Procedure for the use of organisms and biological materials under the Nagoya Protocol at VU Amsterdam

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This procedure document and the associated roadmap was commissioned by the Board of the Faculty of Science and drawn up by the VU Amsterdam Nagoya Protocol Project Group. The project group consists of the following members:

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1 INTRODUCTION

*International regulations apply to the responsible use of plants, animals, microorganisms and materials derived from these, which are defined as **genetic resources (GR)**. These regulations are established in the Nagoya Protocol which entered into force on 12 October 2014. **All GR imported or exported after 12 October 2014 must comply with the corresponding requirements.** The aim is the fair and equitable sharing of the benefits arising from the use of genetic resources. The regulations are incorporated in European laws and regulations (EU 511/2014 and EU 2015/1866). This means that 1) users must determine whether there are regulations attached to the access to and use of the GR in the country of origin and 2) users must agree conditions with the provider on the fair and equitable sharing of the benefits arising from the use of GR and the associated traditional knowledge. In this document, we describe the consequences of the Nagoya protocol for VU Amsterdam and the measures we need to implement to comply with it.*

2 NAGOYA PROTOCOL: CURRENT STATE OF AFFAIRS

2.1 SCOPE OF THE NAGOYA PROTOCOL

The Nagoya Protocol (NP) is based on three main pillars, being measures related to 1) access, 2) benefit sharing and 3) compliance by users of genetic resources (GR). **The main objective of the NP is the fair and equitable sharing of benefits arising from the use of GR and associated traditional knowledge in order to contribute to the conservation of biological diversity and the sustainable use of its components.** This is an elaboration of the Access and Benefit-Sharing (ABS) provisions of the Convention on Biological Diversity (CBD)[1] that was drawn up earlier.

The sharing of benefits means that providers receive a fair share of the benefits arising from the use of the resources they provide, which requires the **Prior Informed Consent (PIC)** of the country of origin. The sharing of the benefits takes place on the basis of **Mutually Agreed Terms (MAT)**. The benefits shared may be financial or non-financial (e.g. knowledge sharing through training programmes and joint publications).
The NP is an international treaty that applies in all countries that have ratified the NP, including the EU, implemented in Regulation EU 511/2014[2], Implementing Regulation EU 2015/1866[3] and Guidance Document 2016/C 313/01[4], and in the Netherlands through the Nagoya Protocol (Implementation) Act[5] that entered into force on 17 November 2016. This means that, as of 12 October 2014, biological materials and organisms classified as GR may no longer be taken out of countries that have ratified the NP before all administrative acts (PIC, MAT, MTA and the Internationally Recognized Certificate of Compliance (IRCC)) relating to GR and subject to the NP have been complied with.

The Dutch Food and Consumer Product Safety Authority (NVWA)[6] has been appointed to supervise the administration of the measures by means of inspections. In case of violation, the NVWA can stop the research and impose imprisonment (up to 1 year), community service or a fourth category fine on users and institutions. In case of intentional violation, this may involve a prison sentence of up to 6 years, community service or a sixth category fine of up to €81,000 for persons and €810,000 for legal entities.

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[1] Convention on Biological Diversity. https://www.cbd.int/convention/text/

[2] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

[3] Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32015R1866&from=NL

[4] Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01). https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:C:2016:313:FULL&from=ES

[5] Nagoya Protocol (Implementation) Act. https://wetten.overheid.nl/BWBR0037150/2019-01-01

[6] Dutch Food and Consumer Product Safety Authority. https://www.nvwa.nl/onderwerpen/nagoya-protocol

The National Focal Point for Access and Benefit-Sharing (or 'ABS desk')[7] has been established to provide information about the NP. This entity falls under the Centre for Genetic Resources (CGN) and the Competent National Authority, which is part of the Ministry of Agriculture, Nature and Food Quality.

Whether the imported/exported organisms or biological materials are subject to the NP depends on the following factors:

a) date of import/export of the material (see 1)
b) interpretation of the definition of genetic resources (GR) (see 2.2)
c) origin of the material (this concerns both the country of origin and the provider) (see 2.3)
d) use of the GR (see 2.4)

The latter three factors are under development (this is explained in the following paragraphs) and have resulted in a number of exceptions which are described in 2.5.

