IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

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

(2021/C 13/01)

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1. INTRODUCTION

This document is intended to provide guidance on the provisions and implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union ([1]) ('the EU ABS Regulation' or 'the Regulation').

The EU ABS Regulation implements in the EU those international rules (contained in the Nagoya Protocol) which govern user compliance – i.e. what users of genetic resources have to do in order to comply with the rules on access and benefit-sharing (ABS) established by the countries providing genetic resources. The Nagoya Protocol also contains rules concerning access measures – but those are not covered by the EU ABS Regulation and accordingly are not addressed in this guidance document.

The Regulation provides also for adoption by the Commission of some additional measures by way of implementing act(s). Subsequently, Commission Implementing Regulation (EU) 2015/1866 ([2]) laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices was adopted on 13 October 2015 ('the Implementing Regulation').

Following consultations with stakeholders and experts from Member States, an understanding was reached that certain aspects of the EU ABS Regulation needed further clarification. In particular the concept of utilisation was perceived as requiring comprehensive feedback. Annex II to this document – concentrated on this concept – has been developed from a series of drafts produced with stakeholder engagement. The present guidance document in its entirety was discussed and developed in cooperation with Member States' representatives gathered in the ABS Expert Group ([3]) and it was also subject to feedback from stakeholders gathered in the ABS Consultation Forum ([4]).

The document clarifies when the EU ABS Regulation is applicable concerning temporal, geographical and material scope (Section 2). The document also explains the core obligations of the Regulation, such as due diligence or submitting due diligence declarations (Section 3 and 4 respectively). With regard to material scope and the concept of utilisation, the document provides in its main part for a general understanding of the requirements of the EU ABS Regulation concerning research and development activities in all commercial and non-commercial sectors, whereas Annex II to the document provides for additional details on the concept of utilisation covering specific sectorial aspects.

This guidance document is not legally binding; its sole purpose is to provide information on certain aspects of the relevant EU legislation. It is thus intended to assist citizens, businesses and national authorities in the application of the EU ABS Regulation and the Implementing Regulation. It does not prejudge any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law. This guidance document does not replace, add to or amend the provisions of the EU ABS Regulation and of the Implementing Regulation; furthermore it should not be considered in isolation but used in conjunction with this legislation.

1.1. Overview of the legal framework

The three objectives of the Convention on Biological Diversity (CBD or 'the Convention') ([5]) are the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources (Article 1 CBD). The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity ('the Protocol') implements and further specifies Article 15 of the Convention, on access to genetic resources; it also includes specific provisions on traditional knowledge associated with genetic resources ([6]). The Protocol establishes international rules governing access to genetic resources and associated traditional knowledge, benefit sharing as well as user compliance measures.

([1]) OJ L 150, 20.5.2014, p. 59
([2]) OJ L 275, 20.10.2015, p. 4
([3]) http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3123&NewSearch=1&NewSearch=1
([4]) http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3396&NewSearch=1&NewSearch=1
([5]) https://www.cbd.int/convention/text/
([6]) https://www.cbd.int/abs/text/default.shtml The Protocol was adopted in Nagoya, Japan, in October 2010 during the tenth Conference of the Parties to the CBD. It entered into force on 12 October 2014, having reached the necessary number of ratifications.

In their implementation of the Protocol with regard to access measures, countries providing genetic resources or associated traditional knowledge ('provider countries') may require prior informed consent (PIC) ([7]) as a prerequisite for access to those resources and knowledge. The Protocol does not *oblige* Parties to regulate access to their genetic resources and/or traditional knowledge associated with them. However, *if* access measures are put in place, the Protocol requires that clear rules are established by provider countries – such rules should ensure legal certainty, clarity and transparency. Benefit-sharing under the Protocol is based on mutually agreed terms (MAT), which are contractual agreements concluded between a provider of genetic resources (in many cases public authorities of the provider country) or traditional knowledge associated with genetic resources, and a natural or legal person accessing the genetic resource and/or associated traditional knowledge for the utilisation thereof (a 'user') ([8]).

An important feature of the Protocol is that it requires Parties to establish compliance measures for users of genetic resources and traditional knowledge associated with genetic resources. More specifically, the Protocol requires Parties to put in place measures (i.e. laws, administrative rules or other policy instruments) to ensure that users within their jurisdiction comply with any access rules established in provider countries. The compliance part of the Protocol is 'transposed' into the EU legal framework by means of the EU ABS Regulation. The EU ABS Regulation entered into force on 9 June 2014 and is applicable from the date on which the Nagoya Protocol entered into force for the European Union, i.e. on 12 October 2014 ([9]). With regard to access measures in the EU, Member States are free to establish such measures, if they deem it appropriate. Such measures are not regulated at EU level, although if established they need to comply with other relevant EU law ([10]).

The EU ABS Regulation is complemented by Implementing Regulation (EU) 2015/1866, which entered into force on 9 November 2015 ('the Implementing Regulation').

Both the EU ABS Regulation and the Implementing Regulation are directly applicable in all Member States of the EU, regardless of the status of the Nagoya Protocol's ratification in different Member States.

1.2. **Definitions used in this guidance**

The key terms used in the guidance are defined in the CBD, the Protocol and the EU ABS Regulation, as follows:

— 'Genetic resources' means genetic material of actual or potential value (Article 3(2) of the Regulation; Article 2 of the CBD).

— 'Utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD (Article 3(5) of the Regulation; Article 2(c) of the Protocol).

The EU ABS Regulation (Article 3) also provides for the following additional definitions:

— 'Traditional knowledge associated with genetic resources' means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources (Article 3(7) of the Regulation) ([11]).

— 'Access' means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol (Article 3(3) of the Regulation).

— 'Mutually agreed terms' means the contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation (Article 3(6) of the Regulation).

([7]) The permission given by the competent national authority of a provider country to a user to access genetic resources for stated reasons, in line with an appropriate national legal and institutional framework.

([8]) It is possible that PIC and MAT may be issued jointly or in one document.

([9]) Some articles, namely Articles 4, 7 and 9, became applicable one year later, i.e. on 12 October 2015; see also Section 2.2.

([10]) Such as for example internal market rules etc.

([11]) 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.

— 'User' means any natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources (Article 3(4) of the Regulation).

The term 'provider country' as used in this document means the country of origin of the genetic resources or any (other) Party to the Protocol that has acquired the genetic resources in accordance with the Convention (see Articles 5 and 6 of the Protocol and Article 15 of the CBD). 'Country of origin' of genetic resources is defined by the CBD as the country which possesses the genetic resources in in-situ conditions.

2. SCOPE OF THE REGULATION

This section addresses the scope of the Regulation in geographic terms, with regard to where genetic resources come from (2.1) and where users are located (2.5), as well as in terms of the time period when resources were accessed (2.2), material and activities (2.3) and actors (2.4) covered by it. It is important to note from the outset that the conditions described below concerning the applicability of the Regulation are cumulative: where the document indicates that 'the Regulation applies' if a certain condition is met, this always presupposes that all the other conditions for being in the scope are also met. This is also reflected in Annex I, which contains an overview of the conditions discussed in this document.

It is possible that ABS legislation or regulatory requirements exists in provider countries which, in some respect, go beyond the scope of the EU ABS Regulation. Such national legislation or requirements remain nonetheless applicable, even if the EU ABS Regulation is not.

2.1. Geographic scope – I: the provenance of genetic resources

This section addresses the conditions under which the Regulation applies to genetic resources from a given area. It first describes the basic conditions before tackling more complex cases.

2.1.1. *A state must exercise sovereign rights over genetic resources for them to be in the scope of the Regulation*

The Regulation only applies to genetic resources over which States exercise sovereign rights (see Article 2(1) of the Regulation). This reflects a key principle of the CBD enshrined in its Article 15(1) (and reaffirmed in Article 6(1) of the Protocol), namely that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation (where such legislation exists). It implies that the Regulation does not apply to genetic resources obtained from areas beyond national jurisdiction (for example, from the high seas), or from areas covered by the Antarctic Treaty System ([12]).

2.1.2. *Provider countries must be a Party to the Protocol and have established access measures on genetic resources for them to be in the scope of the Regulation*

The Regulation only applies to genetic resources from provider countries which are Parties to the Nagoya Protocol and have established applicable access measures ([13]).

In accordance with its Article 2(4), the Regulation applies to genetic resources and traditional knowledge associated with genetic resources to which access measures (applicable ABS legislation or regulatory requirements) apply, and where such measures were established by a country which is Party to the Nagoya Protocol.

A provider country may choose to only establish access measures applicable to *certain* genetic resources and/or resources from *certain* geographic regions. In such cases the utilisation of *other* genetic resources from that country would not trigger any obligations from the Regulation. The measures thus must apply to the specific genetic resource (or associated traditional knowledge) in question, for the Regulation to cover the utilisation of that resource.

Certain types of *activities* – for example, research under specific cooperation programmes – may also be excluded from a given country's access legislation, and in that case such activities would not trigger obligations under the EU ABS Regulation.

([12]) http://www.ats.aq

([13]) 'Access measures' includes measures established by a country following ratification of, or accession to, the Nagoya Protocol, as well as measures which have existed in the country before the Protocol's ratification.

One of the key ABS principles as stated in Article 15(2) of the CBD and further elaborated in Article 6(3) of the Nagoya Protocol is that Parties should facilitate access to genetic resources for environmentally sound uses by other Contracting Parties. For effective access and benefit-sharing, users need legal certainty and clarity when accessing genetic resources. In accordance with Article 14(2) of the Nagoya Protocol, Parties are obliged to put their legislative, administrative or policy measures on ABS on the ABS Clearing-House. This makes it easier for users and the competent authorities in jurisdictions where the genetic resources are utilised to get information on provider country rules. Accordingly, information on both elements: (a) whether a country is a Party to the Nagoya Protocol; and (b) whether the country has access measures in place, can be searched on the ABS Clearing-House (see also below 3.2), the main mechanism under the Protocol for sharing information related to access and benefit-sharing, by searching the country profiles underhttps://absch.cbd.int/countries

In summary, with regard to the Regulation's geographic scope as regards the provenance of genetic resources, the combined effect of Article 2(1) and 2(4) is that the Regulation only applies to genetic resources over which the countries exercise sovereign rights and where access and benefit-sharing measures have been established by a Party to the Protocol, with those measures applying to the specific genetic resource (or associated traditional knowledge) in question. When these criteria are not met, the Regulation does not apply.

2.1.3. *Indirect acquisition of genetic resources*

In cases where genetic resources are obtained indirectly, through an intermediary such as a culture collection or other specialised companies or organisations with a similar function, the user should ensure that prior informed consent was obtained and mutually agreed terms were established by the intermediary when the resources were originally accessed ([14]). Depending on the conditions under which the intermediary accessed the genetic resources, the user may need to obtain new PIC and conclude a new MAT or modify the existing ones, if the intended use is not covered by the PIC and MAT obtained and relied upon by the intermediary. The conditions are originally agreed between the intermediary and the provider country, and hence the intermediaries are best placed to inform the user about the legal status of the material they hold.

The above presupposes, of course, that the genetic resource in question falls within the scope of the Regulation and thus that the material was accessed by the intermediary from the provider country after the entry into force of the Protocol (see below, 2.2). By contrast, it does not matter where the intermediary is located (in a Party to the Protocol or not), as long as the provider country of the resource in question is a Party.

