# Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation

**(Nagoya Ordinance, NagO)**

of 11 December 2015 (Status as of 1 January 2017)

*The Swiss Federal Council,*

based on Articles 23*n* paragraphs 5 and 6, 23*o* paragraph 3, 23*q* paragraph 1 and 26 of the Federal Act of 1 July 1966[1] on the Protection of Nature and Cultural Heritage (NCHA),
in application of the Nagoya Protocol of 29 October 2010[2] on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol),

*ordains:*

## Section 1 General Provisions

### Art. 1 Subject matter

This Ordinance regulates access to and the utilisation of genetic resources and associated traditional knowledge as well as the fair and equitable sharing of benefits arising from their utilisation.

### Art. 2 Definitions

In this Ordinance:

a. *genetic resources* means genetic material of actual or potential value;

b. *genetic material* means any material of plant, animal, microbial or other origin that contains functional units of heredity;

c. *utilisation of genetic resources* means conducting research and development on the genetic or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention of 5 June 1992[3] on Biological Diversity;

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2 SR **0.451.432**
3 SR **0.451.43**

d. *users* means legal or natural persons who in accordance with the Nagoya Protocol utilise a genetic resource or associated traditional knowledge or benefit directly from their utilisation;

e. *commercialisation* means selling products developed on the basis of utilised genetic resources or of utilised associated traditional knowledge, as well as other legal transactions in connection with utilised genetic resources or with utilised traditional knowledge that result in monetary benefits, in particular licences, pledge agreements or similar legal transactions;

f. *internationally recognised certificate of compliance* means a permit or its equivalent issued at the time of access by a competent authority in accordance with Article 6 paragraph 3 letter e and Article 13 paragraph 2 of the Nagoya Protocol and registered with the international Access and Benefit-Sharing Clearing-House.

## Section 2
## Requirements for the Utilisation of Genetic Resources and Associated Traditional Knowledge of other Parties to the Nagoya Protocol

**Art. 3** Due diligence requirement

[1] In meeting the due diligence requirement in accordance with Article 23*n* 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 use and transfer rights;

b. if an internationally recognised certificate of compliance is not available, the following information:
   1. the name and address of the user,
   2. a description of the genetic resource or subject matter and its utilisation,
   3. the date on which the genetic resource was accessed,
   4. the source of the genetic resource,
   5. the 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 utilisation 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.

2 If specific information under paragraph 1 letter b is unknown and cannot be obtained, the reasons must be recorded, kept and passed on to subsequent users.

3 If the name and address of the person under paragraph 1 letter b number 5 are subject to trade secrecy, this information need not be passed on to subsequent users.

4 In an internationally or nationally recognised emergency that threatens the health of humans, animals or plants or the environment, it suffices if the due diligence requirement for the utilisation of genetic resources that are pathogenic or harmful organisms is fully met at the time of the commercialisation of products developed on the basis of the utilised genetic resources.

5 All information specified in paragraphs 1 and 2 must be retained as follows and be made available on request to the implementing authorities:

a. for ten years after the end of utilisation or directly benefiting; and

b. for as long as the genetic resource or the product developed on the basis of the utilised genetic resource is retained.

**Art. 4** Notification requirement

1 Notification as defined in Article 23*o* paragraph 1 NCHA must be given by the user. It must contain the information specified in Article 3 paragraphs 1 and 2 that is available at the time of the notification.

2 Notification may also be given voluntarily, in particular if no commercialisation is intended.

3 The user receives a register number as evidence of the notification.

4 If compliance with the due diligence requirement has already been attested to under Article 7 of Regulation (EU) No. 511/2014[4] or is evident on the basis of information published through the international clearing house under Article 14 of the Nagoya Protocol, the user may notify the Federal Office for the Environment (FOEN) of the register number of the corresponding attestation or publication instead of providing the information under Article 3 paragraph 1.

5 As part of the market authorisation procedure, the user must specify to the competent authority under Article 11 whether the product to be commercialised has been developed on the basis of utilised genetic resources subject to due diligence and notification requirements, and where applicable, the register number.

**Art. 5** Traditional knowledge

The requirements for recording, retaining and passing on information and for notification under Articles 3 and 4 apply, mutatis mutandis, to users of traditional knowledge associated with genetic resources in accordance with Article 23*p* NCHA.

