THE NAGOYA PROTOCOL APPLIED TO SWISS BIOBANKS

Analysis and recommendations

What is the Nagoya Protocol, and how does it apply to biobanks? Specifically, which biobanks are subject to its regulations? Furthermore, which steps need to be taken to ensure compliance with the Nagoya Protocol in Switzerland? These are the questions we tried to address in this analysis, aiming to provide comprehensive guidance and support to Swiss biobanks for a better grasp of the Nagoya Protocol's requirements and its effective implementation.

1. THE NAGOYA PROTOCOL

What is the Nagoya protocol?

Open for signatures in 1992 at the Rio Earth Summit, the Convention on Biological Diversity entered into force on the 29th of December 1993 with three main objectives (1):

A. The conservation of biological diversity;
B. The sustainable use of the components of biological diversity;
C. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

The effective implementation of the third objective of the Convention on Biological Diversity is provided by the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,* abbreviated *Access and benefit-sharing*. This international agreement, adopted on the 29th of October 2010, seeks to establish the legal framework for both providers and users of non-human genetic resources and associated traditional knowledge held by indigenous and local communities. Its primary objective is to clarify the terms and conditions governing access to these resources and ensure the equitable sharing of benefits among the involved parties (2). The Nagoya Protocol entered into force on the 12th of October 2014 and has 141 ratifications as of June 2024.

The *Access and benefit-sharing* mechanisms describe how genetic resources may be accessed, and how users and providers agree on the fair and equitable sharing of the benefits that might result from their use.

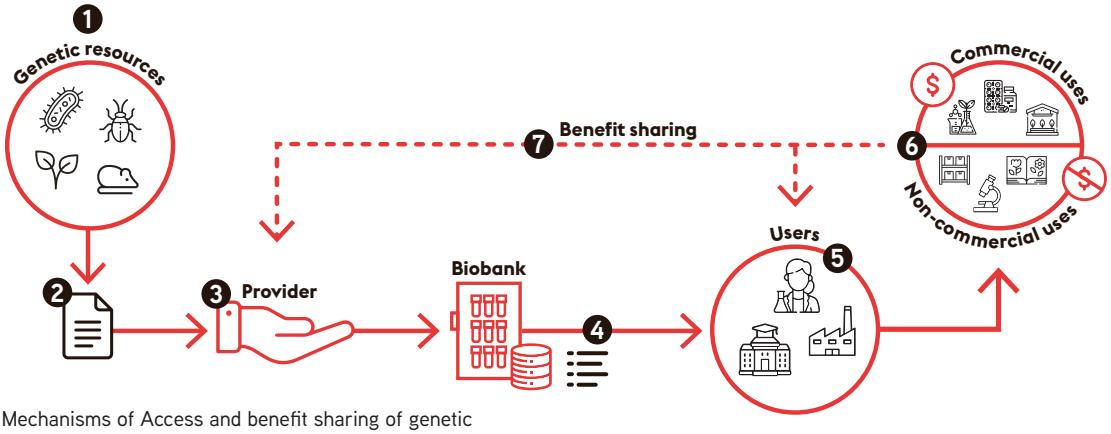
The Nagoya Protocol is an international agreement, but it is crucial to consider that the implementation may vary at the national level.

Access is based on prior informed consent being granted by a provider to a user and *benefit-sharing* is based on negotiations between both parties to develop mutually agreed terms (3).

How does the Nagoya Protocol apply in Switzerland and which national authority supports its implementation?

Guided by the principles of the Nagoya Protocol, the countries that signed the protocol must define, implement, and enforce their own national regulations relating to access to genetic resources on their territory and the sharing of benefits arising from their use. The specificities in the implementation of the Nagoya Protocol vary among the signatory countries, and consequently, so do the requirements. The *Access and Benefit-Sharing Clearing-House* is the reference portal to verify country-specific applications (see "ABS Procedures" 4).

