

### Access and Benefit-Sharing (ABS)

A graphical overview

**Start the guide** 

This material concerns how to work compliantly as a researcher using foreign *genetic resources* and *traditional knowledge* associated with genetic resources. It shows some of the key elements about *Access and Benefit-Sharing (ABS)* requirements in other countries and summarizes how to comply with legal requirements as a researcher active in Sweden, especially the EU ABS regulation 511/2014.

### **About this material**

This overview is for *researchers at Swedish universities* and other non-commercial research institutions. It provides an overview of due diligence obligations under the <u>EU ABS Regulation (511/2014)</u> to consider when using foreign genetic resources or traditional knowledge associated with genetic resources.

You will not learn about the background to the Nagoya protocol or the scope of the EU ABS regulation. Similarly, it will not help you understand if you, according to legislations mentioned within the material, are a user of genetic recourses or traditional knowledge associated with genetic recourses. For this, you must seek supplementary information.

If you are a researcher doing research in Sweden, we suggest the guidance from the Swedish Environmental Protection Agency's guidance pages on the Nagoya Protocol and genetic resources.

Furthermore, this overview does not give legal advice, and you should not use it as the sole source of information. The material has been produced by the Swedish Biodiversity Centre within the SIKTA ABS-project funded by the Swedish Environmental Protection Agency.



### Hi researcher!

Are you working with foreign materials or traditional knowledge? Do you suspect there might be requirements on you about collection permits or sharing benefits from your results?

Learn more



Yes, next step

### Is this for you?

Most importantly:

This information is only relevant for you who plan to use data, samples, sequence information, and/or traditional knowledge **that originates in another country other than Sweden**.

It is an overview for researchers using genetic resources and traditional knowledge associated with genetics recourses.

It will help you find relevant information and plan activities.

It cannot help you to figure out if you are or are not a **user** of any of the above per se, as that is a very complex topic. But it will help you find sources of information and help you realize some requirements on you.

Use the following key to see how likely it is that your research is within the scope of this material.

**QUICK CHECK - IS THIS RELEVANT TO YOU** 

If you plan to use genetic resources or traditional knowledge you should know that each country has the right to set terms for your access and use; the collection event, your activities and purpose, how you may share and save data and materials, and many other things.

**Learn more** 

Here is an overview of things to consider about Access and Benefit Sharing (ABS) processes\* in other countries as well as compliance in Sweden.

### ABC of ABS

Access laws are about requirements and permits for accessing materials and traditional knowledge in a particular country. You may need to negotiate **Benefit-sharing** through legal contracts depending on the regulations in the provider country.

**Compliance** – you need to report your efforts to find ABS regulations in the provider country, and how you have lived up to them during your research activities in Sweden.

Learn more

Ok, let's begin



### Why is this important?

Countries that previously have provided biological resources through history (e.g. in southern Asia, Africa, and South America) do still have a rich biodiversity that attracts many researchers. Today these countries want to have full control over their genetical resources and their uses, and many of them have consequently restricted access. International instruments about ABS have been agreed on by many countries with the purpose of regaining trust and building long-lived solutions for sharing of benefits and research results, and while appreciating and supporting the work of local biodiversity custodians.

### Two main roads

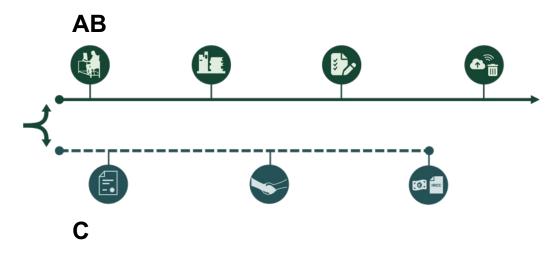
You will see an illustration with two tracks. Together they summarizes the "ABC of the ABS" from the previous slide. Compliance in Sweden and ABS requirements of other countries follow throughout the project's entire length and elements in them are often connected.

