RECOMMENDATIONS FOR ESA MEMBERS

ON HOW TO FOLLOW THE RULES OF THE EU ABS REGULATION

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I. INTRODUCTION

The 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 European Union, as signatory to the Nagoya Protocol, decided to transpose 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 Regulation, it is left to individual Member States to define their own access rules if they wish to do so. The EU regulatory 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 the EU ABS Regulation (in preparation)
- Commission Sectoral Guidance Documents on R&D (in preparation)

NB: At the moment of the present workshop the final version of the horizontal guidance document of the European Commission on the scope of the Regulation is not known to ESA and the work on the sectoral guidance document on plant breeding has not started yet. This means that there are some key issues on which further clarification from official sources (European Commission) is still awaited. This is also the case for the very important question of whether commercial plant varieties are or are not covered by the scope of the Regulation. All these elements have been grey shaded in the present document. Therefore, please note that when you read grey shaded parts in this document you should know that it is the interpretation of ESA which ESA thinks provides a reasonable way forward however has not yet been confirmed by any official authority at European or Member State level.

This 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 the purpose of research and development 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 a number of interpretative guidance documents are still in preparation by the European Commission, there are still many areas of uncertainty 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.[1]
- 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 is provided 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. This is followed by a reference to the relevant provisions of the EU ABS Regulation and of the Implementing Act and guidance documents where relevant. 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 find annexed a decision tree providing assistance regarding the questions to be asked and the decisions to be taken when following the Regulation, as well as a table providing information on the applicable national laws in each EU Member State.[2]

It must be noted that although it is the intention of ESA to take all efforts to develop this document into sectorial best practices for which recognition at European level may be applied for, in its current stage it is possible that not all national or EU authorities would agree with its content.

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 develop an internal system to keep track of the genetic resources coming in and going out of the company (track and tracing).
2. Develop an internal procedure to comply with 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.

[1] The steps outlined in the present document are meant to assist plant breeders in following the rules of the EU ABS Regulation only. Breeders must also continue to comply with other legal obligations that apply; such as intellectual property rights, national ABS measures, import/export regulations; phytosanitary measures, seed marketing regulations, other product authorization rules etc. Please note that this is a non-exhaustive list of legislations that may apply.

[2] Please note that Annexes IV and V (decision tree and table with national laws is not yet included in this document. Those annexes will be included in the final version of he recommendations.

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, perform a due diligence check 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 in the R&D (breeding) process genetic materials may come in or go out[3]
b. Develop an appropriate tracking and tracing system[4]

a. Identify where in the R&D (breeding) process genetic resources may come in or go out

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 type of genetic resources do you use in your R&D (breeding) activities?[5]
- How do you obtain these genetic resources?
- Which departments or positions 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 type of genetic resources leaves your company?
- Which departments or positions are involved in the transfer of genetic resources to another party?

b. 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.

[3] For purposes of research and development.
[4] 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 of the company.
[5] 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.

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

- Possibility to include detailed information per genetic resource (such as species; date of access; provider country; direct source of acquisition; description; purpose used for; for material going out date of exit; destination);
- Possibility to 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;
- Possibility to easily recover the aforementioned information;
- Pedigree option for breeding material, demonstrating the resources used to develop the material, preferably with a linking through option to see the details of a used resource;

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.

It is also advised to make sure that the information remains available at least 20 years after the end of the period of utilization.[6]

Relevant articles

EU ABS Regulation

Article 4(1); 4(3); 4(6); 7(1); 7(2); 9(4); 9(5)

Implementing Act

Article 6

[6] It is to be noted that the EU ABS Regulation uses this language. However, ESA commented on several occasions to the European Commission that in breeding this notion cannot be understood and requested further clarification which is still awaited.

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 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. 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 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. 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 PIC and MAT requirements for such type of genetic resources, which are used for research and development purposes. Therefore, in order to be able to determine whether genetic material 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; (ii) if the genetic resource was accessed in a country that is Party to the Nagoya Protocol and that has established access legislation 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 R&D 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.

Therefore, determine if the genetic resource falls within or outside the scope of the EU ABS Regulation by assessing the following criteria:

a. Assess whether the genetic resource was already in-house before October 12, 2014;
b. In case the genetic resource comes from an *ex situ* collection situated in the EU, assess whether it is a genetic resource that was already part of the collection in question prior to October 12, 2014;
c. 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;[7]
d. 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;
e. Assess for which purpose the genetic resource will be utilized.

