



**RECOMMENDATIONS FOR ESA MEMBERS
ON HOW TO ACCESS AND USE GENETIC
RESOURCES IN COMPLIANCE WITH THE EU
ACCESS & BENEFIT SHARING (ABS)
REGULATION**

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I. INTRODUCTION

The legal background

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted in 2010 in Nagoya, Japan and entered into force on October 12, 2014. The Protocol sets out measures on the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources, benefit sharing and on compliance with national ABS legislation or regulatory requirements.

The core obligation for EU plant breeders is “to exercise due diligence to ascertain that the genetic resources which they utilise have been accessed” according to the law. Compliance with the due diligence obligation should ensure that necessary information relevant to ABS is available all throughout the genetic resources value chain in the Union.¹

The European Union, as signatory to the Nagoya Protocol, decided to transpose only the compliance provisions of the Nagoya Protocol into EU law thereby creating a harmonized legal environment for compliance checks within the EU. Access and benefit-sharing is not governed by the EU legal framework on ABS; it is left to individual Member States to define their own access and benefit-sharing rules if they wish to do so. The EU legal framework implementing the Nagoya Protocol consists of the following:

- 🌿 [EU Regulation no. 511/2014](#) (the EU ABS Regulation)
- 🌿 [Commission Implementing Regulation no. 2015/1866](#) (the Implementing Act)
- 🌿 [Commission Guidance Document on scope of application and core obligations of the EU ABS Regulation](#) (not legally binding)²
- 🌿 Commission Sectoral Guidance Documents on R&D (in preparation; not legally binding)³

NB: The sectoral guidance document on plant breeding has not yet been adopted by the European Commission in its final version. This means that a few areas remain subject to further clarification from the European Commission. These areas have been grey shaded in the present document and a specific explanation is provided, where necessary.

¹ Further explanation on the notion of due diligence can be found in chapter 4.


² Note that the Guidance Documents have been elaborated by the European Commission in consultation with the Member States.

³ Idem.

Purpose of the Recommendations document

This document has been developed by ESA's working group on biodiversity with the aim of assisting ESA members and other plant breeders to follow the requirements of the EU ABS Regulation. Members of ESA are accessing, conserving and using genetic resources for a range of purposes on a daily basis, and wish to carry out these activities in a manner compliant with the applicable rules. However, due to the complexity of applicable legal frameworks, it is felt that further assistance is necessary.

This document is meant to serve as a series of practical recommendations for plant breeders prepared to the best of the knowledge of the ESA WG Biodiversity. Please note that:

-  Due to the fact that the plant breeding and other sectoral guidance documents have still not been adopted by the European Commission, there are some areas of uncertainty that remain with regard to the legal framework.
-  Plant breeders are advised to continuously keep themselves updated on developments on this topic, e.g. through ESA, their national seed association or their ABS National Focal Point.
-  Apart from the steps mentioned in this document, other legal and contractual obligations may be applicable both within and outside the EU.
-  This document does not aim to cover ABS legislation of individual countries. For country specific information please refer to the [ABS Clearing House](#).
-  The present document is not more than a list of recommendations and has no legal value at all.

The present recommendations provide a step-by-step approach to follow the rules of the EU ABS Regulation. The document includes first an overview of the step-by-step approach followed by each step elaborated in detail in separate chapters. In the chapters, explanation is provided on how to fulfil the steps and examples are added, where relevant, to further clarify the approach. For each chapter, a reference to the relevant provisions of the EU ABS Regulation, the Implementing Act and the guidance documents, where relevant, is provided in Annex I. At the end of the document a list of key definitions used in the Regulation, the CBD, the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA), a list of abbreviations and a list of useful links to additional background information are added. Further on, you will also find annexed a decision tree providing an overview with regard to the questions to be asked and the decisions to be taken when following the Regulation. A practical, interactive tool to support ESA members in their compliance with the EU ABS Regulation has also been developed by ESA and is available on-line.⁴ Information on the applicable national ABS laws in each EU Member State is available in the ESA ABS law database.⁵

⁴ <http://abs.euroseeds.eu/#>

⁵ <http://abs.euroseeds.eu/#>

II. OVERVIEW OF THE STEP-BY-STEP APPROACH

In order to follow the rules of the EU ABS Regulation the following step-by-step approach is proposed:

Steps to carry out a preliminary assessment

1. Identify and keep track of the genetic resources coming in and going out of the company (track and trace OR tracking and tracing).
2. Develop an internal procedure to follow the rules of the EU ABS Regulation.

Steps for the acquisition of material

3. Determine whether a genetic resource falls within the scope of the EU ABS Regulation.
4. If the genetic resource falls within the scope of the EU ABS Regulation, find out if due diligence has already been 'automatically' complied with (e.g.: material coming from registered collections; non-Annex I material accessed under SMTA).
5. If due diligence cannot be considered automatically complied with, exercise your due diligence and obtain PIC and MAT if this is required.

Steps for the transfer of genetic resources

6. Know which obligations to comply with when transferring genetic resources to a third party.

Steps for compliance with monitoring requirements

7. Know when and how to make the necessary declarations to the authorities.
8. Be prepared for compliance checks by the authorities.

III. STEP-BY-STEP RECOMMENDATIONS

1. Identify and keep track of what genetic resources are coming in and going out

Steps to take

To follow the requirements of the EU ABS Regulation it is important to have a clear overview of all the genetic material that enters the company and all that leaves the company. Moreover, regarding all the genetic material that comes in to or goes out from the company it is key to know what conditions are linked to them. To be able to do so it is suggested that you:

- a. Identify where genetic materials may come in or go out of the company⁶
- b. Develop an appropriate tracking and tracing system⁷

a. *Identify where genetic resources may come in or go out of the company*

First, you will need to get a clear overview of all the different types of genetic material coming into your company. In order to be able to complete this overview it is recommended to ask yourself the following questions:

- 🌱 What types of genetic resources do you use within your company?⁸
- 🌱 How do you obtain these genetic resources?
- 🌱 Which departments or positions within your company are involved in the acquisition of new genetic resources?

Second, it is important to get an overview of genetic resources leaving your company. In this respect, the following questions are recommended to be asked:

- 🌱 What types of genetic resources leave your company?
- 🌱 Which departments or positions within your company are involved in the transfer of genetic resources to another party?

⁶ For purposes of research and development.

⁷ It has to be noted that the EU ABS Regulation only applies to material that falls within its scope and therefore the tracking and tracing system strictly speaking is only imperative for that material. However, for reasons of practicality it is advisable to have such a system for all genetic material coming in to and going out from the company.

⁸ In this regard one should think of any seeds, pollen or other plant parts - whether collected in the wild or bought on the market; also pests and pathogens such as fungi, bacteria, viruses and insects used in research, resistance tests etc.

c. *Develop an appropriate tracking and tracing system*

Once you have a good overview of the genetic material entering and leaving your company, as well as the positions / departments involved in this process, it is advisable to develop a system, allowing you to track and trace this genetic material and in particular, to trace back any obligations linked to such material.

Possible functionalities for a proper tracking and tracing system could be as follows:

- ✿ Include detailed information per genetic resource (such as species; date of access; country the legislation of which is applicable; direct source of acquisition; description; purpose used for; for material going out date of exit; destination);
- ✿ Include information relating to the presence or absence of rights and obligations related to ABS, including rights and obligations regarding subsequent application and commercialization. Such information should include contractual obligations or a link to a document in which the obligations are listed with regard to a genetic resource (this can be any “access documentation” such as invoice);
- ✿ Enable easy searching and retrieving of the afore-mentioned information;
- ✿ Pedigree option for breeding material, demonstrating the genetic resources used, preferably linking to the details of each resource used;⁹

A digital breeding administration could be a useful starting point for the development of a tracking and tracing system. Combining the breeding administration with the tracking and tracing system can help avoiding double work.

According to the EU ABS Regulation, it is also an obligation to make sure that the information remains available at least 20 years after the end of the period of utilization. Due to lack of clarity on the notion of “end of period of utilization” it is - at this moment in time -impossible for ESA to give further recommendations.

⁹ Please note that this is an option that may be useful to have in a tracking and tracing system but it is not necessary to have such option in order to meet the obligations under the EU ABS Regulation.

2. Develop an internal procedure to follow the rules of the EU ABS Regulation

Steps to take

Besides an internal system to track and trace the genetic resources coming in and going out, it is also recommended to put in place an internal procedure to make sure that during this entry and exit process the requirements of the EU ABS Regulation are followed. This procedure can be as simple or as elaborate as a company prefers, as long as it ensures that for genetic resources, falling under the scope of the EU ABS Regulation, the due diligence obligation is followed.

To accomplish this, it is proposed that the procedure includes at least steps 3 up to and including 7 of this document as elaborated in the following. Furthermore, the aspects below are recommended to be included in the procedure:

- ✿ Make a clear distinction between categories (types of material coming in (e.g.: commercial varieties; genebank material; breeding material; wild material), types of utilization, types of material going out). For each category /activity, it is important to describe the steps to be followed by the responsible personnel.
- ✿ Identify a role or a function within your company for each specific step in the procedure as well as a back-up who can take care of the tasks if need be. Who can acquire new genetic material? Who can analyze and decide whether genetic material falls within the scope of the EU ABS Regulation? Who applies for the necessary permits? Who is responsible for making sure that all required information is stored in the tracking and tracing system? Who is responsible for submitting the due diligence declarations? Is there a need for external support?
- ✿ Determine the actions to be taken if it turns out that a genetic resource has not been acquired in accordance with the applicable ABS rules and thus is not following the rules of the EU ABS Regulation.

Once the internal procedure has been developed, it is important to raise awareness and train the involved employees with the new procedures. Make sure that they know which steps to follow to acquire new genetic resources or when they want to transfer genetic resources.

3. Determine whether a genetic resource falls within the scope of the EU ABS Regulation

Steps to take

To know whether a due diligence check needs to be performed before genetic resources can be utilized you need to know whether the genetic resource falls under the scope of the EU ABS Regulation. If the genetic material does not fall under the scope of the EU ABS Regulation, no due diligence check is required under the EU ABS Regulation.

The scope of the EU ABS Regulation has (i) a material element; (ii) a geographical element; and (iii) a temporal element and the Regulation only applies if all three elements are met.¹⁰ The EU ABS Regulation only applies to genetic resources accessed after the entry into force of the Nagoya Protocol (October 12, 2014) in a country that is Party to the Nagoya Protocol and that has established access legislation for such type of genetic resources, which are utilized. Therefore, in order to be able to determine whether a genetic resource falls within the scope of the EU ABS Regulation one needs to take into account (i) whether the material qualifies as a genetic resource according to the definition of the EU ABS Regulation;¹¹ (ii) if the genetic resource was accessed in a country that is Party to the Nagoya Protocol and that has established access legislation that applies to the genetic resource in question and (iii) if access occurred after October 12, 2014. Furthermore, the EU ABS Regulation only applies in case the genetic resource will be utilized, i.e. is used for research and development purposes in the EU. However, genetic resources governed by a specialized ABS instrument, such as the Multilateral System of the International Treaty on Plant Genetic resources for Food and Agriculture, are excluded from the scope of the EU ABS Regulation.

