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

Federal Office for the Environment FOEN
Legal Affairs Division

The implementation of the Nagoya Protocol in Switzerland

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Agenda

- Overview on the measures taken in Switzerland to implement the Nagoya Protocol
- Legal measures taken in Switzerland:
 - Amendments to the Federal Act on the Protection of Nature and Cultural Heritage
 - The Nagoya Ordinance
- Future work in Switzerland



Overview on the measures taken in Switzerland to implement the Nagoya Protocol

- 14 May 2011** Signing of the Nagoya Protocol → FOEN elaborates a ratification message and a draft amendments to the Federal Act on the Protection of Nature and Cultural Heritage (NCHA)
- 21 March 2014** Parliament adopts the Nagoya Protocol and the amendments to the NCHA
- 11 July 2014** Switzerland ratifies the Nagoya Protocol
- 12 October 2014** The Nagoya Protocol and the amendments to the NCHA enter into force
- 11 December 2015** Federal Council passes the Nagoya Ordinance
- 1 February 2016** The Nagoya Ordinance enters into force



Legal measures taken in Switzerland

Amendments to the **Federal Act on Protection of Nature and Cultural Heritage**:

User compliance measures with regard to genetic resources from other Parties to the Nagoya Protocol:

I. **Due diligence requirement** (cf. Art. 23n NCHA):

Any person who in accordance with the Nagoya Protocol utilizes genetic resources or benefits directly from their utilization (users) must apply due diligence appropriate to the circumstances to ensure that:

- ❖ the resources have been accessed lawfully; and
- ❖ mutually agreed terms for the fair and equitable sharing of the benefits have been established.

II. **Notification requirement** (cf. Art. 23o NCHA)

- ❖ Notification of compliance with due diligence to the FOEN by the time of market authorization or commercialization of a product developed on the basis of a utilized genetic resource

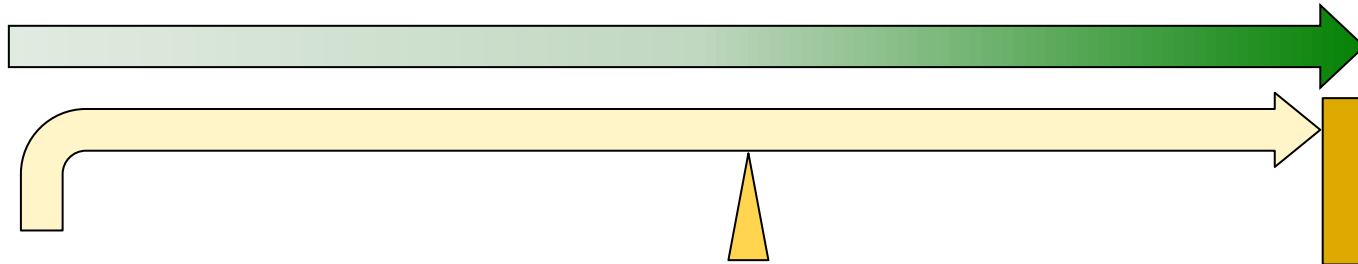
+ **Disclosure of the source** of the genetic resource and traditional knowledge in the patent application (Art. 49a Patent Act).



Legal measures taken in Switzerland

The higher the value of utilized GR the stronger the measure

Increasing value of the GR through research and development



Due diligence

For all users, including for non-commercial and commercial purposes.

Federal Act on the Protection of Nature and Cultural Heritage

Disclosure

Disclosure of source of GR or TK in patent applications.

Swiss Patent Law

Notification

Notification of compliance with due diligence at the time of market authorization or commercialization .

