



The Nagoya Protocol

on top of other obligations

when pursuing research activities outside the EU*

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*** even
outside
Flanders...**

Funding application forms of EU, FWO, BOF, IOF, ...:

6. THIRD COUNTRIES

Does your research involve **non-EU countries**?

1. Do you plan to use **local resources** (e.g., animal and/or human genetic material including that captured by question 6, live remains, materials of historical value, endangered fauna or

→ Name of country/ies:

If your research involves **low and/or lower middle income countries**, are **benefits-sharing** measures foreseen? (vii)

Yes No

2. Do you plan to **import/export** any material from/to other c

→ Name of country/ies:



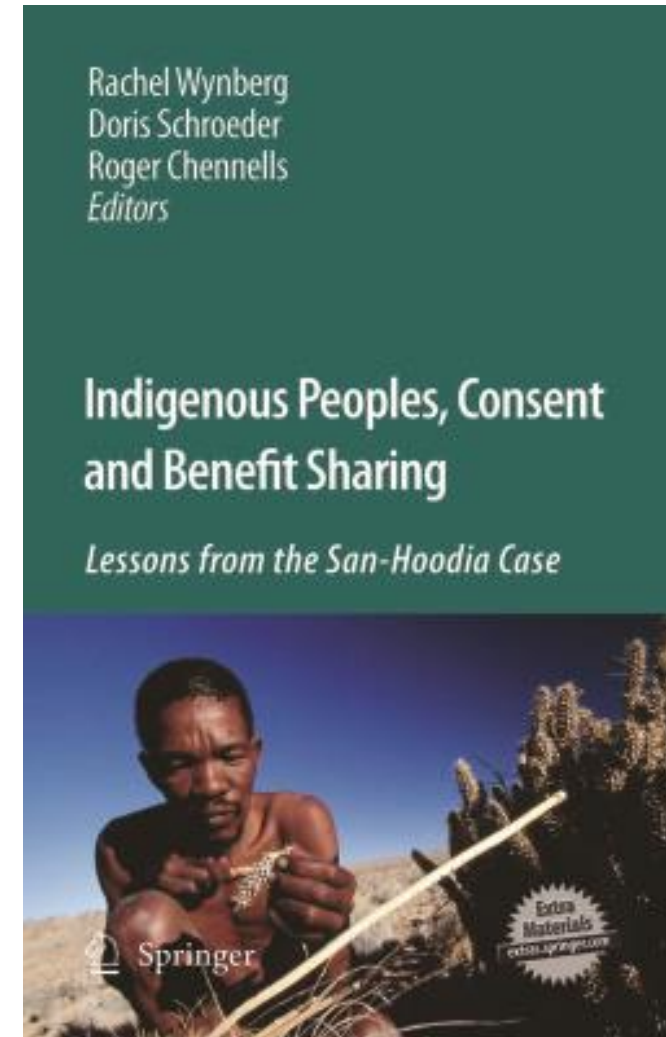
Research Foundation
Flanders
Opening new horizons



1 Intro: ethics are more and more being enforced

Research with international aspects has come into the focus of ethics.

- Undeniable link between **ethical prudence**, good research practices and **legal compliance**
- Countries have **sovereign rights** over the (genetic / biological) resources found on their territory
- *Outcry: “Stop stealing, patenting, benefiting, from our lands.”*
- Idea of **Nagoya Protocol**: acquire **ethical behaviour through** an international **legal framework**



1 Intro: history of Nagoya Protocol



Convention on
Biological Diversity

1992: **Convention on Biological Diversity** (enters into force 1993)

2010: **Nagoya Protocol on Access and Benefit-Sharing** (enters into force 12 October 2014)

2014: **EU Regulation 511/2014 on Access and Benefit-Sharing**

Important!

Not all countries are party to the Nagoya Protocol.

But: **almost every country** has its own **Access and Benefit-Sharing (ABS)** regulation.



<https://absch.cbd.int/>

1 Intro: What is Access and Benefit-Sharing (ABS)?

Access and use of resources lead to the obligation of **negotiated sharing of the benefits** you enjoy from the resources.