Regarding commercial plant varieties¹² a two-tier approach has been adopted by the European Commission which differentiates between commercial varieties that have been legally placed on the EU market and commercial varieties that have not. It is therefore important to know whether the variety that you are accessing is a variety that has been legally placed on the EU market or not.¹³

Therefore, to determine if the genetic resource falls within or outside the scope of the EU ABS Regulation the following criteria would need to be assessed:

- a. Assess whether the genetic resource is a commercial variety that has been legally placed on the EU market (see below definition)
- b. Assess whether the genetic resource was already in-house before October 12, 2014;
- c. In case the genetic resource comes from an *ex situ* collection, assess whether it is a genetic resource that was already part of the collection in question prior to October 12, 2014 (Note that a genetic resource from

¹⁰ See also point 2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 3).

¹¹ For definitions see Annex II of the present document.

¹²In the broad sense, commercial varieties are varieties that are developed and put on the market by breeders and/or farmers.

¹³ NB: This paragraph has been kept grey-shaded. This is because although there is an agreement reached at the level of the Member States, no official document has been adopted or published by the Commission yet. Further on, discussions are still ongoing on the questions whether the exclusion could also be extended to varieties that are covered by UPOV-type plant variety protection.

the country where the *ex situ* collection is based may fall under different treatment. See below for further details under point (b).);¹⁴

- d. Assess whether the country from which the genetic resource is (or was) acquired is (or was) a Party (or not) to the Nagoya Protocol at the time of access and if such country has established access legislation applicable to the genetic resource in question;¹⁵
- e. Assess whether the genetic resource falls under the scope of the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture;
- f. Assess for which purpose the genetic resource will be used.

a. Assess if the genetic resource is a commercial variety that has been legally placed on the EU market

Check if the genetic resource (the variety in this case) that you are accessing (i) is a variety that has been legally protected by EU plant variety rights¹⁶ or by a national plant variety right within the EU; or (ii) is a variety that has been registered in a national variety register or in the EU Common Catalogue;¹⁷ or (iii) is a variety that has been entered in any other public or private list¹⁸ according to EU legislation or international standards with an official or officially recognised description and a denomination.

If the variety that you are accessing responds to one of the above criteria, the use of such variety for subsequent breeding programmes does not fall under the scope of the EU ABS Regulation. Nevertheless, a proof that the variety was legally available on the EU market at the time of access is recommended to be kept.

If the variety that you are accessing does not respond to any of the above criteria, the variety could then fall under the scope of the EU ABS Regulation. Then, a further assessment is relevant to conduct.

Example 1: Breeder A buys a soybean variety in country C, which is an EU Member State. This variety is on the EU Common Catalogue of agricultural plant species therefore, this variety falls outside the scope of the EU ABS Regulation. Breeder A therefore has no obligations under the EU ABS Regulation nevertheless breeder A is recommended to keep his receipt (or other proof of the purchase).

Example 2: Breeder B buys a commercial cucumber variety in country D, which is not an EU Member State. The breeder has to verify if there is any ABS legislation in country D and whether that ABS legislation applies to commercial plant varieties. If it is the case, the breeder has to comply with the ABS obligations in the national law of country D and also with the obligations under the EU ABS Regulation.

¹⁴ Note that national access laws may have provisions which make such national legislation applicable to genetic resources accessed prior to October 12, 2014. Such national provisions should be respected however the EU ABS Regulation still does not apply to such genetic resources. See also point 2.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page6).

¹⁵ See also point 2.1.2, footnote 2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 4). Note that access legislation established by the country includes also measures or legislation that was already established before the Nagoya Protocol came into force.

¹⁶ You can check whether a variety has been legally protected by EU plant variety rights in the CPVO database: <https://cpvoextranet.cpvo.europa.eu/mypvvr/#!/en/publicsearch>

¹⁷ You can check whether a variety is registered on the Common Catalogue here: http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm

¹⁸ For example: <http://www.floricode.com/>; <https://www.kavb.nl/>; <https://www.inao.gouv.fr/Nos-actualites/Des-plants-de-geraniums-reconnus-en-Label-Rouge>; <https://www.floriscope.io/>; <https://fleuroselect.com/>

b. Assess if the genetic material was already in-house before October 12, 2014

Check when the genetic material entered your own company. If it entered (i.e. you obtained it) before October 12, 2014, then the genetic material does not fall under the scope of the EU ABS Regulation.¹⁹

Articles 4 and 7 of the EU ABS Regulation, detailing the obligations of due diligence and declaration of due diligence, only entered into force on October 12, 2015. Nevertheless, it has been stated by the European Commission that the obligations, in principle, still concern all genetic resources accessed after October 12, 2014.²⁰

Example:

In 2013 a colleague went to country A, which is a Party to the Nagoya Protocol, and brought back some black bean seeds. You are now using them in crosses with your breeding lines.

This material was within your company before the entry into force of the Nagoya Protocol, i.e. before October 12, 2014. Therefore, it does not fall within the scope of the EU ABS Regulation. However, you should continue to respect any Mutually Agreed Terms, if agreed at the time of access.

c. In case the genetic material comes from an *ex situ* collection,²¹ assess if it concerns a genetic resource that was already part of a collection prior to October 12, 2014

If you acquire a genetic resource from an *ex situ* collection on or after October 12, 2014 that was already part of an *ex situ* collection prior to October 12, 2014, this genetic resource is considered to fall outside the scope of the EU ABS Regulation.^{22 23}

It does not matter whether a user acquires the genetic resource directly from the person who had the *ex situ* material in its possession on October 12, 2014 or whether it is acquired indirectly, through one or more other

¹⁹ If the genetic resource falls outside the scope of the EU ABS Regulation, it may be assumed that the burden of proof is on the checking authorities to prove the contrary. Nevertheless, during the checks the competent authorities of the Member States may, based on national administrative provisions, ask for reasons and justifications as to why the user considered that a certain genetic resource is out of scope. It is therefore recommended to keep some evidence proving on which basis you decided that a certain genetic resource falls outside the scope of the EU ABS Regulation. (See also point 3.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 12).)

In such a scenario, if it is difficult to get any proof of the acquisition of a material, the user may consider sending a “thank you” note to the provider which may serve as a written proof of such acquisition.

NB: Even if the genetic resource falls outside the scope of the EU ABS Regulation, it is possible that there was national ABS legislation in force in the country of access at the time of access, which needs to be complied with.

²⁰ See point 2.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 6).

²¹ According to Article 3(9) of the EU ABS Regulation “collection” means a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities.

²² It may happen that a certain genetic resource falls outside the scope of the EU ABS Regulation but there still may be ABS obligations linked to the material on a contractual basis. Nevertheless, those do not trigger the application of the EU ABS Regulation.

²³ See also point 2.2 (first example) of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 5.).

persons. The only relevant question should be whether it was part of an *ex situ* collection prior to October 12, 2014.²⁴²⁵

d. Assess whether the country from which you got the genetic material is (or was) a Party (or not) to the Nagoya Protocol at the time of access and has established access rules applicable to the genetic resource in question

Check if the country from which you got the genetic resource is a Party to the Nagoya Protocol at the time of access (you can check this information on the [Access and Benefit-Sharing Clearing House](#)).²⁶

If a country is Party to the Nagoya Protocol, then check whether this Party has established access regulations. For this purpose, it is recommended to first check on the [ABS Clearing House](#). If no legislation has been notified by this Party to the Clearing House you may assume that there are no access rules. Nevertheless, in case of any doubt it is recommended to double-check with the National Focal Point. If the outcome is that there is no access legislation in the Party to the Nagoya Protocol regarding the specific genetic resource you wish to access, the Regulation does not apply.²⁷

If a country becomes a Party to the Nagoya Protocol at a later stage it is assumed that this does not have any retroactive effect; meaning that the genetic resources acquired from that country prior to it becoming a Party to the Nagoya Protocol, continue to fall outside the scope of the EU ABS Regulation.

Note also that applicable legislation may be different for different types of genetic resources such as plant genetic resources for food and agriculture, other plant material, pathogens, bacteria etc. Therefore, it is recommended to check whether there is any specific ABS regime applicable to the specific type of genetic resource one is interested in, in the given country.

e. Assess whether the genetic resource falls under the scope of the Multilateral System of the International Treaty on Plant Genetic resources for Food and Agriculture

According to Article 2(2) of the EU ABS Regulation, it does not apply to genetic resources for which access and benefit-sharing is governed by specialized international instruments. The International Treaty on Plant Genetic Resources for Food and Agriculture is a specialized international instrument; the Multilateral System of the

²⁴ In this respect, it is also worthwhile to note that it may happen that some countries put in place access legislation that applies retroactively, i.e. would also apply to accessions acquired prior to the entry force of the national legislation implementing the Nagoya Protocol. In such situations users are bound by the national law as regards access, nevertheless, the compliance rules of the EU Regulation would still not apply to such material. See also point 2.2 (last box) of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 6).

²⁵ In this respect, it has to be noted that the EU Guidance document on scope refers to a “particular way of indirectly accessing genetic resources through *ex situ* collections in the country of origin” which refers to a situation where the genetic resource is also present *in situ* in the country where the collection is located. In this scenario, the genetic resource, if accessed from the collection after October 12, 2014, will always fall under the scope of the regulation, regardless of the date on which it was acquired by the collection. See point 2.1.3 last paragraph of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 5.).

²⁶ In order to prove this a screenshot from the ABS CH could be saved.

²⁷ For example: Germany, UK, the Netherlands do not have access legislation but this is not necessarily the case for other European countries; you will need to check.

International Treaty governs access and benefit-sharing for genetic resources belonging to the species listed in the Treaty's [Annex I](#). Therefore, a genetic resource does not fall under the scope of the EU ABS Regulation if the genetic resource belongs to a species listed in Annex 1 of the Treaty and has also been explicitly included in the Multilateral System; it is obtained from a country that is [Party to the Treaty](#) or from an *ex situ* collection held in Trust by an International Agricultural Research Centre having signed an agreement with the Treaty (so-called [Article 15 institute](#) such as CIMMYT, ICARDA, CIP, IRRI etc.), and is utilized for food / feed purposes.²⁸²⁹

Example:

A gene discovery project is using 100 wheat accessions acquired from CIMMYT on December 20, 2016.

Material held by International Agricultural Research Centres, such as CIMMYT, is handed out under SMTA since such material is included in the MLS of the Treaty under Article 15 of the Treaty. The 100 wheat accessions are therefore excluded from the scope of the EU ABS Regulation. No due diligence obligation applies.

Example:

Breeder A is accessing accessions of barley and sunflower from the national genebank in country A, on March 22, 2017. He wants to use these accessions for food/feed purposes. Country A is a Contracting Party to the Nagoya Protocol.

Both barley and sunflower are on the Annex I of the International Treaty and country A is a Contracting Party to the Treaty. Breeder A checked with the genebank whether the accessed material is included in the Multilateral System of the Treaty.