Federal Act on the Protection of Nature and Cultural Heritage



Legal measures taken in Switzerland

Note that the **due diligence and notification requirements** are:

- ❖ also applicable for the utilization of traditional knowledge associated with genetic resources unless this knowledge is already freely available to the public (Art. 23*p* NCHA)
- ❖ Only applicable to access to genetic resources in other Party to the Nagoya Protocol, which takes/took place after the entry into force of these provisions (cf. Art. 25*d* NCHA)

and that:

- ❖ Art. 23*n* para. 2 NCHA sets cases in which the due diligence requirement and therefore the notification requirement are not applicable



Legal measures taken in Switzerland

Access measures regarded national genetic resources and measures to support their conservation and sustainable use:

- ❖ Possibility for the Federal Council to regulate access to genetic resources in Switzerland (Art. 23q para. 1 NCHA)
- ❖ Possibility for the Federal Council to support the conservation and sustainable use of genetic resources in Switzerland (Art. 23q para. 2 NCHA)

Sanctions and administrative measures:

- ❖ A fine of up to 100'000 Swiss Francs for any person who willfully fails to provide information or provides false information; a fine up to 40'000 Swiss Francs in cases of negligence
- ❖ No authorization of products developed on the basis of utilized genetic resources if the notification to the FOEN has not been made by the time of market authorization
- ❖ Possibility to take other administrative measures in cases of violation of the due diligence requirement



Legal measures taken in Switzerland

The Nagoya Ordinance:

User compliance measures:

Article 3 – Due diligence

- ❖ minimal information which has to be recorded, stored and transferred to subsequent users
- ❖ pathogens and harmful organisms: in national or international recognized emergency situations the due diligence requirement has only to be met by the time of commercialization of products developed on the basis of these utilized genetic resources
- ❖ storage of the information: as long as the genetic resources and the products are conserved; and 10 years after the end of utilizing or directly benefiting from its utilization



Legal measures taken in Switzerland

Article 4 – Notification requirement

- ❖ notification of the information recorded during the application of due diligence to FOEN
- ❖ a notification can also be made before commercialization on a voluntary basis
- ❖ a reference number issued upon notification by FOEN serves as confirmation
- ❖ simplified notification if compliance with due diligence has already been notified in the EU or in the ABS Clearing House
→ reference number of this notification or information

Article 5 – Traditional knowledge

Articles 3 and 4 are applicable by analogy to traditional knowledge covered by the Art. 23p NCHA



Legal measures taken in Switzerland

Measures to simplify/support user compliance:

Articles 6 and 7 – Recognition of best practices and collections

FOEN sets up and manages a public register of recognized best practices tools and collections

Procedures and criteria that collection has to fulfill in order to be recognized:

- ❖ Provisions contained in Articles 3 to 5 and 8 must be met for the acquisition, conservation and transfer of genetic resources
- ❖ Standardized procedures for tracking the exchange of genetic resources with other collections that don't utilize these genetic resources or don't benefit directly from their utilization
- ❖ On the basis of the application FOEN checks whether the criteria are met; the FOEN can delegate this task to a third person



Legal measures taken in Switzerland

Access measures and measures to support the conservation and sustainable use of national genetic resources:

Article 8 – Access to genetic resources in Switzerland

- ❖ Documentation requirement for accessing genetic resources in Switzerland
- ❖ Notification requirement by the time of commercialization of products based on utilized genetic resources accessed in Switzerland
- ❖ If access and utilization of genetic resources are already documented by the application of a certain procedure and if the FOEN can obtain the information stored no notification is required

→ **no PIC and MAT are required**



Legal measures taken in Switzerland

❖ Article 9 – Conservation and sustainable use

Criteria for financial contributions for the conservation and sustainable use of genetic resources in Switzerland

Measures for the enforcement of the national provisions:

❖ Article 10 and 11 – Task of the authorities

FOEN is the competent authority and the focal point for the Nagoya Protocol. It operates the “centralized checkpoint” and enforces the due diligence and notification obligations in alleged cases of violation of these obligations, etc.

Other authorities check whether a notification to FOEN has been made during the market authorization procedures:

- ❖ Formal check based on the indications by the applicant
- ❖ No authorization if the reference number will not be provided by the end of the procedure



Future work in Switzerland

- Enforcement of the new national provisions
- Elaboration of guidance
- Awareness-raising
- etc.



Thank you for your attention!