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**AD HOC OPEN-ENDED WORKING GROUP
ON ACCESS AND BENEFIT-SHARING**

Fifth meeting

Montreal, 8 - 12 October 2007

Item 3 of the Provisional Agenda *

**COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES AND OTHER RELEVANT
ORGANIZATIONS ON ISSUES OF RELEVANCE TO THE INTERNATIONAL REGIME
ON ACCESS AND BENEFIT-SHARING***Note by the Executive Secretary***INTRODUCTION**

1. In paragraph 6 of decision VIII/4 A, the Conference of the Parties requested the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to continue the elaboration and negotiation of the international regime and to complete its work at the earliest possible time before the tenth meeting of the Conference of the Parties.
2. In paragraph 3 of this decision, Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders were invited “to provide information regarding the inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing to the Secretariat of the Convention four months prior to the fifth meeting of the Working Group on Access and Benefit sharing” and the Secretariat, in paragraph 4, is requested to prepare a compilation of the information provided and to make it available to the Working Group.
3. In paragraph 8 of the same decision, Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders are invited “to submit to the Secretariat further information relevant to the gap analysis” and, in paragraph 9, the Executive Secretary is requested “to prepare, for the fifth meeting of the Working Group on Access and Benefit-sharing, the final version of the gap analysis referred to in decision VII/19 D, annex, paragraph (a) (i)...”.
4. In paragraph 10 of decision VII/4 A, Parties are invited “to submit to the Executive Secretary information on the legal status of genetic resources in their national law, including their property law where applicable”, and the Executive Secretary is requested “to submit a report to the fifth meeting of the Working Group”.

* UNEP/CBD/WG-ABS/5/1.

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5. Further to that request, notification 2006-045 of 25 May 2006 was sent to Parties and Governments, and a reminder (notification 2007-030) was sent on 9 March 2007.

6. In light of the above, this document contains a compilation of submissions provided by Parties and relevant organizations on: 1) existing legal and other instruments at national, regional and international levels 2) the gap analysis and 3) the legal status of genetic resources in their national law.

7. Please note that inputs related to the matrix on the analysis of gaps already made available for the fourth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing are not included in this document.

8. The contributions are made available in the form and language in which they were received. In addition, English translations are also available in this document for contributions received in another language.

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1) COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES AND RELEVANT ORGANIZATIONS ON THE EXISTING LEGAL AND OTHER INSTRUMENTS AT NATIONAL, REGIONAL AND INTERNATIONAL LEVELS

I. SUBMISSIONS FROM PARTIES

COLOMBIA

4. Aportes al análisis de los instrumentos legales y otros vigentes a nivel nacional, regional e internacionales relacionados con acceso y distribución de beneficios.

La formulación de instrumentos de política en materia de recursos genéticos debe partir de los siguientes principios fundamentales:

- Los RG son de importancia crucial para países megadiversos, que son los países de origen y los centros de diversidad de esos recursos genéticos, así como de sus aplicaciones en las áreas tecnológicas, económicas y socio culturales.
- Los mecanismos de acceso a los recursos genéticos y al conocimiento tradicional deben asegurar la conservación y el uso sostenible de la diversidad biológica con todo tipo de beneficios, incluyendo:
 - Beneficios monetarios
 - Transferencia de tecnología
 - Desarrollo de productos de valor agregado
 - Mejora de las economías a favor de los habitantes, particularmente las comunidades locales.
- Es necesario promover la bioprospección y la biotecnología de modo consistente con el uso sostenible de recursos biológicos y genéticos, de acuerdo con las leyes y políticas nacionales y para prevenir la biopiratería, así como el acceso ilegal a los recursos genéticos y al conocimiento tradicional.
- Los recursos genéticos son patrimonio del país, y por lo tanto su conservación y aprovechamiento deben beneficiar al conjunto de la nación colombiana.
- Es obligación del Estado Colombiano velar por la protección y el buen uso de los recursos genéticos y del conocimiento tradicional asociado.
- Es necesario proteger los derechos del país y de las comunidades sobre los recursos genéticos y el conocimiento tradicional.

- El Estado debe promover el acceso y aprovechamiento sostenible de los recursos genéticos con el fin de generar beneficios de dichas actividades.
- La valoración de los recursos genéticos y la obtención de beneficios de distinto orden contribuyen a crear incentivos para la conservación y el aprovechamiento sostenible de los recursos genéticos.
- Si bien la Decisión 485 de 2000 de la Comunidad Andina prohíbe el patentamiento de la materia viva tal y como se encuentre en la naturaleza, el alcance del Régimen de Acceso a Recursos Genéticos en términos de la protección que este ofrezca a través de los instrumentos del Derecho de Propiedad Intelectual debe reconocer algún tipo de protección – bien sea vía DPI o un sistema "sui generis" – para los desarrollos que a partir de esta materia viva se alcancen por medio de la biotecnología.
- La diversidad biológica y genética está íntimamente relacionada con la diversidad única y cultural.
- El régimen de acceso y el sistema de protección del Conocimiento Tradicional deben estar íntimamente relacionados, teniendo en cuenta que el régimen de acceso debe reconocer y proteger los derechos de las comunidades indígenas y locales sobre sus Conocimientos Tradicionales.
- El conocimiento tradicional tiene un carácter holístico, al resultar de la cultura y la forma de vida de las comunidades.
- El conocimiento tradicional es parte del patrimonio cultural de la nación y pertenece a las comunidades indígenas y locales.
- El régimen de acceso y aprovechamiento de los recursos genéticos debe ser costo efectivo, con miras a minimizar los costos de transacción como mecanismo para mejorar la competitividad de la bioprospección en el país respecto a actividades similares en el mercado global.
- El Estado velará porque los acuerdos de distribución de beneficios sean justos y equitativos, y que garanticen que en el desarrollo de los mismos se respeten los derechos de las comunidades locales y grupos étnicos.
- El país reconoce y valora la importancia que tienen la diversidad cultural y el conocimiento tradicional en el contexto multiétnico de la nación, así como su contribución al desarrollo de la sociedad y del conocimiento humano.
- La Política Nacional de Recursos Genéticos debe ser coherente y armónica con las áreas temáticas relacionadas de biotecnología, bioseguridad, propiedad intelectual, entre otras.

CONSIDERACIONES EN LOS OBJETIVOS DE LA POLÍTICA.

Los objetivos del Régimen de Acceso y por ende de una Política Pública en esta materia, deben tener en cuenta los siguientes elementos:

Objetivo general:

Mejorar la capacidad nacional para administrar el acceso a recursos genéticos y distribuir justa y equitativamente los beneficios derivados de dicho acceso con miras a alcanzar un aprovechamiento sostenible de los recursos genéticos, productos derivados y componente intangible, como fuente de desarrollo para el país.

Objetivos específicos:

- Reconocer y proteger los derechos del país sobre los recursos genéticos y de las comunidades locales y grupos étnicos sobre el conocimiento tradicional asociado a dichos recursos.
- Promover el uso sostenible de los Recursos Genéticos con el fin de contribuir con el desarrollo social, económico y ambiental del país.
- Asegurar una distribución justa y equitativa de los beneficios que se deriven del acceso a los Recursos Genéticos.
- Promover la conservación y la utilización sostenible de la biodiversidad.

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- Garantizar una valoración adecuada¹ de los Recursos Genéticos y fortalecer la capacidad negociadora del país.
- Mejorar la capacidad nacional para aprovechar el potencial de los Recursos Genéticos mediante la producción de bienes y servicios que le den valor agregados a los mismos.
- Fortalecer la capacidad de las comunidades locales y grupos étnicos para utilizar y aprovechar de manera sostenible los Recursos Genéticos.
- Reforzar la capacidad científica y tecnológica del país con el fin de apoyar las diversas actividades relacionadas con el aprovechamiento y el acceso de los Recursos Genéticos.
- Desarrollar y mejorar el marco regulatorio sobre acceso y aprovechamiento de los recursos genéticos, y productos derivados.

ESTRATEGIAS DE LA POLITICA DE RECURSOS GENETICOS

El tema de acceso a recursos genéticos cobra importancia con la expedición del Convenio sobre Diversidad Biológica, el cual dispone que los Estados tienen el derecho soberano de explotar sus propios recursos en aplicación de su propia política ambiental y la obligación de asegurar que las actividades que se llevan a cabo dentro de su jurisdicción o bajo su control no perjudiquen el medio ambiente de otros Estados o de zonas situadas fuera de su jurisdicción nacional.

Se requiere adelantar acciones tendientes al fortalecimiento de la capacidad institucional con el fin de dar respuesta a los rápidos y permanentes avances que se presentan en materia de RG. Se hace por tanto necesario contar con un adecuado nivel científico y tecnológico, que con criterios éticos, de sostenibilidad, competitividad y efectividad de las políticas públicas para la protección al medio ambiente, sirva como un instrumento de apoyo para la formulación y ejecución de los Planes y Programas Nacionales de Desarrollo.

En este sentido, la Política Nacional de Recursos Genéticos deberá ser concertada entre todas las instituciones, el sector privado, académico y de investigación y las comunidades, con la implementación de las siguientes Estrategias y Líneas de Acción:

Líneas de Acción Identificadas

1. Desarrollar y ajustar el Marco Jurídico sobre Acceso y Aprovechamiento Sostenible de los RG.

En Colombia rige el régimen de Acceso a Recursos Genéticos establecido por la Decisión 391 de 1996 de la Comunidad Andina de Naciones, el cual hasta el momento ha tenido escasa aplicación práctica en cumplimiento de sus objetivos centrales: Establecimiento de condiciones para la participación justa y equitativa en los beneficios derivados del acceso; Promoción de la consolidación y el desarrollo de las capacidades científicas, tecnológicas y técnicas y Fortalecimiento de la capacidad negociadora del país como miembro de la Comunidad Andina.

Varias causas han sido identificadas como factores de la no aplicación de la Decisión 391: Falta de prioridad en las políticas públicas; Altos costos de transacción resultantes de los sistemas de procedimiento; Complejidad en el sistema de contratación; Problemas de interpretación en cuanto a régimen de propiedad, ámbito de aplicación y beneficios; Falta de instrumentos para la protección del conocimiento tradicional, y Débil capacidad institucional para la evaluación, control y seguimiento. Se evidencian así las dificultades en cuanto al control práctico del acceso, teniendo en cuenta que el Convenio sobre la Diversidad Biológica establece sólo los principios generales para el mismo, dejando la dimensión específica del procedimiento a lo que dispongan las legislaciones nacionales.

¹ En este sentido, deben evaluarse las diferentes metodologías de valoración de recursos naturales que aplicarían para la valoración del recurso genético y su alcance. Deben tenerse en cuenta nociones como el costo fracción del recurso natural, costo de extracción, costo de transformación, costo intangible (know how), valor potencial esperado (valor presente de los ingresos obtenidos y/o esperados).

Se evidencia entonces la necesidad de identificar las posibles soluciones que permitan consolidar un régimen de acceso que sea eficaz para la protección de los derechos del país sobre los recursos genéticos, productos derivados y componente intangible asociado, a la vez que posibilite su aprovechamiento sostenible y la obtención y distribución equitativa de sus beneficios derivados en aras de aprovechar la biodiversidad y los RG como una real ventaja comparativa para el desarrollo del país.

El desarrollo de este diagnóstico tiene por objeto identificar las limitaciones y mejoras necesarias en el régimen jurídico sobre acceso y distribución de beneficios establecido en la Decisión 391, de manera que esta sea un mecanismo que lejos de desincentivar, asimile las prácticas legales de acceso y permita que el país obtenga beneficios tangibles a partir de sus derechos sobre los RG y se convierta en un instrumento que incentive el desarrollo de la capacidad nacional para el aprovechamiento de la diversidad biológica, aplicando criterios de agilidad, transparencia, competitividad y bajos costos de transacción.

Para estos efectos, es necesario avanzar en aspectos relacionados con:

- Reglamentación de procedimientos de acceso a RG ágiles y determinación de tiempos y creación de un Comité de Expertos Interinstitucional en Acceso a Recursos Genéticos.
- Simplificación de trámites y procedimientos del sistema de Contratos de Acceso
- Clarificación de ámbito e interpretación en aspectos de régimen de propiedad, derechos de proveedores y solicitantes, definición de exclusiones y tratamientos diferenciados según la finalidad en las solicitudes de acceso.
- Reglamentación independiente para definir las formas de beneficios (tanto monetarios como no monetarios) y del mecanismo legal para su distribución.
- Definición de los elementos de un Sistema de Protección "sui generis" instrumentos para la Protección del Conocimiento Tradicional
- Establecimiento de un Certificado Legal de Origen de los RG para efectos de aplicación de los instrumentos de Propiedad Intelectual o Industrial en el marco de la Convención sobre Diversidad Biológica.
- Fortalecimiento de la Capacidad Institucional para la evaluación, seguimiento y control.

2. Fortalecer la Cadena de Adición de Valor de los RG y Productos Derivados:

Los objetivos, líneas de acción y estrategias de una política pública en RG deben superar las consideraciones ambientales e involucran el aparato productivo del país. La capacidad de aprovechamiento depende de la cadena de adición de valor, la cual está constituida por diferentes sectores económicos y productivos y actores sociales, que intervienen en distintas etapas del desarrollo de productos y servicios derivados del uso de los RG. La cadena de adición de valor está integrada en general por las actividades de la comunidad científica y académica, el sector privado, el sector público y las comunidades locales. Desde el punto de vista productivo, esta cadena involucra y conecta las actividades de distintos ámbitos como el agrícola, farmacéutico, agroindustria y cosmética, con las actividades de investigación y conservación de los RG. Esta Estrategia responde a las metas de interés social y a las limitantes para la optimización de los niveles de producción según las tendencias tanto nacionales como internacionales de los mercados y en aspectos institucionales, sociales y legales, mediante la definición de acciones de impacto positivo sobre el desarrollo socioeconómico, la competitividad, la calidad de vida y el uso y aprovechamiento sostenible de la base de recursos naturales para la optimización y posicionamiento de las ventajas comparativas que ofrece el país.

Por estos efectos se deberán adelantar acciones en el marco de las Líneas de Acción de:

- Promoción y conservación in situ y ex situ de los RG y Productos Derivados por parte del sector público y privado.
- Promoción de la recuperación, protección y fomento del Conocimiento Tradicional.

- Fortalecimiento de los sistemas de inventarios y colecciones de los RG y de la capacidad científica nacional asociada para incorporarlas al Mecanismo de Facilitación del Convenio sobre Diversidad Biológica y el Protocolo de Cartagena sobre Seguridad en la Biotecnología.
- Fomento a la capacidad nacional para adelantar acciones de Bioprospección en forma competitiva.
- Promoción al desarrollo de la industria nacional con miras al aprovechamiento sostenible de los RG a través del fortalecimiento de cadenas para la adición de valor a los RG y promoción de Alianzas Estratégicas utilizando instrumentos de política como los incentivos tributarios y los programas de responsabilidad social corporativa.

