Guidance on the EU Regulation implementing the Nagoya Protocol

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

Guidance on the scope of application and core obligations

date - 2015

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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 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union ("the EU ABS Regulation" or "the Regulation").

Regulation 511/2014 implements in the EU the international rules established in the Nagoya Protocol governing **user compliance** measures – i.e., what users of genetic resources have to do in order to comply with the international rules on access and benefit-sharing (ABS). Rules in the Nagoya Protocol concerning access measures – established by countries providing genetic resources to regulate access to them – are not implemented by the EU ABS Regulation and accordingly are not covered in this guidance document.

1.1. Overview of the legal framework

The three objectives of the **Convention on Biological Diversity** (CBD)[1] are the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Art. 1 CBD). The **Nagoya Protocol** on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity ("the Protocol") to the CBD implements and further specifies Article 15 of the Convention, on access to genetic resources; it also includes in its scope traditional knowledge associated with genetic resources.[2] The Protocol establishes international rules governing access to genetic resources and associated traditional knowledge as well as user compliance measures.

In their implementation of the Protocol regarding **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 provides for clear rules to be established by provider countries – such rules should provide for legal certainty,

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1 https://www.cbd.int/convention/text/

2 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.

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 or traditional knowledge associated with genetic resources (in many cases public authorities of the provider country) and a natural or legal person accessing the genetic resource and/or associated traditional knowledge for their utilisation (a user).

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**.[3] 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.

The ABS Regulation is complemented by Commission **Implementing Regulation** (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices, which entered into force on 9 November 2015.[4]

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.
- **"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.
- **"Traditional knowledge associated with genetic resources"** means traditional knowledge held by an indigenous or local community that is

[3] Official Journal L 150, 20.5.2014, S. 59 (http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32014R0511&qid=1447872540831&rid=1)

[4] Official Journal L 275, 20.10.2015, S. 4 (http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32015R1866&qid=1447872798629&rid=2)

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.[5]

The EU ABS Regulation also provides for a definition of access:

- **"Access"** means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol.

2. The 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. 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 presupposes that all the other conditions for being in the scope are also met.

! It is possible that ABS legislation exists in provider countries, which, in some respect, goes beyond the scope of the EU ABS Regulation. Users of resources from such countries should comply with national legislation of the provider country and any mutually agreed terms entered into, regardless of whether the EU ABS Regulation is applicable or not.

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

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 Article 15(1) of the Convention (and reaffirmed in Article 6(1) of the Protocol), which recognises that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation (where such legislation exists).

[5] 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 implies that the Regulation does not apply to genetic resources obtained from areas beyond national jurisdiction (e.g. from the high seas), or from areas covered by the Antarctic Treaty System.[6]

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**.

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 country may choose to only establish access legislation 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 legislation thus must apply to the specific genetic resource (or associated traditional knowledge) in question for the Regulation to cover the utilisation of that resource.

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 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 ABS legislation 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**, 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, the combined effect of Article 2(1) and 2(4) is that the Regulation only applies to genetic resources over

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6 [explanation Antarctic Treaty]

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. Transition situations

In cases where genetic resources are obtained by the user indirectly, through an intermediate such as a culture collection, the rules of the provider country still apply. It must then be established whether requirements for prior informed consent and mutually agreed terms were met when the resources were originally accessed. This obligation remains even if the material was transferred to a country that is not a Party to the Protocol and obtained from that country by the user. Thus, if the material as such falls within the scope of the Regulation – which presupposes, inter alia, that the material was obtained by the collection after the entry into force of the Protocol (see below, 2.2) – the Regulation applies.[7]

2.1.4. Non-Parties

ABS legislation is known to exist also in countries which are not (or not yet) Parties to the Nagoya Protocol.[8] Utilisation of genetic resources from those countries is outside of the scope of the EU Regulation. However, users of such resources should comply with national legislation of the provider country and any mutually agreed terms entered into.

2.1.5. Indigenous and local communities

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

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[7] 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, such Party has established access legislation, and that the genetic resources are not covered by specialised international ABS regime (nor are they human genetic resources).

[8] For the list of Parties, see https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml.

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.