[7] See also point 2.1.2 of the EU Guidance document on scope (page 7).

a. 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.[8]

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 clarified by the European Commission that the same obligations apply to the genetic resources accessed between October 12, 2014 and October 11, 2015 as for the material accessed after October 12, 2015.

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

If you acquire a genetic resource from an *ex situ* collection after October 12, 2014 that was already part of the *ex situ* collection prior to October 12, 2014, this genetic resource is considered to fall outside the scope of the EU ABS Regulation.[9] [10]

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 persons. The only relevant question should be whether it was part of an *ex situ* collection on (and/or before) October 12, 2014.[11]

c. Assess whether the country from which the genetic material is (or was) acquired is (or was) a Party (or not) to the Nagoya Protocol at the time of access and has established access rules

Check if the country from which the genetic resource is acquired is a Party to the Nagoya Protocol (you can check this information on the Access and Benefit-Sharing Clearing House: https://absch.cbd.int/countries). If the providing country is not (yet) a Party to the Nagoya Protocol, the genetic resource does not fall under the scope of the EU ABS Regulation.

[8] 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, however it needs to be checked in the national law how the burden of proof is regulated. Nevertheless, it is recommended to have some evidence proving on which basis you decided that a certain genetic resource falls outside the scope of the EU ABS Regulation.

[9] 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.

[10] See also point 2.2 of the EU Guidance document on scope (page 9.).

[11] 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 (top of page 10) of the EU Guidance document on scope.

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: https://absch.cbd.int/search/national-records/MSR. 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,[12] the Regulation does not apply.

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.

d. 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 International Treaty governs access and benefit-sharing for genetic resources belonging to the species listed in the Treaty's Annex I: http://planttreaty.org/content/crops-and-forages-annex-1 . Therefore, if the genetic resource belongs to a species listed in Annex 1 of the Treaty and is obtained from a country that is Party to the Treaty (http://planttreaty.org/content/contracting-parties-treaty) or from an *ex situ* collection held in Trust by an International Agricultural Research Centre having signed an agreement with the Treaty (such as CIMMYT, ICARDA, CIP, IRRI etc.: http://www.planttreaty.org/content/agreements-concluded-under-article-15), and is utilized for food / feed purposes,[13] it does not fall under the scope of the EU ABS Regulation.[14] However, if such a genetic resource is obtained from a country that is not Party to the Treaty but Party to the Nagoya Protocol or is utilized for non-food/feed purposes, the Treaty does not apply and

[12] This is the case for genetic resources for example from Germany, UK, the Netherlands etc. but not necessarily for other European countries; you will need to check.

[13] 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).

[14] See also points 2.3.1 and 5.2 of the EU Guidance document on scope (pages 10 and 26-27).

e. 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.[15] As clarified under Annex I (definitions), utilization is research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.[16]

The range of activities that may occur with genetic resources is wide and may differ significantly sector by sector.[17] In plant breeding many cases exist where genetic resources play a role in the crop characterization 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:[18]

- Genetic resources as testing / reference tools;
- Handling and storing of genetic resources and describing its phenotype;

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.[19]

Relevant articles:

EU ABS Regulation: Article 2; Article 3(1) to (5)

Guidance document on scope: Chapter 2

[15] See also point 2.5 of the EU Guidance document on scope (page 17).
[16] Please check the definition of utilization in Annex II, as well as footnotes 18 and 19.
[17] The current definition of utilization therefore needs further precision. The European Commission has announced that it will elaborate 7 separate sectorial guidance document discussing the notion of R&D and the type of activities it covers for the various sectors covered by the EU ABS Regulation.
[18] The examples provided here are the ones included so far in the EU Guidance document on scope (see point 2.3.3; page 15). Since this topic is going to be covered by the sectorial guidance document on plant breeding further examples may be added here later.
[19] See footnote 6 of the present document and point 3.2 (page 20) of the EU Guidance document on scope.

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 – according to Article 4 of the Regulation - should be exercised to make sure that the genetic resource was obtained in accordance with applicable access and benefit-sharing legislation.