3. Fortalecer la Capacidad Institucional para la Aplicación de la Política de RG.

Teniendo en cuenta el carácter altamente especializado de los asuntos relacionados con el aprovechamiento y acceso de los RG, se requiere garantizar la capacidad institucional para aplicar de manera eficaz la Política en RG. Como resultado de las acciones que se deriven de lo presentado en el presente diagnóstico se busca que el país cuente con criterios y procedimientos claros que permitan solucionar las limitaciones evidenciadas en aspectos de transferencia tecnológica, derechos de propiedad intelectual, participación de los sectores científico, académico y comunitario, distribución de beneficios, entre otros. Así mismo, se propenderá por el fortalecimiento y consolidación de la capacidad nacional para la solución de problemas cruciales, con especial énfasis en el fortalecimiento de grupos de investigación, desarrollo y gestión, con miras a consolidar la capacidad nacional requerida para seleccionar, desarrollar, adecuar, aprovechar e implementar tecnologías que respondan a las condiciones específicas nacionales o regionales, que produzcan impactos favorable en el desarrollo socioeconómico del país, con criterios éticos, de protección al medio ambiente, sostenibilidad, competitividad y beneficio social.

En tal sentido, se adelantarán acciones de fortalecimiento institucional en materia de:

- Atención y resolución de las solicitudes de acceso a RG de manera ágil y oportuna, supeditadas al cumplimiento de los requerimientos establecidos en los procedimientos internos.
- Definición de criterios de negociación a nombre del Estado en los Contratos de Acceso y fortalecimiento de la capacidad de negociación.
- Creación de capacidad institucional para prestar asesoría técnica y jurídica a los solicitantes en la formulación y desarrollo de iniciativas de acceso y en el seguimiento a las solicitudes.
- Seguimiento, monitoreo y control de las obligaciones y responsabilidades en materia de RG.
- Promoción de las actividades dirigidas a mejorar la capacidad nacional para el aprovechamiento de los RG, en particular las relacionadas con Bioprospección, Inventarios y colecciones.
- Mecanismos de distribución justa y equitativa de beneficios monetarios y no monetarios derivados de las actividades de acceso a RG.

ENGLISH TRANSLATION

- Contributions to the analysis of legal and other instruments in effect at the national, regional and international level with regard to access and benefit sharing.

The drafting of policy instruments with regard to genetic resources should draw on the following basic principles:

- Genetic resources (GR) are of crucial importance for megadiverse countries, which are countries of origin and centres of diversity for said genetic resources, as are these resources' applications in technological, economic and sociocultural spheres.
- Mechanisms for access to genetic resources and traditional knowledge must ensure the conservation and sustainable use of biological diversity through all types of benefits, including:
 - Monetary benefits
 - Technology transfer
 - The Development of value added products
 - Economy enhancements to the benefit of inhabitants, particularly local communities.
- It is necessary to promote bioprospecting and biotechnology in a manner consistent with the sustainable use of biological and genetic resources, in accordance with national laws and policies, and to prevent biopiracy and illegal access to genetic resources and traditional knowledge.
- Genetic resources belong to the country's heritage, and their conservation and exploitation must therefore benefit the Colombian nation as a whole..
- It is the Colombian State's obligation to ensure the protection and proper use of genetic resources and associated traditional knowledge.
- It is necessary to protect the country's and communities' rights over genetic resources and traditional knowledge.
- The State must promote access to and sustainable exploitation of genetic resources for the purpose of generating benefits from said activities.
- Attributing value to genetic resources and obtaining benefits of various types from said resources help create incentives for the conservation and sustainable use of genetic resources.
- *Although Andean Community Decision 486 of 2000 prohibits patents on living matter found in nature, the scope of the Regime for Access to Genetic Resources, with regard to the protection it offers through Intellectual Property Rights Instruments, must recognize some type of protection – be it through Intellectual Property Rights or a “sui generis” system – for the developments achieved through biotechnology using said living matter.*
- Biological and genetic diversity is intimately linked to ethnic and cultural diversity.
 - The Regime for Access and the system for the protection of traditional knowledge must be intimately linked, taking into account the fact that the regime for access must recognize and protect the rights of indigenous and local communities over their Traditional Knowledge.
 - Traditional knowledge is holistic in nature, seeing as it arises from communities' culture and lifestyle.
 - Traditional knowledge is part of the nation's cultural heritage and belongs to indigenous and local communities.
 - The Regime for access and exploitation of genetic resources must be cost-effective, with a view to minimizing transaction costs as a means of enhancing the competitiveness of bioprospecting in the country in relation to similar activities on the global market.
 - The State shall ensure that benefit-sharing agreements are fair and equitable, and that their application guarantees respect for the rights of local communities and ethnic groups.
 - The country recognizes and values the importance of cultural diversity and traditional

- knowledge in the nation's multiethnic context, and their contribution to the development of society and of human knowledge.
- The National Policy on Genetic Resources must be consistent and in harmony with the thematic areas linked to biotechnology, biosafety, and intellectual property, among others.

CONSIDERATIONS WITH REGARD TO THE POLICY'S OBJECTIVES

The objectives of the Regime of Access, and therefore of public policy on this issue, must take into account the following elements.

Overall objective:

Build national capacity to administrate access to genetic resources and distribute the benefits arising from said access in a fair and equitable manner, with a view to achieving sustainable exploitation of genetic resources, their by-products and intangible components, as a source of development for the country.

Specific objectives:

- Recognize and protect the country's rights over genetic resources, and the rights of local communities and ethnic groups over traditional knowledge associated with said resources.
- Promote the sustainable use of Genetic Resources, aimed at contributing to the country's social, economic and environmental development.
- Ensure fair and equitable sharing of the benefits arising from access to Genetic Resources.
- Promote the conservation and sustainable use of biodiversity.
- Guarantee that Genetic Resources are assessed at their proper value¹ and strengthen the country's negotiating capacity.
- Enhance national capacity to exploit the potential of Genetic Resources through the production of goods and services that add value to said resources.
- Build the capacity of local communities and ethnic groups to sustainably exploit and use Genetic Resources.
- Build the country's scientific and technical capacity, in order to support the various activities linked to the exploitation of and access to Genetic Resources.
- Develop and improve the regulatory framework for access to and exploitation of genetic resources and their by-products.

STRATEGIES OF THE POLICY ON GENETIC RESOURCES

The issue of access to genetic resources took on importance with the coming into effect of the Convention on Biological Diversity, which stipulates that States have the sovereign right to exploit their own resources as part of the implementation of their own environmental policy, and the obligation to ensure that the activities carried out within their jurisdiction or under their control do not adversely affect the environment of other States or areas located outside of their national jurisdiction.

Activities are required to help build institutional capacity, in order to keep pace with the fast and permanent progress being made in the area of genetic resources. It is therefore necessary to have a proper level of scientific and technological development which, in conjunction with ethical criteria and criteria such as sustainability, competitiveness and effectiveness of public policy for environmental protection,

¹ In this respect, it is necessary to evaluate the various natural resource valuation methods that could apply to assessing the value of genetic resources, and their scope. It is important to keep in mind concepts such as the cost of fractioning the natural resource, extraction costs, processing costs, intangible costs (know-how), expected potential value (current cost of obtained and/or expected gain).

can be used as an instrument to support the formulation and execution of National Development Plans and Programs.

In this respect, the National Policy on Genetic Resources must be coordinated among all institutions, the private sector, the academic and research sector and communities, with the implementation of the following Strategies and Courses of Action:

Identified courses of action

1. Develop and adapt the Legal Framework on Access and Sustainable Exploitation of Genetic Resources

In Colombia, the Regime for Access to Genetic Resources, established by Andean Community Decision 391 of 1996, is in effect. Up until now, it has had very little practical application with regard to fulfilling its central aims: Establishing the conditions for just and equitable sharing of the benefits arising from access; Promoting the consolidation and development of scientific, technological and technical capacities; and strengthening the negotiating capacity of the Member Countries of the Andean Community.

Various causes have been identified as factors in the non-application of Decision 391: lack of priority in public policies; high transaction costs due to procedural systems; complexity of the contract system; interpretation problems with regard to the property regime, the scope of application and benefits; lack of instruments to protect traditional knowledge, and weak institutional capacity for evaluation, monitoring and control. This reflects the difficulties inherent to practical control of access, taking into account that the Convention on Biological Diversity only establishes the general principles for access, leaving the specifics of the process up to national legislation.

There is therefore an obvious need to identify potential solutions that would make it possible to consolidate a regime of access that would be effective in protecting countries' rights over genetic resources, by-products and associated intangible components, while enabling the sustainable exploitation of genetic resources and the achievement and equitable distribution of benefits arising from their use, for the purpose of exploiting the biodiversity of genetic resources as a real comparative advantage for the country's development.

This diagnosis is aimed at identifying the limitations of and necessary improvements to the legal regime of access and benefit sharing established in Decision 391, to make it a mechanism that, far from acting as a disincentive, will stimulate legal access practices, and enable the country to achieve tangible benefits from its rights over Genetic Resources, thus becoming an instrument that will create an incentive for development of national capacity to exploit biological diversity, using criteria such as speed, transparency, competitiveness and low transaction costs.

To achieve this, it is necessary to move forward in aspects linked to:

- Regulating fast processes for access to GR, setting timetables and creating an Inter-institutional Committee of Experts on Access to Genetic Resources.
- Simplifying the steps and procedures involved in the Access Contracts system
- Clarifying the scope and interpretation of aspects of the property regime, the rights of providers and applicants, defining exclusions and different treatments according to the purpose of the access application
- Independent regulations to define the types of benefits (both monetary and non-monetary) and the legal mechanism for benefit sharing.
- Defining the elements of a system of "sui generis" instruments for the protection of Traditional Knowledge
- Establishing a Certificate of Legal Origin of the GR for the application of intellectual or industrial

- property protection within the framework of the Convention on Biological Diversity.
- Building Institutional Capacity for evaluation, follow-up and monitoring.

2. Strengthening the added value chain for GR and their by-products:

The objectives, courses of action and strategies of a public policy on GR must transcend environmental considerations and encompass the country's production apparatus. The capacity for exploitation depends on the added value chain, which is made up of various economic sectors, production sectors, and social actors, who intervene at different stages in the development of products and services arising from the use of genetic resources. The value added chain is generally composed of activities carried out by the academic and scientific community, the private sector, the public sector and local communities. From the production point of view, this chain involves and connects activities in different spheres, such as agriculture, pharmaceuticals, agro-industry, and cosmetics, along with GR research and conservation activities. This strategy meets social interest goals and is sensitive to limitations on the optimization of production levels based on national and international market trends, and based on institutional, social and legal aspects, through the definition of actions that have a positive impact on socio-economic development, competitiveness, quality of life and sustainable use and exploitation of the natural resource base for optimization and positioning of the country's comparative advantages.

For these purposes, action should be taken within the framework of Courses of Action to:

- Promote and conserve RG and by-products in *in situ* and *ex situ* conditions, by both the public and private sector.
- Promote the recovery, protection and fostering of Traditional Knowledge.
- Strengthen inventory systems and collections of GR, and build associated national scientific capacity to incorporate them into the Clearinghouse Mechanism of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.
- Foster national capacity to carry out bioprospecting activities on a competitive basis. Promote the development of national industry with the aim of sustainable exploitation of GR by strengthening value added chains for GR and by promoting strategic alliances using policy instruments such as tax incentives and corporate social responsibility programs.

3. Institutional Capacity Building for Implementation of the Policy on GR.

Taking into account the highly specialized nature of matters linked to the exploitation of and access to GR, it is necessary to guarantee institutional capacity to effectively implement the Policy on GR. As a result of the actions arising from the situation presented in this diagnosis, the goal is for the country to have clear criteria and procedures that will make it possible to resolve the limitations found with respect to technology transfer, intellectual property rights, the participation of scientific, academic and community sectors, benefit sharing, and other issues. There will likewise be pressure to strengthen and consolidate national capacity to solve crucial problems, with particular emphasis on strengthening research, development and management groups, in order to consolidate the national capacity required to select, develop, adapt, exploit and implement technologies that meet specific national or regional conditions, and produce positive impacts on the country's socio-economic development, consistent with ethical criteria and environmental protection, sustainability, competitiveness and social benefit criteria.

Institutional strengthening activities will therefore be carried out in the following areas:

- Addressing and resolving applications for access to GR in a fast and timely manner, subject to compliance with the established requirements of internal procedures.

- Defining the criteria for negotiating Access Contracts on behalf of the State, and strengthening negotiation capacity.
- Institutional capacity-building to provide technical and legal advice to applicants when formulating and developing access initiatives, and when following through with applications.
- Tracking, monitoring and controlling obligations and responsibilities with regard to GR.
- Promoting activities aimed at enhancing national capacity for exploiting GR, particularly those linked to Bioprospecting, Inventories and collections.
- Mechanisms for the fair and equitable sharing of monetary and non-monetary benefits arising from GR access activities.

COSTA RICA

ANÁLISIS DE LOS INSTRUMENTOS JURÍDICOS Y EXTRAJURÍDICOS EXISTENTES A ESCALA NACIONAL, REGIONAL, INTERNACIONAL EN MATERIA DE ACCESO Y PARTICIPACIÓN EN LOS BENEFICIOS:

A continuación se enumeran algunos de los instrumentos jurídicos y extrajurídicos, a escala internacional, regional y finalmente nacional, que poseen mayor relevancia en el tema de Acceso a recursos genéticos y Participación de Beneficios para Costa Rica²

A nivel Internacional, el Convenio sobre la Diversidad Biológica (CBD) constituye al igual que para muchos Países, el instrumento jurídico base para la redacción e implementación de sus respectivos instrumentos regionales y nacionales.

a) El Convenio sobre Diversidad Biológica fue ratificado por Costa Rica mediante la Ley N° 7416 de 30 de junio de 1994, publicada en el Diario Oficial La Gaceta N° 143 de 28 de julio de 1994.

b) El año anterior, nuestro país ratificó el Tratado Internacional de Recursos Fitogenéticos para la Alimentación y la Agricultura, por medio de la Ley N° 8539 del 17 de julio del 2006 publicado en el Diario Oficial La Gaceta N° 185 del 25 de setiembre del 2006.

