samples to ensure transparency.
* Animal genebanks are organised in the European Genebank Network for Animal Genetic Resources (EUGENA), which aims 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; work is on-going 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 EU ABS Regulation. It should be noted that collection holders often accept material under written agreements, which may impose contractual conditions on collection use. Such conditions may be additional to requirements under the EU ABS Regulation.

Article 3(5) of the EU ABS Regulation defines utilisation as “*to conduct research and development on the genetic and/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[[17]](#footnote-18), “*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*”.[[18]](#footnote-19)

Articles 8(a) and 17 of the Nagoya Protocol and Article 7 of the EU ABS Regulation may provide further guidance in considering what constitutes utilisation. The articles mentioned in both legal instruments refer to research rather than to research and development activities.

The general Guidance Document[[19]](#footnote-20) provides examples of ‘upstream’ activities that are either or not to be understood as utilisation (see Chapter 2.3.3 on Research and Development). This document further elaborates on such activities, in particular in the cases described in Chapter 2.3 below.

Furthermore, the general Guidance Document introduces the litmus test as follows: “As a type of ‘litmus test’, users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term ‘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 mainly refer to the use of genetic resources. 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 guidance documents).

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 was a Contracting Party to the Nagoya Protocol at the point of access 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 provider country must be a Party to the Nagoya Protocol and thus exercise sovereign rights over genetic resources, and established access measures on genetic resources at or before the time of access, (2) genetic resources were obtained after the entering into force of the Protocol and the EU ABS Regulation, i.e. on or after 12 October 2014, and (3) accessed genetic resources are utilised within the meaning of the Protocol and the EU ABS Regulation in the EU. Users are referred to the general Guidance document[[20]](#footnote-21) for a more elaborate explanation of these conditions.

The EU ABS Regulation and laws of other Contracting Parties to the Nagoya Protocol 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. Regardless of whether or not in such cases users’ activities fall within 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.

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 general Guidance document, several case studies in section 2.3 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 requires such permits and agreements, and that studies are carried out only if permitted under PIC and MAT.

## 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/her due diligence obligations. The EU ABS Regulation[[21]](#footnote-22) (Art. 7) specifies and the Commission Implementing Regulation[[22]](#footnote-23) 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 funding 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. It is also possible, although rather unusual, that the declarations at both checkpoints might need to be submitted by the same user.

A due diligence declaration is only one element of the due diligence obligations established in the EU ABS Regulation. Other obligations of Article 4 aim to ensure that users access genetic resources and associated traditional knowledge in compliance with applicable laws in the provider countries and 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., In case no R&D is performed by collection holders, they are not users in the meaning of the Regulation and hence do not have the obligation to seek, keep and transfer information to other users. The collection holder could simply refer the user to the original depositor and instruct them to obtain the information themselves. However, general good practice for collection holders is to support users in this respect, through seeking, keeping and transferring the necessary information.

For instance, fungal strains are isolated from wild populations in Spain 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 only for taxonomic research (which is reflected in an MTA). The public collection in the EU Member State is not a user, as it does not perform R&D. Therefore, it is not affected by Article 4 of the EU ABS Regulation and it has no due diligence obligations. However, it is bound by the MTA, which stipulates that the strains can be supplied to third parties for taxonomic research only. Therefore, it has to inform potential users that the material can only be used for taxonomic purposes.

As stated in section 2.3.1 of the general guidance document, on indirect acquisition of genetic resources, intermediaries, such as collection holders, are best placed to inform the user about the legal status of the material they hold.

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, and if this is the case, to make the information on the permit available for potential users and to supply it together with any material given to the potential users. If the permit does not allow the transfer of material to third parties, the material will not be orderable, but it can be marked in the catalogue with a pointer to the CNA that issued the original permit, so that interested parties can contact that CNA to either conclude a new PIC and MAT for access to the collection material or for re-access in the country of origin. If the material subsequently is ordered from the collection by presenting a corresponding enlarged permit issued by the CNA, the collection holder conducts a plausibility check and if positive releases the material for that specific user under the enlarged permit.