2.2 GENETIC RESOURCES (GR)

'Genetic resources' (GR) are understood to mean ***any material of plant, animal, microbial or other origin, containing functional units of heredity, which has actual or potential value***.
This includes soil or water samples, as these may contain organisms with valuable genetic properties. Organisms may also be present on or in biological material classified as GR such as parasites, pests, pathogens, symbionts or microbiota. If these **associated organisms** are deliberately imported into the EU, the use of such associated GR is subject to the NP. Human material is not included, but bacteria and viruses isolated from a patient, for example, are. **Derivatives** may also fall under the NP (see 2.4).

2.3 ORIGINS OF GENETIC RESOURCES

All countries that have ratified the NP must verify whether the original country of origin has set conditions for provision of the material and that all administrative acts (PIC, MAT, MTA and IRCC) relating to GR and subject to ABS laws and regulations have been complied with.[8] The countries that have ratified the NP and their conditions can be found on the 'Access and Benefit-Sharing Clearing-House' website. This may vary from country to country.

In addition to the country of origin, the provider of the biological material must also be taken into account. GR can be obtained in various ways:
a) collected in the wild
b) obtained from registered (ABS Clearing-House website) or other collections
c) through research institutions
d) through companies/organizations or individuals
e) finally, even if the origin of the material is unknown (e.g. the material entered the country illegally and was seized by customs), the due diligence requirement with regard to the NP must still be fulfilled.

The steps to be taken to comply with the due diligence requirement when obtaining GR are described in the flow chart in paragraph 3.2.

2.4 USE OF GENETIC RESOURCES

The NP relates only to the **use** of GR. 'Use' is defined as the performance of fundamental and applied research and/or development (including product development) of the genetic and/or biochemical composition of GR, including through the application of **biotechnology**. The fact that biotechnology is also included under 'use' means that derivatives are also subject to the NP. A **derivative** is '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 hereditary.' Examples are proteins, lipids, enzymes, RNA and organic compounds. In summary, this means that all research involving non-human GR at VU Amsterdam must in principle be assessed to ascertain whether the use of the GR is subject to the NP.[9]

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[7] National Focal Point for Access and Benefit-Sharing (or ABS desk). https://www.absfocalpoint.nl

[8] Access and Benefit-Sharing Clearing-House website. https://absch.cbd.int/

[9] The situation for obtaining and using plant varieties protected by plant variety rights is not yet clear under EU legislation. Until this has been clarified, for safety reasons, plant varieties protected by plant variety rights and obtained abroad should be treated in the same way as other genetic sources and subject to the corresponding requirements.

2.5 EXCLUSION CRITERIA

Exceptions to GR and their use are described below.

