Draft Guidelines

on Access and Benefit Sharing

Regarding the Utilisation of Genetic Resources

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Access and Benefit Sharing
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Introduction

For many years, Switzerland has been actively involved in the discussion on access to genetic resources and benefit sharing. In order to gather useful information and to better understand the issues at a practical level, a survey had been conducted with the private sector and the research community regarding possible benefit sharing mechanisms used in connection with genetic resources. The results of this survey were reported to the COP IV (see document UNEP/CBD/COP/4/Inf. 16). The survey showed that one possible solution to address these issues is the elaboration of a set of guidelines. The present Draft Guidelines have been drawn up with the active collaboration of the partners that were already involved in the above-mentioned survey. They are intended to serve as a starting point in the discussion on access to genetic resources and benefit sharing.

The present Draft Guidelines can be described as follows:

- Their primary function is to serve as a point of reference for all stakeholders involved in access to genetic resources and their utilisation, and in the fair and equitable sharing of benefits arising from their utilisation.
- They aim at (1) promoting the appropriate access to genetic resources, and (2) the fair and equitable sharing of benefits arising from the utilisation of these resources.
- They are based on the sovereignty of States over their genetic resources.
- They set standards and contain principles that should be observed by those stakeholders which adhere to it.
- They are of voluntary nature.
- Due to their voluntary nature, the Draft Guidelines can be applied not only by States, but also by all other stakeholders involved in access to genetic resources and the sharing of the benefits arising from their utilisation.
- They are based on an approach which differentiates the various steps involved in access to genetic resources and the sharing of the benefits arising from their utilisation, that is, they differentiate all steps from the collection of genetic resources to the commercialisation of the results of scientific research and development. The present Draft Guidelines thus follow a process-based approach and list the responsibilities of all stakeholders involved in access to genetic resources and benefit sharing.

Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources

I. General Provisions

Article 1 Objectives

The aim of the Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources (hereinafter "the Guidelines") is to provide a non-discriminatory framework for the appropriate access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation, in conformity with the Convention on Biological Diversity (hereinafter "the CBD"), particularly its Articles 15, 16 and 19.

Article 2 Definitions

2.1 For the purposes of the Guidelines:

- *Access* means the admission for the process of collecting or otherwise acquiring genetic resources;
- *Benefit Sharing* means all forms of compensation for the utilisation of genetic resources, whether monetary or non-monetary, and includes, in particular, the participation in scientific research and development on genetic resources and the making available of the results of such scientific research and development;
- *Donor* means any entity which has the legal right of disposal over the genetic resources being made available to users or intermediaries;
- *Entity* means any natural or legal person or any plurality thereof; any community; any government or any body placed under its authority; or any organisation, regardless of whether the organisation is governmental or non-governmental;
- *Intermediary* means any entity which receives genetic resources and provides them to users or other intermediaries;
- *Provider* means the country of origin of the genetic resources or the country that has acquired the genetic resources in accordance with the CBD and under the jurisdiction of which the genetic resources are made available for users or intermediaries;
- *Scientific Research and Development* includes the process of collecting genetic resources.
- *Sponsor* means any entity which supports, financially or otherwise, the scientific research and development;
- *Stakeholder* means any entity which is, in any way, involved in collecting or otherwise acquiring genetic resources, the utilisation of these resources, the sharing of benefits arising from the utilisation of the genetic resources, and/or has a qualified interest in the conservation and sustainable utilisation of genetic resources;
- *User* means any entity which collects or otherwise acquires genetic resources to conduct scientific research and development on these genetic resources and/or to commercialise the results of this scientific research and development.

2.2 With the exception of the terms defined in Article 2.1 of the Guidelines, the definitions of the CBD shall apply to the Guidelines.

Article 3 Scope

3.1 The Guidelines lay out the conditions under which access to genetic resources shall be granted and under which the sharing of benefits arising out of the utilisation of genetic resources shall be qualified as fair and equitable.

3.2 Genetic resources fall within the scope of the Guidelines only if:

a. they are covered by the CBD, and

b. they are not covered by any other multilateral instrument containing provisions on access to genetic resources as well as the sharing of benefits arising out of the utilisation of genetic resources.

Article 4 Nature of the Guidelines

4.1 The Guidelines are voluntary.

4.2 Governments shall facilitate and promote the observance of the Guidelines by other stakeholders.

4.3 Stakeholders are encouraged to communicate their willingness to act in conformity with the Guidelines to the Clearing House Mechanism established by the CBD.

