Roadmap research and the Nagoya Protocol

Use this tool to determine whether the Nagoya Protocol applies to your research and what the due diligence requirements are (if any).
If in doubt, contact the Nagoya Protocol advisors!

1

Does your research involve at least one of the following situations?

Yes → Go to 2 | No? → Go to 10

The following Genetic Resources (GR) potentially fall under the scope of the Nagoya Protocol (NP)

- **You use non-human biological materials**, such as material from plants, animals, microorganisms (including bacteria, fungi, and viruses) or from another origin that contains functional units of heredity.
- **You use derivatives.** These are naturally-occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of hereditary. Examples are proteins, lipids, enzymes, RNA and organic compounds.
- **You deliberately use associated organisms.** These are organisms present on or in biological material, including humans. Examples are parasites, vermin, pathogens, symbionts or microbiota.

2A

Do you use the GR for fundamental or applied research, or development (including product development)?

Yes→ Go to 2B | No? → Go to 10

2B

Heb je te maken met een situatie die valt onder geen gebruik?

Yes? → Go to 10 | No? → Go to 3

Situations classified as 'non-use':

- You monitor, manage or store biological material. This includes quality controls and checking for plant diseases upon receipt of the GR.
- You describe all observable properties of an organism (its phenotype).
- You taxonomically identify biological or genetic material using morphological or molecular biological techniques, including DNA sequencing.
- You use GR as an assessment or reference tool.
- You isolate microorganisms from imported soil samples and do not study or develop these microorganisms.
  This concerns non-naturally occurring biochemical materials such as synthetic gene elements (DNA and RNA)
- You use yeasts for production processes, and do not study or develop these yeasts.
- You cultivate, reproduce and optimize GR for conservation and reproduction.
- If you are in any doubt about whether your research is covered by 'use' you can contact the VU Nagoya Protocol Advisors by email.

3

Does your situation fall under an exception?

Yes? → Go to 10 | No? → Go to 4

Exceptions that are not subject to the NP:

- The country of origin's GR are subject to specific international instruments or international treaties, such as ITPGRFA and the WHO Pandemic Flu Preparedness Programme (PIP).
- You use pathogenic GR unintentionally introduced within the EU, even if these have spread within the EU. Examples are pathogenic viral infections in tomatoes (tomato brown rugose fruit virus) and humans (SARS coronavirus). Please note: Establishing a viral collection to develop a vaccine is not subject to the NP, however viral samples that a pharmacist actually uses to make the vaccine are subject to the NP.
- You study human microbiota in situ and focus on the unique composition of the microbiota as a whole in samples (biopsies, body fluids, faeces) of an individual. There are two exceptions to this:
  - Do you isolate taxa and for use in follow-up research? These GR are subject to the NP.
  - Do you perform your research on microbiota on sewage samples? Then the unique individual character of the microbiome will be lost and so the isolated GR are subject to the NP.
- You use derivatives for which there is no continuity/coherence with the GR.
- You use associated organisms that are present as contaminants on the GR, that were only found on the GR after it was exported, or of which you cannot determine the country of origin.
- Use of GR confiscated by customs, whereby the country of origin of the GR could not be determined after thorough due diligence (including, for example, a DNA analysis of the GR).
- You will be using GR obtained from published gene sequences or you will obtain digital data from these sequences.

4

The Nagoya Protocol has been in force since 12 October 2014.
Were the GR already demonstrably in the possession of VU Amsterdam before 12 October 2014?

Yes? → Go to 8 | No? → Go to 5A

5A

Has the country of origin ratified the Nagoya Protocol?

Yes? → Go to 5B | No? → Go to 10

Identify the country of origin:

- This is not necessarily the country you are importing the GR from. You must be able to demonstrate that you have made a thorough effort to trace the country origin. Tip: Ask the provider of the GR to establish or demonstrate the country of origin, for example with customs documents and correspondence.
- Check ABS Clearing House to see if the country of origin has ratified the Nagoya Protocol.

Lukt het ondanks gedegen onderzoek niet om het bronland te achterhalen?
→ Go to 9B

5B

Check the website of ABS Clearing House to find the date on which the Nagoya Protocol entered into force in the country of origin. This is the date on which the conditions came into effect.
Were the GR already demonstrably in the possession of VU Amsterdam before that date?

→ Go to 8

Find out which rules you have to comply with by asking the National Focal Point (ABS desk) of the country of origin. Contact details can be found at ABS Clearing House by selecting the country of origin and clicking on ABS National Focal Point (NFP).

Read the tips.

Are you going to use GR obtained from a registered collection?

→ Go to 9D

Are you going to use GR obtained from published gene sequences?

→ Go to 10

Tips

- Preferably choose a country that imposes no or relatively uncomplicated conditions on the GR (provided, of course, that this material is of comparable quality). For example, the Netherlands generally does not impose any conditions on the use of GR.
- Check if you can use GR from published gene sequences, because these are not subject to the NP.
- You could alternatively try to obtain GR from a registered collection. The holder of this collection must provide you with all relevant information and documents on request. This means there will be no additional NP requirements for the microorganisms listed in these registers (irrespective of the country from which they were obtained). View the list of registered collections (including that of DSMZ). Have you decided to use a registered collection? Go to 9D
- You could alternatively consider whether a local partner organization or provider of GR could help you in the country you wish to obtain the GR from.
- This only concerns the Nagoya regulations; do not forget to take other laws and regulations into account as well.
- Do you have any questions? Contact the VU Nagoya Protocol Advisors by email.

→ Go to 10

6

Are you going to use GR obtained from a registered collection?

