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DRAFT GUIDELINES ON ACCESS AND BENEFIT SHARING REGARDING THE UTILISATION OF GENETIC RESOURCES

Document submitted by the Government of Switzerland

1. In a Note dated April 25, 2001, the Permanent Mission of Switzerland to the Office of the United Nations and other International Organizations in Geneva submitted to the World Intellectual Property Organization (WIPO) a document entitled "Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources".

2. The Permanent Mission requested that the document be made available, as a Member State paper, to the participants at the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

3. The document is reproduced in the form received and published as an Annex.

4. The Committee is invited to take note of this document and the Annex to it.

[Annex follows]

Building a New Partnership: Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources

Introduction

This information document introduces the "Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources" (Draft Guidelines) proposed by the Swiss Government. It summarises the process which led to the drawing up of these Draft Guidelines, explains their main features and describes some of the responsibilities of the main stakeholders involved in access to genetic resources and the sharing of the benefit arising from their use, and explicates the system of prior informed consent. Finally, this information document contains remarks on the provisions of the Draft Guidelines dealing with traditional knowledge related to genetic resources.

The Development of the Draft Guidelines

From the early beginning of the Convention on Biological Diversity (CBD), Switzerland has been actively involved in the discussion on access to genetic resources and the sharing of benefits arising from their use. In 1997/98, a survey had been conducted with the private sector and the research community in Switzerland to gather information and to better understand the issues arising at a practical level. This survey showed that one possible solution to address these issues is the elaboration of a set of voluntary guidelines. The results of the survey were presented during the fourth Conference of the Parties (COP 4) of the CBD in Bratislava in 1998 (*see* Document UNEP/CBD/COP/4/INF/16).

In the aftermath of COP 4, the present Draft Guidelines were drawn up by the Swiss State Secretariat for Economic Affairs; the Swiss Federal Institute of Intellectual Property; and the Swiss Agency for the Environment, Forests and Landscape. The partners from the private sector and the research community that had been involved in the above-mentioned survey were given the opportunity of active collaboration in this process. A first outline of the Draft Guidelines was presented to the experts during the CBD's Expert Panel on Access and Benefit Sharing (Expert Panel) held in San José, Costa Rica, in October 1999.

The Expert Panel came to the conclusion, among others, that the fifth Conference of the Parties (COP 5) of the CBD may wish to consider the development of guidelines with respect to prior informed consent and mutually agreed terms which are the two main elements in the framework of access and benefit sharing. This positive conclusion encouraged the involved Swiss Federal agencies to continue their work and to adapt the Draft Guidelines to the results achieved during the Expert Panel.

A core team of three advisors from the mentioned branches of the Swiss Federal administration was working jointly on the Draft Guidelines. This had the advantage that considerations related to ecology, economy and intellectual property rights (IPRs) could be integrated from the beginning of the work. Consultations were held within the Swiss Federal administration and with the private and academic sector as well as non-governmental organisations (NGOs). In April 2000, a workshop was conducted in Berne, Switzerland,

where experts from different countries, representing government agencies, private and public research institutions, indigenous communities, NGOs, and industry participated and discussed the subject mater as well as shared their specific experiences. The aim of this workshop was to exchange experiences and views between the different stakeholders regarding access and benefit sharing and the Draft Guidelines. At the international level, the Draft Guidelines as they currently stand have been discussed at several occasions, including COP 5 (Nairobi, May 2000, *see* document UNEP/CBD/COP/5/Inf/21) and the 2nd meeting of the Panel of Experts on Access to Genetic Resources and Benefit Sharing (Montreal, March 2001, *see* document UNEP/CBD/EP-ABS/2/INF/1).

The open and broad process was very enriching and helpful to the development of the Draft Guidelines. As a consequence, misunderstandings between the different stakeholders could be discussed, clarified or even entirely avoided which helped to build mutual confidence. The issue of access to genetic resources and benefit sharing can only be solved satisfactorily if the relevant sectors of society are involved in the process from the beginning. There is a strong need for a multistakeholder/north-south/public-private partnership. The drawing-up of the Draft Guidelines has demonstrated that such a partnership is not only achievable, but that it is also capable to come up with innovative suggestions.

