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Study

on

Access and Benefit Sharing User Measures in the Swiss Legal Order

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Access and Benefit Sharing User Measures in Switzerland

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Table of Abbreviations

ABS	Access and benefit sharing
AIA	Advance informed agreement
Art.	Article
CBD	Convention on Biological Diversity (Rio Convention)
CHM	Clearing house mechanism
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora (Washington Convention)
e.g.	for example
EC	European Community
Ed.	Edition
EEA	European Economic Area
et seq.	and the following
FAO	Food and Agriculture Organization
FOEN	Federal Office for the Environment
IPEN	International Plant Exchange Network
IR	International Regime on access and benefit sharing
LTP	Law on Therapeutic Products
MAT	Mutually agreed terms
p./pp.	page/pages
para.	paragraph
PIC	Prior informed consent
SATP	Swiss Agency for Therapeutic Products
SCNAT	Swiss Academy of Sciences
SR	Systematical compendium of the Federal Laws
UNU-IAS	United Nations University Institute of Advanced Studies

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Executive summary

The Convention on Biological Diversity (hereinafter CBD), concluded in Rio de Janeiro on 5 June 1992, was ratified by Switzerland in 1994 and entered into force there on 19 February 1995. Its objective, as described in Article 1 CBD, is in particular 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 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, including in particular articles 15 and following and article 8j, relating to the protection of traditional knowledge. Each contracting party must endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other 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 utilization of the genetic resources shall be shared fairly and equitable with the Contracting Party providing such resources and based on MAT (Art. 15.4, 15.5 and 15.7 CBD).

As a user country, Switzerland mainly uses genetic resources through private-sector businesses and scientific research institutions, be it in the pharmaceutical - including biotechnology -, food, cosmetic, and flavor industries, as well as agriculture. All these sectors are interested in a good access to genetic resources. In parallel to measures to be taken in the provider countries, the present study has as object to identify what measures could possibly be taken in a user country such as Switzerland, i.e. what legal, administrative and policy measures could be designed to promote compliance by users of genetic resources and traditional knowledge with measures regarding PIC, MAT, and Benefit Sharing, within the existing international legal system or in the framework of a new international regime (with or without a certification system), the negotiation of which is to be finalized by the Working group on Access and Benefit Sharing (ABS) until the Conference of the Parties in 2010.

Stakeholders in Switzerland have already taken numerous measures in order to comply with the ABS provisions contained in the CBD; several collaborations exist between the industry and developing countries and several best practice guidelines

and recommendations have been developed, such as the one by the Swiss Academy of Sciences (SCNAT) for academic research on genetic resources. An obligation to declare the source of genetic resources and traditional knowledge used in inventions when a patent application is filed was introduced in the Swiss patent law in 2008. But more can be done. Apart from the patent law, the Swiss national legislation does hardly include any provisions for the implementation of the access and benefit sharing obligations resulting from the CBD. The Swiss legal order incorporates different systems of registration and authorization, and provides for the authorities competent for granting them. Such is the case in particular in the pharmaceutical and, partially, the food sectors, as well as agriculture and plant variety protection. Competent authorities in these fields may constitute checkpoints to ensure benefit-sharing.

Two basic options could be envisaged for access and benefit sharing user measures in Switzerland, depending on the existence or not of an international regime which would provide a certification system. As currently discussed in the framework of the CBD, a certificate would be a public document issued by a designated national authority, which could testify the origin, the source or the legal provenance of the genetic resources. A standardized recognized format for certificates could in particular contain information internationally agreed upon, such as the subject-matter covered by the certificate (genetic resources, traditional knowledge), availability of PIC and MAT, including 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. The availability of this certificate could be monitored by the checkpoints in the user country.

In the case **no international certification** system is developed, a requirement of a declaration of source of the genetic resources and traditional knowledge used or introduced into Switzerland could be foreseen, inspired from 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, partially 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 the grant of the protection or authorization, and based on a screening of Swiss decisions by the providing country. Decisions relating to protection, production or marketing authorizations would be refused in Switzerland only in the case the source had not been declared

or if the declaration had included false information – in which case sanctions could also be foreseen –, but not in the case 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. In order to facilitate the work of the provider countries, the published information could be made available and centralized through the clearing house mechanism by the CBD and 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.

In the case **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 exam of the respect of said provisions, by the provider country, prior to the publication of a patent, or the grant of protection, production or marketing right by a user country such as Switzerland. It is hence 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 Food and Agriculture Organization (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 as soon as no valid certificate were provided, ensuring in that way that the providing country's ABS legislation be complied with already before the right is conferred, the latter being refused in the case a valid certificate is not presented.

Checkpoints in Switzerland should be established at a level which not only would ensure the respect of the CBD's ABS provisions, but which would also allow for stakeholders in provider countries to enforce their 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 into trade activities and should avoid duplications.

Such measures would have to be accompanied by public awareness measures, which could stimulate stakeholders in Switzerland to respect access and benefit

sharing principles on a voluntary basis. This would help ensure this respect for genetic resources having already been introduced in Switzerland before the entering 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 implicated, in order to set up a coherent, efficient and not burdensome ABS system.

Résumé

La Convention sur la diversité biologique (ci-après CDB), conclue à Rio de Janeiro le 5 juin 1992, a été ratifié par la Suisse en 1994 et y est entrée en vigueur le 19 février 1995. Son objectif, tel que décrit à l'article 1er CDB, est en particulier d'assurer la conservation de la diversité biologique, l'utilisation durable de ses éléments et le partage juste et équitable des avantages découlant de l'exploitation des ressources génétiques, notamment grâce à un accès satisfaisant aux ressources génétiques. La CDB comprend plusieurs dispositions sur l'accès aux ressources génétiques et sur un partage équitable des bénéfices issus de l'utilisation de ces ressources, en particulier les articles 15 et suivants ainsi que l'article 8j, sur la protection des connaissances traditionnelles. Chaque partie contractante doit s'efforcer de créer les conditions propres à faciliter l'accès aux ressources génétiques utilisées de façon écologiquement rationnelle par d'autres parties contractantes et ne doit pas imposer de restrictions allant à l'encontre des objectifs de la Convention. En même temps, l'accès, lorsqu'il est accordé, doit l'être sur la base de conditions convenues d'un commun accord (mutually agreed terms, MAT) et est soumis au consentement préalable donné en connaissance de cause par la partie contractante qui fournit lesdites ressources (prior informed consent, PIC), à moins d'une décision contraire de cette partie. Enfin, les avantages résultant de l'utilisation des ressources génétiques devront être partagés de façon juste et équitable avec la partie contractante qui fournit ces ressources sur la base de conditions convenues d'un commun accord (art. 15.4, 15.5 et 15.7 CDB).

En tant que pays utilisateur, la Suisse a principalement recours aux ressources génétiques dans le cadre d'entreprises privées et d'institutions de recherche scientifique, que ce soit dans les secteurs pharmaceutique - y compris la biotechnologie -, alimentaire, cosmétique, des arômes, de même que dans l'agriculture. Tous ces secteurs ont intérêt à un bon accès aux ressources génétiques. Parallèlement à des mesures qui doivent être prises dans les pays fournisseurs de ressources génétiques, la présente étude a pour objectif d'identifier les mesures qu'il serait envisageable de prendre dans un pays tel que la Suisse, à savoir quelles mesures légales, administratives et politiques peuvent être prises pour promouvoir le respect, par les utilisateurs de ressources génétiques et de connaissances traditionnelles, des obligations relatives au consentement préalable donné en connaissance de cause, aux conditions convenues d'un commun accord et au partage des bénéfices, que ce soit dans le cadre du système juridique international qui prévaut actuellement ou dans le cadre d'un nouveau régime international (avec ou sans un système de certification), qui

doit être finalisé par le groupe de travail ABS d'ici à la Conférence des parties de 2010.

