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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

(2016/C 313/01)

Table of contents

	<i>Page</i>
1. INTRODUCTION	2
1.1. Overview of the legal framework	2
1.2. Definitions used in this guidance	3
2. SCOPE OF THE REGULATION	3
2.1. Geographic scope — I: the provenance of genetic resources	4
2.2. Temporal scope: the genetic resource must be accessed and utilised as of 12 October 2014	5
2.3. Material scope	6
2.4. Personal scope: the regulation applies to all users	10
2.5. Geographic scope — II: the regulation applies to utilisation in the EU	10
3. OBLIGATIONS ON THE USER	10
3.1. Due diligence obligation	10
3.2. Establishing whether the Regulation is applicable	12
3.3. Demonstrating due diligence when it has been established that the Regulation is applicable	12
3.4. Obtaining genetic resources from indigenous and local communities	13
3.5. Obtaining genetic resources from registered collections	13
4. DIFFERENT EVENTS TRIGGERING DUE DILIGENCE DECLARATIONS	14
4.1. Due diligence declaration at the stage of research funding	14
4.2. Due diligence declaration at the stage of final development of a product	14
5. SELECTED SECTOR-SPECIFIC ISSUES	15
5.1. Health	16
5.2. Food and agriculture	16
Annex I: Overview of conditions for applicability of the EU ABS Regulation	

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. The present guidance document 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⁾.

This guidance document is not legally binding; its sole purpose is to provide information on certain aspects of the relevant EU legislation. It is thus intended to assist citizens, businesses and national authorities in the application of the EU ABS Regulation and the Implementing Regulation. It does not prejudice 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) 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

⁽¹⁾ OJ L 150, 20.5.2014, p. 59.

⁽²⁾ OJ L 275, 20.10.2015, p. 4.

⁽³⁾ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3123&NewSearch=1&NewSearch=1>

⁽⁴⁾ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3396&NewSearch=1&NewSearch=1>

⁽⁵⁾ <https://www.cbd.int/convention/text/>

⁽⁶⁾ <https://www.cbd.int/abs/text/default.shtml>

The Protocol was adopted in Nagoya, Japan, in October 2010 during the tenth Conference of the Parties to the CBD. It entered into force on 12 October 2014, having reached the necessary number of ratifications.

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')⁽¹⁾.

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. 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⁽²⁾.

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 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)⁽³⁾.
- '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).

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 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.

⁽¹⁾ It is possible that PIC and MAT may be issued jointly or in one document.

⁽²⁾ Such as for example internal market rules etc.

⁽³⁾ 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.

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 ⁽¹⁾.

2.1.2. Provider countries must have ratified the Protocol and 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 have ratified the Nagoya Protocol and established applicable access measures ⁽²⁾.

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.

⁽¹⁾ <http://www.ats.aq>

⁽²⁾ '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.

2.1.3. Indirect acquisition of genetic resources

In cases where genetic resources are obtained indirectly, through an intermediary such as a culture collection or other specialised companies or organisations with a similar function, the user should ensure that prior informed consent was obtained and mutually agreed terms were established by the intermediary when the resources were originally accessed⁽¹⁾. Depending on the conditions under which the intermediary accessed the genetic resources, the user may need to obtain new PIC and MAT or modify 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. 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⁽²⁾. 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⁽³⁾, which later became a Party to the Nagoya Protocol. These genetic resources are not covered by the obligations of the 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.

Conversely, there may be cases where access to the genetic resources as well as research and development on such material (i.e. utilisation — see below, 2.3.3) took place exclusively prior to the entry into force of the Protocol. If access to such genetic resources continues afterwards but no research and development is carried out anymore on them, this would be outside of the scope of the Regulation.

→ A cosmetic product (e.g. a face cream) is marketed in the EU that 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.

⁽¹⁾ Consult section 3.4 with regard to genetic resources obtained from *registered* collections.

⁽²⁾ For an updated list of Parties, see <https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml> or <https://www.absch.cbd.int>

⁽³⁾ With regard to genetic resources from the country of origin of those genetic resources obtained through a collection, consult section 2.1.3.

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).

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) ⁽¹⁾ and the WHO's Pandemic Influenza Preparedness (PIP) Framework ⁽²⁾.

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 ⁽³⁾. 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.

⁽¹⁾ <http://planttreaty.org/>

⁽²⁾ <http://www.who.int/influenza/pip/en/>

⁽³⁾ 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.

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) ⁽¹⁾.

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.

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 resources directly from the provider country so that its provenance is clear and the applicability of the Protocol can be clearly established from the outset.

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.

2.3.2. *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.

⁽¹⁾ See <http://www.cbd.int/decision/cop/default.shtml?id=7084> and <http://www.cbd.int/decision/cop/default.shtml?id=12267>, respectively.

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 (p. 8) 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 the Commission's sectorial guidance documents and it could be further addressed in best practices on ABS developed pursuant to Article 8 of the Regulation.

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* ⁽¹⁾ 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.

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 of a genetic resource is combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties, this would qualify as utilisation in terms of the Protocol and the Regulation. As a type of 'litmus test', users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term 'utilisation'.

