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ANNEX 2

ANNEX

to the

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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

ANNEX II: SPECIFIC GUIDANCE ON THE CONCEPT OF UTILISATION

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1. INTRODUCTION

Section 2.3.3 of the Guidance document presents a general understanding of the concept of utilisation under the EU ABS Regulation. This Annex provides further guidance on when genetic resources (falling in temporal, geographical and material scope of the Regulation) are *utilised* in the meaning of the EU ABS Regulation. The issue is particularly relevant for the upstream and final stages of utilisation where there is a need to define activities falling in scope of the Regulation and those that do not. This Annex is thus structured in such a way as to follow, as closely as possible, the logic of the value chain, starting from acquisition, via storing, management of collection, identification and characterisation, and finishing with product development, product testing and placing of a product on a market.

In addition, there are specific challenges related to animal and plant breeding resulting from the fact that the end-product of such breeding activities is also a genetic resource. Hence there is a need for better understanding whether and when genetic resources subject to breeding activities have changed since access of the progenitor and to identify when an activity falls in scope of the Regulation and when not.

Guidance in Annex II is provided by presenting examples (cases), which are not always clear-cut, but allow for identification of conditions that need to be fulfilled in order for the utilisation to fall in scope of the Regulation. These examples are drawn from different sectors and often rely on feedback from stakeholders that identified issues and challenges in interpretation of the Regulation.

Throughout the Annex the assumption is made that all other conditions concerning applicability of the Regulation are met, i.e. genetic resources and/or traditional knowledge associated with genetic resources[1] are accessed in a country that is Party to the Nagoya Protocol with applicable access measures, and that all other geographic and temporal conditions have been met.

In all cases included in the Annex, national ABS requirements remain applicable, even if the EU ABS Regulation is not. It is also assumed that any contractual obligations will be respected. These assumptions are not repeated in the individual cases.

2. ACQUISITION

2.1. Direct or through supply chain

Genetic resources may be accessed directly from a provider country (so country of origin or a country that acquired them in accordance with the Convention). Genetic resources may also be acquired from a third party (intermediary) in a supply chain, or as a commodity. The act of access / acquisition is not itself utilisation and is consequently not in scope of the EU ABS Regulation. Utilisation of those genetic resources, however, triggers the applicability of the EU ABS Regulation.

[1] In the remainder of this guidance, when 'genetic resources' are referred to, this should be read as also including 'traditional knowledge associated with genetic resources', where appropriate.

Acquisition of genetic resources as commodities

Many products (including foodstuffs such as fruit and fish) are imported into the EU and traded within and between EU Member States as commodities. Trading activities do not involve utilisation of genetic resources, and do not fall within scope of the EU ABS Regulation.

(Animal breeding) Acquisition of animals by farmers

Farmers routinely and at a large scale buy animals, semen or embryos from commercial providers, including importers, to maintain the value of their farm herd for production purposes. When farmers acquire animals, semen and embryos for direct production purposes only, and no breeding or other forms of research and development are undertaken, such activities do not represent utilisation and do not trigger obligations under the EU ABS Regulation. For examples where breeding does constitute utilisation, see section 8 of this Annex.

Importation of soil samples

A soil sample is imported to the EU for the purpose of mineral examination. Collection and importation of soil samples does not involve research and development on the genetic and/or biochemical composition of genetic resources. It is thus not considered utilisation and is out of scope of the EU ABS Regulation regardless of whether any microorganisms are subsequently isolated from the soil. However, if microorganisms isolated from a soil sample are selected for research and development and their biochemical compositions are analysed to search for example novel drug components, this is to be considered utilisation in the meaning of the EU ABS Regulation.

The EU ABS Regulation requires that the user needs to exercise due diligence to ascertain that the genetic resources which he/she utilises have been accessed in accordance with applicable ABS legislation. In some cases, genetic resources that have been accessed initially without the intent of utilisation are subsequently selected for utilisation. In such a case the user needs to make sure he/she is in possession of PIC and MAT is established, if so required by the provider country. This applies regardless of whether or not the first actor in the value chain who accessed the genetic resource without intent of utilisation transferred the original documentation to the user, and regardless of whether or not the genetic resource was initially accessed with PIC and MAT (see Art 4 of the Regulation).

In complex value chains, determining whether a genetic resource has been accessed in accordance with applicable ABS legislation might be challenging for a user if proper documentation has not been obtained and transmitted between actors in the chain. It is advisable therefore that in case of acquisition of genetic resources, including for scientific purposes or storage in collections or transmission to others in a supply chain, full documentation regarding access be retained as subsequent utilisation may occur.

2.2. Confiscated material

Genetic resources may be seized by law enforcement officers in cases of illegal import or possession and submitted by the authorities to collections for storage. The country of origin may not be known. Storage of confiscated material in collections is itself not utilisation and consequently is out of scope of the EU ABS Regulation. Should utilisation within the meaning

of the EU ABS Regulation take place subsequently, the user should contact the country of origin of the genetic resource, if it can be determined, to discover its requirements. Although the EU ABS Regulation requires that due diligence be exercised when utilising genetic resources, it does not prohibit the utilisation of material when the origin cannot be identified despite best efforts of the user (see section 3.3 of the Guidance document). However, the user needs to be aware that if new information arises that makes identification of the provider country possible, the provisions of Article 4(5) need to be observed.

In many cases identification of the material including by use of DNA sequences is required; this may enable authorities to pinpoint geographically the origin of the material. Use of DNA sequence data for identification is not considered to be in scope of the EU ABS Regulation and is discussed in section 6 below.

3. STORAGE AND COLLECTION MANAGEMENT[2]

Storing genetic resources in a public or private collection (whether obtained from *in situ* conditions, from a market or shop in the country of origin, or from an *ex situ* collection) does not involve research and development on the genetic or biochemical composition of the genetic resource. Therefore, such activities do not constitute utilisation in the sense of the EU ABS Regulation (see section 2.3.3.1. of the Guidance document). However, the legal ABS requirements of the country where the material is collected remain applicable.

(Pharmaceutical sector)[3] Storage of pathogens pending a decision on their use in a vaccine

Different pathogens are isolated from hosts in various countries as part of global surveillance systems and considered from epidemiological analysis to be a potential public health threat. Initial analysis does not make it clear which, if any, of the isolates will be needed for vaccine development. However, the threat is considered sufficiently great that preparation of vaccines and diagnostics is requested by WHO and by individual governments around the world. Therefore, these pathogens are collected and stored in an already existing collection, as well as exchanged with other collections.

Building up a collection of pathogens with the aim to use them in case of further needs is not considered to constitute utilisation in the meaning of the EU ABS Regulation. However, if at a later stage the vaccine candidates are used to develop a vaccine, this is research and development on the genetic or biochemical composition of the genetic resource and such activity would fall within the scope of the EU ABS Regulation.

Before storing acquired genetic resources in a collection, it is common practice for collection holders to verify the identity of these genetic resources and assess their health status and the

[2] As a reminder, throughout this document, the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

[3] Where examples are prefaced by a reference to a sector in the title, this means that the example is drawn from that sector; the interpretation is however applicable also to other sectors.

presence of pathogens. These activities form an integral part of collection management and are considered as related to (or carried out in support of) such management. They are thus not considered to be utilisation in the meaning of the EU ABS Regulation (see also section 2.3.3.1. of the Guidance document).

(Collection holders) Storing genetic resources as a safe deposit

A culture collection provides a confidential service of safe deposit for a fee. Companies and other bodies can deposit biological material in a secured part of the collection through a contract, where all rights and obligations over the material remain exclusively with the depositor and material is usually neither transferred to third parties nor used for research and development by the collection itself. The complete stock to be stored is either sent by the depositor to the collection, or stock is created by the collection itself by multiplying material received from the depositor. If the collection extracts DNA and performs sequencing, it does so purely for identification or verification.

The handling, storage, and quality checks (including verification by DNA extraction and sequencing upon acceptance) under the service are not considered utilisation in the meaning of the EU ABS Regulation. Since neither the depositor nor the collection is a user in the meaning of the EU ABS Regulation, the obligations of Article 4(3) of the Regulation to transfer or seek relevant information concerning the material do not apply. If the culture collection is asked by the depositors to send the strains out to third parties, it is good practice for the collection holder to refer the third party to the depositor for information on the ABS conditions for access.

General good practice of collection holders upon receiving material is to check if the original permits for collecting genetic resources (where required) allow supply to third-party users and, if this is the case, to make the information on the permits available for potential users and to supply it together with any material to the potential users. If the permits state that the transfer of material to third parties is not allowed, the material cannot be made available according to the conditions set in the permit. A reference to the Competent National Authority (CNA) that issued the original permit could be made in the catalogue, so that the potential user can contact that CNA to either seek a new permit and negotiate a new contract (mutually agreed terms) for access to the collection material or for access to a genetic resource in the country of origin.

(Collection holders) Transfer conditions in the Material Transfer Agreement (MTA)[4]

Fungal strains are isolated from wild populations in a provider country and deposited in a public collection in Germany. In accordance with the MTA, the strains can be supplied to third parties only for non-commercial research. The public collection in Germany does not perform research and development on the strains (hence it is not a user). Therefore, the activity of the German collection is not in scope of the EU ABS Regulation. However, the collection is bound by the MTA, which stipulates that the strains can be supplied to third parties for non-

[4] A Material Transfer Agreement (MTA) is a contract between a provider and a recipient of material, specifying the terms and conditions of the transfer of such material. It covers the rights and obligations of the provider and the recipient, and specifies how benefits are to be shared.

commercial research only. Therefore, in respect of the MTA, the collection should inform potential users that the material can only be used for non-commercial research.

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

(Collection holders) Restrictions on supply to third parties

A public culture collection acquires strains through a taxonomist from a university in country X (the provider country). The taxonomist collected the strains under a permit, according to which sharing of genetic resources with foreign researchers (such as the collection staff based in country Y) is allowed, but further supply of the material to third parties is not. Several new species are discovered by the collection staff but in order to fulfil the requirement of valid publication under rules of nomenclature, the type material of the new species will not only have to be deposited in a public collection but also made available for non-commercial research by third-party users. It is advised that in such a situation the depositor contacts the Competent National Authority (CNA) of the provider country to agree a new agreement (PIC and MAT) which will allow deposit of the material in the public collection and will settle the terms for supply to third-party users. If third-party transfer is allowed, the collection can distribute the material to third parties in line with the terms settled.

Collection holders have the possibility to apply (to the CNA designated under the EU ABS Regulation in their Member State) for inclusion of their collection, or part of it, in the EU Register of Collections (Article 5 of the EU ABS Regulation).

Holders of collections included in the EU Register of Collections have the obligation to supply genetic resources and related information only with appropriate documentation (PIC and MAT where applicable), and to keep records of all samples of genetic resources and related information supplied to third persons for their utilisation. A special situation concerns the deposition of material with confidential origin, as in the following example.

(Collection holders) Deposition of material with confidential origin in a registered collection

A scientist wants to deposit a fungal strain in a public culture collection that is listed in the EU Register of Collections and does not want to disclose the country of origin of that strain, because all information on the provenance is confidential. Thus, the collection will not have information on the terms and conditions under which the fungal strain has been accessed. Therefore, this strain should not be placed in the registered part of the collection, if it was to be distributed to third parties for utilisation. According to Article 5(3)b of the EU ABS Regulation, a registered collection can supply genetic resources to third persons for their utilisation only with documentation providing evidence that the resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and, where relevant, mutually agreed terms. Non-registered collections are not bound to the conditions set out in Article 5(3)b of the EU ABS Regulation.

4. REARING AND MULTIPLICATION[5]

Mere rearing and culturing of genetic resources (without intentional selection), e.g. of microorganisms or insects for biocontrol or of farm animals, is considered not to involve research and development on the genetic or biochemical composition of the genetic resource and, therefore, not to constitute utilisation in the sense of the EU ABS Regulation. The optimisation of the conditions under which genetic resources are reared or cultured is also considered not to constitute utilisation.

(Biocontrol and biostimulants sector) Rearing/culturing (including multiplication) of biocontrol agents or biostimulants for maintenance and reproduction (including 'amplification services')

A biological control agent or biostimulant has been collected in the field or has been obtained from an ex situ *collection and is reared/cultured to ensure maintenance and reproduction.*

Rearing/culturing (including multiplication) of biocontrol agents/biostimulants for maintenance and reproduction does not involve research and development on the genetic or biochemical composition of the genetic resources, acknowledging there may be (unintentional) genetic change. Therefore, this activity does not constitute utilisation in the sense of the EU ABS Regulation.

(Biocontrol and biostimulants sector) Optimising rearing or culturing conditions for organisms

Optimising rearing or culturing conditions for biocontrol agents/biostimulants is normally done in laboratory studies under controlled conditions. The optimisation is geared towards increased reproduction (e.g. cell count of a beneficial bacterium) and/or increased production of a certain biochemical compound.