En Suisse, les parties prenantes ont déjà entrepris bon nombre de mesures visant à respecter les dispositions ABS contenues dans la CBD; plusieurs collaborations existent entre l'industrie et les pays en développement; en outre, diverses lignes directrices concernant les meilleures pratiques et des recommandations relatives à la recherche académique sur les ressources génétiques ont été établies, telles que celles de l'Académie suisse des sciences naturelles. Une obligation de déclarer la source de ressources génétiques et des connaissances traditionnelles utilisées dans une invention lors du dépôt d'un brevet a été introduite dans le droit suisse des brevets en 2008. Mais on peut aller plus loin. Mise à part la loi sur les brevets, l'ordre juridique suisse ne comprend quasiment pas de dispositions mettant en œuvre les obligations relatives à l'accès et au partage des bénéfices contenus dans la CDB. Or l'ordre juridique suisse compte cependant un certain nombre de systèmes d'enregistrement et d'autorisations et prévoit les autorités compétentes pour les mettre en œuvre. Tel est particulièrement le cas dans les domaines pharmaceutique et, en partie, alimentaire, de même que dans les domaines agricole et de la protection des variétés végétales. Les autorités compétentes dans ces domaines pourraient ainsi constituer des points de contrôle pour assurer le partage équitable des bénéfices.

Deux options de base pourraient être envisagées pour des mesures assurant le respect des principes d'accès aux ressources génétiques et de partage des bénéfices en Suisse, dépendant de l'existence ou non d'un régime international prévoyant un système de certification. Comme discuté actuellement dans le cadre de la CDB, un certificat serait un document public, établi par une autorité nationale compétente, laquelle témoignerait de l'origine, de la source ou de la provenance légale des ressources génétiques. Un format standardisé de certificat pourrait en particulier contenir des informations sur lesquelles les parties à la CDB se seraient mises d'accord, tels que l'objet couvert par le certificat (ressource génétique, connaissance traditionnelle), le consentement éclairé et les modalités mutuellement convenues, y compris les usages autorisés et les restrictions d'utilisation. Il pourrait aussi contenir de l'information sur, ou un lien vers, une base de données nationale qui pourrait fournir des informations non-confidentielles sur le consentement éclairé préalable et les modalités mutuellement convenues. L'existence de ce certificat pourrait être contrôlée par les points de contrôle du pays utilisateur.

Dans le cas où **aucun système international de certification n'est développé**, l'exigence d'une déclaration de la source des ressources génétiques et connaissances traditionnelles utilisées ou introduites en Suisse pourrait être prévue, inspirée du système nouvellement introduit dans la législation suisse sur les brevets d'invention. Un tel système devrait prendre place dans le cadre des enregistrements publiés tels que pour les nouvelles variétés végétales, ainsi que pour les autorisations de production de mise sur le marché publiées, tels que dans le domaine pharmaceutique, en partie dans le domaine alimentaire, et dans le domaine agricole: une fois la protection ou l'autorisation accordée, le respect des obligations relatives à l'accès aux ressources génétiques et au partage des bénéfices qui en découlent pourrai être contrôlé par le pays fournisseur de ressources génétiques sur la base de la déclaration de la source en Suisse, suite à un *screening* des décisions suisses par le pays fournisseur. Des décisions accordant un droit de protection, de production ou de mise sur le marché ne seraient refusées en Suisse que dans le cas où la source n'avait pas été déclarée ou si la déclaration contenait des les indications fausses – auquel cas des sanctions pourraient également être prévues –, mais pas dans les cas dans lesquels les mesures liées à l'accès aux ressources génétiques et au partage des bénéfices n'étaient pas respectées dans le pays fournissant les ressources génétiques. Pour simplifier la tâche des pays fournisseurs, les informations publiées pourraient être centralisées et rendues accessibles par le biais du mécanisme de *clearing house.* Par ailleurs, une entente au niveau international sur les notions d'appropriation illicite et d'utilisation abusive des ressources génétiques faciliterait l'identification par les pays utilisateurs et les pays fournisseurs des cas de violation des règles relatives à l'ABS et permettrait d'éviter des allégations injustifiées de biopiraterie.

Dans le cas où un **système international de certification obligatoire** est introduit, l'examen de l'existence d'un certificat établi par le pays fournisseur et attestant du respect de sa législation nationale en matière d'accès aux ressources génétiques et de partage des bénéfices permettrait un examen en amont, par le pays fournisseur, du respect de ces dispositions, préalablement à l'octroi d'un droit de protection (dans le cas des brevets: préalablement à sa publication), de production ou de mises sur le marché par un pays utilisateur tel que la Suisse. Il est donc proposé que l'existence de ces certificats soit contrôlée au moment de l'enregistrement de nouveaux droits de protection, tels que des brevets, ou des certificats d'obtention pour des variétés végétales (à l'exception des variétés couvertes par le système multilatéral d'accès et de partage des bénéfices de l'Organisation des Nations Unies pour l'alimentation et l'agriculture, FAO); au moment où des droits de production sont octroyés; au moment auquel une autorisation de mise sur le marché est accordée; et, de façon plus

limitée, au moment où des ressources génétiques en tant que telles (excluant ainsi les ressources génétiques contenues dans des produits finaux) pénètrent la Suisse. Un tel système permettrait d'assurer que les droits relatifs à l'utilisation des ressources génétiques ne sont conférés en Suisse qu'une fois que les principes relatifs à l'accès aux ressources génétiques et au partage des bénéfices incorporés dans la législation du pays fournisseur sont respectés. Les décisions relatives à la protection, à la production ou à la mise sur le marché seraient refusées, en Suisse, dès lors qu'aucun certificat valable n'est fourni, assurant par là que la législation du pays fournisseurs est respectée même avant que le droit ne soit conféré, ce dernier étant refusé si un certificat valable n'est pas présenté.

Les points de contrôle en Suisse devraient être établis à un niveau qui non seulement permet d'assurer le respect des dispositions de la CDB sur l'accès aux ressources génétiques et le partage des bénéfices, mais également qui permettrait aux parties prenantes dans les pays fournisseurs de mettre en œuvre leurs droits le plus tôt possible. Un tel système ne devrait pas réduire la stimulation à la recherche-développement, devrait être aussi peu intrusif que possible dans les activités commerciales et devrait éviter les dédoublements de procédures.

De telles mesures devraient être accompagnées par des mesures de sensibilisation du public, qui pourraient stimuler les parties prenantes en Suisse à respecter les dispositions pertinentes de la CDB, sur une base volontaire. Ceci serait particulièrement utile pour les ressources génétiques ayant déjà été introduites en Suisse avant l'entrée en vigueur des éventuelles nouvelles dispositions légales.

Enfin, l'élaboration de mesures du côté des utilisateurs impliquerait la participation active des experts des différents Offices et Ministères concernés, afin d'établir un système ABS cohérent, efficace et aussi peu restrictif que possible.

Zusammenfassung

Die Schweiz hat 1994 das in Rio de Janeiro am 5. Juni 1992 abgeschlossene Übereinkommen über die biologische Vielfalt (Convention on Biological Diversity, CBD oder Rio-Konvention) ratifiziert; es ist für die Schweiz am 19. Februar 1995 in Kraft getreten. Zu den Zielsetzungen des Übereinkommens gehören gemäss dessen Art. 1 die Erhaltung der biologischen Vielfalt, die nachhaltige Nutzung ihrer Bestandteile und die ausgewogene und gerechte Aufteilung der sich aus der Nutzung der genetischen Ressourcen ergebenden Vorteile, insbesondere durch angemessenen Zugang zu genetischen Ressourcen. Näher geregelt werden der Zugang zu den genetischen Ressourcen und die ausgewogene Verteilung der aus ihrer Nutzung entstehenden Vorteile (sog. Access and Benefit Sharing, ABS) in den Art. 15 ff. des Übereinkommens. Art. 8j befasst sich mit der Erhaltung und Anwendung traditionellen Wissens.

