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Access and Benefit Sharing User Measures in Switzerland

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This article, based on a study commissioned by the Swiss Federal Office for the Environment, aims at identifying what legal, administrative and policy measures could be designed in a country such as Switzerland to promote compliance by users of genetic resources and traditional knowledge with measures regarding access and benefit sharing (ABS). The framework of the study is set by the existing international legal system and the international regime currently being discussed in the negotiations of the Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization. This article states the situation as at June 2010. Stakeholders in Switzerland have already taken numerous measures in order to comply with the ABS provisions contained in the Convention on Biological Diversity, such as the declaration of the source of genetic resources and traditional knowledge in patent applications or the development of best practice guidelines and recommendations. Can more be done? Two basic options for ABS user measures in Switzerland are examined, depending on the development of the international regime, with or without international certification. Whatever system is finally chosen, it should not reduce the stimulation in research and development, ought to be as little intrusive as possible into trade activities and should avoid duplications.

Keywords access and benefit sharing; CBD; genetic resources; traditional knowledge

The Convention on Biological Diversity (CBD), concluded in Rio de Janeiro on 5 June 1992, was ratified by Switzerland in 1994 and entered into force in Switzerland on 19 February 1995. Its main objective, as described in article 1 CBD, is to ensure the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources. The CBD (in particular articles 15 and 16 *et seq*.) includes a range of provisions on access to genetic resources and on a balanced sharing of the benefits resulting from the use of these resources, so-called access and benefit sharing (ABS).

A genetic resource, in the meaning of the CBD, is to be understood as genetic material of actual or potential value, genetic material being defined as any material of plant, animal, microbial or other origin containing functional units of heredity (article 2 CBD). This definition is also used in the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (article 8), and shall be referred to in the present study.

States have the sovereign right over their natural resources (article 3 CBD). As a consequence, the authority to determine access to genetic resources rests with the national governments, and is subject to national legislation (article 15.1 CBD). Each Contracting Party must endeavor to create conditions which facilitate access to genetic resources for environmentally sound uses by other

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Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention. At the same time, access, where granted, shall be on mutually agreed terms (MAT) and subject to prior informed consent (PIC) of the Contracting Party providing such resources, unless otherwise determined by that Party, whilst benefits arising out of the use of the genetic resources shall be shared fairly and equitably with the Contracting Party providing such resources and based on MAT (articles 15.4, 15.5 and 15.7 CBD).

Generally speaking, a distinction is made between ''provider'' and ''user'' countries of genetic resources,[1] the first being mainly developing, and the second industrialized countries. However, industrialized countries might also be providers (e.g. Australia), whilst some developing countries are providers and users (e.g. Brazil) (United Nations University Institute of Advanced Studies (UNU-IAS) Report, 2003, p. 18).

Switzerland has mainly been seen as a ''user country'', although its specific alpine ecosystems and agro-ecosystems also provide a source of genetic resources. As a user country, Switzerland mainly uses genetic resources through private-sector businesses and scientific research institutions, be it in the pharmaceutical sector—including biotechnology—the food, cosmetic, and flavor industries, as well as agriculture. All these sectors are interested in a good access to genetic resources. In order to ensure this access is provided in respect of the obligations resulting from the CBD, and in parallel to measures to be taken in the provider countries, the Swiss Federal Office for the Environment (FOEN) has suggested identification of what measures could possibly be taken in a user country such as Switzerland. ''User measures'' have been defined by the Scoping Meeting on Capacity Building Approaches for Access to Genetic Resources and Benefit Sharing, as a package of legal, administrative and policy measures designed to promote compliance by users of genetic resources and traditional knowledge with obligations regarding PIC, MAT and benefit sharing. These measures can be applied by either the private or the public sector and may be mandatory or voluntary (Report of the Scoping Meeting, p. 17).

This issue is the object of the present study, which aims to identify possible measures that could be implemented in Switzerland. It further seeks to determine to what extent they might be in Switzerland's interest, how far they could be institutionalized and under which legal conditions. In particular, potential checkpoints, at which the respect of the ABS provisions of the CBD could be controlled, possibly subject to a condition of the existence of an internationally accepted system of certification, are to be identified. Existing procedures for obtaining marketing and importation authorizations set the framework of the study.

The study is structured as follows: First, some relevant international agreements are identified, which serve as a general framework to the issue of access to, and benefit sharing resulting from the use of genetic resources. The study then focuses on the current legal situation in Switzerland, in particular regarding the patent law, research regulations, authorization regimes and import regulations. A possible future legislation is examined in the next part, which tries to identify in which ways user measures could be introduced in the Swiss legal system, including potential checkpoints. Finally, possible sanctions are considered, which would help ensure the respect of the ABS provisions of the CBD.

International Framework

At the international level, beside the CBD, two instruments have been developed; one is currently being negotiated to help implement the access to, and benefit sharing from genetic resources.

First, the Bonn Guidelines were unanimously adopted by the CBD Parties in April 2002 as voluntary guidelines in order to provide input to Parties for the development and drafting of the

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legislative, administrative or policy measures on ABS. They embrace all genetic resources and associated traditional knowledge innovations and practices covered by the CBD, as well as benefits arising from the commercial and other uses, with the exclusion of human genetic resources (article 9 Bonn Guidelines). They suggest the creation of national focal points for ABS[2] and the elaboration of appropriate legal, administrative or policy measures, to support compliance with PIC of the Contracting Party providing such resources and MAT on which access was granted. Measures include, amongst others, preventing the use of genetic resources obtained without the PIC of the Contracting Party providing such resources and cooperation between Contracting Parties to address alleged infringements of ABS agreements (article 16.d Bonn Guidelines). Such measures are also currently being discussed in international negotiations on an international ABS regime.

The second international instrument is the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture of 3 November 2001. The objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security. The Treaty provides, amongst other things, a multilateral system of ABS (part IV, articles 10–13) with the aim of facilitating access to plant genetic resources for food and agriculture and to share the benefits arising out of the use of these resources. It covers major plant genetic resources for food and agriculture as listed in an annexure. Access is provided on the basis of a standard material transfer agreement (MTA) of the Treaty. Although the use of the standard MTA is made compulsory by the Treaty, neither a certificate nor any checkpoints as discussed under the CBD are foreseen in order to control its use or its existence in a particular case. However, the Treaty established a third-party beneficiary under its MTA that has the right to request the appropriate information as required in a number of articles of the MTA (articles 4.3 and 4.4 MTA).