Optimising rearing or culturing conditions does not involve research and development on the genetic or biochemical composition of the genetic resources, acknowledging that during this process (unintentional) change in the genetic composition of the reared genetic resources may occur. Therefore, this activity does not constitute utilisation in the sense of the EU ABS Regulation. However, if the process of optimization involves generating new and improved genotypes, selection of such genotypes would be considered to constitute utilisation in the sense of the EU ABS Regulation.

[5] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

5. EXCHANGE AND TRANSFER[6]

After initial access to genetic resources by a first party, the transfer of genetic resources by the first party to another party – either in their original form or after having undergone genetic changes (such as mutation, selection, hybridization or isolation) – as well as of derivatives obtained from the accessed genetic resources, is very common in all sectors in which genetic resources are used. Both public sector and private sector entities may be involved in the transfer of genetic resources. In all cases the transfer of a genetic resource may be accompanied by the transfer of associated knowledge, which might entail traditional knowledge associated with genetic resources obtained by the first party as well as knowledge acquired in the process of the use of the genetic resource. For example, animal breeders in the EU routinely provide breeding animals or other types of genetic resources (such as semen) to customers in their own and other countries, including EU Member States; also, accessed plant samples might be offered in unchanged form to potential users in the sectors of plant breeding, forest reproductive material, pharma and cosmetics.

Exchange can be regarded as a special form of transfer, in which two parties exchange at least two and often more genetic resources. Exchange is highly common amongst specific actors, for instance collection holders in the public sector, e.g. botanic gardens, zoos, genebanks, biobanks and culture collections, that all share the mandate to maintain specific types of genetic resources for purposes of conservation, research, public education, and/or further utilization by third parties. Some of the exchanges between collection holders take place to create safety back-ups or other approaches to avoid loss of genetic diversity. While being maintained in specific collections, genetic resources may undergo random or specific genetic changes, part of which may remain unnoticed by the collection holder.

In addition, exchange is highly common between other public and private parties across sectors, specifically among parties with similar research and development programmes, often to enlarge the genetic resource base on which research and development can be applied. Recurrent transfer and exchange of genetic resources may take place over prolonged periods of time.

Some transfers and exchanges may involve payments or other recompense, whereas others are executed on equal terms. The history of former transfers of some genetic resources may have been described in detail, whereas for others there may be no such clear history lines.

Trading, transfer and exchange do not constitute research and development on the genetic and/or biochemical composition of the genetic resources involved, and hence do not fall within the scope of the EU ABS Regulation. Thus, a person such as a trader who only transfers material is not a user in the meaning of the EU ABS Regulation (see also section 2.4. of the Guidance document). Such a person has no obligations under the EU ABS Regulation. He/she may, however, be subject to contractual obligations entered into when material was accessed

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and will likely need to provide information to subsequent users to enable the latter to comply with their due diligence obligations. Whenever a genetic resource is transferred, this should be done in accordance with the contractual conditions set up for the respective genetic resource, which may involve the entry into a contract by the transferee.

(Collection holders) Zoo breeding programme

In the framework of a zoo breeding programme, a zoo in the EU obtains an animal from a zoo in another country. Both zoos are official partners in the breeding programme. Breeding to maintain a sustainable genetically viable population of animals and underlying establishment of genetic relations does not qualify as utilisation in the meaning of the EU ABS Regulation, as its sole aim is to secure survival of the (sub)species or population, and thus does not trigger any due diligence obligations under the EU ABS Regulation.

When a genetic resource is transferred in the form received, this does not imply utilisation. The situation is different however in case of the transfer of products that have been developed from genetic resources in scope of the EU ABS Regulation, but which have not yet reached the final stage of development (which can be also referred to as "half products" or "products under development"). Such half products or products under development in case of plant and animal breeding may also be genetic resources. In such a situation the party who has carried out research and development resulting in half product and transferring it further, is a user in the meaning of the EU ABS Regulation. For example, plant breeders may sell half products to other breeding companies, in case these genetic resources appear not relevant to their own breeding programmes, or as a way to create income. Similar transfer of half products based on genetic resources may also occur in other sectors, such as the food and feed, pharmaceutical and cosmetics sectors. If the second party in the chain then further develops the half product and undertakes research and development activities, this party is also a user in the meaning of the EU ABS Regulation. If the research and development activities of the second user result in a product ready to be marketed, then only the second user has the obligation to submit a due diligence declaration (see Art 6(2) of the Implementing Regulation). However, if the half product is offered to other parties on the open market, the developer of the half product would have the obligation to submit a due diligence declaration.

6. IDENTIFICATION AND CHARACTERIZATION OF ORGANISMS AND OTHER ACTIVITIES AT THE BEGINNING OF THE VALUE CHAIN[7]

6.1. Taxonomic identification of organisms and taxonomic research

Taxonomic identification of organisms and taxonomic research are addressed briefly in section 2.3.3.1. of the Guidance document. It should be noted that 'taxonomic identification' and 'identification' do not imply different processes. Identification of organisms is the process of

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providing a name for a sample, i.e. assigning it to a taxon, hence ‘taxonomic’. The name may be at strain, species, genus or other rank depending on the precision of the identification, but in all cases will assign it to a taxon, even if within that taxon it cannot be given a formal scientific name.

Research may require identification and sometimes informal or formal description of the biological or genetic resources (organisms) that are the subject of the research. Taxonomic description and identification may be required at species level, variety level for plant varieties in horticulture and agriculture, strain identification in the case of microbial organisms, breed assignment for animal breeding, or population level for plants and animals for example in the context of environmental work.

During the taxonomic identification process, undescribed species may be recognised and described, where formal description involves providing a new scientific name (with publication in a scientific print or online journal and provision of the DNA sequence data to a public database). Taxonomic identification may be based on a combination of morphological and molecular characters, or on DNA sequence data only, generated by whole genome sequencing or DNA barcodes. Use of genomes for identification of organisms is increasing, for example for pathogenic bacteria affecting human health, since it allows rapid and fine-level discrimination of strains.

In microbiological collections, no genetic resources may be accepted without being taxonomically identified at least to a minimum level, and molecular characterisation is part of the state-of-the-art identification process and quality control. Genetic resources (specimens for taxonomic identification) are often moved internationally to be submitted to expert taxonomists.

Taxonomic identification of biological or genetic resources, by morphological or molecular analysis, including through use of DNA sequencing, is not as such considered to constitute utilisation in the meaning of the EU ABS Regulation, as it does not involve the discovery of specific genetic and/or biochemical properties (see section 2.3.3.1 of the Guidance document; ‘properties’ is considered here as meaning function). It does not “create new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development”, as formulated in the litmus test (see section 2.3.3.1 of the Guidance document). Instead, the DNA or RNA sequence is being used as a tool to identify the organism. Similarly, pedigree testing in animal breeding can be considered a simple identification, distinct from research and development and therefore as such not to fall within the scope of the EU ABS Regulation. Discovery, description and publication of new species would also not qualify as utilisation in the meaning of the EU ABS Regulation, as long as this is done without additional research on the genetic and/or biochemical composition of the genetic resources to discover or making use of the properties (functions) of the genes. Provider countries may set conditions in PIC and/or MAT on the generation, storage, publication and/or distribution of digital sequence data obtained from that genetic resource. These conditions remain applicable, even if the activities do not fall within the scope of the EU ABS Regulation.

However, if the identification or taxonomic description of an organism is combined with research on its specific genetic and/or biochemical composition, specifically the function of the genes, this would qualify as utilisation in terms of the EU ABS Regulation (see section 2.3.3.1 of the Guidance document).

(Public research) Taxonomic identification of human pathogens or associated organisms

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 [preserved sample of the original specimens (genetic resource)] is often deposited in both the provider country and the country where the DNA sequence was analysed, where suitable repositories exist.

Taxonomic identification of specimens is not considered to constitute utilisation in the meaning of the EU ABS Regulation, where it does not include research and development on the genetic and/or biochemical composition of the genetic resource, in particular in the form of discovery of specific genetic and/or biochemical functions. It only establishes the identity of the genetic resource (specimen) and generates passport data. However, in cases where research and development is performed on the genetic and/or biochemical composition of such pathogens, including for example on virulence factors and resistance traits, due diligence requirements apply.

(Pharmaceutical sector) Investigation of gene function discovered through taxonomic analysis

A research institute carries out DNA sequencing of an organism for taxonomic identification. Subsequent analysis of the genetic sequence and functionality encoded by these genes by the same organisation reveals novel and potentially useful antibody gene structures. This subsequent line of research results in the use of immune cells from the organism to develop novel antibody products. The taxonomic identification is not considered to constitute utilisation in the meaning of the EU ABS Regulation. However, subsequent to the initial taxonomic identification, the genetic resource is used for the purpose of product development, making use of the gene function. The research and development involved in this process constitutes utilisation in the meaning of the EU ABS Regulation.

(Cosmetics sector) Taxonomic identification of an organism followed by discovering biochemical function of its genes

A cosmetics company wishes to know the name of a species it is interested in researching and carries out DNA sequencing of specimens for the purpose of taxonomic identification. Taxonomic identification using DNA sequencing is followed by further functional analysis of one of the genes sequenced for the purpose of discovering novel biochemical functions of its products of potential use. This analysis reveals the presence of novel and potentially useful proteins, which are then used to develop cosmetic ingredients.

Because the analysis continued beyond taxonomic identification into analysis of the function of a gene and its products this activity qualifies as utilisation in the meaning of the EU ABS Regulation.

(Public research) Reconstruction of food webs using DNA barcoding of plants and herbivores obtained from* in situ *conditions

A research project constructs a DNA barcode 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.

DNA barcodes are used in two steps, first to build a reference library and an identification tool, based on sampled identified plants, and second to identify plant species from ingested and partly decomposed material in insect's guts which would not have been possible based on morphology. This activity uses DNA sequences for purposes of identification only. Although the research generates new ecological knowledge of the species studied, it does not lead to understanding of functions of genes within the genetic resource examined and therefore does not constitute utilisation under the EU ABS Regulation. See also section 6.6.

(Collection holders; Food and feed sector) Whole genome sequencing

A company purchases 10 microbial strains of unknown identity from a culture collection. The company imports the strains into the EU, performs whole-genome sequencing for the purpose of taxonomic classification of the strains, and deposits the strains in its internal culture collection. A few years later, the genome sequence of one of the strains is analysed by the company for potential lipase genes, and one of the candidate lipase genes extracted from the original strain is used to generate a commercial production strain for this particular lipase.

The whole-genome sequencing for the purpose of taxonomic classification alone is not considered to be utilisation in the meaning of the EU ABS Regulation, since the function of the genes was not studied. However, the subsequent analysis of the genome sequence for candidate genes for commercial production and generation of a production organism for the candidate enzyme, does involve research and development on the genetic and/or biochemical composition of a genetic resource, in particular studying the function of specific genes, and therefore these activities fall within the scope of the EU ABS Regulation.

(Public research) Environmental DNA metabarcode analysis of water samples to discover the numbers of fish species present

Water samples are taken from a river to discover the number of different fish species present. It makes use of DNA released into the water by organisms. To obtain a biodiversity inventory the DNA is purified from the water samples, DNA markers are targeted and sequenced, and the sequences discovered are taxonomically assigned by comparison with reference sequences in a database. The function of the genes is not investigated. Because only the sequence is used, and the functions are not studied or considered, such inventory studies do not constitute utilisation under the EU ABS Regulation.

6.2. Characterisation

Characterisation is the description and documentation of the distinctive nature or features of genetic resources. The characterisation of an acquired genetic resource normally forms a basic and early step preceding further activities. For example, it is part of identification and quality control, which is standard practice in microbial collections. If such characterisation and comparison does not involve the discovery of specific genetic and/or biochemical functions, it does not "create new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development", as formulated in the litmus test (see section 2.3.3.1. of the Guidance document). In such cases, characterisation does not qualify as utilisation in the meaning of the EU ABS Regulation.

However, when the characterisation or description of a genetic resource is combined with research on specific genetic and/or biochemical properties of the genetic resource, this qualifies as utilisation in the meaning of the EU ABS Regulation (see section 2.3.3.1. of the Guidance document).

(Collection holders; Animal breeding) Diversity assessment between and within populations

A study is undertaken to estimate the genetic distance between breeds and the homogeneity within breeds. It can lead to recommendations for population management, but it does not characterize the genetic and or biochemical functions of genes within each breed. Analysis and description may not be of the whole organism. For example, in animal breeding DNA may be extracted from individual blood samples and genotyped with a public SNP chip to calculate genetic distances. This does not provide information on the phenotype or the performance (e.g. growth, reproduction, and productivity), because the SNP markers have been chosen on the basis of polymorphisms across breeds within the species. The genetic resources are used for classification and identification, but not for searching for a particular trait (genetic functional expression) of a breed correlated to one or more genes or selecting on that basis. Therefore, this is not utilisation in the meaning of the EU ABS Regulation.