4 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 Text, OJ L 150 of 20.5.2014, p. 59.

**Art. 6** Recognition of best practices

1 The FOEN keeps a public register of practices that users may apply on the assumption that they meet the requirements under Articles 3–5 and 8.

2 A practice is included in the register if so requested by users or other interested parties and it is demonstrated that the practice meets the requirements under Articles 3–5 and 8. The FOEN must be informed of changes or updates to a recognised practice.

3 The FOEN may also, on its own initiative, include in the register a practice that meets the requirements under Articles 3–5 and 8.

4 If there are signs that through the application of a recognised practice the requirements under Articles 3–5 and 8 are no longer met, the FOEN sets a deadline by which the necessary measures must be taken. If the requirements are not met by the deadline, the FOEN removes the practice from the register.

**Art. 7** Recognition of collections

1 The FOEN, taking account of Article 5 of Ordinance (EU) No. 511/2014[5], 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 acquired, retained 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.

2 A collection is included in the register if requested by a holder and after the FOEN has verified and confirmed the compliance of the collection or a specific part thereof with the requirements under paragraph 1. The FOEN may commission third parties to perform this verification.

3 If there are signs that a collection or a specific part thereof no longer meets the requirements under paragraph 1, the FOEN sets a deadline by which the necessary measures must be taken. If the requirements are not met by the deadline, the FOEN removes the collection or the part concerned thereof from the register.

## Section 3 Genetic Resources in Switzerland

**Art. 8** Access to genetic resources in Switzerland

1 On accessing genetic resources in Switzerland, the user must record and retain and following information and pass it on to subsequent users:

a. the name and address of the user;

b. description of the genetic resource or subject matter and its utilisation;

5 See also footnote to Art. 4 para. 4.

c. date on which and location where the genetic resource was accessed;

d. 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;

e. in the case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

2 If the name and address of the person under paragraph 1 letter d are subject to trade secrecy, this information need not be passed on to subsequent users.

3 The user must notify the FOEN of the information specified in paragraph 1 before market approval or, if such approval is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

4 Notification may also be given voluntarily, in particular if no commercialisation is intended.

5 The user receives a register number as evidence of the notification and, on request, an attestation to the effect that the Swiss provisions on access and sharing of benefits have been complied with.

6 The information specified in paragraph 1 must be retained in accordance with the requirements set out in Article 3 paragraph 5 and be made available on request to the implementing authorities.

7 Genetic resources in respect of which the information specified in paragraph 1 has already been recorded and made available to the FOEN in global form in connection with a different procedure are exempt from the notification requirements under paragraph 3.

**Art. 9** Conservation and sustainable use

1 Applications for financial assistance for the conservation and sustainable use of genetic resources in accordance with Article 23*q* paragraph 2 NCHA must be submitted to the FOEN.

2 Support may be given in particular to the activities of institutions or organisations that engage in *in situ* or *ex situ* conservation, characterisation, or sustainable use of genetic resources or employ benefits arising from the utilisation of genetic resources for the conservation of biodiversity and the sustainable use of their components.

3 Information on genetic resources relating to supported activities must be made available on request to the FOEN.

## Section 4 Duties of the Authorities

**Art. 10** Duties of the FOEN

1 The FOEN is the competent authority and focal point for the Nagoya Protocol. It has the following specific tasks:

a. It operates a national Access and Benefit-sharing Clearing-House.

b. It ensures the liaison between the Secretariat under Article 24 of the Convention of 5 June 1992[6] on Biological Diversity and the international Access and Benefit-sharing Clearing-House.

c. It carries out the tasks specified in Article 13 of the Nagoya Protocol.

d. It ensures the exchange of information with the international Access and Benefit-sharing Clearing-House under Article 14 of the Nagoya Protocol.

e. At the request of other Parties to the Nagoya Protocol, it makes available information relating to compliance with the due diligence requirement; confidential information is made available only if the official secrecy and appropriate protection of privacy are ensured in accordance with Swiss law.

f. It operates an electronic database that contains information relating to the requirements under Articles 3–5 and 8.

g. It publishes information as specified in Article 23*o* paragraph 2 second sentence NCHA and other non-confidential information relating to the requirements under Articles 3–5 and 8.

h. It performs a formal verification of the notifications under Articles 4 and 8.

i. It verifies compliance with the requirements under Articles 3–5 and 8 if tangible signs of their violation exist or when carrying out spot checks; it may also involve the cantons.

j. It operates a public register of best practices, recognised collections and other procedures as specified in Article 8 paragraph 7.

k. It ensures that events related to the execution of the Nagoya Protocol are held, as necessary.

l. It issues reports as specified in Article 29 of the Nagoya Protocol.