If the genebank confirms this, the Breeder will be asked to sign SMTA and these accessions will be considered as out of scope of the EU ABS Regulation. No due diligence obligation applies.

Note: if a genetic resource belonging to a species listed on Annex I of the IT PGRFA is accessed *in situ*, in a country that is Party to the Treaty, it is recommended to contact the National Focal Point³⁰ of the country to clarify what rules apply.³¹

²⁸ Multiple purposes are possible. If a crop is used for both food/feed and industrial purposes, it is considered PGRFA for the purpose of the Treaty. See Annex 2 "Opinion: Non-food /non-feed uses of plant genetic resources for food and agriculture" to the Report of the third meeting of the ad hoc advisory technical committee on the SMTA and the MLS ([IT/AC-SMTA-MLS 3/12/Report](#)).

²⁹ See also point 5.2.1 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 17).

³⁰ Here it is recommended to possibly contact both the National Focal Point under the CBD as well as under the Treaty.

³¹ Article 12.3(h) IT PGRFA provides that "Contracting Parties agree that access to plant genetic resources for food and agriculture found in *in situ* conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body". So far, no standards have been set by the Governing Body.

Example:

In May 2016, a breeder sees a carrot plant besides a road in country A, which is a Party to the Nagoya Protocol.

Carrot is mentioned on the Annex 1 of the Treaty and country A is a Contracting Party to the Treaty. But because it concerns *in situ* access, the EU ABS Regulation may apply. The breeder will need to make sure that applicable ABS obligations are followed.

In case a genetic resource belonging to a species not listed in Annex 1 of the IT PGRFA is accessed from a Party to the Nagoya Protocol which has decided that it will make the given genetic resource (which is under its management and control and in the public domain) available under the terms and conditions of the standard Material Transfer Agreement of the Treaty, such genetic resource falls under the scope of the EU ABS Regulation. However, according to the provisions of the EU ABS Regulation in such a scenario the user is considered to have exercised due diligence.³²

Example:

Accessions of tomato are accessed by Breeder B from the national genebank in country A on April 2, 2015.

Country A is a Party to both the Nagoya Protocol and the Treaty, tomato is however not on Annex 1 of the Treaty. These genetic resources are therefore under the scope of the EU ABS Regulation. But since country A has decided to make available all materials that are in the national gene bank under the terms and conditions of the SMTA, Breeder B is considered to have complied with the due diligence obligation. There is also no due diligence declaration obligation in this case. It is however recommended to keep the SMTA as a proof of compliant access as well as the document / website where it is mentioned that use of the SMTA for the given non-Annex 1 crop is a government decision.

f. Assess for which purpose the genetic resource will be utilized

The EU ABS Regulation applies to the utilization (R&D) of genetic resources within the EU territory.³³ As clarified below in Annex I (definitions), utilization is research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.³⁴

The range of activities that may occur with genetic resources is wide and may differ significantly sector by sector.³⁵ In plant breeding many cases exist where genetic resources play a role in the crop characterization

³² Idem. For more details see step 4.

³³ See also point 2.5 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 10).

³⁴ Please check the definition of utilization in Annex I.

³⁵ The current definition of utilization therefore needs further precision. The European Commission has announced that it will elaborate sectoral guidance documents discussing the notion of R&D and the type of activities it covers for the various sectors covered by the EU ABS Regulation. This work is still ongoing.

process of R&D but have no direct influence on the end product and therefore may not qualify as utilization for the purpose of the EU ABS Regulation. Examples of such cases are:³⁶

- ✿ Genetic resources as testing / reference tools;
- ✿ Quality / phytopathology tests;
- ✿ Handling and storing of genetic resources;
- ✿ Describing of genetic resources in phenotype-based research;
- ✿ Study of genetic resources to assess taxonomic relationships;
- ✿ [Screening (a large number of) genebank accessions to find a trait in just a few of them;]
- ✿ Using pathogens as tools for testing resistance genes in plants;
- ✿ Identification of pathogen strains and races; identification of a pathogen to determine with which disease a plant is infected;
- ✿ Using insects as vectors to infect plants in disease resistance trials;
- ✿ Using micro-organisms as vectors to insert genes;
- ✿ Testing of candidate varieties on the fulfilment of DUS/VCU criteria;
- ✿ Using existing varieties as references in evaluation trials;
- ✿ Use of hybrid components under a license agreement for the purpose of hybrid production;
- ✿ Providing services under a contract to deliver the service to the user of the genetic resource (such as seed treatment, multiplication, VCU, DUS testing, plant health trials etc.)

Example:

Some fungal pathogen spores were imported on purpose to country A in 2015 from country B and you are using them for resistance screening on your breeding lines.

The pathogen spores are genetic resources which were accessed after October 12, 2014 from country B, which is a Party to the Nagoya Protocol and where ABS legislation applies. Nevertheless, you are using them for resistance screening, which is not considered to be R&D on the pathogen, i.e. it is not utilization in the sense of the EU ABS Regulation. For these fungal pathogen spores used for screening the EU ABS Regulation therefore does not apply.

Example:

Breeder A accessed some lettuce genetic resources in country B in 2017. When screening the material, breeder A discovered that the genetic resources were not disease-free but came with some virus strains on them.

³⁶ The examples provided here are the ones included in the EU Guidance document on scope (see point 2.3.3; OJEU C313 of 27.08.2016, pages 8-9) and which have been included, and not disputed, in the draft EU Guidance Document for the Plant Breeding Sector as examples of cases falling outside the scope of the EU ABS Regulation. Some of these activities have been further discussed in the expert group of Member States and where agreement has been found that can be found in the summary records of the meeting of the EU ABS Consultation Forum of December 18, 2017, page 2, point 5: <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=9939>. Regarding large-scale screening, it must be noted that no agreement has been reached so far among the EU Member States, therefore no further recommendation can be given on this issue at this moment in time.

In this case, the pathogens were accessed unintentionally. In this case it has clearly not been the intention of breeder A to import the virus as a genetic resource and therefore it is considered that the EU ABS Regulation does not apply.

Note: In cases where a pathogen or pest is accessed together with a genetic resource but where it is clear that there was no intention on the user to access these resources, the EU ABS Regulation does not apply (see also point 5.11 (intentionality of access) of the EU Guidance document on scope).

If, following the above outlined assessment the genetic material you accessed turns out to be out of the scope of the EU ABS Regulation, competent authorities cannot require you to show certified evidence of being out of scope when compliance checks are carried out.³⁷

³⁷ See footnote 19 of the present document and point 3.2, last paragraph of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 12).

4. If material falls under the scope of the EU ABS Regulation, find out if due diligence is considered to be already ‘automatically’ complied with

In case it has been determined that a genetic resource falls under the scope of the EU ABS Regulation, “due diligence” should be exercised to make sure that the genetic resource was obtained in accordance with applicable access and benefit-sharing legislation.³⁸

Due Diligence is a key concept in the EU ABS Regulation; it refers to the judgment and decisions that can reasonably be expected from a person or entity gathering and using information on a genetic resource in a systematic way. As such, it is not intended to guarantee a certain outcome or aim at perfection, but it calls for thoroughness and best possible efforts.³⁹ Nevertheless, in case – despite all the efforts of the user – it turns out later that some permits had to be obtained at the moment of access, the user will have to obtain those or discontinue utilization. Due diligence is therefore also an obligation of result.

In certain situations, however, the user will be considered to have exercised due diligence, without actually having to perform a due diligence check. In the following situations, due diligence is considered exercised:

- a. You acquire a genetic resource belonging to a species *not* listed in [Annex 1](#) of the IT PGRFA from a Party to the Nagoya Protocol which has decided that it will make the given genetic resource (which is under its management and control and in the public domain) available under the terms and conditions of the [standard Material Transfer Agreement](#) of the Treaty.⁴⁰
- b. You acquire the genetic resource from a registered collection.^{41 42}

³⁸ It has to be noted that EU Member States may introduce ABS measures going beyond the due diligence obligation foreseen in the EU ABS Regulation. Such national provisions should be taken into account. For this purpose, the [ESA EU ABS law database](#) provides further information on national ABS laws of EU Member States.

³⁹ See point 3.1 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 11).

⁴⁰ See point 5.2.1 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 17).

It is however recommended to keep the SMTA as a proof of compliant access as well as the document / website where it is mentioned that use of the SMTA for the given non-Annex 1 crop is a government decision.

⁴¹ Please note that in this case the obligations to keep and transfer information as well as to submit a due diligence declaration still apply.

⁴² Currently there is no list yet of registered collections. Such list will probably be developed, once the first collections have been registered by the European Commission. Note that it is possible, according to the EU ABS Regulation, that a provider registers only part of its collection. Therefore, it is recommended to check whether the genetic resource in question falls within the part of the collection that has been registered. See also point 3.5 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 13).

5. If due diligence is not considered to be ‘automatically’ complied with regarding the genetic resource you access, perform a due diligence check and obtain PIC and MAT if this is required

If your preliminary analysis shows that a genetic resource probably falls under the scope of the EU ABS Regulation and due diligence is not considered to be ‘automatically’ complied with (see chapters 3 & 4), you will have to exercise due diligence and investigate if the genetic resource was accessed in accordance with the applicable access and benefit-sharing legislation. In order to complete this task, you may follow the below recommended steps:

1. Investigate which country’s applicable legislation has to be followed
2. Check if the genetic resource has been accessed in accordance with the applicable access and benefit-sharing legislation
3. Obtain PIC and/or MAT

1. Investigate which country’s applicable legislation has to be followed

1.1. **Collecting from *in situ* conditions** (e.g. from the wild)

The applicable legislation of the country where the material is collected has to be followed.

Example:

Breeder A would like to collect some wild linseeds in country A and some wild grass species in country B.

Since the material is collected *in situ*, in principle the legislation that applies is the legislation of the country where the material was collected, so in the present case Breeder A should contact the National Focal Points of countries A and B to find out about the applicable legislation.

1.2 **Accessing from *ex situ* conditions**⁴³

When assessing which country’s applicable legislation has to be followed when accessing genetic resources from *ex situ* conditions, the user may face different scenarios:

- 1.2.1. If the genetic resource is accessed from *ex situ* conditions in the country in which the genetic resource was collected from *in situ* conditions, the applicable ABS law to follow will be the law of the country where the user accessed the genetic resource.

⁴³ Obtaining material *ex situ* may cover scenarios when material is accessed from a genebank or from a grower or any other holder.

Example:

A company obtains a genetic resource from a genebank in country A in November 2015. The genetic resource can be found *in situ* in country A and has been collected by the genebank in country A. The legislation therefore that the user has to follow is the legislation of country A.

Example:

A breeder gets some plants from a farmer of his local soybean variety in country B in 2016.

Since the genetic resource is a local farmers' variety, the country whose legislation has to be followed by the user in this case would be that of country B.