Article 5 Recognition and Public Awareness of the Convention on Biological Diversity

5.1 Stakeholders shall act in conformity with the objectives of the CBD.

5.2 Stakeholders shall endeavour to strengthen and improve public awareness concerning the objectives of the CBD.

II. Responsibilities of Users, Intermediaries and Sponsors

Article 6 Responsibilities Prior to Access to Genetic Resources

6.1 When taking decisions leading to access to genetic resources, users and intermediaries shall take into account the environmental consequences of their relevant activities.

6.2 Recognising the sovereign rights of States over the genetic resources within their jurisdiction, users and intermediaries shall, unless otherwise determined by the provider, seek informed consent prior to access to genetic resources.

6.3 Before accepting genetic resources from intermediaries or other users, users shall ensure that access to these genetic resources was in accordance with the CBD.

6.4 Intermediaries shall assure that users and other intermediaries accepting genetic resources act in accordance with the CBD.

Article 7 Responsibilities During the Process of Scientific Research and Development

7.1 When collecting genetic resources, all relevant data shall be recorded and described.

7.2 Users and intermediaries shall respect customs, traditions, values and property rights' systems of local and indigenous communities, in particular if use is made of local or

indigenous knowledge related to genetic resources. They shall respond to requests for additional information from local and indigenous communities to the extent feasible.

7.3 Users shall endeavour to carry out scientific research and development on genetic resources, or in the field of biotechnology based on genetic resources, with the effective participation of providers, especially the countries of origin. Such participation shall be on mutually agreed terms containing elements as set out in Annex A of the Guidelines.

7.4 Where feasible, scientific research and development, as referred to in Article 7.3 of the Guidelines, shall be conducted within the territory of such providers.

Article 8 Responsibilities Regarding the Results of Scientific Research and Development and the Transfer of Technology

8.1 Where appropriate, the results of scientific research and development on genetic resources shall be made available. The terms of availability shall be mutually agreed between the users and the other stakeholders involved in the transfer of the genetic resources in question, containing elements as set out in Annex B of the Guidelines.

8.2 Users shall provide for the sharing of the benefits that arise from the commercialisation and other utilisation of genetic resources. This benefit sharing shall be made on mutually agreed terms between users and other stakeholders involved in the transfer of the genetic resources in question, containing elements as set out in Annex C of the Guidelines.

8.3 Subject to international law and national legislation, the holders of intellectual property rights based on genetic resources are encouraged to share their intellectual property rights with other stakeholders who contributed to the conservation of these genetic resources or to the scientific research and development based on these genetic resources.

Article 9 Responsibilities of Sponsors

Sponsors shall take steps to ensure that the stakeholders they sponsor abide by the Guidelines, particularly their Articles 6, 7 and 8 .

III. Responsibilities of Providers and Donors

Article 10 System of Prior Informed Consent

10.1 Providers, having the sovereign right and accepting the responsibility to establish and implement a framework of national policies for the conservation and sustainable utilisation of genetic resources within their territory, shall, within this framework, set up a transparent system of prior informed consent (hereinafter “the System“).

10.2 Providers shall designate a National Contact Point (hereinafter “NCP”) responsible for implementing the System. The NCP shall also be responsible for providing information on the System and any other information which may be needed prior to the access to genetic resources, including providers’ rules and regulations, in particular to users and intermediaries. Where appropriate, the NCP shall assist in solving differences arising between the different stakeholders in matters covered by the Guidelines.

10.3 When implementing the System, the following principles shall be considered and applied:

a. Access to genetic resources shall be facilitated;
b. Restrictions on access to genetic resources shall be non-discriminatory and shall be based on objective criteria in order to conserve biological diversity;
c. Consent of the donors and other stakeholders referred to in Article 7.2 of the Guidelines shall be ensured;
d. Decisions on access to genetic resources shall be documented in a written form and shall be taken within a reasonable period of time so as not to impede the work of users and intermediaries unnecessarily;
e. Mutually agreed terms as referred to in Articles 7 and 8 of the Guidelines shall be negotiated efficiently and within a reasonable period of time.

Article 11 Responsibilities of Donors

Donors are encouraged to co-operate with the other stakeholders, in particular with users and intermediaries, so as to foster the collaboration in the collection of genetic resources and related activities.

IV. Other Provisions

Article 12 Information Received Under the Guidelines

12.1 Unless otherwise declared by the stakeholders involved in the transaction of the genetic resources in question, and subject to Article 12.2 of the Guidelines, any information received under the Guidelines shall not be considered as confidential .

12.2 In any case, the following information shall not be considered as confidential:
a. The name and address of the stakeholders involved in the transfer of the genetic resources in question;
b. The region or area where access to genetic resources is planned to take place;
c. The time frame for the planned access to genetic resources.