Main Features of the Draft Guidelines

The Draft Guidelines are intended to serve as a point of reference for the stakeholders involved in access to genetic resources and the sharing of benefits arising from their use. In other words, the stakeholders shall have an instrument of orientation for their work at hand. Therefore, the Draft Guidelines set standards and contain principles that should be observed by those entities which adhere to them.

The CBD confirms the permanent sovereignty of States over their genetic resources. By doing the same, the Draft Guidelines are intended to give some guidance to Governments on how to implement their obligations regarding access and benefit sharing.

Although guidelines are of voluntary nature, they are a tool that allows predictability and confidence building. Furthermore, the voluntary nature does not mean that guidelines will not be followed. Public pressure to comply with the standards set out can be significant, especially if all interested sectors have been involved in their drawing up from the beginning.

The aim of the Draft Guidelines is twofold:

- Firstly, they aim at the fair and equitable sharing of the benefits arising from the use of genetic resources. The benefit sharing shall be designated to contribute to the conservation of the biological diversity and to foster the sustainable use of genetic resources.

- Secondly, they aim at promoting the appropriate access to genetic resources. Access activities shall create only minimum adverse environmental impacts.

The Draft Guidelines follow a process-based approach. This means that they differentiate between the various steps involved in access to genetic resources and the sharing of the benefits arising from their use. Accordingly, they distinguish the steps from the search for genetic resources to the commercialisation of the results of scientific research and

development. The Draft Guidelines thus describe the responsibilities of the various stakeholders involved, regardless of the sector to which these stakeholders belong, that is, for example, botanical gardens or culture collections of micro-organisms.

This across-the-board approach has the advantage that only one single instrument has to be applied in any given situation. Especially the donor of genetic resources might find it easier to deal with a request for such resources if there is only one instrument to comply with. Nevertheless, already existing sectoral guidelines, such as the Common Policy Guidelines for Participating Botanical Gardens or the MOSAICC Guidelines for microbial resources, may very well give additional guidance to the users of that sector and, thus, further facilitate the implementation of the CBD.

The Responsibilities of the Main Stakeholders

The Draft Guidelines cover the process ranging from the search for genetic resources to the commercialisation of a derived product. They distinguish three different steps. For each of these steps specific responsibilities of users and other stakeholders have been characterised.

Step 1 includes the decision of a user leading to access to genetic resources and ends with the received consent to obtain such resources (Article 6 of the Draft Guidelines). Access is defined as the admission for the collection, obtaining or other acquisition of genetic resources.

Step 2 covers the process of scientific research and development (Article 7 and Annex A of the Draft Guidelines). The collection or other acquisition of genetic resources forms one part of this second step.

Step 3 includes the dealing with the findings of scientific research and development (Article 8 and Annexes B and C of the Draft Guidelines). It also deals with questions regarding the commercialisation and other utilisation of genetic resources or derived products.

Both steps 2 and 3 are based on the instrument of mutually agreed terms. This instrument provides for contractual tools which allow to address the role of IPRs in any transaction of genetic resources according to its specific circumstances.

The System of Prior Informed Consent

The establishment of a system of prior informed consent is one of the main responsibilities of the Governments when implementing their obligations regarding access to genetic resources. This does not mean that they have to set up new legislation. There may already be a legal framework in place that satisfies the CBD.

The Draft Guidelines lay out only minimum standards for such a system in order to meet the needed degree of flexibility and to respect the States' different legal systems. The purpose of these minimum standards is to ensure predictability and participation of the stakeholders involved. Any decision taken within the system shall be subject to a legal review mechanism.

Each country shall designate one or more competent national authorities to implement the system of prior informed consent. These authorities shall perform administrative functions required by the system. In order to provide basic information for those stakeholders seeking access to genetic resources governments shall designate a national focal point. This body can

also serve as a liaison office with the Secretariat of the CBD. Of course, the competent national authorities and the focal point can be one single entity.

Elements of the Draft Guidelines Relevant to Traditional Knowledge

The Draft Guidelines are a possible instrument for access to genetic resources and benefit sharing. As of now, they are not primarily intended to set rules for the protection of traditional knowledge related to genetic resources. Nevertheless, the Draft Guidelines still contain some elements that are relevant to traditional knowledge and its protection.