(Animal breeding) Characterisation of a genetic resource providing knowledge used in breeding

Private breeding companies and public research institutions are involved in genotypic and phenotypic characterisation for the purpose of understanding genetic variation within and between breeds and breeding lines. Molecular approaches include the analysis of genetic markers or (whole) genome sequence data. Phenotypic analysis may involve any performance recording as well as the use of biochemical and other measurement tools. Such activities may also be undertaken for the purpose and in the context of whole genome selection, which allows the prediction of breeding values on the basis of DNA information only.

The generation of information obtained from genotyping, DNA sequence analysis, as well as phenotypic characterisation and subsequent analysis of these types of data, leads to increased knowledge on individual genetic resources through knowledge of traits and their associated genes and creates added value and potential benefits for the breeder. These activities are also central to whole genome selection strategies, as they allow an estimate of breeding value of every animal (genetic resource) and provide a sound basis for selection. These activities are considered to be research and development on the genetic and/or biochemical composition of the genetic resource and hence to fall within the scope of the EU ABS Regulation. The fact that

such activity is a standard activity does not preclude its qualification as one of the first steps in research and development.

Investigation of function of genes: established introduced species

A species of fish was intentionally introduced from one country to another in the 1960s for fishing and has established a viable population in the second country. Fresh specimens of the fish from the second country are obtained by a research consortium wishing to sequence the genome of the species and publish a genome map annotating the genes and their functions.

The research activity qualifies as research and development on the genetic and/or biochemical composition of the genetic resources and thus constitutes utilisation in the meaning of the EU ABS Regulation. Because the fish is established in the second country and the specimens were accessed from in situ conditions in that country, the second country is to be considered as the provider country, and the user should contact that country to clarify whether requirements to obtain prior informed consent and establish mutually agreed terms apply.

(Biocontrol and biostimulants sector) Physico-chemical characterisation of extracts and substances (types of active compounds present) for use as biological control agents or biostimulants

Extracts and substances to be used for biological control or as a biostimulant are extracted from a genetic resource and covered by PIC and MAT. They are characterised, to establish the chemical structure and function of the compounds for use as biological control agents or biostimulants. This activity involves research and development on the genetic and/or biochemical composition of the derivatives of genetic resources. It goes beyond mere description, and therefore it constitutes utilisation in the meaning of the EU ABS Regulation. (See also Guidance document section 2.3.4. on derivatives for additional guidance).

Characterisation also includes gene expression. Research in both commercial and non-commercial settings may be specifically performed to discover the expression of genes, both by morphological (study of phenotype) and biochemical means. Alternatively, research may seek the genetic background of traits of interest, to analyse which genes, gene complexes or regulatory sequences and mechanisms governing their expression are involved. Such trait analysis, even if carried out for non-commercial purposes, is considered to fall within scope of the EU ABS Regulation. However, examination of morphological characteristics alone without examining or making use of the genetic influences on the morphology is not considered to be research and development on the genetic and biochemical composition of the organism and is considered to be out of scope.

(Public research) Research to determine morphological and/or anatomical properties

Analysing and describing the morphological and anatomical properties of parts 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 genetic resources involved, and because of this do not constitute utilisation in the meaning of the EU ABS Regulation. Results of such activities might subsequently 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. Such subsequent activities may fall within scope of the EU ABS Regulation (if other conditions are fulfilled).

(Public research) Research and development on mechanical and optical properties

A research group obtains some brilliantly coloured beetle specimens in order to study the mechanical and optical properties of microstructures on the first pair of wings. In the research 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).

The activities qualify as research and development and are performed on genetic resources. However, the research and development is on their mechanical or optical properties, which are mediated by environmental factors, but not on the genetic and/or biochemical composition of these genetic resources. In consequence, the research activity is not considered as utilisation in the meaning of the EU ABS Regulation and is out of scope.

(Animal breeding) Basic scientific research on the genetic background of traits

Scientific research is specifically performed on the genetic background of traits of interest in breeding animals, to analyse which genes, gene complexes or regulatory sequences and mechanisms governing their expression are involved. Such research may be public research, public-private research or private research, lead to increased knowledge and create added value and potential benefits for the breeder and could ultimately lead to commercial applications.

Genetic research on certain traits of interest involves detailed study of the genome of individual animals for traits (based on the expression of genes) identified in the breeding objectives to meet desired breeding outcomes. Such activities, therefore, are considered to represent utilisation and hence to fall within the scope of the EU ABS Regulation.

(Public research) Research into the function of genes found in forest species without further development

Genetic and biochemical function within accessed genetic resources are investigated in the context of a research project, specific traits are identified, and their genetic background determined. Researchers involved do not consider future product development or commercial application of the results of their research. Their outputs are limited to the publication of the research results in scientific fora.

Research activities 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 of whether product development is intended or not.

(Plant breeding) Virulence of pathogens

A pathogen is subject of research and development by a company specialising in horticultural advice, including through the study of its DNA. Genotypic and phenotypic differences between individual pathogenic strains are studied in the context of virulence of such pathogens.

Studies as described above, involving research on the genetic and/or biochemical composition of the genetic resource (in relation to virulence) constitute research and development in the meaning of the EU ABS Regulation, and hence fall within the scope of the Regulation. If the study involves the mere identification of pathogen strains and races and does not extend beyond, such as in the case of taxonomic identification of a pathogen to determine with which disease a plant has been infected, this does not constitute utilisation in the meaning of the EU ABS Regulation.

6.3. Phylogenetic analysis

Phylogenetic analysis makes use of a plethora of methods of data analysis which can be performed on all kinds of data that have a presumed ancestor-descendant relationship: e.g. in linguistics, or, in a biological context, morphological and chemical aspects or nucleotide sequences (in general "characters"). It can be also performed on gene functionality data, although this is still relatively uncommon.

The result of a phylogenetic analysis is visualised as a network or branching diagram ('tree') with the analysed samples (usually species or intraspecific entities) at the tip of each branch and the arrangement of the branches suggesting relationships between them. In practice, one analysis can generate hundreds or thousands of trees from a single set of samples (simple yes/no matrixes on observed conditions), each differing in relationships depicted and the likelihood that it explains the observations. Sometimes the taxonomist will select a single tree to work with, sometimes he/she will use several, and sometimes he/she will use a computer program to generate a 'consensus tree' that draws on some or all of the others with highest likelihood. In principle, all phylogenetic trees are visualisations of computed individual analyses using computer programs. There are several statistical approaches to assess relationships, and different computer programs use different algorithms for this purpose. Approaches based on different models of evolution may yield slightly different results, especially when evidence from different genome or sequence partitions provide conflicting interpretations. The final trees, therefore, owe as much to the analytical algorithm as to the data used.

The branching diagram produced is often translated into a hypothesis of evolutionary descent. This hypothesis may in turn be transformed into a classification that reflects the branching order of the entities involved (= a phylogeny). The computation of a phylogenetic analysis simply delivers a visualisation ordering the items analysed but the interpretation of that order is up to the researcher.

The subject of biological research in many studies may be gene flow and genetic differentiation between geographically separated populations, their genetic relationships and genetic distinctiveness. The level of gene flow and genetic differentiation among populations is usually measured by methods that sample variable genetic loci across the genome. Other research will compare genetic sequences between specimens as representatives of species or higher taxonomic categories such as family, to investigate their distinctiveness or similarity and thus potential relatedness.

Research involving phylogenetic analysis using genetic resources may therefore be aimed at identifying variation in identity ("passport data" in the terminology of germplasm collections or gene banks) of the species within and between populations and be similar to taxonomic identification. Similarly, it may be aimed at identifying such variation between species or taxa

above species such as genus, tribe or family and grouping the analysed entities. Where such activity does not entail research and development into the genes, and the function of the genes or DNA sequences (if known at all) is neither investigated nor of interest, it is considered to be out of scope of the EU ABS Regulation. However, if research is carried out on the function of the genes, then such activity falls within the scope of the EU ABS Regulation.

(Collection holders) Phylogenetic analyses without consideration of function of genes

A taxonomist studies a group of organisms in preparation of a floristic treatment or taxonomic monograph. As a part of the descriptive process, the taxonomist creates a phylogeny of the taxa involved, using morphological and DNA sequence information obtained from specimens in a collection. This is done without additional research on the genetic resource to discover specific genetic functions of the genes analysed.

The morphological and sequence information is used in a descriptive manner and to recognise taxa at strain, species, or higher levels. The phylogeny is used to provide a classification. In line with the 'litmus' test (see section 2.3.3.1. of the Guidance document), this does not qualify as utilisation in the meaning of the EU ABS Regulation.

If the taxonomist did make use of the function of the genes in the phylogenetic analysis, i.e. the study included discovery of and research on specific genetic and/or biochemical traits, this activity would qualify as utilisation in the meaning of the EU ABS Regulation.

(Collection holders) Phylogenetic analyses including consideration of function of genes

A taxonomist specialising on a group of venomous snakes collaborates with a protein research laboratory to evaluate the link between species relatedness and venom protein similarities, with potential use for snake-bite treatment with antivenom. A phylogeny is reconstructed on the group of snakes and the function of the venom protein of each species is analysed and compared over the phylogeny. The venoms were extracted from snakes as part of the project.

The construction of the phylogeny itself would be out of scope if the properties of the venom or gene function were not used. However, if the venom protein functions or function of the genes were used for the phylogenetic analysis, it would be in scope.

The comparison of the venoms, even if not directly related to the development of a new antivenom product, constitutes utilisation in the meaning of the EU ABS Regulation as it investigates the biochemical composition of a derivative extracted from a genetic resource (see section 2.3.4. of the Guidance document).

6.4. Identification of derivatives

In biotechnology the structures of biochemical compounds such as pheromones or other active metabolites isolated from genetic resources may be identified. Identification of these metabolites typically includes testing their identity and purity in olfactometers. If compounds are only identified, this activity can be regarded as being equivalent to the taxonomic identification of an organism, which does not constitute utilisation in the meaning of the EU ABS Regulation. However, if such analytical studies result in the discovery of new compounds with distinct chemical properties, which are then further studied, or if they are performed to find genotypes with a particularly high content of the target compound, such activity would be

considered utilisation in the meaning of the EU ABS Regulation (see section 2.3.4. of the Guidance document).

6.5. Large-scale screening

Large-scale screening is understood to mean an activity which involves the evaluation of usually large numbers of genetic resource samples against a specific criterion. The process is frequently automated and involves questions of a binary nature (i.e. does this sample match the criterion, or not?). The objectives of the activity are (a) to screen out the vast majority of samples which are not of interest to and will not be used for the research project ("negative") and (b) identify the few samples which may have the potential for further research within the terms of the project ("positive").

Such a type of screening activity, which is based on simple binary questions and resolved by identical tests performed on multiple samples in a standardised way in order to screen out the majority of them, would not fall in scope of the EU ABS Regulation on the basis that it does not amount to utilisation of a genetic resource. It does not constitute "research and development" as understood in the context of the EU ABS Regulation, since no added scientific insight in relation to the screened-out samples is created.

When, however, a researcher starts to look in more depth into the genetic resources which have been identified for further study by the binary process, such activity could fall within the scope of the EU ABS Regulation. Such further research moves beyond the application of standardised binary questions and follows a more individualised testing regime. It is also no longer focused on screening out certain samples but is concentrated on identifying the qualities and properties of those genetic resources which have been selected. The activity of looking more in depth at a genetic resource most typically requires more time than screening. Given that such research creates additional knowledge and new insight into the genetic and/or biochemical composition of those genetic resources, it amounts to utilisation, and so falls within scope of the EU ABS Regulation. This step when a researcher starts to look at genetic resources more in depth can be regarded as the first step in a research and development chain.

(Food and feed sector) Screening

Amylase enzymes (used in the baking industry): in standardized conditions various microorganisms are screened to check which ones contain alpha-amylases; this process will only provide information that alpha-amylase is present in some microorganisms and enable the microorganism samples that do not contain alpha-amylases to be excluded from further examination. It does not provide information on how such amylase performs in the baking process. Such screening to eliminate unwanted microorganisms prior to any analysis is considered screening and out of scope of the EU ABS Regulation.

(Food and feed sector) In-depth analysis of amylase enzymes

Microorganisms in which alpha-amylase has been detected are studied for their value in baking, by testing of the candidate alpha-amylases under real-life conditions in baking applications (using different doughs, different baking conditions, etc.), and their stability (both shelf-life stability and stability in the dough). Such activities examine the biochemical composition and activity of a derivative extracted from a genetic resource in detail and are within scope of the EU ABS Regulation (all other conditions fulfilled).

