

Response by Switzerland to Notification 2012-106

Steps taken towards ratification and implementation of the Nagoya Protocol, including information on draft legal ABS-user-measures, as well as additional issues that may need to be addressed in preparation for the first COP-MOP

Switzerland is pleased to submit information about the steps taken towards ratification and implementation of the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (NP) in Switzerland, including information on draft legal ABS-user-measures, and to share its views on additional issues that may need to be addressed in preparation for the first meeting of the Conference of the Parties to the NP (COP-MOP-1).

As the **ratification procedure in Switzerland is still ongoing**, the draft legal ABS-user-measures presented in this submission shall be understood as a contribution by Switzerland to the discussion on possible approaches on how to implement the NP. In no way shall they be understood as the final measures taken by Switzerland to implement the NP. Indeed, **any measure presented in this submission might be further refined, amended, or omitted once further progress towards ratification is made**. Moreover, the focus of this document is on legally-binding ABS-user-measures; other measures that are also important to implement the NP, such as those to regulate access to genetic resources in Switzerland or legally non-binding measures, such as awareness-raising and capacity-development activities, are not discussed in detail in this document.

1. Steps towards the ratification of the NP in Switzerland

In order to ratify the NP, Swiss authorities have to follow an official ratification procedure, which first starts by signing of the NP followed by the elaboration of a ratification message to the Parliament, including a proposal with draft ABS-measures. The procedure is accompanied by a series of informal and formal consultations. The mandate to ratify the NP will be given to the Swiss Government (i.e. the Federal Council) by the Parliament after its presumed approval.

1.1. Steps that have already been taken

- **Formal consultations** within the Federal Administration and **decision by the Federal Council to sign the NP** on 30 March 2011. A mandate to prepare the necessary ratification procedure was given to the Federal Office for the Environment FOEN.
- **National ABS conference** on the utilization of genetic resources in Switzerland organized by FOEN together with the Federal Office for Agriculture on 6 April 2011. The aim of the conference was to introduce the NP and other relevant international agreements, in particular the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA), as well as existing national ABS-measures (e.g. the disclosure requirement in the Swiss Patent Act) and to evaluate the need for additional ABS-measures in Switzerland. The conference was attended by more than 170 representatives from government agencies, NGOs, industries, academia and politicians ([Conference Webpage](#)).
- **Switzerland signed the NP on 11 May 2011.**

- Elaboration of a **draft ratification message** and additional **draft legal ABS-measures**, including informal consultations within the Federal Administration and with key stakeholders and NGOs.
- Continuation of **awareness-raising and capacity-development activities**, including the update of voluntary guidelines and best practice tools (e.g. <https://abs.scnat.ch>, [ABS Management-Tool](#)).
- First round of **formal consultations within the Federal Administration** on the draft ratification message and the draft legal ABS-measures followed by a revision of these ratification documents.
- Second round of formal consultations and **decision by the Federal Council to open a public hearing** on the ratification documents on 16 May 2012. Every natural and legal person in Switzerland had the possibility to submit its views on these documents until 6 September 2012. **The ratification documents, including the draft legal ABS-measures, can be downloaded from the [national ABS-Clearing-House](#).**

1.2. Next steps to be taken

- Evaluation of the submissions received during the public hearing and revision of the ratification documents, including the draft legal ABS-measures.
- Formal consultations within the Federal Administration and decision of the Federal Council to submit the documents to the competent Committee and the two Chambers of the Parliament.
- A decision by Parliament whether to approve the NP and to adopt the new legal measures can be expected at the earliest in autumn 2013. The case given, the Federal Council will be able to ratify the NP after its approval by the Parliament.
- Amendment of existing and/or elaboration of new regulatory requirements (Ordinances).

2. Approach taken to implement the NP in Switzerland

In general, Switzerland believes that a good implementation of the NP requires **a mixture of legally-binding and non-binding measures that should build on already existing ABS-measures and practices**. Therefore, in a first step, Switzerland carefully evaluated whether there was a need to develop additional measures by comparing existing measures with the obligations according to the NP and by organising a national ABS conference to exchange views with all relevant stakeholders (see above). The conclusion from this analysis and workshop was that there is a need to continue with the implementation of legally-non binding measures (such as awareness-raising and capacity-development activities) but also to develop further legally-binding ABS-measures to fully implement the NP in Switzerland.

Secondly, Switzerland considers that any **ABS-measure should be simple, effective, and take into account the needs and practices of those providing and utilizing genetic resources (GR) and associated traditional knowledge (ATK)**. While sector specific measures might be developed in this regard, **some general measures applicable across all sectors should be adopted in a first place, in order to further implement the NP in every sector**. The draft legal ABS-measures in Switzerland developed so far focus on measures that are applicable across all sectors. They have been elaborated in consultation with relevant ABS-stakeholders and representatives of different Federal government agencies.