Gemäss Rio-Konvention hat sich jede Vertragspartei zu bemühen, Voraussetzungen zu schaffen, um den Zugang zu genetischen Ressourcen für eine umweltverträgliche Nutzung durch andere Vertragsparteien zu erleichtern, und Beschränkungen zu vermeiden, die den Zielen des Übereinkommens zuwiderlaufen. Die Art. 15.4 und 15.5 der Konvention sehen sodann vor, dass der Zugang zu genetischen Ressourcen – vorbehältlich einer anderslautenden Regelung – der auf Kenntnis der Sachlage gegründeten vorherigen Zustimmung der Vertragspartei bedarf, welche die Ressourcen zur Verfügung stellt (Prior Informed Consent, PIC). Wird Zugang gewährt, so hat dieser zu einvernehmlich festgelegten Bedingungen zu erfolgen (Mutually Agreed Terms, MAT). Die Vorteile, die sich aus der Nutzung der genetischen Ressourcen ergeben, sind gemäss Art. 15.7 der Konvention mit der Vertragspartei, welche die Ressourcen zur Verfügung gestellt hat, zu einvernehmlich festgelegten Bedingungen ausgewogen und gerecht zu teilen.

Bei der Schweiz handelt es sich um ein Nutzerland von genetischen Ressourcen. Genetische Ressourcen finden hauptsächlich in der Privatwirtschaft sowie in der wissenschaftlichen Forschung Verwendung, namentlich auf dem Gebiet der Pharmazie, der Biotechnologie, der Lebensmittelproduktion, der Geschmackindustrie, der Kosmetik sowie in der Landwirtschaft. Diese Kreise haben ein vitales Interesse an einem guten Zugang zu genetischen Ressourcen. Im Rahmen der vorliegenden Studie soll geprüft werden, welche gesetzlichen, administrativen oder sonstigen Massnahmen in Nutzerländern wie der Schweiz ergriffen werden könnten, um sicherzustellen, dass die Nutzer von genetischen Ressourcen und traditionellem Wis-

sen ihren Pflichten bezüglich PIC, MAT und Benefit Sharing nachkommen. Die konkrete Ausgestaltung der Massnahmen hängt dabei davon ab, ob es bis zum Jahr 2010 gelingt, ein internationales ABS-Regime (mit oder ohne Zertifikationssystem) zu erarbeiten oder nicht.

In der Schweiz wurden bereits verschiedene Massnahmen zur Umsetzung der ABS-Bestimmungen der Rio-Konvention ergriffen. So arbeiten verschiedene Industriezweige mit Entwicklungsländern zusammen. Ferner wurden Best Practice Richtlinien und Empfehlungen erarbeitet; beispielsweise hat die Schweizerische Akademie der Naturwissenschaften Empfehlungen über den Umgang mit genetischen Ressourcen herausgegeben. Im Weiteren sieht eine im Jahr 2008 im Patentgesetz neu eingeführte Norm vor, dass im Rahmen eines Gesuches für die Patentierung einer Erfindung Angaben über die Quelle allfällig verwendeter genetischer Ressourcen und traditionellen Wissens zu machen sind. Weitere Massnahmen zur Umsetzung der ABS-Bestimmungen auf Gesetzesstufe wären möglich.

In verschiedenen Bereichen, in denen genetische Ressourcen Verwendung finden, wie in der Pharmazie, der Landwirtschaft, bei der Züchtung von Pflanzen und teilweise in der Lebensmittelproduktion, kennt die schweizerische Rechtsordnung verschiedene Zulassungs- und Bewilligungsverfahren. Die für die Zulassung bzw. Bewilligung zuständigen Behörden könnten in Zukunft die Aufgaben einer ABS-Kontrollstelle (Checkpoint) übernehmen, um die ausgewogene Verteilung der aus der Nutzung der genetischen Ressourcen entstehenden Vorteile sicherzustellen. Dabei kommen grundsätzlich zwei verschiedene Umsetzungsmodelle in Frage. Die Wahl hängt davon ab, ob ein internationales Zertifkationsregime eingeführt wird oder nicht.

Die Einführung eines international anerkannten Zertifikates über Ursprung, Quelle oder legale Herkunft einer genetischen Ressource wird gegenwärtig diskutiert. Beim geplanten Zertifikat handelt es sich um ein öffentliches Dokument, das von der dafür zuständigen nationalen Behörde des Ursprungslandes ausgestellt wird. Das geplante Zertifikat enthält insbesondere Angaben über den Gegenstand (genetische Ressource, traditionelles Wissen) sowie über die zulässige Nutzung. Ferner könnte das Zertifikat Auskunft darüber geben, ob der Zugang zu den genetischen Ressourcen mit Zustimmung der Vertragspartei erfolgt ist, welche die Ressourcen zur Verfügung stellt (PIC), und ob der Zugang zu einvernehmlich festgelegten Bedingungen geschehen ist (MAT). Denkbar wäre es auch, dass die wichtigsten Angaben bezüglich PIC und MAT im Zertifikat (oder allenfalls in einer nationalen Da-

tenbank) wiedergegeben werden, soweit diese nicht vertraulich sind. Die Erhältlichkeit solcher Zertifikate wäre allenfalls durch die Kontrollstellen im Nutzerland zu prüfen.

Kann sich die internationale Staatengemeinschaft nicht auf ein Zertifikationssystem einigen, könnte nach dem Muster des Patentgesetzes vorgesehen werden, dass die Nutzer in der Schweiz die Quelle der genetischen Ressourcen und des traditionellen Wissens im Rahmen des Zulassungs- oder Bewilligungsverfahrens deklarieren. Unterlässt es der Nutzer, die notwendigen Angaben zu machen oder macht er falsche Angaben, wird das Gesuch zurückgewiesen. Bei Falschangaben kommen auch weitere Sanktionen in Frage. Die Prüfung, ob die Nutzer die ABS-Bestimmungen eingehalten haben, obliegt bei diesem Modell dem Ursprungsland. Dieses ist allerdings nur in der Lage, deren Einhaltung nachträglich zu kontrollieren, wenn die Zulassungs- und Bewilligungsentscheide veröffentlicht werden. Dies ist beispielsweise bei Pflanzenzüchtungen, pharmazeutischen Produkten, landwirtschaftlichen Produktionsmitteln sowie teilweise bei Lebensmitteln der Fall. Um den Ursprungsländern die Kontrolle zu erleichtern, könnten die Zulassungs- und Bewilligungsentscheide im Rahmen des Clearing House Mechanism der Rio Konvention gesammelt und zur Verfügung gestellt werden. Ebenfalls vereinfachen liesse sich der Umgang mit genetischen Ressourcen, wenn auf internationaler Ebene definiert werden könnte, wann eine Nutzung unzulässig ist und damit gegen die ABS-Bestimmungen verstösst. Ungerechtfertigte Anschuldigungen wegen Biopiraterie könnten so vermieden werden.