Thirdly, negotiations are currently ongoing between parties to the CBD on a Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization. The text being circulated when the present contribution was finalized had not yet been negotiated. It, however, reflects the efforts by the co-chairs to elaborate the elements of a draft Protocol. Negotiating parties may still make further amendments and additions to the text (Report of the First Part of the Ninth Meeting of the Ad hoc Open-ended Working Group on ABS).

The draft stipulates that Parties are to take legislative, administrative or policy measures in order to ensure the fair and equitable sharing of benefits arising out of the utilization of genetic resources and associated traditional knowledge, including in derivatives, with the Party providing such resources or, where applicable, with the indigenous and local community holding such resources or associated traditional knowledge. It is foreseen that access to genetic resources be in principle subject to the PIC of the Party providing them. Parties are in particular to take the necessary legislative, administrative or policy measures to provide for the following:

- Legal certainty, clarity and transparency of their national ABS requirements.
- Easily obtainable information on how to apply for PIC.
- Timely written decisions by a competent national authority.
- Issuance of a permit or internationally recognized certificate as evidence of the decision to grant PIC.
- Where applicable, national law is to recognize and affirm existing rights of indigenous and local communities to genetic resources as well as set out criteria for the PIC and involvement of such communities for access to their genetic resources.

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- Requirement and establishment of MAT at the time of access. Those terms are to be set out in writing and may include a dispute settlement clause, terms on benefit sharing, including any ownership of intellectual property rights and terms on subsequent third-party use.
- Ensuring that traditional knowledge associated with genetic resources held by indigenous and local communities is accessed with the prior informed consent/approval and involvement of indigenous and local communities, and is based on MAT.

A number of key issues are still to be addressed before the Protocol can be adopted at the tenth Conference of the Parties in Nagano, Japan, in October 2010, in particular:

- The relationship with other instruments and processes.
- Temporal and geographical application.
- Monitoring, reporting and tracking, including disclosure requirements and checkpoints.
- Dispute settlement and access to justice.
- Definition of country of origin.
- Utilization of genetic resources in derivatives.
- General benefit sharing and traditional knowledge-related issues, including appropriate recognition of the relationship between ABS activities and traditional knowledge associated with genetic resources.
- Diversity of national circumstances, including cases in which the same genetic resources are found *in situ* within the territory of neighboring Parties.
- Recognition by Parties of the existence and role of customary law.

Current Legal Situation in Switzerland

For the time being, Swiss national legislation hardly contains any provisions for the implementation of the ABS obligations resulting from the CBD. One recent example and, to our knowledge the only one, is the introduction, as of 1 July 2008, of an obligation to declare the source of genetic resources and traditional knowledge used in an invention when a patent application is filed. However, the Swiss legal system incorporates different systems of authorization, on the one hand for the marketing of certain products and, on the other, for their importation. These procedures provide for a number of authorities that are competent for the grant of these authorizations. They may be considered as ''checkpoints''.

Marketing authorizations are provided on the basis of different systems. Competent authorities may be federal authorities, but can, in certain situations, also be regional (cantonal) ones, which might complicate the system. Such is the case for example in the food sector, where the so-called cantonal chemists have their say.

Importations to Switzerland mainly originate from the European Union (EU) or the European Economic Area (EEA), or, as Switzerland is surrounded by EEA countries, transit from those countries. For this reason, the Swiss legislation on importation mainly foresees the case of importations from EEA countries and tends to consider direct importations from third countries as more of a special issue.

Patent Law

The Swiss law on patents, which dates from 1954, has been recently revised in order to comply with latest developments, in particular in the field of biotechnology. The newest version, which entered into force on 1 July 2008, now incorporates provisions on information on the source of genetic resources and traditional knowledge incorporated in inventions which are the object of a patent

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application. Article 49a of the Swiss law on patents foresees that the patent application must contain information on the source of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource. Information must also be contained on traditional knowledge of indigenous or local communities of genetic resources to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge. If the source is unknown to the inventor or the patent applicant, the patent applicant must confirm this in writing.

The concept of source should be interpreted widely. It includes in particular the geographical place of origin in the meaning of preamble paragraph 27 of the European directive on the legal protection of biotechnological inventions, the country of origin, the country providing genetic resources in the meaning of article 2 CBD and other origins, such as gene data banks, botanical gardens, data banks and scientific publications. The multilateral system created by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture may also be a source of genetic resources (Notification of the Swiss Federal Council, p. 76). The Swiss Government recognizes that the declaration of source as required by the patent law is not sufficient in itself as it can only resolve certain aspects of the ABS issue; it expressly recognizes that further measures, in other fields of law, need to be adopted (Notification of the Swiss Federal Council, p. 75).

The notion of source has been chosen voluntarily, rather than that of origin, the latter being insufficiently defined internationally. Besides, the rationale of this choice was to avoid research which would go beyond what may be expected from the patent applicant as to the country of origin of the genetic resources. The source that will be indicated will generally be the country providing genetic resource. As patent applications are published, this allows the latter countries to check if their national legislation related to PIC and benefit sharing has been respected and, if that is not the case, to take the appropriate measures foreseen by their national legal system in order to restore a situation which is in conformity with the local law and possibly take the appropriate sanctions. This implies, however, that the user has a subsidiary company or a regional office in the providing country. As of today, and due to the relative novelty of the law, no such case has occurred to our knowledge.

If a patent applicant does not provide the information relating to the indication of source, the Swiss Federal Institute of Intellectual Property will set a deadline for the applicant in order to provide the missing information. If the information is still not provided at the end of that deadline, the patents will not be granted. Article 81a of the patent law foresees that anyone who willfully provides false information under article 49a is liable to a fine of up to 100,000 Swiss francs. The courts may also order the publication of the judgment. As such, the Swiss patent law goes beyond what is foreseen by paragraph 27 of the preamble of the EU biotechnology directive (Notification of the Swiss Federal Council, p. 77).

Research Regulations and Voluntary Measures

The competence for regulating research in Switzerland is shared between the Confederation and the cantons (article 64 Constitution of the Swiss Confederation). The Federal Law on Research aims at encouraging scientific research, but contains no provisions on the use of genetic resources. None of the federal laws and regulations dealing with the Federal Institutes of Technology or with coordination between universities contains provisions on ABS. Such is also the case for schools of applied sciences.