⁽¹⁾ Frascati Manual — Proposed Standard Practice for Surveys on Research and Experimental Development, p. 30.

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 resources 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.

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 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 when it also includes genetic resources for utilisation, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained. Research and development to be carried out on such derivatives should be addressed in mutually agreed terms that are concluded when accessing the genetic resources themselves. In sum, research and development on derivatives (whether or not containing functional units of heredity) is within scope where they are derived from genetic resources accessed under the Protocol, covered by the required prior informed consent related to genetic resources from which they were derived, and addressed in mutually agreed terms.

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 on p. 6 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 ⁽¹⁾.

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 [...] 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).

⁽¹⁾ These obligations should best be clarified, for example by means of a contract between the user and the person commercialising the product.

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 ⁽¹⁾. While the understanding of the concept may vary somewhat, depending on the context in which it is applied, the following elements can be identified as common and are repeatedly cited in relevant studies and in court decisions:

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

⁽¹⁾ 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).

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 country. 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. 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)⁽¹⁾. Parties to the Nagoya Protocol that have

⁽¹⁾ 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.

regulated access to their genetic resources have the obligation to provide an access permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and if they notify that permit to the ABS Clearing House, it becomes an IRCC. Thus a *national* permit of access granted by a Party to the Protocol becomes an *internationally* recognised certificate when it is notified by that Party to the ABS Clearing House (see Article 17(2) of the Protocol). The reference to an IRCC needs to be also complemented by information on the content of the mutually agreed terms relevant for subsequent users, where applicable.

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

- the date and place of access to genetic resources (or associated traditional knowledge);
- the description of the genetic resources (or associated traditional knowledge);
- the source from which the genetic resources (or associated traditional knowledge) were directly obtained;
- the presence or absence of rights and obligations relating to access and benefit-sharing (including rights and obligations regarding subsequent applications and commercialisations);
- access permits, where applicable;
- mutually agreed terms, where applicable.

Users need to analyse the information in their possession and be convinced that they comply with legal requirements applicable in the provider country. Users who do not have sufficient information or have doubts about legality of access and/or utilisation must either obtain the missing information or discontinue use (Article 4(5) of the Regulation).

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).

3.4. **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.

3.5. **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.

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⁽¹⁾. The EU ABS Regulation does not make a distinction between public and private funding. Both types of funding for research are covered by the obligation to declare due diligence as provided for in Article 7(1).

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

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

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

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

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

Those events include:

- (a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
- (b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
- (c) placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;
- (d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);
- (e) the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

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

⁽¹⁾ According to Article 5(5) of the Implementing Regulation, funding for research — in the context of submitting due diligence declarations at the first checkpoint — is to be understood as 'any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources. It does not cover internal budgetary resources of private or public entities.'

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

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

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

→ **Result of the utilisation:** A French company obtains an access permit for the utilisation of plants from an Asian country (which is a Party to the Protocol and has applicable access measures in place). Research is being conducted on the samples obtained. The research is successful and the company identifies a new active ingredient derived from the plant. The material is then transferred, together with all the relevant information defined in Article 4(3) of the Regulation, to a German company where further development on the product takes place. The German company enters into a 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 above, p. 5).

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). Expedient 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).

5.1.1. *Intentionality of access*

Pathogenic organisms 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 establish the country of origin of such organisms). This may concern aphids or bugs 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. 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.

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) ⁽¹⁾, 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.

⁽¹⁾ <http://www.planttreaty.org/>

Out of the scope of the EU ABS Regulation

- PGRFA covered by Annex I of the ITPGRFA⁽¹⁾, 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 p. 5 above).
- Any PGRFA received under a standard material transfer agreement (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⁽²⁾. Such material is also 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 p. 5 above).

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

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

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

- Annex I PGRFA from countries which are Parties to the Nagoya Protocol but not to the ITPGRFA, and where access regimes apply to the PGRFA in question;
- Non-Annex I PGRFA from Parties to the Nagoya Protocol, whether or not they are also Parties to the ITPGRFA, where national access regimes apply to such PGRFA and they are not subject to SMTAs for the purposes set out under the ITPGRFA;
- Any PGRFA (including Annex I material) used for purposes other than those set out in the ITPGRFA from a Party to the Nagoya Protocol with applicable national access legislation.

5.2.2. Plant breeders' rights

The International Union for the Protection of New Varieties of Plants (UPOV)⁽³⁾ and Council Regulation (EC) No 2100/94 on Community Plant Variety Rights⁽⁴⁾ 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

⁽¹⁾ Annex I contains a list of crop species which are covered by the multilateral system of access and benefit-sharing established by that Treaty.

⁽²⁾ <http://www.planttreaty.org/content/agreements-concluded-under-article-15>

⁽³⁾ <http://upov.int>

As of October 2015, the EU and 24 of its Member States are UPOV Members.

⁽⁴⁾ OJ L 227, 1.9.1994, p. 1.

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.

List of abbreviations

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

ANNEX I

Overview of conditions for applicability of the EU ABS Regulation

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

(*) To be within the scope, *all* conditions must be fulfilled.

(**) GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.