DUE DILIGENCE TOOL FOR IMPLEMENTING ABS REGULATION IN RELATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND THE NAGOYA PROTOCOL (NP)

NEED TO KNOW BEFORE YOU PROCEED:

The **conditions** described below concerning the applicability of the EU 511/2014 are **cumulative**: Where the document indicates that the Regulation applies if a certain condition is met, this always presupposes that all the other conditions for being in the scope are also met.

As part of the legal requirements, art. 7 EU 511/2014, **user compliance to ABS Regulation will be monitored**. This means researchers will have to prove they've taken the necessary steps to comply to this Regulation. This implies:

-researchers have to **log all communication (mails, forms, …) etc. from the start of the procedure (so the moment you start contacting services) and for a period of 20 years** = pieces of proof.
-researchers need **all the necessary permits** to access and utilize the material **before the start of the research** (data collection)
-the **Due Diligence Declaration** used to formalize the proof of compliance **needs to be submitted** or at the stage of research funding (**no later than at the time of the final report** or in absence of such report, at the project's end), or at the stage of final development of a product. (see step 4 in Due Diligence Tool – submitting the information). The collecting of all the necessary information and permits has then taken an end.

In contacting the appropriate services at the provider countries, **closely working together with local partners can be of great help**. In many cases they are more familiar with the administrative processes in their country, they have a more easy and direct link to contact them and are geographically closer to follow up.

STEP 1

Is the imported material a 'genetic resource' or 'traditional knowledge associated with genetic resources' as defined in the NP?

According to Art. 3 (2), EU 511/2014 ***'genetic resources'*** *is defined as genetic material of actual or potential value where* ***'genetic material'*** *is any material of plant, animal, microbial or other origin containing functional units of heredity.* This means that all living organisms - plants, animals and microbes - carry genetic material that could be potentially useful to humans. These resources can be taken from the wild, domesticated or cultivated. They are sourced from environments in which they occur naturally (in situ), or from human-made collections such as botanical gardens, genebanks, seed banks, microbial culture collections (ex situ).***'Traditional knowledge associated with genetic resources'*** *means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources (Art. 3 (7) EU 511/2014).* This refers to the knowledge, innovations and practices of indigenous and local communities around the world, mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, and forestry.

Note 1: traditional knowledge can **only trigger EU ABS Regulation** in case it is **associated with an imported genetic resource**. Thus, if a researcher imports only traditional knowledge without any genetic samples as described in the definition above, no EU ABS requirements exist. **However** out of scope of the EU ABS Regulation, **national ABS** requirements **can** still **apply** (see stap °5).

Note 2: You are **out of scope of the EU ABS Regulation** in case your genetic resources or the associated traditional knowledge are **human** (bacteria or viruses isolated from a human being do constitute a genetic resource in scope of the Nagoya Protocol!) - **synthetic nucleic acids** - **digital sequence information**. **However** out of scope of the EU ABS Regulation, **national ABS** requirements **can** still **apply** (see step °5).

Note 3: You are **out of scope of the EU ABS Regulation** in case your genetic resources or the associated traditional knowledge are covered by **specialized international ABS instruments** such as the International Treaty on Plant Genetic Resources for Use in Food and Agriculture (**ITPGRFA**); the WHO Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (**PIP Framework**) in case of influenza viruses with human pandemic potential. The EU ABS Regulation **however does apply** if the provider country is **not a Party** to the ITPGRFA or PIP Framework but is a Party to the NP or in case the **resource is used for other purposes** than those as described in the special instruments (e.g. food crop utilised for pharmaceutical purpose).

Note 4: You are **out of scope of the EU ABS Regulation** if your genetic resources or the associated traditional knowledge come from **marine areas beyond national jurisdiction** (areas covered by the Antarctic Treaty System, the high seas).

Yes / No

No → Then there are no 'Due Diligence' obligations under EU 511/ 2014. **Follow further instructions °5 to see if, however out of scope of the EU ABS Regulation, national ABS regulation in the provider country is applicable to your genetic resource or associated traditional knowledge. Log all communication.**

STEP 2

Does the use of your imported genetic resource or associated traditional knowledge constitute 'utilisation'?

