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Submission by Switzerland further to decision NP-3/14 on Article 4, Paragraph 4, of the Nagoya Protocol

Reference: S342-1368

Switzerland thanks the Executive Secretary for the Notification 2019-025 inviting for views and information further to decision NP-3/14 on Article 4, Paragraph 4, of the Nagoya Protocol. This submission represents the current reflections of Switzerland regarding the points raised in notification 2019-025, but does not prejudice the Swiss position in the upcoming negotiations.

(a) Information on how specialized international access and benefit-sharing instruments are addressed in domestic measures

General domestic ABS measures in Switzerland

Under the terms of the sovereign rights over its genetic resources, Switzerland has implemented domestic measures for accessing genetic resources in Switzerland. While access to genetic resources in Switzerland does not require prior informed consent (PIC) or the establishment of mutually agreed terms (MAT), users of genetic resources from Switzerland are subject to a documentation requirement, which provides that certain information must be recorded, retained and passed on to subsequent users. Moreover, before market approval in Switzerland or, if such approval is not required, before the commercialization in Switzerland of products developed on the basis of utilized genetic resources, the user must notify the competent national authority of this information.

Furthermore, domestic measures oblige users to exercise due diligence when using genetic resources of other Parties to the Nagoya Protocol, provided that these resources were accessed after the entry into force of the Nagoya Protocol and that these Parties have access regulations in place. This requirement provides that whoever utilizes genetic resources or associated traditional knowledge records and stores information, which provides evidence of compliance with the domestic regulatory requirements on ABS of other Parties of the Nagoya Protocol. Before market approval in Switzerland or, if such approval is not required, before the commercialization in Switzerland of products developed on the basis of utilized genetic resources, the user must notify such information to the competent national authority.

Specialized international access and benefit-sharing instruments in the domestic ABS measures in Switzerland

In line with art. 4, para. 4 of the Nagoya Protocol, the Swiss legislation specifies that genetic resources are not subject to the due diligence requirement if they are covered for a specific use by a specialized international instrument under Article 4 of the Nagoya Protocol (art. 23n para. 2 lit. d Federal Act on the

Protection of Nature and Cultural Heritage [NCHA, SR 451¹]). Switzerland recognizes the multilateral System (MLS) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the FAO and the Pandemic Influenza Preparedness Framework (PIP Framework) of the WHO as specialized international instruments². The application of such specialized international instruments can ensure a more specialized, efficient and non-duplicative approach to regulating access to genetic resources and the sharing of benefits arising from their utilization. This approach allows to take into account the peculiarities of specific sectors, in which genetic resources are utilized, as well as to implement ABS provisions in line with the CBD and the Nagoya Protocol in these sectors.

In the case of access and benefit-sharing to plant genetic resources for food and agriculture (PGRFA) within the ITPGRFA, domestic measures in Switzerland are provided in a specific Ordinance that regulates PGRFA (ORPGAA, SR 916.181³). With regard to influenza viruses with human pandemic potential under the PIP Framework, the general provision of art. 23n para. 2 lit. d NCHA applies (dynamic incorporation by reference).

Hence, Switzerland implemented the provisions of the Nagoya Protocol as a “default mechanism”, which generally applies to genetic resources and associated traditional knowledge, as long as no other specialized ABS instruments, which are in line with the objectives of the CBD and the Nagoya Protocol, are applicable.

(b) Views on the potential criteria contained in the study (summarized in the Annex to decision NP-3/14), taking into account Article 4, paragraphs 1 to 3, of the Protocol

General remarks on the potential criteria

At this stage, it is difficult to evaluate the usefulness of these potential criteria, because it may depend on if, how and by whom these criteria should be applied. Moreover, some of these criteria are very general and some may be difficult to fully meet and assess. Therefore, further considerations and clarifications on the purpose of these criteria would be needed. In particular, it would be important to have a deeper look at other ABS instruments, including new ABS instruments that are under development to refine such potential criteria.