Wird ein internationales Zertifikationssystem eingeführt, so hat dies den Vorteil, dass das Ursprungsland die Einhaltung der nationalen ABS-Bestimmungen durch die Nutzer prüfen kann, noch bevor Nutzerländer wie die Schweiz Schutzreche oder Bewilligungen gewähren. Einzige Aufgabe der schweizerischen Kontrollstellen wäre es bei diesem Modell, bei der Anmeldung der Schutzrechte für ein Patent oder für Pflanzenzüchtungen (sofern diese nicht unter den Geltungsbereich des FAO-Abkommens über pflanzengenetische Ressourcen für Ernährung und Landwirtschaft fallen), zu prüfen, ob ein Zertifikat des Ursprungslandes vorliegt. Die gleiche Prüfung wäre im Rahmen von Bewilligungs- oder Zulassungsverfahren für ein Produkt oder gegebenenfalls bei der Einfuhr von genetischen Ressourcen in die Schweiz vorzunehmen, wobei bei der Einfuhr Endprodukte, die genetische Ressourcen enthalten, ausgenommen bleiben. Kann kein Zertifikat vorgewiesen werden, wird dem Gesuch um Patentierung, Zulassung usw. nicht entsprochen. Auf diese Weise würde sichergestellt, dass nur bei Einhalten der ABS-Bestimmungen

des Ursprungslandes ein Schutzrecht, eine Bewilligung oder Zulassung in der Schweiz erteilt wird.

Die Kontrollstellen sind so auszugestalten, dass die Einhaltung der ABS-Bestimmungen sichergestellt ist und die Ursprungsländer ihre Rechte zu einem möglichst frühen Zeitpunkt wahrnehmen können. Die schweizerischen Massnahmen sollten weder die Forschung und Entwicklung beeinträchtigen noch den Handel erschweren; Doppelspurigkeiten sind zu vermeiden.

Zudem sollte durch weitere Massnahmen die Sensibilisierung für den in der Rio-Konvention vorgesehenen Vorteilsausgleich geschärft werden, so dass die entsprechenden ABS-Prinzipien auch auf freiwilliger Basis erfüllt werden. Dies ist insbesondere für jene genetischen Ressourcen von Bedeutung, die bereits vor Erlass einer ABS-Gesetzgebung in die Schweiz eingeführt worden sind und bei denen kein Vorteilsausgleich erfolgte.

Der Aufbau eines schlüssigen, wirksamen und nicht zu restriktiven ABS-Systems in der Schweiz wird nur mit der aktiven Mitwirkung der Bundesverwaltung möglich sein.

1. Introduction

1.1. General Framework of the Study

Convention on Biological Diversity

The Convention on Biological Diversity (hereinafter CBD), concluded in Rio de Janeiro on 5 June 1992, was ratified by Switzerland in 1994 and entered into force in our country on 19 February 1995[1]. Its objective, as described in Article 1 CBD, is in particular 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 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)[2].

Genetic Resources

A genetic resource, in the meaning of the CBD, is to be understood as a genetic material of actual or potential value, a genetic material being defined as any material of plant, animal, microbial or other origin containing functional units of heredity (Art. 2 CBD). This definition is also used in the Bonn Guidelines[3], and is the one that shall be referred to in the present study.

Access to Genetic Resources and Benefit Sharing

States have the sovereign right over their natural resources (Art. 3 CBD). As a consequence, the authority to determine access to genetic resources rests with the national governments, and is subject to national legislation (Art. 15.1 CBD). Each Contracting Party must endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other 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 utilization of the genetic resources shall be shared fairly and equitably with the Contracting Party providing such resources and based on MAT (Art. 15.4, 15.5 and 15.7 CBD).

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1 SR 0.451.43.

2 See in particular Art. 15, but also Art. 16 et seq. of the CBD.

3 Art. 8 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization of April 2002.

Provider and User Countries

Generally speaking, a distinction between "provider" and "user" countries of genetic resources is made[4]. Whilst the first are mainly developing, and the second are industrialized countries, it can very well be that industrialized countries are also providers (e.g. Australia), whilst some developing countries are providers and user (e.g. Brazil)[5].

User Measures

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 - including biotechnology -sector, 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) suggested to identify 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 Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Benefit-Sharing (BS). These measures can be applied by either the private or public sector and may be mandatory or voluntary[6].

Object of the Study

This issue is the object of the present study, which intends to help identify possible measures that could be implemented in Switzerland, in how far they could be in its interest, how far they could be institutionalized, and under which legal conditions. In particular, possible checkpoints, at which the respect of the access and benefit sharing provisions of the CBD could be controlled, possibly under condition of the existence of an internationally accepted system of certification, are to be identified.

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

5 See UNU-IAS Report, User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity (2nd ed.), 2003, p. 18.

6 Document UNEP/CBD/ABS/EW-CB/1/INF/1, p. 17, Montreal 2–4 December 2002, see www.cbd.int./meetings.

Existing procedures for obtaining marketing and importation authorizations set the framework of the study.

Structure of the Study

The study is structured as follows:

First, some topic international agreements or foreign legislation are identified, which either serve as a general framework to the issue of access to, and benefit sharing resulting from the use of genetic resources, or which provide useful examples of possible systems of control (Chapter 1.2.–1.3.). The study then focuses on the situation in Switzerland *de lege lata* (Chapter 2), in particular regarding the patent law, research regulations, authorizations regimes and import regulations. The situation *de lege ferenda* is examined under Chapter 3, which tries to identify in which ways user measures could be introduced in the Swiss legal system, including possible checkpoints. Before concluding, Chapter 4 tries to identify possible sanctions which would help ensure the respect of the CBD access and benefit sharing provisions.

1.2. International Framework

At the international level, beside the CBD, two instruments have been developed in order to help implement the access to, and benefit sharing from genetic resources:

Bonn Guidelines

First, *the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* 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 legislative, administrative or policy measures on access and benefit sharing. 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 utilization, with the exclusion of human genetic resources[7]. They suggest the creation of national focal points for access and benefit sharing[8] and the elaboration of appropriate legal, administrative or policy measures, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. Measures include, amongst others, preventing the use of ge-

[7] See Art. 9 of the Bonn Guidelines.

[8] In Switzerland, the focal point for ABS is the Federal Office for the Environment (FOEN).

netic resources obtained without the prior informed consent of the Contracting Party providing such resources and cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements[9]. Such measures are also currently discussed in international negotiations on an international ABS regime.

International Treaty on Plant Genetic Resources for Food and Agriculture

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[10]. 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 Convention on Biological Diversity, for sustainable agriculture and food security. The Treaty provides, amongst other things, a multilateral system of access and benefit sharing[11] 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 annex. Access is provided on the basis of a standard Material Transfer Agreement (MTA) of the Treaty. Although the use of the standard material transfer agreement 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 (see Article 4.3 and 4.4. of the MTA).

Further International Agreements

Further international agreements in the field of protection of the environment have been enacted. They serve *specific goals*, such as the protection of human health and the environment against the adverse effects which may result from the generation and management of hazardous wastes and other wastes[12]; the protection of human health and the environment from persistent organic pollutants[13]; the protection of human health and the environment from potential harm resulting from the interna-

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9 See Art. 16.d of the Bonn Guidelines.

10 SR 0.910.6. This treaty entered into force in Switzerland on 20 February 2005.

11 Part IV of the Treaty (Art. 10–13).

12 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal of 22 March 1989, ratified by Switzerland on 31 January 1990 (SR 0.814.05).

13 Stockholm Convention on Persistent Organic Products of 22 May 2001 (POP-Convention), ratified by Switzerland on 30 July 2003 (SR 0.814.03).

tional trade in hazardous chemicals[14]. The Rotterdam Convention e.g. foresees an interesting system of exchange of information to ensure that prior informed consent is given by Contracting Parties for the importation of hazardous chemical products. The system is based on a list of products included in an Annex, the importation of which is subject to authorization by the national competent authorities.