Con la finalidad de implementar en nuestro país este Instrumento Jurídico Internacional, se ha incorporado en el Decreto Ejecutivo N° 33697-MINAE, del 6 de febrero del dos mil siete, publicado en el Diario Oficial La Gaceta N° 74 del 18 de abril del 2007: “Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en condiciones *ex situ*”, una norma transitoria, en la cual se establece, que en tanto no exista una normativa jurídica específica, que pudiera establecer otra disposición al respecto, la Autoridad Nacional para la aplicación de dicho Tratado en el tema de acceso a los recursos fitogenéticos para la alimentación y la agricultura, será la Comisión Nacional para la Gestión de la Biodiversidad, en adelante CONAGEBIO y su Oficina Técnica, de conformidad con la Ley de Biodiversidad N° 7788 y el Decreto Ejecutivo MINAE- N° 31514, para lo cual la CONAGEBIO y su Oficina Técnica utilizarán como órgano de consulta a la Comisión Nacional de Recursos Fitogenéticos (CONAREFI).

c) En relación a la regulación internacional de los Pueblos Indígenas, se ratificó el Convenio 169 sobre Pueblos Indígenas y Tribales, aprobado mediante la Ley N°. 7316 del 03 de noviembre de 1992, publicada en el Diario Oficial La Gaceta N° 234 del 04 de diciembre del 1992.

² En este documento se utilizarán los siguientes acrónimos:

ADPIC: Acuerdo sobre los aspectos de Propiedad Intelectual relacionados con el comercio
CBD: Convención sobre Diversidad Biológica
CONAGEBIO: Comisión Nacional para la Gestión de la Biodiversidad
CONAREFI: Comisión Nacional de Recursos Fitogenéticos
MINAE: Ministerio del Ambiente y Energía
OMPI: Organización Mundial para la Propiedad Intelectual
UNEP: Siglas en inglés del PNUMA: Programa de las Naciones Unidas para el Medio Ambiente
UPOV: Convenio Internacional para la Protección de las Obtenciones Vegetales
WEF: Siglas en inglés: World Economic Forum

d) Protocolo de Cartagena sobre Seguridad de la Biotecnología, fue ratificado por Costa Rica mediante la Ley N° 8537 de 17 de julio de 2006, publicada en el Diario Oficial La Gaceta N° 227 de 27 de noviembre de 2006.

Para el cumplimiento de algunos de los compromisos internacionales adquiridos por nuestro País, con la ratificación del CBD y el Protocolo de Cartagena en particular, la Comisión Técnica Nacional de Bioseguridad, preparó hace algunos meses, como parte del Proyecto UNEP-GEF, una propuesta la Ley de Bioseguridad de Organismos Vivos Modificados y sus Derivados, la cual no ha sido presentada aun ante la Asamblea Legislativa costarricense.

e) Directrices de Bonn sobre Acceso a los Recursos Genéticos y Participación Justa y Equitativa en los Beneficios Provenientes de su Utilización del Convenio de Diversidad Biológica.

Al aprobarse las Directrices, ya nuestro país contaba con un borrador bastante adelantado del actual Decreto Ejecutivo N° 31514-MINAE el cual regula el acceso a los elementos y recursos Genéticos y bioquímicos de la biodiversidad; sin embargo al revisarse este borrador se concluyó por parte de la Oficina Técnica de la CONAGEBIO, que ambos instrumentos eran totalmente congruentes.

f) Directrices Akwe: *Kon*

Los principios estipulados en estas Directrices, serán tomados como insumos al realizar el proceso participativo, necesario en nuestro país, para determinar la naturaleza, los alcances y requisitos de los derechos intelectuales comunitarios *sui generis*.

g) Convenios Internacionales relacionados con el tema de propiedad intelectual:

Dentro de estos instrumentos Internacionales se encuentran los siguientes:

- Convenio de París para la protección de la Propiedad Industrial y sus enmiendas, ratificado mediante la Ley N° 7484 del 28 de marzo de 1995, publicada en el Diario Oficial La Gaceta N° 99 Alcance 18 del 24 de mayo de 1995.

- Convención que establece la Organización Mundial de la Propiedad Intelectual (OMPI), ratificado mediante la Ley N° 6468 del 18 de setiembre de 1980: Autoriza la adhesión de Costa Rica a la Convención que establece la Organización Mundial de la Propiedad Intelectual, firmado en Estocolmo el 14 de julio de 1967.

- Tratado de Cooperación en Materia de Patentes y su Reglamento, ratificado mediante la Ley N° 7836 del 22 de octubre de 1998, publicado en el Diario Oficial La Gaceta N° 232 del 30 de noviembre de 1998.

- Tratado de la OMPI sobre Derechos de Autor, ratificado mediante la Ley N° 7968 del 22 de diciembre de 1999, publicado en el Diario Oficial La Gaceta N° 23 del 02 de febrero del 2000.

- Convenio de Lisboa relativo a la Protección de las Denominaciones de Origen y su Registro Internacional, ratificado mediante la Ley N° 7634, del 3 de octubre de 1996, publicado en el Diario Oficial La Gaceta N° 208 del 30 de octubre de 1996.

- Acuerdo de Marrakech Constitutivo de la Organización Mundial del Comercio, Ley N° 7475 del 20 de diciembre de 1994, publicado en el Diario Oficial La Gaceta N° 245 Alcance 40 del 26 de diciembre del 1994. En el cual se incluye como Anexo 1C el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC).

A nivel Regional,

En el tema de Acceso y Participación de Beneficios para Costa Rica, encontramos específicamente el siguiente instrumento con carácter regional no vinculante:

-Acuerdo Centroamericano para el Acceso a Recursos Genéticos y Bioquímicos y al Conocimiento Tradicional Asociado:

Este instrumento regional, a la fecha ha sido aprobado únicamente por los Ministros de Ambiente de Centroamérica, por lo que aún resta que sea aprobado por los Cancilleres de cada país y ratificado posteriormente por al menos cuatro países.

En Costa Rica cuando se firmó el Acuerdo por parte de los Ministros de Ambiente Centroamericanos, ya regía la Ley de Biodiversidad, sin embargo este instrumento ha servido de marco guía para la redacción de normativa, en el resto de los países de la Región.

A nivel Nacional.

a) Ley de Biodiversidad N° 7788 del 30 de abril de 1998, publicada en el Diario Oficial La Gaceta N° 101 del 27 de mayo de 1998.³:

Es el instrumento nacional base, a través del cual, se regulan y aplican los objetivos del Convenio sobre Diversidad Biológica en forma clara y precisa.

Dentro de los aspectos con mayor importancia que establece esta normativa, encontramos los siguientes:

- Establece como objetivo general, la conservación de la biodiversidad y el uso sostenible de los recursos, así como la distribución justa y equitativa de los beneficios y costos derivados.
- Dispone que las propiedades bioquímicas y genéticas de los elementos de la biodiversidad silvestres y domesticados son de dominio público y que el Estado autorizará la exploración, la investigación, la bioprospección, el uso y el aprovechamiento de los elementos de la biodiversidad que constituyen bienes de dominio público, así como la utilización de todos los recursos genéticos y bioquímicos, por medio de las normas generales de acceso.
- En materia de definiciones, incluye algunas que no se encuentran en el CBD, pero que son necesarias para su interpretación.
- Crea la Comisión Nacional para la Gestión de la Biodiversidad, en adelante CONAGEBIO y la declara como Autoridad Nacional, para regular el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad. Además le asigna entre otras funciones: la Formulación de las políticas referentes a la conservación, el uso sostenible y la restauración de la biodiversidad, sujetándose a la Convención sobre Diversidad Biológica y a otros convenios y tratados internacionales, así como a los intereses nacionales.
- Establece expresamente que a la CONAGEBIO le corresponde proponer las políticas de acceso sobre los elementos genéticos y bioquímicos de la biodiversidad *ex situ* e *in situ* y que actuará

³ El texto completo de la Ley de Biodiversidad, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

como órgano de consulta obligatoria en los procedimientos de solicitud de protección de los derechos intelectuales sobre la biodiversidad, constituyendo sus disposiciones, las normas generales para el acceso a los elementos genéticos y bioquímicos y para la protección de los derechos intelectuales sobre la biodiversidad a las que deberán someterse la administración y los particulares interesados.

- En materia asociada a la propiedad intelectual regula de forma pionera, que obligatoriamente tanto la Oficina Nacional de Semillas como el Registro Nacional de la Propiedad Industrial, deben consultar a la Oficina Técnica de la Comisión antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Asimismo establece que el interesado deberá aportar el certificado de origen emitido por la Oficina Técnica y el Consentimiento Previamente Informado, y en el caso de que existiere oposición fundada por parte de la Oficina Técnica, esto impedirá registrar la patente o protección de la innovación.
- Reconoce y protege expresamente bajo el nombre de Derechos Intelectuales Comunitarios *Sui Generis*, los conocimientos, las prácticas y las innovaciones de los pueblos indígenas y comunidades locales, relacionadas con el empleo de los elementos de la biodiversidad y el conocimiento asociado.
- Establece la necesidad de que la Oficina Técnica de la CONAGEBIO, en asocio a la Mesa Indígena y la Mesa Campesina, defina un proceso participativo con las comunidades indígenas y campesinas, para determinar la naturaleza, alcances y requisitos de estos derechos intelectuales comunitarios *sui generis*.

La Ley de Biodiversidad, se analizará con mayor detalle, en el siguiente punto de este informe denominado: Régimen jurídico de los recursos genéticos en la respectiva legislación nacional.

b) Decreto Ejecutivo N° 31514-MINAE de 3 de octubre de 2003, publicado en el Diario Oficial La Gaceta N° 241 de 15 de diciembre de 2003, y posteriormente reformado por el artículo 1° del Decreto Ejecutivo 32066-MINAE de 19 de marzo de 2004, publicado en el Diario Oficial La Gaceta N° 214 de 2 de noviembre de 2004 denominado: **NORMAS GENERALES PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENETICOS Y BIOQUIMICOS DE LA BIODIVERSIDAD**⁴:

Estas Normas se elaboraron mediante un proceso de redacción, análisis y consulta, dirigido desde el seno de la CONAGEBIO, ante las diversas instancias nacionales, expertos y personas involucradas con el tema, publicándose finalmente por medio de un Decreto Ejecutivo en el mes de diciembre del 2003.

Este Decreto Ejecutivo, reglamenta el Capítulo V, Secciones I y II de la Ley de Biodiversidad N° 7788, desarrollando y precisando, los principios establecidos por la Ley, respecto al tema del acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, permitiendo la ejecución de la normativa de una manera más ágil y eficaz.

Es así como este instrumento legal nacional regula la aplicación de los objetivos del Convenio sobre la Diversidad Biológica y de la Ley de Biodiversidad, e identifica los mecanismos para el otorgamiento del permiso de acceso y la participación en los beneficios, con énfasis en la obligación de los usuarios de obtener el consentimiento previamente informado de los Proveedores del recurso genético y bioquímico, incluye además la identificación de los términos principales para establecer las condiciones mutuamente

⁴ El texto completo del Decreto Ejecutivo N° 31514-MINAE, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

acordadas incluyendo beneficios monetarios y no monetarios y define las responsabilidades para las partes involucradas.

Las regulaciones establecidas en el Decreto Ejecutivo N° 31514-MINAE, serán analizadas con más detalle, en el siguiente punto de este informe denominado: Régimen jurídico de los recursos genéticos en la respectiva legislación nacional.

c) Decreto Ejecutivo N° 33697-MINAE, del 6 de febrero del dos mil siete, publicado en el Diario Oficial La Gaceta N° 74 del 18 de abril del 2007, denominado: **REGLAMENTO PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENÉTICOS Y BIOQUÍMICOS DE LA BIODIVERSIDAD EN CONDICIONES EX SITU**⁵:

Al igual que el Decreto Ejecutivo N° 31514-MINAE, este nuevo reglamento incorporó en el proceso de redacción, la consulta ante diferentes instancias nacionales, personas físicas y jurídicas involucradas con el tema.

De conformidad con el principio básico y fundamental de que las propiedades bioquímicas y genéticas de los elementos de la biodiversidad silvestres o domesticados son de dominio público y que el Estado debe autorizar su investigación, bioprospección, uso, utilización y aprovechamiento, este nuevo Decreto Ejecutivo pretende complementar, mejorar y aclarar, los procedimientos establecidos en el Decreto Ejecutivo N° 31514- MINAE, para garantizar de una forma eficaz, eficiente, clara y precisa los objetivos y fines de la Ley N° 7788.

Específicamente este nuevo Decreto Ejecutivo, garantiza la aplicación ágil y eficaz del procedimiento necesario para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, mantenidos en condiciones *ex situ*, de conformidad con los artículos 6, 17 inciso 3, 62 y 69 de la Ley N° 7788 y el Transitorio 1. del Decreto Ejecutivo N° 31514- MINAE y su Reforma.

Este Decreto Ejecutivo, será analizado con mayor detenimiento en el siguiente punto de este informe: Régimen jurídico de los recursos genéticos en la respectiva legislación nacional.

d) Ley Indígena de Costa Rica N° 6172 del 29 de noviembre de 1977 y su Reglamento Decreto Ejecutivo N° 8487-G de 26 de abril de 1978, publicado en el Diario Oficial La Gaceta N° 89 de 10 de mayo de 1978.

Para efectos de este análisis, creemos necesario recalcar como puntos relevantes de esta normativa, que esta Ley establece en su Artículo 1° la definición de indígenas, indicando que son aquellas personas que constituyen grupos étnicos descendientes directos de las civilizaciones precolombinas y que conservan su propia identidad.

Además regula como medida para conservar el patrimonio arqueológico nacional, la prohibición de buscar y extraer de huacas en los cementerios indígenas, con excepción de las exploraciones científicas autorizadas por instituciones oficiales.

Esta ley fue reglamentada por el Decreto Ejecutivo No. 8487 de 26 de abril de 1978 y mediante el Decreto Ejecutivo No. 13568 de 30 de abril de 1982, se estableció que las Asociaciones de Desarrollo Integral tienen la representación legal de las Comunidades Indígenas y actúan como gobierno local de éstas.

⁵ Para conocer el texto completo del Decreto Ejecutivo N° 33697-MINAE, ver el Anexo 1 de este documento.

e) Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, N° 6867 del 25 de abril de 1983, reformada por la Ley N° 7979 de 6 de enero del 2000 y su Reglamento Decreto Ejecutivo N° 15222 del 12 de diciembre de 1983:

Esta normativa pretende regular claramente a nivel nacional los parámetros necesarios para la protección de los derechos de propiedad intelectual, en sus formas: patentes de invención, dibujos y modelos industriales y de Utilidad.

En el año 2000, mediante la Ley N° 7979 se reformaron varios de los artículos de la Ley N° 6867, dentro de estas modificaciones, específicamente en el artículo 1°, se incluyeron exclusiones de patentabilidad, que no coinciden plenamente con lo establecido en la Ley de Biodiversidad, por lo que deberá en corto plazo, definirse en nuestro país, una sola interpretación legal respecto a este tema.

