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**Guidance Document for Public Research**

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# Introduction

This Guidance document for public research is meant to help users, as well as competent national authorities, to establish whether activities carried out fall within the scope of the (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 users in public research in identifying their due diligence obligations, as specified in Article 4 of this Regulation, 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 Commission Implementing Regulation is available at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866>

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 sectorial Guidance documents, the aim of this document is to arrive at a shared interpretation for public research organisations of the terms “*utilisation*” and “*research and development*” as contained in the EU ABS Regulation. It provides an overview of research and development activities which may lead to a product development process, as well as a classification of activities as being within or outside scope of the EU ABS Regulation. It may be useful to refer to other sectorial Guidance documents for additional guidance on sector-specific issues.

## Coverage

Public research is often understood as comprising entities that are “*irrespective of their legal status, […] either totally or to a substantial share publicly owned [or operated], and/or (are) funded primarily from public sources via base funding (block grants) or through contract-based research, and/or are regulated so as to achieve primarily public missions*”[[2]](#footnote-3).

By focussing on public research organisations, this Guidance document addresses in particular fundamental[[3]](#footnote-4) research carried out for non-commercial purposes, as referred to in Article 8 of the Nagoya Protocol. However, some public research organisations also carry out more applied research and may even undertake product development. The EU ABS Regulation applies to all utilisation of genetic resources or traditional knowledge associated with genetic resources (Article 3(4) of the Regulation), regardless whether the utilisation is commercial or non-commercial, and regardless if the research is fundamental or applied and irrespective of its position in the development chain. Thus, assuming that all other conditions for the applicability of the Regulation have been fulfilled, the due diligence obligations apply to all public research organisations in the EU, regardless whether research is only undertaken for the purpose of generating knowledge or also for the purpose of potential later product development.

Since many activities in public research are undertaken for the purpose of knowledge generation and for the public good, initially many actors may wrongfully assume that legislation on access and benefit-sharing does not apply to their activities. Article 8 of the Nagoya Protocol requires that Contracting Parties shall “.... 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 ....”, and hence national legislation may contain specific provisions related to such non-commercial research. However, neither such specific provisions, nor Article 8 of the Nagoya Protocol, in any way diminish the obligations for users stemming from the EU ABS Regulation. When genetic resources are accessed from another Party to the Nagoya Protocol under such specific and simplified provisions and subsequently utilised in the EU, due diligence has to be exerted and has to be documented with respect to genetic resources accessed.

In the context of this Guidance document public research organisations include universities and other higher education institutions carrying out research such as polytechnic institutes, as well as publicly funded research institutions, and spin-offs and spin-outs of public research organisations. While many public research organisations are public bodies, some public research organisations may be legally registered as private not-for-profit organisations. Non-governmental organisations may also undertake research activities using public funds, e.g. WWF, IUCN, etc. Furthermore, charities may contract or undertake research and development activities. A sharp and unambiguous line between public and private research may be difficult to draw. Moreover, the distinction between public and private research does not equal the distinction between not-for-profit and for-profit, as public research may also be of a for-profit nature, and some private research may be of a fundamental not-for-profit nature.

It is acknowledged that individuals in a personal capacity may also undertake research and development independently from organisations. Such individuals may regard their activities to be of a public nature. The nature and extent of their activities may not always be known to public bodies, including the Competent National Authority responsible for implementation of the EU ABS Regulation. Nevertheless, such individuals, when they utilise genetic resources in the meaning of the EU ABS Regulation, also have to comply with the EU ABS Regulation.

Public research activities are understood to include activities in highly diverse fields, ranging from bioscience, health and agriculture to environmental monitoring and management and food processing, and including basic scientific disciplines like biology, chemistry, oceanography, etc. A major part of these activities will be of a fundamental nature, whereas some of the research may be carried out in collaboration and/or under contract with private sector entities.

Publications in the scientific literature form an important output of public research organisations. In the area of genetic resources, not only research results, but also DNA sequences and other digital data may be published, often with little or no restrictions, in public databases. It is acknowledged that open access to scientific research results is a key focus of the European Open Science Policy Platform.

Where biotechnological tools and methods are applied in public research, this sectorial Guidance document has addressed such use, given that these form an important element of public research. Activities undertaken by collection holders will be specifically addressed in a separate Guidance document.

In some cases, traditional knowledge associated with the accessed genetic resources may also be utilised. “*Traditional knowledge associated with genetic resources*” means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources (See Article 3(7) of the EU ABS Regulation). Its utilisation is also addressed in this document.

## Public research activities

The domains in public research utilising genetic resources are similar to the ones in the private sector: they include the areas of bioscience, health and medicine, food and agriculture, evolutionary and ecological studies, environmental and biodiversity management, and industrial processing activities. These public research activities are performed by universities as well as research institutions. Many public research organisations tend to focus on the first steps in the research and development chain[[4]](#footnote-5), including characterisation and evaluation of genetic resources, and an understanding of and insight into the organisms and the genotypes and phenotypes involved. Some of this research may be undertaken to improve the sustainable use of global biodiversity and to support implementation of the relevant Aichi Targets of the Strategic Plan for Biodiversity 2011-2020 of the Convention on Biological Diversity (UNEP/CBD/COP/DEC/X/2). Various technologies are applied in order to gain insight into the properties of genomes of genetic resources or the sequences of bases that make up the genes, including, but not limited to, whole-genome sequencing, high-density marker mapping, and DNA bar-coding. The primary goals of many public research organisations regard the extension of knowledge in the form of peer-reviewed publications, the creation of public goods and the transfer of knowledge. Publication of the research results is often a major objective, indicator and norm for scientific success, since many funding agencies require publications and many internal procedures and evaluation protocols measure the success of the research by the quality and quantity of publications. Wide and often open collaboration with other research organisations is another major feature of public research activities. However, the performance of many public research organisations is also measured by other criteria such as patent portfolios, the creation of spin-offs, and the volume of contract research. Part of the research undertaken in public research organisations takes place in the context of contract research funded by the private sector, in which case specified conditions may be agreed upon regarding the publishing of the results of the research.

Universities and public research institutes are organisations that perform a key role within society by providing education and the generation of knowledge, but also by fostering links with knowledge users and facilitating technology transfer. A diverse range of policies have been implemented to encourage knowledge transfer, by the European Union, its Member States and at the institutional levels. Various channels are available for establishing links with knowledge users, including through contract research, the patenting and licensing of inventions, as well as academic entrepreneurship. In addition, policies provide support for open publication and/or close collaboration between public research and the private sector.[[5]](#footnote-6) To that effect, in 2010, the European Commission published a communication with detailed recommendations to the Member States, striving towards an “*Innovation Union*”. While direct commercialisation through patenting and licensing and in-house product development represent an important way to contribute to commercialisation, collaborative research, contract research and consulting, often formalised through contracts, form the major channel by which knowledge transfer is accomplished.[[6]](#footnote-7)

Some public research organisations have a much more focussed mandate to generate knowledge and make that available to the knowledge user community, and normally focus on applied research, e.g. in the areas of health and of food and agriculture. However, publishing the results of the research normally remains a major objective.