A particular way of indirectly accessing genetic resources is through *ex-situ* collections in the country of origin of these genetic resources (whether in the EU or elsewhere). If the country in question has in place access rules for such genetic resources and if they are *accessed* from the collection after the entry into force of the Protocol, this falls within the scope of the Regulation, regardless of when the resources were *collected*.

2.1.4. *Alien and invasive alien species*

The guidance offered here refers to **alien species** ([15]) and **invasive alien species** ([16]) as defined under the EU Regulation on the prevention and management of the introduction and spread of invasive alien species (Regulation (EU) No 1143/2014 of the European Parliament and of the Council ([17])). The guidance thus includes species, subspecies and 'lower taxa' such as varieties, races and strains. The exclusions specified in Article 2(2) of Regulation (EU) No 1143/2014 are covered by the provisions of the EU ABS Regulation, if all the relevant conditions apply ([18]).

([14]) Consult Section 3.7 with regard to genetic resources obtained from registered collections.

([15]) 'Any live specimen of a species, subspecies or lower taxon of animals, plants, fungi or micro-organisms introduced outside its natural range; it includes any part, gametes, seeds, eggs or propagules of such species, as well as any hybrids, varieties or breeds that might survive and subsequently reproduce' (Article 3).

([16]) 'Alien species whose introduction or spread has been found to threaten or adversely impact upon biodiversity and related ecosystem services' (Article 3).

([17]) OJ L 317, 4.11.2014, p. 35.

([18]) Regulation (EU) No1143/2014 paragraph 2(2) excludes from its applicability the following cases: '(a) species changing their natural range without human intervention, in response to changing ecological conditions and climate change; (b) genetically modified organisms as defined in point 2 of Article 2 of Directive 2001/18/EC; (c) pathogens that cause animal diseases; for the purpose of this Regulation, animal disease means the occurrence of infections and infestations in animals, caused by one or more pathogens transmissible to animals or to humans; (d) harmful organisms listed in Annex I or Annex II to Directive 2000/29/EC, and harmful organisms for which measures have been adopted in accordance with Article 16(3) of that Directive; (e) species listed in Annex IV to Regulation (EC) No 708/2007 when used in aquaculture; (f) micro-organisms manufactured or imported for use in plant protection products already authorised or for which an assessment is ongoing under Regulation (EC) No 1107/2009; or (g) micro-organisms manufactured or imported for use in biocidal products already authorised or for which an assessment is ongoing under Regulation (EU) No 528/2012'.

Like Regulation (EU) No 1143/2014, the EU ABS Regulation applies to alien species whether or not they may become invasive, and to both alien species which are introduced to the environment intentionally and those introduced unintentionally. Many introductions are unintentional, and involve organisms carried accidentally on transport systems (e. g. in ballast water or as stowaways) or as contaminants within cargoes (as in the case of the New Zealand flatworm, which was probably accidentally introduced in plant pots). A special case is the ingress through man-made corridors (such as the Lessepsian migrants – marine species in the Mediterranean – through the Suez Canal). Other alien species are deliberately introduced into the EU aimed to improve agriculture, horticulture, forestry, aquaculture, hunting/fisheries, landscape, or for other human use. For example, water hyacinth and the waterweed *Elodea nuttallii* have been introduced for ornamental value, the Asian ladybeetle *Harmonia axyridis* for biological control of pests, the raccoon *Procyon lotor* and the pond slider *Trachemys scripta* as pets, and the American mink for fur-farming.

Some alien species spread naturally from one country where they have been introduced to other adjacent countries (sometimes known as secondary dispersal); these are still alien species in these countries.

Alien species once established (i.e. self-sustaining in the wild) are considered as occurring in *in-situ* conditions in the country to which they are not native and into which they have been introduced or spread from another country. Since organisms are established *in situ* they can be understood as falling under sovereign rights of the country where they are established despite the alien status of the taxon within that country. Consequently, the country where access from *in situ* conditions takes place is the country whose rules should be followed. If that country has enacted access legislation applicable to such species and other conditions for applicability of the EU ABS Regulation are met, utilisation of such genetic resources is in scope of the EU ABS Regulation.

— ***Research on an alien species established in the country where specimens were collected***

Specimens of the stone moroko, Pseudorasbora parva*, a fish native to Asia which is now propagating itself in many EU countries after introduction and spreading, e.g. from fish farms in Europe, are collected in an EU country with applicable access legislation. Specimens are collected for research into genetic traits associated with the species' ability to invade new habitats. Although the fish is not native to the EU country, the population is breeding there and has therefore become established. The specimens fall under the sovereign rights of the EU country and its ABS requirements apply. Since the research constitutes utilisation in the meaning of the Regulation, such research is in scope of the EU ABS Regulation.*

2.1.5. *Provider country of released biocontrol organisms*

Certain organisms, such as biocontrol organisms, adapt quickly to a new environment. A biological control agent introduced into a new area may have been obtained from a laboratory, collected in the country of origin or in a country where it had already been successfully introduced or where it has spread by itself. Similarly to the case of alien species described in Section 2.1.4, once such organisms are established in the country where they were released, they fall under its sovereign rights and that country should be treated as the provider country for the purposes of the EU ABS Regulation.

— ***Provider country of biocontrol organisms***

A biocontrol agent is developed from organisms accessed in country A and is subsequently marketed by a company in Country B; country A is the provider country for the development of the agent.

The biocontrol agent becomes established in Country B. Country B should be treated as the provider country for the purpose of any other products developed on the basis of organisms (which have spread from the original biocontrol agent introduction).

2.1.6. *Non-Parties*

ABS legislation or regulatory requirements are known to exist also in countries which are not (or not yet) Parties to the Nagoya Protocol ([19]). Utilisation of genetic resources from those countries is outside of the scope of the EU ABS Regulation. However, users of such resources should comply with national legislation or regulatory requirements of such a country and respect any mutually agreed terms entered into.

([19]) For an updated list of Parties, see https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml or https://absch.cbd.int

2.2. **Temporal scope: the genetic resource must be accessed and utilised as of 12 October 2014**

The EU ABS Regulation applies from 12 October 2014, which is the date when the Nagoya Protocol entered into force for the Union. Genetic resources *accessed* prior to that date fall outside the scope of the Regulation even if *utilisation* of those resources occurs after 12 October 2014 (see Article 2(1) of the Regulation). In other words, the Regulation only applies to genetic resources which were accessed as of 12 October 2014.

— An EU-based research institute obtains microbial genetic resources from a collection located in Germany in 2015. In 1997, the collection obtained the genetic resources in question from a provider country ([20]), which later became a Party to the Nagoya Protocol. These genetic resources are not covered by the obligations of the EU ABS Regulation. However, the user might be subject to contractual obligations first entered into and then passed on by the collection. This should be verified when obtaining the material from the collection.

There may be cases where access to the genetic resources and research and development on such material (i.e. utilisation – see below, 2.3.3) took place prior to the entry into force of the Protocol, but such genetic resources are further accessed after October 2014 to include in the product so developed or in other products. Although access to such genetic resources continues afterwards, if no further research and development is carried out on them, this would be outside of the scope of the Regulation.

— A cosmetic product (e.g. a face cream) marketed in the EU was developed based on genetic resources obtained from a country prior to the Protocol's entry into force. The genetic resources present in the formula of the cream are regularly obtained from that country, including after the time when it became a Party to the Nagoya Protocol and established an access regime. Since no research and development activities are carried out on those genetic resources, this case does not fall within the scope of the Regulation.

Another case concerns a situation where utilisation commenced before 12 October 2014 and extended to after that date with no further access of genetic resources from the provider country. Such activity is also not in scope of the EU ABS Regulation because access took place prior to 12 October 2014. If, at a later date, further samples of the genetic resource were accessed from the provider country then the ongoing research on those further samples would fall within the temporal scope of the EU ABS Regulation. However, any utilisation of the samples obtained before 12 October 2014 would still not fall under the EU ABS Regulation.

An additional clarification may be useful with regard to the dates of entry into application of the EU ABS Regulation. While the Regulation as a whole entered into application on 12 October 2014, Articles 4, 7 and 9 became applicable only one year later. Users are thus bound by the provisions of those Articles as of October 2015, but the obligations in principle still concern all genetic resources accessed after 12 October 2014. In other words, while there is no particular distinction between genetic resources accessed before or after October 2015, the legal obligations on the user are different: until October 2015 Article 4 was not applicable, and hence the user was not under obligation to exercise due diligence (see below, 3.1). This obligation became applicable in October 2015, and since then all the Regulation's provisions apply to all the genetic resources covered by it.

Some Parties to the Nagoya Protocol may have put in place national rules that apply also to genetic resources accessed before its entry into force. Utilisation of those genetic resources would be outside the scope of the EU ABS Regulation. However, national legislation or regulatory requirements of the provider country still apply and any mutually agreed terms entered into should be respected, even if not covered by the EU ABS Regulation.

2.3. **Material scope**

The Regulation applies to the utilisation of genetic resources and of traditional knowledge associated with genetic resources. All three aspects are addressed in this section, in general and with regard to certain specific constellations.

([20]) With regard to genetic resources from the country of origin of those genetic resources obtained through a collection, consult Section 2.1.3.

2.3.1. *Genetic resources*

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

2.3.1.1. Genetic resources governed by specialised international instruments and other international agreements

In accordance with Article 4(4) of the Nagoya Protocol, specialised ABS instruments prevail in respect of the specific genetic resource covered by the specialised instrument and for the purpose of that instrument, if it is consistent with and does not run counter to the objectives of the CBD and the Protocol. Accordingly, Article 2(2) of the EU ABS Regulation makes it clear that the Regulation does not apply to genetic resources for which access and benefit-sharing is governed by such specialised international instruments. This currently includes material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) ([21]) and the WHO's Pandemic Influenza Preparedness (PIP) Framework ([22]).

However, the EU ABS Regulation does apply to genetic resources covered by the ITPGRFA and the PIP Framework, if they are accessed in a country that is not a Party to those agreements but is a Party to the Nagoya Protocol ([23]). The Regulation also applies where resources covered by such specialised instruments are utilised for purposes other than those of the specialised instrument in question (e.g. if a food crop covered by the ITPGRFA is utilised for pharmaceutical purposes). For more detailed information about different scenarios that apply to obtaining and utilising plant genetic resources for food and agriculture, depending on whether the country where such resources are accessed is a Party to the Nagoya Protocol and/or to the ITPGRFA, and depending on the type of use, see Section 5.2 of this document.

2.3.1.2. Human genetic resources

Human genetic resources are out of scope of the Regulation because they are not covered by the CBD and the Protocol. This is confirmed by CBD COP Decision II/11 (para. 2) and CBD COP Decision X/1 (para. 5, specifically for ABS) ([24]).

2.3.1.3. Genetic resources as traded commodities

Trade and exchange of genetic resources as commodities (such as agricultural, fisheries or forestry products – whether for direct consumption or as ingredients, e.g. in food and drink products) fall outside the scope of the Regulation. The Protocol does not regulate issues related to trade, but is applicable only to *utilisation* of genetic resources. As long as there is no research and development on genetic resources (thus no utilisation in the sense of the Protocol – see Section 2.3.3 below), the EU ABS Regulation does not apply.