Actualmente se está discutiendo en la Asamblea Legislativa, en la Plena Tercera, el Proyecto de Ley: “Reforma de varios artículos de la Ley de Marcas y otros signos distintivos y de la Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Unidad” expediente N° 16.118, toda vez que la Comisión Permanente de Asuntos Jurídicos hace pocos meses rindió Informe Unánime Afirmativo.

Con este Proyecto de Ley se pretende modernizar la legislación nacional en materia de protección a los derechos de propiedad intelectual y cumplir de esta manera varios compromisos internacionales. Sin embargo, dentro de estas reformas no se incluye ninguna modificación del mencionado artículo 1° de la Ley N° 6867.

f) Proyecto de Ley de Protección a las Obtenciones Vegetales. Expediente en la Asamblea Legislativa N° 16.327.

La Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, N° 6867 del 25 de abril de 1983, reformada por la Ley N° 7979 de 6 de enero del 2000, anteriormente mencionada, estableció además en su artículo 1° inciso 3) que las obtenciones vegetales tendrán protección mediante ley especial.

Desde hace algunos años se han presentado varios Proyectos de Ley en este sentido, sin embargo en el mes de agosto del 2006, la Oficina de Semillas de Costa Rica, presenta nuevamente un Proyecto de Ley, que se está discutiendo en la Asamblea Legislativa, en la Comisión Permanente de Agropecuarios, el Proyecto de Ley de Protección a las Obtenciones Vegetales, expediente número 16 327.

Esta ley de conformidad con lo establecido en la motivación del Proyecto, pretende cumplir con su promulgación los siguientes objetivos

- “...Dotar al país de un marco legal en esta materia con reconocimiento internacional.
- Cumplir con la legislación nacional que ya establece que las obtenciones vegetales tendrán protección mediante ley especial.
- Contribuir al acceso de nuevas y mejores variedades para los agricultores nacionales.
- Facilitar la introducción de variedades protegidas más competitivas.
- Propiciar un clima favorable para la inversión en investigación y desarrollo de variedades.
- Contribuir al mejoramiento del nivel competitivo del sector agropecuario.
- Facilitar la exportación de productos agrícolas de variedades protegidas.
- Impedir que variedades obtenidas en programas estatales sean comercializadas por particulares sin la debida autorización.
- Potenciar la producción, distribución y utilización de semilla de buena calidad.
- Estimular a la industria nacional de semillas para insertarse en el mercado internacional.

- Fomentar la inversión pública y privada en el desarrollo tecnológico para la conservación y uso de los recursos fitogenéticos.
- Promover el desarrollo científico, técnico y profesional.
- Evitar la competencia desleal en la comercialización de semillas.
- Honrar los compromisos internacionales suscritos por Costa Rica, sobre derechos de propiedad intelectual relacionados con el comercio...”

Además actualmente en la Asamblea Legislativa se encuentra en proceso de discusión el Convenio Internacional para la Protección de las Obtenciones Vegetales (UPOV, Acta de 1991), por lo que se ha pretendido en la medida de lo posible, que este proyecto de Ley nacional sea congruente también con este instrumento internacional, previendo su posible aprobación.

g) Otra legislación.

Además de la normativa nacional señalada anteriormente, la cual regula el tema de acceso a recursos genéticos y la participación de sus beneficios, en Costa Rica también se encuentran vigentes otros instrumentos jurídicos, que indirectamente se relacionan con esta legislación.

Dentro de estos instrumentos jurídicos, citaremos a manera de ejemplo los siguientes:

- a) Ley de Conservación de la Vida Silvestre N° 7317 de 30 de octubre de 1992 publicada en el Diario Oficial La Gaceta N° 235 de 7 de diciembre de 1992 y reformas.
- b) Ley de Creación del INCOPECA N° 7384 de 16 de marzo de 1994 publicada en Diario Oficial La Gaceta N° 62 de 29 de marzo de 1994 y reformas.
- c) Ley de Pesca y Acuicultura N° 8436 de 1° de marzo de 2005 publicada en Diario Oficial La Gaceta N° 78 de 25 de abril del 2005 y reformas.
- d) Ley de Protección Fitosanitaria N° 7664 de 8 de abril de 1997 publicada en Diario Oficial La Gaceta N° 83 de 2 de mayo de 1997 y reformas.
- e) Ley de Semillas N° 6289 de 4 de diciembre 1978 publicada en el Diario Oficial La Gaceta N° 7 de 10 de enero de 1979.
- f) Ley General del Servicio Nacional de Salud Animal, N° 8495 de 6 de abril del 2006, publicada en el Diario Oficial La Gaceta N° 93 del 16 de mayo del 2006.
- g) Ley Forestal N° 7575 de 13 de febrero de 1996 publicada en el Diario Oficial La Gaceta N° 72 de 16 de abril de 1996 y reformas
- h) Ley Orgánica del Ambiente, N° 7554 de 4 de octubre de 1995, publicada en el Diario Oficial La Gaceta N° 215 del 13 de noviembre de 1995 y reformas.

ENGLISH TRANSLATION

ANALYSIS OF EXISTING LEGAL AND EXTRALEGAL INSTRUMENTS AT THE NATIONAL, REGIONAL AND INTERNATIONAL LEVEL WITH REGARD TO ACCESS AND BENEFIT SHARING

This document lists some of the legal and extralegal instruments at the international, regional and, finally, national level, that are most relevant to the issue of Access and Benefit sharing for Costa Rica:¹

At the international level, the Convention on Biological Diversity (CBD) is, as for many countries, the legal instrument used as a basis for drafting and implementing our respective regional and national instruments.

a) The Convention on Biological Diversity was ratified by Costa Rica through Law No. 7416 of June 30, 1994, published in Official Gazette No. 143 of July 28, 1994.

b) The previous year, our country ratified the International Treaty on Plant Genetic Resources for Food and Agriculture through Law No.8539 of July 17, 2006, published in Official Gazette No. 185 of September 25, 2006.

In the aim of implementing this international legal instrument in our country, a provisional regulation has been incorporated into Executive Decree No. 33697-MINAE, of February 6, two thousand and seven, published in Official Gazette No. 74 of April 18, 2007: “Regulation for Access to *ex situ* Genetic and Biochemical Biodiversity Resources,” a provisional regulation stipulating that, as long as there is no specific legal regulation establishing other provisions in this respect, the National Authority for the implementation of said Treaty with regard to access to plant genetic resources for food and agriculture will be the *Comisión Nacional para la Gestión de la Biodiversidad*, hereafter CONAGEBIO and its Technical Office, pursuant to Biodiversity Law No. 7788 and Executive Decree MINAE- No. 31514, for which purpose CONAGEBIO and its Technical Office will call upon the *Comisión Nacional de Recursos Fitogenéticos* (CONAREFI – National Plant Genetic Resource Commission) as an advisory body.

c) With regard to international regulations respecting Indigenous Peoples, ratification of Convention 169 on Indigenous and Tribal Peoples was approved through Law No. 7316 of November 3, 1992, published in Official Gazette No. 234 of December 4, 1992.

d) The Cartagena Protocol on Biosafety was ratified by Costa Rica through Law No. 8537 of July 17, 2006, published in Official Gazette No. 227 of November 27, 2006.

¹ The following acronyms will be used in this document:

TRIPs: Agreement on Trade-Related Aspects of Intellectual Property Rights

CBD: Convention on Biological Diversity

CONAGEBIO: Comisión Nacional para la Gestión de la Biodiversidad (National Commission for the Management of Biodiversity)

CONAREFI: Comisión Nacional de Recursos Fitogenéticos (National Plant Genetic Resource Commission)

MINAE: Ministerio del Ambiente y Energía (Ministry of the Environment and Energy)

WIPO: World Intellectual Property Organization

UNEP: United Nations Environment Programme

UPOV: International Union for the Protection of New Varieties of Plants

WEF: World Economic Forum

In order to fulfill some of the international commitments taken on by our Country upon ratification of the CBD and the Cartagena Protocol in particular, a few months ago the *Comisión Técnica Nacional de Bioseguridad* (National Technical Commission for Biosafety), prepared, as part of a UNEP-GEF project, a draft Law on the Biosafety of Living Modified Organisms and Products Thereof, which has not yet been presented to Costa Rica's Legislative Assembly.

e) The Convention on Biological Diversity's Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization.

When the Guidelines were approved, our country already had a fairly advanced draft of current Executive Decree No. 31514-MINAE, which regulates access to the genetic and biochemical components and resources of biodiversity. However, upon reviewing the draft, CONAGEBIO's Technical Office concluded that both instruments were fully consistent.

f) Akwe: *Kon* Guidelines

The principles set out in these Guidelines will be used as input for the participatory process needed in our country to determine the nature, scope and requirements of *sui generis* community intellectual rights.

g) International conventions linked to the issue of intellectual property:

These international instruments include the following:

- Paris Convention for the Protection of Industrial Property and its amendments, ratified through Law No. 7484 of March 28, 1995, published in Official Gazette No. 99 Insert 18 of May 24, 1995.
- Convention Establishing the World Intellectual Property Organization (WIPO), ratified through Law No. 6468 of September 18, 1980: Authorizes Costa Rica's membership in the Convention Establishing the World Intellectual Property Organization, signed in Stockholm on July 14, 1967.
- The Patent Cooperation Treaty and its Regulations, ratified through Law No. 7836 of October 22, 1998, published in Official Gazette No. 232 of November 30, 1998.
- The WIPO Copyright Treaty, ratified through Law No. 7968 of December 22, 1999, published in Official Gazette No. 23 of February 02, 2000.
- The Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, ratified through Law No. 7634, of October 3, 1996, published in Official Gazette No. 208 of October 30, 1996.
- The Marrakesh Agreement Establishing the World Trade Organization, Law No. 7475 of December 20, 1994, published in Official Gazette No. 245 Insert 40 of December 26, 1994, which includes, in Annex 1C, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

At the Regional Level,

With regard to Access and Benefit Sharing for Costa Rica, we have found, specifically, the following non-binding regional instrument:

-Central American Protocol on Access to Genetic and Biochemical Resources and Associated Traditional Knowledge:

So far, this regional instrument has only been approved by the Ministers of the Environment of Central America, meaning that it still has to be approved by the Foreign Secretaries of each country, then ratified by at least four countries.

When the Agreement was signed by Central America's Ministers of the Environment, Costa Rica's Biodiversity Law was already in effect. Nevertheless, this instrument has been used as a framework guide for drafting regulations in the other countries in the region.

At the National Level

a) Biodiversity Law No. 7788 of April 30, 1998, published in Official Gazette No. 101 of May 27, 1998.²

This is the basic national instrument, through which the objectives of the Convention on Biological Diversity are regulated and implemented in a clear and precise manner.

Here are some of the more important aspects of this legislation:

- It establishes, as a general objective, the conservation of biodiversity and the sustainable use of resources, as well as the fair and equitable sharing of arising benefits and costs.
- It stipulates that the biochemical and genetic properties of the components of biodiversity, wild or domesticated, belong to the public domain. It also states that the State will authorize the exploration, research, bioprospecting, use and exploitation of the components of biodiversity that are part of the public domain, as well as the utilization of all genetic and biochemical resources, by means of general rules of access.
- With regard to definitions, it includes some that are not in the CBD, but are necessary for its interpretation.
- It creates the National Commission for the Management of Biodiversity, hereafter CONAGEBIO, and appoints it as the National Authority for regulating access to the components of biodiversity and its genetic and biochemical resources. It also gives it the duty, among others, to formulate national policies relating to the conservation, sustainable use and restoration of biodiversity, in accordance with the Convention on Biological Diversity and other international agreements and treaties, and in accordance with national interests.
- It expressly establishes that CONAGEBIO has the duty to propose access policies concerning genetic and biochemical components of *in situ* and *ex situ* biodiversity. It must furthermore act as an organ of mandatory consultation in procedures of request for protection of intellectual rights concerning biodiversity. Its provisions constitute the general rules for access to genetic and biochemical components of biodiversity and for the protection of biodiversity-related intellectual rights, with which the administration and interested parties must comply.
- With regard to intellectual property, the Law provides pioneer regulation, as both the National Seed Office and the Registry of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial

² The complete text of the Biodiversity Law is available at: www.conagebio.go.cr in both Spanish and in English.

property to innovations involving components of biodiversity. It also stipulates that interested parties must always provide the certificate of origin issued by the Technical Office of the Commission and the Prior Informed Consent. Registration of a patent or protection of the innovation is prohibited in the event of justified opposition from the Technical Office.

- It recognises and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge.
- It establishes the need for CONAGEBIO, by means of its Technical Office and in association with the Indigenous Peoples Board and the Small Farmers Board, to define a participatory process with indigenous and small farmer communities to determine the nature, scope and requirements of these *sui generis* community intellectual rights.

The Biodiversity Law will be analyzed in greater detail under the next point in this report, entitled: Legal Regime Governing Genetic Resources in the Respective National Legislation.

b) Executive Decree No. 31514-MINAE of October 3, 2003, published in Official Gazette No. 241 of December 15, 2003, and later amended by Article 1 of Executive Decree 32066-MINAE of March 19, 2004, published in Official Gazette No. 214 of November 2, 2004, entitled: **GENERAL STANDARDS FOR ACCESS TO THE GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY**³:

These standards were developed using a drafting, analysis and consultation process governed from within CONAGEBIO, with the various national bodies, experts and stakeholders involved, and were finally published by Executive Decree in December 2003.

This Executive Decree regulates Chapter V, Sections I and II of Biodiversity Law No. 7788, developing and specifying the principles established by the Law with respect to access to genetic and biochemical components of biodiversity, making it possible to enforce the standards more quickly and effectively.

That is how this national legal instrument regulates implementation of the objectives of the Convention on Biological Diversity, and of the Biodiversity Law. It identifies mechanisms for granting access permits and distributing benefits, with an emphasis on the users' obligation to obtain prior informed consent from the providers of the genetic and biochemical resource. It furthermore identifies the main wordings for establishing mutually agreed terms, including monetary and non-monetary benefits, and defines the responsibilities of the parties involved.

The regulations established in Executive Decree No. 31514-MINAE, will be analyzed in greater detail under the next point in this report, entitled: Legal Regime Governing Genetic Resources in the Respective National Legislation

c) Executive Decree No. 33697-MINAE, of February 6, two thousand and seven, published in Official Gazette No. 74 of April 18, 2007, entitled: **REGULATION FOR ACCESS TO GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY IN EX SITU CONDITIONS**⁴:

³ The complete text of Executive Decree No. 31514-MINAE, is available at: www.conagebio.go.cr, in both Spanish and English.

⁴ For the complete text of Executive Decree No. 33697-MINAE, see Annex 1 of this document.

Like Executive Decree No. 31514-MINAE, this new regulation incorporated, throughout the drafting process, the outcomes of consultation with various national bodies, individuals and legal entities involved in this issue.