Innovation and knowledge transfer referred to above may regularly involve the access to and use of genetic resources.

A series of activities can be recognised, in line with activities described in the other sectorial Guidance documents, including:

* + Sourcing, identification and storage of genetic resources;
  + Performing fundamental research;
  + Performing applied research without private partners;
  + Performing research within public-private partnerships; and
  + Developing products and placing these on the market.

Collaborative research and contract research as well as consultancy activities have become increasingly common in the public sector, both between EU-based entities and between institutions based within and outside the EU. Exchange of genetic resources and/or derivatives takes place regularly in the context of such activities. Such collaborations include customary practices involving partners from countries from outside of the EU (which may provide genetic resources during the project cycle), and including information exchange, technology transfer and capacity building as important forms of non-monetary benefit-sharing.

In accordance with Article 7(1) of the EU ABS Regulation, Member States and the Commission shall request the recipients for funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4. In line with the requirements of the EU ABS Regulation and the national law of the Member States, funding agencies may have set rules to the utilisation of genetic resources to which the recipients of funds are legally bound. In particular, government-controlled funding agencies may increasingly do so.

## Types and sources of genetic resources used

***Types of genetic resources***

Public research organisations undertake research on genetic resources of all domains (plant, animal, fungal/microbial). Such genetic resources might be obtained as whole organisms but instead, DNA or RNA may be obtained, or environmental samples (such as soil samples) containing many genetic resources. Finally, derivatives of genetic resources might be obtained, either in connection to the transfer of the associated genetic resources or not.

In addition, digital sequence data and other digitalised information obtained from genetic resources may be used for the purpose of performing research and development, including for the purpose of comparison with newly isolated organisms, as well as for the purpose of education and training.

***Sources of genetic resources and associated traditional knowledge***

EU based universities and public research institutes access many genetic resources for the purpose of performing research in the context of collaboration with universities or research institutes established in the provider country. Such access may be in the form of a donation, purchase or exchange. Alternatively, EU based universities and public research institutes may be involved in activities collecting genetic resources from *in situ* conditions in provider countries. Visiting students and visiting scientists may access genetic resources in their home country for the purpose of their own research, which they may perform whilst visiting EU based universities or public research institutes. Whereas traditionally such transfers of genetic resources would take place on an informal basis, more recently the utilisation of such genetic resources has increasingly been governed by Material Transfer Agreements by the provider and user institutions.

In this context, genetic resources may also be obtained from existing collections, located either in the provider country (including within the European Union) or elsewhere, but also from individual researchers’ collections. In addition, researchers may obtain genetic resources by buying these in markets or shops, or through mediators who specialise in accessing and selling genetic resources. In many cases, access conditions will allow for conservation of the involved genetic resources in collections, and for return or destruction of the genetic resources that have been studied after finalisation of the research.

Traditional knowledge may be associated with genetic resources obtained. In some cases such associated traditional knowledge may be obtained in conjunction with the access to the genetic resources involved, and use of such associated traditional knowledge will normally be covered in the PIC and MAT. In other cases, traditional knowledge regarding the use of specific genetic resources may be independently sourced from third parties or from literature, although its employment may still be mentioned in PIC and MAT. The EU ABS Regulation covers both utilisation of the genetic resources and of the associated traditional knowledge concerning such genetic resources.

## Actors in public research

The following actors are involved in public research:

* Universities;
* Public research institutes;
* Collection holders[[7]](#footnote-8);
* Funding agencies, including government agencies and charities; and
* International organisations/associations,
* Non-governmental organisations;
* Independent researchers and amateurs.

This Guidance document focuses strongly on the activities of universities and public research institutes. Charities with a research mandate may play a role in knowledge transfer as well, either by performing research themselves or by providing funds to allow research and development. Such charities show features of public research organisations as well as private sector research efforts, and may therefore find guidance on obligations stemming from the EU ABS Regulation in the present document.

In addition to their funding source, public research actors also share informal and evolving norms of performing science[[8]](#footnote-9), in which both goals and general attitudes can be attributed both to the individual researcher and to the institution as a whole. In addition to the attitude of the individual researcher, who often regards publishing for the public good as a major objective, the relative autonomy of individual researchers and decentralised decision-making in public research as compared with actors and practices in the private sector form another striking feature. In connection to the relative autonomy of the research undertaken, in many public research organisations it may not be immediately evident who is responsible for the implementation of proper measures to comply with the provisions of the EU ABS Regulation.

In this context it should be noted that various actors in the public sector have introduced best practices, and such best practices may qualify for registration in accordance with Article 8 of the EU ABS Regulation.

# Classification of activities in relation to utilisation of genetic resources

## Introduction

This chapter explores the range of activities that may be carried out in the context of research and development in the public research, and relates these activities to the EU ABS legislation and, more specifically, to the obligations of users that may follow from the 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[[9]](#footnote-10), “*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*”.[[10]](#footnote-11)

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[[11]](#footnote-12) 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 main activities undertaken in public research, and lists whether the activities concerned are considered to fall inside or outside the scope of the EU ABS Regulation.

In the context of this Guidance document, public research is understood as both fundamental and applied research carried out by universities, other higher education institutes and public research institutes, as well as other entities such as non-governmental organisations and private individuals, in various disciplines. Whereas some public research utilising genetic resources is of a purely fundamental nature, other public research may be carried out in the framework of public-private partnerships and may lead to product development. In the latter case the role of the public research institution is often to perform upstream research. Yet another type of public research institutes, such as in health and food and agriculture, is focussed on applied research.

The cases mainly refer to the utilisation of genetic resources. In some cases, traditional knowledge associated with the genetic resource involved may be utilised 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 to public research, as some cases may occur in all sectors for which sector-specific Guidance documents have been developed.

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 have ratified the Protocol and thus exercised 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 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[[12]](#footnote-13) 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. In general, it is possible that ABS legislation and regulatory requirements in provider countries go beyond the scope of the EU ABS Regulation. Users in the EU are expected to respect such national legislation and requirements, as outlined in chapters 2.2 and 3.1 of the general Guidance document.

## 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[[13]](#footnote-14) specifies and the Commission Implementing Regulation[[14]](#footnote-15) 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 obligations, 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.