→ *A research institute obtains microbial genetic resources from a collection in 2015. In 1997, the collection obtained the genetic resources in question from a provider country, which later became a Party to the Nagoya Protocol. The research institute (user) which obtains the genetic resources from the collection in 2015 is not covered by the obligations of the Regulation.*

Conversely, there may be cases where utilisation took place exclusively prior to the entry into force of the Protocol and where access continues afterwards – this would also be outside of scope of the Regulation.

→ *A cosmetic product (e.g., a face cream) is marketed in the EU that was developed based on research and development carried out prior to Protocol's entry into force. The genetic resources present in the formula of the cream are regularly obtained from this state, 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 and they are obtained as commodities (see below, p. 11), this case would not fall within the scope of the Regulation.*

It is also possible that ex-situ collections (in the EU or elsewhere) hold material which originates from and exists in natural habitats in the country where the collection is established. If the country in question establishes access rules for such genetic resources and if such resources are accessed from a collection after the entry into force of the Protocol, this falls within the scope of the Regulation.

! Parties to the Nagoya Protocol may have put in place national rules that apply to genetic resources accessed before its entry into force. Utilisation of those genetic resources would be outside the scope of the EU Regulation. However, users of such

genetic resources should be aware of national legislation of the provider country and any mutually agreed terms entered into.

2.3. Material scope

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" (Art. 3), where "genetic material" means "any material of plant, animal, microbial or other origin containing functional units of heredity" (Art. 2 CBD). "Functional units of heredity" are not defined in the Convention or the Protocol but are generally understood to include genes and DNA.

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 and for the purpose of the specialized instrument if they are consistent with and do not run counter to the objectives of the CBD and the Protocol. In line with this, Article 2(2) of the EU ABS Regulation makes it clear that it 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) and the WHO's Pandemic Influenza Preparedness (PIP) Framework.

However, the EU Regulation would apply to genetic resources covered by 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.

The Regulation would also apply 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 to the ITPGRFA, and depending on the type of use, see section 5.2 of this document.

Human genetic resources

Human genetic resources are **out of scope** of the Regulation because they are not covered by the scope of 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).

Genetic resources as traded commodities

Trade and exchange of genetic resources as commodities (such as agricultural or forestry 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 research and development is carried out on genetic resources which originally entered the EU as commodities, this falls within the scope of the EU ABS Regulation. In that case the user is expected to contact the provider country and obtain prior informed consent and establish mutually agreed terms concerning their utilisation of such genetic resources.

Commodities are distributed from different origins to destinations all around the world. If users wish to utilise a commodity as a genetic resource, they would be well advised to access the genetic 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.

In the case of commodities where it is not possible to obtain all the information required by Article 4(3)(b) of the Regulation, and in particular to establish the provider country, the users should document this fact and provide reasons why it was not possible to obtain such information, and pass this record further in the value chain. If the user was diligent in the attempts to establish the information required under Article 4(3)(b) of the Regulation, such documentation will be considered sufficient for the purpose of fulfilling the due diligence obligation under Article 4(1) of the Regulation.

Privately held genetic resources

Depending on the access legislation of any given provider country, the Regulation may apply to privately held genetic resources from that country.

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 the 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 (see Article 3(7) of the Regulation).

In order thus to be in scope of the EU ABS Regulation the traditional knowledge associated with genetic resources needs to be related to utilisation of genetic 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).

The definition of utilisation provided for in the Protocol and repeated in the Regulation is quite broad and covers many 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. The EU can of course not establish its own interpretation of the term utilisation, in a way that would either widen or limit the definition contained in the Protocol.

Users need to assess whether the specific activities they undertake should be considered as utilisation in the meaning of the Protocol and the Regulation or not, keeping in mind they will be the ones applying for prior informed consent and negotiating mutually agreed terms. Establishing this will form part of the due diligence exercise. The section below (*Research and development)* as well as examples of activities are meant to help users to establish whether the activities carried out fall within the scope of the Regulation. The issue could also be addressed in best practices on ABS developed pursuant to Article 8 of the Regulation.

Research and development

The terms "research and development" 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 in the Protocol and in the light of its purpose.[9]

→ *The purchase of seeds or other reproductive material by a farmer for planting and harvesting purposes does not involve research and development, and hence is outside of the Regulation's scope. The same applies to the purchase of a young bull by a company in order to sell the semen to other breeders.*

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 (Art. 8(a) Nagoya Protocol), while also preventing loopholes at the beginning of the value chain which would endanger the functionality of the ABS system as a whole.