(Public research) Using eDNA to screen for target organism

Water samples are taken from a river to determine if an invasive species of fish is present, using environmental DNA (eDNA). The water samples are tested with a DNA marker specific to the invasive species, which will determine if the DNA of the fish is in the water or not. This type of screening is similar to identification, does not involve study of the properties of genes, and is not in scope of the EU ABS Regulation.

(Pharmaceutical sector) Functional metagenomics and antibiotic discovery

Researchers screened environmental DNA (eDNA) from >2,000 soil samples by PCR with primers targeting the gene for an enzyme known to be active in the biosynthesis of a class of antibiotics. This large-scale screening is out of scope of the EU ABS Regulation. Following this initial screening the samples in which the desired gene was found were analysed with next generation sequencing, which revealed the presence of related antibiotic biosynthetic genes. Analysis of the sequences revealed a clade with hitherto unknown genes linked to antibiotic production systems and, from this, novel antibiotics were developed. The analysis using next-generation sequencing and development of antibiotics was targeted on specific organisms focussed on their genetic and/or biochemical composition and is within scope of the EU ABS Regulation.

The distinction between screening activities and more in-depth analysis may not always be clear-cut. Users are thus recommended to identify the end of screening activities and the beginning of any subsequent research activities, and keep records of this, as part of their due diligence obligation, for potential checks by the competent authorities.

6.6. Behavioural studies

Genetic resources (for example, insects, mites and nematodes) may be studied to elucidate to what extent their behaviour will qualify these species as potentially effective biological control agents. Such studies may also involve efforts to clarify the conditions under which such behaviour would be optimally expressed.

The activities qualify as research and development and are performed on genetic resources. However, the research and development is not carried out on the genetic and/or biochemical composition of these genetic resources but on their behavioural properties. Behaviour cannot necessarily be directly deduced from the genetic and/or biochemical components of the genetic resource, since they are resultant from genetic and environmental interactions. However, when research considers genetic influence on behaviour this would be in scope of the EU ABS Regulation.

7. GENETIC RESOURCES AS TOOLS[8]

7.1. Using genetic resources as testing or reference tools

The application of genetic resources as testing or reference tools is not considered to constitute utilisation in the meaning of the EU ABS Regulation, and therefore would not fall within its scope (see section 2.3.3.2 of the Guidance document). This is because at that stage the material is not the object of the research in itself but only serves to confirm or verify the desired features of other products developed or under development. In addition, the use of genetic resources as attractants, e.g. for monitoring pests and potential pests to determine whether control actions may be needed, is also not considered utilisation in the context of the EU ABS Regulation.

Examples of such testing/reference tools are:

- Laboratory animals used to test their reaction to medical products;
- Pathogens used for testing the resistance of plant varieties;
- Pathogens used for testing biocontrol and biostimulant agents;
- Rats used in toxicological studies aimed at testing synthesised compounds;
- Bacteria used for testing the effectiveness of compounds that are candidates for new antibiotics against those bacteria.

(Pharmaceutical sector) Use of animals in animal test models

The efficacy of a chemically synthesised compound is tested in an animal test model in an EU country. The animal test model involves rats that show a certain type of cancer. The rats are used as tools for research and development. Research and development is not carried out on the rats. Therefore, the use of the rats to test the compound does not constitute utilisation of genetic resources in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Use of research tools to understand cellular processes

A green-to-red photo-switchable fluorescent protein derived from an Octocorallia *species is used in the EU as a tool for tracking dynamics of a cosmetic ingredient and monitoring selective cell fate. In this activity, the protein derived from a genetic resource is a research and development tool; the research and development activities are not carried out on the genetic resource, and hence such activity does not constitute utilisation in the meaning of the EU ABS Regulation.*

[8] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

(Cosmetics sector) Applying a genetic resource as a reference to validate an* in vitro *test model for anti-aging activity

A test for measuring the activity of a cosmetic ingredient is developed on the basis of a commercially available human proteinase. The test is validated with a plant extract with known and well-established anti-aging activity obtained from a genetic resource. The human proteinase does not fall in the scope of the EU ABS Regulation because it is of human origin. Validation of the test is done with a plant extract, but no research and development is carried out on the genetic and/or biochemical composition of the plant genetic resource itself. Such validation is not considered utilisation in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Use of a pathogen to make reagents for test validation

An influenza virus is accessed and material from the virus itself and antibodies against the virus are used as reference materials to validate diagnostic assays or to standardise quality assurance tests for the vaccine. The genetic resource (the virus) is used for validation purposes only, and this activity does not constitute utilisation in the meaning of the EU ABS Regulation.

(Plant breeding) Using existing varieties as references in evaluation trials

In plant breeding, the performance of newly developed breeding materials is routinely tested against existing varieties and other genetic resources used as reference materials. Such use of genetic resources does not involve research on the reference materials. Therefore, the use of these genetic resources does not constitute utilisation in the context of the EU ABS Regulation.

(Biotechnology sector) Use of pathogens to monitor effectiveness of crop protection products

Pathogens are used to carry out resistance monitoring for crop protection products and to perform virulence monitoring of pathogens, both common activities in agriculture to safeguard crop yield. Such monitoring, which serves to monitor the effectiveness of crop protection products, does not involve research and development of the pathogens as a genetic resource and therefore this activity is not in scope of the EU ABS Regulation.

7.2. Development of testing or reference tools

Although the application of genetic resources as testing/reference tools is not considered utilisation in the meaning of the EU ABS Regulation (see section 2.3.3.2. of the Guidance document and section 7.1 of Annex II), research and development may have been carried out on those genetic resources with the aim of turning them into (improved) testing or reference tools. As such this research and development would fall under the scope of the EU ABS Regulation (see section 2.3.3.2 of the Guidance document).

(Biotechnology sector) Development of a detection kit to monitor the presence of transgenic material in food

To monitor if food contains material from transgenic plants, a government authority in an EU Member State develops a detection kit for performing on-the-spot checks. The detection kit contains plant antibodies and cell lines. The antibodies have been produced using antigens obtained from a transgenic plant with a new protein.

Genetic resources used are the transgenic plant, lab cell lines harbouring transgenes and expressing the characteristic protein(s) found in the transgenic plants, and cell lines producing antibodies against these proteins. Derivatives are the target proteins and the antibodies raised against them. The development of the detection kit involves research and development on the cell lines, the products of gene functionality, the antibodies, and all genetic resources utilised for producing them, and constitutes utilisation in the meaning of the EU ABS Regulation.

(Cosmetics sector) Development of a novel test system

An EU research institute develops a new in vitro *test (also often called target test) for a specific cosmetic effect based on a plant cell line.*

The research institute studies the genetic and/or biochemical composition of the plant cell line. Since research and development is performed on the genetic and/or biochemical composition of the plant cell line, including products of gene function, this constitutes utilisation of genetic resources (i.e. the plant cell line) in the meaning of the EU ABS Regulation.

(Animal breeding) Development of methods for traceability purposes

The development of methods for the purpose of traceability of a genetic resource and its products may involve detailed study of the genome of individual animals for traits. If such activities involve research on the genetic and/or biochemical composition of the genetic resources, in particular the function of genes as revealed in traits, they are considered utilisation in the meaning of the EU ABS Regulation.

(Animal breeding) Development of diagnostic tools for proving the identity of high-quality products

For the identification of high-quality products from particular breeds (for example, in the case of typical products from the Hungarian Grey cattle, Japanese Wagyu cattle or the Spanish Iberico pig) diagnostic tools or tests are developed, which address food product quality and reveal the presence and quantities of certain compounds (e.g. poly-unsaturated fatty acids vis-à-vis saturated fatty acids). If the development of these testing tools involves research on the genetic and/or biochemical composition of the genetic resources, in particular the function of genes as revealed in traits, this is considered to constitute utilisation in the meaning of the EU ABS Regulation. For more information on animal breeding see section 8.6.

7.3. Vector or host

Vectors (e.g. insects or micro-organisms) may be used to introduce foreign material (e.g. pathogens or genes) into host organisms. Typically, specimens of such vectors have been developed to facilitate such introduction, and in many cases a research and development programme does not involve any other changes to the vector than the incorporation of the genetic material to be introduced in the target plant.

In such cases, the use of the vector or host does not constitute utilisation of such host organisms or vectors in the context of the EU ABS Regulation. However, the study of introduced genetic material constitutes utilisation of those gene sequences in the meaning of the EU ABS Regulation. Also, the activity of optimising the performance of a vector or host qualifies as utilisation in the meaning of the EU ABS Regulation.

(Plant breeding) Using insects as vectors to infect plants in disease trials

In disease resistance breeding programmes, vector insects (e.g. aphids) may be used to transmit a given disease of interest on which the breeder wants to perform plant selection (e.g. in breeding programmes introducing resistance to specific viruses and viroids). The use of vector insects as a vehicle to introduce pathogens in order to test resistance levels in plants does not imply research and development on the genetic and/or biochemical composition of the vector insect and therefore does not constitute utilisation of such vectors in the context of the EU ABS Regulation.

(Biotechnology sector) Using* E. coli *as a host for Bt genes

Bt genes represent a certain set of genes from the species Bacillus thuringiensis that code for proteins which are toxic to very specific groups of insects, and harmless for other organisms. Bt genes can be cloned in E. coli as one step in a gradual assembly of a Bt gene expression construct for transformation to develop insect-resistant genetically modified cotton.

The use of the Bt gene to develop a genetic construct qualifies as utilisation of the Bt strain in the meaning of the EU ABS Regulation. The E. coli cloning host is only used as a vehicle, and such use of the cloning host does not qualify as utilisation of the E. coli strain in the meaning of the EU ABS Regulation.

(Biotechnology sector) Optimising a cloning vector

The DNA sequence of a cloning vector consisting of a plasmid is optimised, so that the expression level of a gene-of-interest can be improved. For example, Agrobacterium *species contain plasmids that can transfer DNA into plant cells, resulting in crown galls. Scientists have removed the crown gall inducing genes of* Agrobacterium *strains and replaced these by regulatory sequences and expressed genes so that the strains can be used for the purpose of introduction of useful genes in many agricultural crops. The activity of optimising a cloning vector qualifies as utilisation of the* Agrobacterium *plasmid in the meaning of the EU ABS Regulation.*

7.4. Biofactory

Genetic resources may be exploited to produce active compounds, which are subsequently extracted. This use of a genetic resource as a biofactory does not amount to utilisation in the meaning of the EU ABS Regulation, since it does not involve research and development on the genetic and/or biochemical composition of this genetic resource. However, if it is combined with research and development on the genetic and/or biochemical composition of that genetic resource, e.g. to discover specific genetic and/or biochemical functions that may optimise compound production, this research would qualify as utilisation in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Use of animal cells for vaccine manufacturing

Animal cells are imported for use in an established manufacturing process for virus vaccines.

As long as no research and development is performed on the animal cells, this activity does not constitute utilisation in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Engineering of animal cells for optimal virus production properties

Animal cells are imported in order to develop a new manufacturing process for influenza vaccines and then engineered for high growth properties. Since the cells are developed for high growth properties this activity can be considered as being utilisation in the meaning of the EU ABS Regulation.

7.5. Laboratory strains

A laboratory strain is a living organism or virus that has particular and invariant properties that make it unique, most typically for research purposes, and is available for mass production and transfer to third parties. Such a strain has originally been isolated from the environment and modified and/or selected to optimise its use in laboratory conditions. Laboratory strains have been developed in microbial, plant and animal species such as *Arabidopsis* plants and mice, and viruses (such as bacteriophages). Laboratory strains of mice and rats, commonly used in biomedical studies, are homozygous and prone to specific diseases. Laboratory strains are created by laboratories to meet specific research needs: lines are created according to the studies that will be conducted on them. They are mainly used as a model for research.

Strains of biological material used in laboratories have diverse origins and exchange histories and have often been extensively transferred between laboratories. They may have been used for various purposes in experimental work, and precise characteristics may have been made available in publications. Laboratory strains are made up of several constituents from different genetic resources, e.g. due to (repeated) crossing in the laboratory involving multiple isolates, or from the introduction of genes from one or more donor isolates. Alternatively, they result from mutation and selection. However, genetic resources stored in *ex situ* collections or cultures should not necessarily be considered as laboratory strains by the mere fact of having been subject to mutation.

Typically, laboratory strains have been genetically modified *intentionally* in experimental research by random mutagenesis or by more precise molecular techniques. However, mutations may also have occurred unintentionally during sub-culturing, prolonged storage or as a result of preservation technologies, with these unintentional mutations subsequently intentionally conserved in and characterising the strain.

A “laboratory strain” therefore is usually characterised by the fact that it is:

– Genetically defined (at least for traits of interest), and with low or no genetic heterozygosity, often inbred or clonal. However, older laboratory strains may be defined by their phenotype rather than by their genotype.

– Distinct from the original strain or parental materials isolated from *in situ* conditions or obtained from a public culture collection, characterized by a genetic and/or biochemical composition that has been intentionally created or conserved[9].