According to Art. 3 (5), EU 511/2014 ***'utilisation'*** *means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.* It refers to the process of researching the beneficial properties of genetic resources and using them to increase scientific knowledge and understanding, or to develop commercial products. *Art. 3 (4) describes* ***'user'*** *as a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources.* EU 511/2014 refers to ***'biotechnology'*** *as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.* In Article 2 of the Nagoya Protocol, the term ***'derivatives'*** *is defined as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.*

Note 1:
•Research that constitutes mere **screening**, purely **descriptive** work, or the use of a genetic resource **as a research tool**, are **not utilisation**.
•The use of **plasmids, viral vectors, host organisms** and alike as such does not constitute utilisation. The **study of gene(s) of interest inserted into those vectors or hosts may** constitute utilisation.

Note 2:
•Research and/or development can both trigger due diligence obligations under EU 511/2014. The EU ABS Regulation therefore is **not only** applicable to research with **real (commercial) valorisation potential**.

Note 3: if the utilisation of the genetic resource or associated traditional knowledge **doesn't take place in an EU Member State**, your research is **out of scope** of the EU ABS Regulation. **Take step °5**.

Note 4: the EU ABS Regulation only applies to research that is subject to **external funding** in the form of a **grant**. The Regulation doesn't make a distinction between public or private funding. **Take step °5.**

Yes / No

No → Then there are no 'Due Diligence' obligations under EU 511/ 2014. **Follow further instructions °5 to see if, however out of scope of the EU ABS Regulation, national ABS regulation in the provider country is applicable to your genetic resource or associated traditional knowledge. Log all communication.**

STEP 3

Was the imported genetic resource or associated traditional knowledge accessed after 12 October 2014?

On 12 October 2014 the Nagoya Protocol entered into force. Genetic resources accessed prior to that date fall outside the scope of the EU ABS Regulation even if utilisation occurs after 12 October 2014. *According to Art. 3 (3), EU 511/2014* ***'access'*** *means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol.* However, it is possible that the provider country already had national ABS legislation or regulatory requirements before the Nagoya Protocol entered into force. These conditions are derived from the Convention on Biological Diversity that already entered into force on 29 December 1993. All material acquired before 1993 is out of scope of any ABS legislation.

Note 1:
< 1993: out of scope of any ABS Regulation or requirements
1993 – 2014: possible national ABS Reglation
> 2014: EU ABS Regulation and possible national ABS Regulation

Note 2:
It is not the date of collection of the genetic resource that matters but the **date of access by the user**.

Yes / No

No → Then there are no 'Due Diligence' obligations under EU 511/ 2014. **Follow further instructions °5 to see if, however out of scope of the EU ABS Regulation, national ABS regulation in the provider country is applicable to your genetic resource or associated traditional knowledge. Log all communication.**

STEP 4

Is the provider country Party to the Nagoya Protocol?

In order to translate the Nagoya Protocol into practice, countries need to create the necessary conditions and take the measures required by the Protocol to ensure that a framework is in place to implement ABS. This legal process contains different stages from signing, ratification, acceptance, approval and accession of the NP, eventually making the country a party to the NP.

Note 1:
Research can only be in scope of the EU ABS Regulation if the provider country is a party to the NP. More specific, there needs to be a **date in the column 'Party'** in the overview 'List of Parties to the Protocol' (see actions).

Note 2: the process of becoming a party is long and legal. Up-to-date info has to be transferred to the CBD-CH as soon as possible, however some **administrative delay** is possible. Therefore **only checking the 'List of Parties to the Protocol' for determining parties is insufficient** (see actions).

It's possible a country decided not to become a party to the NP (= **non party**). In that case the resource is out of scope of the EU ABS Regulation. However the provider country could still have national ABS Regulation (also see step °3).