Although the Swiss Federal Law on Research foresees that the Confederation may link financial aid to the condition that measures be taken to encourage the valuation of results and to guarantee to the inventors an equitable part of the revenues generated by the commercial

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exploitation of the result, no mention is made of the need to take into account the ABS obligations as resulting of the CBD.

At university level, which is regulated by cantonal rules, no specific provisions are found on ABS either. Nonetheless, universities seem to be more and more aware of the necessity of respecting the provisions on ABS contained in the CBD. However, obtaining PIC for access to genetic resources, the elaboration of fair MAT and agreement on benefit sharing seem to be mainly based on ethical and moral obligations rather than legal ones.

The Swiss Academy of Sciences (SCNAT) has dealt with this topic and developed a set of recommendations in a brochure entitled "Access and Benefit Sharing—Good practice for academic research on genetic resources" and addressing the needs of academic research in Switzerland.[3] These guidelines, which have been distributed to all research institutions confronted with the issue of ABS, provides recommendations and checklists for the researchers, allowing them to undertake their work in conformity with the requirements of the CBD on PIC, MAT and benefit sharing. This, however, takes place only on a voluntary basis. In 2007, the SCNAT established a new consulting service, providing assistance to researchers in their administrative, negotiation and, if necessary, conflicting procedures relating to ABS. Hence today, research centers in Switzerland have access to the necessary tools allowing them to undertake their research in conformity with the CBD.

Several Swiss botanical gardens are also committed to the respect of the ABS principles contained in the CBD, in particular by joining the International Plant Exchange Network (IPEN) and thereby adhering to its code of conduct, which includes regulations for sharing benefits with countries that provide plant material.[4]

Authorization Regime in the Pharmaceutical and Biotechnological Field

One important sector in which genetic resources are being used is the pharmaceutical sector. The introduction of pharmaceutical products onto the market is subject to authorization, which is granted on the basis of the Federal Law on Medicines and Medical Devices [Law on Therapeutic Products (LTP)]. The aim of this law is to ensure that quality therapeutic products which are safe and efficient are put on the market, in order to protect the health of human beings and animals. The system aims in particular at protecting consumers of therapeutic products against deception and at ensuring that research and development in the pharmaceutical field takes place under favorable conditions (article 1 LTP).

The authorization system applies to all operations relating to therapeutic products (medicines and medical devices), in particular as regards their production and marketing. It covers in particular pharmaceutical products, which, in the definition of the law, covers also biological products, including those containing genetic resources. Production under the LTP includes all stages, from the acquisition of the basic materials to the conditioning of the end product, including its preparation and quality control. Production is subject to authorization, which is delivered if certain conditions (such as professional qualifications, quality insurance, etc.) are fulfiled. Pharmaceuticals have to be produced in conformity with recognized rules of good production practices. These rules are developed in a Federal Council regulation, which takes into account the international standards (articles 5–7 LTP). The authorization is given by the Swiss Agency for Therapeutic Products (SATP; Swissmedic) and is published.

Ready-to-use pharmaceuticals generally need an authorization from the SATP, unless, in particular, they are prepared in small quantities or if they are produced in order to undertake clinical trials. In order to obtain the authorization, it is necessary to prove that the products or the process is of good quality, safe and efficient. The applicant must also show that he is in possession

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of an authorization to produce, import or trade which is issued by the competent authority. The applicant must have its domicile, headquarters or a subsidiary in Switzerland. The SATP controls that these conditions are fulfiled. The application for marketing authorization must include a certain amount of information, including designation of the pharmaceutical product, the name of the producer, the process of production, composition, quality, therapeutic effects and result of clinical trials (articles 9–11 LTP). A simplified procedure is foreseen in certain situations, in particular when active ingredients of the products are already known, for products of complementary medicine, and in other cases such as pharmaceutical products produced by a hospital chemist and covering the needs of the hospital, or in the case of medicine which is important for rare diseases. The authorization is given by the SATP if the conditions are fulfiled. The SATP can, however, link the authorization to further charges and conditions. The authorization, which is published, is valid for 5 years and can be renewed (articles 9–11, 14 and 16 LTP).

The use of intermediary products is also subject to authorization, linked to security issues (article 3 paragraph 1 lit. d Ordinance of the SATP).

An authorization from the SATP is also required in order to import ready-to-use medicine. The Federal Council may also foresee an authorization regime for the importation of products which are not ready for use (article 18 LTP; Ordinance on Authorizations in the Field of Medicines).

All clinical trials on human beings must take place under recognized rules of good practices for clinical trials. These rules are elaborated by the Federal Council (article 53 LTP; Ordinance on Clinical Trials of Therapeutic Products). Ethics commissions guarantee the protection of the research subject (article 57 LTP).

Control of the market is ensured jointly by the SATP and the cantons, which share competence in this matter. Inspections are generally undertaken by the SATP (articles 51–60 LTP).

A system of international administrative assistance is foreseen by the law, which provides that the services of the Confederation dealing with marketing and import authorizations for medicines may request information from foreign authorities, as well as provide some information in certain cases (article 64 LTP).

The SATP can implement a range of administrative, as well as criminal measures in order to ensure the LTP is respected. Administrative measures may for example include deadlines to re-establish a situation in conformity with the law; suspension or revocation of authorizations; closing establishments; seizure and possibly destruction of products; prohibition of advertising; and publication of decisions. Criminal sanctions may include imprisonment or fines of up to 100,000 Swiss francs in cases of (professional) fabrication, marketing, import or export of products which are not in conformity with the pharmacopeia, or of infringement of provisions relating to advertising, labeling, etc. In the case of use of false certificates, criminal sanctions are also possible on the basis of the Federal Law of 6 October 1995 on Technical Barriers to Trade.

Handling of Organisms

In order, in particular, to protect biological diversity, the introduction into circulation in Switzerland of genetically altered organisms, pathogenic organisms or non-native invertebrate animals is subject to authorization; the public has a right to be informed and has access on request to the information provided by the applicant (articles 12 and 18 Law on Genetic Engineering; article 7 Plant Protection Ordinance; article 25 *et seq*. Release Ordinance). The authorization is given by different federal offices, according to the type of product concerned, as shown in Table 1.