However, if and when research and development is carried out on genetic resources which originally entered the EU as commodities, the intended use has changed and such new use falls within the scope of the EU ABS Regulation (provided the other conditions for application of the Regulation are also met). For example, if an orange placed on the EU market is used for consumption, this is outside of the scope of the Regulation. However, if the same orange is subject to research and development (e.g. a substance is isolated from it and incorporated into a new product), this would fall under the rules of the EU ABS Regulation ([25]).

([21]) http://www.planttreaty.org/

([22]) http://www.who.int/influenza/pip/en/

([23]) As noted at the beginning of Section 2, the conditions for applicability of the Regulation are cumulative. The statement 'the Regulation applies' therefore implies that, in addition to the specific condition in question, all other conditions for applicability of the Regulation are also fulfilled – i.e. the genetic resources were accessed in a Party to the Protocol which has in place relevant access measures, they are accessed after October 2014, and the genetic resources are not covered by specialised international ABS regime (which in the circumstances described above is the case due to the fact that the provider country is not a party to such specialised agreement); furthermore they are not human genetic resources.

([24]) See http://www.cbd.int/decision/cop/default.shtml?id=7084 and http://www.cbd.int/decision/cop/default.shtml?id=12267, respectively.

([25]) This is without prejudice to Section 8.4 of Annex II on plant commercial varieties.

In the case of such changes in the use of what was until then considered as a commodity, the user is expected to contact the provider country and clarify whether requirements to obtain prior informed consent and establish mutually agreed terms apply to this utilisation of such genetic resources (and if yes, obtain the necessary permits and establish mutually agreed terms).

If users wish to utilise (in the sense of carrying out research and development) a commodity which is a genetic resource, they might be well advised to access that resource directly from the provider country so that its provenance is clear and the applicability of the Protocol can be clearly established from the outset.

2.3.1.4. Privately held genetic resources

Depending on the access measures of any given provider country, the Regulation may apply to genetic resources from that country which are privately held, for example in private collections. In other words, whether genetic resources are held privately or publicly is not as such relevant in defining the applicability of the Regulation.

2.3.1.5. Pathogenic genetic resources and pests introduced unintentionally to the EU territory

Pathogenic organisms ([26]) and pests can spread in an uncontrolled manner. For example, they may appear together with foodstuffs imported in the EU or traded between Member States, where the intention was to transfer a commodity and not the accompanying pathogenic organisms. Pathogens may also appear together with travelling individuals, where it is also not the intention to distribute the pathogenic organisms (and where furthermore it may be impossible to identify the country of origin of such organisms). This may concern aphids or other pests present on plants or timber imported as commodities, bacteria such as *Campylobacter* present on imported meat, or Ebola viruses carried by travellers or by other individuals (e.g. sick health care workers) that are transferred to an EU Member State for medical treatment. This might also concern contaminant organisms in foods or fermentation products, which can cause loss of consignments if not treated, or health problems were they to be consumed. In all those cases there is clearly no intention of introducing or distributing the harmful organisms as genetic resources. It is therefore considered that the Regulation does not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such are introduced unintentionally to a place in the EU territory, be it from a third country or from a Member State with access legislation in place. This remains the case when such genetic resources are transferred from one EU Member State to another.

The exclusion from scope of the EU ABS Regulation set out in the last paragraph applies on the introduction of organisms when they are utilised following collection from human travellers or imports. Should a pathogen or pest become established *in situ* in an EU country following introduction, they fall under sovereign rights of the country where they are established. If the country has enacted access legislation applicable to such species and other conditions for applicability of the EU ABS Regulation are met, utilisation of such genetic resources is in scope of the EU ABS Regulation. See also text above on alien species (Section 2.1.4).

— A new viral disease of tomatoes, called tomato brown rugose fruit virus, was first observed in the Near East in 2014, and has since been detected in the EU. Virus isolates taken from imported fruits are used for analysis; since the particular organisms isolated originated in another country and are unintentionally introduced any utilisation is out of scope of the EU Regulation.

— Research on the virus also made use of virus isolates from plants growing in EU countries after the virus had established itself in the EU; these isolates from populations established in the EU were compared with those of other countries as well as with related plant viruses. In particular, genetic properties related to spreading and survival of the virus were studied. Since this study involved research into pathogens that had become established in EU countries and were collected in situ there, the relevant ABS regulations of the country where they were accessed apply, and the use of the genetic resource involved (tomato virus) is in scope of the EU ABS Regulation.

([26]) Pathogenicity is co-determined by the pathogen's virulence and the host's immunity, and, in other words, is always conditional.

— A person who recently visited various countries in East Asia reported to a doctor after her return to the EU with severe pneumonia-like symptoms. In hospital the person was diagnosed as suffering from Severe Acute Respiratory Syndrome (SARS). Samples were taken from the patient for further diagnosis and confirmation of the infectious agent. A coronavirus was isolated from these samples. The DNA sequence of the isolate was compared with other SARS-associated coronavirus isolates, and symptoms of the patient were compared with those of other SARS patients showing slightly different symptoms (nature and severity of the symptoms, period over which symptoms remained in relation to differences of the genome sequences of the virussec isolates). All isolates were from patients who contracted the virus outside the EU. Since this study involved research into a pathogen brought into the EU unintentionally, the use of the genetic resource involved (SARS causing coronavirus) is out of scope of the EU ABS Regulation.

2.3.1.6. Associated organisms brought to the EU on an (accessed) genetic resource

Many biological specimens or samples have other organisms associated with them, such as parasites, pests, pathogens, symbionts or its microbiota. An associated organism should be thus understood as any organism residingin or on another one. In some cases, conditions for utilization of associated organisms are specified in PIC and MAT applicable to the genetic resource obtained. In other cases, PIC and MAT for the genetic resource obtained do not contain information concerning the utilization of associated organisms. In the latter situation, such an organism, even when stored in a collection, cannot be considered as introduced unintentionally to the EU territory, since it was brought to the EU together with the deliberately accessed genetic resource. The user is thus advised to contact the provider country and clarify whether requirements to obtain prior informed consent and establish mutually agreed terms apply to the utilisation of such organisms associated with the genetic resources accessed.

In general, users or collections that access genetic resources, and obtain PIC and negotiate MAT for genetic resources, may consider negotiating conditions of access in a manner to address also associated organisms in the PIC and MAT.

Association of organisms can take place at different times, including after the original genetic resource was accessed. Therefore it may not always be possible to determine when and where the association took place (e.g., if the association appeared during the travel or transfer in different countries, or even after being stored in a collection). In these situations it may not be possible to identify the provider country (see also Section 3.3 below).

— Some plants have endosymbiotic bacteria living inside their root cells, helping the plants to grow. A plant is accessed by a research group in a university in the EU under PIC and MAT conditions, which do not address associated material. After its arrival, the research group in the university establishes that the plant contains an endosymbiotic bacterium. The researchers are advised to contact the provider country and clarify whether they need to obtain new or revised PIC and MAT.

— A contaminant organism is discovered and isolated from a microbial strain deposited in a collection. The contaminant could have originated from the country of origin of the primary strain, from the country where the depositor works, or from a country through which it was transported. If the country of origin cannot be traced, the EU ABS Regulation does not prevent the collection from retaining the contaminant strain or making it available for utilisation. As good practice, the collection may inform potential users that the material is of unknown origin.

2.3.1.7. Human microbiota

The term 'human microbiota' is used here to refer to all microorganisms (such as bacteria, fungi, and viruses) residing on or in the human body and 'microbiome' to the collective genomes of those microorganisms (i.e. the collective genetic resources).

The human microbiota comprises more than 10 000 species of bacteria, archaea, fungi, protists and viruses that reside on or within human tissues and biofluids, and in many different organs including the skin. While some of the microbiota is present in human infants at birth, the microbial diversity increases subsequently, to become characteristic (unique) for each individual within the first few years of life. It may change during the lifetime of a human individual, responding to changes in diet, place of residence and proximity to other people; its composition still however remains unique. The microbiota

includes symbiotic species and the microbiome includes genes that are essential for human health and proper physiological functioning. For example, loss or changes in relative proportions of microbiota components (dysbiosis) can be associated with disease, obesity or other negative physical conditions. Some species comprised in the human microbiota may also occur in other species such as in other mammals and in birds, and some may occur as free-living species in the environment.

While associated with human beings and essential for the well-being and survival of the human individual, the human microbiome represents genetic resources of non-human nature. The human microbiota is thus to be considered separate from human genetic resources, since it comprises distinct and different organisms. However, because of the symbiotic interaction between the microbiota and the human body, which results in a unique composition of microbiota in each individual, special conditions apply under the EU ABS Regulation to the use of human microbiota (see next paragraph). Furthermore, additional ethical considerations and legal requirements apply: most legal frameworks and ethical codes of conduct recognize the right of the individual to grant personal consent/permission prior to sampling and studying samples taken from his/her body, and address security of personal information that might be associated with and derived from the composition of the microbiota ([27]).

Recognizing the uniqueness of the human microbiota to each individual and the functionality of the microbiota in human health, the study of the microbiota as such is considered to be out of scope of the EU ABS Regulation. Thus, when the microbiota is studied *in situ* (i.e. in or on the body), given that such studies focus on the microbiota as a whole, the studies are considered to be out of scope of the EU ABS Regulation. The genetic and/or biochemical composition of these human microbial communities may be also studied in samples taken from the body or body products obtained from an individual. When such studies focus on the unique composition of the microbiota from an individual human, for example on its function with respect to that individual, such studies are considered to be out of scope of the Regulation.

However, when research and development activities are carried out on individual taxa isolated from a sample of the human microbiota, this isolate no longer represents the unique microbial composition characteristic of an individual human, and the studies are considered within scope of the EU ABS Regulation. This conclusion stems from the understanding that the identity of the selected isolated taxa under study is not unique to an individual human and can no longer be regarded as representing the unique microbial composition of an individual human microbiota. In this context, it should be noted, however, that mere taxonomic identification of a genetic resource is not considered to constitute research and development in the sense of the Regulation (see Section 2.3.3.1). This also applies to cases of the identification of the individual taxa present in a sample taken from a human microbiota.

—***1. Study on association of gut flora with mental health*** ([28])

The composition of the gut flora was studied in human faecal samples to explore the relationship between the human gut's microbiota and mental health. This study examined faecal matter samples obtained from individuals; it further identified and quantified the taxa present, namely it identified that species in the genera Faecalibacterium *and* Coprococcus *were more common in people who claimed to enjoy a high mental quality of life, while those with depression had lower than average levels of* Coprococcus *and* Dialister *species.*

The initial part of the study, concentrated on examination of the human microbiome as a whole, is considered to be out of scope of the Regulation as the microbiome is specific for and unique to each individual. The further part of the study, which identified species, is also considered to be out of scope of the EU ABS Regulation (since it only regards taxonomic identification).

([27]) These ethical considerations do not preclude a country exerting sovereign rights over the genetic resources contained in the human microbiota, and PIC and MAT may still be required according to national legislation.

([28]) In all five examples in this section, the source of the microbes studied is taken from individual human beings and in accordance with applicable ethical rules and national rules on personal consent.