A loophole would open up if basic, non-applied research was excluded from the scope of the Regulation as a general rule, independently of how the results of such research may subsequently be used.[10] Typically, the results of basic research are published and as such they may indeed become the basis for further applied research. 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. In principle, basic and applied research are thus both to be considered as "utilisation" in the sense of the Protocol and Regulation.[11]

Similarly, various types of scientific institutions – including ones which are mostly (or even exclusively) engaged in activities without commercial intent – can be concerned by the Regulation. It would also be wrong to make a distinction between types of funding – public/non-commercial and private/commercial – with regard to applicability of the Regulation. Both types of funding for research are covered by the provisions of Article 7(1), i.e. they trigger the obligation to demonstrate due diligence (see section 4.1 below).

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9 Vienna Convention on the Law of Treaties, Art. 31(1)

10 See also Article 8(a) of the Protocol, when it provides for "taking into account the need to address a change of intent" for research contributing to the conservation and sustainable use of biodiversity.

11 The OECD's 2002 Frascati Manual (Proposed Standard Practice for Surveys on Research and Experimental Development – p. 30) also includes basic as well as applied research in the definition of R&D.

There are still 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 of a collection for conservation purposes, including storage of resources or quality/phytopathology checks and verification of material upon acceptance. The mere description of a genetic resource in phenotype-based research 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 proprieties that may be of actual or potential value, this would qualify as utilisation in terms of the Protocol and the Regulation. In principle, the further an activity is removed from accessing the genetic resources and the further it is situated "downstream" in the value chain, the greater the likelihood that this particular activity would fall within the scope of the Regulation.

As a type of "litmus test", users should ask themselves whether what they are doing with the genetic material is something another user would also need to do if that other user performed the whole process by himself, from the accession of the genetic resource till the final development of a product and putting it on the market. If in this comparison the activity in question seems to be an element of the process that creates new insight into the characteristics (i.e. the actual or potential value) of the genetic material which is of (potential) benefit to the further process, then the activity goes beyond mere description, should be considered research and therefore falls under the term "utilisation".

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

For the reasons mentioned above, an exhaustive list of 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 leading to incorporation of an active biochemical compound isolated from a genetic resources into a new anti-wrinkle beauty cream;
- Genetic modification – creation of a genetically modified animal, plant, or microorganism containing a gene from another species.
- Selection programme to create a new plant variety based on landraces or naturally occurring plants.
- *Creation* or *improvement* of yeasts 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 of relevant raw materials for subsequent incorporation in a product where the properties of the biochemical compound contained in the genetic material are already known and therefore no research and development is carried out (such as for example supply of Aloe Vera, Shea nut, 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 to test their reaction to medical products or laboratory reference material (including reference strains), reagents and samples of proficiency tests or pathogens for testing resistance of plant varieties.

    - At an earlier stage, however, the same genetic resource may itself have been the object of research and development, with the aim of turning it into a (better) testing tool, 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 the object of research and development. For example the use of yeasts in the brewing of beer is not as such to be considered as utilisation of genetic resources, although biotechnology in a broad sense is applied in the beer production process.

Derivatives

The definition of utilisation in the Protocol and the Regulation applies to research and development on **genetic resources** and/or on any **naturally occurring biochemical compounds** contained in the material accessed under the domestic ABS regime, "including through the application of biotechnology". Biotechnology, in turn, is defined as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" in the CBD (Art. 2, see also Art. 2(d) of the Protocol). Thus 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".

Given this definition of the term derivatives in the Protocol, they are to be understood as expressions of the metabolism of biological or genetic resources, rather than products or results of human activities undertaken on genetic resources (such as

chemical compound extracted from genetic resource or synthetic gene segments produced by human manipulation). This understanding is also reflected in the reference to *naturally occurring* biochemical compounds (Article 2(e) – see above). Examples of derivatives include thus proteins, lipids, enzymes, RNA and organic compounds such as flavonoids, essential oils or resins from plants etc.). In some situations those derivatives may no longer contain functional units of heredity.