In accordance with the basic, fundamental principle that the biochemical and genetic properties of the components of biodiversity, wild or domesticated, belong to the public domain, and that the State must authorize the exploration, research, bioprospecting, use, utilization and exploitation thereof, this new Executive Decree is aimed at complementing, improving and clarifying the procedures set out in Executive Decree No. 31514- MINAE, to guarantee the objectives and purposes of Law No. 7788 in an effective, efficient, clear and precise way.

Specifically, this Executive Decree guarantees the quick and effective implementation of the necessary procedure for access to the genetic and biochemical components and resources of biodiversity maintained in *ex situ* conditions, in accordance with Articles 6, 17 paragraph 3, 62 and 69 of Law No. 7788 and Provisional Clause 1 of Executive Decree No. 31514-MINAE and its Revision.

This Executive Decree will be analyzed in greater detail under the next point in this report, entitled: Legal Regime Governing Genetic Resources in the Respective National Legislation.

d) Indigenous Law of Costa Rica No. 6172 of November 29, 1977 **and its Regulation, Executive Decree** No. 8487-G of April 26, 1978, published in Official Gazette No. 89 of May 10, 1978.

For the purpose of this analysis, we consider it necessary to highlight, as relevant points of this legislation, that this Law establishes, in Article 1, a definition of Indigenous people, indicating that they are persons who belong to ethnic groups that are directly descended from pre-Columbian civilizations and who maintain their own identity.

It also regulates, as a measure to preserve national archaeological heritage, the prohibition against searching for and extracting *huacas* (pre-Columbian tombs) from indigenous cemeteries, with the exception of scientific explorations authorized by official institutions.

This law was regulated by Executive Decree No. 8487 of April 26, 1978; and through Executive Decree No. 13568 of April 30, 1982, it was established that the Comprehensive Development Associations legally represent Indigenous Communities and act as their local government.

e) Law on Patents for Inventions, Industrial Drawings and Models, and Utility Models, No. 6867 of April 25, 1983, amended by Law No. 7979 of January 6, 2000 and its **Regulation, Executive Decree** No. 15222 of December 12, 1983:

This legislation aims to regulate clearly, at the national level, the necessary parameters for the protection of intellectual property rights, in the form of invention patents, industrial drawings and models, and utility models.

In 2000, through Law No. 7979, various articles of Law No. 6867 were amended. These amendments included, specifically in Article 1, exclusions from patent that do not fully coincide with the stipulations of the Biodiversity Law. This means that, in the short term, our country will have to define a single legal interpretation with regard to this issue.

Discussions are currently taking place in the Third Plenary of the Legislative Assembly regarding the Draft Law: “Reform of various Articles of the Law on Trademarks and other Distinctive Markings, and of the Law on Patents for Inventions, Industrial Drawings and Models, and Utility Models”, file No. 16.118,

seeing as the Standing Commission on Legal Affairs handed down a Unanimous Affirmative report a few months ago.

This Draft Law intends to modernize national legislation in the area of intellectual property right protection, thus fulfilling various international commitments. However, none of these reforms mention any amendments to above-mentioned Article 1 of Law No. 6867.

f) Draft Law for the Protection of New Plant Varieties. Legislative Assembly File No. 16.327.

The Law on Patents for Inventions, Industrial Drawings and Models, and Utility Models, No. 6867 of April 25, 1983, amended by above-mentioned Law No. 7979 of January 6, 2000, also stipulates, in Article 1, paragraph 3) that new plant varieties will be protected by a special law.

For a few years now, various Draft Laws have been presented to this effect. However, in the month of August, 2006, the Seed Office of Costa Rica once again presented a Draft Law, which is being discussed by the Legislative Assembly, within the Standing Commission of Agriculture and Livestock Producers, as the Draft Law for the Protection of New Plant Varieties, file No. 16 327.

According to what is set out in the justification for the Draft, this law seeks to achieve the following objectives when passed:

- "...Give the country a legal framework in this area, with international recognition.
- Comply with national legislation, which already stipulates that new plant varieties will be protected by a special law.
- Contribute to access to new and better varieties on the part of our national farmers.
- Facilitate the introduction of more competitive protected varieties.
- Promote a favourable climate for investment research into and development of plant varieties.
- Contribute to improving the competitiveness of the agriculture and livestock sector.
- Facilitate the exportation of protected varieties of agricultural products.
- Prevent new varieties obtained through government programs from being sold by individuals, without the proper authorization.
- Boost the production, distribution and use of good quality seed.
- Stimulate the national seed industry to insert itself into the international market.
- Encourage public and private investment in technical development for the conservation and use of plant genetic resources.
- Promote scientific, technical and professional development.
- Prevent disloyal competition in the sale of seeds.
- Honour the international commitments made by Costa Rica with regard to trade-related intellectual property rights..."

Furthermore, the Legislative Assembly is currently discussing the International Convention for the Protection of New Varieties of Plants (UPOV, Act of 1991), which is why the intent has been, as much as possible, to make this draft national Law consistent with that international instrument as well, with an eye to its possible approval.

g) Other Legislation

In addition to the national legislation indicated above, which regulates access to genetic resources and benefit sharing, Costa Rica also has other legal instruments in effect that are indirectly linked to this legislation.

These instruments include, for example:

- a) Wildlife Conservation Law No. 7317 of October 30, 1992, published in Official Gazette No. 235 of December 7, 1992 and amendments.
- b) Law Creating INCOPECA, No. 7384 of March 16, 1994, published in Official Gazette No. 62 of March 29, 1994, and amendments.
- c) Fishery and Agriculture Law No. 8436 of March 1, 2005, published in Official Gazette No. 78 of April 25, 2005 and amendments.
- d) Plant Health Protection Law No. 7664 of April 8, 1997, published in Official Gazette No. 83 of May 2, 1997 and amendments.
- e) Seed Law No. 6289 of December 4, 1978, published in Official Gazette No. 7 of January 10, 1979.
- f) General Law on the National Animal Health Service, No. 8495 of April 6, 2006, published in Official Gazette No. 93 of May 16, 2006.
- g) Forestry Law No. 7575 of February 13, 1996, published in Official Gazette No. 72 of April 16, 1996, and amendments
- h) Organic Law on the Environment, No. 7554 of October 4, 1995, published in Official Gazette No. 215 of November 13, 1995 and amendments.

ISLAMIC REPUBLIC OF IRAN

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In The Name of God

January, 17, 2007

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XXXXXXXXXXXXXXXXXXXXXXXXXXXX
Secretariat of Convention on Biological Diversity

Subject: Re- Decision VIII/4 on Access and Benefit-sharing : International regime on access and benefit-sharing

Dear Sir Madam,

Pursuant to your notification letter No SCBD/SEU/VN/VP/54834 dated on 25th May 2006, regarding requested information about a/m subject, you will find below the information in question.

A) National Law

- 1) The instruction regarding the issuance of animals and wildlife entering and exodus permissions.
- 2) Fossil exportation act.
- 3) According to the article 1 of hunting and fishing act (approved on 1967), emphasizing on protection and preserving of endangered species as genetic resources.
- 4) According to ratified no 11896 , importing and exporting of wild animals and birds dependent to EPO's prior permission .
- 5) According to the article 114 of the Iranian third development plan act (Approved on 2000), emphasizing on protection of genetic resources, exportation of such resources have been exempted from the exporting facilities.
- 6) According to Iranian Import/Export regulation, importing and exporting of any kind animal and plant productions as well as agricultural crops including natural and LMO depends upon specific law.
- 7) According to Plant Protection Legislation, importing of Plant Components or even apart of those plants requires prior permission.

B) International Commitments

- 1) Islamic Republic of Iran is a member of International Treaty Plant Genetic Resource for Food and Agriculture and is committed to respect it.
- 2) Islamic Republic of Iran is a member of CITES Convention and is committed to respect the terms and conditions. There is a list of Iran's wildlife which is included in the exhibits of the said convention.
- 3) Islamic Republic of Iran is a member of BIODIVERSITY Convention and is committed to respect it.
- 4) Islamic Republic of Iran has accepted the CARTAGENA Protocol and is committed to respect it.

PAKISTAN

Inputs from Pakistan to Decision VIII/4 on Access and benefit sharing

The Government of Pakistan is making efforts to fulfill its obligations and comply with the COP decisions. A comprehensive review of actions taken so far has been presented in the Third National Report submitted to the Secretariat. A gist of the same is presented below:

The Plant Breeders Rights Act (draft) has been developed that includes ban on use of GURTS The Biodiversity directorate has developed a project for the implementation of Bonn Guidelines in Pakistan and SDPI that has provisions of involving the local communities and small scale farmers in the decision making processes. Inter Cooperation, a non profit organization, is also implementing a project in three districts of the NWFP by involving the local communities. Another who i.e. the sustainable development policy institute SDPI is also working in this regard.

Many NGOs and Rural Support Programmes, GEF funded projects have worked at the grass root level for organization of communities in rural areas Such community organizations through awareness raising programmes are now in a position of decision making and running their businesses at their own. These fora can be effectively involved in decision making processes related to genetic use restriction techniques.

Another project titled “Mountain Area Conservation project” MACP has organized and established many community organizations in the four conservancies of the project area to enhance and strengthen their capacity to be effectively involved in decision making to conservation and sustainable use; however more work is needed on traditional knowledge innovations and practices. Community based management plans have been prepared for the Joint Forest Management in the NWFP with financial support of donor funded/ national funded projects. This includes the Mountain Areas Conservancy Project (MACP) programme of work.

The draft Access and Benefit Sharing Law has been circulated to all stakeholders and the comments are being received. It will take some time to present the Act to the legislature. Prior Informed Consent (PIC), Material Transfer Agreement (MAT) and Mutually Agreed Terms (MTA) shall be part of the legislation. Section 15 (2B) of the Patent Ordinance 2000 provides for disclosure and prior informed consent information in connection with biological material used in inventions for which patent application has been filed.

Pakistan has ratified the ITPGRA that includes procedures for the exchange of genetic material for research purposes. The legislation in this regard (the Plant Breeders Rights Act) and other legislation are under process. The Bio-safety Rules have been notified that address procedures for the exchange of genetically modified genetic material.

The Lok Virsa that supports the traditional craftsmen, artists and artisans, has established a Lok Virsa museum and organizes a festival on annual basis to display the traditional knowledge/ cultural expressions of the local and indigenous communities.

The Ministry of Health recognizes the traditional medicinal practices and has established the National Council for Tibb. The Pakistan Museum of Natural History is preparing a database of traditional knowledge.

There is a general realization that coordination amongst the various stakeholders is needed to address the complex issues related to ABS. A project on ABS in particular on implementation of Bonn Guidelines in Pakistan has also been prepared and is in the pipeline for approval.

SWITZERLAND

3. Information regarding the inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing.

A number of instruments (legally binding or not) regulating access and benefit sharing already exist (guidelines for academic research, code of conduct for botanical gardens, ABS agreements and regulations under the International Treaty on Plant Genetic Resources for Food and Agriculture, ABS-Management Tool for private companies, government agencies, research centres and communities, etc.). A comprehensive survey on existing legal and other instruments regulating access and benefit sharing would greatly facilitate the development of an internationally recognized instrument respecting the CBD provisions.

II. SUBMISSIONS FROM RELEVANT ORGANIZATIONS

**THE WORLD CONSERVATION UNION (IUCN)
ENVIRONMENTAL LAW CENTER (ELC)**

In response to your request for relevant information relating to inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, we would like provide the following information.

In the recent years IUCN has undertaken and coordinated research and analysis on a large number of ABS related measures. With regard to the Secretariat's request we would like to draw your attention to the following publications.

1) An in-depth analysis of selected ABS instruments is provided in the IUCN publication

Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity, edited by Santiago Carrizosa, Stephen B. Brush, Brian D. Wright, Patrick E. McGuire, IUCN ENVIRONMENTAL POLICY AND LAW PAPER No. 54 (2004), available at <http://www.iucn.org/themes/law/info04.html> .

The research undertaken focuses on ABS legislation status, IPRs and bioprospecting projects in 41 Pacific Rim countries, many of which share ecological similarities in large terrestrial and marine regions, and also share the need to regulate access to their rich genetic resources.¹

The publication presents comparative analyses (Chapters 1 through 3) and a selection of eight case studies that show in detail the status and experiences of five countries that have ABS policies in place and three countries that were, at the time of the study (2002-2004), developing legal ABS frameworks² (Chapters 4 through 11, each concluding with recommendations). Chapters 12 and 13 present legal issues regarding the international regime and conclusions, lessons and recommendations based on the analysis undertaken.

In particular, the analysis in Chapter 1 compares instruments of nine countries and one region (Andean Community) by the following topics:

- Ownership
- Scope
- Access procedure
- Prior Informed Consent (PIC)
- Benefit Sharing and Compensation Mechanisms
- IPRs and the Protection of Traditional Knowledge
- *In situ* Biodiversity Conservation and Sustainable Use
- Enforcement and Monitoring.

¹ The comparative analysis is based on 13 in-depth reports as well as 49 expert surveys from 33 countries. Specific issues that the experts had been asked to discuss included: a) the process that led to or will lead to the development of national ABS laws and policies; b) successes and concerns that countries experienced during the design of these regulations; c) successes and concerns experienced during the implementation of these regulations; d) influence of these frameworks and IPR issues on bioprospecting initiatives; and e) novel benefit-sharing strategies that have been implemented locally.

² Colombia, Costa Rica, Mexico, Philippines, USA, Australia, Chile and Malaysia.

It concludes in its Final Comments:

“The CBD’s provisions on access to genetic resources, traditional knowledge, technology transfer, and benefit sharing (...) are closely linked to CBD articles that address biodiversity conservation, sustainable use, monitoring, and capacity building objectives (...). While countries such as Costa Rica and Nicaragua have established this connection directly through the design of comprehensive single laws and policies that implement all of the provisions of the CBD, other countries such as Australia, Colombia, Ecuador, Mexico, Peru, Philippines, Samoa, and Thailand have developed single ABS regulations that are complemented by existing or future environmental, sustainable development, or biodiversity related laws or policies.

In any case, ABS laws and policies of these countries aim at implementing the CBD and they share key similarities that include: a) the establishment of bilateral agreements between bioprospecting groups and the national government that must be negotiated on mutually agreed terms; b) the recognition of national sovereignty over biological and genetic resources within national borders; c) the establishment of procedures for obtaining PIC from government authorities and the providers of samples and traditional knowledge (except for Thailand which requires PIC only from government authorities); and d) the equitable sharing of benefits derived from the use of biological diversity. However, as expected, these laws and policies also present several differences that are simply the result of different policy or regulatory options taken by countries and the expression of different legal systems, cultural beliefs, and social and economic conditions. For example, countries with large percentages of indigenous population are still trying to figure out strategies to protect indigenous knowledge. Furthermore, most of the countries examined in this chapter are working on policies that show concern about the potential negative impact of on access activities on the environment.