—***2. Investigation of potential psychobiotics isolated from a human faecal sample***

Following studies associating Faecalibacterium *and* Coprococcus *species with high mental quality of life these taxa were considered as potential leads for psychobiotics – live organisms that, when ingested in adequate amounts, confer health benefits in patients suffering from psychiatric illness. These bacteria were isolated from human faecal material and research was carried out on the biochemical pathways by which this might take place and their efficacy as a treatment. This research and development is considered to constitute utilisation in the meaning of the EU ABS Regulation and hence is within scope of the Regulation.*

—***3. Production of neurotransmitters in human gut biota***

The microbial DNA in human faecal samples was tested for production of neurotransmitters or precursors for substances like dopamine and serotonin. Both chemicals have complex roles in the brain and imbalances have been linked to depression. The presence of these chemicals was found to be high in faecal samples taken from individuals when compared to their expression in bacterial samples taken from the general environment where the individuals were living (i.e. not human faeces). Because the study took place on an unmodified sample from the human microbiota it is considered out of scope of the EU Regulation.

—***4. Testing of* Lactobacillus rhamnosus *strains for use in probiotics***

Colonies of the common gut bacterium Lactobacillus rhamnosus *isolated from samples taken from different human individuals were tested for their abilities to inhibit attachment of* Escherichia coli *to human colon cells. This study was intended to identify the strain with the greatest inhibitory effect to use in a new probiotic to counter diarrhoea. The study of the genetic and biochemical composition of the strain and function of the genes is carried out on individual taxa isolated from human microbiota, and as such it is considered to constitute utilisation in the meaning of the EU ABS Regulation (and hence is in scope of the Regulation).*

Provider country of human microbiota

The provider country of human microbiota is considered to be the country where the microbiota was sampled. An exception is when the microbiota is sampled from an individual immediately on entry from another country where he/she is normally resident; then the provider country is considered to be the country of residence. This is because, other than by pathogenic infection, the composition of the microbiota is unlikely to have changed during a direct journey. An indirect or protracted journey may cause uncertainty about the country which can exercise sovereign rights (for an explanation about situations where the provider country cannot be identified see Section 3.3. below).

—***5. Geographical scope and access***

Faecal samples are sent by various individuals to a laboratory in an EU country as part of a global study on the human microbiota. In the laboratory, individual microbial strains are isolated for research.

The first individual is living in the country where the sample is collected/taken. The country where the sample is taken is considered to be the provider country.

A second individual has travelled directly from another country (where she is resident) to the EU country where the strains will be analysed; the sample is collected as soon as she arrives. In this case the country where the traveller came from is understood to be the provider country.

The second individual has a further sample taken some months after arrival. As time has elapsed since entry and change in microbiotal composition may have taken place, the country where the sample is taken is understood to be the provider country.

If samples are taken from sewage samples there is no direct connection to a human host, and individual microbiomes are more difficult to characterise because of potential contamination. Research and development on the genetic or biochemical composition of microbiota of such samples, for example to assess antibiotic resistance levels in a population, is considered to be in scope of the EU ABS Regulation.

2.3.2. *Traditional knowledge associated with genetic resources*

Traditional knowledge associated with genetic resources can provide a guide to potential uses of the genetic resources. There is no internationally accepted definition of traditional knowledge, but Parties to the Nagoya Protocol which regulate access to traditional knowledge associated with genetic resources may have a domestic definition of traditional knowledge.

In order to ensure flexibility and legal certainty for providers and users, the EU ABS Regulation defines 'traditional knowledge associated with genetic resources' as 'traditional knowledge held by an indigenous or local community that is relevant for utilisation of the genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources' (Article 3(7) of the Regulation).

In order thus to be in scope of the EU ABS Regulation, traditional knowledge associated with genetic resources needs to be related to the utilisation of those resources and it must be covered by the relevant contractual agreements.

2.3.3. *Utilisation*

'Utilisation of genetic resources' is defined in the Regulation, exactly as in the Protocol, as 'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology, as defined in Article 2 of the Convention' (Article 3(5) of the Regulation). This definition is quite broad and covers various activities relevant for many sectors, without providing for a list of specific activities to be covered. Such lists were considered during negotiations on the Nagoya Protocol but were not included in the end, so as not to pre-empt changes in the rapidly evolving knowledge and technology in this domain.

Provider countries may have established different conditions for different types of utilisation in their access legislation, excluding some activities from their scope (see above, 2.1.2). Therefore users need to analyse the applicable access rules of the provider country and assess whether the specific activities they undertake fall under the scope of these rules, keeping in mind they will be the ones applying for prior informed consent and negotiating mutually agreed terms. The following section (*Research and development*) as well as the examples of activities given below (Section 2.3.3.2) are meant to help users to establish whether their activities fall within the scope of the Regulation. This issue is also at the core of Annex II of this document and it could be further addressed in best practices on ABS developed pursuant to Article 8 of the Regulation.

2.3.3.1. Research and development

The terms 'research and development' – which in the context of the Protocol refer to research and development on the genetic and/or biochemical composition of genetic resources – are not defined in the Nagoya Protocol or the EU ABS Regulation, and interpretation of these terms should be based on their ordinary meaning in the context they are used and in the light of the purpose of the Regulation.

The *Oxford Dictionary* definition of 'research' is: 'the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions'.

The OECD's 2002 *Frascati Manual* ([29]) includes basic as well as applied research in the definition of research and development (R & D): 'research and experimental development comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications'.

Many transactions or activities involving genetic resources do not have any elements of research and development, and are hence outside of the scope of the Regulation.

— Given that the mere planting and harvesting of seeds or other reproductive material by a farmer does not involve research and development, this is outside of the Regulation's scope.

([29]) Frascati Manual – Proposed Standard Practice for Surveys on Research and Experimental Development, p. 30.

Additional efforts may be necessary to determine whether a particular scientific activity constitutes utilisation in the sense of the Regulation, and hence falls within its scope. Questions arise in particular with regard to 'upstream' activities, which typically follow closely the access to a genetic resource. The challenge here is not to put any unnecessary burden on activities which frequently also contribute to the conservation of biodiversity and as such are to be encouraged (Article 8 (a) of the Nagoya Protocol), while ensuring the functionality of the ABS system as a whole.

Typically, the results of basic research are published and as such they may become the basis for further applied research with commercial relevance. Researchers involved in basic research may not necessarily be aware of it at that stage, but their findings may still turn out to have commercial relevance at a later stage. Depending on the specific activity undertaken, both basic and applied research may be considered as 'utilisation' in the sense of the Protocol and Regulation. Similarly, various types of scientific institutions can be concerned by the Regulation.

There are nonetheless certain upstream activities which are *related to* (or carried out in support of) research but should not as such be considered 'utilisation' in the meaning of the Regulation – e.g. the maintenance and management of a collection for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance.

Identification of a genetic resource is also to be considered to precede utilisation. Taxonomic identification of biological or genetic material, by morphological or molecular analysis, including through use of DNA sequencing, is not 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 functionality (properties – see also 'litmus test' below). There is no difference whether the taxonomic identification points to a previously named entity or an unnamed entity. Taxonomic studies, where they do not look into genetic properties (functionality), are thus not within scope of the EU ABS Regulation.

Similarly, the mere description of a genetic resource in phenotype-based research such as morphological analysis normally would also not amount to utilisation.

However, if the description or characterisation of a genetic resource is combined with research on that resource, i.e. the research is focussed on discovery or examination of specific genetic and/or biochemical traits, this would qualify as utilisation in terms of the Protocol and the Regulation (see also Section 6.1 of Annex II and examples therein). The definition of utilization of genetic resources, i.e. to conduct research and development on the genetic and/or biochemical composition of genetic resources, is thus understood to apply to research and development on gene function and inheritable traits. As a type of 'litmus test', users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and development and therefore falls under the term 'utilisation'.

2.3.3.2. Examples of activities falling (or not falling) under the Regulation's definition of 'utilisation'

For the reasons mentioned above, an exhaustive list of relevant activities cannot be provided but the following cases may help to illustrate activities that are clearly examples of utilisation and therefore within the scope of the Regulation:

— Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a cosmetic product.

— Breeding programme to create a new plant variety based on landraces or naturally occurring plants.

— Genetic modification – creation of a genetically modified animal, plant, or microorganism containing a gene from another species.

— *Creation* or *improvement* of yeasts, resulting from human action through a research and development process, to be used in manufacturing processes (but see below, example on *application* of biotechnology).

By contrast, the following activities are not utilisation within the meaning of the Regulation and therefore would not fall within its scope:

— Supply and processing of relevant raw materials for subsequent incorporation in a product where the properties of the biochemical compound contained in the genetic resources are already known and therefore no research and development is carried out – such as, for example, supply and processing of Aloe Vera, Shea nut or butter, rose essential oils, etc. for further incorporation into cosmetics.

— Genetic resources *as testing/reference tools:* 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. This may include laboratory animals used to test their reaction to medical products, or laboratory reference material (including reference strains), reagents and samples of proficiency tests or pathogens used for testing the resistance of plant varieties.

— At an earlier stage, however, research and development may have been carried out on those genetic resources, with the aim of turning them into (better) testing or reference tools, and as such would be within the scope of the Regulation.

— Handling and storing of biological material and describing its phenotype.

— The application of biotechnology in a way which does not make the genetic resource in question the object of research and development. For example, the use of yeasts in the brewing of beer, where no research and development is carried out on the yeast, and it is used 'as is' in the process of brewing, is not to be considered as utilisation of that genetic resource.

2.3.4. *Derivatives*

The definition of utilisation in the Protocol and the Regulation applies to 'research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'. Biotechnology, in turn, is defined in the CBD as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' (Article 2, see also Article 2(d) of the Protocol). Thus, through the concept of 'biotechnology', the definition of utilisation is interlinked with the definition of 'derivatives' in Article 2(e) of the Protocol, which clarifies that 'derivative' means 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity'. Examples of derivatives include proteins, lipids, enzymes, RNA and organic compounds such as flavonoids, essential oils or resins from plants. Some such derivatives may no longer contain functional units of heredity. However, as the reference to *naturally occurring* biochemical compounds makes clear, the definition does not cover material such as synthetic gene segments.

Derivatives are referred to in the definition of biotechnology, which in turn is mentioned in the definition of utilisation, but no corresponding reference is to be found in the substantive provisions of the Protocol, including those related to utilisation, which ultimately determine its scope of application. Consequently, access to derivatives is covered by the EU ABS Regulation when it also includes genetic resources for utilisation, e.g. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained or when research and development to be carried out on such derivatives is addressed in mutually agreed terms transferred to the user.

In other words, there needs to be an ascertainable level of continuity between a derivative and the genetic resource from which it was obtained for research and development activities on derivatives to fall in the scope of the EU ABS Regulation.

Such continuity is considered to exist in the following situations:

— The research and development activities conducted using a derivative form part of a research project covering the genetic resource and include obtaining the derivative.

— A user has obtained the derivative or commissioned a third party to obtain the derivative from a genetic resource in a research collaboration or as a specific service (e.g. under a service agreement).

— The derivative is acquired from a third party and it is transferred with PIC and MAT conditions that cover the respective research and development activities using the derivative.