1. Date: The GR was demonstrably in the possession of VU Amsterdam before 12 October 2014 (even if it is used on a later date). **Important note!** GR provided and used before 12 October 2014 that will continue to be provided and used after 12 October 2014 are **not** excluded from the NP**.**
2. GR definition: human biological material excluded. **Note:** any bacteria and viruses isolated from a patient are **not** excluded from the NP.
3. GR access measures in the country of origin: GR and associated traditional knowledge for which no access measures (applicable laws or regulations on access and benefit sharing) have been established by a country party to the NP, such as **the Netherlands**.
4. Ratification of the NP by the country of origin: GR of countries that have not ratified the NP. The countries that have ratified the NP can be found on the 'Access and Benefit-Sharing Clearing-House' website.[10] These countries may apply different rules to the materials supplied than the EU. **Important note!** The original country of origin must be identified if there is an intention to use a GR!
5. **Non-use**:
    a. The storage and characterization of biological material (e.g. in a collection), including quality or phytopathological controls and controls upon receipt of the material. Ascertain if the use or reuse of stored GR is subject to the NP.
    b. Phenotypic description.
    c. Taxonomic identification of biological or genetic material using morphological or molecular biological techniques, including DNA sequencing.
    d. Planting and harvesting seeds or other plant reproductive material by a farmer.
    e. Supplying and processing raw materials for processing into a product whereby the properties of the biochemical compound in the genetic resource are already known.
    f. Trade, sharing and transport of GR.
    g. GR as assessment or reference tools.
    h. Use of yeasts in production processes, whereby no research and development of these yeasts takes place.
    i. Breeding and multiplication of organisms and agents (GR), including the optimization of these processes, for conservation and reproduction.
    j. Isolating potentially valuable microorganisms from imported soil samples, whereby no research and development of these microorganisms takes place.
    k. Non-naturally occurring biochemical materials, including synthetic gene elements (DNA and RNA).
6. The use of the genetic material is subject to specific international instruments or international treaties, including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[11] and the WHO Pandemic Flu Preparedness Programme (PIP)[12], provided the relevant countries are parties to these instruments or treaties.
7. The use of GR obtained from geographical areas outside national jurisdiction (i.e. not subject to sovereign rights, e.g. the high seas or areas subject to the Antarctic Treaty System).
8. The use of a GR of which the country of origin is unknown after thorough due diligence.
9. The use of pathogenic GR, including pests and pathogens (on/in humans, animals, plants, microorganisms, food, or other materials) unintentionally introduced within the EU territory, even if these have spread within the EU.
   Examples are pathogenic viral infections in tomatoes (tomato brown rugose fruit virus) and humans (SARS coronavirus).
   Important note! If a viral collection is established for the development of a vaccine that is not subject to the NP, the use of the often-limited quantity of viral samples by a pharmacist for actually preparing the vaccine **is** subject to the NP.
10. The study of human microbiota in situ, with a focus on the unique composition of the microbiota as a whole, in samples (biopsies, body fluids, faeces) of an individual.

[10] Access and Benefit-Sharing Clearing-House website. https://absch.cbd.int/.

[11] International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). http://www.fao.org/plant-treaty/overview/texts-treaty/en/

[12] WHO Pandemic Flu Preparedness Programme (PIP). https://www.who.int/influenza/preparedness/en/

Important note! *Exception 1)* if taxa are isolated and then used for follow-up research, they are considered GR and are subject to the NP. *Exception 2)* if research into microbiota is carried out on sewage water samples, the unique individual character of the microbiome is lost and the isolated GR will be subject to the NP.

11. Use of derivatives for which there is no continuity/coherence with the GR.
12. Use of associated organisms that are present as contaminants on the GR, that were only found on the GR after it was exported, or of which the country of origin cannot be determined.
13. Use of materials confiscated by customs, whereby the country of origin of the GR could not be determined after thorough due diligence (including a DNA analysis (not subject to the NP) of the GR).
14. Digital information obtained from a GR (digital genetic (DNA) sequence and chemical structure information obtained from public databases).

2.6 REQUIREMENTS OF INSTITUTIONS AND EMPLOYEES THAT USE GR

According to the EU ABS laws and regulations, a **user** is defined as: 'a natural or legal person who uses genetic resources or the associated traditional knowledge.' The user must demonstrably endeavour (**due diligence requirement/proper due diligence**) to identify the country of origin and provenance of GR that may be subject to the NP, establish the applicable national legislations, agree on the rules and administrative instructions governing its use with the country of origin and provider, and carefully document this information. The entire process of collecting, storing, sharing and analysing must be carefully documented and made available throughout the European Union's GR **value chain** for 20 years after last use.

Due diligence concerns not only individuals such as researchers, but also organizations such as universities and other research institutions that use GR or traditional knowledge associated with GR. VU Amsterdam helps researchers to ensure due diligence by:

1. Providing legal assistance in preparing and/or obtaining the necessary documents, including PIC and MAT (or MTA) by the VU grant office and IXA.
2. Archiving the relevant documents (including legal contracts and mail correspondence) and results obtained in Labservant for a period of 20 years after last use.
3. Organizing internal supervision of the use of GR according to EU ABS laws and regulations (see also 3.2.1).