In addition, information relating to the proprieties of the organisms must be provided to the recipient (article 15 Law on Genetic Engineering).

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Table 1: Authorization Procedure

Application	Competent authority	Applicable licensing procedure
(a) Therapeutic products	Swiss Agency for Therapeutic Products	Therapeutic Products Ordinance of 17 October 2001
(b) Foodstuffs, additives and processing aids	Federal Office of Public Health (FOPH)	Foodstuffs and Utility Articles Ordinance of 23 November 2005
(c) Plant propagation material exclusively for use in forests	Federal Office for the Environment (FOEN)	Release Ordinance of 10 September 2008
(d) Plant propagation material for all other uses	Federal Office for Agriculture (FOAG)	Seeds Ordinance of 7 December 1998
(e) Plant protection products	FOAG	Plant Protection Products Ordinance of 18 May 2005
(f) Fertilizers	FOAG	Fertilizers Ordinance of 10 January 2001
(g) Animal feedstuffs	FOAG	Animal Feedstuffs Ordinance of 26 May 1999
(h) Immunological products for veterinary use	Federal Veterinary Office (FVO)	Therapeutic Products Ordinance of 17 October 2001
(i) Import of harmful organisms that are not genetically modified nor particularly hazardous for agricultural crops or horticultural production	FOAG	Plant Protection Ordinance of 28 February 2001
(j) Biocide products	FOPH	Biocide Products Ordinance of 18 May 2005
(k) All other uses	FOEN	Release Ordinance of 10 September 2008

Source: Article 26 Release Ordinance.

Established national organizations for the protection of the environment have a right to appeal authorizations given for the introduction into circulation of genetically altered organisms to be used in the environment. Criminal sanctions are foreseen in case the law is not respected (articles 28 and 35 Law on Genetic Engineering).

The use of genetically altered and pathogenic organisms in confined areas is subject to an evaluation of the risks by the person using such organisms. Depending on the degree of risk at stake, a notification or an authorization is required (article 9 and annexure 2 Ordinance on the Handling of Organisms in confined Areas).

Import Regulations

To date, Switzerland does not provide any special provisions of law relating to the import of genetic resources. For the protection of humans, animals, plants and the environment, however, Switzerland generally regulates the import of *living plants*, *animals*, *animal products* and *foods of animal origin* into Switzerland. The import of such products (containing genetic resources) is made dependent on the existence of import documentation and certificates. The documents enclosed with the goods are required to provide information concerning the origin of the plants, animals and

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animal products. The inspection bodies for the import into Switzerland are, in particular, the customs administration and the border veterinarian service, but also various offices of the federal government. Custom authorities, however, operate on a sampling basis.

In relation to the European Community (EC), trade with agricultural products (plants, plant products, animals, animal products, etc.) is governed by the Agreement between the Swiss Confederation and the EC on Trade in Agricultural Products of 21 June 1999; the import regulations applicable with respect to the EC therefore deviate from those applicable with respect to third-party states. In connection with the import of *plants* from third-party states, a plant protection certificate must be presented; in connection with goods from the EC, a plant passport is required. This proves that, based on the inspections at the level of the production and processing, the plants and plant products conform to the phytosanitary requirements of the EC. Products from third-party states require a plant protection certificate as far as the border of the EC. At the border, they are checked in terms of their conformity with the EC regulations. If the import inspection is positive, the imported goods receive an EC plant passport. In the absence of a plant protection certificate or a plant passport, the import of plants into Switzerland is basically impossible (articles 10 and 12 Plant Protection Ordinance).

In connection with *animals* and *animal products*, a distinction is likewise made based on whether they stem from member states of the EC or from other (third-party) states. Animals and animal products from member states of the EC are not inspected by the border veterinarian service when they are brought into Switzerland. The same also applies with respect to animals and animal products from the EC which originally stem from third-party states, provided that a document and identification inspection as well as a physical inspection was carried out at the outer border of the EC (article 18 paragraph 1 Ordinance on the Import, Transit and Export of Animals and Animal Products). If animals and animal products are imported directly into Switzerland from third-party states by air, a document and identification inspection as well as a physical inspection must be conducted (article 16 Ordinance on the Import and Transit of Animals from Third Party States in Air Traffic; article 22 Ordinance on the Import and Transit of Animal Products from Third Party States in Air Traffic).

The importation of microorganisms also needs to respect the provisions of the Plant Protection Ordinance of 28 February 2001 and requires an authorization, which depends on the provision of information allowing the Federal Office of Agriculture to evaluate the phytosanitary risks/utility that the (micro)organism represents for Switzerland. Information to be provided includes the scientific denomination, the region of origin, possible risks, foreseen use, provider, data relating to the shipment and address of the claimant.[5]

Food can—apart from food of animal origin—basically be imported into Switzerland without certificates, regardless of whether it stems from the EC or from third-party states; an exception currently applies only with respect to the import of wild mushrooms from Eastern Europe. Imported food, however, must conform to the requirements of the Swiss food legislation (article 2 paragraph 3 Food Act). This must be monitored by the food importer by means of self-monitoring (article 23 Food Act; article 49 *et seq*. Ordinance on Foodstuffs and Utility Articles). The customs offices are responsible for the inspection of food at the border (article 67 *et seq*. Ordinance on Foodstuffs and Utility Articles; article 62 *et seq*. Ordinance of the Federal Department of Home Affairs (FDHA) on the Enforcement of the Food Legislation); within Switzerland, the inspection is carried out by the cantons, under the direction of the cantonal chemists (article 40 Food Act; article 56 *et seq*. Ordinance on Foodstuffs and Utility Articles).

Finally, for the protection of endangered species of wild animals and plants, the import, transit and export of *animals and plants* based on the Convention on International Trade in Endangered

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Species of Wild Fauna and Flora (Washington Convention; CITES) is subject to a permit requirement. Protected species may be imported or pass through Switzerland in transit only if the permits or certificates required under the CITES and through the Ordinance for the Protection of Species are to hand. Permits and certificates must conform to the requirements of the CITES and prove without any gap the origin of the dispatch that they accompany (article 7 paragraphs 1 and 2 Ordinance for the Protection of Species). The Protection of Species Inspection Ordinance lists the animals, plants and products as to which a document and identification inspection as well as a physical inspection must be conducted in each situation. In all other cases, the Federal Veterinary Office (FVO) or an inspection body commissioned by it carried out a document inspection (article 29 Ordinance for the Protection of Species).