Yes → Go to 9D

Are you going to use GR obtained from published gene sequences?

Yes → Go to 10 | No → Go to 7

Inform the Nagoya Protocol advisors and your departmental manager that you want to use GR in your research.

- Complete the inventory form. If you have not received this form:
- Describe your research, which GR you are using, what you are going to do with it and for what purpose.
- Do you share GR with other organizations who also participate in the research? Describe these participating organizations.
- Explain why you think the GR are subject to the NP.

7

Make sure you have all the correct documents.

Follow these steps:

- Contact the Grants Desk for the required documents. Depending on the rules of the country of origin, this usually involves a request for Prior Informed Consent (PIC) and an agreement laying down the conditions (MAT) for sharing and using the GR.
- Contact the national authority (CNA) of the country of origin responsible for granting access to GR. There may be more than one CNA. You can find contact info under Country Profiles/Competent National Authority in the ABS Clearing House.
- Make an agreement with the provider that describes the mutually agreed terms (MAT) for sharing of benefits. Important: This also applies to GR that you are offered informally through, for example, fellow academics or local communities in a country.
- Submit the request for PIC based on the MAT to the CNA by completing the Request PIC template

→ Go to 9

8

Demonstrate that the GR were in the possession of VU Amsterdam before 12 October 2014 or before the NP came into force in the country of origin.
This could be in the form of a publication. Is this not possible? Archive the documentation that demonstrates possession. This could include emails, acknowledgements of receipt, labels on packaging, written conditions of use, etc.

→ Go to 10

9

Have you received PIC and MAT authorization?

Yes? → Go to 9A | No response from the CNA? → Go to 9B

No authorization provided? Look for an alternative, such as GR from another country or a registered collection.

9A

Follow these steps to meet the due diligence requirements:

- Ask the CNA to prepare an Internationally Recognized Certificate of Compliance (IRCC) and submit it to the CBD. The CBD will publish it on the ABS Clearing House website, which demonstrates that you are authorized to use the GR.
- Retain all packaging labels, receipts and accompanying documents (PIC, MAT, MTA) after you have received the GR, because these are evidence of the application for and receipt of the GR. The NVWA may ask to see these documents during an audit.
- Make photos, copies or scans of the documents, merge them into a single PDF and save them in Labservant. As long as Labservant is not yet operational you can email the PDF to the Nagoya Protocol Advisors.

→ Go to 9E

9B

Ask the Nagoya Protocol Advisors what the best option is. We will consider whether it might be better for you to look for an alternative, such as GR from a registered collection or another country.

Have you decided to use these GR anyway?

→ Go to 9C

9C

Make sure you meet your minimum due diligence requirements as described in the inventory form. The following information is required:

- date on which you were granted access to the GR
- country of origin of the GR or the traditional knowledge of the GR
- description of the GR, including traditional knowledge
- the provider or the source from which you obtained the GR
- any known existing and future rights and obligations for access and sharing
- access permits and any mutually agreed terms

→ Go to 9E

9D

You are going to use GR obtained from a registered collection.

- Ask the collection holder to supply the relevant documents: Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) or the Material Transfer Agreement (MTA). The collection holder and you as a user have a duty to retain all documents for 20 years after their last use.
- Retain all packaging labels, receipts and accompanying documents (PIC, MAT, MTA) after you have received the GR, because these are evidence of the application for and receipt of the GR. The NVWA may ask to see these documents during an audit.
- Make photos, copies or scans of the documents, merge them into a single PDF and save them in Labservant. As long as Labservant is not yet operational you can email the PDF to the Nagoya Protocol Advisors.

→ Go to 10

9E

Do you receive research funding? Or are you marketing a product?

Yes? Submit a declaration of due diligence. | No? → Go to 10

Submit a declaration of due diligence for each applicable situation using the European Commission's DECLARE tool.

Does your department not have a DECLARE account yet? Your departmental manager can request an account from the coordinating BSO.

10

You are about to start your research. Some final tips:

- This tool describes which NP rules apply to your situation, but there may be additional laws and regulations.
- Check if there are any special restrictions on the use of the GR, such as licenses, claims, special provisions, patents, etc. This varies per country.
- Is this the case, do you suspect it this, or are you unsure? Contact the Nagoya Protocol advisors and the Grants Desk.
- Good to know: If the intended use of your research is going to change you must amend the terms agreed with the provider and record these in a new MAT. Do the same if you are using a registered collection. Then obtain a new PIC from the country that provided the GR.

Good luck with your research!

List of abbreviations

ABS	Access and Benefit-Sharing
ABSCH	Access and Benefit-Sharing Clearing House Platform of the Convention on Biological Diversity (CBD). Provides an overview of the regulations in the countries that have ratified the Nagoya Protocol and the Convention on Biological Diversity.
CBD	Convention on Biological Diversity
CNA	Competent National Authority The national authority responsible for granting access to GR.
GR	Genetic Resources
IRCC	Internationally Recognized Certificate of Compliance The IRCC is granted based on the PIC and MAT and published on the ABSCH website.
MAT	Mutually Agreed Terms Agreement between the provider and the recipient of GR. This document describes the conditions of use of GR and the sharing of the benefits derived from it.
MTA	Material Transfer Agreement Agreement that governs the transfer of GR. May be part of an MAT.
NFP	National Focal Point First point of contact in the country of origin who provides information on the GR regulations of the Nagoya Protocol in that country.
PIC	Prior Informed Consent Prior approval to access and use of GR provided by the competent authorities. PIC is provided by the CNA.