The researcher is personally responsible for complying with the rules of the NP and the due diligence measures (see 3.1).
The NVWA[13] supervises compliance with the NP by the University and its employees as external party (see 2.1).

3 IMPLEMENTATION OF THE NP AT VU AMSTERDAM

Several steps have to be followed when importing and exporting GR in order to comply with the requirements of the NP at VU Amsterdam. The duties and responsibilities of the employees and organizational units involved are described below.

Nagoya Protocol advisors are appointed by the Board of the Faculty of Science to coordinate the implementation of the NP at VU Amsterdam and support the user of GR in this process. These advisors are the Policy Officer for Operations and the coordinating BSO. They advise researchers and PIs respectively on how to comply with the requirements of the NP, such as who they can turn to for support for specific parts the procedure, and they advise on biological samples subject to the NP. These advisors also maintain contact with the representatives of other universities and research institutes in the Netherlands that are involved in the local implementation of the NP. Other duties and responsibilities related to the implementation of the NP are described below.

[13] Dutch Food and Consumer Product Safety Authority. https://www.nvwa.nl/onderwerpen/nagoya-protocol

3.1 DUTIES AND RESPONSIBILITIES

- **Head of Department:** has final responsibility for compliance with the NP within the department.
- **Principal investigator/team leader (PI):** is responsible for registering and archiving information on imported and exported GR.
- **Researcher:** researchers who use GR are responsible for complying with the due diligence requirements including all administrative acts (such as registering and archiving the documentation in Labservant) and informing the NP advisors of the requisite administrative acts (PIC, MAT, MTA and IRCC) (see 2.6).
- **Coordinating BSO**: Advises researchers and PIs on the procedure to comply with the NP obligations and is responsible for internal supervision of the implementation of the NP. The inspections coincide with the annual GMO audits. If necessary, additional audits will be carried out on compliance with the NP.
  The BSO is also responsible for issuing DECLARE accounts to departmental managers. These accounts are required for GR research grants and for marketing products based on GR material, whereby in the latter case a declaration of due diligence must be submitted via the EU's DECLARE IT system (see also the user guide[14]).
- **Departmental managers:** are responsible for managing departmental DECLARE accounts and databases and controlling the routing procedure for signing PIC/MAT/MTA contracts via the routing form.
- **Senior analysts:** actively identify the use of GR in scientific research and inform researchers, the coordinating BSO and the departmental manager of their findings.
- **Policy officer for operations:** advises researchers and PIs on the procedure for complying with the NP requirements and supports the BSO during the audit of the annual report on GR obtained from Labservant.
- **VU Grant Office:** informs researchers applying for research grants of the due diligence requirements regarding the use of biological materials that can be classified as GR under the Nagoya Protocol. Also provides support during negotiations after the grant has been awarded, including on MAT and MTA. A standard template and checklist will preferably be used for MAT or MTA. The Grant Office provides the requisite documents to the researcher and assists with filling them out where necessary.
- **IXA:** prepares the above-mentioned templates and corresponding checklist. Also provides support during negotiations where necessary and legal expertise required to fill in the templates where this expertise is not available within the Grant Office. The Director of Operations (and not the researcher) signs the documents.
- **Director of Operations:** has authority to sign PIC/MAT/MTA contracts.

3.2 COMPLYING WITH THE DUE DILIGENCE REQUIREMENT

As of 12 October 2014, conditions apply to the inclusion and/or use of non-human biological materials, organisms and microorganisms classified as GR in scientific research and obtained from countries that have ratified the NP. The sharing and use of the GR is subject to compliance with all administrative acts (PIC, MAT, MTA and IRCC) relating to the GR and to the EU ABS laws and regulations. This is the known as the **due diligence requirement**, or **proper due diligence**. In practice this means that, before obtaining and/or using the GR, a researcher is required to make or comply with agreements with the country of origin and the provider regarding access to the GR and the reasonable and equitable sharing of the benefits resulting from its use (if these agreements have already been made). In ongoing research projects, if it has been established that the GR are subject to the NP, the administrative acts in the context of the due diligence requirement must be carried out retroactively.