- 1.2.2. If the collection from which the user is accessing the genetic resource is a collection under the control of the State and if the genetic resource accessed has not been collected by the collection *in situ* in the country of establishment but somewhere else, then the user may assume that the applicable ABS law to follow will be the law of the country where the collection is located.
- 1.2.3. If the collection from which the user is accessing the genetic resource is NOT a collection under the control of the State and did not collect the material from the country where the collection is established, the user should seek, and the holder of the genetic resource (from whom the user is accessing it) should provide the information to the user regarding the country whose legislation is applicable.

Practical advice:

In principle, the user should be able to rely on the information provided by the *ex situ* holder of the genetic resources (from whom the user is accessing) about the country whose legislation has to be followed. In any event, since it is the obligation of the user to seek information on the legal status of the genetic resource, it is recommended to explicitly ask the question, when accessing a genetic resource from an *ex situ* holder, whether the country whose laws are applicable is the country where the holder is located or whether it is another country.

Example:

In 2016 breeder B would like to obtain a number of wild *Fragaria* species from a genebank in country A; some tomato from the national genebank in country B and some eggplant accessions from a botanical garden in country C.

In all three countries, Breeder B should enquire with the holder of the genetic resources regarding the legal status of the genetic resource and should follow the indications received from the holder.

In country A, it turns out that the genetic resource belongs to a wild species in country A. Breeder B therefore has to check the applicable legislation in country A.

In country B, the genebank states that the tomato genetic resources come from country D where no ABS legislation exists. Breeder B has no further obligations regarding the tomato genetic resources

In country C, the botanical garden informs that the eggplant material comes from country F and provides the PIC and MAT under which those were accessed. Those PIC and MAT however do not cover the possibility to use in breeding. Breeder B therefore has to go back to country F and obtain the necessary PIC and MAT.

1.2.4 It will however not always be reasonably possible to determine which country's applicable legislation has to be followed and complied with. For such cases, ESA suggests the following practical solutions:

- i. In case of accessing breeding material, there is no country that possesses the material in *in situ* conditions. The country where the breeder is located should therefore be considered the country to deal with.

Example:

Breeder A wants to share its breeding material (so material that he has developed) with breeder B.

Since it is about breeding material, the country where breeder A is located, should be regarded as the country whose legislation is applicable.

- ii. Sometimes material that is bought on a local market or in a plant shop cannot be identified. For such material, the country where the material is bought, should be considered as the country to deal with, unless there is an indication that the material comes from another country. For example, the display in the store mentions another country. Or a specific country is mentioned on the package in which the material is sold. In such case, the country that is mentioned should be seen as the country whose legislation should be followed.⁴⁴

Example:

Breeder A buys a tomato in the supermarket in country B in September 2016.

The supermarket has placed a sign next to the tomatoes, indicating the price as well as the country of origin, being country C. Country C should therefore be considered the country whose legislation is applicable.

⁴⁴ As a matter of practical advice, it is always useful to document access to genetic resources also with pictures/photographs. In such situations, it can prove very helpful and users are highly recommended to take pictures of stalls and signs and price tags, since in some cases this might be the most simple and direct way to prove things.

Example:

Breeder A buys a melon on a local market in country B.

The market stall does not mention any country of origin. The melon is furthermore not packaged. Country B should therefore be considered the country whose legislation is applicable.

2. Check if the genetic resource has been accessed in accordance with the applicable access and benefit-sharing legislation

Once you know which country's legislation applies, you will need to determine if the genetic resource has been accessed in accordance with the legislation of that country. When a genetic resource is accessed from *ex situ* conditions, in principle the user should be able to rely on the information provided by the *ex situ* holder of the genetic resource about whether the genetic resource has indeed been accessed in accordance with such legislation.

Example:

Company A obtains a genetic resource from a university in country B. The university has collected the genetic resource *in situ* in country C.

The university informs Company A that it is possible for the university to transfer the material to Company A under the conditions specified by the university. If Company A has no reason to doubt the information provided by the university, no further investigation is necessary.

Only if Company A doubts the information provided by the university, or if the university does not know if it can transfer the material, Company A will have to go back to country C, if it wishes to access the material.

In case the *ex situ* holder is unable to provide such information, or there are reasons to doubt the provided information, the user has to make such assessment. In such a scenario, or in case genetic resources are collected *in situ*, the following steps could be applied:


- i. Go to the website of the [ABS Clearing House](#) and look for the country the legislation of which you have to investigate. The relevant legislation may have been posted on this website. If you don't find any legislation on the Clearing House it is recommended to contact the National Focal Point of the country to enquire about existing legislation.⁴⁵
- ii. If the legislation has been published but you cannot find the answer you are looking for or have doubts (e.g. because of the language of the documents), it is advised to contact the National Focal Point of that country. The name and contact details are listed on the [ABS Clearing House website](#). Ask the National Focal Point whether the acquisition of the

⁴⁵ See also point 3.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 12).


genetic resource would be in line with the applicable access and benefit-sharing legislation.

- iii. Check whether the type of material (wild material, landrace, from a public or private collection, eventually commercial varieties, pathogens, DNA-samples etc.) that you are accessing is included in or excluded from the scope of the national legislation. If it is excluded, the EU ABS Regulation does not apply and therefore there are no further user obligations to comply with.


From the investigation conducted under steps 1 & 2 above, there are three possible outcomes:

-  No PIC and MAT are required for the genetic resource in question.

In case you come to the conclusion that no access rules apply (i.e. no PIC and MAT are required by the country concerned), the EU ABS Regulation does not apply.

-  No PIC is required but a registration or notification system is in place with regard to access and MAT needs to be established before products developed via the utilization of the genetic resource can be commercialized.

In this scenario, it may happen that the national law provides for an obligation to notify or register your access with the competent national authorities. On the other hand, in this scenario MAT is required (which is a separate obligation from the notification or registration of use). In this case, it is recommended to start negotiating the MAT as soon as possible to be certain that the outcome of the utilization can be commercialized.

-  PIC and MAT need to be obtained with respect to the genetic resource in question.

In the last scenario, you will need to obtain PIC and negotiate MAT in order to be able to use the genetic resource.⁴⁶

What to do in case you are facing difficulties in getting the necessary information about the applicable legislation and obligations?

It may happen (even though countries must provide access to genetic resources) that a National Focal Point denies access to the requested genetic resource. In such a scenario, it is recommended to refrain from accessing and utilizing the genetic resource in question. It is also recommended to bring such a case to the attention of the National Focal Point of your own country as well as national associations, ESA or ISF depending on the country concerned.

⁴⁶ It is to be noted that already existing MATs are recommended to be checked and reviewed in order to understand whether the conditions cover the intended activities.

It may also happen that you are not able to get the required information perhaps because the National Focal Point does not respond at all, or does not provide a clear/satisfactory answer to the question whether the genetic resource can be accessed in line with the applicable access legislation. In such a scenario, it is for the user to assess and decide whether or not to access and use the genetic resource in question. According to the EU ABS Regulation, if the user has insufficient information or uncertainties persist, the user should either obtain an access permit (or its equivalent) or should discontinue utilisation.⁴⁷

ESA proposal for national associations:

ESA believes that the utilization of genetic resources is key to achieve the goals of the CBD and the Nagoya Protocol and therefore, in principle it should not be considered as breach of the due diligence obligation provided for in the EU ABS Regulation if utilization is continued in situations where the user has followed the steps outlined below and despite all these efforts the user was not able to get the necessary answer from the National Focal Point explaining how the genetic resource can be accessed in compliance with the applicable legislation,

For the above purpose, the user would need to be able to demonstrate that:

- i) it has contacted the National Focal Point in writing in whatever way (e-mail; registered mail; fax etc. followed by a phone call) using the contact details available on the ABS Clearing House;*
- ii) it has sent at least one written reminder (again in whatever way), using the contact details indicated on the ABS Clearing House;*
- iii) it has tried to contact the National Focal Point by phone based on contact details available in the ABS Clearing House to enquire whether the previously sent written communications were received in good order;*
- iv) it has informed the National Focal Point of the country where its registered office is based in writing about the inability to receive any answer as outlined above from the National Focal Point of the country the legislation of which applies to the genetic resource in question.*

The above actions must be done with a reasonable time period in-between in order to provide the National Focal Point with sufficient time to respond. Reminders should be sent with a difference of at least a week. The same applies to phone calls. A period of at least two months should pass during which the above efforts have to be carried out before the user can say that it has done everything that can be reasonably expected.

It is then up to the discretion of the user to decide whether to utilize or discontinue the use of the genetic resource. This assessment may be different for the different types of genetic resources. For example, in case of in situ material (so material collected in the wild), it seems wise to make sure that you have PIC or know that PIC is not necessary before initiating the collection mission. In case of genetic resources bought on the market, received from a genebank or a local university, the situation might be less problematic.

Please note that the approach presented in this box is purely the approach desired by ESA and has not been approved by any official EU bodies. Following this approach without having the consent of the national authorities carries too many risks and is thus not recommended. However, it is recommended

⁴⁷ See also point 3.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 12).

to the National Seed Associations and/or companies to propose this approach to the national competent authorities. In some countries this approach may be acceptable to the authorities whereas in others it may not be the case. In the lack of endorsement of such approach by the European Commission it is not possible to make such recommendation at the European level but it is advised to try this approach on the national level.

- 3. Obtain PIC and/or MAT if required** (you only need to consider this step if the outcome of your investigation under steps 1 & 2 indicate that the applicable legislation requires you to obtain PIC and/or MAT).

In most cases, you will first need to apply for PIC. The application process will differ country by country; therefore, it is recommended to ask the National Focal Point of the country of access to explain the procedure that has to be followed.

3.1 Issues to consider when preparing for the PIC application process:

- a. For what purpose, do you want to use the genetic material? It is advisable to formulate the intended purpose broadly in order to avoid repeating the application process at a later stage. Examples could be:
 - i. Only research with no commercial objective
 - ii. Traditional plant breeding for product development and commercialization
 - iii. Classical and new breeding techniques, including possibly GM, for commercial processes
- b. To avoid discussions later on, make it clear at the start that you are a commercial company and therefore want to be able to commercialize the results that you generate by using the genetic resource. Avoid situations where this would only be allowed after obtaining approval again.
- c. Clarify who can be allowed to use the material (think of foreign subsidiaries, joint research/breeding activities or third party service providers). Make sure that it is clear to whom you may transfer the material and under what conditions.
- d. Clarify to which countries the material may be transferred
- e. Obtain the necessary explanation regarding the procedure on how to obtain and export the material
- f. Make sure that you will have sufficient time to use the genetic material. Find out if the PIC is valid only for a limited period. If yes, find out if this limited period only applies to accessing the material and whether you are free to continue using the material after the limited period has ended or if your user rights would also end after the limited period?
- g. Find out if it is necessary to cooperate with a local company or institute, in order to obtain PIC.

In most cases, obtaining PIC will not be enough and you will also need to negotiate MAT. It is advisable to try to negotiate the MAT during or soon after the PIC application process takes place, so that you know whether you have certain and acceptable conditions to use the material.