You must always follow ABS laws of other countries, but only in some instances will you be within the scope of the ABS compliance laws acting on you in Sweden. Follow both tracks and read the sources of information in both; it should lower the risks of missing out on important aspect of compliance.

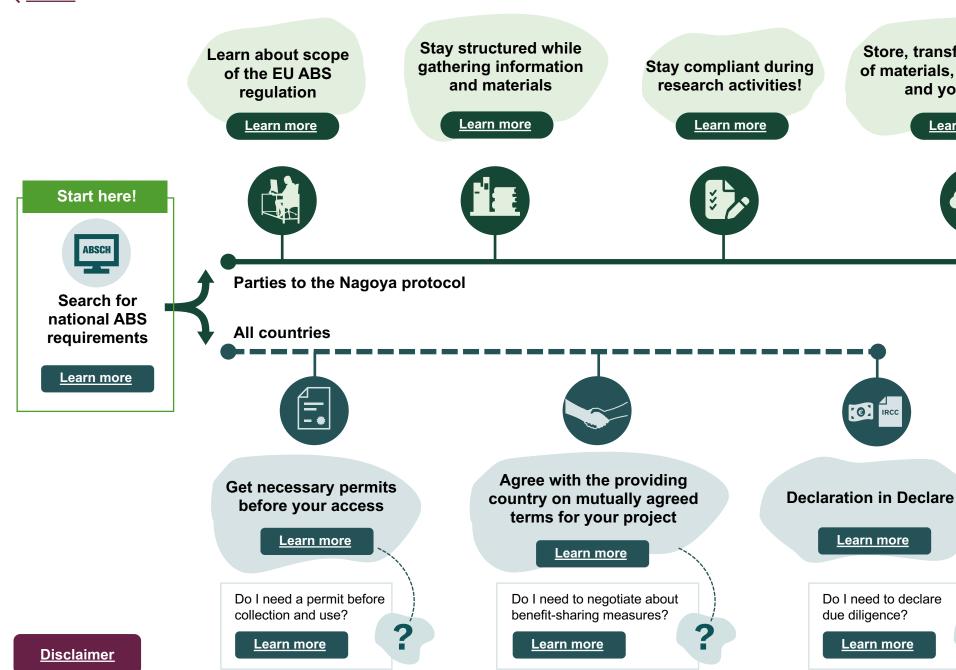
#### **ABC of ABS**

The lower track (blue) will mainly take place abroad and with officials of other countries. Expectations on you will differ in each country. You must follow each country's definitions of, for instance, "genetic resources" or "traditional knowledge".

If ABS laws exist and are relevant to your research project, you must also ensure that you meet requirements about compliance in Sweden. The upper track (green) together with the lower aids in fulfilling the needs.







Store, transfer and dispose of materials, documentation and your results

Learn more

Controls of your activities in Sweden

Learn more

### Congratulations!

You have acted towards a fair and sustainable use of natural resuorces and with respect for indigenous & local knowledge





# Search for ABS legislation for genetic resources and/or associated traditional knowledge

The Access and Benefit Sharing Clearing-house (ABSCH) is the best\* place to get started. Decide from the information you acquire about a country if your project is within the scope of the laws. Consider the definitions in each source, for instance "genetic resources" or "use". Many benefit to search for information about ABS requirements a part of the overall research project planning process.

#### **How to use ABS Clearing-House**

#### Note:

- 1. You are responsible for finding out about ABS requirements. Do "what it takes" while searching for information for you to get convinced.
- 2. You must confirm compliance for each new project or each re-use of materials, including materials from third parties like collections of samples, collaborators, companies, and so on.
- 3. If you are assisted by others: where the research takes place is highly relevant, and legal requirements for locals vs. foreigners are often different.
- 4. Finding information takes time, especially for specific countries (e.g., non-parties to the Nagoya protocol).



## How to use the ABS Clearing-House (ABSCH)\* to find national ABS laws

- 1. Go to the relevant country profile at ABSCH
- 2. In the country profile, look for posts under the headings
  - a) <u>ABS Procedure</u>: that summarize ABS requirements in that country. These are sometimes shown as flow charts. Only some countries have them.
  - b) <u>Legislative</u>, <u>Administrative</u>, <u>or Policy Measure</u> for ABS legislation and other relevant administrative requirements.