In addition, laboratory strains can be:

– Managed under a record of laboratory maintenance over several generations, with a publicly traceable history regarding ancestry and/or pedigree;

and/or

– Shared by laboratories/researchers.

Laboratory strains are often maintained and sold by laboratories or farms that guarantee the purity of the line and with a health monitoring report. They may be certified as SPF (specific pathogen free), SOPF (specific and opportunistic pathogen free) or Germ free.

Whereas it is standard practice to document the provenance of laboratory strains, and many of them are well documented in scientific literature, it is nonetheless possible that in some cases the country of origin of the original strains on which old laboratory strains are based cannot be determined due to lack of proper documentation. This is likely to be an issue with older strains. In some organisms, such as laboratory mice, earlier crossbreeding, before the initiation of the inbreeding process, has resulted in strains with genes originating from more than one country.

Many laboratory strains have been used in laboratories for a significant amount of time. Laboratory strains created prior to entry into force of the Nagoya Protocol fall outside the scope of the EU ABS Regulation for temporal reasons.

Isolation of genetic material from the environment and its subsequent modification is in scope of the EU ABS Regulation. A researcher who creates a strain (which may over time become a new laboratory strain) based on material in scope of the EU ABS Regulation is a user in the meaning of the EU ABS Regulation.

A newly created strain remains in scope of the EU ABS Regulation as long as it is not publicly available to others for research and development purposes. Before the strain is made publicly available to others, the developer of the laboratory strain needs to submit a due diligence declaration (end of utilisation process). If the strain has become a new laboratory strain and is shared by laboratories/researchers, its further use is out of scope of the EU ABS Regulation. However, contractual agreements agreed in PIC and MAT concerning benefit sharing resulting from further use of newly developed laboratory strains need to be respected.

[9] Strains that only differ from the original strain due to unintentionally induced mutations should not be for that reason alone regarded as "laboratory strains". Many old strains kept in collections have accumulated such mutations but do not fit other characteristics given above, and should not be considered laboratory strains. However, if such unintentional mutations have been subsequently deliberately conserved and made homozygous within the strain, and are used as a characteristic of the strain, then this is likely to be a laboratory strain.

8. BREEDING[10]

8.1. Crossing and selection

A large variety of plant and animal as well as microbial species is used in research and development for the purpose of product development. This variety includes species used in food and agriculture, aquaculture, ornamental species and pets, as well as microbials used in food production or biological control, and may involve whole individuals, their parts, or plant and animal cell lines, as well as microbial cultures. In general, crossing and selection (including in cases of unintentional mutation) are considered to involve research and development of either parental materials or offspring, or alternatively of the source and selected microbial stocks. Where genetic resources falling in scope of the EU ABS Regulation are introduced for the purpose of crossing and selection, the resulting research and development falls within the scope of the EU ABS Regulation, which triggers due diligence obligations.

Such obligations may concern activities undertaken by many actors, including private breeding companies, public research institutions, farmer-breeders and hobby breeders, as well as actors improving insect populations or microbial species. Farmers and breeders are often trading or exchanging breeding stock of rare and traditional animal breeds and plant varieties amongst themselves, most often within the country but sometimes across borders. They may also be members of traditional seed networks, breeders' associations or breeders' networks (usually at national level). Exchange of breeding material largely takes place between farmers and/or hobbyists, often within the network/association, and contributes to the conservation of the specific breed or variety. Such trade or exchange, or crossing and selection, for the purpose of maintenance and conservation of rare or traditional breeds and varieties is considered to be out of scope of the EU ABS Regulation. However, if the activities involve crossing and selection for the purpose of improving or changing the properties of established breeds and varieties, such activities would qualify as utilisation and hence fall within the scope of the EU ABS Regulation. For example, rare sheep breeds have been improved to render these breeds resistant to the scrapie disease.

8.2. Reproductive technologies

The development and application of reproductive technologies (*in vitro* fertilisation and semen sexing in animals; cell, tissue and organ culture in plants) normally do not constitute research and development on the plant and animal genetic resources and hence are not in scope of the EU ABS Regulation. However, the development of reproductive technologies may require investigation of the genetic and/or biochemical composition of plants and animals of the target species, and this may represent utilisation and trigger obligations under the EU ABS Regulation.

[10] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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. Also, it should be noted that the access and use of specific plant genetic resources may be governed by the provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture, a specialised instrument according to the Nagoya Protocol. These assumptions are not repeated in the individual cases.

8.3. Genome editing and targeted mutation

Increasingly, new technologies allow for genome editing at the single nucleotide level and are directed at the introduction of one or more specific mutations for the purpose of improving traits of interest or to 'repair' genetic abnormalities. Such genome editing will normally be based on knowledge acquired through research and development, including the determination of DNA sequences of a genetic resource linked to a desired property, informing the creation of proper DNA constructs for the purpose of genome editing. Improvement of plants and animals by genome editing is therefore considered research and development and to fall within the scope of the EU ABS Regulation, as it results from research and development activities on the genetic and/or biochemical composition of the given genetic resources.

Modified organisms may also be created by means of other techniques such as for the purpose of Release of Insects carrying a Dominant Lethal (RIDL), or radiation technology. The modified organisms may be only male, sterile, or producing non-viable offspring. Since the genetic composition of genetic resources is modified through the use of these technologies on genes selected for their function, such activities are considered utilisation in the meaning of the EU ABS Regulation.

8.4. Use of commercial plant varieties

A commercial plant variety refers to any plant variety that has been (legally) placed on the market, whether still available on the market or not.

Plant varieties developed for agriculture and horticulture commonly require registration in the EU Common Catalogues or in the national or regional catalogues/registers of Member States prior to their commercialisation. For plant varieties subject to intellectual plant variety protection or commonly known, there is a requirement for a denomination and description in these catalogues/registers.

For some varieties, such as of ornamental species, registration of varieties prior to their commercialisation is not required. Suppliers nevertheless have to keep lists with the denomination and a detailed description of all plant varieties they place on the market. Such lists need to describe how a particular variety differs from the other varieties most closely resembling it. When a variety is subject to plant variety protection (PVP; see below), or is commonly known, there is no requirement for an additional denomination and detailed variety description, as this already was part of the PVP registration process.

Many plant varieties are also subject to intellectual property protection under the Community Plant Variety Rights regime or by a national plant variety rights system, both based on the international UPOV Convention (including ornamental species). Some varieties might also have traits that are patent-protected or have been bred using processes protected by patents[11]. Both forms of intellectual property rights protection (patent and plant variety system) involve a detailed registration of the protected plants or varieties, and their properties.

[11] See Articles 3 and 4 of Directive 98/44/EC on the protection of biotechnological inventions

When a variety is subject to compulsory registration prior to market access official tests are performed by, or under control of, Member States authorities to verify its characteristics as distinct, uniform and stable. Such tests are carried out as one of the preconditions for registration. The same type of tests take place when a variety is subject to intellectual property protection under Community or national Plant Variety Rights scheme based on the UPOV Convention. Major field crops require also additional testing in the context of Variety Cultivation and Use. For agricultural landraces and varieties which are naturally adapted to local and regional conditions, and for vegetable landraces and varieties which have been traditionally grown in particular localities and regions, with no intrinsic value for commercial crop production, specific EU directives apply (2008/62/EC and 2009/145/EC respectively).

Marketing of commercial plant varieties is common both globally and in the EU. (The EU Catalogues currently contain approximately 45,000 varieties; about 25,000 varieties have Community plant variety rights). According to the applicable EU Marketing Directives[12], no restriction on marketing of registered varieties can be set unless specifically authorised by EU law.

A commercial plant variety should thus be understood as a plant variety made available on the market, with systems in place for its identification and characterisation, with reference to one or more of the following:

a) The variety has been legally protected by a plant variety right in accordance with the provisions of Regulation (EC) No 2100/94 or in accordance with national provisions[13];

b) The variety has been registered in a national or common catalogue of varieties of agricultural plant and vegetable species, or in a list or register of forest reproductive material, fruit or vine varieties;

c) The variety has been entered in any other public or private list according to EU legislation and/or international standards containing officially recognised denomination and description.

A user (plant breeder) developing a new variety using material in the scope of the EU ABS Regulation (i.e. material from a Nagoya Protocol country with enacted ABS legislation, accessed after its entry into force etc.[14] is subject to due diligence obligations in line with Article 4 of the EU ABS Regulation. Likewise, the user needs to submit a due diligence

[12] See Articles 16 of Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, and Article 6 of Directive 2002/55/EC on the marketing of vegetable seeds, Article 17 of Directive 2008/90/EC on the marketing of fruits

[13] Although acquiring protection right does not equal the right to commercialise, the standard practice is to market a variety for which protection rights have been acquired. In cases where a variety cannot be marketed because of non-compliance with other legislation (such as for example, a GMO variety would fail to meet GMO-relevant requirements, or a variety would not pass the VCU test necessary for its registration), the protection rights will almost invariably be withdrawn.

[14] For an overview of the conditions, please consult Annex I of this document

declaration under Article 7(2) of the Regulation prior to the registration of such a variety or its placing on the market[15].

Further use of a commercial variety that has been legally placed on the EU market for subsequent breeding programmes does not fall within the scope of the EU ABS Regulation, as the subsequent breeder relies on a new and different genetic resource, different from the initial genetic resource (accessed under the Nagoya Protocol and in scope of the EU ABS Regulation). When a variety is entered in one of the European Catalogues or in a national catalogue or a register of Member States, or when it is indicated on a list of varieties with an official or officially recognised denomination and description, it is considered to be a new variety different from existing varieties of common knowledge.

Furthermore, when a new variety is protected by a plant variety right according to the UPOV Convention, including under Regulation 2100/94/EC on Community Plant Variety Rights, it is considered to be novel and distinct from existing commercial varieties or varieties of common knowledge. Further use in subsequent breeding programmes of varieties that have been protected by a plant variety right according to the UPOV Convention, including varieties having obtained protection by a plant variety right according to the UPOV Convention also in a country outside of the EU, is thus considered to be out of scope of the EU ABS Regulation, as the breeder who uses a plant variety that has been protected by a plant variety right relies on a new and different genetic resource, which is sufficiently different from parental genetic resources used to create the protected variety according to UPOV requirements (see also section 5.2.2. of the Guidance document).

Consequently, no due diligence obligation applies, and no due diligence declaration is required with regard to breeding activities involving the use of varieties that have been legally commercialised in the EU and/or protected by a plant variety right according to the UPOV Convention inside or outside of the EU.

It needs to be noted however that benefit-sharing obligations may apply to further use of a commercial plant variety depending on the contractual obligations made with a provider country by the initial user and passed on to subsequent users and such obligations, where they exist, need to be respected.

All registered conservation varieties[16] are included in the national catalogues of varieties in accordance with the provisions of Commission Directive 2009/145/EC and Commission Directive 2008/62/EC. In line with the definition of a commercial plant variety (see above), the use of such varieties included in the national catalogues for further breeding activities is not covered by the scope of the EU ABS Regulation.

(Plant breeding) Use of a crop wild relative, landrace or farmer's variety in a breeding programme

[15] See Article 6 of Commission Implementing Regulation (EU) No 2015/1866

[16] Conservation varieties are landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion (EU Directive (2009/145/EC).

A plant breeder accesses a crop wild relative in situ or a landrace or farmer's variety[17] from farmers' fields and uses this material in a breeding programme to introduce useful traits in commercial breeding materials.

A breeding activity using such material (in scope of the EU ABS Regulation) is considered utilisation in the meaning of the EU ABS Regulation. Due diligence obligations therefore apply. The user needs to submit a due diligence declaration when a new variety is registered or placed on the market.

(Plant breeding) Use of a variety placed on the EU market in a breeding programme

The same or another plant breeder acquires this new variety placed on the EU market and developed based on a crop wild relative from the wild or a landrace or farmer's variety accessed from farmers' fields and uses this material in a further breeding programme to introduce some useful traits in other commercial breeding material.

Since the subsequent breeder does not rely on material within the scope of the EU ABS Regulation, no due diligence obligations apply.

8.5. Use of forest reproductive material

Council Directive 1999/105/EC[18] regulates the marketing of forest reproductive material. According to this Directive, forest reproductive material of tree species (except when clonally propagated) is not identified as belonging to a variety (as is the case for commercial plant varieties) but is identified as derived from approved basic materials described by a set of criteria (such as location name, origin, effective population size, age and development of the stand, health and resistance, wood quality). Forest reproductive material may consist of either seed (including as contained in e.g. cones or fruits), vegetative plant parts (cuttings, buds, etc.) or whole plants, including seedlings.