3.2 Issues to consider when negotiating Mutually Agreed Terms:

- a. Clearly describe to which genetic resources the MAT applies. Make it as broad as necessary but be careful that it is not formulated so broadly that it would also limit your rights to use your own material.
- b. Link it to the PIC (already acquired or to be acquired).
- c. Use definitions to make the scope of the rights and obligations clear.
- d. Clearly define what situations trigger benefit-sharing and clarify all necessary details. For example, define the level of incorporation/contribution of genetic resources that triggers financial benefit sharing.
- e. Avoid open ends: make sure that a country cannot ask for more benefit-sharing at any time unless you have specifically agreed thereto in the MAT.⁴⁸
- f. When negotiating benefit sharing arrangements try to agree upon roughly the same conditions for all countries to avoid creating a precedent.
- g. Negotiate conditions that do not require you to pass on obligations to subsequent users of a commercial product (such as commercial varieties or any other products that you commercialize).
- h. Think of and be clear on a termination arrangement for the benefit sharing obligations.
- i. Determine whether you might want to terminate the contract in the future and whether this would be possible and under what conditions. Clarify what the consequences of such termination are for use of the collected material and of the results that you have developed using the collected material.
- j. Agree on which country's judicial system is going to be used in case of dispute. Decide whether you want to go to court or perhaps use arbitration instead. If you agree on arbitration, put this clearly in the MAT.
- k. Clarify the rules for passing on original material to others. Clarify if and under what conditions it can be shared with subsidiaries, service providers, universities, other breeders, etc? Avoid situations that involve the original provider in approving or reviewing the transfer of genetic resources to other users.
- l. Clarify the rules for passing on the results and intellectual property of your research and development activities. Get clarity on whether you are completely free to share your results with whomever you want or - if not – that the imposed limitations are acceptable and workable for you. If you could only commercialize a new variety after the country has given its approval, your time and effort to develop the variety may have been in vain.
- m. Clarify the rules for sharing information resulting from use of the genetic resource, including through publishing such results in the public domain. Avoid conditions that block further use of your results when published in the public domain.

⁴⁸ For the sake of assistance, you may consult the [Annex](#) to the Nagoya Protocol on monetary and non-monetary benefits.

6. Know which obligations to follow when transferring genetic material

When you want to transfer a genetic resource to a third party, there are two aspects to keep in mind:

- ✿ contractual obligations that may affect the transfer;
- ✿ the obligations under the EU ABS Regulation to transfer certain information to subsequent users.

Before a transfer, check contractual obligations that may affect the transfer

When a genetic resource has been acquired on the basis of an agreement (including MAT), it is important to check in the agreement whether there are any conditions linked to the transfer of the material to third parties. If you have acquired the genetic resource on the basis of an already existing agreement, this agreement may (unfortunately) contain provisions that limit the right to transfer the genetic resource to a third party. Therefore, first you have to check whether you are free to transfer the material or whether you would first need to apply for permission or inform the provider of the genetic resource. If you are free to transfer the material to a third party there could still be an obligation to render certain provisions applicable to the third party. You may then need to sign an agreement with the third party in which the third party accepts such conditions.

Obligations under the EU ABS Regulation to transfer specific information to subsequent users

According to the EU ABS Regulation, the internationally recognized certificate of compliance or in the absence of such certificate, specific information has to be transferred to subsequent users of genetic resources. When transferring a genetic resource to a third party it is recommended to transfer the above-mentioned certificate as well as the relevant content of the MAT.⁴⁹ If there is no such certificate, the following information should be provided according to the EU ABS Regulation:

- a. The date and place of your access of the genetic resource;
- b. A description of the genetic resource;
- c. The source from which you directly obtained the genetic resource;
- d. The presence or absence of rights and obligations relating to access and benefit-sharing;
- e. Access permits, where available;
- f. MAT, where applicable.

⁴⁹ It may happen that the entirety of the Mutually Agreed Terms is confidential as such. In such a situation, there will be a conflict between the obligations stemming from Article 4(3)(vi) of the EU ABS Regulation and the confidentiality provisions of the MAT. In such a scenario, the user should contact the National Competent Authority to indicate the problem and to ask for assistance to resolve it.

7. Know when and how to make the necessary declarations to the authorities

To demonstrate that users have fulfilled their due diligence obligations, Due Diligence Declarations have to be made at the relevant checkpoints according to Article 7 of the EU ABS Regulation.

Two such checkpoints have been defined in the EU ABS Regulation:

- ✿ at the stage of receipt of research funding
- ✿ at the stage of final development of a product

7.1 Receipt of research funding

When funding for research is received for a project in which genetic resources falling under the scope of the EU ABS Regulation are utilized, a due diligence declaration has to be made. The declaration must be made by the recipient of the funding to the competent authority of the Member State where the recipient is established; or if the recipient is established outside the EU, where the funded research is carried out.

According to the Implementing Regulation, the declaration should be made when the first part of the funding has been received and all genetic resources to be utilized in the project have been obtained but not later than at the moment when the final report of the project is established; or in the absence of such report when the project ends.⁵⁰ In practice this provision means that unless national law requires you to do otherwise, the due diligence declaration can be done at the end of the project.

If there are several users involved in the project, only one declaration may be submitted by the project coordinator if so agreed by the parties to the project. For the declaration, the on-line '[DECLARE](#)' tool, developed by the European Commission, should be used.⁵¹

According to the Implementing Regulation 'funding for research' covers any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources. However, it does not cover internal budgetary resources of private or public resources.

Example:

A breeding company and a university set up a collaborative research project. The breeding company pays the University for this project. If genetic resources, that fall in the scope of the EU ABS Regulation, are used in the performance of such bilateral project, then a due diligence declaration will have to be made. Parties can agree in the project agreement that such declaration is made by the University.

⁵⁰ National law may further specify the timing when such declaration needs exactly to be made. See point 4.1 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 14).

⁵¹ The [DECLARE tool](#) has been developed based on the template foreseen for this purpose in Annex II of the Implementing Regulation. In case a Member States is not using DECLARE, the declaration form should be based on the same template. In the [ESA ABS law database](#), you also find information on the authority to which the due diligence declaration has to be submitted in the different Member States

Therefore, if you are involved in a research project for which funding has been received, then it is recommended to consider the following elements:

- 🌱 Clarify with the funding agency whether the funding received for the project qualifies as ‘funding for research’ under the Implementing Regulation;
- 🌱 If yes, make sure that if several users are involved in the project an agreement is made that only the project coordinator makes one declaration for the whole of the project;
- 🌱 If you are the project coordinator, check whether it is already clear what genetic resources will be “utilized” in the project in the sense of the EU ABS Regulation; if not yet known then wait and make the declaration at the end of the project, if the national applicable law allows for that.

According to Article 7(1) of the EU ABS Regulation the competent authorities should request the recipients to declare whether they have exercised due diligence. It is nevertheless recommended to check how this obligation is exactly implemented in the national laws of the Member States and to get in touch with the national authorities and inquire about their approach.

7.2. At the stage of final development

At the stage of final development of a product, the user of a genetic resource that falls under the scope of the Regulation must make a Declaration of Due Diligence to the competent authority of the Member State in which the user is established. According to the EU Regulation, a due diligence declaration only has to be made once per product, and prior to the first of the following events:

- i. when market approval or authorisation is sought for the product developed via the utilization of genetic resources;
- ii. in case a notification is required prior to placing the product on the Union market, when such notification is submitted;
- iii. if no market approval, authorization or notification is required, when placing the product on the Union market⁵² for the first time;
- iv. when the result of the utilization⁵³ is sold or transferred 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 (i), (ii) and (iii);
- v. when utilisation in the Union has ended and its outcome⁵⁴ is sold or transferred to a natural or legal person outside the Union.

In practice, for breeding companies normally the declaration of due diligence will have to be made according to point (i) prior to submitting an application for variety registration, or point (iii) when placing the product on

⁵² Placing on the Union market is defined in Article 6(4) of the Implementing Act. The definition is reproduced in Annex II of the present document.

⁵³ Result of utilization is defined in Article 6(3) of the Implementing Regulation. The definition is reproduced in Annex II of the present document.

⁵⁴ The difference between result and outcome of utilization is explained in the EU Guidance document on scope under point 4.2 (OJEU C313 of 27.08.2016, page 15).

the Union market for the first time where there is no variety registration required (such as for ornamentals, non-regulated species etc.). In some cases, declarations may need to be made according to points (iv) or (v).

For example, when a genetic resource (e.g. a parent line) is licensed to another breeder, the licensor should transfer all information to the licensee according to step 6. Whether the licensor has an obligation to make a due diligence declaration under point (iv) above will depend on whether or not the licensee is doing further R&D on the genetic resource. If there is no further R&D done on the genetic resource by the licensee, the licensor has the obligation to submit a due diligence declaration when transferring the genetic resource to the licensee since according to the EU ABS Regulation the licensee will not be considered as a user.⁵⁵ If however the licensee is performing further R&D on the licensed genetic resource, the licensee will utilise the genetic resource and thus will have to make the due diligence declaration once any of the situations from (i) to (v) occur.

In-company transfers are not considered to be falling under the definition of transfer for the purpose of point (iv), therefore such transfers do not entail a due diligence declaration obligation.⁵⁶

If genetic resources are provided to a third party for the purpose of carrying out services under the terms of a contract according to which the genetic resources are delivered back to the user of the genetic resources once the service is completed (such as seed treatment, health testing, multiplication, DUS testing etc.), this does not constitute transfer in the sense of the EU ABS Regulation and its Implementing Act and therefore, no due diligence declaration has to be made either by the user of the genetic resources or the service provider when the genetic resources move from one to the other with no transfer of ownership on the genetic resources.

For the declaration, the on-line '[DECLARE tool](#)', developed by the European Commission, should be used.⁵⁷ In the ESA ABS law database you will find information on national implementation of the EU ABS Regulation in the 28 Member States where you also find to which authority the due diligence declaration has to be submitted in the different Member States.

If you acquire genetic resources from a country that is Party to the Nagoya Protocol but which has determined that PGRFA under its management and control and in the public domain, not listed in Annex I of the Treaty, is subject to the conditions of the SMTA, no due diligence declaration has to be made.⁵⁸

On the contrary, when you access material falling under the scope of the Regulation from a registered collection, the obligation to make a due diligence declaration still applies.⁵⁹

⁵⁵ See point 2.4 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 10).

⁵⁶ See point 4.2 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 15.).

⁵⁷ The [DECLARE tool](#) has been developed based on the template foreseen for this purpose in Annex III of the Implementing Regulation. In case a Member States is not using DECLARE, the declaration form should be based on the same template.

⁵⁸ See also step 4 above. See as well point 5.2.1 of Commission Guidance document on scope (OJEU C313 of 27.08.2016, page 17).

⁵⁹ See point 3.5 of the EU Guidance document on scope (OJEU C313 of 27.08.2016, page 13).

