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Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union

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

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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 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council[2] 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

[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

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.

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

[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.

[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.

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).

[9] Some articles, namely Article 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].

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

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.

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 under https://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

[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.

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). The guidance thus includes species, subspecies and 'lower taxa' such as varieties, races and strains. The exclusions specified in Article 2(2) of Regulation 1143/2014 are covered by the provisions of the EU ABS Regulation, if all the relevant conditions apply[17].

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

[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] Regulation 1143/2014 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 528/2".

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[18]. 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.

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[19], 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.

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

[19] With regard to genetic resources from the country of origin of those genetic resources obtained through a collection, consult section 2.1.3.

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.

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)[20] and the WHO's Pandemic Influenza Preparedness (PIP) Framework[21].

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[22]. 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)[23].

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[24].

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[20] http://www.planttreaty.org/

[21] http://www.who.int/influenza/pip/en/

[22] 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.

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

[24] 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[25] 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

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

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.

→ 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 residing in 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[26].

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[27]
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).

→ 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*

[26] 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.
[27] 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.

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*[28] 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.*

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

[28] Frascati Manual — Proposed Standard Practice for Surveys on Research and Experimental Development, p. 30.

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 (the 'REACH' Regulation)[29], 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

[29] 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.

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.

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[30].

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[31]. 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:

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

[31] 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 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.

- 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 [32] 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.

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

[32] 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).

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)[33]. 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

[33] 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.

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).

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[34]. 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;

[34] 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.

(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.

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 license 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)[35], 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.

[35] http://www.planttreaty.org/

Out of the scope of the EU ABS Regulation[36]:

- PGRFA covered by Annex I of the ITPGRFA[37], 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).

- 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[38]. 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;

[36] 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).

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

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

– 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.*

→ 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)[39] and Council Regulation (EC) No 2100/94 on Community Plant Variety Rights[40] 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.).

[39] http://upov.int
As of October 2015, the EU and 24 of its Member States are UPOV Members.
[40] 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