These conventions have different goals than that of the CBD and in particular its ABS provision provided in Article 15, which is to facilitate access to genetic resources for environmentally sound uses by Contracting Parties, whilst ensuring prior informed consent is provided for the access to those resources and benefits arising from their use are shared. All the instruments in these conventions aim at giving the *importing* country the possibility of stopping the importation of products dangerous to the environment. Contrary to access and benefit sharing issues, they do not intervene at the export-country level (the provider country or the country of origin), nor do they refer to ownership. Although they may be source of inspiration for an international ABS regime, they cannot as such be transposed and applied in the framework of Article 15 CBD.

The same is true for the *Cartagena Protocol on Biosafety*[15], which seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory[16].

CITES

The *Convention on International Trade in Endangered Species of Wild Fauna and Flora* (Washington Convention, CITES) may be more of a source of inspiration, as it deals with conservation of animals and plants rather than with security issues[17]. CITES aims at ensuring that international trade in specimens of wild animals and plants does not threaten their survival. CITES provides varying degrees of protection to more than 30,000 species of animals and plants, whether they are traded as

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[14] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade of 10 September 1998 (PIC-Convention), ratified by Switzerland on 10 January 2002 (SR 0.916.21).

[15] Cartagena Protocol on Biosafety of 29 January 2002, ratified by Switzerland on 26 March 2003 (SR 0.451.431).

[16] See www.cbd.int/biosafety/background.shtml.

[17] Convention on International Trade in Endangered Species of Wild Fauna and Flora of 3 March 1973 (CITES), ratified by Switzerland on 9 July 1974 (SR 0.453).

live specimens, fur coats or dried herbs. CITES works by submitting international trade in specimens of selected species to certain controls. All import, export, re-export and introduction from the sea of species covered by the Convention has to be authorized through a licensing system. Each Party to the Convention must designate one or more Management Authorities in charge of administering that licensing system and one or more Scientific Authorities to advise them on the effects of trade on the status of the species. The species covered by CITES are listed in three Appendices, according to the degree of protection they need[18]. The export of a specimen of a species included in the appendixes requires the prior grant and presentation of an export permit, which is only granted under certain conditions, in particular that the specimen was not obtained in contravention of the laws of the exporting State for the protection of fauna and flora. A so-called Management Authority of the State of export is responsible for controlling that such is the case. The import of a specimen of a species included in the appendixes requires the prior grant and presentation of an import permit and either an export permit or a re-export certificate. An import permit is only granted when conditions regarding living conditions and purposes of use have been met. These conditions are examined respectively by scientific and management authorities of the importing State[19]. As far as possible, Parties must ensure that specimens pass through any formalities required for trade with a minimum of delay. To facilitate such passage, a Party may designate ports of exit and ports of entry at which specimens must be presented for clearance[20]. The convention also states sanctions in case the procedure is not respected, including in particular criminal sanctions against illegal trade in, and/or possession of, specimens, and the confiscation or return to the State of export of such specimens. In addition, a Party may provide for any method of internal reimbursement for expenses incurred as a result of the confiscation[21].

1.3. The Example of Norway

The Government of Norway has recently proposed new legislation to Parliament on access to genetic material and benefit-sharing. It is part of a new Nature Diversity Act on conservation and sustainable use of biological diversity which, in its topic provisions, stipulates the following:

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18 See www.cites.org/eng/disc/how.shtml.
19 Art. III to V of the Convention.
20 Art. VIII.3.
21 Art. VIII.1. and 2. For its implementation in Switzerland, see here under Section 2.5.

- Genetic material from nature is to be considered as a common resource that belongs to the community in Norway. The State shall manage access to the material. The utilization should benefit the environment and people, both nationally and internationally;
- Regulations can provide that access to genetic material requires consent from the Ministry. If the material is transferred, the original conditions for the consent apply to the subsequent receivers. Access to public collections and for utilization and processing for agriculture and forestry does not require consent;
- An obligation for public collections to register and make publically available what kind of genetic material is withdrawn from the collection;
- An obligation for persons and entities not to apply for intellectual property rights limiting the use of the material withdrawn from public collections, unless the material has been changed substantially.

User Measures

The proposed legislation also introduces a number of user measures:

- It states an obligation under Norwegian law to disclose the country of origin and/or the country from where the material is collected and to follow the conditions set out in a prior informed consent of the provider country, as well as mutually agreed terms. This obligation applies when genetic material is used for research and commercial purposes in Norway;
- It contains conditions for import, to ensure that Norwegian users of genetic material comply with national regulation in provider countries. Import for utilization in Norway from a State that requires consent for collection or export can only take place if such consent has been obtained. Paragraph 60 gives the State the possibility to enforce the obligations set out in the MAT/PIC by law suit or by other means, in favor of those who have set them, as well as to issue sanctions (§§ 69–75). As the law just recently entered into force, there are no cases reported yet to the Government claiming breach of conditions for withdrawal or export of genetic material[22];
- For genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture for research and commercial purposes, it provides that the material shall be accompanied by information verifying that these resources are accessed in accordance with the Standard Material Transfer Agreement under the Treaty.

[22] Information from the Ministry of the Environment of Norway of 6 August 2009.

The proposal takes into account the rights of indigenous peoples and local communities, both in the access and the benefit-sharing provisions. It also defines the available remedies and penalties which can be issued by Norwegian Courts in cases of breach of the obligation resulting from the Act.

Parliament has now adopted the Government's proposal, without changes. The law entered into force on 1st July 2009, except the chapter on invasive species, which will enter into force at a later date. A checkpoint is already foreseen in the Norwegian Patents Act, and further ones are planned, such as in the cases of requests for research funds and product approval applications. These, as well as implementing details of the law, are yet to be elaborated in regulations.

Norway already has provisions on access and benefit-sharing for genetic material of marine origin in the Marine Resource Act, which entered into force on 1st January 2009. The Marine Resource Act and the Nature Diversity Act will be implemented within a holistic management framework[23].

2. Situation in Switzerland *de lege lata*

The example of the Patent Law

For the time being, the Swiss national legislation does hardly contain any provisions for the implementation of the access and benefit sharing obligations resulting from the CBD. One recent example and, to our knowledge the only one, is the introduction, as of 1st 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 which are competent for the grant of these authorizations. They may be considered as "checkpoints".

Marketing authorizations

Marketing authorizations are provided on the basis of different systems. Competent authorities may be federal authorities, but may, in certain cases, also be regional (cantonal) ones, which may make the system somewhat complicated. Such is the

[23] Statement by Norway regarding the proposal of new legislation made at the ABS Working Group meeting 7 in April 2009 in Paris.

case for example in the food sector, where the so-called cantonal chemists have their say.

Importation

Importations to Switzerland mainly originate from the European Union 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 case.

2.1. Patent Law

The Swiss law on patents[24], which dates of 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 1st 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 application. Art 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.

Concept of Source

The concept of source must be interpreted widely. It includes in particular the geographical place of origin in the meaning of preamble paragraph 27 of the European directive on protection of biotechnological inventions[25], the country of origin, the country providing genetic resources in the meaning of Art. 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 re-

[24] SR 232.14.

[25] Directive 98/44/EC of the European Parliament and of the Council of 6th July 1998 on the legal protection of biotechnological inventions.

sources[26]. 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 an access and benefit sharing issue; it expressly recognizes that further measures, in other fields of law, need to be adopted[27].

The notion of source has voluntarily been chosen, rather than that of origin, the latter not being sufficiently precisely defined internationally. Besides, the rationale of this choice was to avoid to the patent applicant the need of undertaking researches which would go beyond what may be expected from him 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 prior informed consent 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.

Sanctions

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 lacking information. If the information is still not provided at the end of that deadline, the patents will not be granted. Art. 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[28].

[26] See Message of the Swiss Federal Council on the Modifications brought to the Patent Law, doc. 05.082 of 23 November 2005, p. 76.
[27] Message of the Swiss Federal Council (note 26), p. 75.
[28] Message of the Swiss Federal Council (note 26), p. 77.

