

Nagoya Protocol Implementation

Examples of Application in Switzerland

NADIR ALVAREZ

DIRECTOR OF THE NATURAL SCIENCES STATE MUSEUM
OF THE CANTON DE VAUD

What kind of biological material do you store in your biobank, and where was it collected?

Whole (insects, birds, etc) and partial specimens (skin, bones, leaves, flowers, etc), tissue samples (blood, organs, excrements, etc), DNA extractions. A large part is from Switzerland, while the other part can be from all over the world (the ratio between Swiss and non-Swiss specimens largely depends on the museum or botanical gardens—the larger the collections, the more likely the ratio is in favor of non-Swiss collections).

How did you determine if this material falls under the scope of the Nagoya Protocol?

Since Switzerland joined the Nagoya protocol, any international project with specimen collection in signing countries must follow the regulations. Within the European Union however, there are certain exceptions, for instance when the objective of the work is purely phylogenetics- or systematics-oriented¹.

Do you share biological material with other legal entities within or outside CH?

Museums and botanical gardens collaborate with other institutions hosting natural history collections, such as through the SwissCollNet initiative, which funds projects for reconditioning and digitizing specimens involving at least two associated institutions. They also collaborate with universities for research purposes and serve as recipients for tissue or DNA collections developed over a lifetime by retiring professors. Usually, the preferred university partner is the university within the same or the closest canton.

How do you fulfill the due diligence requirement of the Nagoya protocol?

By receiving authorizations from official entities of the visited country and filling the available form².

Do you sign Prior Informed Consent / Mutually Agreed Terms to access or share biological material? If so, in what form?

The authorizations should cover the terms of use of imported genetic resources. But since museums and botanical gardens are not involved in commercial activities, the agreements are usually less complex than in other fields, as they are mostly based on scientific collaborations reflected in publications.

NOAM SHANI

HEAD OF TEAM CULTURE COLLECTION AT AGROSCOPE

What kind of biological material do you store in your biobank, and where was it collected?

We primarily store pure cultures of microorganisms, mainly bacteria and yeasts from the Swiss dairy sector. Most of these strains have been isolated by Agroscope from Swiss cheese factories. However, some isolates were collected abroad before Switzerland ratified the Nagoya Protocol and even before the protocol was established. Additionally, we have some isolates obtained from public collections, as well as from universities.

How did you determine if this material falls under the scope of the Nagoya Protocol?

Given that some strains were isolated a long time ago, we sometimes lack detailed information about their origins. To avoid any confusion, we have decided that all isolates from abroad will be used solely as reference materials for analysis. These are not used commercially nor sent outside of Agroscope, even if they were isolated before the Nagoya Protocol came into effect.

Do you share biological material with other legal entities within or outside CH?

Yes, but only Swiss isolates and always with a Material Transfer Agreement.

¹ See pages 44-45 of [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112\(02\)&rid=6](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&rid=6)

² FOEN FO for the E. Nagoya Protocol [Internet]. Available from: <https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--fachinformationen/nagoya-protokoll.html>

How do you fulfill the due diligence requirement of the Nagoya protocol?

We have established contracts with stakeholders in the dairy sector, allowing us to isolate and collect strains from Swiss dairy products. For strains isolated from non-dairy products, a Material Transfer Agreement is systematically established. We meticulously document the origin of each new isolate. All our isolations are restricted to Switzerland, as Agroscope's main beneficiary is the Swiss agro-food sector. Nevertheless, we strive to apply the principles of the Nagoya Ordinance to all our isolates. If we use isolates from abroad as reference, they are usually sourced from public collections.

Do you sign Prior Informed Consent / Mutually Agreed Terms to access or share biological material? If so, in what form?

No, we don't.

IMANE EL IDRISSE

SENIOR SPECIMEN BIOBANK ASSOCIATE AT FIND

What kind of biological material do you store in your biobank, and where was it collected?

We store clinical samples from patients with different infectious diseases. The sample types are typically blood, urine, swab, etc. Our samples are collected in Low and Middle-Income Countries (LMICs) in line with FIND's mission.

How did you determine if this material falls under the scope of the Nagoya Protocol?

Human clinical samples are usually considered outside the scope of the Nagoya Protocol. However, in recent years, we have begun assessing the National Legislation on Access and Benefit-Sharing (ABS) of countries in which we collect samples via the Access and Benefit-Sharing Clearing-House (ABSCH) platform. In case of uncertainty, we complement our assessment by contacting the ABS National Focal Point (NFP) for confirmation on whether the samples we collect are subject to specific ABS national legislation. Moreover, all our collections are conducted in partnership with a national entity, usually a University. The agreement between FIND and the collection site therefore always includes benefit-sharing, such as funding and capacity-building.

Do you share biological material with other legal entities within or outside CH?

Our samples are either stored in a main biorepository in the US or in smaller biorepositories in the countries where the collections are conducted. Our samples are collected with the purpose of being distributed to advance research on diagnostic tests. We hence frequently share our samples to other entities worldwide.

How do you fulfill the due diligence requirement of the Nagoya protocol?

We consider benefit sharing as best practice. The contract agreement between FIND and the collection site always includes specific shared benefits, such as funding and capacity building at a minimum, in exchange of the access to the clinical samples. Through all its clinical research activities, FIND is committed to strengthening capacity at study site level, not only by providing funding to conduct the study but also by providing training, purchasing equipment and software, and setting up standard procedures and work instructions that the site can use across their operations. Access and Benefit sharing are at the core of our decentralized biobanking model where the site and FIND have equal access to the samples by complying with the sample access procedure.

Do you sign Prior Informed Consent / Mutually Agreed terms to access or share biological material? If so, in what form?

We never encountered a situation where, as per national requirement of the collection country, our samples were considered in scope of the Nagoya Protocol and Prior Informed Consent / Mutually Agreed terms were therefore legally required, although this could occur in the future. We do however always have an agreement in place between us and the collection site that details the sample size of the collection and the benefits shared to the site.