In Switzerland, the Nagoya protocol was ratified and included in the *Federal Act on the Protection of Nature and Cultural Heritage* (NCHA) which came into force on the 12th of October 2014 (5). Its practical application is regulated by the *Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (NagO), which took effect on the 1st February 2016 (6). NagO regulates both the access to genetic resources on the Swiss territory and the provisions for users in Switzerland to adhere to the *Access and Benefit-sharing* directives applicable in the provider countries that have ratified the Protocol. The Federal Office for the Environment (FOEN) is the competent national authority to support the users in the execution of the Nagoya Protocol.



Insert 1. Mechanisms of Access and benefit sharing of genetic resources stored in biobanks in Switzerland, for material collected after 2014. Adapted from (3).

1 Genetic resources

Any material of plant, animal, microbial or other non-human origins that contains functional units of heredity (nucleic acids and derived biomolecules), of actual or potential value, either *in situ* or *ex situ*.

***Ex situ*:** Found in botanical gardens, commercial or university collections or biobanks

***In situ*:** Found within ecosystems and natural habitats

2 Mechanisms in Switzerland to access Genetic resources originated from:

Parties that signed the Nagoya Protocol

The *Access and Benefit-Sharing Clearing-House* (4) must be consulted. Depending on the countries the following requirements may apply:

- Due diligence requirement, *i.e.*, collect specific information (NagO art. 3)
- Sign Prior Informed Consent
- Sign Mutually Agreed Terms (see toolbox provided in (16))

Switzerland

- Due diligence requirement, *i.e.*, collect specific information (NagO art. 8)

Non-Parties to the Nagoya Protocol

No requirement. However, collecting specific information (NagO art. 3), and signing Prior Informed Consent and Mutually Agreed Terms is considered best practice.

Prior informed consent: Permission given by the competent national authority of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework.

Mutually Agreed Terms: Agreement reached between the providers of genetic resources and users on the conditions of access and use of the resources, and the benefits to be shared between both parties.

3 Providers

Governments or civil society bodies, which can include private land owners and communities within a country, who are entitled to provide access to genetic resources and share the benefits resulting from their use.

4 Mechanisms in Switzerland to share Genetic resources within and outside Switzerland:

Due diligence requirement, *i.e.*, pass on to subsequent users specific information, according to the origin of the genetic resources (NagO art. 3, 8). (notification form: (7))

Biobanks should document this information in their BIMS (see SBP Nagoya dataset provided in **Annex 1**)

5 Users

Legal or natural persons who in accordance with the Nagoya Protocol utilize a genetic resource or associated traditional knowledge or benefit directly from their utilization.

Users are responsible for sharing the benefits derived from genetic resources with the providers.

6 Utilization

To conduct research and development on the genetic or biochemical composition of genetic resources, including through the application of biotechnology.

a. **Example of utilization:**

Non-commercial

e.g., taxonomy, ecology and evolution, conservation, academic research, identification and isolation of active compounds, genetic research

Commercial

e.g., biotechnology, horticulture, pharmaceuticals

b. **Examples of biobanking activities usually not considered as utilization in Europe (12):**

Maintenance and management of a biobank for conservation purposes, including storage of resources or quality/phytopathology checks, and verification of material upon acceptance (but the subsequent research performed on the biological material may be considered as a utilization).

Taxonomic identification of biological or genetic material, by morphological or molecular analysis, including through use of DNA sequencing (but the subsequent research performed on gene or protein function is considered as utilization).

→ Determining whether a specific biobanking activity constitutes utilization according to the ordinance can be challenging, as the precise use of the biological material for research is not always known in advance.

The National Focal Point for the Nagoya Protocol should be contacted for support, when needed (contact.np@bafu.admin.ch).

→ Users of Genetic Resources must notify the FOEN of the information required by the Swiss provisions to the Nagoya Protocol before market approval or, if such approval is not required, before the commercialization of products developed on the basis of utilized genetic resources (notification form: (7)).