You might <u>not always find all necessary information</u> in ABSCH. If so, or if you need help figuring out if there are ABS laws of concern to you, you must check further sources.

- a) Look for environmental statutes and mentioning's of ABS on web pages of national authorities ("Competent National Authority" in ABSCH)
- b) ask the ABS contact person in the country that holds the genetic resource and/or the associated traditional knowledge ("ABS National Focal Point") directly.

### Country

#### Party to the Nagoya Protocol

- 1 ABS National Focal Point
- Competent National Authority
- Legislative, Administrative or Policy
- 2 ABS Procedure
- National Model Contractual Clause
- Internationally Recognized Certifica
- 1 National Websites or Databases
- 4 Checkpoint
- Checkpoint Communiqué
- 1 Interim National Reports on the Imp



Articles 14 and 17 of the Nagoya Protocol: information is submitted to the ABSCH as part of the compliance process. The competent authorities (SEPA in Sweden) have to share national information with the ABSCH. This ensures that information is exchanged.





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b) <u>Legisla</u> admini:

Why is this so?

A complicating factor now is that not all countries have had the resources to publish the information in appropriate channels (like ABSCH) so it mat take some time to gather information. Also, many are in the progress of drafting laws and administrative tools for ABS that might be hard to find. As a research you can help to create and optimize local routines and tools by using the official channels.

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## Learn if your research is within the scope of the EU ABS regulation

If the provider country is part of the Nagoya protocol and/or has national ABS laws, you must learn about the scope of the EU ABS regulation (511/2014). When you use foreign genetic resources and traditional knowledge related to genetic resources, <u>and</u> your activities are within scope\* of the regulation there are some extra due diligence obligations. You must do due diligence for new projects and also when you plan to re-use acquired (by you or a third party).

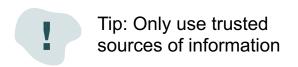
Consider the project and the regulation's

- a) temporal scope
  - i.e. if you can show that material was originally collected in the origin country prior to 12th of October 2014
- b) geographic scope
  - Only parties to the Nagoya protocol are covered.
- c) material scope

The materials or traditional knowledge are covered by the regulation's definitions.

...as well as the nature and purpose of your activities (use)







Tip: The access and benefit-sharing requirements are discussed with the country of interest, but your research activities in Sweden (the "use") are controlled here and your questions concerning them should be to the SEPA.

### In practice:

- 1) Read the <u>EU ABS regulation</u> about genetic resources and/or traditional knowledge associated with genetic resources
- 2) Read about **usage** in the in the <u>guidance document from the EU commission</u>
  - 1) Search the cases, try to relate them to your activities
  - 2) If you find no mention of your type of activities (or similar): ask SEPA how to interpret the laws for your type of activities. They may either answer directly or bring your question to the commission for advice
- Complement with information from SEPA, especially concerning traditional knowledge (the Swedish Environmental Code can expand the scope for projects using traditional knowledge)

Recall: It is the regulations in the provider country that determine the requirements of PIC (*prior informed consent*) and MAT (*mutually agreed terms*). It only deviates regarding the compliance apparatus and due diligence requirements.



Tip: Sikta pdf

## Stay structured while gathering information

Part of the <u>compliance process</u> is figuring out whether your activities fall within the <u>scope of access and benefit-sharing laws in other countries</u>. But you also need to be able to show that you have the permits, consents and agreements required by the supplier country. In order to fulfill due diligence obligations, you should have a routine for saving verifications of your efforts.

**Document** your efforts of searching and interpreting ABS laws. Save something to prove (and remember!) that you initially have searched for the information.