Due Diligence is a key concept in the EU ABS Regulation; however it does not give any direction as to how such obligation may be fulfilled. According to Article 4 of the EU ABS Regulation it means the obligation of users to seek, keep and transfer information to subsequent users. The Commission Guidance document on the scope of the Regulation gives some hints as to what should be included under due diligence. According to those hints, 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.[20]

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

a. Due diligence is considered exercised if 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.

b. Due diligence is considered exercised as regards the seeking of information if you acquire the genetic resource from a registered collection.[21]

c. If you access and use for further breeding any commercial varieties that are sold on the EU market

Relevant articles:

Article 4(4) and 4(7) of EU ABS Regulation

Guidance document on scope: Chapter 3

[20] See point 3.1 of the EU Guidance document on scope (page 18).
[21] 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. See also point 3.4 of the EU Guidance document on scope (page 21).

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

Once you have determined that a genetic resource falls under the scope of the EU ABS Regulation and due diligence is not considered to be 'automatically' complied with, you will have to exercise due diligence to make sure that the genetic resource has been accessed in accordance with the applicable access and benefit-sharing legislation. This means that you will first need to find out what the applicable access and benefit-sharing legislation is and how to apply it to the particular genetic resource in question (due diligence investigation).

The outcome of the due diligence investigation can be as follows:

- no PIC and MAT are required for the genetic resource in question;

You have normally already done this analysis under point 3 since 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 needed but MAT need 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.[22]

<u>Steps recommended to follow the due diligence obligation:</u>

1. Determine which country's applicable legislation you have to follow:
    a. Collecting from the wild (*in situ)*: applicable legislation of the country where the material is collected

[22] 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.

b. Obtaining *ex situ*[23]: in principle access takes place under the terms defined by the provider of the genetic resource and one can rely on the information provided by such provider. Should the provider indicate that uncertainties may exist as to the legality of access regarding the genetic resource if the provider states that (s)he has no knowledge as to where the genetic resource was obtained from, the applicable legislation of the country of access should apply. Only in cases where the provider specifically indicates that the user has to go back to a specific country to regularize access should it be necessary to go back to that given country to ask for PIC and MAT.
c. Transfer of breeding material between companies: the same approach should apply as above. The applicable legislation of the country in which the provider of the genetic resource is established should apply.
d. Buying seeds, fruits or propagating material from the local market: applicable legislation of the country where it was bought, unless indication that another country's law applies. In such case, in principle a label on the package could indicate the place of production and the denomination of the variety.
    i. E.g. tomato in a box in the supermarket, stating they were produced in Spain and you do not know the variety: look into the Spanish legislation.
    ii. E.g. tomato in a box in the supermarket and it is not indicated where they come from: look at the legislation of the country where you buy the product.

2. Once you know which county's legislation applies, the following steps could be applied:
    i. Go to the website of the ABS Clearing House (https://absch.cbd.int/countries) 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 CH it is recommended to contact the National Focal Point of the country to enquire about existing legislation.[24]
    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: https://absch.cbd.int/search/national-records/NFP. Ask the National Focal Point whether the acquisition of the genetic resource would be in line with the applicable access and benefit-sharing legislation.

    iii. Check whether the type of material (wild, landrace, from a public or private collection, commercial varieties[25], pathogens, DNA-samples etc.) that you are accessing is included

[23] Obtaining material ex situ may cover scenarios when material is accessed from a genebank or from a grower or any other holder.
[24] See also point 3.2 of the EU Guidance document on scope (page 19).
[25] In case commercial material is not defined in the national legislation, it could be defined as any biological plant material, reproductive or not, that belongs to:

- a variety listed on a national, European or international register or catalogue of plant varieties, or
- a variety not yet listed that may be officially put on the market because the registration process is ongoing, or
- a variety listed in a company's sales catalogue or web shop, under a unique variety or brand name, except where landraces and/or crop wild relatives are concerned, or
- a variety that is commercialized on the market in a labelled bag, or with a preprinted label attached. -- except where landraces and/or crop wild relatives are concerned,

in or excluded from the scope of the national legislation.[26] If it is excluded, the EU ABS Regulation does not apply and therefore there are no further user obligations to comply with.

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, and it is also recommended to bring such a case to the attention of the National Focal Point of your own country.

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. 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.