Sometimes, material deposited in a public collection has to be made available for non-commercial research by third-party users, e.g. in order to fulfil the requirement of valid publication of a new species under rules of nomenclature. In this case, it would be good practice to obtain permission from the provider country for transfer to third parties before the material is deposited.

For instance, a public culture collection acquires strains through a taxonomist from a University in the country of origin. The taxonomist collected the strains in the provider country under a permit, 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 made available for non-commercial research by third-party users. The Competent National Authority (CNA) of the provider country needs to be contacted to agree on a new agreement (PIC and MAT) which will allow deposit of the material in the public collection and will settle the terms for supply to third-party users. Only if third-party transfer is allowed can the collection distribute the material without further necessity to make a new agreement with the provider country.

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

Collection holders have the possibility to apply (to the CNA designated under the EU ABS Regulation in their Member State) for inclusion of 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, the EU ABS Regulation and the general Guidance document indicate that they have the obligation to supply the genetic resources together with all the relevant information and to keep records of all samples of genetic resources and related information supplied to third persons for their utilisation. The user who has received the material from the collection has the duty to keep and transfer this information. 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, relying on the information provided by the collection.

A special situation concerns the deposition of material with confidential origin, as in the following example.

A scientist wants to deposit a fungal strain for deposit in a public culture 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. According however to Art. 5(3) of the EU ABS Regulation and the general guidance document, a registered collection must supply genetic resources to third persons for their utilisation only with documentation providing evidence that the resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and, where relevant, mutually agreed terms. In this situation, there is no information on the terms and conditions under which the fungal strain has been accessed, so this strain cannot be distributed to third parties by the registered collection with the evidence requested by the EU ABS Regulation. The question whether or not the strain should be accepted for deposition (without supply to third parties) is not dealt with in the EU ABS Regulation.

## Specific case analysis for Collection Holders

This chapter presents activities discussed in Chapter 1. In the activities described and classified below, 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.

***2.3.1. Acquisition and storing***

*Case 1*

|  |  |
| --- | --- |
| *Title* | ***Genetic resources held in a collection without PIC and MAT*** |
| *Description* | Genetic resources are present in a collection. Prior Informed Consent (PIC)[[23]](#footnote-24) and Mutually Agreed Terms (MAT)[[24]](#footnote-25) are absent. There are no records of whether or not PIC and MAT were ever obtained. |
| *Analysis* | If the material is not subjected to utilisation in the meaning of the EU ABS Regulation, the Regulation does not apply and no due diligence is required under the Regulation. However, if the genetic resources are later selected for utilisation by collection staff members, the collection holder is obliged to determine whether this is within scope of the EU ABS Regulation and, if so, PIC and MAT have to be sought from the provider country, if required by that country. If the genetic resources are utilised by a third party, this third party is obliged to determine whether this is within scope of the EU ABS Regulation and, if so, PIC and MAT have to be sought from the provider country, if required by that country. |

*Case 2*

|  |  |
| --- | --- |
| *Title* | ***Collecting genetic resources from in situ conditions******and storing them in a collection*** |
| *Description* | Genetic resources are collected from *in situ* conditions in a provider country and stored in a collection. |
| *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’.  Storing in 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 legal requirements of the country where the material is collected *in situ*.  If the genetic resources are later selected for utilisation by collection staff members, the collection is obliged to exercise due diligence to determine whether this is within scope of the EU ABS Regulation and, if so, to ensure that the necessary documents (PIC and MAT) are in place. If the genetic resources are utilised by a third party, this third party is obliged to exercise due diligence to determine whether this is within scope of the EU ABS Regulation and, if so, it needs to ensure that the necessary documents (PIC and MAT) are in place. |

*Case 3*

|  |  |
| --- | --- |
| *Title* | ***Collecting genetic resources from a market or shop in the country of origin and storing them in a collection*** |
| *Description* | Specimens of organisms are acquired from a market or shop in the country of origin and stored in a collection. |
| *Analysis* | Buying from a market and storing in a collection 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 legal requirements of the provider country.  If the genetic resources are later selected for utilisation by collection staff members, the collection is obliged to exercise due diligence to determine whether this is within scope of the EU ABS Regulation and, if so, to ensure that the necessary documents (PIC and MAT) are in place.  If the genetic resources are utilised by a third party, this third party is obliged to exercise due diligence to determine whether this is within scope of the EU ABS Regulation and, if so, to ensure that the necessary documents (PIC and MAT) are in place. |