Derivatives are referred to in the definition of utilisation, but no corresponding reference is to be found in the substantive provisions of the Protocol. While derivatives as such are thus within the scope of the Protocol, ultimately it is the definition of utilisation which determines whether the Protocol and Regulation apply to specific derivatives. Access to derivatives is covered when it also concerns access to genetic resources for their utilisation, i.e. when access to a derivative is combined with access to a genetic resource from which the derivative was obtained. The research and development carried out on naturally occurring biochemical compounds contained in genetic material should be addressed in mutually agreed terms that are concluded when accessing genetic resources. Consequently, 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 prior informed consent related to genetic resources from which they were derived and addressed in mutually agreed terms.

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 organizations such as universities or other research organizations, as well as to small and medium sized enterprises and multinational companies, which utilise genetic resources or traditional knowledge associated with genetic resources.

A person who only **transfers** material will not be 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. 11 above.)

Similarly, a person or entity which *only* **commercialises** products which have been developed based on utilisation of genetic resources or associated traditional

knowledge will not be 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.

2.5. Geographic scope – II: the regulation applies to all users 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 would fall outside of the scope of the Regulation. If a company commercialises in the EU a product developed through utilisation of genetic resources but where the **full** research and development process took place outside of the EU, this would not be covered by the EU ABS Regulation.

→ *A US company develops a product based on genetic resources in the US. The entire research and development process takes place outside of the EU. Consequently such utilisation would not fall within the scope of the 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 (see 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.[12] While understanding of due diligence concept may vary 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 has implications which vary with 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 associated with the genetic resources and/or traditional knowledge associated with them.

If a user takes reasonable measures in the seeking, keeping, transferring and analysing of information, thus applying due diligence, the user will be compliant with the EU ABS Regulation and should avoid liability vis-à-vis subsequent users. The key for an adequate due diligence is therefore obtaining an understanding of the legal aspects of the transaction, and using that knowledge to implement a thorough and tailored investigation. As indicated above, due diligence may vary depending on circumstance. 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 measures that work best in their respective context, and also to develop sectorial best practices.

Users also need to be aware that when the intended use changes, there might be a need 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, it should be done in accordance with the MAT, which may involve the entry into contract by the transferee.

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[12] 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) or in "conflict minerals" ().

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 resources were not 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, 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 which penalties may apply. Users should be aware of such measures to avoid breaching national legislation even while being compliant with the EU 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 material comes from 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 is a logical next step. This can also be checked on the ABS Clearing House (https://absch.cbd.int), which is the main mechanism under the Protocol for sharing information related to access and benefit-sharing. In accordance with Article 14(2) of the Nagoya Protocol, Parties are obliged to put their ABS legislation 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.

If there is no such information on the Clearing House but there are reasons to believe that access legislation 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 legislation 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 subsequently it becomes clear that the genetic resources have not been accessed in accordance with applicable access legislation, as mentioned in the previous section, 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 desired. This 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 will privilege the utilisation of those genetic resources for which the applicability of the EU Regulation was checked in a thorough way.

There is no need for users to obtain certificates or written confirmation from their competent authorities for genetic resources in their possession which fall outside of the scope of the Regulation (most likely for temporal reasons). In other words, 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 can 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

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 due diligence under Article 4(3) of the EU ABS Regulation. 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 its terms (see Article 4(3)(a) of the Regulation). 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-CH, it becomes an IRCC. Thus a national permit of access granted by a Party to the Protocol becomes an IRCC when it is notified by that Party to the ABS Clearing House (see Article 17(2) of the Protocol).

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 of genetic resources (or associated traditional knowledge);
- the description of the genetic resources (or associated traditional knowledge);
- the source where 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 will be obliged to retain any information relevant for access and benefit-sharing for a 20 year period after the end of the period of use (Article 4(6) of the Regulation).

3.4. Obtaining genetic resources from registered collections

Where genetic resources are obtained from a registered collection, the user is considered to have exercised due diligence as regards **the seeking of information**. This means that the user will not be expected to enquire about 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), when requested by the Member States and the Commission, or under Article 7(2). In this case, the declaration should be made using the information provided by the 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.

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. 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 (Regulation (EU) 2015/1866) clarifies in Article 5(2) the timing for filing such a declaration. It 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). The national authorities may further specify the timing. This can be done either in the context of individually targeted request or by general legal/administrative provisions.

4.2. Due diligence declaration at the stage of final development

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 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.

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. This may require that the different actors in the value chain communicate with each other in order to establish who is the last user in the value chain is.

