



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of the Environment,
Transport, Energy and Communications DETEC

Federal Office for the Environment FOEN
Soil and Biotechnology Division

Access & Benefit Sharing, the Nagoya Protocol and its Implementation in Switzerland



SCNAT Workshop

Bern

September 9, 2016



Contents

- Purpose of the Nagoya Protocol
- Scope of the Swiss Regulation in NCHA and NagO
- User measures: Due Diligence and Notification Requirement
- System of Registered Collections
- Access to Genetic Resources in Switzerland
- National Focal Point

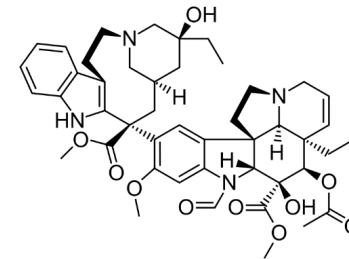


Utilisation of Genetic Resources

Pharma



Madagascar periwinkle
(*Catharanthus roseus*)

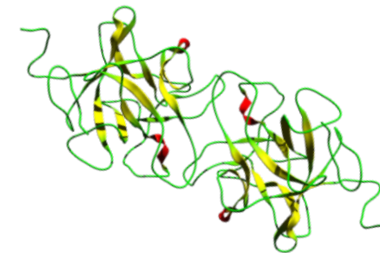


Vincristine und Vinblastine
Indol alkaloids for chemotherapy

Food



Miracle fruit (*Synsepalum dulcificum*)
originates from tropical West Africa



Miraculine, a glycoprotein that
converts acidic to sweet.

Agriculture



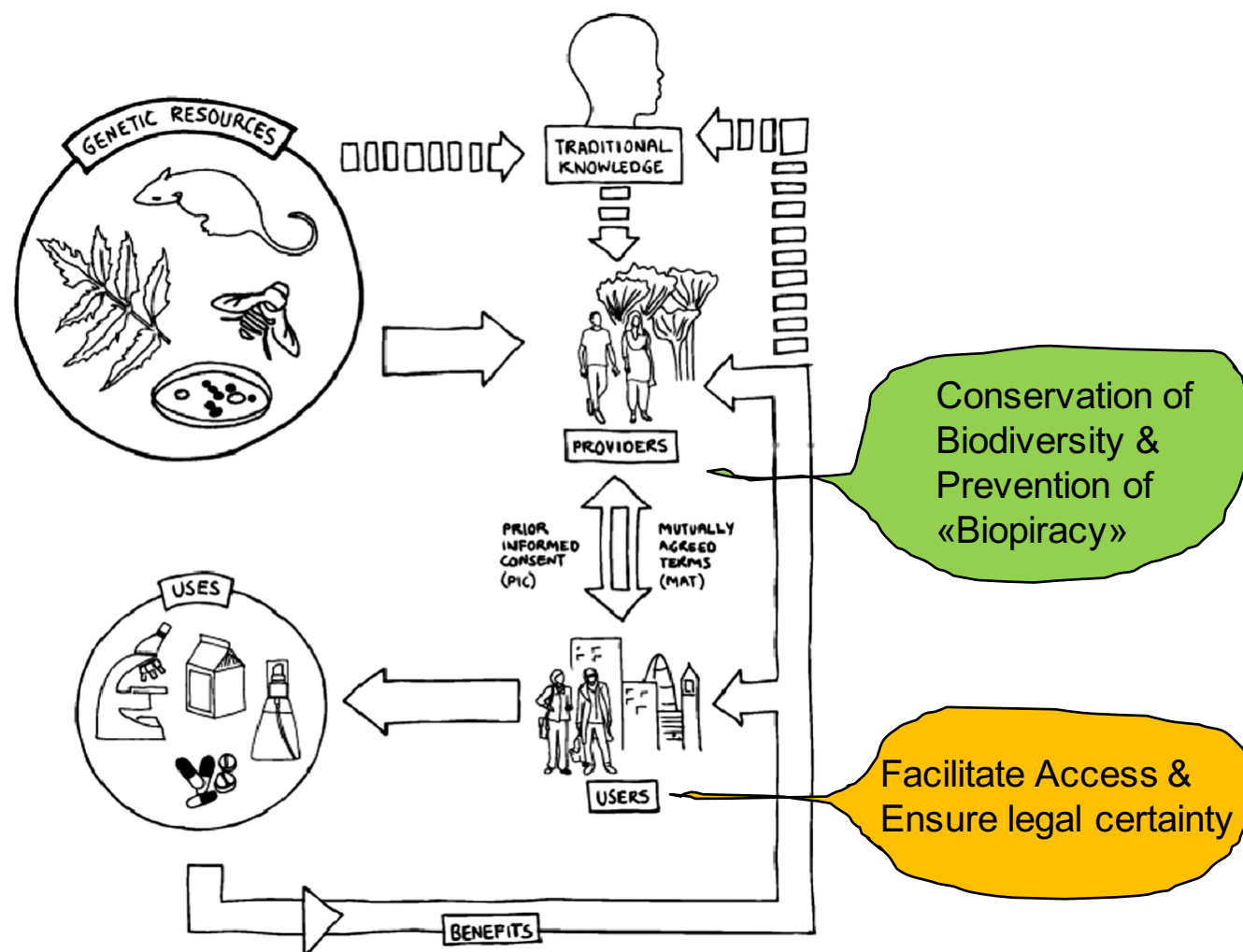
Phytophthora resistance in **wild relative**
of the potato from Mexico