One element is the participation of indigenous and local communities in the decision making process. If use is made of genetic resources relevant to traditional knowledge or of such knowledge itself, indigenous and local communities shall have the opportunity to participate both in the negotiations of mutually agreed terms and in the system of prior informed consent. Furthermore, each user shall respect customs, traditions, values and customary laws of these communities and shall respond to requests for specific information.

Another element is the participation in benefit sharing. The benefits shall be shared with the involved stakeholders as directly as possible. If indigenous and local communities are involved, they shall participate in the benefit sharing.

As yet another element, holders of IPRs that are based on genetic resources are encouraged to share such rights with the stakeholders that contributed to the conservation of the used genetic resources or to the scientific research and development based on these resources. If indigenous or local communities are such stakeholders, they are the addressees of such possible sharing of IPRs.

Probably the most important element relevant to traditional knowledge within the Draft Guidelines is the continued traditional use of genetic resources. This includes that the continued traditional use of genetic resources shall not be impeded by any property right granted in the context of scientific research and development, commercialisation or other utilisation of genetic resources.

Conclusion

The Draft Guidelines are intended to facilitate the considerations on access to genetic resources and the sharing of the benefits arising from their use within the relevant international fora, such as the CBD and WIPO. They address the issue of traditional knowledge only in the context of access and benefit sharing. Nevertheless, the provisions of the Draft Guidelines dealing with these aspects of traditional knowledge could be further expanded. They relate to intellectual property rights where appropriate, but allow to take into account other regulatory choices. In our view, the Draft Guidelines show that an instrument that is process-based and that accordingly lists the responsibilities of the various stakeholders involved, may be the appropriate way of addressing the issues arising at the multilateral level. It is possible to take into account the interests of the different stakeholders involved in one single tool. This single tool approach is not only able to ensure the needed degree of flexibility, but also to provide predictability and an equally levelled playing field.

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

Submission by the Government of Switzerland

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

I. GENERAL PROVISIONS

Article 1 Objectives

1.1 The objectives of the Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources (hereinafter "the Guidelines") are 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.

1.2 The Guidelines aim at ensuring that access activities create minimum adverse environmental impact and foster the sustainable use of genetic resources.

1.3 The Guidelines aim at ensuring that fair and equitable benefit sharing be designed to contribute to the conservation of biological diversity and to foster the sustainable use of genetic resources.

Article 2 Use of terms

2.1 For the purposes of the Guidelines:

- *Access* means the admission for collecting, obtaining 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 findings of such scientific research and development and the transfer of technology;
- *Donor* means any entity under the jurisdiction of a providing country which has the legal right of disposal over the genetic resources being made available to users and which is not a user;
- *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 this organisation is governmental or non-governmental;
- *Mediator* means any entity which is independent from stakeholders and acts as trustworthy facilitator in the negotiations of the mutually agreed terms of a transaction of genetic resources;
- *Providing country* means the country of origin of the genetic resources, or the country that has acquired the genetic resources in accordance with the CBD, under the jurisdiction of which the genetic resources are made available for users;
- *Sponsor* means any entity which supports, financially or otherwise, the scientific research and development;

- *Stakeholder* means any entity which is involved in, or affected in its traditional use of genetic resources by, the collection or other acquisition of genetic resources, the utilisation of these resources and the sharing of benefits arising from their utilisation;
- *Traditional use* means the use of genetic resources by indigenous and local entities embodying customs, traditions, values and knowledge of such entities.
- *User* means any entity which collects, obtains or otherwise acquires genetic resources to conduct scientific research and development on these genetic resources, to commercialise the findings of this scientific research and development, or to supply other entities with these genetic resources.

2.2 With the exception of the terms defined in Article 2.1 of the Guidelines, the use of terms 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 the FAO Global System for the Conservation and Utilisation of Plant 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 and, in particular, concerning the rules of access and benefit sharing.

II. RESPONSIBILITIES OF USERS, DONORS AND SPONSORS

Article 6 Responsibilities Prior to Access to Genetic Resources

6.1 When taking decisions leading to access to genetic resources, each user shall take into consideration the environmental consequences of the access activities.

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

6.3 Before passing on genetic resources, assurance has to be sought that the user which obtains these genetic resources acts in accordance with the CBD.