In order for material to be considered commercial, it does not have to be actually acquired in the labelled bag itself. It could also be acquired without the bag. As long as it can be reasonably demonstrated that it belongs to a variety, defined above. For example, you receive some seeds from a grower, which seeds belong to a commercial variety. The grower does not give the original bag to you, but puts the seeds in another, unlabeled bag. As long as you can reasonably prove that the seeds belong to the commercial variety, for example having a transfer document from the provider that identifies the material or by taking a picture of the bag, in the possession of the grower, it should still be possible to qualify this material as commercial.

[26] As it is not yet clear whether commercial varieties fall in or outside the scope of the EU regulation this exercise has to be done.

ESA best practice 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. and / or by phone) 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 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.

Steps to obtain PIC and MAT

As said above, the outcome of the due diligence investigation can be that you need to obtain PIC and 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 you need to follow.

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.

<u>Issues to consider when negotiating Mutually Agreed Terms:</u>

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.[27]
f. When negotiating benefit sharing arrangements try to agree upon roughly the same conditions for all countries to avoid creating a precedent.
g. Avoid conditions that 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.

[27] For the sake of assistance, you may consult the Annex to the Nagoya Protocol on monetary and non-monetary benefits: https://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37

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.

Relevant articles:

Article 4(2) of the EU ABS Regulation

EU Guidance document on scope: Chapter 3

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), this agreement may (unfortunately) contain provisions that limit the right to transfer the genetic resource to a third party. It is therefore important to first 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[28] to a third party it is recommended to transfer the above-mentioned certificate as well as the relevant content of the MAT. 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.

Relevant articles:

Article 4(3) of the EU ABS Regulation

[28] Here the understanding of ESA is that this obligation to transfer information to subsequent users only applies to genetic resources "in the form received". This point however is to be further clarified in the sectorial guidance document.

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

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.[29]

If there are several users involved in the project, only one declaration has to be submitted by the project coordinator if so agreed by the parties to the project. The declaration has to be made by completing the template foreseen for this purpose in Annex II of the Implementing Regulation.[30]

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.

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;

[29] 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 (page 22).

[30] In Annex IV to this document you will find a table including 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 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.

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 market[31] for the first time;

iv. when the result of the utilization[32] 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 outcome 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 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).

The declaration has to be made by completing the form foreseen for this purpose in Annex III of the Implementing Regulation to the competent authority of the Member State in which the user is established. In Annex IV to this document you will find a table including 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.[33]

[31] Placing on the Union market is defined in Article 6(4) of the Implementing Act. The definition is reproduced in Section II of the present document.
[32] Result of utilization is defined in Article 6(3) of the Implementing Regulation. The definition is reproduced in Section II of the present document.
[33] It is known that the European Commission is developing an on-line application by which due diligence declarations can be made provided that the Member State concerned has joined the application.

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 are in the public domain, not listed in Annex I of the Treaty, is also subject to the conditions of the sMTA, no due diligence declaration has to be made.[34]

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.[35]

Relevant articles:

Article 7 of the EU ABS Regulation

Articles 5 and 6; Annexes II and III of the Implementing Regulation

Guidance document on scope: Chapter 4

[34] See also point 4 above. See as well point 5.2.1 of Commission Guidance document on scope (page 26).
[35] See point 3.4 of the EU Guidance document on scope (page 21).

8. Be prepared for the 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 individual decision of 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 table provided in Annex IV to this document.

Although it is hard to foresee at this moment in time how the checks will be performed, in order to be ready for compliance checks by the competent authorities, it is advisable to at least take preparatory actions such as:

- 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.
- 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, like 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 would be the best placed.

Relevant articles:
Articles 9, 10 and 11 of the EU ABS Regulation

Annex I

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)

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[36] 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)[37]

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)

[36] It is to be noted that at this moment in time it is not yet clear whether the European Commission interprets R&D as practically referring to research and/or development, thereby catching also activities which do not necessarily involve a development step. The interpretation of the European Commission is to be monitored.

[37] According to the interpretation of the European Commission, the EU ABS Regulation only applies to utilization within the territory of the EU. Therefore, in case of a variety bred outside the EU and then marketed on the EU market, the EU ABS Regulation does not apply.

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 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 II

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(M)	Access and Benefit-Sharing Clearing House (Mechanism)
CBD	Convention on Biological Diversity
NFP	National Focal Point

Annex III

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): http://www.planttreaty.org/

Annex IV

Decision tree

Annex V

National legislation implementing the EU ABS Regulation