Resistant **cultivated potato**



Access und Benefit Sharing



Quelle: www.cbd.int



Convention on Biological Diversity CBD



1993: «The objectives of this Convention [...] are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources [...]»

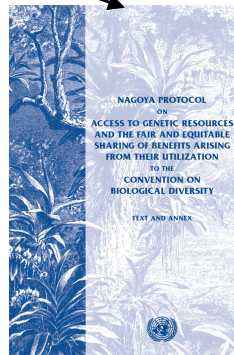
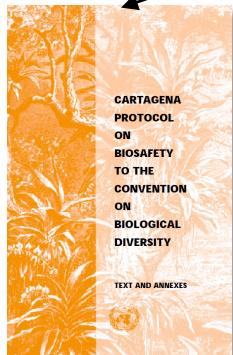
- Art. 15 (1) clarifies that States have sovereign rights over their natural resources and the authority to regulate access.
- Art. 8 (j) requires CBD Parties to respect, preserve, and maintain the knowledge, innovations and practices of indigenous and local communities [...] and encourages the equitable sharing of the benefits arising from their utilisation.
- Art. 16 (3) requires CBD Parties to take legislative, administrative, or policy measures to provide access to and transfer of technology that makes use of genetic resources accessed on MAT and in accordance with international law.
- Art. 19 (1) requires CBD Parties to take legislative, administrative, or policy measures to ensure the effective participation by providers in biotechnological research on the genetic resources.



CBD and subsequent regulations



1993: «The objectives of this Convention [...] are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources [...].»



2014: «The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources [...].»

Article 15

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.



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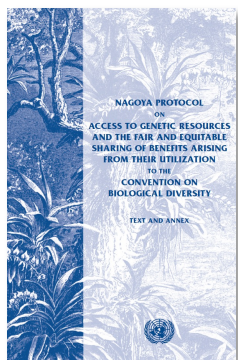
Use of Terms



Convention on
Biological Diversity

"*Genetic resources*" means genetic material of actual or potential value.

"*Biotechnology*" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.



"Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;