7 Benefits

Resulting from the utilization of Genetic Resources, to be shared between the people or countries using the resources (users) and the people or countries that provide them (providers).

Monetary

e.g., royalty payments, joint ownership of intellectual property rights

Non-monetary

e.g., R&D, knowledge, training and education, transfer of technology

→ More examples of Monetary and non-monetary benefits can be found in the annex "Monetary and Non-Monetary Benefits" to the Nagoya protocol (2).

→ The sharing of eventual benefits is negotiated between CH and the provider country, party of the Nagoya Protocol, in the Mutually agreed terms.

Implementation of the Nagoya Protocol in Switzerland

Biobanks must notably comply with the due diligence requirement, *i.e.*, record, keep and pass on to subsequent users certain defined information (see **insert 2**) related to the genetic resources used (NCHA Art. 23n-q, Art. 26; NagO Art.3, 8).

The Nagoya Protocol and the corresponding Swiss provisions regulate the utilization of genetic resources and not the collection nor the storage. NagO Art.3, 5, 8 specified that the recorded information linked to genetic resources, must be kept for ten years after the end of utilization, and for as long as the genetic resources or the product whose development is based on the use of the resources is conserved, and can be passed on to subsequent users.

Both information related to the due dilligence requirement or to the utilization of genetic resources can be notified on a voluntary basis to the FOEN with the forms available in (7).

SBP recommendations

A. **In the case of biobanks, as utilization is envisioned and possible, SBP recommends to follow the due diligence requirement and record all necessary information** (see **insert 2**)**. If this utilization within the meaning of the Nagoya Protocol is confirmed, then this recommendation becomes an obligation, to comply with the application of the NagO in Switzerland.**

B. **Regarding the retention time, biobanks should keep this information for 10 years after the end of utilization and for as long as the samples are stored in the collection, archive, or infrastructure.**

LIST OF INFORMATION TO BE RECORDED (ART. 3 NagO - due diligence requirement)

For Genetic Resources collected outside Switzerland:

1. the name and address of the biobank,
2. a description of the genetic resource, and its utilization,
3. the date on which the genetic resource was accessed,
4. the source of the genetic resource,
5. (Unless subject to trade secrecy), the name and address of the person who provided the genetic resource, the date of its acquisition and, if available, a confirmation from the person that the genetic resource was acquired lawfully for the utilization concerned and may be transferred,
6. in the case of transfers of genetic resources: the name and address of the subsequent user and the date of the transfer,
7. where required, the permit or its equivalent as evidence of the prior informed consent of the entitled Party to the Nagoya Protocol as well as information on use and transfer rights,
8. where required, evidence that mutually agreed terms for the fair and equitable sharing of benefits have been established.

If specific information is unknown and cannot be obtained, the reasons must be recorded, kept, and passed on to subsequent users.

For Genetic Resources collected in Switzerland:

1. the name and address of the biobank;
2. a description of the genetic resource, and its utilization;
3. the date on which and location where the genetic resource was accessed;
4. (Unless subject to trade secrecy) in the case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition;
5. in the case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

Insert 2 : List of information to be recorded by the biobanks as per the due dilligence requirement.

2. THE NAGOYA PROTOCOL APPLIED TO BIOBANKS

Is this international agreement applicable to all biobanks?

Human genetic resources are excluded from the Nagoya Protocol and subject to specific legislation in Switzerland, respectively the Human Research Act (HRA) and the Human Research Ordinance (HRO) (9, 10). However, non-human biobanks can collect, process and store specimens or samples of animal, plant or microbial origin for research purposes. These biological samples contain genetic material and are considered as genetic resources.

What is the status of the non-human samples, which potentially also contain genetic information and personal data of human origin?