2.2. Research Regulations and Voluntary Measures

Federal level

The competence for regulating research in Switzerland is shared between the Confederation and the cantons[29]. A federal law on research aims at encouraging scientific research, but contains no provisions on the use of genetic resources[30]. None of the federal laws and regulations dealing with the Federal Institutes of Technology or with coordination between universities contains provisions on access and benefit sharing. 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 exploitation of the result, no mention is made of the need to take into account the access and benefit sharing obligations as resulting of the CBD.

University level

At the university level, which is regulated by cantonal rules, no specific provisions may be found on access and benefit sharing either. Nonetheless, universities seem to be more and more aware of the necessity of respecting the provisions on access and benefit sharing contained in the CBD. However, the obtainment of prior informed consent for access to genetic resources, the elaboration of fair mutually agreed terms, and agreement on benefit sharing seem to be mainly based on ethical and moral obligations rather than legal ones.

Swiss Academy of Sciences

The Swiss Academy of Sciences (SCNAT) has dealt with this theme and developed a set of recommendations in a brochure titled "Access and Benefit Sharing – Good practice for academic research on genetic resources" and addressing the needs of the academic research in Switzerland[31]. These guidelines, which have been distributed to all research institutions confronted with the issue of access and benefit sharing, provides recommendations and check-lists for the researchers, allowing them to undertake their work in conformity with the requirements of the CBD on prior informed consent, mutually agreed terms 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, conflictual procedures relating to ABS. Hence today, research centers

[29] Art. 64 of the Federal Constitution of the Swiss Confederation of 18 April 1999 (SR 101).
[30] See Federal Law on Research of 7 October 1983 (SR 420.1).
[31] See abs.scnat.ch/downloads/ABS_Brochure.pdf.

in Switzerland have access to the necessary tools allowing them to undertake their research in conformity with the CBD.

Code of conduct for Botanical gardens

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[32].

2.3. 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)[33]. The goal of this law is to ensure that quality therapeutic products which are sure and efficient are put on the market, in order to protect 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 favourable conditions[34].

Production of Pharmaceuticals

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 fulfilled. 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[35]. The authorization is given by the Swiss Agency for Therapeutic Products (Swissmedic) and is published.

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[32] See www.bgci.org/files/ABS/IPEN/conduct.pdf.
[33] SR 812.21.
[34] Art. 1 LTP.
[35] See Art. 5–7 LTP.

Marketing authorization

Ready-to-use pharmaceuticals in principle need an authorization from the SATP, unless, in particular, where they are prepared in a very little quantity or if they are produced in order to undertake clinical tests. In order to obtain the authorization, it is necessary to prove that the products or the process is of good quality, secure and efficient. The applicant must also show that he is in possession of an authorization to produce, import or trade which is delivered by the competent authority. The applicant must have its domicile, headquarters or a subsidiary in Switzerland. The agency controls that these conditions are fulfilled. 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[36]. A simplified procedure is foreseen in certain cases, 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 are important for rare diseases. The authorization is given by the Agency if the conditions are fulfilled. The Agency can, however, link the authorization to further charges and conditions. The authorization, which is published, is valid for 5 years and can be renewed[37].

Intermediary products

The use of intermediary products is also subject to authorization, linked to security issues[38].

Importation

An authorization from the agency 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[39].

Clinical trials

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[40]. Ethics commissions guarantee the protection of the research subject[41].

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36 Art. 9–11 LTP.

37 Art. 9–11, 14 and 16 LTP.

38 Art. 3 para. 1 lit. d of the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements relating to Marketing of Medicines of 9 November 2001 (SR 812.212.22).

39 Art. 18 LTP as well as Federal Ordinance on Authorizations in the Field of Medicines (SR 812.212.1.).

40 Art. 53 LTP, and Federal Ordinance on Clinical Trials of Therapeutic Products (SR 812.214.2).

Market control and inspections

Control of the market is ensured jointly by the Agency and the cantons, which share competences in this matter. Inspections are generally undertaken by the Agency[42].

International administrative assistance

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[43].

Sanctions

The agency can take a range of administrative, as well as criminal measures in order to insure the Law on Therapeutic Products is respected. Administrative measures may include e.g. deadlines to re-establish a situation in conformity with the law; suspension or revocation of authorizations; closing establishments; seizure and possibly destruction of products; interdiction 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, labelling, 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[44].

2.4. 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 upon request to the information provided by the applicant[45]. The

41 Art. 57 LTP.
42 Art. 51–60 LTP.
43 Art. 64 LTP.
44 SR 946.51.
45 Art. 12 and 18 of the Federal Law on Genetic Engineering in the Non-Human Area (Genetic Engineering Law) of 21 March 2003 (SR 814.91); Art. 25 et seq. of the Ordinance on the Handling of Organisms in the Environment (Release Ordinance) of 10 September 2008 (SR 814.911) and Art. 7 of the Ordinance on the Protection of Plants (Plant Protection Ordinance) of 28 February 2001 (SR 916.20).

authorization is given by different federal offices, according to the kind of product at stake, as shown in the following table[46]:

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	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

Besides, information relating to the proprieties of the organisms must be provided to the recipient[47].

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[48].

46 Art. 26 of the Release Ordinance.
47 Art. 15 of the Genetic Engineering Law.
48 Art. 28 and 35 of the Genetic Engineering Law.

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[49].

2.5. 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 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.

Import of Plants

In relation to the European Community (EC), the trade with agricultural products (plants, plant products, animals, animal products, etc.) is governed by an agreement between Switzerland and the European Community[50]; 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 up until 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 not possible[51].

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[49] Art. 9 and Annex 2 of the Ordinance on the Handling of Organisms in confined Areas of 25 August 1999 (SR 814.912).

[50] Agreement between the Swiss Confederation and the European Community on Trade in Agricultural Products of 21 June 1999 (SR 0.916.026.81).

[51] Art. 10 and 12 Plant Protection Ordinance. The Plant Protection Ordinance is based on Art. 149 et seq. of the Federal Law on Agriculture (Law on Agriculture) of 29

Import of Animals and Animal Products

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[52]. If animals and animal products are imported directly into Switzerland from third party States via aircraft, a document and identification inspection as well as a physical inspection must be conducted[53].

Micro-organisms

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 phyto-sanitary 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[54].

Import of Food

Food can – apart from the foods of animal origin – basically be imported into Switzerland without certificates, regardless of whether they stem 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[55]. This must be monitored by the

April 1998 (SR 910.1), the International Plant Protection Convention of 6 December 1951 (SR 0.916.20) and Annex 4 to the Agreement between the Swiss Confederation and the European Community on Trade in Agricultural Products of 21 June 1999.

52 Art. 18 para. 1 of the Ordinance on the Import, Transit and Export of Animals and Animal Protects of 18 April 2007 (SR 916.443.10).

53 Art. 16 of the Ordinance on the Import and Transit of Animals from Third Party States in Air Traffic of 18 April 2007 (SR 916.443.12); Art. 22 of the Ordinance on the Import and Transit of Animal Products from Third Party States in Air Traffic of 27 August 2008 (SR 916.443.13).

54 See note 45 and www.blw.admin.ch/themen/00012/00080/index.html?lang=fr.

55 Art. 2 para. 3 of the Federal Law on Food and Utility Articles (Food Act) of 9 October 1992 (SR 817.0).

food importer by means of self-monitoring[56]. The customs offices are responsible for the inspection of food at the border[57]; within Switzerland, the inspection is carried out by the cantons, under the direction of the cantonal chemists[58].