Food and Utility Articles

In the area of food, a distinction is made between imported food and food produced in Switzerland.[6] Food produced in Switzerland that complies with the requirements of the food legislation and that are circumscribed in a product-specific ordinance[7] may be introduced into commerce without any permit. New types of food or functional foods that are not defined in a product-specific ordinance, on the other hand, require a permit of the Federal Office of Public Health (FOPH) (article 5 paragraph 1 Ordinance on Foodstuffs and Utility Articles). For the production of food, flavor might be used as food additive (article 1 paragraph 1 Ordinance of the FDHA concerning allowed Food Additive). The FOPH publishes periodically a list with the newly admitted types of food in the Swiss Official Journal of Commerce and on the internet (article 6 paragraph 4 Ordinance on Foodstuffs and Utility Articles). Genetically altered food is not permitted to be introduced into commerce unless it has been approved by the FOPH (article 21 *et seq*. Ordinance on Foodstuffs and Utility Articles; Ordinance of the FDHA on Genetically Altered Food).

Cosmetics belong to utility articles. The FDHA defines in an ordinance which substances are allowed in cosmetics and what information has to be provided on the package. Compliance with the regulations must be monitored by the producer by means of self-monitoring. In addition, periodical and risk-based official controls will be exercised (articles 35, 49 and 56 Ordinance on Foodstuffs and Utility Articles; Ordinance of the FDHA on Cosmetics).

Agriculture

Numerous agricultural means of production may be introduced into commerce in Switzerland only after having passed through an approval procedure (article 160 Law on Agriculture). An approval procedure is foreseen for seeds (article 10 *et seq*. Seeds Ordinance), agricultural pesticide (article 4 *et seq*. Plant Protection Products Ordinance), fertilizer (articles 2, 3, 7 *et seq*. Fertilizer Ordinance) and animal feed (article 3 *et seq*. Animal Feedstuffs Ordinance). The permit takes place either through inclusion in a list (catalog of seeds, list of fertilizers, list of animal feed) or based on a permit procedure (agricultural pesticides, fertilizers). The approval authority is the Federal Office for Agriculture (FOAG). The permitted agricultural means of production are published either by the Federal Department of Economic Affairs or the FOAG.

Other Fields

The protection of new plant varieties is subject to a registration procedure. Besides the material obligations and in order to obtain the protection, formal obligations also need to be complied with. According to the Federal Law on the Protection of Plant Varieties and its implementation regulation, the application for protection of a plant variety must contain a number of indications and documentation, including (relating to the acquisition of the variety) if the holder is not, or is

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not the only, initial breeder or, if multiplication material or product of a harvest has been sold or transferred in another way with the agreement of the holder or one of its predecessors, the date and place of transfer (article 9 Law on the Protection of Plant Varieties; articles 7–10 Ordinance on the Protection of Plant Varieties). A similar regulation is applicable in the case of seeds (article 5 Ordinance on the Production and Circulation of plant multiplication material).

The CBD requires Parties to take measures relating to the *ex situ* conservation of components of biological diversity, with a method to complete *in situ* measures (article 9 CBD). The International Treaty on Plant Genetic Resources for Food and Agriculture also stipulates such measures in the field of food and agriculture. In particular, Parties must cooperate to promote the development of an efficient and sustainable system of *ex situ* conservation, giving due attention to the need for adequate documentation, characterization, regeneration and evaluation, and promote the development and transfer of appropriate technologies for this purpose with a view to improving the sustainable use of plant genetic resources for food and agriculture (see in particular articles 5.1 and 15 International Treaty on Plant Genetic Resources for Food and Agriculture).

At the federal level, requirements have been issued in order for an institution to be recognized as a registered scientific organization in the meaning of article VII.6 CITES (Ordinance on the Recognition as a Registered Scientific Organization by means of the CITES). But generally, provisions relating to *ex situ* conservation of biological diversity may be found in a variety of legislation, including on forestry;[8] on the release of organisms in the environment (Release Ordinance); on the protection of species; on the protection of plant varieties; on plant multiplication material (Law on the Protection of Plant Varieties and its ordinance of application; Ordinance on the Production and Circulation of plant multiplication material) and on a voluntary basis,[9] as discussed above.

Possible Future Legislation

The Alternative: With or Without International Certificate of Origin

At the present stage of the international negotiations on the establishment of an international ABS regime, one alternative becomes apparent: either an international certificate of origin is established, or it is not. The choice has consequences at the national level. Before examining this alternative more closely, choices lying within the international regime relating to the concept of certificates of origin, source or legal provenance need to be addressed.

The Concept of Certificates of Origin, Source or Legal Provenance

There are several options regarding the type of system appropriate for the concept of certificates of origin, source or legal provenance: a *legally binding system*, a *voluntary system* or a *mixed one*. Depending on the system chosen, the provider and/or the user countries would be required to provide/request a certificate. In a voluntary system, it would be in the countries' discretion to do so (Report of the Meeting of the Group of Technical Experts on an Internationally Recognized Certificate of Origin/Source/legal Provenance, pp. 5, 7).

A certificate of origin, source or legal provenance is considered to be a public document, issued by a designated national authority and possibly listed in a common international database.

This certificate could be monitored by specific checkpoints appointed by the competent national authority of the user countries and listed in the common international database. These checkpoints could possibly be the same authorities as the ones issuing those certificates as a provider. Such checkpoints could be the registration points for commercial applications (e.g. product approval processes) or the intellectual property rights offices (especially patent and plant variety authorities).

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At the international level, a registry containing electronic copies of the certificate or the unique identifier of the certificate could serve as a clearing house mechanism (CHM). The countries and/or the checkpoints would have to notify this registry when dealing with a certificate.

A standardized internationally recognized format for certificates could contain (other than the codified unique identifier) information agreed upon, such as the subject-matter (genetic resources, traditional knowledge) covered by the certificate, uses permitted and restrictions of use. It could also contain information on, or a link to, a national database providing non-confidential information of PIC and MAT (Report of the Meeting of the Group of Technical Experts on an Internationally Recognized Certificate of Origin/Source/legal Provenance, pp. 8–11).