Whereas individual users should verify whether their activities fall within the scope of the EU ABS Regulation, the management of public research organisations is understood to also bear responsibility for the activities undertaken by its staff and/or on its premises. It is therefore important for the management of public research organisations to clearly define and communicate responsibilities regarding due diligence obligations within the organisation and to regularly monitor compliance with internal rules, whilst respecting relevant legislation. This applies not only to the organisation staff, but also to the actions of visiting scientists and students who may introduce genetic resources from foreign origin, often their home country, for research purposes. Whereas the final responsibility for such compliance is legally determined and usually rests with the research institutions on behalf of their employees and students, it may be important for management of public research organisations to raise awareness amongst its staff and to introduce clear instructions in the organisation regarding the responsibilities in relation to the utilisation of genetic resources, and to have process and policies in place to this end. In particular, management may best ensure traceability of genetic resources, derivatives and documents like material transfer agreements including mutually agreed terms (MAT) and permits showing prior informed consent (PIC), in order to meet the obligations stipulated in Article 4 of the EU ABS Regulation. In view of the above, public research organisations are advised to develop best practices regarding the utilisation of genetic resources by their staff and/or on their premises. Article 8 of the EU ABS Regulation offers the possibility that such best practices are recognised by the Commission.

Some users may seek to access the genetic resources by collecting these from the wild or from farmers or local communities (*in situ* conditions). Other users seek access to genetic resources held in *ex situ* collections, either collected in the country where the collection is based or obtained from third countries. Users subsequently use these genetic resources in R&D programmes to create new knowledge and/or to develop new products. Generally speaking, such R&D activities are considered utilisation and hence fall in the scope of the EU ABS Regulation. However, if the collected genetic resources are only stored for the purpose of potential later utilisation, such storage in itself does not constitute utilisation in the meaning of the EU ABS Regulation. In case of access of genetic resources from an *ex situ* collection, it remains part of the due diligence obligation of the user in the EU to check whether the genetic resources accessed from the collection have been obtained (by the collection holder) in agreement with requirements of the provider country.

EU-funded and other cross-boundary research programmes and projects have strongly increased in importance. Such projects and programmes involve actors (partners) from different EU countries, which may closely collaborate in generating research results, implying that either in parallel or subsequently different consortium partners may work with the same genetic resources or their derivatives. All consortium partners may be users of genetic resources in the meaning of the EU ABS Regulation. If so, all partners need to exert due diligence according to Article 4 of the EU ABS Regulation, which in cases like this will include the obligation to record data on information provided to subsequent users. According to Article 5.3 of the Implementing Regulation the consortium partners can decide that only one partner shall submit a due diligence declaration at the stage of receiving research funding where utilisation of genetic resources is involved. If the partners decide so, according to the same article, this declaration shall be submitted by the coordinator. If the coordinator is not established in an EU Member State, the consortium partners should designate a partner that is established in a Member State where part of the research project is carried out. Each research activity has to be declared only once. Evidence regarding which partner obtained genetic resources, and ensured PIC and MAT and which partners utilised genetic resources is best to be documented. Such practices resemble those involved in contract research, and – as good practice - should be ideally included in the consortium agreement underlying the execution of the EU funded programme or project.

In this context, genetic resources may have been acquired from a Party to the Nagoya Protocol by one consortium member, and both genetic resources as well as derivatives extracted from these genetic resources may be shared within the consortium in the context of a joint research project. Assuming that the research activities of each consortium member qualify as “*utilisation*”, i.e. that each member carries out research and development on the genetic and/or biochemical components of the acquired genetic resources, in relation to the consortium member that first acquired the genetic resources (the “*acquiring consortium member*”), each other consortium member is to be considered a “*subsequent user*” as meant in Article 4 of the EU ABS Regulation. Data on the transfer of information on genetic resources transferred to subsequent users should therefore ideally be kept by the acquiring consortium member. Likewise, this member is expected to keep information on the transfer of derivatives to other consortium members, if these derivatives were obtained from the genetic resources and their utilisation is covered by the mutually agreed terms.

Public-private partnerships involving the performance of joint research activities have become increasingly common in public research. The division of research tasks and the intensity of collaboration between researchers from the public and private sector within such partnerships may vary. For example, close collaboration occurs if a research centre is established to enable scientists from the university and from a company to work side by side, and is located within the university premises and financed by both parties. All partners in a public-private partnership may be users of genetic resources in the meaning of the EU ABS Regulation. However, each research project in scope of the Regulation only has to be declared once. The partners in a public-private partnership are advised to agree which partner accepts responsibility to report at the research funding stage to the competent national authority in the relevant EU Member State. Evidence regarding which partner accessed/ obtained genetic resources, and ensured PIC and MAT, and which partners utilised genetic resources is best to be documented. Such best practices resemble those involved in EU-funded research, and should ideally be included in the partnership agreement underlying the public-private collaboration.

In the course of a research and development process involving the use of genetic resources, a public research organisation may decide to outsource by contract further development of a product to another entity, or to transfer genetic resources to a spin-out or spin-off developed by the organisation or an independent company. If the research and development involves utilisation of genetic resources, these activities fall within the scope of the EU ABS Regulation. Both organisations are responsible for compliance with the EU ABS Regulation. The public research organization may have to file a due diligence declaration if the research and development was funded from external sources in the form of a grant. Normally, the organisation developing the final product has the obligation to submit a due diligence declaration prior to placing of a product on the market (for specific events triggering the duty to submit a due diligence declaration at the stage of final development of a product see Article 6 of the Commission Implementing Regulation). The outsourcing/transferring organisation has to keep all relevant records regarding the research and development steps.

## Analysis of specific cases for public research

This chapter presents more in details activities introduced 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. Sourcing, identification and storage of genetic resources***

*Case 1*

|  |  |
| --- | --- |
| Title | **Accessing genetic resources for identification and storage purposes** |
| Description | As a prerequisite for research and development activities, genetic resources may be accessed in a provider country (e.g. from *in situ* conditions) or obtained from existing collections. Upon access, the exact identity of the obtained materials may be determined (see cases below), and the materials may be stored for later use. |
| Analysis | Access and storage of genetic resources as such do not amount to utilisation in the meaning of the EU ABS Regulation. However, proper documentation of the genetic resources is advisable to facilitate later utilisation. Provider countries may set conditions to the access and subsequent utilisation of the genetic resources involved. The recipient of the genetic resource is expected to comply with the conditions set by the provider country. Recipients of genetic resources are recommended to document information regarding access conditions set by the provider country, for the purpose of future utilisation in the organisation and for further transfer to third parties. Moreover, the collection holder may set additional conditions or require additional obligations regarding the transfer and subsequent use of genetic resources obtained from their collections. |