8. Be prepared for compliance checks by the national authorities

According to the EU ABS Regulation, Member States must check on a regular basis whether users of genetic resources in their country comply with the obligations under the EU ABS Regulation. How often and according to what modalities such checks will take place will depend on the risk-based plan established separately by each and every Member State. For shortcomings detected in the course of such checks, the competent authorities may foresee interim measures (and sanctions should an infringement of the obligations under the EU ABS Regulation be established). Information on the authorities competent in the different Member States and on the possible penalties can be found in the ESA ABS law database.

Although still unclear how compliance checks by the competent authorities will be performed, it is advisable to at least take these preparatory actions:

- ✿ Make sure that you can easily demonstrate the internal procedure(s) in the company/organization that you have developed to respond to the obligations of the EU ABS Regulation. Providing information on how you communicated the procedure(s) within your company could also be useful.⁶⁰
- ✿ Be prepared to demonstrate the track and tracing system used to keep track of the material coming in and going out.
- ✿ Be ready to show any administrative records related to genetic materials including access documentation, but also breeding books, records of own collection etc.
- ✿ Show field trials on request.
- ✿ Identify a role/function that will be the main spokesperson of the company during the communications with the competent authorities. Preferably someone who has been closely involved in setting up the procedure and who thus has the complete overview of movement of genetic resources.

⁶⁰ Note that this is useful to have but this is not a requirement to meet the obligations under the EU ABS Regulation.

Annex I - References to relevant provisions in legislation & EU guidance

Chapter	EU ABS Regulation	Implementing Regulation	Horizontal Guidance Document
1. Identify and keep track of what GRs are coming in and going out	Articles 4(1); 4(3); 4(6); 7(1); 7(2); 9(4); 9(5)	Article 6	
2. Develop an internal procedure to follow the rules of the EU ABS Regulation			
3. Determine whether a GR falls within the scope of the EU ABS Regulation	Articles 2; 3(1) to 3(5)		Chapters 2 and 5
4. If material falls under the scope of the EU ABS Regulation, find out if due diligence is considered to be already 'automatically' complied with	Articles 4(4); 4(5); 4(7)		Chapters 3.5 and 5.2.1
5. If due diligence is not considered to be 'automatically' complied with regarding the GR you access, perform a due diligence check and obtain PIC and MAT, if this is required	Article 4(2)		Chapter 3
6. Know which obligations to follow when transferring genetic material	Article 4(3)		
7. Know when and how to make the necessary declarations to the authorities	Article 7	Articles 5; 6 and Annexes II; III	Chapter 4
8. Be prepared for compliance checks by the national authorities	Articles 9; 10; 11		

Annex II - Definitions

Genetic resource: means any material of plant, animal, microbial or other origin containing functional units of heredity that is of actual or potential value. (Article 3(1) and (2) of EU ABS Regulation)

In-situ conditions: means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

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 EU ABS Regulation)

User: means a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources. (Article 3(4) of the EU ABS Regulation)

Utilization 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 Convention. (Article 3(5) of the EU ABS Regulation)⁶¹

Result of the utilization: means products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilization of the genetic resource and traditional knowledge associated with genetic resources. (Article 6(3) of Implementing Act)

Placing on the Union market: means the first making available of a product developed via utilization of genetic resources and traditional knowledge associated with genetic resources on the Union market, where making available means the supply by any means, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. Placing on the market does not include pre-commercial trials, including clinical, field or pest resistance trials, nor the making available of unauthorized medicinal products in order to provide treatment options for individual patients or groups of patients. (Article 6(4) of Implementing Act)

Plant Genetic Resources for Food and Agriculture (PGRFA): means any genetic material of plant origin of actual or potential value for food and agriculture.

Prior Informed Consent (PIC): means a prior consent from the provider of the genetic resource authorizing access to the genetic resource. PIC is foreseen in Article 15(5) of the CBD. Article 6(3)(e) of the Nagoya Protocol further clarifies that Contracting Parties shall provide an access permit or an equivalent at the time of access as proof of PIC.

Mutually Agreed Terms (MAT): means the contractual terms negotiated between provider and user determining the conditions under which utilization of the genetic resources and benefit-sharing shall be carried

⁶¹ The EU ABS Regulation only applies to utilization within the territory of the EU due to the fact that EU law has no extra-territorial effect. Therefore, in case of a variety bred outside the EU and then marketed on the EU market, the EU ABS Regulation does not apply.

out. MAT is foreseen in Article 15(4) of the CBD and Article 6(3)(e) of the Nagoya Protocol states that the access permit or its equivalent should also serve as a proof of establishment of MAT.

Standard Material Transfer Agreement (SMTA): means the standard material transfer agreement provided for in Article 12(4) of the ITPGRFA. Facilitated access to genetic resources under the Multilateral System of the Treaty is provided pursuant to the terms of [the SMTA](#).

National Focal Point: means an institution designated by the Contracting Parties to the CBD/Nagoya Protocol to liaise with the Secretariat of the CBD and to make available information on procedures for accessing genetic resources and for establishing mutually agreed terms, including information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

Internationally recognized certificate of compliance: means an access permit or its equivalent issued in accordance with Article 6(3)(e) of the Nagoya Protocol and made available to the ABS Clearing House.

Annex III - Abbreviations

ABS	Access and benefit-sharing
PIC	Prior informed consent
MAT	Mutually agreed terms
SMTA	Standard material transfer agreement
IT PGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
ABS CH	Access and Benefit-Sharing Clearing House
CBD	Convention on Biological Diversity
NFP	National Focal Point
NP	Nagoya Protocol
GR	Genetic Resource

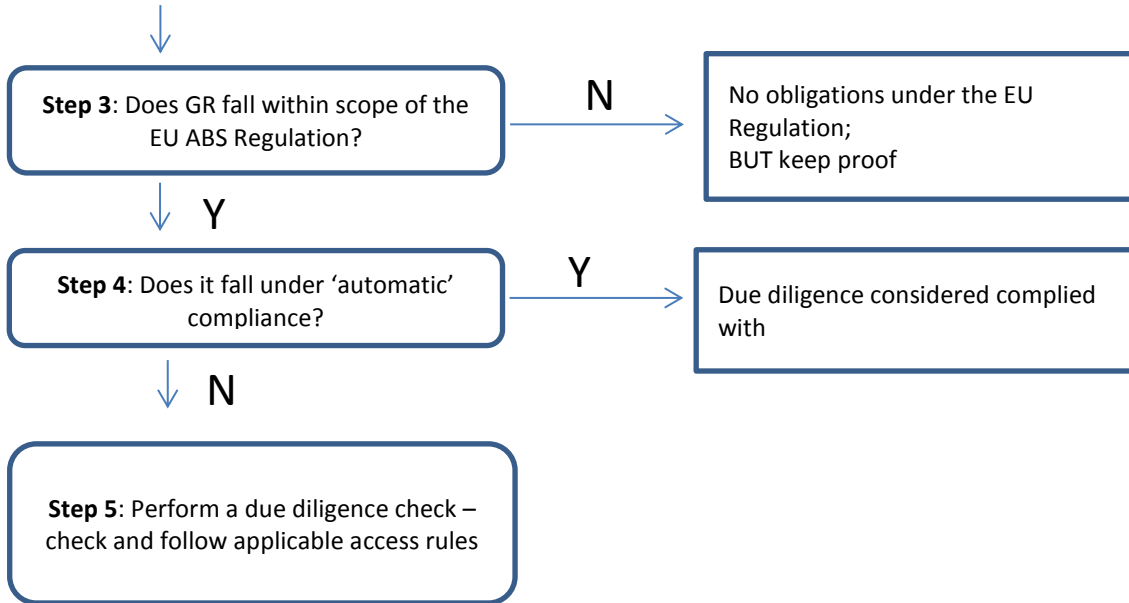
Annex IV - Useful websites

- ✿ ABS website of DG Environment of the European Commission:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
- ✿ FAQ of the DG Environment on the EU ABS Regulation:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Q_As_on_ABS.pdf
- ✿ Website of the Nagoya Protocol: <https://www.cbd.int/abs/>
- ✿ Website of the ABS Clearing House: <https://absch.cbd.int/>
- ✿ Website of the Convention on Biological Diversity (CBD): <https://www.cbd.int/>
- ✿ Website of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA):
www.planttreaty.org
- ✿ Website of the European Cooperative Programme for Plant Genetic Resources (ECPGR):
<http://www.ecpgr.cgiar.org/>
- ✿ ISF interactive information tree: <https://members.worldseed.org/public/genetic-resources.jsp>
- ✿ ESA ABS site: <http://abs.euroseeds.eu/#>