Check the status of the provider country on the List of Parties to the Protocol

To make sure you're dealing with the most up-to-date information:
•Consult the national authorities of the provider country – use contact details of the NFP and CNA
•Check with a research partner/ collaborator/institution in the provider country;
•Consult the Research Coordination Office at Hasselt University, or licensing managers of the Technology Transfer Office. Contact nagoya@uhasselt.be
•Log all communication

For further instructions and real life examples, see DDT Contact Manual

No → Then there are no 'Due Diligence' obligations under EU 511/ 2014. **Follow further instructions °5 to see if, however out of scope of the EU ABS Regulation, national ABS regulation in the provider country is applicable to your genetic resource or associated traditional knowledge. Log all communication.**

Yes ↓

Your research is in scope of the EU ABS Regulation. As part of exercising due diligence there are a number of requirements for researchers.

According to *Art. 4 EU 511/2014 'exercising due diligence' means the researcher fulfills all ABS requirements*, related to obtaining access to the material and the conditions that apply. Due diligence refers to the judgement and decisions that can reasonably be expected from a person or entity in a given situation. It is about gathering and using information in a systematic way. As such it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts (GD 2016/C313/01)

OBTAINING THE INFORMATION
Note 1: Resources can be obtained **in situ** (in the natural habitat) and ex situ (as part of collections, botanical gardens, (commercial) specialised company, …). For **ex situ** resources, whether the genetic resources are held privately or publicly is not as such relevant in defining the scope of the EU ABS Regulation. It is however important to know if a **collection is registered or not**. A registered collection (Art. 5, EU 511/2014) gives researchers a certain quality assurance since the collection meets a number of criteria, set out in the Regulation. *Art. 4, (7) points out that users obtaining a genetic resource from a supplier included in the register of collections shall be considered to have exercised due diligence.* Most importantly, ***the obligation to supply the genetic resources together with all the relevant information rests with the holder of the registered collection*** (GD 2016/C313/01).
The EU commission shall establish and maintain a ***register of collections*** *within the EU Union (****internet-based*** *and easy accessible) that meet the requirements of the EU 511/2014 Regulation (Art. 5 EU 511/2014).*

Note 2:
It does not matter where the supplier is located, as long as the provider country of the resource is a Party to the NP. For example, if a collection hosted in Brasil delivers a certain organism from Venezuela, the user should receive a PIC and MAT delivered by the CA in Venezuela or contact the CA of Venezuela if PIC and MAT need to be modified.

SUBMITTING THE INFORMATION
According to Art. 4, EU 511/2014 a **due-diligence declaration** needs to be submitted to the NCA. The due diligence declaration **can be an IRCC, or another document containing the following information**:
•The date and place of access of the genetic resource.
•The description of the genetic resource.
•The source from which the genetic resource were directly obtained.
•The presence or absence of rights and obligations relating to access and benefit-sharing.
•Access permits where applicable.
•Mutually agreed terms, including benefit-sharing arrangements, where applicable.

The declaration needs to be made at the stage of research funding **no later than at the time of the final report (or in absence of such report, at the project's end), or at the stage of final development of a product**. Within the period defined in the Implementing Regulation, the Member States' national authorities may further specify the timing. This can be done either in the context of individually targeted requests or by general legal/administrative provisions (GD 2016/C313/01). **At this point Belgium has no further specifications with regards to timing or procedure to file the declaration.**

Note 1:
However **submitting** the due diligence **declaration can wait** till the project's end, **exercising due diligence cannot**. This starts at the latest before the collection of the data. This also implies that all the **necessary information needs to be collected** at the start of the project and **logged** in the university systeem **appropriately**.

Note 2:
Universities are waiting for further instructions from Belgian government on how and where to submit the DDD

CHECKING THE INFORMATION
The (Belgian) competent authorities shall carry out checks to verify whether users comply with their obligations. The checks may include an examination of: (a) the measures taken by a user to exercise due diligence; (b) documentation and records that demonstrate the exercise of due diligence in relation to specific use activities; (c) instances where a user was obliged to make declarations. On-the-spot checks may also be carried out, as appropriate. Where, following the checks referred to, shortcomings have been detected, the competent authority shall issue a notice of remedial action or measures to be taken by the user. Depending on the nature of the shortcomings, Member States may also take immediate interim measures (Art. 9 EU 511/ 2014). Member States shall lay down the rules on penalties applicable to infringements and shall take all the measures necessary to ensure that they are applied (Art. 11 EU 511/2014)..