*Case 2*

|  |  |
| --- | --- |
| Title | **Performing DNA sequence analysis** |
| Description | Many research programmes involving the use of genetic resources encompass the determination of DNA sequences of the genetic resources studied. Such DNA sequencing activities may be undertaken for various reasons and with various intentions. The digital sequence data obtained are often published in public databases. |
| Analysis | If DNA sequence information is only obtained for the purpose of identification or classification (such as is often the case in DNA bar-coding) without acquiring new insights in the genetic and/or biochemical properties of the organism involved, such activities do not fall under the scope of the EU ABS Regulation. If the DNA sequence is determined to obtain further information on the genetic and/or biochemical properties of the genetic resource, the DNA sequence analysis and use of DNA sequence information for that purpose is to be considered in scope of the EU ABS Regulation.  Importantly, provider countries may set conditions in PIC and MAT on the generation, storage, publication and/or distribution of all acquired digital sequence data. These conditions need to be respected, even if the activities do not fall within the scope of the EU ABS Regulation. |

*Case 3*

|  |  |
| --- | --- |
| Title | **Use of digital sequence information** |
| Description | Researchers use DNA sequence data of samples of genetic resources that have been made available in public databases (including in association with scientific publications), in order to discover interesting genetic and/or biochemical components in the genetic resources studied. Such use is likely to increase with the availability of new technologies allowing the introduction of fine-tuned changes in the genome (“*genome editing*”). |
| Analysis | This issue is still under consideration by the Parties to the Protocol, in the light of recent technological developments. Without prejudice to the outcome of that consideration, the use of digital sequencing data stored in publicly available databases or obtained against a fee from commercial data providers, could be considered to be out of scope of the EU ABS Regulation. However, the use or publication of such data may be covered by conditions set in the mutually agreed terms, which should be respected. Those who accessed the genetic resources and obtained sequence data should respect the conditions of the agreement entered into with the provider country, and inform subsequent actors about any rights and obligations attached to the digital sequence data obtained and related to any further uses of it. (This type of activity is also addressed in Chapter 2.3.3 of the general Guidance document.) |

*Case 4*

|  |  |
| --- | --- |
| Title | **Taxonomic identification** |
| Description | Describing and documenting the basic characteristics of an acquired genetic resource is a basic and early step preceding further activities. Taxonomic identification may be at species level or below, for example at strain level in the case of microbial organisms. Increasingly, taxonomic identification is based on DNA sequences or other molecular means, including by whole genome sequencing or in the context of DNA bar-coding. More in particular, research requires the identification, and sometimes the formal description, of the genetic resource used, which may be based on a combination of morphological and molecular characters, or on DNA sequence data only. In public collections, molecular characterisation is part of the state-of-the-art identification process and quality control. In microbiological collections, no biological material may be accepted without being identified at least to a minimum level. In analytic work performed in national laboratories, DNA sequence analysis may be required e.g. to assess the presence of previously derived virulence factors and/or resistances to antimicrobial agents. Genetic resources (specimens for identification) will need to be accessed, and often moved internationally to be submitted to expert taxonomists. Identified voucher material are often deposited in both the source and target countries, where suitable repositories exist. |
| Analysis | Proper identification of the acquired genetic resource forms a prerequisite for subsequent R&D. Taxonomic identification of genetic material, in the form of verification of received material by morphological or molecular analysis, even when relying on DNA sequence information, is not considered to constitute utilisation in the meaning of the EU ABS Regulation, since the act of identification does not automatically and in itself generate new knowledge on the genetic resource concerned. It only establishes the identity of the genetic resource, and generates passport data. (This type of activity is also addressed in the general Guidance document, section 2.3.3).  For the analysis of newly isolated human, animal or plant pathogens, the general Guidance Document provides additional guidance in chapter 5.1. In cases where research and development is performed on the genetic and/or biochemical properties of such pathogens, including in virulence factors and resistance traits, and where the country of origin has been identified, due diligence requirements apply, as well as PIC and MAT requirements depending on the legislation in the country of origin. |

***2.3.2. Performing fundamental and/or applied research***

*Case 5*

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| --- | --- |
| Title | **Using traditional knowledge held by indigenous people and local communities** |
| Description | A researcher collects plants and proceeds to conduct phyto-chemical analyses to study their pest control potential based on surveys of traditional knowledge kept by indigenous peoples on traditional disinfection practices. |
| Analysis | If the utilisation of the traditional knowledge is described in the MAT agreed with the provider country, the use of the traditional knowledge falls within the scope of the EU ABS Regulation. In case the access to the genetic resources and the access to the traditional knowledge, e.g. maintained in one or more public databases, constitute two different and unrelated activities and involve different sources accessed at different points in time, then the use of the traditional knowledge may not constitute utilisation in the meaning of the EU ABS Regulation. In order thus to be in scope of the EU ABS Regulation, traditional knowledge associated with genetic resources needs to be related to the utilisation of those resources and it must be covered by the relevant contractual agreements. |

*Case 6*

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| Title | **Using herbarium specimens and/or traditional knowledge associated with herbarium specimens** |
| Description | A research centre keeps a herbarium of plant sheets obtained from locations in various countries, associated with an ethno-botanical survey record compiling traditional medical properties, local names, data on informants and modes of preparation. A researcher based in the EU obtains access to some herbarium sheets and corresponding records. The researcher samples or extracts some of the mounted plants for further analysis, and analyses also the associated traditional knowledge. |
| Analysis | If the researcher undertakes research activities involving the genetic and/or biochemical properties of the herbarium materials and/or the associated traditional knowledge inscribed in the herbarium sheets, these activities constitute utilisation in the meaning of the EU ABS Regulation, and thus requires obtaining PIC and MAT from the provider country, where appropriate. Whether the genetic resources and the associated traditional knowledge are accessed directly from *in situ* conditions or indirectly from a collection has no bearing on the applicability of the EU ABS Regulation. |

*Case 7*

|  |  |
| --- | --- |
| Title | **Carrying out research to determine morphological and/or anatomical properties of organisms** |
| Description | Analysing and describing the morphological and anatomical properties of organisms are activities undertaken regularly in various biological research disciplines. Methods include light microscopy, scanning or transmission electron microscopy and others. These do not include research on the genetic or biochemical composition of the organisms involved. Results of such activities might be relevant for basic research and conservation, e.g., the taxonomic description of species, but also for subsequent fundamental and applied research leading to technical and commercial applications. |
| Analysis | Such activities are not research and development on the genetic and biochemical composition of the organism concerned and do not constitute ‘utilization’ in the meaning of the EU ABS Regulation. However, provider countries’ access regulations might apply. Any subsequent research involving the genetic and/or biochemical properties of the organisms studied would constitute utilisation in the meaning of the EU ABS Regulation. |

*Case 8*

|  |  |
| --- | --- |
| Title | **Carrying out research on genetic and/or biochemical properties of a genetic resource with no intent of product development** |
| Description | Genetic and biochemical properties of accessed genetic resources are investigated in the context of a research project, and specific traits are analysed allowing further research and development. Research results and data are made public. Researchers involved do not consider future product development or commercial application of the results of their research. Their activities are limited to scientific publication of the results of their research. |
| Analysis | Such research activities that reach beyond taxonomic classification and that involve analysis of the genetic and/or biochemical composition of the genetic resources are considered utilisation. Hence, these activities fall in the scope of the EU ABS Regulation and researchers have to fulfil due diligence obligations, regardless whether product development is intended or not. |