Human samples may be collected, processed, and stored in biobanks as part of infectious disease diagnostic or quality control processes, and reused for microbiological research. The microorganisms present in the samples will then be isolated, propagated, and re-stored for later use, for example to develop new treatments or vaccines. In a response letter dated of 21 March 2018 to the SBP Working Group of Microbiology and the Swiss Society of Microbiology, Swissethics stated that "purely biological material of viruses, bacteria or fungi and the research with this material are not covered by the HRA, if the research does not involve health-related personal data" and that "under no circumstances the DNA of the patients/probands also contained therein" is analyzed.

The human microbiome[1] is considered as «borderline » for the application of the Nagoya Protocol. The Swiss FOEN, in line with the EU[2] (see definition in [11]) has clarified the following position: "the Nagoya Protocol […] does apply to research and development activities carried out on different isolates of the human microbiome" (13, 11, 14).

In practice however, there could be complex specimens where both human and non-human genetic material would be present and co-sequenced (e.g., faecal samples).

SBP recommendations

A. **As soon as no human DNA is analyzed and the link between the pathogen and the specific person cannot be traced without disproportionate effort, human microbiological samples fall out of the scope of the HRA and can be considered in the scope of the Nagoya Protocol and the corresponding Swiss provisions. Such samples contained in biobanks are thus considered non-human and should comply with NagO in Switzerland.**

B. **It is really the utilization of the genetic resource that will then guide the application of the regulations, i.e., whether the human or non-human genetic material is used for research or development purposes. In the complex situation where the genetic material of both origin, human and non-human, would be used, the two regulatory systems would not be mutually exclusive and would both apply.**

3. CONCLUSION

In conclusion, SBP recommends that non-human biobanks should always comply with the due diligence requirement. In practical terms, this means that recording the information required by the due diligence requirement should be part of the routine documentation activity of a non-human biobank. This information should be collected as part of the sample-related data[3] (8) and ideally filled in a Biobank Information Management System (BIMS) (see SBP Nagoya dataset provided in annex 1).

1 All of the symbiont microorganisms of humans, their genetic material and their environment (see definition in (11)).

2 EU Regulation No 511/2014, §2.3.1.7. (12)

3 All information pertaining to the biological material, which is an integral part of the biobank (e.g., origin, provenance, nature, characterisation, conditions of collection, storage, processing, or access, etc.).

USEFUL LINKS

- Swiss Biobanking Platform: https://swissbiobanking.ch
- The Nagoya Protocol on Access and Benefit-sharing (hosted by the The Convention on Biological Diversity website): https://www.cbd.int/abs/
- Federal Office for the Environment (FOEN), Nagoya Protocol webpage: https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/nagoya-protocol.html
- Swiss Confederation, Protection of Nature and Cultural Heritage: https://www.fedlex.admin.ch/eli/cc/1966/1637_1694_1679/en
- Nagoya Ordinance: https://www.fedlex.admin.ch/eli/cc/2016/39/en#a8
- Swiss Academy of Sciences, Swiss biodiversity forum webpage: https://biodiversity.scnat.ch/activities_and_projects/abs
- More information on Access and benefit sharing mechanisms and good practice for academic research in Switzerland can be found on the website of the Swiss Academies of Arts and Sciences. Notably two practice guides have been edited to describe how to access genetic resources and associated traditional knowledge and share benefits with provider countries and how to write Mutually Agreed Terms (15, 16).