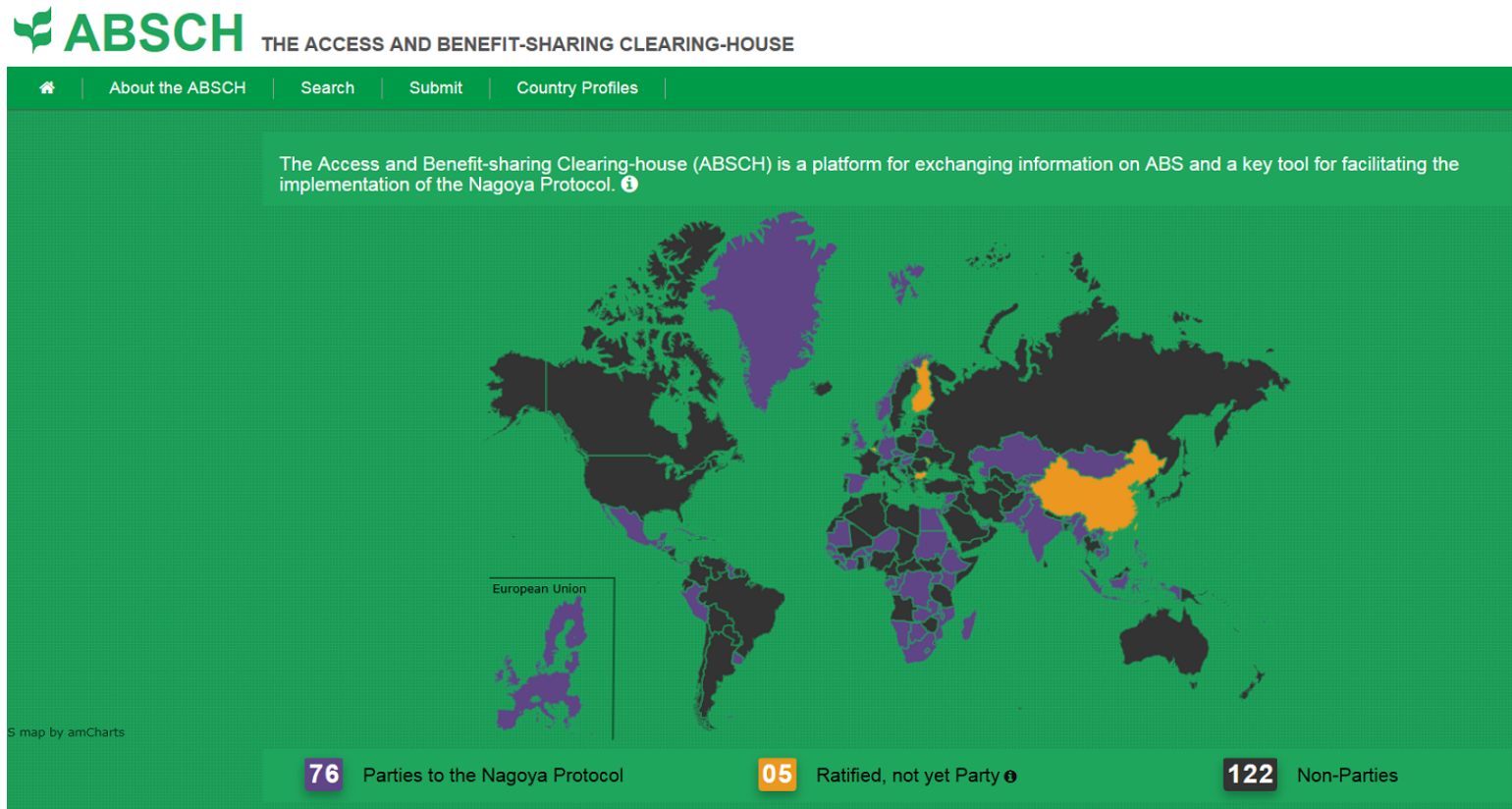
Corner stones of the Nagoya Protocol

- ❑ **Access:** Access to genetic resources only after Prior Informed Consent of the provider
- ❑ **Benefit Sharing:** Benefit Sharing respects Mutually Agreed Terms between user and provider
- ❑ **Compliance:** User measures ensure compliance with regulations of provider
- ❑ **National Focal Points** and **International Clearing House** as information exchange platforms
- ❑ **traditional knowledge** is addressed





Parties to the Nagoya Protocol



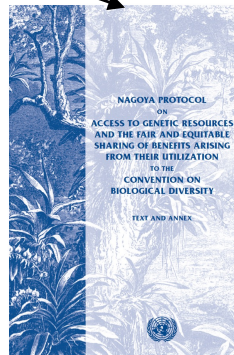
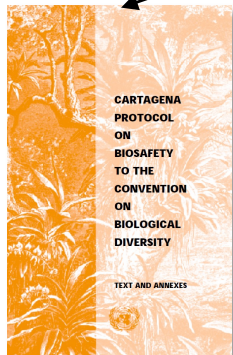
- ❑ The Nagoya Protocol entered into force on October 12, 2014.
- ❑ 76 Parties to date, including the EU



CBD and subsequent regulations



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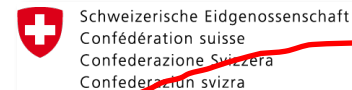