Should the idea of negotiating this with a government paralyze you?

What benefit-sharing do you already do?

- cooperation with local institutes
- co-publications
- capacity building (collections, education, training, ...)
- ...

What other benefit-sharing might be negotiated?

- often (semi-)dictated
- non-monetary options
- monetary options
- usually well balanced
- often none are required!

2 When to comply?



Convention on
Biological Diversity

Is the Nagoya Protocol relevant to my research?

As soon as one of the situations below applies.

- I want to **transfer** biological material from one country to another.
- I want to **sample** biological material outside of Flanders (even in Wallonia).
- Biological material is being **sent** to me.
- I am using biological material **from a collection or a third person**, and it dates from 2014 or later.
- I am accessing or using **traditional knowledge** associated with biological resources.

2 When to comply?

Cumulative conditions to be in scope:

1. Material scope

→ Almost any biological material, **except:**

2. Geographical scope

3. Time scope

4. Utilization scope

- **Human material**
- **Influenza viruses with human pandemic potential**
(covered by the Pandemic Influenza Preparedness (PIP) Framework)
- **Plant Genetic Resources for Food and Agriculture**
(PGRFA) listed in Annex I of the International Plant Treaty (ITPGRFA), with use related to food or agriculture, and accessed ex situ, and in a country that is party to the ITPGRFA

2 When to comply?

Cumulative conditions to be in scope:

1. Material scope

2. Geographical scope

3. Time scope

4. Utilization scope

If accessed:

- in sovereign territory of a country that ...
 - is a party of the Nagoya protocol (at the time of access)
 - has established measures* relating to ABS for the genetic resource you intend to use

→ Hence not:

- in **marine areas** beyond national jurisdiction
- in the area covered by the **Antarctic** Treaty System

* 2019: Flemish Decree on Access and Benefit-Sharing
2020: Walloon Decree on Access and Benefit-Sharing

2 When to comply?

Cumulative conditions to be in scope:

1. Material scope
2. Geographical scope
3. Time scope
4. Utilization scope

To be in scope, *access* of material must be on or after 12 October 2014.

2 When to comply?

Cumulative conditions to be in scope:

1. Material scope
2. Geographical scope
3. Time scope
4. Utilization scope

→ Almost **any utilization...** (e.g., research, development, product development)

Not in scope:

- genetic resources as **commodities** (such as agricultural, fisheries or forestry products)
- genetic resources used as a **tool**

Often less stringent rules apply to:

- **fundamental / basic / non-commercial research**
- research on **taxonomy/biodiversity**

3 What must I do?

Double compliance:

1. **Comply** with the **country's** legislation.
2. Most important rule: **comply** with **EU Regulation 511/2014**.



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



Why is this 'more' important?

- The EU regulation monitors compliance **for users in EU** (and penalties).
- It also assists researchers in some 'difficult situations'.

3 What must I do?

Most importantly: act timely.

Negotiations with countries can take long ... and can go wrong.

You might need:

- Prior Informed Consent (P.I.C.)
- negotiated Mutually Agreed Terms (M.A.T.) relating to:
 - use of the material (limits, transfers, third users)
 - benefit-sharing provisions (non-monetary / monetary)
- Material Transfer Agreements (M.T.A.'s) if taken on private ground, ...

4 Support at Ghent University

→ For all ethics-related issues: start your search in the Ghent University [Framework of Good Research Practice](#) or read the [Ethics webpage](#)



→ Visit the renewed [Nagoya webpages](#) in [English](#) and [Dutch](#), with links to practical **research tips**:

- [How can I **know** if my research is in scope of the Nagoya Protocol?](#)
- [How can I **find** the ABS legislation of a specific country?](#)
- [What are my **obligations** if my research is in scope of the Nagoya Protocol?](#)
- [What should I do to comply with the **EU ABS Regulation**?](#)
- [Is **traditional knowledge** associated with genetic resources also subject to the Nagoya Protocol?](#)

Click on all links!

4 Support at Ghent University

Research Department Ethics Policy team

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First contact point:
[data stewards](#)

Other ethical question or doubt? Also contact us.