*Case 9*

|  |  |
| --- | --- |
| Title | **Chemical cues collected from sorbent material: studying behaviour in frogs** |
| Description | A PhD student in the European Union performs research on chemical (odour) communication cues (i.e. signals for action) between frogs. The chemical compounds studied are extracted from water held in phytotelmata (small pools in plants). Water that had contained frogs for a number of days was collected from *in situ* conditions in a provider country and brought to a university in the EU where the compounds were extracted and identified as aromatic organic compounds. Subsequently, in the provider country bio-assays were conducted to test the effect of the isolated chemicals. The chemicals had an effect on the frog behaviour, indicating that they were acting as cues to avoid deposition of more tadpoles in the same pools. No frogs were accessed in the course of the study. |
| Analysis | Derivatives (chemical compounds in water samples) were accessed without access to the genetic resources by which the derivatives were produced. Hence, the research activities do not fall within the scope of the EU ABS Regulation.  If frogs had been imported to the European Union and the compounds would have been extracted from the same frogs in the European Union, such activity would constitute research on a derivative of a genetic resource accessed by a user in an EU Member State, and hence the activity would be covered by the EU ABS Regulation.  Importantly, provider countries may set alternative conditions in PIC and MAT. |

*Case 10*

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| Title | **Performing R&D on structural characteristics of genetic resources** |
| Description | A research group obtains some brilliantly coloured *Coleoptera* specimens (beetles) in order to study the mechanical and optical properties of microstructures on the first pair of wings. In the research project plan, it is foreseen that the study may lead to applications in engineering, e.g. by designing similar structures on new materials in order to enhance resistance to abrasion, or lustre (biomimesis, biomimicry). |
| Analysis | The activities qualify as R&D and are performed on genetic resources. However, the R&D is not targeted on the genetic and/or biochemical characteristics of these genetic resources but on their mechanical or optical properties. The mechanical and optical properties cannot be directly deduced from the genetic and biochemical components of the genetic resource, since they are the resultant from genetic and environmental interactions. In consequence, the research activity is not considered as utilisation in the meaning of the EU ABS Regulation and consequently no user obligations are applicable to this group. Provider country legislation may require PIC and MAT with the provider country. |

*Case 11*

|  |  |
| --- | --- |
| Title | **Utilisation of commodities as genetic resources in R&D** |
| Description | Many products (including food and agricultural products) are imported into the EU and traded within and between EU Member States as commodities. A user may purchase such commodities from the market with the intention to study and utilise such genetic resources for his/her research project, involving the genetic and/or biochemical properties of such commodities. |
| Analysis | If research and development is carried out on genetic resources which originally entered the EU as commodities, such utilisation of commodities falls within the scope of the EU ABS Regulation. In this case, users are obliged to exercise due diligence and to identify the country which was the provider country of the commodity concerned, in order to agree on PIC and MAT with that provider country, if required. For further information see also Chapter 2.3.1 (Material Scope, Genetic resources as traded commodities) of the general Guidance document. |

*Case 12*

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| Title | **Reconstruction of food webs using DNA bar-coding of plants and herbivores obtained from *in situ* conditions.** |
| Description | A research project constructs a DNA bar-code reference library of the local plant flora in order to identify which plants are grazed upon by which herbivorous insect species. The local plant flora is sampled from the field in the provider country. In a second step herbivorous insects are sampled and the same barcode region used to build the plant reference library is sequenced from the insect’s gut or haemolymph. Resulting sequences are matched against the reference library in order to identify which plant species the insect has fed on. The result is a food web map between primary producers and herbivores indicating one-to-one (specialist) or one-to-many (generalist) relationships and new knowledge on the biology (food plant) of insect species. |
| Analysis | DNA barcodes are used in two steps, first to build a reference library, an identification tool, based on sampled identified plants, and second to identify plant species from ingested and partly decomposed material in insect’s which would not have been possible based on morphology. This activity uses DNA sequences for purposes of identification and generates new ecological knowledge of involved species and of the local community. Whereas the research bears a relation to genetic or biochemical properties of the genetic resources, host patterns cannot be simply regarded as an expression of genetic properties, as ecological factors will also influence such patterns. In other words, the research is not targeting the genetic or biochemical properties of the genetic resources and therefore does not constitute utilisation under the EU ABS Regulation. The project is however accessing genetic resources in the country of origin and needs to apply for PIC and negotiate MAT, if required by that country. |

*Case 13*

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| --- | --- |
| Title | **Screening large numbers of samples to select genetic resources of interest** |
| Description | In many research programmes it is common practice to screen a large number of genetic resources, for example accessions obtained from a collection holder or collected directly from the wild, 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 properties, or to study their genetic relationships. 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. |
| Analysis | Unresolved issue; see chapter 3 |

*Case 14*

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| Title | **Using host organisms and vectors** |
| Description | In R&D programmes, genes may be studied and modified with the use of host organisms and vectors. Typically, specimens of microbial vectors (often plasmids or viruses) have been developed to facilitate such introduction, and in many cases a R&D programme does not involve any other changes to the micro-organism or the vector than the mere introduction of the gene(s) to be studied and developed for further use purposes in the vector DNA. |
| Analysis | In those cases in which host organisms and vectors are used to introduce and study foreign DNA, and where such introduction does not involve any changes to the micro-organism or the vector used other than the introduction of the genes to be introduced and studied, such use of the microbial host or the vector does not constitute research and development on the host organism or the microbial vector, and hence the use of such host organism and microbial vectors does not constitute utilisation of such host organisms or vectors in the context of the EU ABS Regulation. However, the study of the introduced gene sequences constitutes utilisation of those gene sequences in the meaning of the EU ABS Regulation. |

*Case 15*

***2.3.3. Participating in partnerships***

*Case 15*

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| Title | **Providing a defined research task under a service agreement** |
| Description | Genetic resources are imported directly from a provider country by a company based in the EU. The genetic resources are transferred by the EU based company to a subcontractor that is a public research organisation based in the EU or elsewhere. The subcontractor is requested to identify new bioactive compounds for and on behalf of the company. The production of extracts and/or search for active extracts and/or naturally occurring compounds is performed by the sub-contractor of the company. |
| Analysis | In case the sub-contractor in the EU acts on behalf of a service requestor and has no ownership or rights on the genetic resources nor the results of the R&D activities, the parties may decide that the due diligence obligations shall remain with the service requestor. The terms of the contractual relationship between the company and a subcontractor based in the EU should then explicitly determine that it is the company that is the legal person who shall fulfil the due diligence obligations  In absence of such agreement, the activities of the sub-contractor do constitute utilisation in the meaning of the EU ABS Regulation, and therefore the subcontractor is required to fulfil the due diligence obligations under the Regulation. |