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 but the outcome may also be subject to further research and development which, however, take place outside of the EU. The concept of “outcome of utilisation” is thus broader than “result of utilisation”.

→ *A French company obtains plants from an Asian country (with access legislation 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 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 product-specific 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 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 is reached when the result of utilisation is sold or transferred to a natural or legal person within the EU (i.e. the Belgian company) for the purpose of placing a product on the Union market (Article 5(d) of the Implementing Regulation).*

Publication of scientific papers is not considered as fulfilling the criteria of being sold or transferred in the meaning of Article 6(2)(d) and 6(2)(e) of the Implementing Regulation.

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 sector

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. 10).

More generally, the Protocol recognizes 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).

5.1.1. Intentionality of access

Pathogenic organisms and pests can spread in an uncontrolled manner. For example, they may enter the EU together with imported meat, where the intention was to provide a commodity on the EU market and not the accompanying pathogenic organisms. Pathogens may also enter the EU with travelling individuals, where it is also not the intention to bring the pathogenic organisms into the EU (and where furthermore it may be impossible to establish the country of origin of such organisms). In all those cases there is clearly no intention of bringing such genetic resources to the EU territory.

Where access is not intentional, it is considered that the Regulation does not apply to a pathogenic organism or pest present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such is introduced unintentionally to the EU territory. This may concern, for example, aphids or bugs present on plants or timber imported as commodities to the EU, bacteria such as *Campylobacter* present on imported meat, or Ebola viruses carried by an individual travelling to the EU.

5.2. Genetic resources for 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 recognizes 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)). Furthermore, it needs to be taken into account that in the plant and animal breeding sectors the end product of the utilisation of genetic resources is again a genetic resource.

5.2.1. Different scenarios concerning plant genetic resources

There are various scenarios that apply to obtaining and utilising plant genetic resources for food and agriculture (PGRFA), 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)[13], and depending on the type of use. The overview below describes different situations and the applicability of the EU Regulation in those situations.

Out of scope of the EU Regulation

- Plant genetic resources included in Annex I[14] 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. 10 above).

- Any material from International Agricultural Research Centres (IARCs) such as those of the Consultative Group on International Agricultural Research (CGIAR)[15] and other gene banks which are part of the Multilateral System under the ITPGRFA – such material is not covered by the sovereign rights of any Party (see Section 2.1.1 above).

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

- Non-Annex 1 material, whether from ITPGRFA Parties or non-Parties, supplied under the terms of the standard material transfer agreements (sMTAs), where this is explicitly included in access laws. 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 shall be 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.

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13 http://www.planttreaty.org/

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

15 http://www.planttreaty.org/content/agreements-concluded-under-article-15

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

- Annex 1 PGRFA from countries which are Parties to the Nagoya Protocol but not to the ITPGRFA, and where access regimes apply to PGRFA;
- Non-Annex 1 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.

  Although non-food/feed uses are not intended by the sMTA developed under ITPGRFA, this is not precluded and the standard material transfer agreements can be used as mutually agreed terms for such further uses[16]. This should be clarified at the point of access and (mutually) agreed with providers.

5.2.2. Plant breeders' rights

The International Union for the Protection of New Varieties of Plants (UPOV)[17] and the Council Regulation (EC) 2100/94 on Community Plant Variety Rights[18] 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; (c) acts done for the purpose of breeding, or discovering and developing other varieties (Article 15 of Reg. 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 the Protocol does not affect the rights and

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[16] http://www.planttreaty.org/sites/default/files/ac_smta_mls2_repe.pdf (agenda item 9)
[17] http://upov.int. As of October 2015, the EU and 24 of its Member States are UPOV Members.
[18] OJ L 227, 1.9.1994, p. 1

obligations derived from existing international agreements (if they do not pose a serious damage or threat to biological diversity).

The ongoing use of material protected under the UPOV plant breeders' rights regimes coming from Parties to UPOV should as a rule not be in conflict with implementation of the duties stemming from the Regulation given that Parties to the UPOV Convention are not entitled to put restrictions on further use of a protected variety when such material is used for further breeding. This would be in breach of the breeder's exemption provided for in Article 15 of the UPOV Convention, as such material is required to be freely available to allow the ongoing use of protected plant varieties for further research, breeding and training.