- a) Note legal documents you find
- b) Note names and titles of contact persons, or save correspondence
- c) Document and save the results of your efforts to interpret the requirements for PIC and MAT.
- d) Make a folder and save your files there during the project

#### Then, when needed:

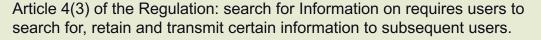
- 1. Obtain the prior informed consent (PIC)
- 2. Establish mutually agreed terms (MAT)
- 3. Declare due diligence in accordance with the ABS Regulation



Tip: Sikta pdf









### Stay compliant!

Your project may fall within or out of scope of the EU regulation if you alter your activities during the project. Keep track of your project changes to ensure that it does not deviate for the terms of you PIC and MAT. Be prepared to apply for new permits when conditions change!

#### Therefore:

- Monitor your activities during the project. Are there changes in your research that does not correspond to the project descriptions your PIC and MAT are based on? Have you altered the materials, collections methods, purpose of studies, country of the activities?
- If there are mutually agreed terms of use you must ensure that you work according to them. Don't share materials or data illegally. Benefit sharing may require continuous documentation and feedback routines from the beginning of the project.









### Store, transfer and dispose of materials, documentation and your results according to agreed terms and permits

#### **Keep information for 20 years**

You must keep PICs, MAT and other documentation necessary to follow up on the due diligence requirements for 20 years after the project has ended.

Note: This is often longer than normal archiving routines at Swedish universities.

#### Inform subsequent users of the conditions as described in PIC and MAT

The EU ABS regulation require you to inform subsequent users of material and data about any terms of use connected to them, including materials and data you store (if the storage is allowed according to MAT).

#### **Practical tips:**

- ✓ Dispose of materials and unused raw data so that no one else (or you!) may use it illegally.
- ✓ Make notes about how you met the requirements of MAT (if applicable).
- ✓ If you plan to transfer materials to collections or re-use them, make sure to mention this in the negotiations for MAT!





Article 4(3) of the Regulation: search for, retain and transmit information to subsequent users.





### Congratulations!

You have acted towards a fair and sustainable use of natural resuorces and with respect for indigenous and local knowledge.





### About the prior informed consent (PIC)

ABS laws are unique to each country. Access requirements like PICs are based on national legislation. If a country require you must be able to answer any questions about legal requirements for collections, export, use, or acquisition of samples to or from third parties. Hence the need to communicate with ABS contact persons in the origin country about the application processes or terms.

#### ABS is about trust!

Communicate via official contact persons and authorities or people assigned by them.

Be transparent and honest in your applications – don't hide details or use phrasing risks the creation of doubt.

### The Prior Informed Concent (PIC)\* is a permit that is granted to you before you start to collect and use material or data

It can be both illegal and arrogant to neglect PIC requirements. Don't expect that you can arrange permits after; there might be conditions about the collection that you will be unable to resolve later. Remember that ABS processes are not standardized and require time.

### Assume you need a PIC

Check before applying for funding (if applicable). You strengthen your application by showing the funding agencies you have considered ABS!

### Apply as early as possible (if applicable)!

Choose your language and explain details so that they enable the reviewers of your application to make informed decisions, e.g., authorities or representatives for indigenous peoples and local communities.



<sup>\*</sup>The term is used by parties to the Nagoya protocol, but may be called something else in the legislation



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### Do you need a prior informed consent?

Based on the information you gathered from official sources in the previous step, decide if you need to get prior informed consent (PIC)\* for your research activities.

Find information about the PIC requirements as well as the application process:

- 1. as "ABS procedures" in ABSCH or on official webpages, if available (ABSCH guide)
- 2. Check the web pages of national authorities (under "CNA" or "NFP" in the country profile in ABSCH)
- 3. Contact the national focal point in the country of interest for advice
  - a) by e-mail (gives written "evidence" to keep)
  - b) by calling (make a note about names, contact details, and dates)
  - c) ask local collaboration partners for help'
  - d) Other efforts, depending on the importance of the material/data. Can you visit? Ask authorities via LinkedIn or social media?



Tip: Ask the national focal point also about other relevant national legislation for your project!