***2.3.4. Placing products on the market***

*Case 16*

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| Title | **Developing final products resulting from utilisation of genetic resources ready for marketing** |
| Description | Whereas public research may only occasionally result in the development of products, nevertheless it does occur. In particular, Some public research institutes, including in health and in agriculture, develop commercial products under a government mandate, and both universities and research institutes may undertake activities generating and marketing final products in spin-offs and spin-outs. Alternatively, the marketing of a final product may be contracted to a commercial partner. |
| Analysis | All research and development involving utilisation of genetic resources and resulting in final products ready for marketing falls within the scope of the EU ABS Regulation, regardless whether such products serve public health, food safety or environmental purposes. Before such products are placed on the market, a due diligence declaration under the EU ABS Regulation needs to be submitted. This obligation also applies in case the actual marketing is contracted to a commercial partner (who will not be a user in the meaning of the EU ABS Regulation). |

*Case 17*

|  |  |
| --- | --- |
| Title | **Performing tests required for market approval** |
| Description | For many products, tests are required to provide information on the identity, purity, efficacy, safety and other properties of the developed product for which market approval is being applied for. |
| Analysis | If such tests are performed on the finished product, for which no additional development is foreseen, and if the results of the tests are not used to develop further changes in the finished product for which market approval is requested, such tests are not considered to constitute utilisation in the meaning of the EU ABS Regulation, and hence not to fall within the scope of the EU ABS Regulation. Alternatively, if the test is performed on a genetic resource under development and generates new knowledge on the genetic and/or biochemical components of the genetic resource used, this test falls within the scope of the EU ABS Regulation. If the final product fails the test and requires further research and development activities, these further activities also fall within the scope of the EU ABS Regulation |

# 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 and assessing the value of selected genetic resources**

In many research programmes 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 research activities. Such discarded samples are therefore considered not to have been the subject of research and development. Moreover, few samples may be selected for a further assessment of the presence or absence of wanted or unwanted traits. Such activity can be regarded as part of the large-scale screening programme and does not yet constitute research and development in the meaning of the EU ABS Regulation. Whereas the large-scale screening of genetic resources could be considered as to only select useful samples and to precede research and development, it could be argued that in contrast, the subsequent use of any samples (normally very few) identified as potentially useful and subsequently incorporated into breeding programmes will qualify as utilisation in the context of the EU ABS Regulation.
* Large-scale screening creates new knowledge on the presence and/or absence of specific traits, or the level of certain biochemical activity. The creation of such knowledge should be seen as the result of utilisation and therefore qualifies as within the scope of the EU ABS Regulation.

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

**3.2 Population genetic, phylogenetic and phylogeographic analyses using molecular markers**

In many studies gene flow and genetic differentiation between geographically separated populations as well as genetic relationships and the variation and distribution of traits of interests between these populations form the subject of research. A related goal is to evaluate the genetic distinctiveness of populations. The level of gene flow and genetic differentiation among populations is usually measured by methods that sample variable genetic loci across the genome. Samples will be taken from a number of individuals from each population.

Two different positions have been taken regarding the question whether such research should be qualified as utilisation of the genetic resources concerned, or – in other words – if the genetic and/or biochemical properties of the genetic resources concerned are the subject of research in such studies.

One position holds that this research provides new insights into the genetic diversity of the genetic resources and their distribution patterns and hence constitutes utilisation under the EU ABS legislation. The research in question is related to taxonomic research but clearly distinguishable, as the insights obtained are more far-reaching than those stemming from the determination of the taxonomic identity of a sample.

The other position holds that use of the genetic resources is aimed at identifying variation in “passport data” of the species within and between populations, similar to identification. The function of the molecular loci used for this purpose by either AFLP, microsatellite, DNA Barcode other sequence or RAD-seq is never investigated nor of interest. Thus, the research does not entail R&D into the genetic or biochemical properties of the genetic resources and does not constitute utilisation under the EU ABS legislation. If the properties of the genes are examined in concert with the analysis, the activities would be brought within scope.

In order to bring these positions together and to resolve this issue the criteria to be used may be to ask whether a study is undertaken (1) for taxonomic purposes only or is simply examining the level of genetic differentiation among populations to understand the patterns of speciation, or (2) to identify desirable traits in a species/population that will be further used in research and development, including in plant or animal breeding. Studies described under (1) would not fall under the scope of the EU ABS Regulation, whereas studies under (2) would be within scope. An absolute criteria and a hard line might be difficult to establish and each activity might have to be evaluated to establish whether it adds new information and insight that can be used for further/subsequent research and development.

**3.3 Carrying out public research tasks for the purpose of identification or quality assessment**

Various public research organisations in EU Member States are tasked by their government to carry out research, based on law and/or regulations, in particular to monitor food safety, human, animal and plant health, and/or product quality. Sometimes, suitable methodology enabling identity tests or quality checks is not yet available for the purpose, for example because of the emergence of new pests and diseases or new product quality demands. The public research organizations involved may have a legal obligation to develop such tests. Performing this task may involve the use of genetic resources for the purpose of developing a new product (e.g. diagnostic tests to monitor new pests or diseases or contaminants in food products).

Diverging positions can be taken regarding whether these activities are within the scope of the EU ABS Regulation. Some stakeholders have argued that this should be considered not to be the case, since such research and development, also when resulting in new products, is a response to government requests and based on the legally defined mandate of the institution involved. Others have argued that the nature of the research and development determines whether the activity is within or outside the scope of the EU ABS Regulation. If such activities only involve the carrying out of identity tests or quality checks of a research product, a commodity, or an unidentified organism provided by a third party, without research and development involving a genetic resource on the tool by which the analysis is performed, such activities do not fall within the scope of the EU ABS Regulation. However, if the government mandate implies or leads to the generation of new products using the obtained genetic resources by the organisation involved (e.g. diagnostic tests), the research would fall within the scope of the EU ABS Regulation.

**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.

On the one hand, it could be argued that laboratory strains are not natural resources in the sense of Article 15(1) of the CBD and therefore they do not fall under the scope of the CBD, the Nagoya Protocol and the EU ABS Regulation.

On the other hand, it can be argued that laboratory strains are at least partly based on genetic resources obtained from outside the laboratory. Their distinguishing properties may even have been obtained from these genetic resources. Therefore, the use and transfer of these strains should be in agreement with the conditions set in the original PIC and MAT under which the genetic resources were obtained. If no PIC and MAT are available, 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.

# Annex. Background information

## General principles

The European Commission has developed a general Guidance document[[15]](#footnote-16) 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 (EC) No 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 public research

The following paragraphs have been directly derived from the OECD Science, Technology and Innovation Outlook 2016 report, in particular its Chapter 3, entitled the Future of Science Systems. They provide further background to the organisation of public research that has also been addressed in Chapter 1 of the main document.