REFERENCES

1. United Nations. Convention on Biological Diversity [Internet]. 1992 [cited 2024, March 21]. Available from: https://www.cbd.int/doc/legal/cbd-en.pdf

2. Secretariat of the Convention on Biological Diversity. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity: text and annex / Secretariat of the Convention on Biological Diversity. [Internet]. Secretariat of the Convention on Biological Diversity; 2010 [cited 2024, March 21]. Available from: https://www.cbd.int/abs/

3. Secretariat of the Convention on Biological Diversity. ABS Information Kit - English [Internet]. 2011 [cited 2024, March 21]. Available from: https://www.cbd.int/abs/information-kit-en/

4. Secretariat of the Convention on Biological Diversity. ABSCH | Access and Benefit-Sharing Clearing-House [Internet]. [cited 2024, March 21]. Available from: https://absch.cbd.int/en/

5. Swiss Confederation. SR 451 - Federal Act of 1 July 1966 on the Protection of Nature and Cultural Heritage (NCHA) [Internet]. [cited 2024, March 21]. Available from: https://www.fedlex.admin.ch/eli/cc/1966/1637_1694_1679/en

6. Swiss Confederation. SR 451.61 - Ordinance of 11 December 2015 on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Ordinance, NagO) [Internet]. [cited 2024, March 21]. Available from: https://www.fedlex.admin.ch/eli/cc/2016/39/en#a8

7. FOEN FO for the E. Nagoya Protocol [Internet]. [cited 2024, March 21]. Available from: https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--fachinformationen/nagoya-protokoll.html

   Form Notification Due Diligence: in German / in French
   Form Notification Access: in German / in French

8. Watson JW, Carlile GA, Williams DT. The value of virtual biobanks for transparency purposes with respect to reagents and samples used during test development and validation. Rev Sci Tech OIE [Internet]. 2021 Jan 1 [cited 2024, March 21];40(1). Available from: https://doc.oie.int/dyn/portal/index.xhtml?page=alo&aloId=41315

9. SR 810.30 - Federal Act of 30 September 2011 on Research involving Human Beings (Human Research Act, HRA) [Internet]. Available from: https://www.fedlex.admin.ch/eli/cc/2013/617/en

10. SR 810.301 - Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) [Internet]. Available from: https://www.fedlex.admin.ch/eli/cc/2013/642/en

11. Dosch A, Sprumont D. Le statut juridique du microbiome humain - Sur mandat de l'Office fédéral de l'environnement (OFEV) [Internet]. 2020 [cited 2024, March 21]. Available from: https://www.bafu.admin.ch/dam/bafu/fr/dokumente/biotechnologie/rechtsgutachten/rechtsgutachten-microbiome-humain.pdf.download.pdf/Le%20status%20juridique%20du%20microbiome%20humain.pdf

12. 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 2021/C 13/01 [Internet]. 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021XC0112(02)

13. FOEN. Nagoya_Frequently Asked Questions [Internet]. 2021 [cited 2024, March 21]. Available:

   in french from: https://www.bafu.admin.ch/dam/bafu/fr/dokumente/biotechnologie/fachinfo-daten/faq_nagoya_verordnung.pdf.download.pdf/nagoya_questionsfrequemmentposeesfaq.pdf

   and in german from: https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/fachinfo-daten/faq_nagoya_verordnung.pdf.download.pdf/faq_nagoya_verordnung.pdf

14. Sollberger K. The Human Microbiome and the Nagoya Protocol: A challenging implementation - Legal expert brief on behalf of the Swiss Federal Office for the Environment [Internet]. 2020 [cited 2024, March 21]. Available from: https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/rechtsgutachten/final-legal-expert-brief-on-the-human-microbiome.pdf.download.pdf/Final_Legal%20Expert%20Brief%20on%20the%20Human%20Microbiome.pdf

15. Swiss Academies of Arts and Sciences. Utilization of genetic resources and associated traditional knowledge in academic research - A good practice guide for access and benefit-sharing. Jahrb Für Wiss Ethik. 2016;11 (4).

16. Swiss Academies of Arts and Sciences. Agreement on Access and Benefit-sharing for Academic Research: A toolbox for drafting Mutually Agreed Terms for access to Genetic Resources and to Associated Traditional Knowledge and Benefit-sharing. Jahrb Für Wiss Ethik. 2018 May 1;23(1):255–98. Available from: https://biodiversitaet.scnat.ch/activities_and_projects/abs/toolbox

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