## About benefit-sharing and mutually agreed terms (MAT)

For your research project you may have to negotiate about mutually agreed terms of use – MAT\*. MAT can be about requirements of benefit-sharing as well as other expectations on your usage. Read more about benefit-sharing for non-profit research.

MATs are legal contracts and the drafting of them is often coordinated by the <u>Competent National Authority (CNA)</u>. Ask for help at your university for help with drafting of MAT contracts, or with translations and interpretation of texts. Usually it is someone else that should sign the contract, and since it is not a standard contract it might not be enough with the head of department. Check within your organization!

Feel free to suggest benefit-sharing measures based on your needs and resources - or simply because you like the rationale of ABS.

Make sure that the MAT reflect on how you should report back about benefit-sharing or other time-sensitive issues.

During negotiations, remember that ABS is novel to most involved; you, your university, authorities and representatives for indigenous peoples and local communities. Don't attempt to save time by bypassing steps in the decision chain or hiding relevant information. To save time, instead:

- ✓ Ask at the initial inquiry about handling times (expect them to be longer).
- ✓ Remind the coordinating person about your own time-frames
- ✓ Prepare to be actively involved



Tip: Never sign a contract you do not understand – whatever reason.



Tip: Never accept terms that you don't think you can live up to!



### Why is MAT important?

As a researcher you can help with local efforts to preserve biodiversity in other countries.

Your contributions are passed on to local communities and indigenous peoples (IPLCs) for their work with sustainable methods of agriculture, forestry, or nature conservation work.

But benefit-sharing should not be regarded as a one-way "fee", as it is essentially about contributing to local nature conservation.

MAT should include terms for future use, material transfer to third parties (like museum collections or biobanks), innovation, patents, change of use within the current project, amongst many other things.

### Are there benefit-sharing requirements?

As with the PIC, you are responsible for figuring out if there are benefit-sharing requirements – save a record of your negotiations to prove your compliance (see Compliance)

If benefit-sharing is required, it is likely that you have came across information about that at this stage.

In the information from previous steps about ABS requirements, check needs for benefit-sharing and to negotiate on mutually agreed terms of use – MAT\*

If you are unsure about this step, ask local ABS contact persons (as for PIC)

## When and how to declare due diligence in Sweden

The due diligence declaration is a small administrative task that is needed, but it must be done at a certain time, at defined "check points" within the preparation phases of the project. Within the EU we use the common IT tool "Declare" for declarations. You should follow your organizations' routines\* about due diligence declarations and the IT tool Declare.

#### WHEN

### Submit your declaration at these "check points"

✓ If you receive external funding for the project.

#### After

- a) you receive the first instalment and
- b) all GR/TKGR used within the project have been received

#### **But before**

- a) The final report is submitted (if applicable)or
- b) at the end of the project (if no final report is required by the funding agency)
- ✓ If a product has been produced and is ready to be introduced on the market. Relevant to many within academia but not nearly as common as receiving funding.

#### HOW

#### You need either

- a) An International Recognized
   Certificate of Compliance
   (IRCC) <u>PLUS</u> information about
   the MAT of relevance for
   subsequent users.
- b) The PIC and the MAT

Read more about declarations on SEPA:s guidance pages.



Tip: A detailed procedure for submitting a declaration can be found in the User Guide for the DECLARE NAGOYA IT system.



Tip: Most Swedish universities have assigned ABS contact persons that you can ask about due diligence declarations.



### Need for due diligence declaration

If your project falls within the <u>scope of the EU ABS regulation</u> you have to show and **declare** due diligence. **Excercising** due diligence is broadly speaking the overall process that you learn by acting on the content in this information material. If you fail to do so you might be fined an Environmental Sanction Charge of 5.000 SEK.

If the EU ABS Regulation is relevant for your research, you need to submit a due diligence declaration only in the following two situations:

- 1. If you receive external funding for the project
  Note: No need for further product development or commercial interests, basic research is enough
- If a product has been produced and is ready to be introduced on the market.

Hence, even where there are situations where you do not need to declare due diligence! You still need to consider the rest of the due diligence requirements.