*Case 4*

|  |  |
| --- | --- |
| *Title* | ***Accessing contaminations of commodities*** |
| *Description* | Material is imported into the EU as a commodity. At border inspection, contaminations are detected (e.g. a pests or diseases on plant material, seeds in soil samples, or stowaway animals). The material is sent to an institute providing an identification service and maintaining a public collection. The institute may identify pathogenic, non-pathogenic or invasive species. Out of scientific interest, the institute decides to place all organisms (whether they are pathogenic or not) in the public collection, recording the non-EU country as the provider country. |
| *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.  If the specimens are later selected for utilisation in the sense of the EU ABS Regulation, the following considerations apply: access to a pathogenic organism or pest that was unintentionally introduced to a place in the EU territory 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 the user should check the requirements of the provider country, with PIC and MAT being negotiated if required by that country.  However, intentionality of access is still subject to discussion (see also section 3.2 of this document). |

*Case 5*

|  |  |
| --- | --- |
| *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* | Collecting 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.  If the specimens are later selected for utilisation in the sense of the EU ABS Regulation, the user should apply due diligence. If it is likely that the associated organisms came from the same country as the specimen of the host, the original PIC and MAT covering the collecting of the host organism should be consulted to see if they also cover associated organisms; if not, or if there is no PIC and MAT, it should be checked with the provider country of the host organism if conditions are attached to the associated organisms and if the provider country requires PIC and MAT on such material. If this is the case, this country should be approached to provide PIC and MAT. If it is more plausible that the associated organisms came from another country (e.g. a transit country or the country of the *ex situ* collection), it should be investigated if that country requires PIC and MAT, and this country should be approached to provide PIC and MAT. |

*Case 6*

|  |  |
| --- | --- |
| *Title* | ***Collecting associated organisms from a human host*** |
| *Description* | Specimens of associated organisms are collected from a human host |
| *Analysis* | Collecting 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.  If the specimens are later selected for utilisation in the sense of the EU ABS Regulation, the following considerations apply. 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 associated organisms from the scope of the EU ABS Regulation or the Nagoya Protocol. The user is required to exercise due diligence, to establish if possible the country of origin, i.e. the provider country, and to request PIC and MAT, if appropriate.  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).  However, intentionality of access is still subject to discussion (see also section 3.2 of this document). |

*Case 7*

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| --- | --- |
| *Title* | ***Isolating microbes from foods processed with recorded or unrecorded traditional methods and storing them in a collection*** |
| *Description* | Microbes are acquired from traditionally processed foods whose methods of production and use a) have been recorded previously by researchers in the field and been published or b) have not been recorded previously by researchers in the field and have not been published. The microbial genetic resources are stored in a collection. Later, the microbial genetic resources are used by collection staff in R&D. |
| *Analysis* | Incorporation into a collection itself does not involve R&D on the genetic or biochemical composition of the genetic resources. Therefore, storing does not constitute ‘utilisation’ of the genetic resources in the sense of the EU ABS Regulation.  When the microbial genetic resources are later selected for utilisation in the sense of the EU ABS Regulation by collection staff, the user is required to exercise due diligence to establish if possible the country of origin, i.e. the provider country, and to request PIC and MAT, if appropriate. In both cases a) and b), the user is obliged to declare the intended use of traditional knowledge in the preparation of the foods 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 ABS Regulation.  However, some aspects concerning traditional knowledge associated with genetic resources are still subject to discussion (see section 3.3 of this document). |

*Case 8*

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| --- | --- |
| *Title* | ***Accessing traditional knowledge associated with genetic resources 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 publicly available. 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* | The ABS requirements regarding aTK in India should be checked and complied with by the researcher. If the aTK is associated with a plant species (whether or not using a formal scientific name), and if it is included in the MAT, utilisation of the aTK falls within scope of the EU ABS Regulation.  However, some aspects of traditional knowledge associated with genetic resources are still subject to discussion (see section 3.3 of this document). |