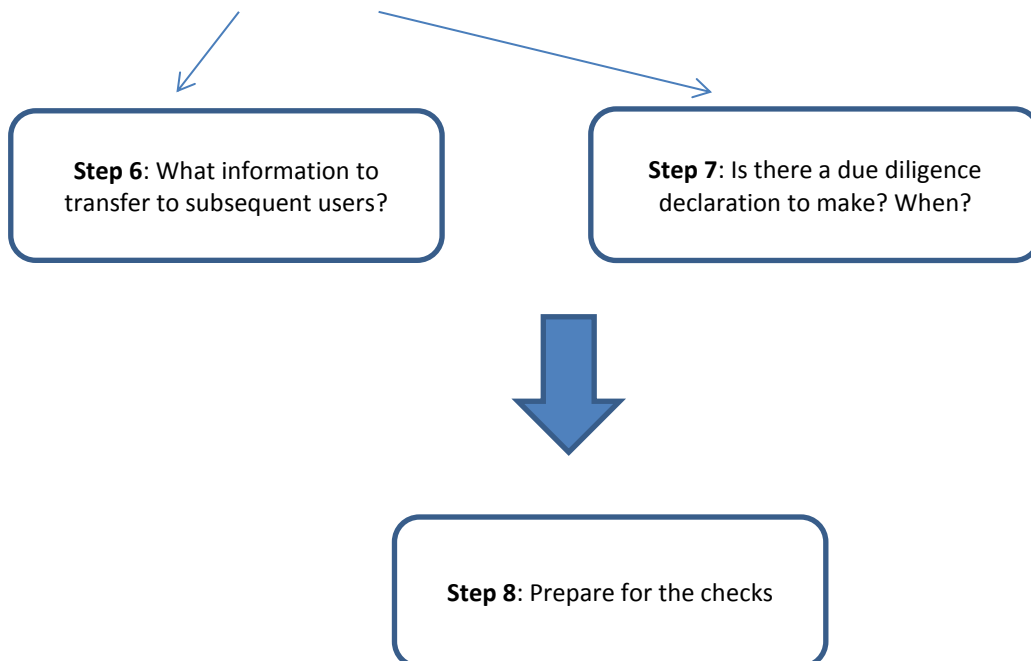
Annex V - Decision trees

Preparatory phase:
Step 1: Create T&T system
Step 2: Develop internal procedure

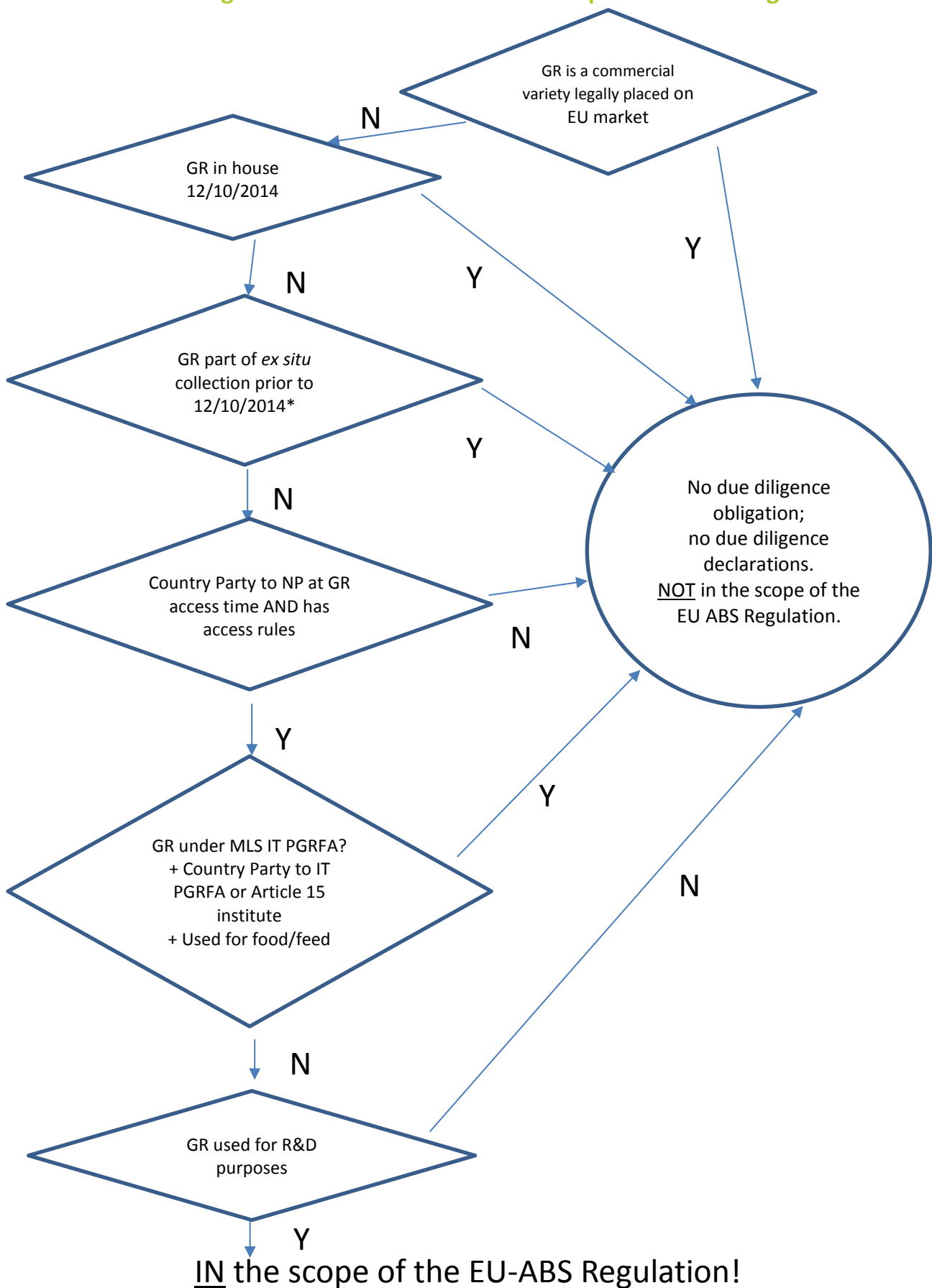
INCOMING GENETIC RESOURCE



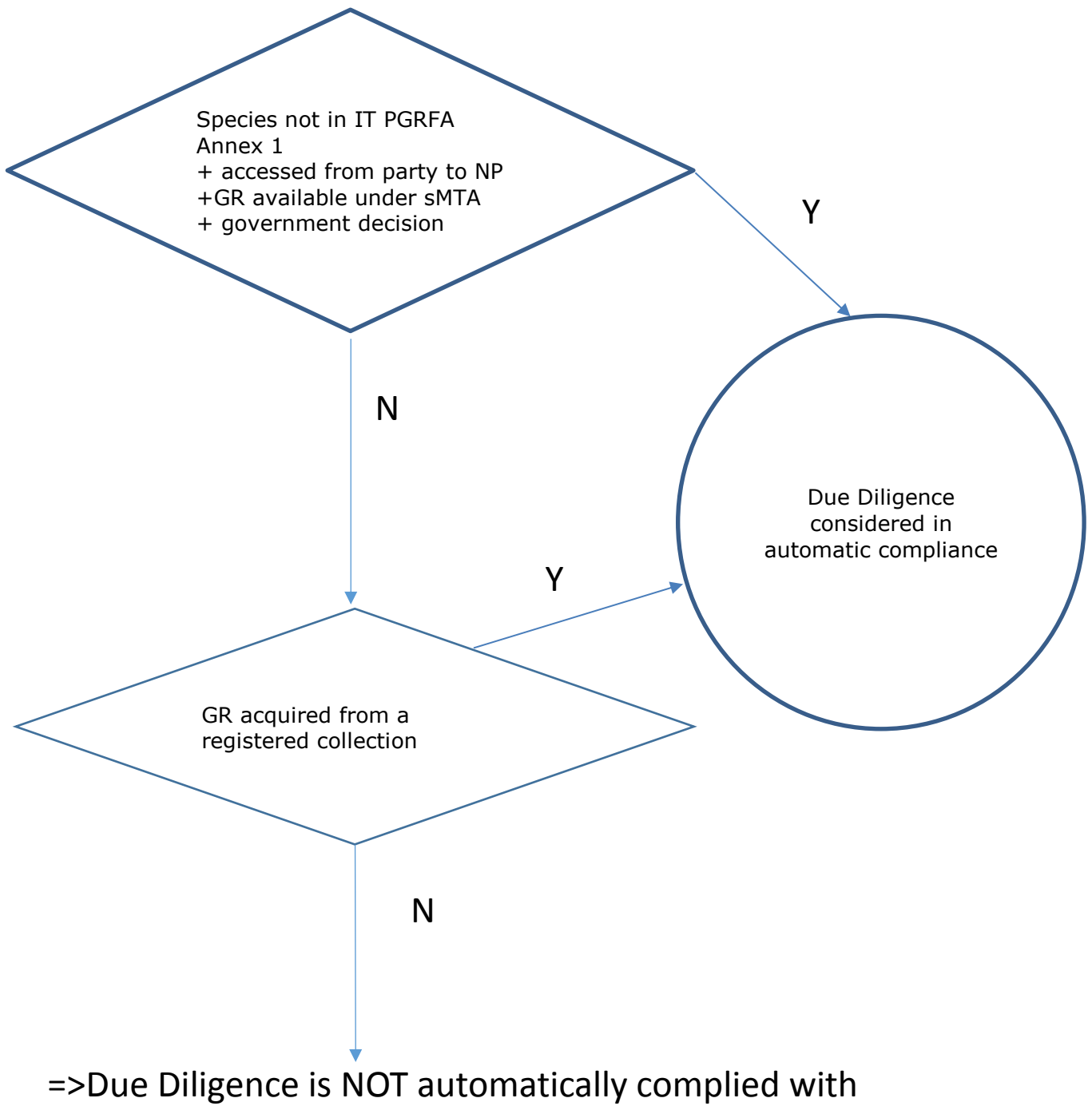
EXITING GENETIC RESOURCE



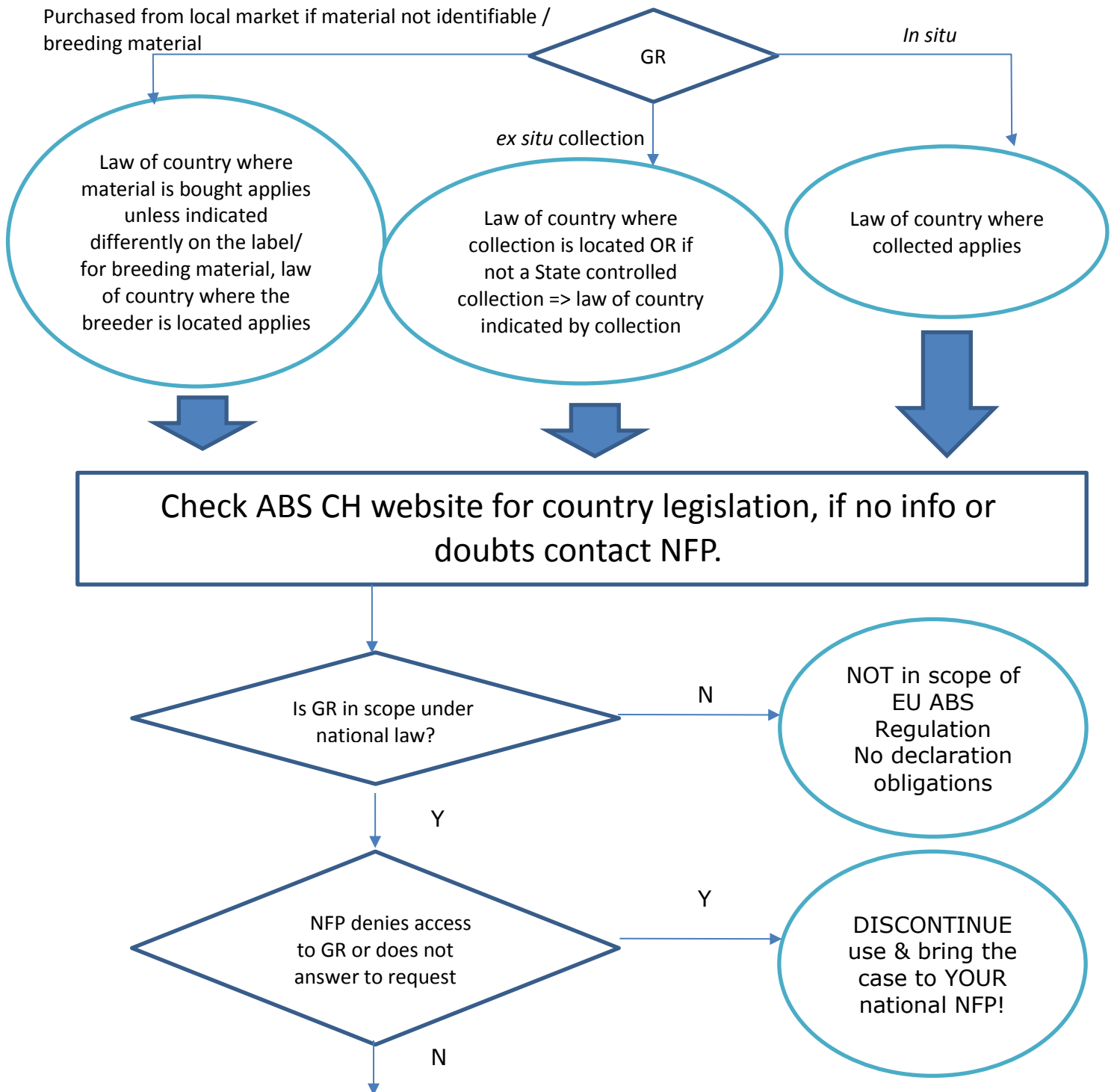
STEP 3: Determining whether GR falls within the scope of EU ABS Regulation