Such continuity does not exist if the derivative is acquired from a third party as a product available on the market and it is transferred without PIC and MAT conditions that cover research and development activities on the derivative. As a consequence any research and development that is merely using derivatives that are traded and obtained as commodities (such as the harvest or waste products of agriculture, forestry, aquaculture and alike, including oils, molasses, starches, and other refinery products, animal by-products such as milk, silk, wool grease, beeswax), without PIC and MAT attached or without any access to a specific genetic resource, would not be considered as being within the scope of the EU ABS Regulation.

— ***Continuity***

1. *Whole plants, plant parts or their seeds (cultivated or wild species) are imported by a fragrance company to the EU (PIC and MAT were obtained, as required); the company extracts and purifies new essential oils by solvent extraction to search for certain new fragrance ingredients. Volatile compounds are purified and identified. Their potential for new fragrance ingredients is evaluated. There is continuity between the genetic resources and the derivatives as the research and development activities conducted using a derivative form part of a project covering the genetic resource and include obtaining the derivative. Therefore, the research on the essential oils in search for potential new fragrance ingredients is in scope of the Regulation.*

2. *EU-based company A requests a service from company B outside of the EU (Party to the Nagoya Protocol) to harvest a plant and obtain specific essential oil from it, which is later on passed to the company A for further research and development. PIC and MAT for the plant was obtained, as required. Although the EU-based company A does not access the genetic resource itself but a derivative thereof, there is a continuum in the activities conducted by both companies, from the access to the genetic resource and the production of the derivative by company B to the further research and development activities performed in the EU by company A. This continuum is evidenced by the specific request placed by Company A on Company B to produce the derivative. In such case, access to the derivative is combined with access to the genetic resource from which it was obtained, and the research and development activities conducted by the fragrance company A constitute utilisation and fall in scope of the EU ABS Regulation.*

3. *A researcher accesses an isolated derivative from a collection in the EU. The derivative was isolated from a genetic resource accessed in a Party to the Protocol with applicable access legislation after 12 October 2014. The collection holds PIC and MAT covering the use of this isolated compound. The researcher uses that compound to do research and development as a part of a project aiming at exploring new natural components with beneficial properties for the growth of hair. Continuum exists since the derivative is acquired from a collection and it is transferred with PIC and MAT conditions that cover the respective research and development activities using the derivative. Therefore, the researcher's activities carried out on the compound fall in scope of the EU ABS Regulation.*

4. *A researcher accesses compounds isolated from microorganisms from a compound library, for which the library does not hold PIC and MAT (hence, the compounds are transferred to the researcher without PIC and MAT). The researcher tests the compounds to establish their potential effectiveness against Parkinson's disease. Since the compounds are acquired without PIC and MAT, no continuity can be established between the compounds and the microorganisms from which they have been extracted. Consequently, the testing and analysis of the compounds does not fall in scope of the EU ABS Regulation.*

5. *A company based in the EU acquires a batch of orange essential oil from an intermediary based outside the EU; the batch of oils is transferred without PIC and MAT applicable to them. The company analyses the composition of the oils to identify known and new chemical structures and to determine their organoleptic (odour, flavour, texture) properties. The analytical data obtained by the EU company guides further research and development towards the creation of a new food flavour. No continuum exists between acquiring the batch of oils extracted (derivatives) and the genetic resources from which they were extracted: when the acquisition of the batch of oils takes place, no PIC and MAT applicable to them is transferred to the buyer. The use of such derivatives falls out of scope of the EU ABS Regulation because no continuum can be ascertained, and they are bought from an intermediary as commodity. Consequently, the investigation and chemical analysis carried out on them fall outside the scope of the EU ABS Regulation.*

ABS legislation or regulatory requirements of provider countries might however be applicable also to derivatives accessed as commodities or otherwise accessed without PIC and MAT conditions being attached. Although utilisation of such derivatives is outside of the scope of the EU ABS Regulation, users of such derivatives should comply with national legislation or regulatory requirements of the provider country.

The Nagoya Protocol and the EU ABS Regulation do not define what 'naturally occurring' means. Some inspiration can be drawn from the Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([30]) (the 'REACH' Regulation), which in its Article 3(39) defines a substance 'which occurs in nature' as 'a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means.' The REACH Regulation acknowledges that not all chemical treatments lead to a change of the compound. The REACH Regulation defines in its Article 3(40) what is 'not chemically modified' as 'a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities'. In analogy with the definition under the REACH Regulation, a naturally occurring compound can be considered a compound of which the chemical structure has not been changed. By consequence, a compound of which the chemical structure has been changed as a result of research and development activities is not considered as naturally occurring and hence not in scope of the EU ABS Regulation.

— ***Chemical modification and chemically-modified compounds***

1. *Pyrethrins represent a type of pesticides naturally occurring in* Pyrethrum *plants. A batch of* Pyrethrum *flowers is obtained by a company wishing to carry out research and development of the pyrethrins contained in the flowers. By conventional processing,* Pyrethrum *flowers are ground and treated with an organic solvent to yield pyrethrum extract or insecticidal essential oils. The main objective of the extraction process is to obtain a light-coloured product, with a high recovery of pyrethrin active ingredients. The resulting product contains derivatives that have not been chemically modified. Thus the use of the derivatives in further research and development falls in scope of the EU ABS Regulation.*

2. *A company wishes to carry out research and development on pyrethroids. Pyrethroids are synthetic chemical insecticides whose chemical structures are adapted from the chemical structures of the pyrethrins and act in a similar manner to pyrethrins. Since pyrethroids are not naturally occurring, any research and development using pyrethroids falls outside the scope of the EU ABS Regulation.*

2.3.5. *Information on genetic resources*

It could be argued that the Protocol deals with access to and utilisation of genetic resources *as such* and therefore does not regulate issues concerning digital information obtained from genetic resources. However, the implications of this distinction are still to be considered by the Parties to the Protocol, in the light of recent technological developments. Without prejudice to the outcome of that consideration, the use of digital data obtained from gene sequencing, which is frequently stored in publicly available databases, could be considered to be out of scope of the ABS Regulation.

In any case, the use or publication of such data might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.

([30]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

2.4. **Personal scope: the regulation applies to all users**

The due diligence obligations stemming from the EU ABS Regulation apply to all users of genetic resources falling within the scope of the Regulation. A user is defined in the Regulation as 'any natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources' (Article 3(4) of the Regulation). This is independent of the users' size or of the intent of the use (commercial or non-commercial). Thus the due diligence obligation applies to individuals, including researchers, and to organisations such as universities or other research organisations, as well as to small and medium sized enterprises and multinational companies, which utilise genetic resources or traditional knowledge associated with genetic resources. In other words, the entities carrying out utilisation activities (researchers or other organisations) have to comply with the due diligence obligations of the EU ABS Regulation as long as all other conditions are fulfilled regardless of their size or whether they are profit or non-profit entities.

A person who only transfers material is not a user in the meaning of the Regulation. Such a person may, however, be subject to contractual obligations entered into when material was accessed and will likely need to provide information to subsequent users to enable the latter to comply with their due diligence obligations (see also the point on genetic resources as traded commodities in Section 2.3.1.3 above).

Similarly, a person or entity which only commercialises products which have been developed based on utilisation of genetic resources or associated traditional knowledge is not a user in the meaning of the Regulation – regardless of where the development of the product took place. Such a person may, however, be subject to contractual obligations entered into when the material was accessed or at the point of change of intent, especially concerning the sharing of benefits ([31]).

2.5. **Geographic scope – II: the regulation applies to utilisation in the EU**

The obligations stemming from the EU ABS Regulation apply to all users of genetic resources (falling within the scope of the Regulation) which utilise genetic resources or traditional knowledge associated with genetic resources *within the EU territory*.

Consequently, the utilisation of the genetic resources outside of the EU falls outside of the scope of the Regulation. If a company commercialises in the EU a product that it has developed through utilisation of genetic resources where the utilisation (thus the *entire* process of research and development) took place outside of the EU, this is not covered by the EU ABS Regulation.

3. **OBLIGATIONS ON THE USER**

3.1. **Due diligence obligation**

The core obligation on users under the Regulation is to 'exercise due diligence to ascertain that the genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with the applicable access and benefit-sharing legislation or regulatory requirements' of the provider countries of these genetic resources, 'and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements' (Article 4(1) of the Regulation).

The concept of 'due diligence' has its origins in business administration, where it is regularly applied in the context of corporate decisions on mergers and acquisitions, for example when evaluating assets and liabilities of a company before deciding on its acquisition ([32]). While the understanding of the concept may vary somewhat, depending on the context in which it is applied, the following elements can be identified as common and are repeatedly cited in relevant studies and in court decisions:

— Due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation. It is about gathering and using information in a systematic way. As such it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts.

([31]) These obligations should best be clarified, for example by means of a contract between the user and the person commercialising the product.

([32]) In European public policy, 'due diligence' is employed also in relation to issues such as international trade in timber (http://ec.europa.eu/environment/forests/timber_regulation.htm) and 'conflict minerals' (*Proposal for a Regulation of the European Parliament and of the Council setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum and tungsten, their ores, and gold originating in conflict-affected and high-risk areas*, COM(2014) 111, 5 March 2014).

— Due diligence goes beyond the mere adoption of rules and measures; it also entails paying attention to their application and enforcement. Inexperience and lack of time have been held by the courts not to be adequate defences.

— Due diligence should be adapted to the circumstances – e.g. greater care should be applied in riskier activities, and new knowledge or technologies may require adaptation of previous practices.

In the particular context of the EU ABS Regulation, compliance with the due diligence obligation should ensure that *the necessary information* related to the genetic resources is available all throughout the value chain in the Union. This, in turn, will enable all users to know of and respect rights and obligations attached to the genetic resources and/or traditional knowledge associated with them.

If a user – no matter at which step in the value chain – takes reasonable measures in the seeking, keeping, transferring and analysing of information the user will be compliant with the due diligence obligation under the EU ABS Regulation. This way the user should also avoid liability vis-à-vis subsequent users, although this aspect is not regulated by the EU ABS Regulation.

As indicated above, due diligence may vary depending on circumstances. Also in the context of ABS implementation, due diligence does not prescribe the same type of measures for all users, even though all users need to be duly diligent, but leaves them some flexibility to take specific measures that work best in their respective context and given their capacities. Associations of users (or other interested parties) may also decide to develop sectorial best practices describing those measures which are considered to work best for them.

As part of their overall due diligence obligation, users also need to be aware that when the intended use of a genetic resource changes, it might be necessary to seek new (or modify the previous) prior informed consent from the provider country and establish mutually agreed terms for the new use. Whenever a genetic resource is transferred, this should be done in accordance with the MAT, which may involve the entry into contract by the transferee.

If a user has exercised due diligence in the sense described above, thus meeting a reasonable standard of care, but it eventually turns out that a specific genetic resource utilised was illegally acquired in a provider country by an earlier actor in the chain, this would not result in a breach by the user of the obligation under Article 4(1) of the Regulation. Nonetheless, if the genetic resource was not accessed in accordance with applicable access legislation, the user is required to obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation, as required by Article 4(5) of the Regulation. This means that in addition to the obligation of conduct as described above, the Regulation also provides for an obligation of result, once it is clear that PIC and MAT should have (but have not) been obtained.