6.4 Before obtaining genetic resources, assurance has to be sought that the stakeholder which has passed on these genetic resources acted 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 regarding these resources shall be recorded and described.

7.2 Each user shall respect customs, traditions, values and customary laws of indigenous and local communities, in particular if use is made of indigenous and local knowledge related to genetic resources or to the conservation and sustainable use of the biological diversity. The user shall respond to requests for additional information from indigenous and local communities to the extent feasible.

7.3 Each user shall endeavour to carry out scientific research and development on genetic resources, or in the field of biotechnology based on genetic resources, with the participation of the providing country, especially the country 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 the providing country.

7.5 The research and development activities shall not impede, in any way, the continuation of traditional use of genetic resources.

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

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

8.2 Each user 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 the user and the 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, each holder of intellectual property rights that are based on genetic resources is encouraged to share its intellectual property rights with the stakeholders that contributed to the conservation of these genetic resources or to the scientific research and development based on these genetic resources.

8.4 The commercialisation and other utilisation of genetic resources shall not impede, in any way, the continuation of the traditional use of genetic resources.

Article 9 Co-operation

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

Article 10 Sponsorship

Each sponsor shall take the necessary steps to ensure that the stakeholders it sponsors abide by the Guidelines, particularly their Articles 6, 7 and 8 .

III. RESPONSIBILITIES OF PROVIDING COUNTRIES

Article 11 System of Prior Informed Consent

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

11.2 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 legal grounds and 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 and mutually agreed terms as referred to in Articles 7 and 8 of the Guidelines shall be documented in a written form;

(e) Decisions on access to genetic resources shall be taken within a reasonable period of time (XX days);

(f) 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 (YY days).

11.3 Any decision taken within the System shall be subject to a legal review mechanism.

Art 12 Competent National Authorities and National Focal Point

Each providing country shall designate Competent National Authorities (hereinafter "CNA") and one National Focal Point (hereinafter "NFP"). The CNA shall be responsible for implementing and performing the administrative functions required by the System. Where appropriate, the CNA shall assist in solving differences arising between the different stakeholders in matters covered by the Guidelines. The NFP shall be responsible for providing information to stakeholders on the System and any other information which may be needed prior to the access to genetic resources and for liaison with the Secretariat of the CBD. The Providing country may designate a single entity to fulfil the functions of both CNA and NFP.

IV. OTHER PROVISIONS

Article 13 Information Received Under the Guidelines

13.1 Unless otherwise declared by one of the stakeholders involved in the transaction of the genetic resources in question, and subject to Article 13.2 of the Guidelines, any information received under the Guidelines shall not be considered as confidential .

13.2 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 14 System of Certification

The stakeholders are encouraged to create a system of certification as described in Annex D of the Guidelines.

Article 15 Mediator

15.1. The stakeholders involved in a transaction of genetic resources are encouraged to seek support by a mediator when negotiating the mutually agreed terms as referred to in Articles 7 and 8 of the Guidelines.

15.2. The mediator shall facilitate the negotiations of mutually agreed terms between the stakeholders involved in a transaction of genetic resources with the aim of obtaining a balanced outcome for such stakeholders.

Article 16 Capacity Building

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

Article 17 Reporting by Stakeholders Regarding the Application of the Guidelines

The 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 18 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 shall endeavour that their scientific research and development on genetic resources contribute to the development of the providing countries' scientific and technological capacities for the sustainable use of genetic resources, including, as far as possible, the establishment and improvement of the innovative capacities of the providing countries, in particular developing countries. Users 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;
- Trust Funds.

ANNEX B

Availability of Findings of Scientific Research and Development (Article 8.1 of the Guidelines)

Availability of the findings 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 undertake every appropriate and feasible effort to make available, on mutually agreed terms, the findings 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 findings 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.
- Trust Funds

ANNEX D

System of Certification (Article 14 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. In order for this system to fulfil its objectives, it seems preferable to realise uniform standards instead of a plurality thereof. Realising differing standards is likely to cause misunderstandings on the content and perspicuity of the granted certificates. A regional or international system of certification should thus be in the foreground. When creating this system, the involved stakeholders are encouraged to consider the suitability of any existing institution or mechanism already involved in certification or standardisation.

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