Article 2 of Directive 1999/105/EC recognises the following four categories of forest reproductive material[19]: (i) 'source-identified', i.e. reproductive material derived from basic material which may be either a seed source or stand located within a single region of provenance and which meets the requirements set out in Annex II of the Directive[20]; (ii) 'selected', i.e. reproductive material derived from basic material which shall be a stand located within a single region of provenance, which has been phenotypically selected at the population level and which meets the requirements set out in Annex III of the Directive[21]; (iii) 'qualified', i.e. reproductive material derived from basic material which shall be seed orchards, parents of families, clones or clonal mixtures, the components of which have been phenotypically selected

[17] The terms landrace and farmer's variety are used interchangeably in literature to describe any distinct crop plant group developed and maintained by farmers in their fields.

[18] Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material

[19] Annexes II to V set up minimum requirements for the approval of basic material intended for the production of reproductive material to be certified as a specific category; Annex II deals with "source-identified", Annex III with "selected", Annex IV with "qualified" and Annex V with "tested".

[20] In short, the location where the material has been collected must be stated;

[21] In short, the origin of the material must be stated; the stand must show adaptation to ecological conditions and also sufficient growth and quality;

at the individual level, and which meets the requirements set out in Annex IV of the Directive[22] – testing has not necessarily been undertaken or completed; (iv) 'tested', i.e. reproductive material derived from basic material which shall consist of stands, seed orchards, parents of families, clones or clonal mixtures; the superiority of the reproductive material must have been demonstrated by comparative testing or an estimate of the superiority of the reproductive material calculated from the genetic evaluation of the components of the basic material; the material shall meet the requirements set out in Annex V of the Directive[23]. The EU publishes the Community List of Approved Basic Material for the production of Forest Reproductive Material. Only approved basic material may be used for producing forest reproductive material with the intention of marketing.

Whereas similarities exist between forest reproductive material and plant commercial varieties as both are defined under EU seed *acquis* (e.g. the exclusion of marketing restrictions), differences also occur. Given the fact that for the forest reproductive material category "source-identified" no breeding and/or selection is involved, and for the category "selected" only a limited degree of selection is employed, forest reproductive material falling under these two categories does not automatically represent a new genetic resource, substantially different from the original population. However, the other two categories of forest reproductive material, i.e. "qualified" and "tested" can be regarded as new genetic resources different from the ones from which they have been derived.

Consequently, if new forest reproductive material falling in the category "qualified" or "tested" is developed, using material that falls within the scope of the EU ABS Regulation, (i.e. material from a Nagoya Protocol country with ABS legislation, accessed after the entry into application of the EU ABS Regulation etc.), the user (breeder) is subject to due diligence obligations according to Article 4 of the EU ABS Regulation, and a due diligence declaration under Article 7(2) of the EU ABS Regulation needs to be submitted prior to placing the newly developed forest reproductive material on the market. Further use in subsequent breeding and selection programmes of reproductive material belonging to these two categories of forest reproductive material that has already been legally placed on the EU market does not fall in scope of the EU ABS Regulation, as the subsequent breeder relies on a new genetic resource different from the original one (accessed under the Nagoya Protocol and in scope of the EU ABS Regulation). Consequently, no due diligence obligation applies, and no due diligence declaration is required with regard to breeding activities involving the use of forest reproductive material from the categories "tested" and "qualified" that have been legally commercialised in the EU. Yet, benefit-sharing obligations may apply depending on the contractual obligations made with a provider country by the initial user and be passed on to subsequent users, and such obligations, where they exist, need to be respected.

The cultivation, propagation and marketing of forest reproductive material is not covered by the EU ABS Regulation. However, if a breeder uses forest reproductive material of the categories "source identified" or "selected", and in case the material falls within the scope of the EU ABS Regulation, due diligence requirements apply if such material is used for further breeding. The certification system under Directive 1999/105/EC allows for clear identification

[22] Requirements are set for seed orchards, parents of family, clones and clonal mixtures;

[23] Requirements are set for tests, for genetic evaluation of components of basic material and for comparative testing of reproductive material; conditions of approval are also specified.

and determination of the origin of any forest reproductive material, where the material is not autochthonous or indigenous to the country where the use takes place. In situations where the origin of the material is indeterminable, the material can still be used, as the EU ABS Regulation requires the user to be duly diligent when utilising genetic resources, but it does not prohibit the utilisation of material of unknown or indeterminable origin (see section 3.3 of the Guidance document). However, the user needs to be aware that if new information arises that allows the provider country to be identified then the provisions of Article 4(5) need to be observed.

8.6. Use of animals for breeding

A specific feature of the use of animal genetic resources in breeding is that the output of breeding efforts results in a new breeding animal or lineage of animals exhibiting desired traits, which may then be used in further breeding activities. In this respect, animal breeding resembles plant breeding. However, there are also significant differences between animal and plant breeding. The procedures, the way genetic resources are managed, the stakeholders or actors involved and the final target in each of these fields are markedly different. While the main target in plant breeding is developing and marketing of new commercial varieties, the commercial outcome of animal breeding is an improved progeny from selected parents in consecutive generations that may and most typically will be involved in further breeding. In animal breeding, continuous genetic improvement within breeds or lines forms the basic approach. New distinct breeds or lines are created only from time to time, by combining particular features of different breeds or lines, or by introgressing new genetic material. Breeding companies and breeders' associations coordinate the efforts towards breeding goals as desired by farmers, end-users, consumers and society at large. It is relevant to note that, due to veterinary measures in the EU, the list of countries from which animal or reproductive material can be imported is limited, because only a limited number of countries can meet the EU veterinary standards[24].

Regulation (EU) 2016/1012 provides the regulatory framework for the breeding, trade in, and entry into the Union of purebred breeding farm animals (bovine, porcine, ovine, caprine and equine species), and of their germinal products. It also provides an adapted regulatory framework for hybrid breeding pigs and their germinal products, produced by private companies operating in closed production systems. Regulation (EU) 2016/1012 does not oblige breeders to take part in a breeding programme led by an officially recognised EU breeding society or operation but only provides for such opportunity. While no such regulatory framework exists for other animal species, this guidance document also applies to the use of such other species, including species held as pets and species used in aquaculture.

Different scenarios can be envisaged when animal genetic resources in scope of the EU ABS Regulation (thus from a Nagoya Party which established applicable access legislation etc.) are introduced and used by a breeder in an EU country.

[24] See Regulation (EU) 2016/429 (the so-called 'EU Animal Health Regulation'); art. 229-256; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.084.01.0001.01.ENG

1. The purebred breeding animal is entered in a breeding book [25] of an officially EU recognized breeding society, according to Regulation (EU) 2016/1012. When mating [26] (using either an animal or its reproductive material) is aimed at breed improvement through selection for desired traits and therefore involves research and development on the genetic and/or biochemical composition of the parents and progeny, the mating between a newly accessed genetic resource (live animals or reproductive material in the form of semen or embryos) that is in scope of the EU ABS Regulation and an animal from own breeding stock is to be regarded as utilisation within the scope of the EU ABS Regulation. When the product (offspring) of this mating is registered in a breeding book of an officially EU recognized breeding organisation as a new line or breed, subsequent use of this product in breeding activities does not fall within the scope of the EU ABS Regulation. A due diligence declaration needs to be submitted when the product is registered in the 'book'.

2. The breeding animal or its reproductive material is introduced in an EU country by a commercial breeding company or breeders' association that runs an 'in house' breeding programme, e.g. for hybrid breeding pigs, poultry and fish. Such a breeding company usually only sells improved hybrid products on the market. The company may need many generations of (in house) selection in their base lines after introduction of breeding material from a provider country before a commercial product derived from the originally introduced breeding material will be sold on the market. When mating is aimed at breed improvement through selection for desired traits, therefore involving research and development on the genetic and/or biochemical composition of the parents and progeny, the incorporation of a newly accessed genetic resource in scope of the EU ABS Regulation in this in-house breeding work falls under the EU ABS Regulation. The marketing of the commercial product may be subject to benefit sharing, depending on what is agreed in the MAT. The company needs also to submit a due diligence declaration prior to placing the newly developed product on the market. Once on the market, the commercial product is to be considered a new genetic resource, and further breeding activities with this product are out of scope of the EU ABS Regulation.

   The ownership of genetic resources maintained in the breeding programme may also be transferred to a different legal entity before a commercial product is marketed. If the transferred product is a product ready to be commercialized without any further research and development by the recipient, a due diligence declaration needs to be submitted by the party making the transfer (as this party will be a user in the meaning of the Regulation). If, however, the transferred product is a half-product, and the new owner continues the breeding programme or utilises the half-product in another breeding programme, this new owner is considered to be a user in the meaning of the EU ABS Regulation as well and is the only entity subject to due diligence obligations, including the duty to submit a due diligence declaration, if the new user places an end-product on the market. The new owner also needs to respect all benefit-sharing obligations linked to use of the genetic resources transferred.

[25] As defined by (EU) 2016/1012, a breeding book means: (a) any herd-book, flock-book, stud-book, file or data medium which is maintained by a breed society consisting of a main section and, where the breed society so decides, of one or more supplementary sections for animals of the same species that are not eligible for entry in the main section; (b) where appropriate, any corresponding book maintained by a breeding body.

[26] Mating is considered to include artificial insemination (AI), as well as 'natural mating'.

3. The breeding animal (livestock or pet) or its reproductive material is introduced by an individual breeder not covered by Regulation (EU) 2016/1012. When mating, involving research and development on the genetic and/or biochemical composition of the parents and progeny, is aimed at breed improvement through selection for desired traits, the mating between a newly accessed genetic resource in scope of the EU ABS Regulation and an animal from the EU breeding stock is to be regarded as within the scope of the EU ABS Regulation. Offspring of the breeding material that was introduced by this particular breeder can be employed in further breeding and/or can be sold to other breeders. The sold product is to be considered a new genetic resource, and its further use in breeding activities is out of scope of the EU ABS Regulation. It is the responsibility of the breeder who made the product to submit a due diligence declaration.

In all scenarios, the (potential) value of the offspring sold to subsequent breeders is incorporated in the commercial price paid by the subsequent user, and possible benefit-sharing arrangements (according to MAT) may be incorporated in the market price of the offspring.

9. PRODUCT DEVELOPMENT, PROCESSING AND PRODUCT FORMULATION[27]

9.1. Product development

Whenever product development involves research and development on the genetic and/or biochemical composition of genetic resources, it is considered utilisation and is thus in scope of the EU ABS Regulation.

(Pharmaceutical sector) Creation of an artificial gene cluster

A soil sample is imported from a provider country. The importing company directly amplifies bacterial DNA of unknown identity from the soil and uses the amplified DNA to create artificial gene clusters/operons. Transgenic microorganisms are produced expressing the artificially constructed gene cluster. The metabolites produced by said genetically modified microorganisms are analysed and screened for new compounds not present in the wild type variant of the transgenic microorganism, serving as a host. Subsequently, newly identified compounds are tested for specific biological activities. In the course of the research and development process, functional units of heredity of organisms present in the soil sample are used in order to deliver products of gene expression for further study, even if these organisms are not identified. Therefore, the research and development activities constitute utilisation in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Development of chimeric antibodies

An isolated chimeric antibody comprising human complementarity-determining regions (CDRs) sequences in an animal antibody gene background is functionally characterised and further modified (e.g. affinity maturation; humanisation of framework sequences). The antibody sequence was taken directly from an animal and was not synthesized de novo using DNA sequence from a public database. The introduced changes in the amino acid sequence of the chimeric antibody may enhance its efficacy and reduce unwanted side-effects.

Research and development is carried out on the non-human sequences of the antibody (which is considered a derivative from an antibody-producing cell line) focussing on the function of those sequences (replacement of non-human by human sequences in order to enhance the efficacy of the antibody in the human patient), and therefore this activity qualifies as utilisation in the meaning of the EU ABS Regulation.

[27] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

(Pharmaceutical sector) Development of a host cell production system

A host cell system acquired from a provider country is modified for the specific recombinant expression of a particular target protein, for example to produce a specific glycosylation pattern, and may not be suitable for expression of other proteins. The host cell system is itself subject of research and development activities to achieve expression of the target protein, i.e. the product of gene function. These research and development activities constitute utilisation in the meaning of the EU ABS Regulation.

(Food and feed sector) Improvement of product characteristics

A company accesses a fungal strain for its known phospholipase activity. However, in application tests the phospholipase turns out not to be sufficiently temperature stable. Therefore, the strain is genetically engineered to produce more temperature-stable phospholipase, and a recombinant production strain is subsequently generated for commercial-scale production. Construction of recombinant production strains for more temperature-stable phospholipase variants involves research and development on the genetic and/or biochemical composition of the fungal strain. Therefore, it is considered to represent utilisation of the genetic resource in the meaning of the EU ABS Regulation.