While public research systems have their own specific trend dynamics – for example, with regard to research funding, where and how research is performed and reported, and researcher career paths – they are also affected by wider changes in economies and societies. What do these changes mean for public research? In particular:

* What resources will be dedicated to public research?
* Who will fund public research?
* What public research will be performed and for what purpose?
* Who will perform public research?
* How will public research be performed?
* What will public research careers look like?
* What outputs and impacts will be expected of public research?
* What will public research policy and governance look like?

Universities and public research institutes (PRIs) often undertake longer-term and higher-risk research. Although they account for less than 30% of total OECD research and development (R&D) expenditure, universities and PRIs perform more than three-quarters of total basic research. They also undertake a considerable amount of applied research and experimental development that has more immediate potential for translation into tangible societal benefits. As the main funders and shapers of public research, governments have the potential to influence global and national science systems, well beyond the administrative and institutional borders of public research.

***What resources will be dedicated to public research?***

Global R&D capacity has doubled in the last 15 years, a remarkable expansion driven by two important factors. First, business expenditure accounts for a growing share of global R&D as firms’ expenditure on R&D has increased faster than public R&D expenditure during times of economic growth. Although firms will continue to rely on intangible investment and innovation to compete in global markets, the expansion of business R&D expenditure may slow or even halt.

***Who will fund public research?***

Any spending squeeze by national governments in OECD countries will pose many challenges for public research, since governments account on average for 90% of total higher education and government R&D expenditure. The dominance of government spending in public research is particularly striking in the largest public R&D performers, Japan (98%) and the United States (96%). Public research is slightly less dependent on funding from national governments in the European Union (83%), reflecting lower shares in the Netherlands (72%), Belgium (71%) and the United Kingdom (70%). In European countries, funding from the European Commission, which is also public funding, is important as well. This is particularly true for the southern and eastern European countries, which receive substantial support for R&D through the EU Structural and Cohesion Funds as part of EU regional policy to reduce intra-European disparities in income, wealth and opportunities.

Despite fiscal pressures, national governments will remain the main funders of public research in the foreseeable future, but businesses may increase their financial contribution, both reflecting shortfalls in government funding on the one hand, and industry’s interest in accessing complementary knowledge and sharing risk on the other. Universities are more likely to capture business funding, following long-term patterns in industry funding of universities and public labs’ research. Public-private partnerships will remain strategic policy instruments and will help mobilise new sources of funding. Benefits include more immediate socio-economic impacts and increased flow of personnel and ideas between the two sectors. While increased business involvement may reinforce a desirable market perspective in academic research, it can also lead to growing short-termism and greater focus on incremental rather than fundamental, breakthrough research. It may also affect other practices, e.g. in placing some restrictions on open data sharing.

Charities, foundations and philanthropists have become increasingly prominent funders of university research in recent years, a trend that may well continue. Such funding is especially prominent in the health domain – for example, the Wellcome Trust, based in the United Kingdom, funds a wide range of medical research, the French Association for Myopathy (Association française contre la myopathie) funds research on rare diseases, and the Gates Foundation provides a large share of global research funding related to tropical diseases.

While hardly a new phenomenon, science philanthropy – involving often large donations from wealthy individuals – is a fast-growing source of funding for public research (OECD, 2014a). Science philanthropy is typically concentrated in specific fundamental and translational research areas, as well as in institutions at the scientific frontier, and is estimated to provide almost 30% of annual research funds in leading US universities (Murray, 2012). This raises questions about the future of research for the public good: while private donations are widely welcomed, they can be oriented by personal interests and may be dissociated from public goals, thus diverting research towards.

***What public research will be performed and why?***

Various megatrends will heavily influence future research and innovation agendas. Many urgent challenges call for new technological breakthroughs and large-scale institutional and organisational changes that will in part depend on new research. Some examples include: achieving more sustainable growth; the needs of ageing societies; environmental pressures, notably climate change; the depletion of natural resources; threats to energy, water and food security; and, various health issues.

There has already been a general shift in research policy agendas towards environmental and societal challenges, and the “greening” of national research policies has been prominent in many OECD countries since the late 2000s. Country responses to the latest science, technology and innovation (STI) policy survey show that achieving sustainable growth or addressing societal challenges are among the top STI policy priorities in a growing number of OECD countries and emerging economies. This reorientation is reflected in public budgets for R&D, which have shifted in past decades towards environmental and health-related objectives.

At the international level, the European Union’s Horizon 2020 framework programme also focuses on a series of societal challenges, including health, demographic change, food security, sustainability, clean energy, green transport, climate action, and inclusive and secure societies, while the UN-initiated Sustainable Development Goals and the COP21 climate agenda both articulate roles for science and innovation in reaching their targets. However, many challenges are ill-structured “*wicked problems*”, involve much uncertainty, and cannot be solved through science and technology alone. It will be important for future policy making to articulate the appropriate roles of science in the socio-technical transitions necessary to deal with these challenges and to adjust policy expectations accordingly.

The breakdown of public R&D budgets by socio-economic objective reveals certain specialisation patterns. For instance, the United States has a clear policy orientation towards health R&D (including medical science), which absorbs 24% of its public R&D allocation in 2016. The United Kingdom (22%), Luxembourg (18%), and Canada (17%), devote around a fifth of their R&D budgets to health issues.2 Mexico (19%), Japan (11%) and Korea (9%) have prioritised energy R&D. While these specialisation patterns will certainly change over the next 15 years, significant shifts take time in the absence of major shocks, since sunk costs in research infrastructures and specialist research workforces imply a substantial degree of lock-in around current research fields.

The focus on societal challenges is unlikely to displace the long-standing emphasis on public science’s expected contributions to national economic competitiveness. These concerns will still frame countries’ research policy agendas, which will more than ever seek to better link public research with business needs and to attract and retain increasingly mobile knowledge assets, talent and S&T investments.

**Who will perform public research?**

There has been a global shift in national public research systems towards academic excellence and a concentration of resources in world-class research organisations, the vast majority of which are universities. The university model that links teaching and research more closely and involves students upstream in research activities has spread widely, and universities have taken the place of PRIs as the main performers of public research. The share of higher education expenditure on R&D in total public research has increased steadily over recent decades in the OECD area, as the share of government expenditure on R&D has declined. Still, universities and public research institutes are very heterogeneous. For example, in most countries, only a small percentage of universities carry out the majority of the research. Such universities often have a considerable degree of autonomy in how they balance and implement their missions, which is influenced by both their size and relative wealth, factors that vary enormously even within individual countries. So while such universities are a critical part of public research systems, governments typically have only limited direct control over them.