[2] The FOEN encourages users to voluntarily share the benefits arising from the utilisation of genetic resources or associated traditional knowledge in a fair and equitable way even when there is no legal obligation to do so. It aims to ensure that the benefits are used to conserve biological diversity and the sustainable use of their components.

### **Art. 11** Duties of other authorities

[1] As part of the market authorisation procedure in accordance with the ordinances listed below, the competent authorities verify whether evidence of compliance with the notification requirement as specified in Articles 4, 5 and 8 exists for products developed on the basis of utilised genetic resources or associated traditional knowledge:

| Product | Competent authority | Applicable regulation |
|---|---|---|
| a. Therapeutic products (Human and animal therapeutic products) | Swiss Agency for Therapeutic Products (Swissmedic) | Ordinance of 21 September 2018[7] on Therapeutic Products |

6 SR **0.451.43**

7 SR **812.212.21**. The reference was adjusted to 1 Jan. 2019 in application of Art. 12 para. 2 of the Publication Act of 18 June 2004 (SR **170.512**).

| Product | Competent authority | Applicable regulation |
|---|---|---|
| b. Immunological therapeutic products for use by veterinaries | Federal Food Safety and Veterinary Office (FSVO) | Ordinance of 21 September 2018[8] on Therapeutic Products |
| c. Foodstuffs, additives, processing aids | FSVO | Ordinance of 23 November 2005[9] on Foodstuffs and Utility Articles |
| d. Plant protection products | Federal Office for Agriculture (FOAG) | Ordinance of 12 May 2010[10] on Plant Protection Products |
| e. Fertilisers | FOAG | Ordinance of 10 January 2001[11] on the Placing on the Market of Fertilisers |
| f. Animal feedstuffs | FOAG | Ordinance of 26 October 2011[12] on the Production and Marketing of Feedstuffs |
| g. Plant propagation material exclusively for use in forests | FOEN | Ordinance of 10 September 2008[13] on the Handling of Organisms in the Environment |
| h. Plant propagation material for all other uses | FOAG | Ordinance of 7 December 1998[14] on the Production and Placement on the Market of Plant Propagation Material |
| i. Biocide products | Federal Office of Public Health (FOPH) | Ordinance of 18 May 2005[15] on Biocide Products |
| j. Chemicals | FOPH | Ordinance of 5 June 2015[16] on Protection against Dangerous Substances and Preparations |
| k. Other products | FOEN | Ordinance of 10 September 2008 on the Handling of Organisms in the Environment |

[2] If no evidence of compliance with the notification requirement is submitted at the beginning of the process, the competent authorities require users to submit evidence of compliance before the authorisation process is completed.

[3] The competent authorities refuse authorisation if the user or users fails to submit evidence of compliance with the notification requirement.

[4] The competent authorities forward to the FOEN the information from the user or users concerning compliance with the notification requirement at its request.

8 SR **812.212.21**. The reference was adjusted to 1 Jan. 2019 in application of Art. 12 para. 2 of the Publication Act of 18 June 2004 (SR **170.512**).
9 SR **817.02**
10 SR **916.161**
11 SR **916.171**
12 SR **916.307**
13 SR **814.911**
14 SR **916.151**
15 SR **813.12**
16 SR **813.11**

## Section 5 Final Provisions

**Art. 12** Amendments of other legislation

The amendment of other legislation is specified in the Annex.

**Art. 13** Commencement

[1] Subject to paragraph 2 below, this Ordinance comes into force on 1 February 2016.

[2] Article 8 comes into force on 1 January 2017.

*Annex*

## Amendments of other legislation

The legislation below is amended as follows:

...[17]

17 The amendments may be consulted under AS **2016** 277.