This review also shows that most ABS laws and policies are comprehensive, but sometimes confusing, costly, and difficult to implement. They share provisions and principles that need further clarification. For example, countries such as Colombia, Peru, Ecuador, Costa Rica, and the Philippines that have had ABS laws in place since the mid-1990s are still trying to define the scope of their access laws, the strategies to protect the knowledge of indigenous peoples, and the conditions to facilitate access to noncommercial bioprospecting activities. In contrast, Samoa’s ABS conditions consist of one page with an oversimplified proposal to facilitate access that will still need further clarification, but which is practical and refreshing. New proposals for ABS laws and policies are also dealing with similar issues and trying to resolve new ones (e.g., the ownership issue in Malaysia). In the USA, NPS [National Park Service] regulations are analogous to some of the provisions of ABS laws and policies that other countries have proposed and these NPS regulations facilitate ABS goals in NPS land.

In synthesis, ABS laws and policies developed under the umbrella of the CBD have created a complex and comprehensive scenario for access and exchange of genetic resources. This is the result of a process marked with conceptual and operational concerns and difficulties that still continue even for countries that pioneered ABS regulations in the mid-1990s...”

2) *A Comparative Analysis of Legislation and Practices on Access to Genetic Resources and Benefit-Sharing (ABS), Critical Aspects for Implementation and Interpretation*, by J. Cabrera Medaglia, published under *The ABS Project* of the IUCN ENVIRONMENTAL LAW CENTRE, available at: http://www.iucn.org/themes/law/absdocuments/eng_critical_aspects.pdf

This publication of 2004 provides a comparative analysis of 14 legal and other instruments on ABS (including draft laws) at regional, national and sub-national level³ (Part I). The analysis is presented in the form of tables with respect to the following aspects:

³ ANDEAN Decision 391, Brazil, Acre, Amapa, Bolivia, Costa Rica, India, Philippines, Malaysia-Sarawaw, Bhutan, Australia, OAU, ASEAN and Venezuela.

Table I Selected General Provisions on ABS

Table II Definition of Genetic Resources

Table III What Constitutes 'Utilization of Genetic Resources'?

Table IV Ownership

Table V Legal Provisions for Enforcement and Monitoring

Table VI Separate Analysis of Access and Benefit Sharing Concepts

Table VII IPR Related Issues

Table VIII Whether or not the Legal and Institutional Arrangements for ABS Support and Integrate with National Conservation and Sustainable Uses Objectives

Table IX Double Permission

Table X *Ex Situ* Collections and Special Legal Treatment for Different Sectors, Including Agriculture

Part II of the publication provides an analysis of the implementation of ABS regulations in three selected countries (in text form).⁴ This analysis focuses, *inter alia* on the following questions:

- State of the implementation of the law
- Practical definition of genetic resource, utilization and access to genetic resources
- Limits and restrictions imposed on access for specific uses
- Ownership of genetic resources
- Interpretation of access and benefit-sharing
- Monitoring & legal remedies based on environmental considerations
- Different treatment for agricultural GR & ex-situ collections
- Double permission requirements
- IPR related issues.

The publications are available at the indicated websites. Should your Secretariat wish to be provided with hard paper copies, please contact IUCN's Environmental Law Centre (Godesberger Allee 108-112, D-53175 Bonn, Germany, Tel.: ++49 228/26 92 231, Fax: ++49 228/26 92 250, e-mail: ELCsecretariat@iucn.org).

⁴ Costa Rica, the Philippines and Venezuela.

WORLD TRADE ORGANIZATION (WTO)



WORLD TRADE ORGANIZATION
ORGANISATION MONDIALE DU COMMERCE
ORGANIZACIÓN MUNDIAL DEL COMERCIO

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Mr. Ahmed Djoghlaif
Executive Secretary
Secretariat of the Convention on Biological Diversity
413 Saint-Jacques Street, Suite 800
Montreal, Quebec H2Y 1N9
Canada

56624

RECEIVED
Nov 17 2006

ACTION VN
FILE _____
INFO G.D., H.L.

13 NOV 2006

Div. Reference: IT309-CBD
Reg. Reference: ORG/355

Dear Mr. Djoghlaif,

In response to your communications of 25 May 2006, in which you invited relevant organizations, including the WTO, to submit to the Secretariat of the Convention on Biological Diversity further information, including regarding an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit sharing and information relevant to the gap analysis according to Decision VIII/4 adopted by the Conference of the Parties (COP), we are pleased to provide an update of the discussions in the WTO on related matters. We do not have information to provide on international certificates of origin/source/legal provenance or on the need and possible options for indicators for access to genetic resources under the Strategic Plan. With respect to capacity building for access and benefit sharing, while we do not have any activities specifically tailored to the points raised in your questionnaire, we cover in our TRIPS technical cooperation activities the ongoing work in the WTO on the issue of the relationship between the TRIPS Agreement and CBD with a view to assisting developing countries to participate as effectively as possible in this work.

Work in the WTO on the relationship between the TRIPS Agreement and the Convention on Biological Diversity first began in the WTO Committee on Trade and Environment following the mandate given in the Decision on Trade and Environment adopted at Marrakesh in April 1994. The principal forum for this subject in the WTO moved to the Council for TRIPS in 1999 when the review of Article 27.3(b) of the TRIPS Agreement, which relates to the patentability of plant and animal inventions, was initiated. Since the adoption of the Doha Ministerial Declaration on 14 November 2001, which in paragraph 19 instructed the Council for TRIPS to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore, work has been undertaken on these issues in the regular meetings of the Council for TRIPS. The Doha Ministerial Declaration also dealt with the issue of Implementation-Related Issues and Concerns in its paragraph 12. The relationship between the TRIPS Agreement and the CBD is one of the outstanding implementation issues. The Decision on the Doha Work Programme, adopted by the General Council on 1 August 2004 (the so-called "July Package"), reaffirmed the existing mandates on Implementation-Related Issues and Concerns and called for a redoubling of efforts in order to find appropriate solutions. A consultative process of the Director-General was undertaken to this effect. In its treatment of the outstanding implementation issues, the Hong Kong Ministerial Declaration of December 2005 specifically mentioned the relationship between the TRIPS Agreement and the CBD (in addition to the issue of extension of geographical indications). It provided for the consultative process to be further intensified and for the Director-General to report to each regular meeting of the TNC and the General Council.

J.

Accordingly, the issue of the relationship between the TRIPS Agreement and the CBD has been addressed on two tracks: in the regular meetings of the Council for TRIPS and in the consultative process for addressing the outstanding implementation issues. The discussion in the regular meetings of the TRIPS Council has considered a proposal made by a group of developing countries, led by India, Brazil and Peru, to amend the TRIPS Agreement to include an obligation on patent applicants to disclose the origin of biological resources and of traditional knowledge used in inventions as well as evidence of prior informed consent and of fair and equitable benefit sharing. Norway has supported an amendment of the TRIPS Agreement to introduce a mandatory requirement to disclose the source of genetic resources and traditional knowledge or the country of origin if it is known, provided the penalties for non-disclosure lie outside the patent system. The European Union has supported a mandatory requirement to disclose the origin or source of genetic resources and associated traditional knowledge that would cover all national, regional and international patent applications, while insisting that the legal effect of failure to disclose should be outside the patent system. Switzerland has proposed making explicit in the regulations of the World Intellectual Property Organization's Patent Co-operation Treaty (PCT) that parties to the PCT may require patent applicants to disclose the source of genetic materials and traditional knowledge on which inventions are directly based. The United States, supported by some other Members, has the position that a national-based approach using tailored national solutions, including contracts, is sufficient to ensure that the objectives of the CBD in relation to access and benefit sharing are met and that it would neither be helpful nor desirable to involve the patent system. Some Members have expressed their desire to have a fact-based discussion based on national experiences in order to examine the issues involved.

The work done in the regular meetings of the TRIPS Council from 1999 to February 2006 has been summarized in Secretariat notes IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1. The discussions in the TRIPS Council at its meetings of March and June 2006 are recorded in the minutes of the Council for TRIPS (IP/C/M/50-51) and those at the October meeting will be recorded in IP/C/M/52. At these meetings, papers, including certain proposals on access and benefit sharing, were submitted by a group of developing countries (IP/C/W/470 and IP/C/W/474 and its Addenda), Brazil (IP/C/W/475), Peru (IP/C/W/484), the United States (IP/C/W/469), Japan (IP/C/W/472) and Norway (IP/C/W/473). Copies of all the above-mentioned documents can be found on the WTO website (www.wto.org).

As regards the Director-General's consultative process, the discussions this year have focused both on the merits of different policy options in this area and on the relation of this issue to the Doha Round of negotiations. Some countries sought a clear agreement that a solution would be negotiated as part of the outcome to the Round. Some other WTO Members considered that there was no negotiating mandate on this matter and that it would not be appropriate to create one.

I hope that the above information is useful.

Yours sincerely,



Adrian Otten
Director
Intellectual Property Division

**2) COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES AND RELEVANT
ORGANIZATIONS ON THE GAP ANALYSIS**

I. SUBMISSIONS FROM PARTIES

CANADA
Submission by Canada
Notification 2006-045:
Information on the Gap analysis

Inputs to the Matrix

In preparation for the fourth meeting of the Ad-hoc Open-ended Working Group on ABS, Canada contributed extensively to the matrix. (See Canadian submission contained in document UNEP/CBD/WG-ABS/4/3).

Gap analysis

In Canada's view, the matrix exercise has helped to elucidate and enhance understanding of the relationship between the ABS-related provisions of the CBD and those of other international instruments.

Nevertheless, this exercise and any subsequent compilations do not represent a full and comprehensive analysis of gaps. Further it should be noted that while of some utility, the associated matrix is not a substitute for a full gap analysis. In Canada's view, the matrix is merely a tool to summarize the outcome of the individual analyses conducted to date by Parties and others as to whether any gaps exist in the current international regime, whether such gaps should be filled, and if so, how.

Whether something constitutes a "gap" is a matter of perception, and not all gaps would necessarily warrant filling. For example, we would note that since obligations arising under mutually agreed arrangements may be contractual obligations between providers and users, disputes arising in these arrangements are likely to be resolved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practice. Although such arrangements are not referenced in the matrix, it could be argued that private international law in this area is sufficient and there is no gap, even though it does not easily fall under the matrix headings. Another example is that some of the gaps might be geographical in nature, such as the Antarctic and other areas beyond national jurisdiction. This may be difficult to fully reflect in the matrix.

Paragraph 9 of Decision VIII/4 calls for the preparation of the final version of the gap analysis. While many Parties to Convention have been requesting this analysis as a key document to guide the negotiations of an ABS International Regime, no such complete and neutral analysis of gaps has yet been done. Canada believes that this analysis would play a concrete and constructive role at the fifth meeting of the Open-ended Working Group on Access and Benefit-sharing and would like to propose that the Executive Secretary to the Convention on Biological Diversity consider commissioning this work to an independent researcher.

Canada's views on the matrix contained in Annex II

As per the report of the third meeting of the Open-Ended Working Group on Access and Benefit-sharing,

"Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders [are invited] to provide information to the Executive Secretary on the basis of the matrix contained in annex II to the present recommendation and the potential additional elements and options three months before the fourth meeting of the Working Group, in order to facilitate further analysis of gaps in existing national, regional and international legal and other instruments relating to access and benefit-sharing".

Attached is Canada's initial and non-exhaustive input to the matrix. It contains the key elements of some existing international treaties and agreements that, in Canada's view, already cover the basic principles of access to genetic resources and benefit-sharing.

In Canada's view, the matrix exercise has helped to elucidate and enhance understanding of the relationship between the ABS-related provisions of the CBD and those of other international instruments. Nevertheless, this exercise and any subsequent compilations do not represent a full and comprehensive analysis of gaps. Although at WGABS-3 Canada did not object to the matrix, we did express concerns that it might be viewed as a substitute for a full gap analysis. In our view, it is simply a tool to summarize the outcome of the individual analyses so far conducted by Parties and others as to whether any gaps exist in the current international regime, whether such gaps should be filled, and if so, how. Whether something constitutes a "gap" is a matter of perception, and not all gaps necessarily warrant filling. For example, we would note that since obligations arising under mutually agreed arrangements may be contractual obligations between providers and users, disputes arising in these arrangements are likely to be resolved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practice. Although such arrangements are not referenced in the matrix, it could be argued that private international law in this area is sufficient and there is no gap, even though it does not easily fall under the matrix headings. Another example is that some of the gaps might be geographical in nature, such as the Antarctic and other areas beyond national jurisdiction. This may be difficult to fully reflect in the matrix.

WGABS-5 needs to engage in a more detailed discussion, rendered more complex because the elements included in the matrix are not yet agreed. Interpretation of the elements included in the attached matrix will vary depending on the understanding Parties have of the need for, objectives, elements and efficiency of a potential international regime on ABS. It will also vary depending on the interpretation of what constitutes a regime. It is difficult for the matrix, even as complex as it is, to fully reflect all aspects of this discussion.

COLOMBIA

↓ Elementos a ser tenidos en cuenta en el marco de la negociación del Régimen Internacional de ABS

- La discusión, negociación y adopción de un régimen internacional² de Acceso y Distribución de Beneficios (ADB) en el marco del Convenio sobre la Diversidad Biológica, deberá incluir en su ámbito los productos derivados, garantizar la observancia y cumplimiento de la legislación nacional, reconocer la soberanía y derechos del país de origen y disponer los mecanismos de seguimiento y control adecuados.
- Paralelamente, se debe discutir, negociar y adoptar un Sistema Internacional *sui generis* de Protección al Conocimiento Tradicional, que reconozca los derechos de propiedad colectiva de las comunidades y grupos étnicos sobre sus conocimientos tradicionales, el derecho a la participación y a

² La naturaleza del Régimen Internacional de ABS tal y como se está negociando en el marco del CBD, implica que puede ser un instrumento único o una serie de instrumentos que pueden tener o no el carácter de jurídicamente vinculante.