Finally, Switzerland is convinced that any ABS-measure to implement the NP should create an **“ABS-enabling environment”**, that is **a system that facilitates research and devel-**

opment on GR in order to add value to GR and to enhance the potential benefits that can be shared, while at the same time ensures compliance with domestic ABS-regulatory requirements of the Parties to the NP that provided the GR. The draft legal ABS-measures in Switzerland have been developed accordingly (see 2.3. and 2.3).

2.1. Existing ABS-measures in Switzerland

An analysis of existing access provisions to GR in Switzerland can be downloaded under the following link: [L'accès aux ressources génétiques en droit Suisse](#). Moreover, Switzerland already introduced a number of ABS-user-measures prior to the adoption of the NP, including a [disclosure of source requirement](#) in the Swiss Patent Act that is also proposed on the international level, voluntary approaches based on the [implementation of the Bonn Guidelines](#) and the [IT-PGRFA](#). More information with regard to existing ABS-measures in Switzerland can be found on the [national ABS Clearing-House](#) or in chapter 1 of the draft ratification message.

2.2. Additional draft legal ABS-measures in Switzerland

As described above, Switzerland drafted additional legal ABS-measures with the aim to close the gap between the existing ABS-measures and the obligations according to the NP. These measures as well as the draft ratification message that contains explanatory notes to the measures (chapter 5) can be downloaded in German, French, and Italian on the webpage of the [national ABS Clearing-House](#). A **non-official English translation** of the draft legal ABS-measures as well as of the explanatory notes is also available on this webpage. As explained above, these measures have to be further revised (see 1.2.). A schematic representation of the draft legal ABS-user-measures is provided below (Figure 1).

In short, Switzerland intends to introduce **three additional measures** in its legal system by **amending the Federal Act on the Protection of Nature and Cultural Heritage** (please download the draft legal ABS-measures for the precise wording and for further details):

- I. **A due diligence requirement** (Implementation of Art. 5 and 15 of the NP)
 - Whoever is utilizing a GR or benefiting from the utilization of a GR shall apply due diligence to ensure that:
 - access to the GR took place in accordance with the domestic ABS regulatory requirements of the Party to the NP that provided the GR;
 - benefits will be shared in a fair and equitable way.
 - The minimal information that has to be recorded and passed on to subsequent users will be further regulated on the “Ordinance” level.
- II. **A notification requirement** (Implementation of Art. 15.3 and 17 of the NP)
 - Compliance with the due diligence requirement has to be notified at the time of market authorization or commercialization of a utilized GR to a centralized checkpoint at the Federal Office for the Environment (FOEN).
 - The centralized checkpoint might transfer information related to compliance with the due diligence requirement to the Party that provided the GR or to the ABS-CH. The utilized GR, its source and further non-confidential information contained in the notification may be published.
 - There will be a designation of further “checkpoints” in existing procedures to check whether a notification was made at FOEN (e.g. in the authorization procedure for pharmaceuticals)

III. A possibility to regulate access to GR in Switzerland and to support their conservation and sustainable use (Implementation of Art. 6, 8 and 9)

Measures I. and II. will also apply to the utilization of **ATK**. Moreover, Switzerland will have the possibility to take following **measures in cases of non compliance with the new ABS-measures**:

- A fine of up to 100'000 Swiss Francs (approx. 100'000 USD) to whoever intentionally provides no or wrong information according to the notification requirement; for whoever acts through negligence, the fine will be up to 40'000 Swiss francs.
- No authorization for utilized GR or ATK if the notification to the centralized checkpoint has not been made by the time of market authorization.
- A possibility to take administrative measures in cases of violation of the due diligence requirement (administrative order). The focus of the implementation of these measures will be on cases of alleged violation of ABS-regulatory requirements of Parties to the NP that provided the GR.