Some Member States may introduce additional ABS-related measures going beyond the due diligence requirements of the EU ABS Regulation, to breaches of which penalties may apply. Users should be aware of such measures to avoid breaching national legislation even while being compliant with the Regulation.

3.2. **Establishing whether the Regulation is applicable**

To determine whether obligations stemming from the Regulation apply to any given genetic resource, a potential user has to establish whether the material in question falls within the scope of the Protocol and of the EU ABS Regulation. This enquiry should be made with diligence and reasonable care. It involves determining whether the provider country of the material is a Party to the Protocol or not. The list of Parties is available on the ABS Clearing House website. If the provider country is on this list, finding out whether it has applicable access and benefit-sharing legislation or regulatory requirements is a logical next step. This can also be checked on the ABS Clearing House (https://absch.cbd.int).

In accordance with Article 14(2) of the Nagoya Protocol, Parties are obliged to put legislative, administrative or policy measures on ABS on the ABS Clearing-House. This makes it easier for users and the competent authorities in jurisdictions where the genetic resources are utilised to get information on provider country rules. Parties to the Protocol are also under the obligation to notify to the ABS Clearing House legislative measures put in place to implement the compliance 'pillar' of

the Protocol (i.e. Articles 15-17). This, in turn, makes it easier for the providers of the genetic resources to get information on the compliance measures in user countries. This way the ABS Clearing House serves as a main point for sharing all information related to the Protocol.

If there is no information about applicable access and benefit-sharing measures on the Clearing House but there are reasons to believe that access legislation or regulatory requirements may nonetheless exist, and in other situations where the potential user considers that it might be useful, contact should be made directly with the provider country's National Focal Point (NFP) designated under the Protocol. If the existence of access measures is confirmed, the NFP should also be in a position to clarify what procedures are required to access genetic resources in the country in question. If despite reasonable attempts to obtain an answer from the NFP there is none, the (potential) users need to decide for themselves whether or not to access or utilise the genetic resources in question. The necessary steps in order to establish the applicability of the EU ABS Regulation are then considered to have been undertaken.

If it is subsequently established that the Regulation actually *is* applicable to genetic resources previously believed to be outside of the scope, and it becomes clear that the genetic resources have not been accessed in accordance with applicable access legislation, the user will be required to obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation. It is therefore recommended to make best efforts when establishing the existence of applicable access legislation. In some cases the user may consider that undertaking steps beyond the ones described above is desirable. Such (additional) efforts would help to ensure that the genetic resources can safely be used further down the value chain, and it will increase their value insofar as downstream users are likely to privilege the utilisation of those genetic resources for which the applicability of the EU ABS Regulation was checked in a thorough way.

There is no need to obtain certificates or written confirmation from competent authorities for genetic resources which fall outside of the scope of the Regulation (most likely for temporal reasons). In particular, certified evidence of being out of scope of the Regulation will not be required when the authorities carry out checks on user compliance. However, during such checks the competent authorities might, based on provisions of administrative law of the Member States, ask for reasons and justifications why certain material is considered to fall outside of the scope of the Regulation. It is therefore advisable to keep evidence and proofs of such reasons and justifications.

3.3. **When it is not possible to identify the provider country**

In some cases, despite best efforts being applied (as explained above, in Section 3.2), the provider country cannot be identified. Examples where this might be the case include (i) genetic resources are confiscated by authorities implementing CITES regulations ([33]) and, although the region from which the genetic resource originated can be determined the exact country of origin cannot; (ii) collection-held genetic resources that originally entered the EU unintentionally as a pathogen on a traveller or a pest on commodities or as non-pathogens by the same routes, and it is impossible to determine whether they were acquired in the country where the traveller or commodities came from or during transfer; (iii) associated organisms on specimens in a collection, the origin of which cannot be discovered; (iv) genetic resources purchased as commodities, for example through the internet, without any indication of their origin. If the country where the genetic resources originated cannot be identified there is no means of determining what if any national legislation or regulation applies. As the EU ABS Regulation does not forbid utilisation of genetic resources of unknown origin, utilisation may take place in such circumstances. However, similarly to situation where the user establishes applicability of the Regulation (Section 3.2), the user needs to be aware that if new information arises that allows the provider country of the genetic resources being utilised to be identified then the provisions of Article 4(5) need to be observed. Likewise, the competent authorities might also (based on provisions of administrative law of the Member States) ask for reasons and justifications why certain material is considered to fall outside of the scope of the Regulation during checks. It is therefore advisable to keep evidence and proofs of such reasons and justifications.

([33]) The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is an international agreement, with the aim of ensuring that international trade in wild animals and plants does not threaten their survival. CITES works by subjecting international trade in specimens of selected species to certain controls. All import, export, re-export and introduction from species covered by the Convention has to be authorized through a licensing system established by national laws of the Parties (here referred to as CITES regulations) (www.cites.org).

3.4. **Carrying out regulatory tasks**

Various public organisations in EU Member States are tasked by their government to carry out research based on law and/or regulations, in particular to monitor food safety, human, animal and plant health, and/or product quality. Depending on the activities undertaken, such work might fall within scope of the EU ABS Regulation.

The fact that the activities are carried out in response to government requests and based on the legally defined mandate of the institution involved, does not determine whether these activities are within the scope of the EU ABS Regulation or not. It is the nature of the research and development that determines whether the activity is within or outside scope. If the activities only involve carrying out identity tests or quality checks of a research product, a commodity or an unidentified organism provided by a third party, such activities do not fall within the scope of the EU ABS Regulation. However, if the activities involve research and development on the genetic or biochemical composition of the genetic resources in question, this would constitute utilisation of the genetic resources and thus fall within the scope of the EU ABS Regulation.

3.5. **Demonstrating due diligence when it has been established that the Regulation is applicable**

For the purpose of demonstrating compliance with the due diligence obligation, Article 4(3) of the Regulation requires users to seek, keep and transfer to subsequent users certain information. There are two ways to demonstrate the due diligence required by Article 4(3).

Firstly, due diligence can be demonstrated with reference to an internationally recognised certificate of compliance (IRCC) which is either issued for the user in question, or the user can rely on it because the particular utilisation is covered by the terms of the IRCC (see Article 4(3)(a) of the Regulation) ([34]). Parties to the Nagoya Protocol that have regulated access to their genetic resources have the obligation to provide an access permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and if they notify that permit to the ABS Clearing House, it becomes an IRCC. Thus a *national* permit of access granted by a Party to the Protocol becomes an *internationally* recognised certificate when it is notified by that Party to the ABS Clearing House (see Article 17(2) of the Protocol). The reference to an IRCC needs to be also complemented by information on the content of the mutually agreed terms relevant for subsequent users, where applicable.

If an IRCC is not available users must seek the information and acquire the relevant documents listed in Article 4(3)(b) of the Regulation. This information is:

— The date and place of access to genetic resources (or associated traditional knowledge),

— The description of the genetic resources (or associated traditional knowledge),

— The source from which the genetic resources (or associated traditional knowledge) were directly obtained,

— The presence or absence of rights and obligations relating to access and benefit-sharing (including rights and obligations regarding subsequent applications and commercialisations),

— Access permits, where applicable,

— Mutually agreed terms, where applicable.

Users need to analyse the information in their possession and be convinced that they comply with legal requirements applicable in the provider country. Users who do not have sufficient information or have doubts about legality of access and/or utilisation must either obtain the missing information or discontinue use (Article 4(5) of the Regulation). For situations where it is not possible to identify a provider country, and hence where use does not need to be discontinued, see Section 3.3.

Users are obliged to retain any information relevant for access and benefit-sharing for a 20 year period after the end of the period of utilisation (Article 4(6) of the Regulation).

([34]) An IRCC may either be issued for a specific user or have more general application, depending on the law and administrative practice of the provider country and the terms agreed.

3.5.1. *Responsibilities of research institutions and of researchers employed*

As a researcher would not be doing the activities if he was not employed by the organisation, the management of the organisation (research institution, university etc.) to which a researcher or student is attached has responsibilities as employer or organisation providing training and oversight for the activities undertaken by its staff and/or on its premises, and may in some circumstances be identified as the user. When research and development activities undertaken by its staff and/or on its premises fall within the scope of the EU ABS Regulation, researchers also need to ensure compliance with the EU ABS Regulation. It is therefore important for the management of such organisations to clearly define responsibilities regarding due diligence obligations within the organisation. The organisations should consider introducing internal rules regarding the responsibilities in relation to the utilisation of genetic resources, and have clear procedures and policies in place. Management of organisations may also instruct its staff who in the organisation is allowed to engage in obtaining a permit (PIC) and negotiating a contract (MAT) and under which conditions, and whether signature of PIC and MAT requires approval of organisation management.

The requirements under the EU ABS Regulation concern not only research and development activities of the organisation staff, but also the actions of visiting scientists and students who may introduce genetic resources of foreign origin, often their home country, for research purposes and carry out research and development within the organisation. The organisation is therefore advised to conclude a formal agreement with the visitor setting out (i) who has the responsibility to ensure that due diligence has been done in regard to the material being utilised; (ii) who has responsibility to submit a due diligence declaration, if required.

3.5.2. *Responsibilities of service requestors and service providers*

It is common practice that research and development activities are carried out by subcontractors, toll manufacturers or service providers (in the following referred to jointly as 'service providers'). Among others, many universities and small and medium-sized enterprises (SMEs) provide specialised services in this regard. Such services may include, for example, DNA and protein sequence determination, DNA or protein synthesis and identification of bioactive compounds and extraction methods. Although such service providers may be carrying out activities that would normally qualify them as users under the EU ABS Regulation, under certain conditions the obligations for due diligence could rest with the entity which is subcontracting the work ('service requestor'). In this regard, reference can be made to the EU Regulations on personal data protection, which use the concept of data controller and data processor, where the data controller continues to assume all legal obligations related to personal data protection with regard to data processed by a service provider.

Thus all activities carried out by service providers potentially falling in scope of the EU ABS Regulation, when performed at request of the service requestor, would not qualify them as users in the meaning of the EU ABS Regulation if the following conditions are met, and are explicitly set out in the service agreement:

(i) The service provider can only perform the activities as listed and specifically described in the service agreement, and is not granted the right to perform any other research and development or exploitation activities on the genetic resources provided or the results obtained by performing the services under the service agreement;

(ii) The service provider has the obligation to return or destroy all material and all information pertaining to the research and development at the end of the service agreement. If a copy is kept for archiving purpose, the entity subcontracting the service will be informed thereof;

(iii) The service provider is not granted any rights on the genetic resources or any proprietary rights related to the results obtained by performing the services under the service agreement;

(iv) The service provider does not have the right to transfer material or information to any third party or another country and has an obligation to keep all information received and generated under the service agreement confidential (including no right to publish); and

(v) The service requestor has the obligation to comply with all obligations under the EU ABS Regulation related to the material provided to the service provider.

If these conditions are met, it is the service requestor that is considered to be the user in the meaning of the EU ABS Regulation.

The service provider receives typically a service fee, which is not to be understood as 'grant' in the meaning of the Implementing Regulation.