A. In case the resource is obtained in situ:
Contact the NFP and CNA to:
•Check if permission must be obtained to access and use its genetic material. If this is required, it will mostly be in the form of **PIC**;
•Gain information on the conditions (**MAT**) that are likely to apply access and use of genetic materials.
•To formalise the MAT, **ALWAYS contact Technology Transfer Office**
B. In case the resource is obtained ex situ:
Contact the registered collection to:
•Receive the permission to access and use its genetic material. It will mostly be in the form of **PIC.**
•Get information on the conditions (**MAT**) that apply to access and use of genetic materials.
Note 1:
Depending on the conditions under which the intermediary accessed the genetic resources, the user may need to obtain new PIC and MAT or modify existing ones, if the **intended use is not covered by the PIC and MAT** obtained and relied upon by the intermediary. So, if the intended use of the genetic resouce is different from yours, **take option A (step 4, see above).**
C. In case the resource is obtained ex situ:
Contact the unregistered collection to:
See step B (step 4, see above).
In case the supplier doesn't fulfill his responsabilities, the researcher needs to take responsability: see step A (step 4, see above).

After approving and formalising the MAT, the Technology Transfer Office will send the final MAT to the NCA of the provider country. In response, the DDD will be handed to the Technology Transfer Office by the NCA of the provider country. In case the PC is not able to fulfill this requirement, Technology Transfer Office, together with the researcher, will collect the necessary information (see background information) in a document, with optional format. The Technology Transfer Office will send this document to the CA (Belgium – procedure and institution to be determined) who will transmit the information to the ABS CH, the EU Commission and the NCA of the PC (Art. 7 EU 511/2014).

STEP 5

Does the provider country have national ABS legislation or regulatory requirements that apply to the genetic resource or the associated traditional knowledge?

It is possible that the provider country already had national ABS legislation or regulatory requirements before the Nagoya Protocol entered into force. These conditions are derived from the Convention on Biological Diversity that already entered into force on 29 December 1993. **This national Regulation could also imply certain requirements on top of the requirements as set out in the EU ABS Regulation.**

To find national ABS Regulation:
•Consult a research partner/collaborator/institution in the provider country.
•In case the provider country is Party to the NP (See °4) use the website of the ABS CH to:
- find indications of existence of access legislation.
- find contact details of the ABS NFP and the CNA
•**Always consult the national authorities of the provider country (NFP & CNA) for official confirmation.**

No → **There is no national ABS Regulation.**

Yes ↓

Your research also has to comply with additional national ABS Regulation.

•Always **log all communication and documents thoroughly**; this includes all emails, versions of the agreements, etc. (so not just the final documents!).

•Make sure your files are **stored safely**, in a long-term format **for 20 years**. We are working towards a central filing system for all proof related documents to the Nagoya Protocol. Until this system is up and running, we ask individual researchers to keep records.

•Make a **clean file** so other people can easily understand the process and retract the necessary information.

•Keep a **close link to the project administration** and other ABS related documents concerning the project.

•Use the IRCC as a **standardized log of your genetic materials**. Make sure it is properly linked to the material samples, if archived.

•Use the genetic resources obtained **only in accordance with the conditions agreed upon in the MAT**, and carefully document the use you make of them.

•Be prepared to **send notice** of the intended use of a genetic resource **when applying for a public or private grant and prior to marketing** a product for which a genetic resource has been used.

•Make sure to **communicate briefly but clearly about the conditions for access and use of the genetic materials when publishing on established research results**.

•If the **access to and use of** the genetic materials during the research project **exceeds the conditions** as agreed upon in the MAT, the original conditions need to be **renegotiate**d. A new contract needs to be laid down. **Conact the Technology Transfer Office, retake step 4.**

Then you have to access the samples according to the procedures described in that legislation, and fulfill any obligations following from that legislation.

STEP 6

To log material and store information and documentation