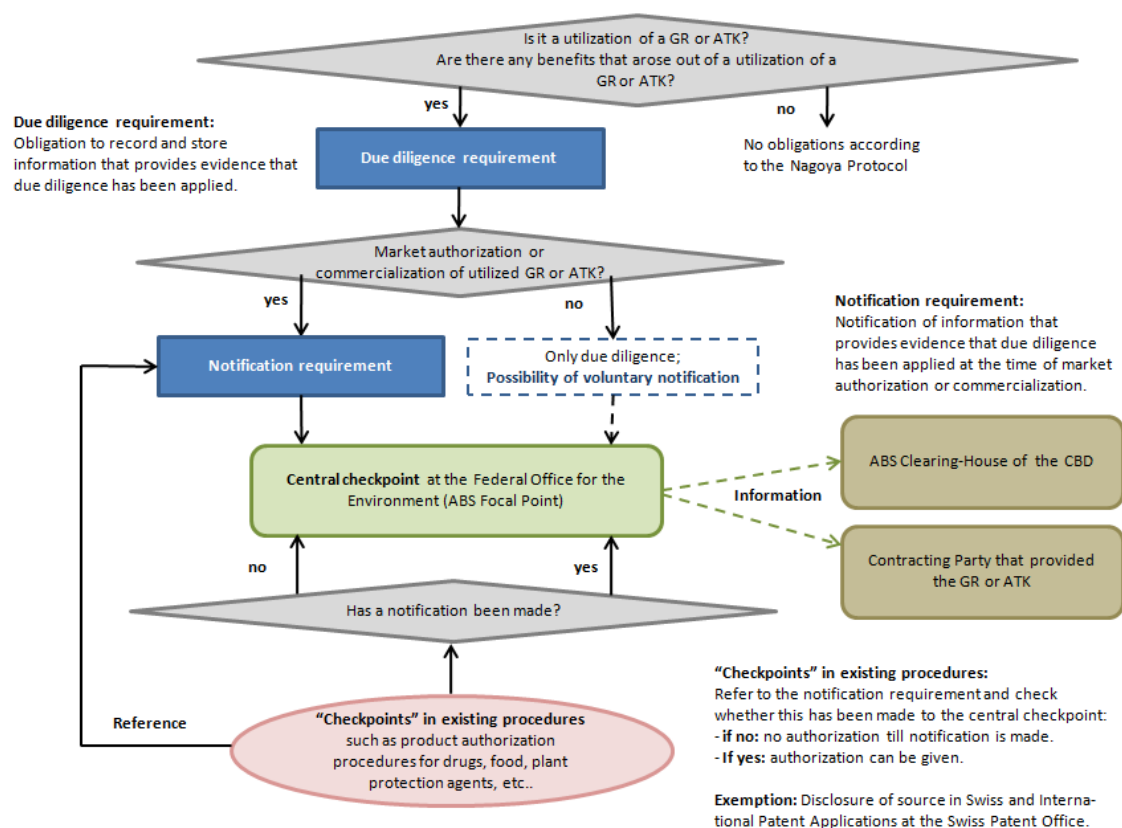


Figure 1: Simplified schematic representation of the draft legal ABS-users-measures in Switzerland

2.3. Rationale for the draft legal ABS-user-measures in Switzerland

A system that facilitates research and innovation on GR while at the same time ensures compliance with ABS

In order to create a system that facilitates research and innovation on GR while at the same time ensures compliance with ABS, Switzerland developed draft legal ABS-user-measures that are applicable across all sectors and that take into account differences of the utilization of GR along the innovation chain of these resources. Moreover, the system should guarantee

that the administrative burden will be minimal and acceptable for all partners involved, including for the research communities, industries, and last but not least for the competent national authorities that will need to implement these new measures. Therefore, not every measure will apply to all users along the innovation chain. In fact, the higher the value of the utilized GR or ATK gets, the stronger the measure to ensure compliance with ABS becomes (see Figure 2 below). For instance, while there will only be a due diligence requirement for users at the beginning of the innovation chain (e.g. for non-commercial research activities), the notification requirement at the end of the innovation chain should provide a strong incentive to all users along the chain to comply with the ABS-regulatory requirements.

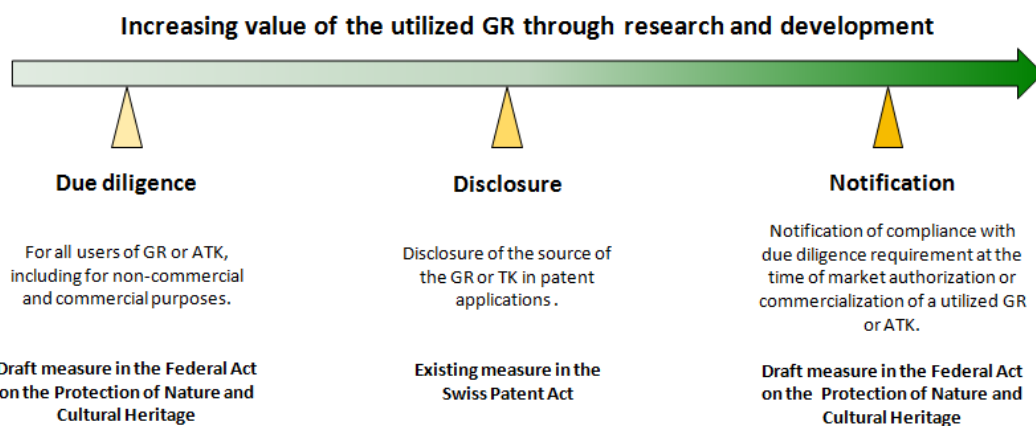


Figure 2: Illustration of the different legal ABS-user-measures along the innovation chain. The higher the value of a utilized GR or ATK gets, the stronger the measure to ensure compliance becomes.