As with any laws you must always be able to show that you comply with the legislation of the country from which material or data are obtained. If the provider country is not a party to the Nagoya protocol, you will still need to make sure that you understand the national requirements regarding MAT terms and benefit-sharing.

### Compliance checks in Sweden

Swedish compliance checks regarding ABS are based on EU legislation and the scope of the EU ABS regulation, not national ABS laws. However, it is subject to national environmental law and may result in an Environmental Sanction Charge. These checks are for those who have collected genetic material or traditional knowledge in countries that at the time were parties to the Nagoya protocol and had developed applicable ABS laws.

The Swedish Environmental Protection Agency (SEPA) is the competent authority in Sweden when it comes to compliance regarding genetic resources and traditional knowledge associated with genetic resources and the EU ABS regulation. Read more about the requirements on <u>SEPA:s webb page</u>.

By following the lower track of this graphic guideline you've probably already completed the groundwork for the compliance aspects of the EU ABS regulation. The upper track should've prepared you for checks and helped you to lessen risks of illegitimate use of materials after the projects have ended.

The inspection will cover research projects on genetic resources and your research centre's system for ensuring due diligence; for example, how are the routines planned, implemented, improved and followed up when it comes to showing due diligence? How does the university work with the traceability? How is the division of responsibilities?



**Competent National Authority (CNA)** 

<u>Legislative</u>, <u>Administrative or Policy Measure (MSR)</u>

**Internationally Recognized Certificates of Compliance (IRCC)** 

**National Websites or Databases (NDB)** 

**Checkpoint (CP)** 

### **Competent National Authority (CNA)**

Authorities that are designated to be responsible for providing advice on the permit procedure, how to establish mutual agreed terms (MAT) and how to obtain prior informed consents (PIC). They are also, where applicable, responsible for the issuance of written certificates showing that the access requirements have been fulfilled.

**Legislative, Administrative or Policy Measure (MSR)** 

**Internationally Recognized Certificates of Compliance (IRCC)** 

National Websites or Databases (NDB)

Checkpoint (CP)

### **Competent National Authority (CNA)**

### Legislative, Administrative or Policy Measure (MSR)

Measures adopted on the national level to implement the Nagoya Protocol access and distribution obligations. Here you can see whether a country has access legislation or not.

**Internationally Recognized Certificates of Compliance (IRCC)** 

**National Websites or Databases (NDB)** 

**Checkpoint (CP)** 

**Competent National Authority (CNA)** 

<u>Legislative</u>, <u>Administrative or Policy Measure (MSR)</u>

### **Internationally Recognized Certificates of Compliance (IRCC)**

A permit or equivalent document that has been issued in conjunction with the access as a certificate showing that the genetic resource and/or associated traditional knowledge to which the certificate applies has been obtained in accordance with prior informed consent and mutually agreed terms.

**National Websites or Databases (NDB)** 

**Checkpoint (CP)** 

**Competent National Authority (CNA)** 

**Legislative, Administrative or Policy Measure (MSR)** 

**Internationally Recognized Certificates of Compliance (IRCC)** 

**National Websites or Databases (NDB)** 

Information and links to national websites or databases that are relevant for ABS. Here you can find information on the procedure for access to genetic resources and/or associated traditional knowledge.

**Checkpoint (CP)** 

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### **Checkpoint (CP)**

Checkpoints (CP) In the EU these are checkpoints at which you as a user declare due diligence. You do this on two occasions. 1) after the first partial payment of research funding has been received or not later than the end of the project or when the final report is submitted. 2) in the final development stage of a product. The time for the first declaration applies even if no further product development occurs. In Sweden the declarations are sent to DECLARE.

**Competent National Authority (CNA)** 

<u>Legislative</u>, <u>Administrative or Policy Measure (MSR)</u>

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**National Websites or Databases (NDB)** 

**Checkpoint (CP)** 

### **Checkpoint Communiqué (CPC)**

A summary of the information that has been gathered in or received by a checkpoint (CP). In the EU the declarations on due diligence are the checkpoint communiqués.