Import of endangered Species of wild Animals and Plants

Finally, for the protection of endangered species of wild animals and plants, the import, transit and export of *animals and plants based on the Washington Convention for the Protection of Species* (CITES) is subject to a permit requirement[59]. Protected species may be imported or pass through Switzerland in transit only if the permits or certificates required under the Convention and through the Ordinance on the Protection of Species are on hand. Permits and certificates must conform to the requirements of the Convention and prove without any gap the origin of the dispatch that they accompany[60]. The Protection of Species Inspection Ordinance[61] lists the animals, plants and products as to which a document and identification inspection as well as a physical inspection must in each case be conducted. In all other cases, the Federal Veterinary Office or an inspection body commissioned by it carried out a document inspection[62].

2.6. Food and Utility Articles

Production of Food, Food Additive

In the area of food, a distinction is made between imported food and food produced in Switzerland[63]. Food produced in Switzerland that complies with the requirements of the food legislation and that are circumscribed in a product-specific ordinance[64] may be introduced into commerce without any permit. New types of food or func-

[56] Art. 23 of the Food Act; Art. 49 et seq. of the Ordinance on Foodstuffs and Utility Articles of 23 November 2005 (SR 817.02).

[57] Art. 67 et seq. of the Foodstuffs and Utility Articles Ordinance; Art. 62 et seq. of the Ordinance of the Federal Department of Home Affairs on the Enforcement of the Food Legislation of 23 November 2005 (SR 817.025.21).

[58] Art. 40 of the Food Act; Art. 56 et seq. of the Foodstuffs and Utility Articles Ordinance.

[59] Convention on International Trade in Endangered Species of Wild Fauna and Flora of 3 March 1976 (CITES; SR 0.453).

[60] Art. 7 paras. 1 and 2 of the Ordinance for the Protection of Species of 18 April 2007 (SR 453).

[61] Ordinance of the Federal Department of Economic Affairs on Inspections within the Scope of the Convention for the Protection of Species (Protection of Species Inspection Ordinance) of 16 May 2007 (SR 453.1).

[62] Art. 29 of the Ordinance for the Protection of Species.

[63] As to the import provisions for food, see Section 2.5.

[64] As to these Ordinances, see SR 817.022.101 – 817.022.111.

tional foods that are not defined in a product-specific ordinance, on the other hand, require a permit of the Federal Office of Public Health[65]. For the production of food flavor might be used as food additive[66]. The Federal Office of Public Health publishes periodically a list with the newly admitted types of food in the Swiss Official Journal of Commerce and in the internet[67]. Genetically altered food is also not permitted to be introduced into commerce unless it has been approved by the Federal Office of Public Health[68].

Cosmetics

Cosmetics belong to the utility articles. The Federal Department of Home Affairs defines in an Ordinance which substances are allowed in cosmetics and which information has to be provided on the package. The compliance with the regulations must be monitored be the producer by means of self-monitoring. In addition, periodical and risk-based official controls will be exercised[69].

2.7. Agriculture

Approval proceeding

Numerous agricultural means of production may be introduced into commerce in Switzerland only after having passed through an approval proceeding[70]. An approval proceeding is foreseen for seed[71], agricultural pesticide[72], fertilizer[73] and animal feed[74]. The permit takes place either through inclusion on a list (catalog of

[65] Art. 5 para. 1 of the Foodstuffs and Utility Articles Ordinance.

[66] Art. 1 para. 1 of the Ordinance of the Federal Department of Home Affairs concerning allowed Food Additive of 22 June 2007 (SR 817.022.31).

[67] Art. 6 para. 4 of the Foodstuffs and Utility Articles Ordinance.

[68] Art. 21 et seq. of the Foodstuffs and Utility Articles Ordinance; Ordinance of the Federal Department of Home Affairs on Genetically Altered Food of 23 November 2005 (SR 817.022.51).

[69] Art. 35, 49, and 56 of the Foodstuffs and Utility Articles Ordinance; Ordinance of the Federal Department of Home Affairs on Cosmetics of 23 November 2005 (SR 817.023.31).

[70] See Art. 160 of the Law on Agriculture.

[71] Art. 10 et seq. of the Ordinance on the Production and Introduction into Commerce of Vegetable Reproduction Material (Seed Ordinance) of 7 December 1998 (SR 916.151).

[72] Art. 4 et seq. of the Ordinance on the Introduction into Commerce of Plant Protection Products (Plant Protection Products Ordinance) of 18 Mai 2005 (SR 916.161).

[73] Art. 2, 3, 7 et seq. of the Ordinance on the Introduction into Commerce of Fertilizers (Fertilizer Ordinance) of 10 January 2001 (SR 916.171).

[74] Art. 3 et seq. of the Ordinance on the Production and the Introduction into Commerce of Animal Feed (Animal Feedstuffs Ordinance) of 26 May 1999 (SR 916.307).

seed, list of fertilizers, list of animal feed) or based on a permit proceeding (agricultural pesticides, fertilizers). The approval authority is the Federal Office for Agriculture. The admitted agricultural means of production are published either by the Federal Department of Economic Affairs or the Federal Office for Agriculture.

2.8. Other Fields

Plant Varieties

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 execution 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 in cases in which the holder is not or is 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[75]. A similar regulation is applicable in the case of seeds[76].

Ex-situ collections

The CBD requires parties to take measures relating to the ex-situ conservation of components of biological diversity, with a means to complete in-situ measures[77]. The International Treaty on Plant Genetic Resources for Food and Agriculture also foresees 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[78].

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 Art. VII.6

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[75] Art. 9 of the Federal Law on the Protection of Plant Varieties of 20 March 1975 (SR 232.16); Art. 7–10 of the Ordinance on the Protection of Plant Varieties of 25 June 2008 (SR 232.161).

[76] Art. 5 of the Ordinance on the Production and Circulation of plant multiplication material (SR 916.151).

[77] Art. 9 CBD.

[78] See in particular International Treaty on Plant Genetic Resources for Food and Agriculture, Art. 5.1 and 15.

CITES[79]. But generally, provisions relating to ex-situ conservation of biological diversity may be found in a variety of legislations, including on forestry[80]; on the release of organisms in the environment[81]; on the protection of species[82]; on the protection of plant varieties; on plant multiplication material[83] and on a voluntary basis[84], as discussed hereinabove.

3. Situation in Switzerland *de lege ferenda*

3.1. The alternative: with or without international certificate of origin

At the present stage of the international negotiations on the establishment of an international access and benefit sharing regime, one alternative appears: either an international certificate of origin is established, or it is not. The choice has consequences at the national level. Before examining this alternative any closer, choices lying within the international regime relating to the concept of certificates of origin, source or legal provenance need to be addressed.

3.1.1. The concept of the certificates of origin, source, legal provenance

Options

There are several options regarding the type of system appropriate for the concept of the certificate of origin, source or legal provenance: a *legally binding system*, a *voluntary system* or a *mixed one*. Depending on the system chosen, the provider

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79 Ordinance on the Recognition as a Registered Scientific Organization by means of the Convention on the Convention on International Trade in Endangered Species of Wild Fauna and Flora of 20 October 1980 (SR 453.3).

80 Art. 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.

81 Release Ordinance, see above, Section 2.4.

82 See above Section 2.5.

83 Federal Law on the Protection of Plant Varieties of 20 March 1975 (SR 232.16) and its ordinance of application; Ordinance on the Production and Circulation of plant multiplication material (SR 916.151).

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

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[85].

Public Document 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.

Checkpoints 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).

Registry 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.

Content 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 prior informed consent (PIC) and mutually agrees terms (MAT)[86].