The Case in which No International Certificate Is Introduced

If no international certificate is introduced, the risk remains that checkpoints will have difficulties in examining whether the legislation of a given Party to the CBD on ABS is respected. Such a scenario would imply that checkpoints are familiar with the legislation of all 191 Parties to the CBD. It would also be necessary for those checkpoints to study numerous ABS contracts in the official languages of the Contracting Parties. In such a case, the control of the existence of PIC and MAT would therefore prove to be problematic.

If there is no international certificate, a system of declaration of source could be established in the framework of existing registration and authorization procedures, as recently established in the Swiss patent law. Checkpoints would have to limit their examination to the declaration of source, when the object of the registration or authorization is a genetic resource or is directly based on this resource, as is the case in the revised patent law. What is directly based on a resource could be defined in the international regime. The conformity test with the provider country's national legislation would be left to the latter. The examination of the existence of a declaration of PIC or MAT is not recommended, as it would also place the burden of testing its conformity with the law of the providing country with the Swiss authorities, and the same difficulties as described above would arise. The system based on the declaration of source is only possible if decisions have been published and are therefore accessible to the public, including in particular providers of genetic resources, such as, beside the patent system where it already exists, in the case of marketing authorization for pharmaceutical products, for agricultural means of production and newly admitted types of food as well as for applications for protection of new plant varieties. However, in connection with the import of plants, animals, animal products, etc., the import permits are not published. In these cases, the international regime could determine that such information shall be published, which would allow for providers to control the respect of their national ABS legislation. In order to facilitate the work of the provider countries, the published information could be centralized and made available through the CHM. Moreover, an international understanding of misappropriation and misuse of genetic resources would make it easier for user and provider countries to identify cases of infringement of ABS rules and avoid unjustified allegations of biopiracy.

Besides, duplications would need to be avoided, that is if a marketing authorization was required for a patented pharmaceutical product using genetic resources, the source of which would already have been declared in the patent application. But it has to be noted that, on occasion, products necessitating an authorization are based partly on resources which are the object of a patent application and partly on resources which are not. In such cases, the declaration of the source would be necessary for the resources which have not been the object of the patent, but not for those of which the source has already been declared in the patent application.

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The Case in which an International Certificate Is Introduced

The introduction of an international certification system (the content of which is subject to negotiation) would probably be most suitable to ensure that ABS measures foreseen in the legislation of the providing country (such as PIC, MAT and benefit sharing) are respected. For the same reasons as mentioned in the previous section, it is suggested that checkpoints would limit their control to the existence of such a certificate, based on the presumption that its content is in conformity with the legal obligations set forth in the country having issued the certificate, and based on the international regime. In such a way, the system would prove to be most efficient, in the interest of both providers and users.

If, in a specific situation, an applicant does not provide the certificate, the checkpoint could set a deadline for the submission of the missing certificate. If the certificate were not to be provided on time, the requested authorization (marketing, registration) would not be granted. Willful provision of a false certificate could be liable to a fine, and courts could order the publication of the judgment. The system established in the patent law could be a source of inspiration here.

Neither the CBD nor the Bonn Guidelines are of any help on the issue of timely application of ABS measures. The legal principle of non-retroactivity of laws basically implies that certificates would have to be provided for applications filed as of the date of entry into force of the respective laws. The date as of which certificates must be made available would have to be set in the international regime in order to be applicable in an equitable manner amongst all parties to the CBD. Here again, the principle of non-retroactivity of laws would imply the application of the system to new cases, that is genetic resources which would have been accessed to as of the ratification of the international regime/entering into force of the modified legislation in Switzerland, both having to be coordinated.

The principle of non-retroactivity of laws, however, would exclude a number of genetic resources which are already in circulation. If a new use is found for a genetic resource already in circulation in Switzerland, the principle of non-retroactivity would also apply: indeed, the principle of good faith requires that possessors of genetic resources do not have imposed on them new conditions which were not contractually foreseen or were not foreseen in the decision providing them the right of use. The timely application of the system should therefore be subject to negotiation and be provided for in the international regime.

However, bioprospecting is likely to continue in the future due to the development of new biopharmaceutical compounds, for which "natural products research is vital to identify novel products to alleviate human health problems" (UNU-IAS Report, 2009, p. 21 and references included therein). Therefore, even in application of the principle of non-retroactivity, the system would be justified and useful.

Conceivable Checkpoints

Patent Law

The Swiss patent law has recently been revised and introduced the obligation to declare the source of genetic resources and traditional knowledge used in a product or process for which the patent has been applied for. Some time will be necessary in order to evaluate its efficiency. However, it is noteworthy that the Swiss patent system provides for the first checkpoint in Switzerland.

If an international regime for a certificate of source or of origin for genetic resources was to be agreed upon between all parties to the CBD, the verification by the Swiss Federal Institute of Intellectual Property could be extended from the declaration of source to the availability and provision by the applicant of a copy of the certificate, containing the information agreed upon internationally (declaration of source, of origin, proof of the existence of MAT, etc.).

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Research Regulations and Voluntary Measures

For the time being, respect of the CBD provisions on ABS by universities and research institutions are based on a voluntary basis. Measures could be taken in Switzerland in order to further encourage researchers (be it at university or industry level) to respect ABS principles of the CBD on a voluntary basis, such as is the case with universities, applying the recommendations of the SCNAT. This would require public awareness measures, which could be ensured by the FOEN in its capacity as a focal point.

A more binding measure might be introduced in federal laws on research, which would link the financing of research projects including genetic resources by the Confederation to the respect of CBD as regard ABS. This could also be the case in projects to be funded by the Swiss National Science Foundation, and in the research principles included in the law on the Swiss Federal Institutes of Technology.

At the cantonal level, laws or regulations on universities could include a provision either encouraging or obliging researchers to respect those same provisions.

Authorization Regime in the Pharmaceutical and Biotechnological Field

The SATP (Swissmedic) could also serve as a checkpoint in the process in which a production or a marketing authorization is required for a pharmaceutical product using genetic resources.

As pharmaceuticals have to be produced in conformity with recognized rules of good production practices, contained in a Federal Council regulation and taking international standards into account (articles 5–7 LTP), it could be envisaged including standards relating to ABS in such a regulation.