*Case 9*

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| --- | --- |
| *Title* | ***Storing genetic resources as a safe deposit*** |
| *Description* | A culture collection provides a confidential service of safe deposit for 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 usually not 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 usually 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 that the material has been accessed in compliance with applicable laws in the provider countries (but it would be good practice to do so). 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.  If the culture collection plans to carry out research activities on the genetic resources in safe deposit, this would be ’utilisation’ in the meaning of the EU ABS Regulation.  If the culture collection is asked by the depositors to send the strains out to third parties, it is good practice for the collection holder to refer the third party to the depositor for information on the ABS conditions for access. |

*Case 10*

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| --- | --- |
| *Title* | ***Deposition of a contaminant organism in a culture collection*** |
| *Description* | A microbial strain is deposited by a scientist who has worked with the strain in a 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 organism, which it subsequently isolates from the original strain. The contaminant organism could have originated from the country of origin of the primary strain, from the country where the depositor works, or from a country it was transported through. The depositor is not aware of the presence of the contaminant. Out of scientific interest, the collection decides to deposit the contaminant strain in the public collection and record the country of origin as “unknown”. |
| *Analysis* | Deposition and storage of genetic resources in itself does not constitute utilisation in the meaning of the EU ABS Regulation.  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 cannot be traced, the collection may deposit the strain in its public collection with the indication that this material is of unknown origin, and provide interested parties with any information on the possible countries of origin of the organism that was found as a contaminant originally. Although the EU ABS Regulation requires that due diligence be exercised when utilising genetic resources, it does not prohibit the utilisation of material with unknown/indeterminable origin.  However, intentionality of access is still subject to discussion (see also section 3.2 of this document). |

*Case 11*

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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). |

*Case 12*

|  |  |
| --- | --- |
| *Title* | ***Storing alien species found in the country of the collection holder*** |
| *Description* | An alien species (micro-organism, plant or animal) is discovered in the country of a collection holder, which does not regulate access to genetic resources, and stored in a collection. This organism may be invasive, a pest or non-pest, and may cause damage to biodiversity, ecosystems and ecosystem services. The country of origin cannot be traced. |
| *Analysis* | Incorporation into a collection itself does not involve R&D on the genetic or biochemical composition of the genetic resources. Therefore, this activity does not constitute ‘utilisation’ of the genetic resources in the sense of the EU ABS Regulation.  If the organism is supplied to third parties for utilisation, the user has the responsibility of undertaking a due diligence assessment to determine whether PIC and MAT are required. |

***2.3.2. Identification***

*Case 13*

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| --- | --- |
| *Title* | ***Identification on the basis of phenotype*** |
| *Description* | Specimens are identified using phenotypic characteristics 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 and described (with publication in a scientific journal). |
| *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 not amount to utilisation. Therefore, the identification on the basis of phenotype is not considered ‘utilisation’ in the meaning of the EU ABS Regulation.  Discovery, description and publication of new species would also not qualify as utilisation in the meaning of the EU ABS Regulation, as long as this is done without additional research on the genetic and/or biochemical properties of the genetic resources. |

*Case 14*

|  |  |
| --- | --- |
| *Title* | ***DNA extraction and sequencing for identification and/or identity checks*** |
| *Description* | Specimens are identified using characteristics that involve DNA sequencing or biochemical analysis. Undescribed species may be recognised and described. |
| *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”, as formulated in the litmus test in the general guidance Document.  Under the litmus test criterion, there is no difference between the process whether the result points to a previously named entity or an unnamed entity. |