— *Genetic resources are imported directly from a provider country by a company based in the EU. The genetic resources are transferred by the EU based company to a service provider based in the EU or elsewhere. The service provider is requested to identify new bioactive compounds for and on behalf of the company. The production of extracts and/or search for active extracts and/or naturally occurring compounds is performed by the service provider. The service requestor specifies the tasks subcontracted and retains all rights in the material and its products. In this case, the service provider acts on behalf of the service requestor and has no ownership or rights on the genetic resources nor the results of the research and development activities. If the service provider and service requestor agree that the due diligence obligations shall remain with the service requestor, the terms of the contractual relationship between the two should then explicitly determine that it is the service requestor that is the legal person who shall fulfil the due diligence obligations. In absence of such agreement, the activities of the service provider do constitute utilisation in the meaning of the EU ABS Regulation, and therefore the service provider, if based in the EU, is required to fulfil the due diligence obligations under the EU ABS Regulation.*

— *If the service provider is based outside the EU, the service requestor should still ensure that Regulation compliance is addressed in the service agreement and, if conditions i-iv above are met, should assume due diligence requirements in the EU. The service provider is subject to the ABS laws and regulations of the country it is based in.*

— *If the service provider is based in the EU and the service requestor outside the EU, subject to conditions (i)-(iv) above being met, the work of the service provider is considered to be out of scope of the EU ABS Regulation.*

3.6. **Obtaining genetic resources from indigenous and local communities**

If genetic resources – and particularly traditional knowledge associated with genetic resources – are obtained from indigenous and local communities, it is best practice for the views and position of the communities holding the genetic resources or traditional knowledge associated with genetic resources to be taken into account and reflected in mutually agreed terms, even if this is not required by the national legislation.

3.7. **Obtaining genetic resources from registered collections**

Where genetic resources are obtained from a collection registered (entirely or partly) under Article 5 of the Regulation, the user is considered to have exercised due diligence as regards the seeking of information as far as resources from (the relevant, registered part of) that collection are concerned. In other words, when material is obtained from a collection which had only part of its samples registered, the presumption of having exercised due diligence as regards the seeking of information applies only if the genetic resource is obtained from the registered part. A collection is advised to keep any genetic resource for which the provider country cannot be identified apart in its unregistered part, using whatever storage or labelling system is appropriate, as distribution of such material would not comply with conditions set up in Article 5(3) b of the EU ABS Regulation.

Being considered to have exercised due diligence as regards the seeking of information means that the user will not be expected to enquire about ('seek') the information listed in Article 4(3) of the Regulation. The obligation to supply the genetic resources together with all the relevant information rests with the holder of the registered collection. However, the duty to keep and transfer this information rests with the user. Similarly, the obligation remains to make a declaration under Article 7(1) of the Regulation, when requested by the Member States and the Commission, or under Article 7(2) of the Regulation (see below, Section 4). In this case, the declaration should be made using the information provided by the collection.

Here again (see Section 3.1), users need to be aware that when the intended use changes, there might be a need to seek new or updated prior informed consent from the provider country and establish mutually agreed terms for the new use, if it is not covered by the PIC and MAT obtained and relied upon by the registered collection.

4. **DIFFERENT EVENTS TRIGGERING DUE DILIGENCE DECLARATIONS**

There are two 'checkpoints' defined in the EU ABS Regulation at which a due diligence declaration is to be submitted by the users of genetic resources. For both checkpoints, the contents of the required declaration are specified in annexes to the Implementing Regulation (Regulation (EU) 2015/1866).

4.1. **Due diligence declaration at the stage of research funding**

The first checkpoint (defined in Article 7(1) of the Regulation) concerns the research stage, when a research project involving utilisation of genetic resources and traditional knowledge associated with genetic resources is subject to external funding in the form of a grant ([35]). The EU ABS Regulation does not make a distinction between public and private funding. Both types of funding for research are covered by the obligation to declare due diligence as provided for in Article 7(1).

The language of Article 7(1) of the Regulation makes it clear that such a declaration needs to be requested by the Member States and the Commission. Given that those requests also need to be applicable to private funding not controlled by public authorities, many Member States envisage implementation of this obligation through legislative or administrative measures at national level, and not necessarily through requests targeted to individual recipients of funding.

The Implementing Regulation clarifies in Article 5(2) the timing for filing such a declaration. The declaration needs to be made after the first instalment of funding has been received and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded project have been obtained, but in any case no later than at the time of the final report (or in absence of such report, at the project's end). Within the period defined in the Implementing Regulation, the Member States' national authorities may further specify the timing. Again, this can be done either in the context of individually targeted requests or by general legal/administrative provisions.

The time of application for the grant or the time of obtaining it has no relevance for whether a due diligence declaration needs to be requested and filed. The only determining factor here is the time of access to the genetic resources (or traditional knowledge associated with genetic resources).

4.2. **Due diligence declaration at the stage of final development of a product**

The second checkpoint at which a due diligence declaration is to be submitted by users is the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with genetic resources. The Implementing Regulation (Article 6) refers to five different instances but also clarifies that the declaration is to be made only once, at the first (i.e. the earliest) event occurring.

Those events include:

(a) Market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

(b) A notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

(c) Placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;

(d) The result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

(e) The utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

The first three of those events concern cases where the users both developed the product and intend to place it on the EU market. In that context they might be searching market approval or authorisation for a product developed via the utilisation of genetic resources, or they might file a notification required prior to placing of such product on the market, or they may just place the product on the market if no market approval, authorisation or notification is required for the product in question.

([35]) According to Article 5(5) of the Implementing Regulation, funding for research – in the context of submitting due diligence declarations at the first checkpoint – is to be understood as 'any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources'. It does not cover internal budgetary resources of private or public entities.

The latter two events (d) and (e) are not directly linked to the placing of a product on the market (or the intention to do so) by the user but they address other relevant situations. More specifically, under scenario (d) a user transfers or sells the result of utilisation to another person (natural or legal) within the Union, and it is the intention of *that person* to place the product on the EU market. Since that person will not be involved in utilisation (research and development) but will only manufacture the product and/or place it on the market, the activities of such a person do not fall within the scope of Regulation, as explained in Section 2.4 above. Therefore, it is for the last user in the value chain (as defined by the Regulation) to file a due diligence declaration.

The definition of the term 'result of the utilisation' (see Article 6(3) of the Implementing Regulation) makes it clear that the user is under the obligation to file a due diligence declaration for the result of utilisation only if the next person in the value chain can manufacture a product based on the result of utilisation and no further utilisation (research and development) takes place. The different actors in the value chain may have to communicate with each other in order to establish who the last user in the value chain is. Such communication might also be required in situations involving changes of intent – for example, when a downstream actor changes plans and decides not to conduct any utilisation activities after all, but places a product containing the genetic resources in question (such as for example shampoo) on the market. In this case the previous actor would need to file a due diligence declaration.

The situation under letter (e) is one where utilisation has ended in the EU. This scenario is different from and more generic than scenario (d). In scenario (e) the outcome of utilisation may allow for manufacturing of the product without further utilisation, or the outcome may be subject to further research and development which, however, takes place outside of the EU. The concept of 'outcome of utilisation' is thus broader than 'result of utilisation'.

— ***Result of the utilisation****: A French company obtains an access permit for the utilisation of plants from an Asian country (which is a Party to the Protocol and has applicable access measures in place). Research is being conducted on the samples obtained. The research is successful and the company identifies a new active ingredient derived from the plant. The material is then transferred, together with all the relevant information defined in Article 4(3) of the Regulation, to a German company where further development on the product takes place. The German company enters into a licence agreement with a Belgian company. That technology transfer does not require any further research and development. The Belgian company makes a notification prior to placing of the product on the EU market for the first time, as required by EU legislation. However, given that the Belgian company does not carry out any research and development and is therefore not a user in the sense of the EU ABS Regulation, it is for the German company to file a due diligence declaration at the checkpoint 'final stage of development of a product'. In this case that stage has been reached when the result of utilisation is sold or transferred to a natural or legal person within the EU (i.e. to the Belgian company) for the purpose of placing a product on the Union market (Article 6(2)(d) of the Implementing Regulation).*

— ***Outcome of utilisation****: A Spanish company obtains an access permit for utilisation of plants from a South American country (which is a Party to the Protocol and has applicable access measures in place). Research is being conducted on the samples obtained. The research is successful and the company identifies a new active ingredient derived from the plant. The material is then transferred, together with all the relevant information defined in Article 4(3) of the Regulation, to a Dutch company where further development on the product takes place. The Dutch company decides not to continue with the development of the product but sells the outcome of their activities to a US company, which may intend to carry out further research and development. The Dutch company files a due diligence declaration at the checkpoint 'final stage of development of a product'. In this case that stage has been reached when the utilisation in the Union has ended and the outcome of utilisation is sold or transferred to a natural or legal person outside of the EU (i.e. to the US company) – regardless of the future activities undertaken by the company outside of the EU (Article 6(2)(e) of the Implementing Regulation).*

Transfers between entities of the same company are not considered as transfer in the meaning of Article 6(2)(d) and 6(2)(e) of the Implementing Regulation, therefore filing of a due diligence declaration is not required.

Publication of scientific papers is also not considered as a sale or transfer of the result or outcome of the utilisation in the meaning of Article 6(2)(d) and 6(2)(e) of the Implementing Regulation and therefore filing of a due diligence declaration is not required. However, the general due diligence obligation may still apply, if all the conditions for applicability of the Regulation are met. In that case the obligation to seek, keep and to transfer relevant information to subsequent actors rests with the author(s) of the scientific paper.

5. SELECTED SECTOR-SPECIFIC ISSUES

While targeted and comprehensive guidance on the utilisation of genetic resources is needed for a range of different sectors, some are facing specific issues closely related to the scope of the Regulation. A few of those issues are addressed in this section.

5.1. Health

Pathogenic organisms that pose a threat to human, animal or plant health are generally within the scope of the Regulation, given that they are covered by the Nagoya Protocol. However, specialised ABS instruments in the meaning of Article 4(4) of the Nagoya Protocol may also be applicable to certain pathogenic organisms. Material which is covered by specialised international instruments for access and benefit-sharing that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol, such as the WHO's Pandemic Influenza Preparedness (PIP) Framework, is outside of the scope of the Protocol and the Regulation (see Article 2(2) of the Regulation and Section 2.3.1.1 above).

More generally, the Protocol explicitly recognises the importance of genetic resources to public health. In the development and implementation of their access and benefit-sharing legislation or regulatory requirements, Parties are required to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health (Article 8 (b) of the Protocol). Expeditious access and benefit sharing should therefore also be aimed at with regard to non-pathogenic genetic resources in emergency situations.

The Regulation gives special status to a pathogenic organism that is determined to be (or is determined likely to be) the causing pathogen of a present or imminent public health emergency of international concern or a serious cross-border threat to health. To these genetic resources an extended deadline for compliance with the due diligence obligation applies (see Article 4(8) of the Regulation).

5.2. Food and agriculture

The special nature of genetic resources for food and agriculture and the need for distinctive solutions related to such resources are widely acknowledged. The Nagoya Protocol recognises the importance of genetic resources to food security and the special nature of agricultural biodiversity. It requires Parties to consider, in the development and implementation of their ABS legislation or regulatory requirements, the importance of genetic resources for food and agriculture and their special role for food security (Article 8(c) of the Protocol). Another particularity of plant and animal breeding is that the end product of the utilisation of genetic resources in those sectors is again a genetic resource.