As for the public research institute, this typically includes a range of research performers, from those performing fundamental research using expensive large research infrastructures to others providing technical services to small and medium-sized enterprises. Those PRIs that focus on more applied research and that are closer to end-market needs have suffered particularly heavy funding cuts, and their existence in public research continues to be contested. A major challenge for such institutes has been their difficulty in accounting for the wide range of activities they perform, many of which are not readily amenable to audit and assessment using classical indicators. Many institutes also have large research infrastructures and ageing workforces that are expensive to maintain and that were developed for a different era when government and national industrial champions were major customers for their research. Over the next 15 years, as universities further ramp up their “*third mission*” and commercialisation activities and increasingly co-operate with the business sector, the overlap between the missions and tasks of PRIs and of universities is likely to grow, with the potential to increase both the competition and co-operation between them. In many OECD countries, public research institutes and universities are increasingly strongly linked through joint projects, PhD training, co-publication, joint appointments, joint research centres and, in some cases, co-location. A few countries, such as Denmark, have even taken the step of merging public research institutes with universities. Such linkages and mergers can be expected to grow in the face of further convergence in organisational missions and public spending constraints.

**How will public research be performed?**

Internationalisation in research goes beyond large, multinational research infrastructures, of course, and research co-operation and academic mobility have internationalised sharply in recent decades. National research policy frameworks are increasingly shaped by a more global context, as STI networks extend beyond national frontiers. Countries, firms, universities and researchers are increasingly organised in open and collaborative networks that connect local research and innovation hubs across frontiers. Ideas, assets and resources concentrate in these pockets of excellence. With new technologies, collaborators in different countries can communicate easily and cheaply, and it is easier than ever to obtain information about research communities in other countries. The global scale of grand challenges could lead to further expansion in international research projects and international co-ordination, as exemplified by recent G7 initiatives on Alzheimer’s disease, poverty-related diseases and anti-microbial resistance. Governments will also face pressure to continue efforts to remove barriers in national funding regimes to further international research collaboration. The international mobility of researchers is already high and could increase. Both of these trends could however be countered by wider societal pressures to retrench behind national borders and curb international migration.

Digital technologies are set to radically modify the way science is conducted and the way the results of research are disseminated. A new paradigm of “*open science*” is emerging, which encompasses: 1) open access to scientific journals; 2) open research data; and 3) open collaboration enabled by information and communication technologies. In parallel, the availability and scale of data available for, and produced by, science have massively increased, as has the ability to interrogate and analyse those data. “*Big data*” and data-driven research are now ubiquitous across scientific disciplines and open exciting possibilities to address previously inaccessible scientific challenges. At the same time, many hurdles will remain over the next decade. For example, public research organisations that have incurred most of the storage, preservation and access costs until now will be challenged to find sustainable funding and business models. Legal issues around ownership of large-scale datasets, potentially collected or generated by machines or software providers, and issues around privacy, confidentiality and security will be difficult to resolve, but they will attract considerable policy attention as all spheres of the public research system (including researchers, publishers, funders and policy makers) embrace open data. Sharing results openly online and reusing results and data produced by others also pre-supposes a radical shift in academic culture that will take time to occur and will need to be incentivised. Whilst science is collaborative, it is also intensely competitive. Individual scientists and their institutions are to a very large extent judged by their publication outputs, often using standardised journal bibliometric measures. They therefore have little incentive to share data and experimental material. Mechanisms that accredit the publication of datasets and other collaborative efforts will be essential for promoting open data.

***What outputs and impacts will be expected of public research?***

The increased investment in public research over the last 15 years or so has also led to a growing number of scientific publications. Parallel to and in synergy with the evolution of strategic research for major societal challenges, the global trend towards more competitive funding has seen most governments introduce performance-based elements in core institutional funding and move towards more contractual arrangements. Accordingly, governments have resorted to using tools such as performance agreements, new funding mechanisms and performance metrics to orient public research activities towards national research priorities and to strengthen scientific performance. Further developments along these lines can be expected, though this will likely meet challenges and even resistance. The limits of performance metrics, including what they fail to measure, the costs of the associated data collection, and the scope for gaming measurement systems and adversely distorting behaviours, means that their use will continue to be contested. The commercialisation of public research has become a major goal of national S&T policies over the last few decades and a key function of universities and public labs. A growing number of policy initiatives aim to foster co-operation between industry and science and accelerate the transfer of public research results to society, while a growing number of research system intermediaries aim to smooth and improve transfers (e.g. technology transfer offices, patent funds, intellectual property brokers, etc.). These efforts have only been partially successful, in part because of their inappropriateness in many settings where knowledge and technology transfer occur more effectively through other channels. The very rapid growth in patenting seen in the last 15 years has already begun to tail-off as universities and public labs become more strategic and selective in building their intellectual property portfolios. The mixed success of university-owned technology transfer offices over the last 15 years or so has also seen new arrangements emerge, including technology transfer “*platforms*” that are both cross-institutional and specialised in particular areas of research or technology.

Policy will take an increasingly broad approach to the socio-economic benefits of public research over the next 15 years, which will coincide with the deeper and more extensive engagement of universities and public labs with society, both locally and further afield. As research and innovation landscapes become more open and complex – with more actors and interactions – universities and PRIs will further develop research relationships with the likes of patient groups, “*maker communities*” and environmental groups. Student entrepreneurship is also likely to grow, supported by a broadening of PhD training curricula.

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. OECD (2011), *Public Research Institutions: mapping sector trends,* OECD Publishing, Paris, p.27. [↑](#footnote-ref-3)
3. The terms fundamental research and basic research are used interchangeably. Some literature refers to upstream research to indicate these activities. [↑](#footnote-ref-4)
4. Different steps in the R&D chain can be undertaken by the same or by different actors. [↑](#footnote-ref-5)
5. Arundel and Wunsch-Vincent. 2016. Conceptual Framework: Leveraging public research for innovation and growth. OECD. Paris. [↑](#footnote-ref-6)
6. EC. 2010. Communication from the Commission to the European Parliament, the Council, the Europaan Economic and Social Committee and the Committee of the Regions. SEC (2010) 1161. [↑](#footnote-ref-7)
7. See separate Guidance Document on Collection Holders [↑](#footnote-ref-8)
8. Robert K. MERTON, “*Priorities in Scientific Discovery: a chapter in the sociology of science*”, *American Sociology Review,* 22:6, 1957, pp. 635-659; Henry ETZKOWITZ, “*The norms of entrepreneurial science: cognitive effects of the new university-industry linkages*”, *Research Policy,* 27:8, 1998, pp. 823-833. [↑](#footnote-ref-9)
9. Section 2.1. p.30 [↑](#footnote-ref-10)
10. 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-11)
11. Commission Notice (2016/C 313/01) [↑](#footnote-ref-12)
12. 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-13)
13. 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-14)
14. General Guidance document also provides some additional explanation concerning submission of due diligence declarations. [↑](#footnote-ref-15)
15. 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-16)