STEP 4: Due diligence automatically complied with

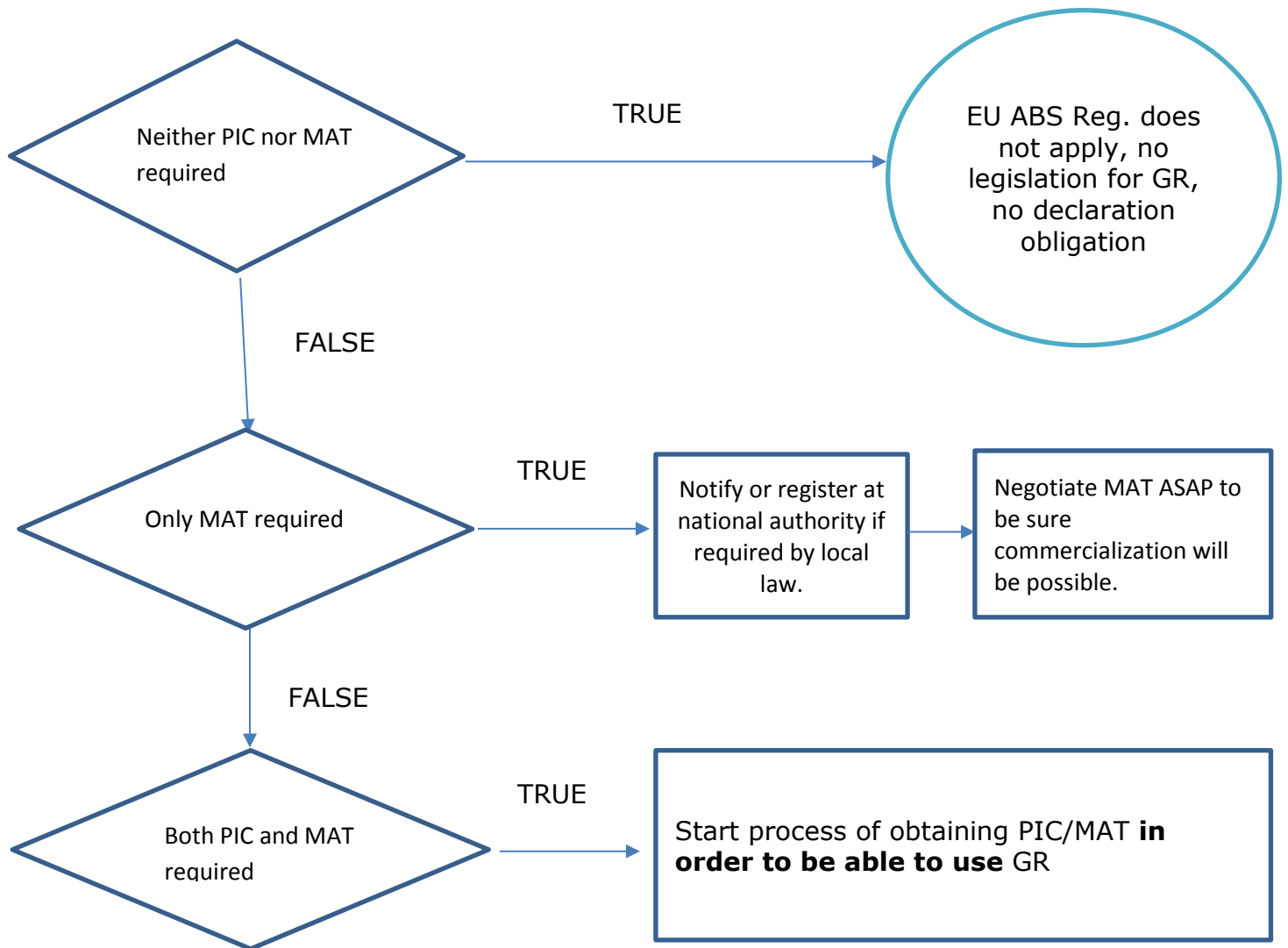


STEP 5: How to follow the due diligence obligation? – Finding out the applicable legislation



Follow up based on PIC/MAT of local law

STEP 5: How to follow the due diligence obligation – Checking requirements in applicable national ABS law



STEP 5: Obtaining PIC & MAT

PIC application process: preparatory steps & questions to consider

Define purpose/use of GR
-Research/breeding
-crosses with whole gene pool? GM?

Clarify if results will be commercialized

Clarify who can be allowed to use material, can material be transferred/ under what conditions / to which countries?

Obtain explanation on how to obtain/export material

Plan timeline, ensure PIC will be valid until and during commercialization. Will material still be usable after expiration of PIC?

Find out if cooperation with local company or institute is required for PIC.

Generally PIC and MAT required so start MAT at same time to ensure both are possible.

MAT application process: preparatory steps & questions to consider

Link to PIC application
Describe material to which it applies, should be broad but should not limit rights to use material.
Clear definition of scope of rights and obligations

Clearly define conditions which trigger benefit sharing. Try to make agreements consistent across countries. Avoid open ends.

Avoid conditions requiring passing on of obligations for commercial varieties.

Clear termination conditions and cut-off point. Clarify consequences for GR and results obtained using GR.

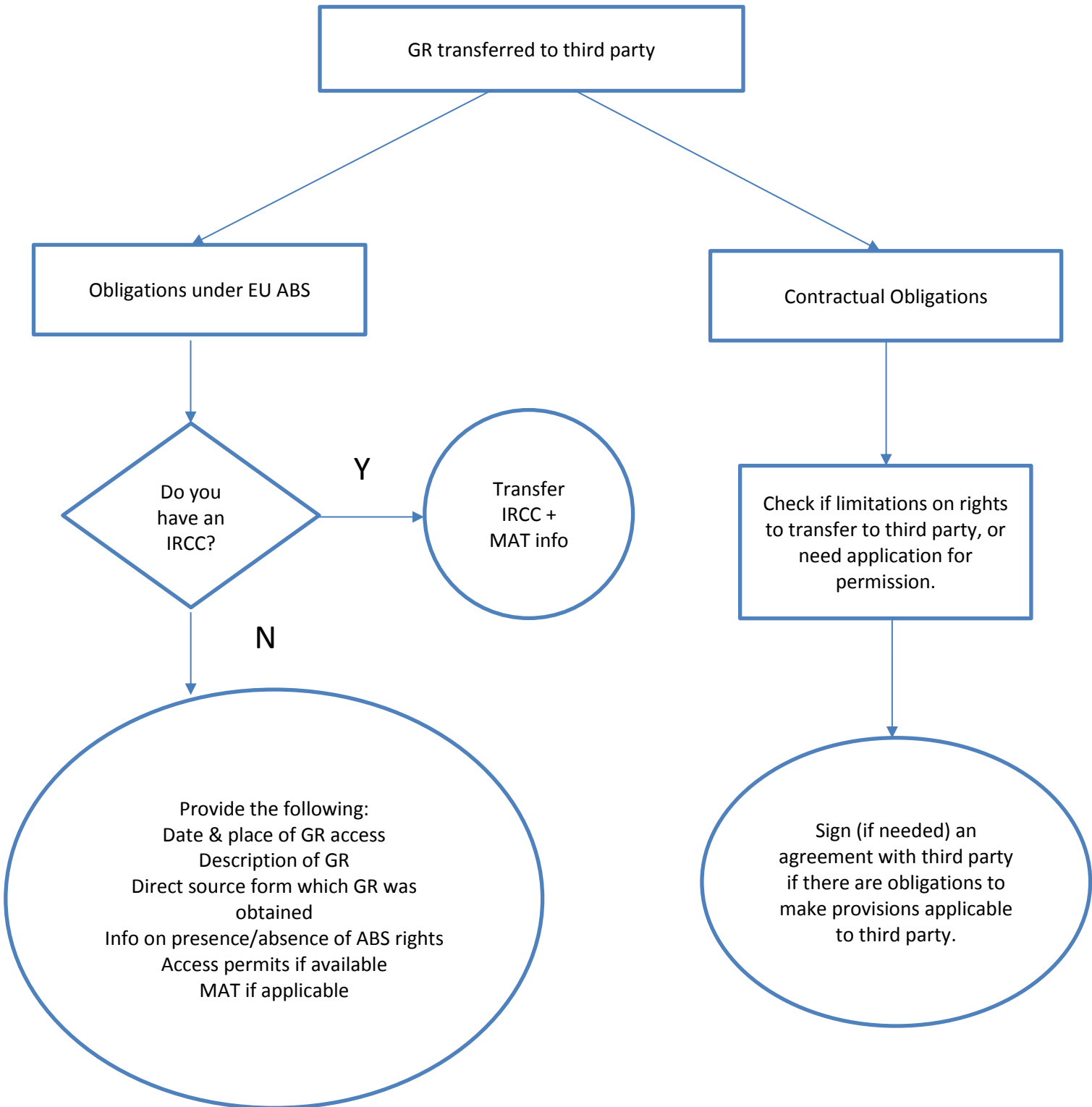
Determine jurisdiction country. Determine if arbitration should be used instead.

Clarify terms for passing materials on to others including subsidiaries, service providers, universities, other breeders.

Clarify terms for passing results of R&D further on. Are there limitations? Are these acceptable? Is country approval needed for commercialization?

Clarify rules for sharing information resulting from the use of GR, including publication of results in public domain. Avoid clauses that block further use of such published results.

STEP 6: Obligations to follow when transferring material



STEP 7: Declaration at receipt of research funding

WHEN?

AFTER initial funding received AND all GR obtained
AND
BEFORE final research report released OR project end

WHO?

Made **by** recipient of research funding

Funding = any research grant under Implementing Regulation

2. Made to Member State authority of recipient or where research is carried out if recipient is established outside EU
3. If Multiple parties in project, DD is made by Project Coordinator if so agreed.

HOW?

- 1 DD is prepared per project (provided group involved in project agreed upon 1 declaration)
- Declaration is submitted by Coordinator of the project if so agreed
- Through the [DECLARE tool](#) developed by the European Commission

STEP 7: Declaration at the stage of final development

WHEN? Before the 1st of the following events

1. Market approval or authorization sought for product being development with GR
2. If notification required before placing product on Union market, BEFORE notification submitted
3. When placing product on Union market for 1st time
4. When result of utilization of GR sold or transferred within Union for purposes in 1-3 above.
5. When utilization in Union has ended and outcome sold or transferred outside Union

WHO?

Made **by** User of the GR

2. Made **to** Member State authority where user is established

HOW?

- Through the [DECLARE tool](#) developed by the European Commission