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

*Case 15*

|  |  |
| --- | --- |
| *Title* | ***Performing taxonomic studies using morphological and sequence information*** |
| *Description* | A taxonomist studies a certain group of organisms, e.g. in preparation of a floristic treatment or taxonomic monograph. Species are delimited with the use of both morphological and sequence information, and some are described as new. As a part of the descriptive process, the taxonomist creates a phylogeny of the taxa involved, also using morphological and sequence information obtained from specimens in a collection. The properties associated with the genes are not identified or used in this process. |
| *Analysis* | The morphological and 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 ‘litmus’ test given in the general Guidance document, this does not qualify as utilisation in the meaning of the EU ABS Regulation. |

*Case 16*

|  |  |
| --- | --- |
| *Title* | ***Preparation of a taxonomic monograph using morphological and sequence information as well as analysis of genetic or biochemical***  ***properties*** |
| *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 associated with the genes are identified and analysed for the description. |
| *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. However, the activity includes research on the genetic resource to discover specific genetic and/or biochemical properties or traits. Therefore, this activity qualifies as utilization in the meaning of the EU ABS Regulation. |

*Case 17*

|  |  |
| --- | --- |
| *Title* | ***Comparative research combining phylogeny with protein properties*** |
| *Description* | A taxonomist specialising on a group of venomous snakes collaborates with a protein research laboratory to evaluate the link between species relatedness and venom protein similarities, with potential use for snake-bite treatment with antivenom. A phylogeny is reconstructed on the group of snakes and the venom protein of each species is analysed and compared over the phylogeny. The venoms were extracted from snakes accessed with PIC and MAT. |
| *Analysis* | The phylogeny is used to compare the properties of the venom proteins and the relatedness of the snakes. The construction of the phylogeny would be out of scope if the properties of the venom or genes were not used. If the venoms were analysed and used for the phylogenetic analysis, or properties of the genes were used, it is likely to be in scope.  The comparison of the venoms, even if not directly related to the development of a new antivenom product, constitutes utilisation in the meaning of the EU ABS Regulation as it investigates the biochemical composition of a derivative. |

*Case 18*

|  |  |
| --- | --- |
| *Title* | ***Diversity analysis of domestic breeds*** |
| *Description* | DNA is extracted from individual blood samples and genotyped with a public SNP chip to calculate genetic distances. This does not provide any information on the phenotype or the performance, because the SNP markers have been chosen on the basis of polymorphisms across breeds within the species. The aim of the study is to estimate the distance between breeds and the homogeneity within breeds. It can lead to recommendations for population management but it does not characterize the genetic and or biochemical properties of each breed. |
| *Analysis* | The genetic resources are used for classification and identification, but not for searching for a particular trait of a breed. Therefore, this is not utilisation in the meaning of the EU ABS regulation. |

*Case 19*

|  |  |
| --- | --- |
| *Title* | ***Genomic research on species intentionally introduced into an EU country and later accessed in that EU country*** |
| *Description* | A species of fish was intentionally introduced from a non-EU country of origin to an EU country in the 1960s for fishing, and has established a viable population in the EU country, that has since then experienced genetic change. A collection holder in the EU country provides fresh material from his/her country to a research consortium wishing to sequence the genome of the species and publish a genome map annotating the genes and their functions. |
| *Analysis* | As the genome is sequenced to publish a genome map also annotating the functions of the genes, the research activity qualifies as R&D on the genetic and biochemical properties of the genetic resources and thus constitutes utilisation in the meaning of the EU ABS Regulation. The user should seek PIC and MAT from the EU country, if required by that country. |

***2.3.4. Collection maintenance***

*Case 20*

|  |  |
| --- | --- |
| *Title* | ***Maintenance of a sustainable genetically viable population of animals*** |
| *Description* | The objective of zoo breeding programmes is to obtain a sustainable genetically viable population. Such programmes aim at reconstituting as much as possible the original diversity of the species and thus at restoring the *status‐quo‐ante*, and not at changing it compared to wild populations. |
| *Analysis* | Breeding to maintain a sustainable genetically viable population of animals does not qualify as ‘utilisation’ in the meaning of the EU ABS Regulation, and thus does not trigger any due diligence obligations. This in contrast to agricultural breeding programmes that aim at changing the genetic constitution of the respective resources in order to improve specific properties of breeds, varieties etc. However, acquisition of animals from another country should be done in line with the legal requirements of the provider country. |