FROM : DIR ASUNTOS ECONOMICOS

FAX NO. : 5666001

May. 29 2007 12:15PM PB

- la distribución justa y equitativa de los beneficios, y que tenga como base el Consentimiento Fundamentado Previo a partir de lo dispuesto en el Art. 6 (j) del Convenio sobre la Diversidad Biológica.
- Es necesario reglamentar el alcance del sistema actual de Derachos de Propiedad Intelectual respecto a los recursos biológicos y genéticos en reconocimiento de los derechos soberanos del Estado sobre sus recursos naturales y la noción de dominio eminente fundamentada en la conservación de la biodiversidad y el desarrollo sostenible a través de mecanismos que promuevan la transferencia de tecnología y la creación de capacidad.
 - En este sentido, deben incorporarse los desarrollos en la armonización del actual sistema ADPIC con las necesidades normativas específicas a la reglamentación del acceso y protección de los recursos genéticos y conocimientos tradicionales en el marco de los DPI y el CDB, en consideración de las normas regionales y nacionales vigentes (Decisiones 391 y 486 de la Comunidad Andina)
 - El Régimen debe procurar definir el alcance de eventuales bases de datos y registros de uso de recursos genéticos y de conocimientos tradicionales para ser utilizados por las autoridades competentes, con la finalidad de efectuar un control a las prácticas de acceso a los recursos genéticos y conocimientos tradicionales en el marco de los DPI y el CDB. En este sentido debe determinarse el tipo de información que se manejaría en esta base de datos, en consideración que los registros no serían equivalentes al conocimiento y prácticas científicas per se relacionadas con el uso de recursos genéticos y/o conocimientos tradicionales.
 - Es necesario también promover el conocimiento público informado sobre los Recursos Genéticos, Productos Derivados y Conocimientos Tradicionales, y los procedimientos asociados a su utilización, con miras contribuir a la mayor eficiencia de las solicitudes de acceso ante la Autoridad Nacional Competente, así como de los beneficios, derechos y responsabilidades que se derivan de su uso y aprovechamiento. Lo anterior no sólo contribuiría a un mayor seguimiento de las prácticas de acceso sino a una proliferación de los beneficios que de esta práctica se desprendan, incluyendo la transferencia de tecnología y conocimientos que contribuyan a la capacidad científica y tecnológica del país para el aprovechamiento de RG.
 - Es necesario fomentar la capacidad científica y técnica nacional en RG, para poder seleccionar, desarrollar, adecuar e implementar tecnologías que brinden soluciones a problemas específicos nacionales y/o regionales a partir del aprovechamiento de los recursos genéticos y la diversidad biológica.

Esto implica desarrollar acciones en las siguientes áreas:

- Evaluación de la capacidad actual y limitaciones para la evaluación técnica, jurídica y económica de las solicitudes de acceso.
- Identificación de las barreras de industria implícitas en la normatividad vigente sobre acceso a recursos genéticos y propuestas para minimizar el impacto de las mismas.
- Fortalecimiento institucional a entidades de investigación y transferencia tecnológica
- Facilitades y diseño de incentivos para la investigación en RG
- Vinculación del sector científico y de investigación al desarrollo empresarial a los procesos de formulación de políticas relacionadas con la administración de RG y la distribución de beneficios asociados.
- Fortalecimiento de grupos de investigación y de gestión, multidisciplinarios e interinstitucionales
- Modernización y fortalecimiento de programas de formación de capital humano
- Evaluación de las posibilidades de introducir procedimientos diferenciados de acuerdo con las diferentes finalidades del acceso a recursos genéticos.

Espero que las anteriores consideraciones sean de utilidad. Agradecemos interponga sus buenos oficios para remitir la presente información a la Secretaría del Convenio de manera oportuna.

ENGLISH TRANSLATION

Elements to be taken into account in the context of negotiating the international regime for ABS

- The discussion, negotiation and adoption of an international regime¹ for access and benefit sharing (ABS) within the framework of the Convention on Biological Diversity, must encompass by-products, guarantee observance of and compliance with national legislation, recognize the sovereignty and rights of the country of origin, and provide for the proper monitoring and control mechanisms.
- In parallel, there should be discussion, negotiation and adoption of an International *sui generis* system for the protection of traditional knowledge, which recognizes the collective property rights of communities and ethnic groups over their traditional knowledge, the right to participation, and the right to fair and equitable benefit sharing based on Prior Informed Consent as set out in Article 8 (j) of the Convention on Biological Diversity.
- It is necessary to regulate the scope of the current Intellectual Property Rights system with regard to biological and genetic resources to recognize the sovereign rights of the State over its natural resources, and the notion of eminent domain based on the conservation of biodiversity and sustainable development through mechanisms that promote technology transfer and capacity building.
- In this respect, it is necessary to incorporate developments in the harmonization of the current TRIPS system with the regulatory requirements specific to regulating access to and protection of genetic resources and traditional knowledge in the context of Intellectual Property Rights and the CBD, taking into consideration the regional and national regulations in effect (Andean Community Decisions 391 and 486)
- **The Regime must be able to define the scope of potential databases and registers of genetic resource use and traditional knowledge, for use by the competent authorities, for the purpose of controlling practices of access to genetic resources and traditional knowledge within the framework of intellectual property rights and the CBD. In this respect, it is necessary to determine the type of information that will be handled in said database, taking into consideration that the registers will not be equivalent to the knowledge and scientific practices *per se* related to the use of genetic resources and/or traditional knowledge.**
- It is also necessary to promote informed public knowledge of Genetic Resources, by-products and Traditional Knowledge, and of the processes linked to their use, with the aim of helping to increase the efficiency of applications for access submitted to the Competent National Authority, and knowledge of the benefits, rights and responsibilities arising from the use and exploitation of genetic resources. The above will not only contribute to greater monitoring of access procedures, but will also lead to a proliferation of benefits arising from these practices, including technology and knowledge transfer contributing to the country's scientific and technological capacity to exploit GR.
- It is necessary to foster national scientific and technical capacity with regard to GR, in order to be able to select, develop, adapt or implement technologies that provide solutions to specific national and/or regional problems based on the exploitation of genetic resources and biological diversity.

This involves developing actions in the following areas:

- Assessing current capacity and limitations with regard to the technical, legal and economic evaluation of applications for access.
- Identifying obstacles to industry implicit in the legislation in effect on access to genetic resources, and making proposals to minimize such obstacles.
- Providing institutional strengthening to research and technology transfer entities.

¹ The nature of the International Regime for ABS, as it is being negotiated within the framework of the CBD, implies that it could be a single instrument or various instruments, which may or may not be legally binding.

- Facilitating and designing incentives for GR research
- Connecting the scientific sector and the business research and development sector with the processes for drafting policies related to GR management and the distribution of associated benefits.
- Strengthening multidisciplinary and inter-institutional research and management groups.
- Modernizing and strengthening human capital training programs.
- Evaluating the possibility of introducing different procedures according to different reasons for accessing genetic resources.]

ETHIOPIA

INFORMATION RELEVANT TO THE GAP ANALYSIS

Here is some information in requests made from your office in various notifications (Ref SCBD/SEL/VN/VP/54834) sent to the focal point in Ethiopia to submit experiences and reports on the implementation of issues related to access and benefit sharing. Some of them are updates to what we have reported before.

Low level of awareness among stakeholders and the general public
Constraint of technical capacity among key relevant institutions,
Limited access to relevant information and experience
Lack of coordination and synergy among relevant national institutions

EUROPEAN COMMUNITY AND ITS MEMBER STATES

EU submission in reply to Notification 2006-045

Observations by the European Community and its Member States on the gap analysis

In response to the above-mentioned notification, the EU would like to provide two observations regarding the gap analysis.

First, there is a continuing need for a real analysis of the current system of ABS governance to support parties to take an informed choice on the appropriate focus of the negotiations.

In the terms of reference of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, parties to the CBD agreed to elaborate and negotiate an international ABS regime "drawing on *inter alia* an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts; experiences with their implementation; compliance and enforcement mechanisms; and any other options." (Decision VII/19 D, Annex (a) (i)).

According to Decision VII/19 D, Annex (a) (ii), this analysis will support the Ad Hoc Working Group on ABS to examine whether and to what extent possible elements of an international ABS regime are part of existing instruments and how to address the gaps.

Based on recommendation 3/1 of the Third Meeting of the ABS Working Group, the European Community and its Member States provided information on existing instruments to the Executive Secretary. Other parties, governments and relevant stakeholders did so as well. The Executive Secretary compiled the information received in Document UNEP/CBD/WG-ABS/4/3 prior to the Fourth Meeting of the ABS Working Group.

However, a proper analysis of the information contained in this document and drawn from other sources still needs to be undertaken. Against this background, the Eighth Conference of the Parties requested the Executive Secretary to present the final version of the gap analysis to the Fifth Meeting of the ABS Working Group (see Decision VIII/4, A para. 9).

In line with the terms of reference for the ABS negotiations, the final version of the gap analysis needs to clearly spell out which of those elements that have been identified as possible elements of an international ABS regime are already parts of existing instruments and where gaps exist.

The gap analysis should also include a review of national compliance and enforcement mechanisms/regulations in place.

This analysis will support parties in their effort to focus the negotiations on those areas where additional international rules would add value to the current system of ABS governance. A clear focus of the negotiations will also help to complete the work in the ABS Working Group at the earliest possible time before the tenth Meeting of the Conference of the Parties to the CBD.

Second, there are some areas where the EU, based on its own analysis, would see that the international ABS negotiations could add value to the current system of ABS governance.

These are:

- International minimum requirements on national access legislation and practice that could serve as reference point for user measures across different jurisdictions.
- Exploring ways to prevent the use of genetic resources that were not obtained in accordance with access legislation of provider countries, respectively with international minimum requirements on access.
- Sectoral work on standardising Material Transfer Agreements.

Subject: EU submission on standardising choices in Material Transfer Agreements

In preparing for ABS WG5 and WG6, the EU has identified sectoral work on standardising choices in Material Transfer Agreements as one way to enhance legal certainty and compliance with ABS requirements and thus add to a conducive environment for the fair and equitable sharing of benefits arising from utilisation of genetic resources. Therefore, sectoral work on standardising choices in Material Transfer Agreements should in the EU's view be considered in the negotiations on an international ABS regime.

Recalling paragraph A.2 lit (c) of COP Decision VIII/4 which calls upon Parties to submit additional inputs relating to access and benefit sharing, the EU herewith submits the attached summary of an expert meeting on standardising Material Transfer Agreements. We see this as a major contribution to the further elaboration and negotiation of an international ABS regime during the Fifth and Sixth Meetings of Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

We hope therefore that this document will be considered in the preparation of the background material for these meetings and would also request it to be included among the INF documents for ABS WG5.

The EU intends to raise the issue of standardising choices in Material Transfer Agreements in discussions under the agenda item of fair and equitable sharing of benefits at ABS WG5.

**Expert Meeting on Standardising Choices in Material Transfer Agreements
Brussels, 12 February 2007
Summary of Results**

(i) I. Introduction

It is likely that work on standardising choices in Material Transfer Agreements (MTAs) will play a role in the ongoing negotiations of an international regime on access and benefit-sharing (ABS). So far, however, there has been little systematic discussion on this issue and how it could fit into the emerging framework of international ABS governance.

An expert meeting organised by the European Commission on 12 February 2007 in Brussels aimed to facilitate such discussion. The meeting focussed on three aspects:

- lessons that can be learned from the negotiations of a standard MTA under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA);
- implications for standardisation of MTAs if best use is made of latest IT-based technologies that allow for the low-cost tracking of genetic resources, associated user conditions and traditional knowledge;
- the potential role of private international law for the enforcement of rights and obligations set out in MTAs.

This document summarises the main results from this meeting.

(ii) II. Legal and Political Context

According to *Article 15.7* of the Convention on Biological Diversity (CBD), each Contracting Party "shall take legislative, administrative or policy measures, as appropriate...with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and

other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

The *Bonn Guidelines* explicitly mention the development of standardised Material Transfer Agreements (MTAs) and benefit-sharing arrangements for similar resources and similar uses as a means to provide legal certainty and clarity and to minimise transaction costs. Appendix I of the Bonn Guidelines suggests some elements for inclusion in MTAs.

The *terms of reference for the ABS negotiations* in the Annex to Section D of Decision COP VII/19 mention the Bonn Guidelines, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) as well as codes of conduct, and other approaches developed by specific user groups or for specific genetic resources, including model contractual arrangements among the elements that shall be considered by the ABS Working Group.

Prior to ABS WG4, some *parties suggested* considering the standardisation of MTAs, resp. the development of model or standard provisions for MTAs as a means to address gaps in international ABS governance.¹

CBD COP8 confirmed the COP7 mandate of the ABS negotiations but did not undertake substantive considerations on the issue of standardisation of MTAs.

III. Aspects of relevance to discussions on standardising choices in MTAs

1. Usage of terms

In the context of the CBD ABS negotiations, it might be misleading to use the term "standardisation" of MTAs. Different than in the case of the IT-PGRFA, where one compulsory standardised MTA was adopted in June 2006, it does not seem feasible to replicate this approach within the CBD framework. The standard MTA adopted under the IT-PGRFA will be used for transactions of specific genetic resources that are generally known and maintained under ex-situ or in-situ conditions and only when these genetic resources are accessed for research, breeding or training for the purpose for food and agriculture. MTAs in the CBD ABS context, in contrast, apply to transactions of all types of genetic resources within the scope of the CBD, whether these are already known or are yet to be discovered and identified through bioprospecting, and for all possible uses of genetic resources.

Speaking of "standardisation" of MTAs in the CBD context should therefore be understood to refer to the development of a menu of standardised choices of MTA-text for issues of a more general nature and for specific uses/ user chains of genetic resources.

2. Rationale for the standardisation/ limitation of choices

- Limiting choices of participants in MTA negotiations sets boundaries to the available negotiation space and thus lowers transaction costs for the negotiation and conclusion of MTAs;
- Limiting choices to a set of tested/ workable options, raises legal certainty for providers and users of genetic resources that a contract is valid and can be executed;
- Limiting choices constrains the use of power in MTA negotiations and thus protects the weaker party;
- Offering a menu of standardised choices facilitates the establishment of direct links to electronic networks to exchange information on genetic resources and associated user conditions.

3. Contextual preconditions for successful standardisation of MTAs

- Efforts to standardise MTAs are much more likely to succeed if stakeholders in a specific user chain have practical experience with transactions of specified materials and related negotiations of MTAs.

¹ See eg. Doc. UNEP/CBD/WG-ABS/4/3 "Matrix on the Analysis of Gaps".

Such experience creates a common background and understanding amongst stakeholders that should make use of standardised choices of MTA text.

- Further discussions and reflections on practical cases are needed to determine whether it is feasible and useful to standardise choices for the conclusion of MTAs when genetic resources to be accessed are not yet known or whether such efforts are only useful when accessing clearly identified genetic resources.
- Another issue for further reflection is whether there is potential value in distinguishing between MTAs that apply to non-commercial, basic research activities on the one hand side and MTAs applying to commercial uses of genetic resources further downstream in the value chain on the other hand side.

