THE INTERNATIONAL FRAGRANCE ASSOCIATION

International Organization of the Flavor Industry

IFRA-IOFI Guidance Document for the Flavor and Fragrance Industry for dealing with the Nagoya Protocol and Access and Benefit Sharing (ABS) Regulations

Annex – Switzerland

IFRA-IOFI Nagoya Protocol TF

April 9th, 2020

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1 Introduction

Switzerland ratified the Nagoya Protocol on 11 July 2014. The Protocol and the amendments of the Natural and Cultural Heritage Protection Act #451 (hereafter referred as NCHA) came into force on October 12, 2014. The Federal Council passed the Nagoya Ordinance #451.61 on 11 December 2015. Together with the Nagoya Protocol and the provisions of the Federal Act on the Protection of Nature and Cultural Heritage it forms the basis for the legal use of genetic resources. The Nagoya Ordinance also regulates the access to genetic resources in Switzerland. It came into force on 1st February 2016. Most of the legal texts are available as non-official English translations.

The regulatory approach in Switzerland is largely consistent with the approach of the European Union. Since Swiss users exchange many genetic resources, in particular with users in EU Member States, such alignment is useful.

2 National Authorities and Relevant institutions

The **Federal Office of the Environment (FOEN)** [1)] is the competent authority and National Focal Point for the Nagoya Protocol. It has the following specific tasks:

- It operates as national Access and Benefit Sharing Clearing House.
- It ensures the liaison between the Secretariat of the Convention on Biological Diversity and the international Access and Benefit Sharing Clearing House.
- It ensures the exchange of information with the international Access and Benefit Sharing Clearing House.
- 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.
- It operates an electronic database that contains information regarding due diligence and reporting obligations, additional information, official forms, and frequently asked questions
- It publishes information relating to compliance with the due diligence requirement and other non-confidential information
- It performs a formal verification of the notifications.
- It verifies compliance if tangible signs of their violation exist or when carrying out spot checks; it may also involve the cantons.
- It operates a public register of best practices, recognised collections and other procedures.
- It ensures that events related to the execution of the Nagoya Protocol are held, as necessary.
- It updates the Conference of the Parties on measures taken for implementing the Protocol.

The **Federal Food Safety and Veterinary office (FSVO)** and the **Federal Office of Public Health (FOPH)** are the competent authorities for market authorisation procedure including for products developed on the basis of utilised genetic resources or associated traditional knowledge related to foodstuffs, additives, and processing aids, or chemicals, respectively. [2)]

They forward to the FOEN the information from the user or users concerning compliance with the notification requirement.

3 Access

3.1 Applicable Legislation

The Nagoya Ordinance #451.61 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 utilization.

3.2 Main legislative principles

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

- the name and address of the user;
- description of the genetic resource or subject matter and its utilisation;
- date on which and location where the genetic resource was accessed;
- in case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition;
- in case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

The information specified above must be retained and be made available on request to the implementing authorities:

- for 10 years after the end of utilisation or directly benefiting therefrom; and
- for as long as the genetic resource or the product developed on the basis of the utilised genetic resource is retained.

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

Notification is also required if a product is marketed abroad whose development was based on a genetic resource from Switzerland.

Notification may also be given voluntarily, in particular if no commercialisation is intended. Such reporting requirement facilitates cooperation with partners in other Contracting Parties to the Nagoya Protocol (e.g. EU countries), as the legal origin of the genetic resources must be identified.

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

Genetic resources which have already been recorded and made available to the FOEN in global form in connection with a different procedure are exempted from the notification requirement.

There is no legal benefit sharing obligation for users utilizing genetic resources of Switzerland. However, 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.

If the genetic resource is collected in the wild for a commercial objective (e.g. sourcing and/or R&D with commercial purpose, etc.), the user should get an authorization from the Canton as defined under NCHA art. 19. [1)]

3.3 Known grey zones

Though not officially written by the authority, the Swiss authorities are likely to follow European Commission Guidance documentation when finalized. This would potentially be confirmed in their frequently asked questions document, reviewed on a regular basis.
Grey zones relate to those currently discussed at the European level i.e.

- status of derivatives (continuity/discontinuity)
- human microbiome
- status of digital sequence information
- high throughput screening

4 Utilization

4.1 Applicable Legislation

The Nagoya Ordinance #451.61 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 utilization. The Regulation encompasses the geographical, material and temporal scope of the Nagoya Protocol.

4.2 Main legislative principles

If utilization is performed in Switzerland, then users fall under the scope of the Nagoya ordinance #451.61. Users of genetic resources must record, keep and pass on the following information to subsequent users:

- the Internationally Recognised Certificate of Compliance (IRCC) issued in accordance with the provisions of the Nagoya Protocol as well as any information on use and transfer rights;
- if an IRCC is not available, the following information:
    - the name and address of the user,
    - a description of the genetic resource or subject matter and its utilisation,
    - the date on which the genetic resource was accessed,
    - the source of the genetic resource,
    - 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,
    - in the case of transfers of genetic resources, the name and address of the subsequent user and the date of the transfer, 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,

- where required, evidence that mutually agreed terms for the fair and equitable sharing of benefits have been established.

The information specified above must be retained and be made available on request to the implementing authorities:

- for 10 years after the end of utilisation or directly benefiting; and
- for as long as the genetic resource or the product developed on the basis of the utilised genetic resource is retained.

It is the task of the users to prove compliance with the due diligence obligations. Accordingly, the user must notify the FOEN of the information specified above before market approval or, if such approval is not required, before the commercialisation of products developed on the basis of utilised genetic resources, or associated traditional knowledge.

If, under national law, no benefit sharing was required, the written acknowledgments of genetic resource providers should be kept, if available, demonstrating that no benefit sharing was required. However, 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.

Crucial, however, is that the genetic resource is “utilized” within the meaning of the Nagoya Protocol. Genetic resources that are solely used as a commercial or consumer good and not utilized in the meaning of the Nagoya Protocol are not covered by due diligence obligations under the Swiss legislation.

If no evidence of compliance with the notification requirement is submitted prior to commercialisation, the competent authorities require users to submit evidence of compliance before the authorisation process is completed.

In case of non-compliance, the users have to fulfil them retrospectively, or discontinue the use of the genetic resource, or cease commercialization.

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

Additional information: there is a simplified notification process available for genetic resources already notified at EU Level.

4.3 Known grey zones

As the term ‘research and development’ is neither defined in the Convention on Biological Diversity, nor in the Nagoya Protocol, nor in the Swiss regulations, it should be understood in the context of the Nagoya Protocol. In line with the EU approach on the topic, if the activity creates new insight into characteristics of the genetic resources which is of (potential) benefit to the further process, it should be regarded ‘utilisation’.

5 Sanctions

According to NCHA (Article 24a), intentional misrepresentation or failure to comply with the obligation to notify is punished by fines of up to 100,000 Swiss francs, up to 40,000 Swiss francs for negligent misrepresentation or disregard. In addition, the judge may order the publication of the judgment.

6 Abbreviations

EU	European Union
FOEN	Federal Office of the Environment
FOPH	Federal Office of Public Health
FSVO	Federal Food Safety and Veterinary office
IRCC	Internationally Recognised Certificate of Compliance
NCHA	Natural and Cultural Heritage Protection Act #451

7 References

FOEN dedicated webpage with FAQ document:
https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/nagoya-protocol.html

Art 11 of the Swiss Nagoya ordinance #451.61.

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