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

*Case 21*

|  |  |
| --- | --- |
| *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. Such conditions, where existent, need to be respected. |

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

*Case 22*

|  |  |
| --- | --- |
| *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 to maintain a sustainable genetically viable population of animals does not qualify as ‘utilisation’ in the meaning of the EU ABS Regulation, and thus does not trigger any due diligence obligations. However, acquisition of animals from another country should be done in line with the requirements of the provider country, with Prior Informed Consent (PIC)[[25]](#footnote-26) and Mutually Agreed Terms (MAT)[[26]](#footnote-27) on intended use being negotiated if required by that country. |

# Unresolved issues

This chapter lists issues on which no consensus has been reached until now. In particular, it deals with activities that 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. A small number of samples may be selected for 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 may 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 general 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.”

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 may lead to different 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.

If 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. 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.

It can be argued that 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. It should be made clear under what conditions and for which uses unintended access allows the material to be out of scope of the Regulation. In response of the difficulties in distinguishing pathogens and non-pathogens, rules could be established on unintentional access that are not dependent on pathogen or pest status of a genetic resource.

It can also be argued that countries are responsible for exporting healthy material, and that, whatever organism is found on this material, it makes no sense to have to go back to that country to acquire PIC and MAT. In this view, all contaminants, whether considered pathogens or not, on imported material should be excluded from the scope of the EU ABS Regulation.

*This issue affects Cases 4, 6 and 10 above*.

**3.3. Traditional Knowledge associated with genetic resources.**

The wording of the Nagoya Protocol and of the Regulation is ambiguous on the meaning of Traditional Knowledge associated with genetic resources (aTK). There are two alternatives: (i) TK that is accessed at the same time and place as the GR, or (ii) TK that refers to GR that can be identified, with the TK not necessarily having been accessed with the GR. These alternatives carry very different implications for collection management and for research. The EU ABS Regulation describes aTK 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.

Different opinions exist as to the position of published TK. Some argue that published TK is not in scope of the Protocol, while others hold that the publication of TK does not invalidate the rights of the originators, because 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 the PIC. Failure to mention this when seeking PIC may well invalidate the PIC. If the use of the aTK is then included in the MAT, the provisions of the EU ABS Regulation apply.

*This issue affects Cases 7 and 8 above*.

**3.3 Laboratory strains**

A laboratory strain is biological material that has been kept alive for research in the laboratory based on one or more particular properties that make it unique for research purposes. 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 also 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, users should apply due diligence 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, it is good practice for the culture collection holder to ascertain which requirements have to be met in order to legally distribute the strains to third party users.

If, however, no information on its provenance exists, and the collection holder is unable to find any information in the literature that could prove that the strain is in or out of scope (for instance out of the temporal or geographic scope), the matter would remain unresolved, as is the question whether or not to distribute and/or use these strains. Although the EU ABS Regulation requires that due diligence be exercised when utilising genetic resources, it does not prohibit the utilisation of material with unknown/indeterminable origin.

**3.5 Genetic resources transferred before 2014**

This issue is illustrated by a real-life case brought forward. A tree species was very rare in country A, where its populations were considered to be endangered. Individuals from the remnant populations were vegetatively propagated and planted in an *ex situ* genetic conservation collection in country B before 2014. PIC from the providing country A was obtained before establishing the collection, but no MAT or other contract was negotiated or needed at the time. A decade later (after 12 October 2014) a joint European project wishes to perform 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 had remained in country A.

DNA‐analysis with the aim of characterising the genetic diversity within a population or an *ex situ* collection does not constitute ‘utilisation’ in the meaning of the EU ABS Regulation, as long as this is done without additional research on the genetic resources to discover specific genetic and/or biochemical properties. Therefore, such activities do not constitute ‘utilisation’ in the meaning of the EU ABS Regulation.

If, however, research would be done on the genetic resources to discover specific genetic and/or biochemical properties, the question is from which country permission for this use should be sought. It can be argued that the user would have to seek PIC and MAT from country B, if required by that country, because the genetic resource was accessed from country B that acquired the genetic resource from country A in accordance with the CBD. As the genetic resources were transferred from country A to country B before 2014, there can be no due diligence obligations towards country A on the basis of the EU ABS Regulation.