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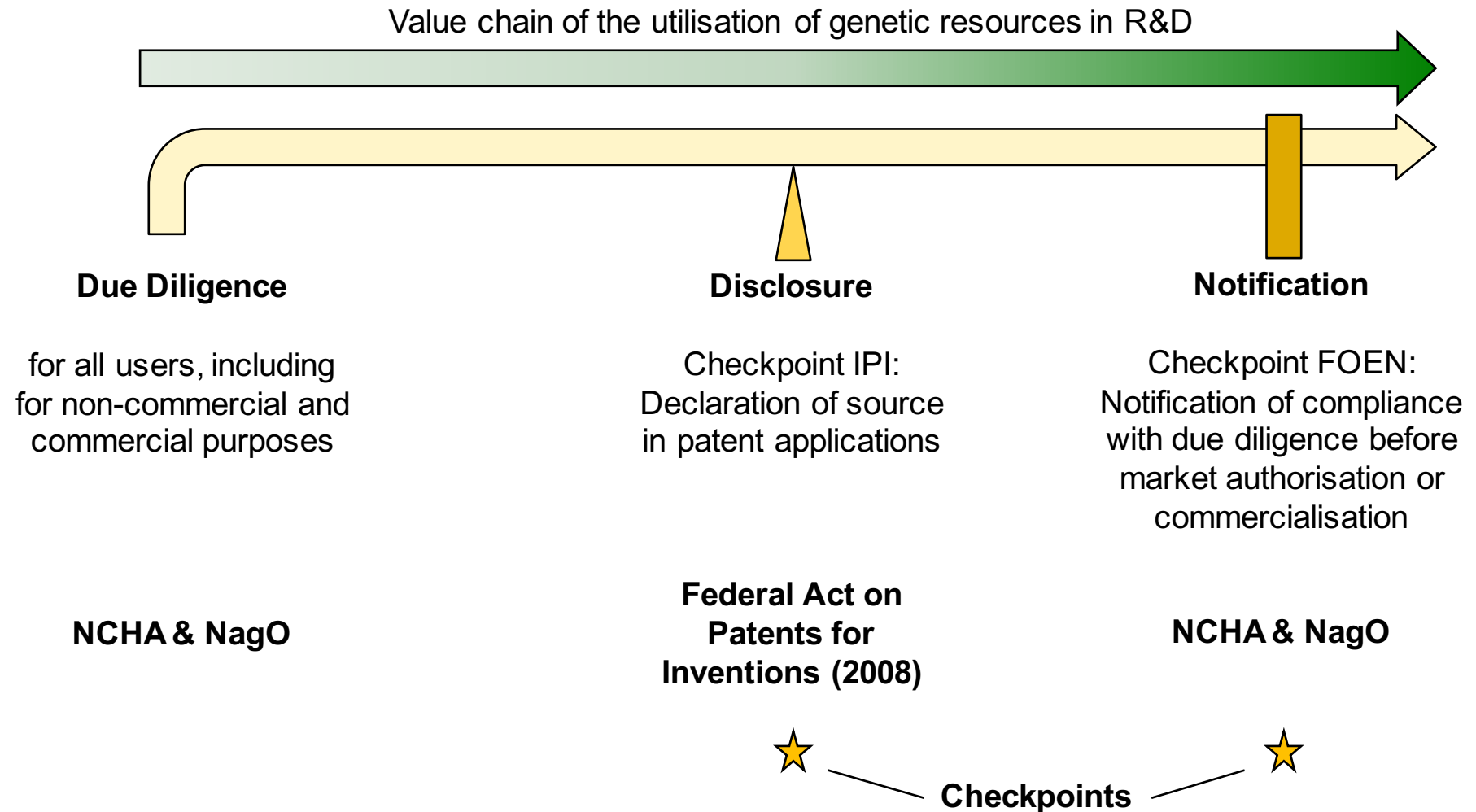


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User measures Switzerland





Scope of user measures Switzerland

User measures in NCHA and NagO are applicable to genetic resources, if:

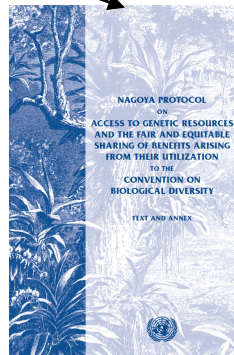
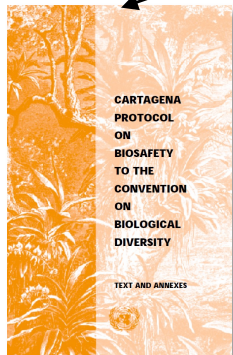
- the provider is a **party to the Nagoya Protocol**.
- the provider **has access regulation** in place.
- the genetic resource was accessed after **October 12, 2014**.



CBD and subsequent regulations



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Federal Act on the Protection of Nature and Cultural Heritage (NCHA)

In general:

- The amendments in the NCHA were necessary for the ratification in 2014

Main points:

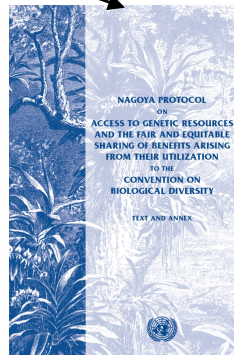
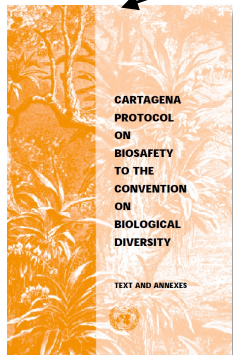
- Introduction of a due diligence and notification requirement for genetic resources
(NCHAArt. 23n para 5, 6; NCHAArt. 23o para 3)
- These requirements are applicable to traditional knowledge too
(NCHAArt. 23p)
- Opens a possibility to regulate access to genetic resources in Switzerland
(NCHAArt. 23q para 1)