In general, it is highly important for Switzerland that the development of such criteria does not lead to any hierarchies between the Nagoya Protocol and other international instruments related to genetic resources and associated traditional knowledge. Article 4, paragraph 4 of the Nagoya Protocol does not refer to a formal process of recognizing specialized instruments within the CBD or the Nagoya Protocol. Switzerland is of the view that Parties can take such a decision to recognize a specialized instrument by themselves. The study outlined different possibilities for recognition of specialized instruments in the context of Art. 4, paragraph 4 of the Nagoya Protocol. Nevertheless, the only acceptable procedure for an instrument to be recognized as a specialized instrument in the sense of Art. 4 should be the recognition by a Party or a group of Parties – corresponding to scenario 3 of the study. The potential criteria shall only serve as a general and non-prescriptive guideline for Parties, as these criteria may be more specific than Art. 4, paragraph 4 of the Nagoya Protocol.

As of today, the MLS of the ITPGRFA and the PIP Framework are widely recognized as such instruments. These recognitions never took the form of a COP-MOP decision, but were the result of recognition by Parties themselves. It is therefore difficult to assess the need to adopt in advance fixed criteria and a method to that end. Ultimately, the establishment of these criteria should not result in preventing valuable initiatives by Parties.

¹ <https://www.admin.ch/opc/en/classified-compilation/19660144/index.html#id-3c>

² <https://www.admin.ch/opc/de/federal-gazette/2013/3009.pdf> (see page 3030)

³ <https://www.admin.ch/opc/fr/classified-compilation/20151992/index.html>

Specific remarks on the potential criteria

1. *Intergovernmentally agreed* — The instrument would be developed and agreed through an intergovernmental process. The instrument may be binding or non-binding.

The first set of criteria on the “intergovernmental” nature of an instrument is reasonably clear, although the term “internationally agreed” may be more favourable, as it is less restrictive. Nevertheless, the way how an instrument is *developed* may not be relevant, as long as it is intergovernmentally agreed. Including binding as well as non-binding instruments provides the required flexibility to cover different types of instruments apart from international treaties, such as the WHO PIP Framework.

2. *Specialized* — The instrument would:

(a) Apply to a specific set of genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol;

(b) Apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources which require a differentiated and hence specialized approach.

The second set of criteria specifies the “specialization” of an instrument. Article 4, paragraph 4 of the Nagoya Protocol should apply to instruments that regulate genetic resources and/or traditional knowledge associated with genetic resources which would otherwise fall under the scope of the Nagoya Protocol. Whether an instrument applies to specific uses that *require* a differentiated approach may be difficult to assess. While the Nagoya Protocol serves as a “default mechanism”, which is applicable for all genetic resources, there may be specific sets or specific uses of genetic resources, for which a specialized approach may be more practical, but such an approach may not necessarily be *required*. In addition, it is not clear, if these two criteria ((a) and (b)) are to be applied cumulatively.

3. *Mutually supportive* — The instrument would be consistent with and supportive of, and not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol, including with respect to:

(a) Consistency with biodiversity conservation and sustainable use objectives;

(b) Fairness and equity in the sharing of benefits;

(c) Legal certainty with respect to access to genetic resources or traditional knowledge associated with genetic resources and to benefit-sharing;

(d) Contribution to sustainable development, as reflected in internationally agreed goals;

(e) Other general principles of law, including good faith, effectiveness and legitimate expectations.

The third set of criteria describing “mutual supportiveness” contains several criteria that are rather general and therefore would be very difficult to fully meet as well as to assess. In particular it is unclear which form “fairness and equity in the sharing of benefits” would take in case of instruments based on bilateral or multilateral principles. The meaning of “legal certainty with respect to genetic resources or traditional knowledge associated with genetic resources” is unclear as well as what is meant by legal certainty with respect to benefit-sharing. Furthermore, it remains unclear, whether these criteria ((a) to (e)) need to be applied cumulatively. Thus, several of these criteria remain vague and it is unclear how these could be applied (e.g. fairness and equity, good faith, effectiveness and legitimate expectations). In addition, any criteria to characterize the term “mutually supportive” should be assessed with care, as this term is used in a variety of other international agreements and processes. Finally, art. 4, para. 4 of the Nagoya Protocol does not refer to the term “mutually supportive”, but to “consistent with, and does not run counter to the objectives of the Convention and its Protocol”. The term “mutually supportive” is however used in the preamble of the Nagoya Protocol as well as in art. 4, para. 3 of the Nagoya Protocol, which relates to the implementation of the Nagoya Protocol itself.