On the other hand, it can be argued that this is only true if the original PIC explicitly permitted further transfer of the genetic resource, and that 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 that country.

**3.6 Registered collection and IRCC with confidential information about conditions of use**

The situation may occur that a scientist sends a strain to a public and registered collection in the EU for deposit. The depositor provides an IRCC number, and detailed information on date and place 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.

Different views exist on the proper way to handle this situation. The curator may see 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 third parties, with the third party having the responsibility to check if his/her activities stay within the limits set in the IRCC. On the other hand, it may be argued that, as there is no information on the terms and conditions under which the strain has been accessed, this strain cannot be distributed to third parties by the registered collection with the evidence requested by the EU ABS Regulation.

# Annex. Background information

## General principles

The European Commission has developed a general Guidance document[[27]](#footnote-28) 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 their activities

Natural History Museums, botanical collections 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 not very common.

## Economic features

Most benefits shared by collection holders are non-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 botanical collections, 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 activities. 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[[28]](#footnote-29).

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 are 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 practices for the preservation and use of such collections, 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[[29]](#footnote-30).

The European Forest Genetic Resources Programme (EUFORGEN)[[30]](#footnote-31) 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 that 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 in 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[[31]](#footnote-32).

## 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*

Collection holders are linked to pre-breeding and breeding activities with the objectives to increase diversity available to users. 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. 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-2)
2. Not to be confused with open and online DNA sequence depositories such as GenBank (NCBI), EMBL or DDJB. [↑](#footnote-ref-3)
3. The conservation of components of biological diversity outside their natural habitats. [↑](#footnote-ref-4)
4. Management of genetic diversity by farmers within their own agricultural, horticultural or agri-silvicultural systems. [↑](#footnote-ref-5)
5. Human genetic resources are out of scope of the EU ABS Regulation because they are not covered by the CBD and the Nagoya Protocol. [↑](#footnote-ref-6)
6. OECD, Biological Resource Centres. Underpinning the future of Life Sciences and Biotechnology http://www.oecd.org/sti/biotech/2487422.pdf [↑](#footnote-ref-7)
7. http://www.fao.org/agriculture/crops/thematic-sitemap/theme/seeds-pgr/gbs/en/ [↑](#footnote-ref-8)
8. http://www.bgci.org/policy/ipen/ [↑](#footnote-ref-9)
9. https://www.bgci.org/policy/abs\_principles/ [↑](#footnote-ref-10)
10. http://cetaf.org/sites/default/files/final\_cetaf\_abs\_coc.pdf [↑](#footnote-ref-11)
11. http://www.ggbn.org/ggbn\_portal/ [↑](#footnote-ref-12)
12. http://www.ggbn.org/docs/ABS\_Guidance/GGBN%20Guidance%20\_Best\_Practice\_June\_2015-Final.pdf [↑](#footnote-ref-13)
13. 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-14)
14. 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-15)
15. http://bccm.belspo.be/projects/trust [↑](#footnote-ref-16)
16. http://www.isber.org/?page=BPR [↑](#footnote-ref-17)
17. Section 2.1. p.30 [↑](#footnote-ref-18)
18. 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-19)
19. 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-20)
20. 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-21)
21. 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 the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. [↑](#footnote-ref-22)
22. The general Guidance document also provides some additional explanation concerning submission of due diligence declarations. [↑](#footnote-ref-23)
23. 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-24)
24. 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-25)
25. 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-26)
26. 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-27)
27. 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-28)
28. http://www.wfcc.info [↑](#footnote-ref-29)
29. https://asas.org/docs/default-source/wcgalp-posters/437\_paper\_8691\_manuscript\_289\_0.pdf?sfvrsn=2 ) [↑](#footnote-ref-30)
30. www.euforgen.org [↑](#footnote-ref-31)
31. www.euforgen.org/forest-genetic-resources/poplars-clones-database [↑](#footnote-ref-32)