Such could also be the case for phytosanitary products, which benefit from a simplified marketing procedure. However, if said products and/or molecules on which they are based are patented, and requirements of declaration of source (in the present legal environment) or of the existence of a certificate (in a future system) have been complied with, a multiplication of procedures needs to be avoided. The requirement of proving the existence of a certificate could then be waived at Swissmedic and a copy of the patent documentation would be sufficient.

One important drawback may, however, be the need for Swissmedic to check in each case where no certificate is presented, whether the absence of a certificate is justified in view of the CBD, its international implementing regime and the applicable national laws.

Food and Agriculture

The adherence to the ABS provisions of the CBD can be reviewed within the scope of the existing *approval procedure* for food, provided that such a procedure is contemplated, and in the approval procedure for agricultural means of production. By way of analogy to article 49a of the patent law, it may be foreseen that the application for a permit must contain information concerning the source of the genetic resource, whereby the certificate of origin is to demonstrate that the ABS provisions of the CBD were adhered to. The approval authority that is responsible for the product (the FOPH, in the case of food, and the FOAG, in the case of agricultural means of production) must take over the tasks of the checkpoint within the scope of the approval procedure.

Import Regulations

The import of genetic material into Switzerland can be made dependent on proof of a certificate of origin, as this is already the case with plant protection certificates, in connection with the import of plants, etc. In particular, the customs administration as well as, in the case of animals, the border

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veterinarian service, come into consideration as checkpoints; individual federal offices, such as the FVO, the FOAG and the FOPH may likewise take over tasks.

Import regulations, however, are only suitable in certain cases. Custom authorities operate on a sample basis. Besides, it is not feasible to inspect all genetic resources at the border, due to the characteristics of genetic resources: they are elements of natural products that can be imported as such, but with the aim of making use of the genetic resources they contain. In addition, import regulations are of limited value where movements of physical samples is not required because analysis of the samples may have been done in the country of origin, and only the resulting information is exported (over, e.g., the internet).[10] Import regulations are likewise unsuitable for the use of traditional knowledge.

For the reasons set out above, the import procedure only comes into consideration as a means to review compliance with the ABS provisions to a limited extent. A possibility might exist by defining certain product categories that are to be inspected upon import.

Other Fields

If genetic resources have been necessary for the development of a new plant variety, it could also be envisaged that the office for the protection of varieties, which is competent for the delivery of protection titles, might examine the existence of a certificate of source or of origin. Such a certificate could be included in the documentation and indications which are requested in order to obtain the protection of a new plant variety. It could also be applicable in the case of seeds, for which the FOAG is competent.

As regards *ex situ* collections, it has been mentioned that provisions relating to biological diversity may be found in several pieces of legislation, including on forestry, on the release of organisms in the environment, on the protection of species, on the protection of plant varieties and on plant multiplication material. The competent offices in those cases might act as checkpoints.

It also has to be mentioned that *ex situ* collections, being very often related to scientific institutions such as universities, would also be subject to legislation dealing with research.

FOEN as Focal Point

FOEN is the Swiss focal point for ABS. As such, it is responsible for providing information and national regulations relating to ABS issues. The question of its role arises if an international certification regime is established. Although each authorization procedure has its own particularities and may differ according to the type of procedure involved (right of protection, production, marketing or importation), collaboration between different offices within one procedure is common administrative practice. Such is the case, for example, in the procedures relating to dissemination of genetically altered organisms, non-native invertebrate animals or pathogenic organisms or for the use of genetically altered organisms or pathogenic organisms in confined areas.

It could accordingly be envisaged, in particular in the above-mentioned cases, centralizing the examination of certificates from provider countries within FOEN. Such a procedure might facilitate procedures for applicants, who could directly refer to the focal point for the examination of the certificate.

It is also suggested that FOEN, as the Swiss focal point, could be the authority issuing certificates in case Switzerland is the providing country. FOEN would also continue being the appropriate authority for the coordination with foreign authorities (in particular focal points) not only for negotiations, as is already the case nowadays, but also if coordination is necessary, for

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instance where doubts appear as to authenticity of a certificate, and more generally, as a point of exchange of information in the CHM.

Finally, FOEN would also have an important role in building and raising awareness in issues relating to ABS, thus increasing voluntary application of ABS principles arising in particular from the CBD and the Bonn Guidelines.

Remedies

Article 27 CBD foresees a dispute settlement procedure between State Parties through negotiation, mediation and arbitration. However, no procedure is foreseen for a situation in which interests of users of genetic resources are at stake, such as individuals, research institutions or companies. As a result, and in the absence of an international agreement providing for the competence of the courts of a given country and specifying the applicable legislation, remedies are subject to the sovereignty of each State Party to the CBD.

If no international certificate is introduced, the need for remedies may be felt in a less stringent way than in case a certificate is introduced. In the first situation, possibilities of appeal need to be available in a user country such as Switzerland when a right of protection, commercialization or circulation is denied to an applicant on the ground of absence of declaration of source.

If an international certificate is introduced, there may be a number of situations in which an applicant in a user country such as Switzerland, although he has undertaken all efforts to obtain the certificate, cannot provide it. Such situations may include the following:

- The provider country unjustifiably refuses to issue a certificate.
- The administrative procedure for the grant of a certificate or the judicial procedure (e.g. appeal against the administrative decision relating to a certificate) is unjustifiably long.
- The provider country violates the CBD rules on ABS, such as minimal access standards.
- The certificate contains false information which is not due to the applicant.

Generally, in all these cases, the principle of state sovereignty and of territoriality of laws implies that the applicant would have to take legal action in the providing country. However, in order to avoid blocking the legitimate use of genetic resources, it is argued that the right of protection, circulation or commercialization ought not to be refused to the applicant on the grounds of absence of the certificate mentioned above, when the existence of these grounds can be proven by the applicant. The international regime would though have to define the following issues:

- Reasonable duration of administrative and judicial procedures for the grant—or refusal—of certificates.
- Cases in which a State Party to the CBD may refuse to issue a certificate.
- Cases in which no certificate has to be presented.
- Respect of human rights.
- Possibly a definition of public policy.

The same principles should apply if an applicant fails to present a certificate, arguing that it had been refused to him on the basis of reasons contrary to Swiss public policy (e.g. human rights, violation of the principle of good faith). However, applicants may invoke public policy only exceptionally; the refusal of a certificate in the provider country must be in obvious contradiction with Swiss legal rules.