A centralized checkpoint linked to the national focal point for the NP and additional decentralized “checkpoints” in existing market authorization procedures

In principle, Switzerland already has a checkpoint for ABS at the Federal Institute of Intellectual Property. The disclosure of source requirement in the Swiss Patent Act fulfils the minimal requirements according to article 17 of the NP. However, as stated in the message to the revision of the Swiss Patent Act as well as during the negotiations of the NP, Switzerland considers that the disclosure of source in patent applications is not sufficient to fully implement ABS. Indeed, most uses of GR and ATK take place without leading to any patent application.

Therefore, initially the question arose, whether there should be a designation of further checkpoints in existing procedures or whether there is a need for a centralized checkpoint in order to effectively implement Article 17 of the NP. While checkpoints in existing procedures might have the advantage of being more sector-specific, consultations with different Federal Authorities showed, that defining several checkpoints managed by different Federal Authorities would constitute a huge challenge for a coherent and effective implementation of the NP.

The draft-legal measures in Switzerland therefore foresee a centralized checkpoint linked to the national focal point for the NP at the Federal Office for the Environment (FOEN) as well as additional “checkpoints” in existing market authorization procedures (see Figure 1). While only the centralized checkpoint at FOEN fulfils the requirements according to Article 17 of the NP and deals with substantial issues related to the implementation of the NP, the additional “checkpoints” in existing procedures will check whether a notification to the centralized checkpoints was made (see also Figure 1). Therefore, they enhance the effectiveness of the centralized checkpoint, while at the same time, the administrative burden for the competent authorities involved in these procedures remains minimal. Moreover, the designation of a centralized checkpoint has the advantage that it is applicable to all users of GR or ATK

across all sectors and that the users know which competent authority in Switzerland is dealing with substantive issues related to the implementation of the NP.

An incentive for other Parties to ratify the NP

The draft legal ABS-user-measures in Switzerland will only apply to the utilization of GR and ATK provided by other Parties to the NP. Moreover, in order to be applicable and consistent with the principle of non-retroactivity the measures will only apply to accesses to GR and ATK that took place after the entry into force of the NP. The legal status of those GR and ATK acquired before the entering into force of the NP for Switzerland or from countries that did not ratify the NP will not be changed by introducing the new legal ABS-measures in Switzerland. Switzerland believes that this is important to ensure practicability. Indeed, only Parties to the NP might have the minimal regulatory system in place, including Competent National Authorities and an ABS Focal Point, that is essential in order that users can comply with the due diligence requirement. Moreover the approach respects acquired rights and will provide a strong incentive for other Parties to ratify the NP as soon as possible.

3. Additional issues that may need to be addressed in preparation for the first meeting of the Conference of the Parties

In general, Switzerland believes that the **work plan set out in annex II of decision X/1 of the Conference of the Parties to CBD covers all issues that are relevant for the preparation of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP-1)**. While substantial progress has been made on some issues of the work plan during ICNP-1 and ICNP-2, others require further consideration with a view to facilitating decision-making at COP-MOP-1.

Switzerland believes that it is most important that the ABS Clearing-House will be fully functional by the time of entering into force of the NP. In this regard, Switzerland welcomes the establishment of the pilot-phase of the ABS Clearing-House. While the modalities of the ABS Clearing-House might be further refined based on the feedback from the implementation of the pilot phase, **there might also be a need to address certain issues related to the ABS Clearing-House in more detail for the preparation of COP-MOP-1**. In particular, there seems to be **divergent views with regard to the notification of permits or their equivalent to the ABS Clearing-House as well as on the internationally recognized certificate of compliance**.

While Article 14, Paragraph 2 (c), states that Parties shall make available to the ABS Clearing-House permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, Switzerland considers that this provision should be read in conjunction with other relevant provisions dealing with issues related to permits and to the internationally recognized certificate (Art. 6, Para. 3(e) and Art. 17, Para. 2 and 4). **In order to avoid a collection of permits or their equivalents in different languages and formats, to facilitate the search of information, and to ensure that only non-confidential information will be made available through the ABS Clearing-House, the minimum information set out in Article 17, Paragraph 4, might be more appropriate to be made available to the ABS Clearing-House than a copy of the permit or its equivalent as such.** A unique identifier should link the internationally recognized certificate with the original permit or its equivalent stored by the Parties that provided the GR.

Finally, additional issues mentioned in Paragraph 7 of the report of the Expert Meeting on the modalities of operation of the ABS Clearing-House (UNEP/CBD/ABS/EM-CH/1/4) could also be addressed during further considerations on the modalities of operation of the ABS Clearing-house.