3.2.1 Identification of GR subject to the NP

In order to help researchers comply with the due diligence requirements in new, ongoing and completed research projects, various support services and systems are in place to raise awareness at different stages of the research process:

1. Awareness of the due diligence requirements for using GR that may be subject to the NP in scientific research will be raised during existing courses for researchers, including 'Preparing

[14] User guide/FAQs - DECLARE NAGOYA IT system. https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/questions-and-answers-for-declare-users.docx

the Data Management Plan (DMP)' provided by the University Library and the 'Research Integrity Course' (a mandatory course for all PhD students). A university-wide course on 'Basic Skills for Laboratory Work' is also under development.

2. A mandatory field for material subject to the NP will be included in the Project Budget Template (in the future this will be a digital project form).
3. If external funding provided for GR research falls under the scope of the EU ABS Regulation, the funding body will remind the applicant to submit a declaration of due diligence using the EU-wide DECLARE tool on the website of the European Commission (this will be done before the external funding is granted).
4. The IXA registration form and the procedure for assigning a legal advisor both include a question on the use of material subject to the Nagoya Protocol.
5. An explicit question on material subject to the NP is included in the University Library's DMP tool for preparing a data management plan.
6. Researchers are informed of the documents needed to comply with the due diligence requirements for obtaining and using GR (PIC, MAT, MTA and IRCC) when they register biological materials in Labservant.
7. A check is built into the routing matrix for preparing and approving project funding contracts for material subject to the NP which is submitted to the Director of Operations by the departmental manager.

4 MONITORING OF COMPLIANCE WITH THE REGULATIONS BY THE GOVERNMENT

The government monitors compliance with the GR regulations in the NP value chain at two stages:

1. During the application procedure, through a declaration of due diligence in the DECLARE tool as part of a grant application (public and private).
   The declaration must be submitted after the first payment has been received and all the GR and associated traditional knowledge used in the funded project have been obtained, and in any case no later than the submission of the final report. The NVWA supervises compliance with the regulations (see 2.1).
   Note: Research that is financed from internal funds is not supervised in this manner but must comply with ABS laws and regulations and is audited by the NVWA[15].
2. During the final development phase when a product is marketed.

5 LITERATURE AND WEBSITES

Convention on Biological Diversity https://www.cbd.int/convention/text/

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01).

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:C:2016:313:FULL&from=ES

Nagoya Protocol (Implementation) Act (in Dutch) https://wetten.overheid.nl/BWBR0037150/2019-01-01

National Focal Point for Access and Benefit-Sharing (or ABS desk) https://www.absfocalpoint.nl

Access and Benefit-Sharing Clearing-House website https://absch.cbd.int/.

Dutch Food and Consumer Product Safety Authority https://www.nvwa.nl/onderwerpen/nagoya-protocol

- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) http://www.fao.org/plant-treaty/overview/texts-treaty/en/
- WHO Pandemic Flu Preparedness Programme (PIP) https://www.who.int/influenza/preparedness/en/
- DECLARE tool user guide https://ec.europa.eu/environment/nature/biodiversity/-international/abs/materialen.htm

[15] Dutch Food and Consumer Product Safety Authority. https://www.nvwa.nl/onderwerpen/nagoya-protocol

6 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.
BSO	Biosafety Officer
CBD	Convention on Biological Diversity
CNA	Competent National Authority The national authority responsible for granting access to GR.
EU	European Union
GR	Genetic Resource
IRCC	Internationally Recognized Certificate of Compliance The IRCC is granted based on the PIC and MAT and published on the ABSCH website.
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture.
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. In the Netherlands, this is the Centre for Genetic Resources (CGN).
NP	Nagoya Protocol
NVWA	Dutch Food and Consumer Product Safety Authority
PI	Principal Investigator
PIC	Prior Informed Consent Prior approval to access and use of GR provided by the competent authorities. PIC is provided by the CNA.
PIP	Pandemic Flu Preparedness Programme (PIP)

APPENDIX 1: ROAD MAP FOR DUE DILIGENCE REQUIREMENTS