Article 13 System of Certification

Stakeholders are encouraged to collaborate in creating a system of certification as described in Annex D of the Guidelines.

Article 14 Capacity Building

Governments, taking into account in particular the special needs of developing countries and countries with economies in transition, shall endeavour to promote technical and scientific co-operation in the fields of sustainable utilisation of genetic resources and the conservation of biological diversity.

Article 15 Relationship of the Guidelines with Other International Agreements

The Guidelines are to be implemented in conformity with other international agreements, in particular the CBD and its protocols.

Article 16 Reporting by Stakeholders Regarding the Application of the Guidelines

Stakeholders are encouraged to periodically report on actions taken regarding the application of the Guidelines to the Clearing House Mechanism established by the CBD. Where appropriate, these reports may be integrated into the reporting mechanism as laid out in Article 26 of the CBD.

Article 17 Annexes to the Guidelines

The Annexes to the Guidelines form an integral part of the Guidelines.

Annex A: Effective Participation in Scientific Research and Development (Article 7.3 of the Guidelines)

Users and intermediaries shall endeavour that their scientific research and development on genetic resources contribute to the development of the providers' scientific and technological capacities for sustainable utilisation of genetic resources, including, as far as possible, the establishment and improvement of the innovative capacities of the providers, in particular developing countries. Users and intermediaries shall make reasonable and sincere efforts to enable other stakeholders involved in the transfer of the genetic resources in question to participate in the scientific research and development on these resources, or in the field of biotechnology based on these resources.

Possible elements for the mutually agreed terms for the effective participation in scientific research and development as referred to in Article 7.3 of the Guidelines include, *inter alia*:

- Regular reporting of users on the state of the relevant scientific research and development on genetic resources;
- Collaboration in education and training;
- Collaboration in scientific research and development programs;
- Participation in product development;
- Joint ventures;
- Co-authorship of publications.

Annex B: Availability of Results of Scientific Research and Development (Article 8.1 of the Guidelines)

Availability of the results of scientific research and development is an important aspect of the sharing of benefits arising from the utilisation of genetic resources. Moreover, it provides the basis for further scientific research and development and forms an important cornerstone of social and economic development. Users and sponsors shall make every appropriate and feasible effort to make available, on mutually agreed terms, the results of scientific research and development to the other stakeholders involved in the transfer of the genetic resources in question.

Possible elements for the mutually agreed terms regarding the availability of the results of scientific research and development as referred to in Article 8.1 of the Guidelines include, *inter alia*:

- Regular reporting of users on the state of the relevant scientific research and development on genetic resources;
- Admittance to *ex situ* facilities of genetic resources and to databases;
- Admittance to taxonomic, biochemical, ecological, horticultural and other information and data;
- Joint ventures;
- Co-authorship of publications.

Annex C: Sharing of Benefits Arising from the Commercialisation and Other Utilisation of Genetic Resources (Article 8.2 of the Guidelines)

When determining the mode for the sharing of benefits arising from the commercialisation and other utilisation of genetic resources, the short, medium and long term interests of all stakeholders involved shall be considered. Furthermore, some modes of benefit sharing may become effective immediately, whereas others become effective only in the distant future due to the period of time needed for the benefits to arise. Additionally, benefit sharing can be awarded not only in monetary, but also in non-monetary forms. Finally, when determining the mode of benefit sharing, the involved stakeholders are encouraged to consider the suitability of any existing institution, mechanism or facility.

Possible elements for the mutually agreed terms regarding the sharing of benefits arising from the commercialisation and other utilisation of genetic resources, as referred to in Article 8.2 of the Guidelines, include, *inter alia*:

- Transfer of knowledge and technology, in particular knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilisation of biological diversity.
- Collaboration in education and training;
- Collaboration in scientific research and development programs;
- Participation in product development;
- Joint ventures;
- Admittance to *ex situ* facilities of genetic resources and to databases;
- Joint ownership of patents and other relevant forms of intellectual property rights;
- Providing means for a fund at the local, national, regional or multilateral level;
- Fee per sample collected or otherwise acquired;
- Licence fee in case of commercialisation;
- Royalties.

Annex D: System of Certification (Article 13 of the Guidelines)

The functioning of the Guidelines strongly depends on the mutual trust and confidence between the different stakeholders. One viable means to foster this mutual trust and confidence would be the creation of a system of certification, which would confirm the abidance to the Guidelines by the stakeholder being certified. When creating this system of certification, the involved stakeholders are encouraged to consider the suitability of any existing institution or mechanism already involved in certification or standardisation.