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Cases of violation of the international regime could be brought by the Parties (i.e. Switzerland or the provider country) to the dispute settlement procedure foreseen by article 27 CBD. As an alternative, the Swiss legislator could provide that, in such situations, no certificate has to be presented. However, the applicant would have to present the reasons for which he was unable to obtain a certificate in the providing country.

Possible Sanctions

If the user fails to provide the necessary information concerning the source of the genetic resources or if he provides incorrect, incomplete or misleading information, the question arises as to possible sanctions. Within the scope of the *approval procedure* for pharmaceuticals, agricultural means of production, etc., it can be contemplated that the approval application will be rejected if the applicant does not provide any explanation as to the source of the genetic resource. If the applicant provides incorrect information, declaring for instance that no genetic resources were being used, a revocation of the approval that has been granted would come into consideration, in addition to criminal law sanctions (fine, monetary penalties).

If a breach of the ABS provisions of the CBD is ascertained within the scope of an *import procedure*, the imported goods can be seized, confiscated and, as the case may be, destroyed. Corresponding measures are provided, for example, under the Ordinance for the Protection of Species (article 33 *et seq*.).

Conclusion

A number of ABS user measures could be foreseen in Switzerland and be implemented by different federal offices acting as checkpoints. Basically, two options would be available, depending on the existence or not of an international regime which would provide a certification system.

If *no international certification* system were to be developed, a requirement of a declaration of source of the genetic resources used or introduced into Switzerland could be provided, inspired by the newly implemented requirement in the Swiss patent law. Such a system would have to take place in the framework of published registration procedures, such as for new plant varieties, as well as of published production and marketing authorizations, such as for pharmaceutical products, food and agriculture. Based on the users' declaration of source in Switzerland, the respect of ABS requirements would be controlled and ensured by the country providing the genetic resources, after publication of the patent application or of the grant of protection or authorization, as the case may be, and based on a screening by the providing country of Switzerland's decisions. Decisions relating to protection, productions or marketing authorizations would be refused in Switzerland only if the source has not been declared or if the declaration has included false information—sanctions could then be foreseen—but not in the event that ABS measures in the providing country are not complied with, the examination of this question taking place at a later stage, in the country providing the genetic resources.

Transmission of information relating to granted authorizations or protection through the CHM could help provider countries have access to the necessary information. Furthermore, an international understanding of the concept of misappropriation and misuse of genetic resources would make it easier for user and provider countries to identify cases of infringement of ABS rules and avoid unjustified allegations of biopiracy.

If *a compulsory international certification system* is introduced, the examination of the existence of a certificate from the provider country, attesting the respect of its national legislation relating to ABS, would allow for an earlier examination of the respect of said provisions, in the provider country, before the publication of a patent, or the grant of protection, production or marketing

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right. It is therefore suggested that the existence of said certificates be controlled at the point of registration of new protection rights such as patents, and plant varieties not covered by the multilateral system of the International Treaty of the FAO; at the point at which production rights are granted; at the point at which marketing rights are granted; and, to a more limited extent, at the point where genetic resources as such (excluding genetic resources contained in end products) enter Switzerland. Such a system would ensure that rights relating to the use of genetic resources are conferred in Switzerland only once ABS principles incorporated in the provider country's legislation have been complied with. Decisions relating to protection, production or marketing authorizations would be refused in Switzerland in the event that no valid certificate has been provided, ensuring in that way that the providing country's ABS legislation has been complied with already before conferring any rights.

Efficiency of the process would be guaranteed by the fact that the certificate would be issued by the provider country on the basis of its national legislation, based itself on an international regime; the examination by the checkpoint in Switzerland would therefore be limited to the existence of the certificate.

Checkpoints in Switzerland should be established at a level which would not only ensure the respect of the CBD's ABS provisions, but also allow stakeholders in provider countries to enforce their contractual rights at the earliest possible stage. Such a system should not reduce the stimulation in research and development, ought to be as little intrusive as possible as regards trade activities and should avoid duplications.

Unless the international regime establishes a date of retroactive application of the system, in case genetic resources are already in circulation before the introduction of the certification system, no certificate will be available or necessary.

Such measures would have to be accompanied by public awareness measures, which could stimulate stakeholders in Switzerland (including universities, schools of applied science, industry and distributors) to respect ABS principles on a voluntary basis. This would help ensure respect for genetic resources which have already been introduced in Switzerland before the entry into force of the new legal provisions.

Finally, the elaboration of user measures in Switzerland would require the active participation of experts from the different offices and ministries involved in order to set up a coherent, efficient and not burdensome ABS system.

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Notes

The opinions and points of view expressed in the document are exclusively the authors. In no way do they necessarily reflect the views of the contributors or of the Federal Office for the Environment (FOEN).

1 Article 2 CBD defines the country providing genetic resources as the country supplying genetic resources collected from *in situ* sources, including populations of both wild and domesticated species, or taken from

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ex situ sources, which may or may not have originated in that country. User countries are not defined in the CBD.

2 In Switzerland, the focal point for ABS is the FOEN.

3 See ⟨http://abs.scnat.ch/downloads/ABS_Brochure.pdf⟩ [Accessed June 2010].

4 See ⟨http://www.bgci.org/files/ABS/IPEN/conduct.pdf⟩ [Accessed June 2010].

5 See ⟨http://www.blw.admin.ch/themen/00012/00080/index.html?lang=fr⟩ [Accessed June 2010].

6 As to the import provisions for food, see above, ''Current Legal Situation in Switzerland, ''Import Regulations''''.

7 As to these ordinances, see SR 817.022.101–817.022.111.

8 Article 24 of the federal Law on Forests of 4 October 1991 (SR 921.0) gives the competence to the Confederation to legislate on the origin, the utilization, the trade and the maintenance of forestry plant and seeds. Certification of provenance for species of trees is issued by cantonal authorities according to the federal Ordinance on Reproduction Material for Forestry (SR 921.552.1); and the federal Ordinance on Forests (SR 921.01) contains provisions on the production, utilization, import and export of reproduction material, which are subject to authorization.

9 See the SCNAT Good Practices and IPEN Code of Conduct.

10 Likewise skeptical UNU-IAS Report, User Measures, pp. 26 *et seq*.

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