CBD and subsequent regulations



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Nagoya Ordinance (NagO)

In general:

- ❑ came into force February 2016
- ❑ is harmonised with EU-Ordinance 511/2014
- ❑ EU has an additional checkpoint at the stage of research funding

Main points:

- ❑ Due diligence and notification requirement are described in detail
(NagO Art. 3, 4, 5)
- ❑ Introduction of a system for recognised collections
(NagO Art. 7)
- ❑ Introduction of rules for access to genetic resources in Switzerland
(NagO Art. 8, entry into force in January 2017)



Due Diligence and Notification (Art. 3, 4, 5 NagO)

- ❑ Users of genetic resources have to follow access and benefit sharing regulations of parties to the Nagoya Protocol
- ❑ **Due diligence** from the time of access to the genetic resource or associated traditional knowledge
- ❑ **Notification** before market authorisation or commercialisation

Art. 3 Due diligence requirement

¹ To execute the due diligence requirement in accordance with Article 23ⁿ NCHA, users must in particular record, keep and pass on the following information to subsequent users:

- a. the internationally recognised certificate of compliance issued in accordance with the provisions of the Nagoya Protocol as well as any information on utilisation and transfer rights;
- b. if an internationally recognised certificate of compliance is not available, the following information:
 1. name and address of the user or users,
 2. description of the genetic resource or subject matter and its utilisation,
 3. date on which the genetic resource was accessed,
 4. source of the genetic resource,
 5. name and address of the person from whom the genetic resource was acquired directly, date of its acquisition and, if available, a confirmation from the person that the genetic resource was acquired lawfully for the

[...]



System of recognised collections (Art. 7 NagO)

- ❑ FOEN keeps a public register of recognized collections.
- ❑ The system is voluntary
- ❑ **Aim:** A recognized collection complies with user measures and uses standardised practices and instruments. It is thereby trustworthy for both users and providers.

Art. 7 Recognition of collections

¹ The FOEN, taking account of Article 5 of Ordinance (EU) No. 511/2014⁵, keeps a public register of recognised collections for which the holder guarantees that:

- a. the requirements under Articles 3–5 and 8 are met when genetic resources and related information are recorded, kept and passed on; and
- b. standardised practices and instruments are applied to ensure the traceability and monitoring of exchanges when genetic resources and related information are exchanged with other collections that do not utilise the genetic resources concerned or benefit directly from their utilisation.

[...]



Access to genetic resources in CH (Art. 8 NagO, from Jan. 2017)

- Documentation requirement when accessing genetic resources in Switzerland
- Notification requirement in case of market authorisation or commercialisation
- **Aim:** Monitoring of the utilisation of genetic resources in Switzerland

Art. 8 Zugang zu genetischen Ressourcen im Inland

¹ Beim Zugang zu genetischen Ressourcen im Inland hat der oder die Nutzende folgende Information aufzuzeichnen, aufzubewahren und an nachfolgende Nutzende weiterzugeben:

- a. Name und Adresse des oder der Nutzenden;
- b. Beschreibung der genetischen Ressource oder des Gegenstandes sowie deren Nutzung;
- c. Zeitpunkt und Ort des Zugangs zur genetischen Ressource;
- d. beim unmittelbaren Erwerb der genetischen Ressource von einer dritten Person: Name und Adresse dieser Person sowie Zeitpunkt des Erwerbs;
- e. bei Weitergabe der genetischen Ressource: Name und Adresse des oder der nachfolgenden Nutzenden und Zeitpunkt der Weitergabe.

[...]



National Focal Point

You are welcome to address your specific questions to us:

National Focal Point to the Nagoya Protocol

E-Mail: contact.np@bafu.admin.ch

Phone: +41 58 463 92 68

Our homepage provides notification forms, FAQs and useful documents for implementation:

The screenshot shows the official website of the National Focal Point for the Nagoya Protocol in Switzerland. The header includes the Swiss flag and the text 'Federal Office for the Environment FOEN'. The main navigation bar has tabs for 'Topics A-Z', 'Publications, media', 'Data, indicators, maps', and 'The FOEN'. The 'Biotechnology' section is highlighted. The main content area is titled 'Nagoya Protocol' and contains a brief introduction to the protocol, its objectives, and the competent authority. A right sidebar lists 'Legislation' and 'Useful documents for implementation'.

www.bafu.admin.ch/nagoyaprotocol