(Food and feed sector) Analysis and use of side effects of production strains

Classical, wild-type fungal production strains for industrial enzymes typically contain, next to the main enzymatic activity, a variable and often diverse range of enzymatic side activities due to gene functional expression. The products of these side activities will usually also be present in the final food product, because commercial food enzymes typically are only partially purified. Depending on the food production process in which such an enzyme is used, a particular side activity may prove to provide synergistic benefits. A company has developed a production process for a fungal amylase for baking applications using fungus A. Subsequently, the company accesses a closely related fungus B, analyses which side activities of fungus B provide added value in baking applications, and uses this knowledge to optimise the process in such a way that more of this value-adding side activity is produced.

Analyses for relevant side activities of this fungus B, in combination with their use for optimising the production process, are to be considered utilisation of fungus B in the meaning of the EU ABS Regulation, since they constitute research and development on the genetic and/or biochemical composition of the genetic resources.

(Cosmetics sector) Improved cosmetic ingredients

It is known from published literature that blueberries are rich in vitamin A, C and E. An ingredient supplier wishes to identify a blueberry variety with a significantly higher level of vitamin A, C and E. It is not known where to source such blueberries and how the vitamin content varies with blueberry varieties. The ingredient supplier purchases samples from wild and cultivated blueberry plants from different countries and conducts research on the biochemical composition of all received samples, analysing the proportions of the desired vitamins in order to select the best source. This research delivers insights into the characteristics of the genetic resource which are of benefit to the further process of product development of the improved cosmetic ingredient.

Blueberries are plant genetic resources. Since their biochemical composition is studied in order to deliver insights into the characteristic of the genetic resource for development of an improved cosmetic ingredient, such activity qualifies as utilisation in the meaning of the EU ABS Regulation.

(Cosmetics sector) Preparation of novel essential oils to find new fragrance ingredients

Whole plants, plant parts or their seeds are imported by a fragrance company. New essential oils are produced by solvent extraction for the first time to search for certain new fragrance ingredients. Volatile compounds are purified and identified.

The extraction and purification of new essential oils and new volatile compounds, respectively, from a genetic resource, and the evaluation of their potential as new fragrance ingredients deliver insights into the characteristics of the genetic resource which are of benefit to the further process of product development and constitute research and development on the biochemical composition of the plant genetic resource. Therefore, this activity constitutes utilisation in the meaning of the EU ABS Regulation.

(Pharmaceutical sector) Using compounds isolated from a genetic resource as candidates for a drug

A microorganism that was isolated from a soil sample in a provider country is imported by a pharmaceutical company into the EU. The genetic and biochemical composition of the microorganism are analysed. Compounds are isolated from the microorganism and used in further tests to identify development candidates for new drugs for treatment of Parkinson's disease. The isolated compounds are to be considered derivatives. Selection of development candidates through testing their biochemical activity for the treatment of Parkinson from the isolated microbial compounds that are derivatives (and continuity with genetic resources is assured) constitutes utilisation in the meaning of the EU ABS Regulation (see section 2.3.4. of the Guidance document).

(Cosmetics sector) Investigating a Ginseng variety accessed together with traditional knowledge

A company producing cosmetic products obtains a new variety of a Ginseng plant from a country which a Party to the Nagoya Protocol with national legislation regulating access to genetic resources as well as traditional knowledge associated with genetic resources. The company investigates the antioxidant efficacy of this variety. Indications of the antioxidative properties of the new Ginseng variety were obtained from traditional knowledge of the inhabitants of the village where the ginseng variety was collected, and this was described in the MAT applying to the utilisation of the new Ginseng variety.

Investigating the antioxidative properties of the new Ginseng variety involves research on the genetic and/or biochemical composition of the genetic resources and thus constitutes utilisation in the meaning of the EU ABS Regulation. As the traditional knowledge is related to the utilisation of the accessed Ginseng variety and is included in the MAT, utilisation of this traditional knowledge also falls within scope of the EU ABS Regulation.

9.2. Processing

The processing of genetic resources for subsequent incorporation of those genetic resources or compounds contained in those genetic resources in a product in cases in which the properties of the genetic resource and/or its compounds are already known or not relevant does not constitute utilisation in the sense of the EU ABS Regulation (see section 2.3.3.2 of the Guidance document). Examples are the processing of tomatoes to produce a purée or a juice, the processing of Aloe Vera, shea nut or butter and rose essential oils for further incorporation into cosmetics, and the extraction of organisms to obtain substances for use in biocontrol. The extracts and/or purified biochemical compounds may be marketed and/or further processed by third parties. However, if the properties of the genetic resource and/or its compounds are investigated, the activity constitutes utilisation in the sense of the EU ABS Regulation.

(Biotechnology sector) Processing of raw materials for subsequent incorporation into a product

Company A buys a protease as an ingredient from Company B to be used in a washing powder. Company B has made the enzyme product based on a gene that originates from a microorganism. Company B has obtained PIC and negotiated MAT with the country of origin and made a due diligence declaration when the enzyme product was placed on the EU market for all types of cleaning and cleansing uses. Before use in the washing powder, further work is needed by Company A to find the optimal conditions for stability and performance of the protease in the particular washing powder. If this work results in the creation of more knowledge on the properties of the protease, it constitutes utilisation in the meaning of the EU ABS Regulation.

(Food and feed sector) Development of 'process flavours'

'Process flavours' are typically generated by heating a reducing sugar (such as glucose or xylose) with amino acids (or sources thereof such as yeast extracts, protein hydrolysates etc.) together with further raw materials such as fats (e.g. chicken fat), table salt and water. The sensorial profile is optimised according to the intended application in an iterative process by variation of the reaction parameters (within typical ranges, e.g. for temperature, duration, concentration of individual raw materials and moment of addition) and subsequent sensorial evaluation. This type of activity constitutes processing. The properties of the biochemical compound are already known. No research and development is carried out on the genetic and/or biochemical composition, and therefore this activity does not constitute utilisation in the meaning of the EU ABS Regulation.

(Biocontrol and biostimulants sector) Preparation of fermentation broths for use in biocontrol or as biostimulants

Microbial biocontrol products or biostimulants are often produced/multiplied in liquid culture. In many cases, the microbes are not used as such. Instead, the microbes are often sterilised, and the resulting fermentation broth is used. This activity is production making use of existing research outputs and does not involve new research on the genetic and/or biochemical composition of the genetic resources, and therefore it does not constitute utilisation in the meaning of the EU ABS Regulation.

(Food and feed sector) Use of a standard production process for a lactic acid bacterium

Starter cultures based on lactic acid bacteria are ingredients that are used for producing fermented finished products.

The production process of a starter culture (or a probiotic) typically consists of:

- A propagation step wherein a lactic acid bacterium is introduced in a suitable growth medium and reproduced to form the biomass;

- A concentration step that is generally carried out by centrifugation or by separation processes (e.g. ultrafiltration system);

- A preservation step most often done by deep freezing or by lyophilisation; and

- A blending/packaging step (e.g. more than one strain is typically added to the final, commercial product).

A company, which is a supplier of starter cultures to the dairy industry, obtains from a collection a new Streptococcus thermophilus *strain and uses an already existing industrial process recipe for the production of a starter culture with the acquired* S. thermophilus *strain, with no process adaptation required. Such industrial adaptation work does not include research and development on the genetic and/or biochemical composition of the genetic resource. Therefore, such development does not constitute utilisation in the meaning of the EU ABS Regulation.*

9.3. Product formulation

Formulation of a product by mixing ingredients or by adding compounds, without research on the genetic and/or biochemical composition of the genetic resources, does not constitute utilisation in the sense of the EU ABS Regulation. Examples are the formulation of a new flavour composition for use as ingredient in food and beverage products by re-combining and physically processing ingredients with known sensory, taste and other functional properties, and the adding of adjuvants, feeding additives or preservatives to the active ingredient of a biocontrol or biostimulant product to ensure optimal product quality, handling and/or shelf-life.

When, however, research and development is carried out on the genetic and/or biochemical composition of the genetic resources or compounds contained in those genetic resources, it constitutes utilisation in the sense of the EU ABS Regulation.

(Biotechnology sector) Product formulation to optimize the performance of the product

Company A buys a protease as an ingredient from Company B to be used in a washing powder. Company B has made the enzyme product based on a gene that originates from a microorganism. Company B has obtained PIC and negotiated MAT with the country of origin and made a due diligence declaration when the enzyme product was placed on the EU market for all types of cleaning and cleansing uses. Before use in the washing powder product, further formulation work is needed by Company A to find the optimal conditions for stability and performance of the washing powder by changing the proportions of the ingredients (including the protease). Since such formulation work does not involve research and development on the biochemical composition of the protease, it does not constitute utilisation in the meaning of the

EU ABS Regulation.

(Food and feed sector) Development of new product forms

In the EU, enzymes that are authorised as food processing aids or feed additives are usually marketed as preparations with a guaranteed minimum enzyme activity per gram of the formulated product. As a classical life cycle management measure for a food processing enzyme preparation it is possible to create a more concentrated product form, e.g. by removal of water, with a higher guaranteed minimum enzyme activity per gram of formulated product compared with the initial product, without otherwise changing the product composition. Increasing the enzyme concentration in the final product does not involve research and development on the genetic and/or biochemical composition of the genetic resource, which is unchanged and unstudied. Such development of new product forms does not constitute utilisation in the meaning of the EU ABS Regulation.

(Cosmetics sector) Preparation of a formulation prototype

Ginseng is known for its cosmetic properties, one of which is the antioxidative effect. A producer of finished cosmetic products obtains a well known variety of a Ginseng plant and confirms its known antioxidant efficacy in various prototype formulations to finalise a new finished cosmetic product formulation.

The properties of the Ginseng variety are already known from public reports and scientific literature. Newly combining ingredients with well-known properties does not involve research and development on the genetic and/or the biochemical composition of the genetic resource and therefore these activities do not constitute utilisation in the meaning of the EU ABS Regulation.

(Cosmetics sector) Formulation of a product using a new ginseng variety

An untried variety of ginseng is imported with the intent of developing a new cosmetic product. Although the properties of ginseng species are generally known, the chemical composition of the required active ingredient in this new variety is not known, so it is analysed and tested to determine whether it is as effective as other ginseng varieties and, if so, how it should be combined with other ingredients to produce a suitable cosmetic. The formulation of the product involves research and development on the biochemical composition of the genetic resource to deliver insights into its characteristics for development of a product and therefore these activities do constitute utilisation in the meaning of the EU ABS Regulation.

10. PRODUCT TESTING[28]

10.1. Product testing (including regulatory tests)

Many if not all products which are developed via utilisation of genetic resources and are to be placed on the market, are subjected to various tests regarding their identity, purity, quality, efficacy or safety, in order to establish whether such products meet expected product standards or market standards. Product testing is applied during all phases of the research and development process and across all sectors utilising genetic resources.

Product testing can be regarded as an essential element of research and development of a commercial product. In all phases of development candidate products will be subjected to testing, e.g. to verify if an active ingredient has been purified or certain product qualities have been retained, strengthened or improved. Testing may regard the performance of the genetic resource(s) or their derivatives involved in product development, or alternatively of other essential ingredients or components of a candidate product. Such testing forms an essential element of the research and development process and therefore is considered to constitute utilisation in the meaning of the EU ABS Regulation (if this involves research and development on the genetic and/or biochemical composition of (a) genetic resource(s)). Such testing however does not yet involve testing of the final product.

For a number of product categories tests may be required by law and regulations; such tests are most often carried out on the final product, which is the output of the research and development process. These may involve tests using established facts on the genetic and/or biochemical composition of the genetic resource as a benchmark against which performance of the product is tested. Most typically, such tests on final products do not lead to further development or change of the composition or properties of the product and hence are not considered to constitute research and development in the meaning of the EU ABS Regulation. However, in cases in which regulatory test results lead to further development or alteration of the genetic resource incorporated in the final product before being placed on the market, or such product testing of the candidate product has generated new knowledge and is regarded to contribute to further research and development of the genetic and biochemical composition of the genetic resource incorporated in the final product, such activity does constitute utilisation in the meaning of the EU ABS Regulation.

Whereas in some sectors (e.g. plant and animal breeding) cases leading to further research and development in response to the regulatory final tests may be rare, in other sectors (e.g. the pharmaceutical sector), early testing of products under development for safety and efficacy requirements defined by law and regulations is very common.

Product testing may also be applied on specific commercial product lots (e.g. lots of medicinal products, or plant seed lots) to verify if individual commercial lots fulfil set product standards.

[28] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

Confirmatory tests on individual product lots to verify whether they meet product standards are not considered to constitute utilisation in the meaning of the EU ABS Regulation, since they do not involve research and development on the genetic or biochemical composition of the genetic resource and do not deliver additional insights into the characteristics of the genetic resource for development of the product. However, if the product test results are used to modify the product or its production process through research and development on the genetic resource, such tests are regarded to contribute to further research and development of the product and hence to be in scope of the EU ABS Regulation.