Genetic resources for food and agriculture might be covered by access rules different from more general ABS rules applicable in a given provider country. The applicable specific ABS legislation or regulations may be found on the ABS Clearing-House. Also, the National Focal Points for the Nagoya Protocol of a provider country can be of assistance here as well.

5.2.1. *Different scenarios concerning plant genetic resources*

There are various scenarios under which plant genetic resources for food and agriculture (PGRFA) can be obtained and utilised, depending on whether the country where genetic resources are accessed is a Party to the Nagoya Protocol and/or to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) ([36]), and depending on the type of use. The overview below describes different situations and explains the applicability of the EU ABS Regulation in each of those situations.

Out of the scope of the EU ABS Regulation ([37]):

— PGRFA covered by Annex I of the ITPGRFA ([38]), included into its multilateral system and obtained from ITPGRFA Parties. Such material is covered by a specialised international instrument for access and benefit-sharing that is consistent with, and does not run counter to, the objectives of the Convention and the Nagoya Protocol (see Article 2 (2) of the Regulation and Section 2.3.1.1 above).

([36]) http://www.planttreaty.org/

([37]) However, the genetic resources are in scope of the EU ABS Regulation if they are utilised for purposes other than research, breeding and/or training for food and agriculture (e.g. if a food crop covered by the ITPGRFA is utilised for pharmaceutical purposes).

([38]) Annex I contains a list of crop species which are covered by the multilateral system of access and benefit-sharing established by that Treaty.

— PGRFA received under a standard material transfer agreement (SMTA) from third persons/entities who themselves received them under an SMTA from the multilateral system of the ITPGRFA.

— Any PGRFA received under an SMTA from International Agricultural Research Centres such as those of the Consultative Group on International Agricultural Research or other international institutions that have signed agreements under Article 15 of the ITPGRFA ([39]). Such material is also covered by a specialised international instrument for access and benefit-sharing (the ITPGRFA) that is consistent with and does not run counter to, the objectives of the Convention and the Nagoya Protocol (see Article 2(2) of the Regulation and Section 2.3.1.1 above).

Within the scope of the EU ABS Regulation but due diligence obligation considered complied with:

— Non-Annex I PGRFA, whether from ITPGRFA Parties or non-Parties, supplied under the terms of the SMTAs. If a Party to the Nagoya Protocol has determined that PGRFA which is under its management and control and in the public domain but not included in Annex I to the ITPGRFA will also be subject to the terms and conditions of the standard material agreements used in the ITPGRFA, a user of such material is considered to have exercised due diligence (see Article 4(4) of the Regulation). Consequently, for this type of material a due diligence declaration is not required.

Within the scope of the EU ABS Regulation – due diligence needs to be demonstrated:

— Annex I PGRFA from countries, which are Parties to the Nagoya Protocol but not to the ITPGRFA, and where access regimes apply to the PGRFA in question;

— Non-Annex I PGRFA from Parties to the Nagoya Protocol, whether or not they are also Parties to the ITPGRFA, where national access regimes apply to such PGRFA and they are not subject to SMTAs for the purposes set out under the ITPGRFA;

— Any PGRFA (including Annex I material) used for purposes other than those set out in the ITPGRFA from a Party to the Nagoya Protocol with applicable national access legislation.

— ***PGRFA covered by the multilateral system (MLS) of the ITPGRFA and found in in-situ conditions in Parties to the ITPGRFA***

Some users seek access by collecting genetic resources from the wild (e.g. crop wild relatives) or from farmers' fields (variously called farmers' varieties or landraces). These genetic resources may be utilised in breeding programmes to introduce useful traits in commercial breeding materials.

For PGRFA covered by the MLS and found in in situ *conditions in countries that are Parties to the ITPGRFA, Article 12.3.h of the Plant Treaty is applicable. This article states that access to plant genetic resources for food and agriculture found in* in situ *conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body of the ITPGRFA. Until the ITPGRFA has agreed an access policy for genetic resources belonging to crops listed in Annex I and found in* in situ *conditions, these need to be accessed and utilised according to national legislation of the provider country, and will fall within the scope of the EU ABS Regulation, if accessed from a country that is a Party to the Nagoya Protocol and such country has established access legislation applicable to such genetic resources.*

([39]) http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview

— ***Change of use of a genetic resource accessed under the ITPGRFA***

After accessing genetic resources under the terms and conditions of the SMTA, which provides access for the purpose of research, breeding and training for food and agriculture, a change in intent may occur, and the accessed genetic resource may be utilised in the framework of a research and development programme resulting in a product for chemical, pharmaceutical and/or other non-food/feed use.

Such use does not fall in scope of the ITPGRFA, also the SMTA does not allow the utilisation for non-food or non-feed purposes. The new utilisation of the genetic resource falls thus within the scope of the EU ABS Regulation in cases where the other conditions of the EU ABS Regulation are met.

5.2.2. *Plant breeders' rights*

The International Union for the Protection of New Varieties of Plants (UPOV) ([40]) and Council Regulation (EC) No 2100/94 on Community Plant Variety Rights ([41])provide for the possibility to obtain plant variety rights. These are a special type of intellectual property rights in the context of plant breeding. There are some limitations to the effects of plant variety rights, inter alia, they do not extend to (a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes; and (c) acts done for the purpose of breeding, or discovering and developing other varieties (Article 15 of Regulation (EC) No 2100/94, corresponding to Article 15(1) of the UPOV Convention). Point (c) is known as the 'breeders' exemption'.

The UPOV Convention does not constitute a specialised ABS instrument in the meaning of Article 4(4) of the Protocol. However, the Nagoya Protocol makes it clear – and the EU ABS Regulation confirms this (see Recital 14) – that it should be implemented in a manner which is mutually supportive with other international agreements, provided they are supportive of and do not run counter the objectives of the Convention on Biological Diversity and the Nagoya Protocol. Furthermore, Article 4(1) of the Protocol provides that it does not affect the rights and obligations derived from existing international agreements (if they do not pose a serious damage or threat to biological diversity).

The EU ABS Regulation is respectful of UPOV obligations: the compliance with the duties stemming from the Regulation does not conflict with the UPOV obligation to provide for the breeders exemption. In other words, the duty to apply due diligence is not in conflict with the ongoing use of material protected under the UPOV plant breeders' rights regime and coming from Parties to UPOV (see also Annex II, Section 8.4).

([40]) http://upov.int As of October 2015, the EU and 24 of its Member States are UPOV Members.
([41]) OJ L 227, 1.9.1994, p. 1.

LIST OF ABBREVIATIONS

ABS –	Access and benefit-sharing
CBD –	Convention on Biological Diversity
CITES –	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP –	Conference of the Parties
DNA –	Deoxyribonucleic acid
FAO –	Food and Agriculture Organisation
IRCC –	Internationally recognised certificate of compliance
ITPGRFA –	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT –	Mutually agreed terms
NFP –	National Focal Point
OECD –	Organisation for Economic Cooperation and Development
PGRFA –	Plant genetic resources for food and agriculture
PIC –	Prior informed consent
PIP –	Pandemic Influenza Preparedness
RNA –	Ribonucleic acid
SMTA –	Standard material transfer agreement
UPOV –	International Union for the Protection of New Varieties of Plants
WHO –	World Health Organisation

ANNEX I

OVERVIEW OF CONDITIONS FOR APPLICABILITY OF THE EU ABS REGULATION

		Within scope (cumulative conditions (*))	Outside of scope
Geographic scope (provenance of GR (**))	*Access in …*	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is …	Party to the Nagoya Protocol	Not a Party to the Protocol
	Provider country has …	Applicable access legislation	No applicable access legislation
Temporal scope	*Access …*	On or after 12 October 2014	Before 12 October 2014
Material scope	*Genetic resources*	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument
		Non-human	Human
		Obtained as commodities but subsequently subject to R & D	Used as commodities
	Utilisation	R & D on genetic and/or biochemical composition	No such R & D
Personal scope		Natural or legal persons utilising GR	Persons *only* transferring GR or commercialising products based on it
Geographic scope (utilisation)	*R & D …*	Within the EU	*Exclusively* outside of the EU

(*) To be within the scope, all conditions must be fulfilled.
(**) GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.

ANNEX II

SPECIFIC GUIDANCE ON THE CONCEPT OF UTILISATION

TABLE OF CONTENTS

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.

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.

([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.

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 Article 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.

[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.

(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 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.

[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.

(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-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]) 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.

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. **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.

([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.

([6]) 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.

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 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 Article 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 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).

(7) 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) 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.*

(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.

([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.

(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.

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

([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.

([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.

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.

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.

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 (Commission Directives 2008/62/EC ([12]) and 2009/145/EC ([13]) 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 ([14]), 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 Council Regulation (EC) No 2100/94 ([15]) or in accordance with national provisions ([16]);

(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. ([17]) 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 declaration under Article 7(2) of the Regulation prior to the registration of such a variety or its placing on the market ([18]).

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.

([11]) See Articles 3 and 4 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).

([12]) OJ L 162, 21.6.2008, p. 13.

([13]) OJ L 312, 27.11.2009, p. 44

([14]) See Article 16 of Council Directive 2002/53/EC (OJ L 193, 20.7.2002, p. 1) on the common catalogue of varieties of agricultural plant species, and Article 6 of Council Directive 2002/55/EC (OJ L 193, 20.7.2002, p. 33) on the marketing of vegetable seeds, Article 17 of Council Directive 2008/90/EC (OJ L 267, 8.10.2008, p. 8) on the marketing of fruits

([15]) OJ L 227, 1.9.1994, p. 1.

([16]) 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.

([17]) For an overview of the conditions, please consult Annex I of this document.

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

Furthermore, when a new variety is protected by a plant variety right according to the UPOV Convention, including under Regulation (EC) No 2100/94 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 ([19]) 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

A plant breeder accesses a crop wild relative in situ *or a landrace or farmer's variety* ([20]) *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 ([21]) 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.

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

([20]) 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.

([21]) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

Article 2 of Council Directive 1999/105/EC ([22]), recognises the following four categories of forest reproductive material: (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 ([23]); (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 ([24]); (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 at the individual level, and which meets the requirements set out in Annex IV of the Directive ([25]) – 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 ([26]). 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 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

([22]) 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'.

([23]) In short, the location where the material has been collected must be stated.

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

([25]) Requirements are set for seed orchards, parents of family, clones and clonal mixtures.

([26]) 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.

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 ([27]).

Regulation (EU) 2016/1012 of the European Parliament and of the Council ([28]) 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.

1. The purebred breeding animal is entered in a breeding book ([29]) of an officially EU recognized breeding society, according to Regulation (EU) 2016/1012. When mating ([30]) (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

([27]) See Regulation (EU) 2016/429 of the European Parliament and of the Council (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 (OJ L 84, 31.3.2016, p. 1)

([28]) OJ L 171, 29.6.2016, p. 66.

([29]) 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.

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

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.

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** ([31])

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.

([31]) 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 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.

(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** ([32])

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. 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.

([32]) 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.

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 licensing) 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 licensing (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** ([33])

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.

([33]) 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.

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).

(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
	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
	Investigating a Ginseng variety accessed together with traditional knowledge	9.1. Product development, processing 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

Sector	Case	Section
	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
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

Sector	Case	Section
	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
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