3.1.2. The case in which no international certificate is introduced

In the case no international certificate is introduced, the risk prevails that checkpoints will have difficulties in examining whether the legislation of a given party to the CBD on access and benefit sharing is respected. Such a scenario would imply that checkpoints are familiar with the legislation of all 191 parties to the CBD. It would also imply for those checkpoints to study numerous ABS contracts in the official languages of the contracting parties. In such a case, the control of the exis-

[85] Document UNEP/CBD/WG-ABS/5/7: Report of the meeting of the group of technical experts on an internationally recognized certificate of origin/source/legal provenance, Lima 22□25 January 2007, pp. 5 and 7, see www.cbd.int./meetings.

[86] Document UNEP/CBD/WG-ABS/5/7 (note 85), p. 8□11.

tence of a prior informed consent and of mutually agreed terms would hence prove to be problematic.

Declaration of source

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 within the Swiss authorities, and the same difficulties as described hereinabove would arise. The system based on the declaration of source is only possible in the case decisions have been published and are hence 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. In connection with the import of plants, animals, animal products, etc. the import permits are however 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 clearing house mechanism. 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, i.e. in the case 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 in some cases, 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 a case, 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.

3.1.3. The case in which an international certificate is introduced

Role of Checkpoints

The introduction of an international certification system (the content of which is subject to negotiation) would probably be the 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 under Section 3.1.2. above, 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.

Absence of certificate

If, in a specific case, an applicant were not to provide the certificate, the checkpoint could set a deadline for the applicant in order to provide 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.

Non-retroactivity

Neither the CBD nor the Bonn guidelines are of any help on the issue of timely application of ABS measures. The legal principal of non-retroactivity of laws implies in principle 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 to apply the system to new cases, i.e. 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. The case of a new use which would be found for a genetic resource already in circulation in Switzerland is also likely to arise. However, the principle of non-retroactivity cannot but apply in that case too: indeed, the principle of good faith requires that possessors of genetic resources be not imposed 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, bio-prospecting 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"[87]. Hence even in application of the principal of non-retroactivity, the system would be justified and useful.

3.2. Conceivable Checkpoints

3.2.1. 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 mutually agreed terms, etc).

3.2.2. Research Regulations and Voluntary Measures

For the time being, respect of the CBD provisions on access and benefit sharing 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 the university or the 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 FOEN in his capacity of focal point.

[87] UNU-IAS Report, Benefit Sharing in ABS: Options and Elaborations, 2009, p. 21 and references included therein.

It could however be foreseen to introduce a more binding measure, to be included in federal laws on research, which would link the finance of research projects including genetic resources by the Confederation to the respect of CBD as regard access and benefit sharing. Such 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.

3.2.3. Authorization Regime in the Pharmaceutical and Biotechnological Field

The Swiss Agency for Therapeutic Products (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[88], it could be envisaged to include standards relating to ABS in such a regulation.

Such could also be the case for phytosanitary products, which benefit of 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. In such a case, the requirement of proving the existence of a certificate could be waived at Swissmedic, where a copy of the patent documentation could 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 certificate is justified in view of the CBD, its international implementing regime and the applicable national laws.

3.2.4. Food and Agriculture

[88] See Art. 5–7 LTP.

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 Federal Office of Public Health, in the case of food, and the Federal Office for Agriculture, in the case of agricultural means of production) must take over the tasks of the checkpoint within the scope of the approval procedure.

3.2.5. Import Regulations

The import of genetic material into Switzerland can be made dependent on the 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 veterinarian service come into consideration as checkpoints; individual federal offices, such as the Federal Veterinary Office, the Federal Office for Agriculture and the Federal Office of Public Health 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 goal of making use of the genetic resources they contain. In addition, import regulations are of only limited value where movements of physical samples is not required because analysis of the samples has been done in the country of origin, and only the resulting information exported (over, for example, the internet)[89]. Import regulations are likewise unsuitable for the use of traditional knowledge.

Based on the above-named reasons, the import procedure comes into consideration as a means to review compliance with the ABS provisions only to a limited extent. A possibility would exist by defining certain product categories that are to be inspected upon import.

[89] Likewise skeptical UNU-IAS Report, User Measures (note 5), p. 26 et seq.

3.2.6. Other Fields

Plant varieties

In the case in which genetic resources have been necessary for the development of a new plant variety, it could also be foreseen that the Office for the protection of varieties, which is competent for the delivery of protection titles, would 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 Federal Office for Agriculture is competent.

Ex situ collections

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[90], on the release of organisms in the environment[91], on the protection of species[92], on the protection of plant varieties and on plant multiplication material[93]. It could be envisageable to foresee that the competent offices in those cases 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.

3.2.7. FOEN as Focal Point

The Federal Office for the Environment (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 in the case an international certification regime is established arises. Although each authorization procedure has its own specificities 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 e.g. in the procedures relating to dissemination of genetically altered organisms, non-native

[90] See note 80.
[91] See note 81.
[92] See above Section 2.5.
[93] See note 83.

invertebrate animals or pathogenic organisms or for the use of genetically altered organisms or pathogenic organisms in confined areas[94].

It could accordingly be envisaged, in particular in the above-mentioned cases, to centralize the examination of certificates from provider countries within FOEN. Such a way of proceeding could 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 the cases 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 in the case coordination is necessary, for instance where doubts appear as to authenticity of a certificate, and more generally, as a point of exchange of information in the clearing house mechanism.

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

3.3. Remedies

Article 27 CBD foresees a dispute settlement procedure between State parties through negotiation, mediation and arbitration. However, no procedure is foreseen in the case 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.

In the case no international certificate is introduced, the need for remedies may be felt in a less stringent way than in the case a certificate is introduced. In the first case, 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.

[94] See above, chapter 2.4.

In the case 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.

In principle, 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 certificate mentioned above, when the existence of these grounds can be proven by the applicant. The international regime would however have to define the following issues:

- Reasonable duration of administrative and judicial procedures for the grant - or refusal - of certificates;
- Case in which a state party to the CBD may refuse to issue a certificate;
- Case in which no certificate has to be presented;
- Respect of human rights;
- Possibly a definition of public order.

The same principals should apply in the case in which an applicant would not present a certificate, arguing that it had been refused to him on the basis of *reasons contrary to Swiss public order* (e.g. human rights, violation of the principle of good faith). However, applicants may only invoke public order in exceptional cases; the refusal of a certificate in the provider country must be in obvious contradiction with the Swiss legal order.

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 cases, no certificate has to be presented. However, the applicant would have to pre-

sent the reasons for which he was not able to obtain a certificate in the providing country.

4. 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 drugs, 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, by his declaring, e.g., that no genetic resources were being used, a revocation of the approval that has been granted comes 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 Protection of Species Ordinance for the Enforcement of the Washington Protection of Species Convention (CITES)[95].

5. Conclusion

A number of access and benefit sharing 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.

Declaration of source

In the case *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 foreseen, inspired from 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,

[95] Art. 33 et seq. of the Protection of Species Ordinance.

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 in the case the source had not been declared or if the declaration had included false information, but not in the case 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 clearing house mechanism 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.

Certificate

In the case *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 exam of the respect of said provisions, in the provider country, prior to the publication of a patent, or the grant of protection, production or marketing right. It is hence 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 Food and Agriculture Organization (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 as soon as no valid certificate would be provided, ensuring in that way that the providing country's ABS legislation be complied with already before the right is conferred, the latter being refused in the case a valid certificate is not presented.

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 hence be limited to the existence of the certificate.

Checkpoints in Switzerland should be established at a level which not only would ensure the respect of the CBD's ABS provisions, but which would also allow for 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 the case genetic resources are already in circulation prior to the introduction of the certification system, no certificate will be available or necessary.

Public awareness measures

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 access and benefit sharing principles on a voluntary basis. This would help ensure this respect for genetic resources having already been introduced in Switzerland before the entering into force of the new legal provisions.

Participation of the Offices

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

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