(Food and feed sector) Detecting and correcting off-notes

Tests of a flavour formulation are carried out. If the test detects an off-note (unpalatable flavour), the results may either lead to (i) a redefinition of the specifications of the raw materials but no alteration of the product development process, in which case the use of the results does not fall within the scope of the EU ABS Regulation, or lead to (ii) a change in the product development process, in which case the analysis would contribute to the qualities of the new and altered product and hence fall within the scope of the EU ABS Regulation.

Furthermore, the quality of commodities to be placed on the market may be tested, e.g. for their suitability to be used as food or feed. Such tests may measure the absence of certain toxins or the presence of certain levels of nutrients. Because such tests do not involve research and development activities, they do not constitute utilisation in the meaning of the EU ABS Regulation.

In some cases, genetic resources or products developed with the utilisation of genetic resources may be used as tools to carry out such product testing. When genetic resources are used as testing/reference tools they are not being utilised within the meaning of the Regulation (see section 2.3.3.2. of the Guidance document and Chapter 7 in Annex II).

10.2. Clinical trials

Pharmaceutical product development and placing on the market of medicinal products is strictly regulated in the EU. Various clinical trials must be performed in order to obtain market approval. These trials are performed as a four-phase activity during the product development process.

The first two phases (Phase I and II) focus on the activity of a new drug under investigation. Phase I focusses on safety, pharmacokinetics/pharmacodynamics, dose finding and, in the case of vaccines, immune responses, and Phase II on safety and efficacy. The results of the trials will feed back into product design. If activities within these two phases involve research and development on the genetic and/or biochemical composition of genetic resources, such activities will fall within scope of the EU ABS Regulation.

The last two phases (Phase III and IV, the latter taking place following licencing) are designed to confirm and further demonstrate the findings of earlier phases of testing drug candidates for safe and effective use in the intended indication and recipient population. Phase III studies are intended to provide an adequate basis for marketing approval, confirming product safety and efficacy, and sometimes further exploring such aspects as dose-response relationship or use in wider and more diverse populations. Phase IV studies commence after licencing (and hence after the submission of a due diligence declaration) and are designed to optimise the medicinal product's use, for example on interactions with other drugs and through additional safety

studies. The processes involve, for example, monitoring side effects, comparison with commonly used treatments and already approved pharmaceutical products and collecting more information for analysis than previously available. Studies in phases III and IV thus normally only aim at confirming and extending understanding of the product's clinical use. If the tests only confirm the results obtained in Phases I and II, and no further research and development is performed on the product, these phases will not normally constitute utilisation under the EU ABS Regulation. However, in some cases Phase III and IV studies provide new scientific insights related to side effects, comparison with other medicines etc. When, as a result of such tests, the product is biochemically modified (and thus further utilisation takes place involving research and development on the genetic and/or biochemical composition of the genetic resources used to develop the product), such tests fall within the scope of the EU ABS Regulation.

Alternatively, genetic resources may become only object of the product development in Phase III and IV studies, after research and development in Phase I and II has been exclusively carried out on the basis of DNA sequence and other information. In such latter cases, the research and development studies carried out in the context of Phase III and IV and involving genetic resources only in these phases is considered to be within scope of the EU ABS Regulation, since the actual performance of the end-product can only be established in the form of the genetic resource used.

11. MARKETING AND APPLICATION[29]

When a product – which has been developed through research and development on a genetic resource in scope of the EU ABS Regulation - reaches the final stage of development and is subsequently placed on the EU market, there are certain obligations set up by the EU ABS Regulation. Namely, the user needs to submit a due diligence declaration (see also Section 4.2 of the Guidance document). These obligations are applicable to all users, regardless whether they come from commercial or non-commercial entities.

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 a spin-off commercial enterprise created for the purpose. Alternatively, the marketing of a final product may be contracted to a commercial partner. If the research and development involving utilisation of genetic resources leading to a final product falls within the scope of the EU ABS Regulation, regardless whether the products serve public health, food safety or environmental purposes, the requirements of the Regulation must be followed. 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 if the actual marketing is contracted to a commercial partner (who will not be a user in the meaning of the EU ABS Regulation).

[29] As a reminder, throughout this document the assumption is made that genetic resources are accessed in a country that is Party to the Nagoya Protocol and has established access measures on genetic resources and traditional knowledge associated with genetic resources, and that all other geographic and temporal conditions 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 individual cases.

(Public research) Products developed by public research institute spin-off and then marketed by another company

A university researcher discovers a gene product in his academic research that shows the potential to form the basis of a new antibiotic. A spin-off company is formed by the university to facilitate his ongoing research and the development of a product that might be commercialised. Once the product is created the company then sells the rights to a pharmaceutical company, which does not carry out any further research and development but places the product on the EU market. The spin-off company which conducted the research and development is responsible for making a due diligence declaration (the pharmaceutical company is not a user since it has not carried out any research and development activities).

Where no research and development on a genetic resource in scope of the EU ABS Regulation took place leading to development of a product, marketing activities do not trigger obligations of the EU ABS Regulation, and no due diligence declaration is required.

(Biocontrol and biostimulants sector) Marketing of an existing product for a new use

A substance which is already used for a vegetable oil in food is subsequently granted approval as a basic substance under the plant protection products legislation (as defined in Article 23 of Regulation (EC) No 1107/2009) and allowed to be used for plant pest control. This product may have to meet the requirements of other regulations, but the requirements of the EU ABS Regulation are not triggered by regulatory procedures alone, without utilisation in the meaning of the EU ABS Regulation.

(Biocontrol and biostimulants sector) Application of biocontrol agents/products and biostimulants

Extracts with or without purification and/or naturally occurring compounds are applied as biocontrol products (botanicals/metabolites/molecules/mixtures) or biostimulants. No research is carried out on the genetic and/or biochemical composition of the genetic resources and hence this activity does not constitute utilisation in the meaning of the EU ABS Regulation.

However, if there is research and development on the genetic and/or biochemical composition of the extracts (and there is continuity with the genetic resource as set out in Section 2.3.4. of the Guidance document), e.g. to discover their efficacy and specific biochemical function or activities, this qualifies as utilisation in the meaning of the EU ABS Regulation.

12. CASE INDEX

The table below provides a list of examples used in the guidance with reference to sectors from which the examples in Annex II are drawn. It should be however remembered that the interpretation provided in the examples is also applicable to other sectors. *(Click on the case)*

Sector	Case	Section
Animal breeding	Acquisition of animals by farmers	2.1. Acquisition: Direct or through supply chain
	Basic scientific research on the genetic background of traits	6.2. Identification and characterization: Characterisation
	Characterisation of a genetic resource providing knowledge used in breeding	6.2. Identification and characterization: Characterisation
	Development of diagnostic tools for proving the identity of high-quality products	7.2. Genetic resources as tools: Development of testing or reference tools
	Development of methods for traceability purposes	7.2. Genetic resources as tools: Development of testing or reference tools
	Diversity assessment between and within populations	6.2. Identification and characterization: Characterisation
Biocontrol and biostimulants	Application of biocontrol agents/products and biostimulants	11. Marketing and application
	Marketing of an existing product for a new use	11. Marketing and application
	Optimising rearing or culturing conditions for organisms	4. Rearing and multiplication
	Physico-chemical characterisation of extracts and substances (types of active compounds present) for use as biological control agents or biostimulants	6.2. Identification and characterization: Characterisation
	Preparation of fermentation broths for use in biocontrol or as biostimulants	9.2. Product development, processing and product formulation: Processing
	Rearing/culturing (including multiplication) of biocontrol agents or biostimulants for maintenance and reproduction (including 'amplification services')	4. Rearing and multiplication
Biotechnology	Use of pathogens to monitor effectiveness of crop protection products	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools

Sector	Case	Section
Biotechnology	Development of a detection kit to monitor the presence of transgenic material in food	7.2 Genetic resources as tools: Development of testing or reference tools
	Optimising a cloning vector	7.3. Genetic resources as tools: Vector or host
	Processing of raw materials for subsequent incorporation into a product	9.2. Product development, processing and product formulation: Processing
	Product formulation to optimize the performance of the product	9.3. Product development, processing and product formulation: Product formulation
	Using E. coli as a host for Bt genes	7.3. Genetic resources as tools: Vector or host
Collection holders	Deposition of material with confidential origin in a registered collection	3. Storage and collection management
	Diversity assessment between and within populations	6.2. Identification and characterization: Characterisation
	Phylogenetic analyses without consideration of function of genes	6.3. Identification and characterization: Phylogenetic analysis
	Phylogenetic analyses including consideration of function of genes	6.3. Identification and characterization: Phylogenetic analysis
	Restrictions on supply to third parties	3. Storage and collection management
	Storing genetic resources as a safe deposit	3. Storage and collection management
	Transfer conditions in the Material Transfer Agreement (MTA)	3. Storage and collection management
	Whole genome sequencing	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
	Zoo breeding programme	5. Exchange and transfer
Cosmetics	Applying a genetic resource as a reference to validate an in vitro test model for anti-aging activity	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools
	Development of a novel test system	7.2. Genetic resources as tools: Development of testing or reference tools
	Formulation of a product using a new ginseng variety	9.3. Product development, processing and product formulation: Product formulation
	Improved cosmetic ingredients	9.1. Product development, processing and product formulation: Product development
Sector	**Case**	**Section**
Cosmetics	Investigating a Ginseng variety	9.1. Product development, processing

	accessed together with traditional knowledge	and product formulation: Product development
	Preparation of a formulation prototype	9.3. Product development, processing and product formulation: Product formulation
	Preparation of novel essential oils to find new fragrance ingredients	9.1. Product development, processing and product formulation: Product development
	Taxonomic identification of an organism followed by discovering biochemical function of its genes	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
Food and feed	Analysis and use of side effects of production strains	9.1. Product development, processing and product formulation: Product development
	Detecting and correcting off-notes	10.1. Product testing (including regulatory tests)
	Development of 'process flavours'	9.2. Product development, processing and product formulation: Processing
	Development of new product forms	9.3. Product development, processing and product formulation: Product formulation
	Improvement of product characteristics	9.1. Product development, processing and product formulation: Product development
	In-depth analysis of amylase enzymes	6.5. Identification and characterization: Large-scale screening
	Screening	6.5. Identification and characterization: Large-scale screening
	Use of a standard production process for a lactic acid bacterium	9.2. Product development, processing and product formulation: Processing
	Whole genome sequencing	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
Generic	Acquisition of genetic resources as commodities	2.1. Acquisition: Direct or through supply chain
	Importation of soil samples	2.1. Acquisition: Direct or through supply chain
	Investigation of function of genes: established introduced species	6.2. Identification and characterization: Characterisation

Sector	Case	Section
Pharmaceutical	Creation of an artificial gene cluster	9.1. Product development, processing and product formulation: Product development
	Development of a host cell production system	9.1. Product development, processing and product formulation: Product development
	Development of chimeric antibodies	9.1. Product development, processing and product formulation: Product development
	Engineering of animal cells for optimal virus production properties	7.4. Genetic resources as tools: Biofactory
	Functional metagenomics and antibiotic discovery	6.5. Identification and characterization: Large-scale screening
	Investigation of gene function discovered through taxonomic analysis	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
	Storage of pathogens pending a decision on their use in a vaccine	3.Storage and collection management
	Use of a pathogen to make reagents for test validation	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools
	Use of animal cells for vaccine manufacturing	7.4. Genetic resources as tools: Biofactory
	Use of animals in animal test models	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools
	Use of research tools to understand cellular processes	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools
	Using compounds isolated from a genetic resource as candidates for a drug	9.1. Product development, processing and product formulation: Product development
Plant breeding	Use of a crop wild relative, landrace or farmer's variety in a breeding programme	8.4. Breeding: Use of commercial plant varieties
	Use of a variety placed on the EU market in a breeding programme	8.4. Breeding: Use of commercial plant varieties
	Using existing varieties as references in evaluation trials	7.1. Genetic resources as tools: Using genetic resources as testing or reference tools
	Using insects as vectors to infect plants in disease trials	7.3. Genetic resources as tools: Vector or host
	Virulence of pathogens	6.2. Identification and characterization: Characterisation

Sector	Case	Section
Public research	Environmental DNA metabarcode analysis of water samples to discover the numbers of fish species present	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
	Products developed by public research institute spin-off and then marketed by another company	11. Marketing and application
	Reconstruction of food webs using DNA barcoding of plants and herbivores obtained from in situ conditions	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
	Research and development on mechanical and optical properties	6.2. Identification and characterization: Characterisation
	Research into the function of genes found in forest species without further development	6.2. Identification and characterization: Characterisation
	Research to determine morphological and/or anatomical properties	6.2. Identification and characterization: Characterisation
	Taxonomic identification of human pathogens or associated organisms	6.1. Identification and characterization: Taxonomic identification of organisms and taxonomic research
	Using eDNA to screen for target organism	6.5. Identification and characterization: Large-scale screening