4. Elements to consider for inclusion in a menu of standardised choices for MTAs

As a starting point, it seems useful to distinguish between elements of general importance/ relevance and elements of contextual/ sectoral relevance.

a) General elements to consider for inclusion

- Model clauses may stipulate that access for non-commercial or basic research purposes could be linked to an obligation to make the resulting knowledge publicly available²;
- Model clauses on the settlement of disputes arising between parties of a MTA;

b) elements of contextual/ sectoral importance

- Specifying notions of what constitutes an "utilisation" of genetic resources in the sense of Article 15.7 CBD in specific chains of users of genetic resources.
- Identification of sectoral reference points that are characteristic for research and product development based on genetic resources in specific chains of users of genetic resources. E.g., identifying the typical boundary between non-commercial and commercial research.
- Specifying sectoral notions of non-monetary and monetary benefit-sharing.

5. Complementary aspects to consider

- Efforts to modularise and limit choices in MTAs for specific sectoral uses of genetic resources should consider the low-cost, advanced communication opportunities of modern electronic networks as part and parcel of the standardisation process.
- Key considerations during the process of standardisation on chosen and excluded options should be documented in a clearly understandable manual to support potential users. This should also include identification of cases in which use of the standard MTA is advisable and cases in which it should not be used.
- Confidential elements will generally be negotiated for individual contracts and do not seem to lend themselves to standardisation. Modern communication networks, including the internet, do, however, allow for adequate protection of confidential information through graduated access to information on genetic resources and associated user conditions.
- In the case of the IT-PGRFA governments have eventually opted for a compulsory standard MTA. In the context of the CBD ABS negotiations, standardised choices for MTAs for specific user sectors should remain optional. If proposed choices are regarded as useful by both providers and users of genetic resources they will be used even if their use is not compulsory, simply because it makes practical sense to do so. Mandatory choices for MTAs would lack the necessary flexibility to negotiate individual conditions for special cases and also to adapt MTAs to the widely differing uses

² This leaves room for properly negotiated agreements with a different content. An MTA could, for instance, grant exclusive access to research material for a limited time-span.

of genetic resources in specific user chains. Parties to the CBD could, however, consider establishing a mechanism/ procedure to formally identify those sectoral standard MTAs that are regarded as fully in line with the CBD, the Bonn Guidelines and the requirements of the proposed international ABS regime.

6. Consideration on the process of standardisation

It does not seem useful in the CBD ABS context that governments themselves negotiate menus of standardised choices of MTA-text for specific user chains. Nevertheless, governments have important contributions to make to processes of standardisation. This might include identifying some sectors that seem ripe for standardisation, spelling out minimum process requirements (openness, transparency etc), providing financial support to sectoral processes developing standard MTAs/ modularised choices for MTAs, suggesting general elements that should be taken into account (see above) and formally identifying those standardised MTAs that are regarded as fully in line with the CBD, the Bonn Guidelines and the requirements of the proposed international ABS regime

ISLAMIC REPUBLIC OF IRAN

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C) **Gap Analysis**

- 1) Incompletion of all resources' Genetic identification including Endemic and Non-endemic
- 2) Non-Identification of all species and Potential and Actual Genetic Resources are unknown.
- 3) There is no sufficient assurance to prevent the exodus of Genetic Resources from country particularly unknown Resources.
- 4) There is lack of integrated plan and enough coordination regarding Genetic Resources Protection.
- 5) There was insufficient good management system in the past and consequently, missing some of Genetic Resources in the form of extinct or pillaged species without having their Genetic Identifications.

NORWAY

Further information relevant to the gap analysis

Norway refers to an earlier submission on the topic dated October 26, 2005, where a gap analysis is enclosed.

SWITZERLAND

Parties are invited to submit to the Secretariat by 31 December 2006:

1. Further information relevant to the gap analysis;

1. Concerning the gap analysis, Switzerland has already submitted- with other governments and relevant organizations and stakeholders - a detailed gap analysis prepared for the 4th ad hoc open-ended working group on access and benefit-sharing (Granada, 30 January-3 February 2006). For further details please refer to our contribution made for that meeting included in the document UNEP/CBD/WG-ABS/4/3.

However, if a comprehensive compilation has already been made by the Secretariat, the complete analysis - as requested by the Eight Conference of the Parties in Decision VIII4 (para 9) is still needed to be presented in the final version of the gap analysis. This analysis should mainly aim to identify clearly the elements that already exist to be possibly included in the international regime and where are the main critical gaps. On our view, such an analysis should enable the Parties to better focus on essential elements to elaborate an effective and operational international regime by identifying the minimum set of requirements, measures and practices on ABS to be effectively used across different jurisdictions.

II. SUBMISSIONS FROM RELEVANT ORGANIZATIONS

PhRMA



December 20, 2006

Mr. Ahmed Djoghlaf
Executive Secretary
Secretariat of the Convention on Biological Diversity
World Trade Centre
413, Saint-Jacques, Suite 800
Montreal, Quebec
Canada
H2Y 1N9



RE: Decision VIII/4 on Access and Benefit-sharing: International Regime on Access and Benefit-sharing; Notification to International Organizations, Indigenous and local community representatives and all relevant stakeholders regarding further information relevant to the gap analysis

Dear Secretary Djoghlaf:

Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) appreciate the opportunity to participate in the discussions relating to an international regime on access and benefit-sharing, particularly with regard to information that may be relevant to the gap analysis.

As stated in Decision VIII/4A, paragraph 3, Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders are invited "to provide information regarding the inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing..." According to paragraph 8, all relevant stakeholders are invited to "submit to the Secretariat further information relevant to the gap analysis."

Information regarding analysis of existing legal or other instruments at the national, regional or international levels is best provided by those Parties, Governments and international organizations responsible for implementing and enforcing such instruments. PhRMA notes, however, that a thorough analysis of any possible gaps in existing legal instruments must necessarily include an understanding of those instruments and where they succeed or fail. Gaps may also exist due to the absence of national laws, creating failure of users to access genetic resources and resultant lack of benefits. Without evidence of the gaps in existing national laws or gaps resulting from the absence of national laws, it is difficult to envision how an effective international regime, created

Pharmaceutical Research and Manufacturers of America

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with the goal of promoting and safeguarding fair and equitable benefit-sharing, can be devised. Indeed, negotiation of an international regime on access and benefit-sharing cannot proceed in a vacuum.

It is therefore discouraging that, to date, little information has been provided by Parties regarding existing national legislation, or where such national instruments have proved unsuccessful. We note that document UNEP/CBD/WG-ABS/4/INF/4 provided a similar compilation of submissions relating to existing national, regional and international legal or other instruments. Regrettably, while several of the Parties that have most actively pursued an international regime have also implemented national legal instruments, those same Parties did not participate in the submission to ABS-WG 4. Presumably, these Parties feel that national legislation has not been sufficient to meet the access and benefit-sharing goals of the CBD, but there is no indication as to what they believe the shortcomings to be.

PhRMA believes that the most appropriate means for regulating access to genetic resources and associated traditional knowledge is through national legislation. That is, of course, what is contemplated by the CBD. Many of the genetic resources that have been cited as having been subject to misappropriation are readily available through ordinary channels of trade and commerce. For example, each of the genetic resources identified in document WIPO/GRTKF/IC/8/12 can be purchased from exporters without restriction on the use of the resources. Similarly, the turmeric used in US Patent No. 5,401,504, which has been the subject of allegations of misappropriation, was purchased from a grocery store in the United States (see column 5, lines 3-4). Therefore, as with trade in other commodities, PhRMA believes that regulation of trade in genetic resources is best accomplished by national legislation.

The gaps analysis will require full participation of the Parties and careful consideration of both the positive and negative aspects of existing national and regional measures. We therefore welcome the efforts of the Secretariat to compile further information relevant to the gap analysis.

Sincerely,



Richard H. Kjeldgaard
Assoc. V.P., International Intellectual Property

3) COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES AND OTHER RELEVANT ORGANIZATIONS ON THE LEGAL STATUS OF GENETIC RESOURCES

I. SUBMISSIONS FROM PARTIES

AUSTRALIA

Submission on Legal Issues surrounding ABS in Australia's domestic law

Implementation of the access and benefit sharing (ABS) provisions of the Convention on Biological Diversity (CBD) in Australia is made difficult by a complex web of existing law governing the ownership and use of native biological resources, and therefore the genetic resources contained within them.

Ownership may exist in some biological resources but not in others, subject to existing statutory and common law. In general, existing rights to native biological resources depend on the type of resource and where they are found. Some biological resources are in government hands, but much is also in private hands.

The Federal Government controls access to resources found on Commonwealth lands and waters (described below), and State and Territory Governments control resources found on state lands and waters up to 3 nautical miles from the coast. However, even where Governments control access they do not necessarily have ownership rights. Private owners control access to biological resources found on freehold land. On leasehold land, an exclusive right of possession allows the lessor to effectively control access to biological resources. In many circumstances, more than one entity will have some right over the same biological resources.

Indigenous lands have different associated rights affecting control of the biological resources found on them. For instance, exclusive native title and exclusive possession by an indigenous land trust may allow the traditional owners or the land trust to control access to the biological resources on that land.

The adoption of ABS legislation in Australia therefore affects the existing rights of landowners and raises complex legal questions.

In 2002 the Australian federal, state and territory Governments agreed upon a 'nationally consistent approach', based on the Bonn Guidelines. The document sets out the general principles on which legislation is to be based in each jurisdiction, but also provided a framework to implement subtle variations in their ABS systems. This is highlighted by slight differences in the scope of the ABS systems of the three Governments who have so far completed implementation.

- . Queensland's Biodiscovery Act covers state land and waters, but the Government chose not to intervene in access on private and indigenous land. Existing common, statutory and contract law governs access in those areas.
- . The Northern Territory's system takes another approach, covering all land and sea within the Northern Territory with the exception of lands owned by the federal government.
- . The Federal system covers lands owned and leased by, or reserves established by, the federal government, and waters more than 3 nautical miles from the coast to the extent of national jurisdiction.

All these are consistent with the CBD which does not prescribe one single 'right' way to implement its provisions on ABS. Indeed one of the strengths of the CBD is that it allows parties a high degree of flexibility to implement ABS systems taking into account their existing law.

Discussions in the ABS Working Group need to take account of the great differences in ownership and access rights to genetic resources in different parties.

CANADA

**Submission by Canada
Notification 2006-045:
Legal status of Genetic Resources**

Legal Status of Genetic Resources

Domestic discussions are currently taking place in Canada around ABS. The determination of the legal status of genetic resources in Canada is a central question to this policy development process.

Issues around legal status, ownership, and access granting authority (ies) are currently being considered by a range of policy-makers at all levels of governments in Canada. Complex legal considerations require further exploration and no conclusions have yet emerged from this on going initiative.

Notwithstanding the status of domestic discussions on this issue, Canada believes that, at the global level, further information on the legal status of genetic resources would help advance the global and national discussions on this topic.

COLOMBIA

FROM : DIR ASUNTOS ECONOMICOS

FAX NO. : 5666881

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COLOMBIA

Decisión VIII/4 sobre ABS: Régimen Internacional sobre Acceso a Recursos Genéticos y Distribución de Beneficios

Régimen Jurídico de los Recursos Genéticos en la Legislación Colombiana

- En lo relacionado con el estatus legal de los recursos genéticos en la legislación nacional, en Colombia existe un amplio marco jurídico a través del cual el Estado busca garantizar la conservación y uso sostenible de la biodiversidad y los demás recursos naturales renovables existentes en el territorio. A su vez, este viene acompañado de políticas, estrategias, proyectos, programas y acciones que hagan viable el cumplimiento de los objetivos generales de este cuerpo legislativo.
- Conforme al inciso 2 artículo 81 de la Constitución Política, el Estado colombiano es el único facultado para regular la utilización, el ingreso o salida de los recursos genéticos del país. Respondiendo a este mandato, la Ley 99 de 1993 en el numeral 21 del artículo 5 le asignó al Ministerio del Medio Ambiente, la función de "regular, conforme a la Ley, la obtención, uso, manejo, investigación, importación, exportación, así como la distribución y el comercio de especies y estirpes genéticas de fauna y flora silvestres; regular la importación, exportación y comercio de dicho material genético, establecer los mecanismos y procedimientos de control y vigilancia, y disponer lo necesario para reclamar el pago o reconocimiento de los derechos o regalías que se causen a favor de la nación por el uso de material genético".
- De igual manera, debe tenerse en cuenta la Decisión 391 de la Comisión del Acuerdo de Cartagena relativa al Régimen Común sobre Acceso a los Recursos Genéticos, que entró en vigencia el 17 de julio de 1995, fecha de su publicación en la Gaceta Oficial del Acuerdo. La Decisión Andina 391 es el primer marco jurídico regional que regula el acceso a los recursos genéticos y sus productos derivados, de tal forma que además de establecer el procedimiento que se debe surtir para lograr el acceso a dichos recursos, se destaca que sus postulados respetan lo previsto en el Convenio de Diversidad Biológica, y obviamente dentro de ese marco, reconociendo y valorando los derechos y la facultad de decidir de las comunidades sobre sus conocimientos, innovaciones y prácticas tradicionales asociados a los recursos genéticos y sus productos derivados.
- A través del Decreto 730 de 1997 el Gobierno Nacional designó al Ministerio del Medio Ambiente (hoy Ministerio de Ambiente, Vivienda y Desarrollo Territorial) como la Autoridad Nacional Competente, en los términos y para los efectos establecidos en la decisión 391 de la Comisión del Acuerdo de Cartagena relativa al Régimen Común sobre Acceso a los Recursos genéticos. Conforme a lo dispuesto en esta norma, al Ministerio del Medio Ambiente (hoy Ministerio de Ambiente, Vivienda y Desarrollo Territorial) le compete expedir las regulaciones administrativas internas necesarias para el cumplimiento de dicha decisión; recibir, tramitar y autorizar o no las solicitudes de acceso a recursos genéticos y negociar y suscribir en consecuencia los respectivos contratos de acceso; supervisar y controlar el cumplimiento de las condiciones de los contratos de acceso y establecer los mecanismos de seguimiento y evaluación a que haya lugar; entre otras cosas.
- A través de la Resolución 0620 de 1997, se delegaron una serie de funciones al interior del Ministerio de Medio Ambiente (hoy Ministerio de Ambiente, Vivienda y Desarrollo Territorial) en lo relacionado con el acceso a los recursos genéticos y se estableció el procedimiento interno para tramitar las solicitudes de acceso a los recursos genéticos y sus productos derivados, de tal forma que se estipuló con claridad la competencia de cada una de las dependencias de este Ministerio que deben adelantar algún procedimiento en esta materia ante una eventual solicitud.
- A través del Decreto 2385 de 2004, se modificó la estructura del Ministerio de Ambiente, Vivienda y Desarrollo Territorial y se asignó a la Dirección de Licencias, Permisos y

FROM : DIR ASUNTOS ECONOMICOS

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Trámites la función de adelantar el procedimiento relacionado con las licencias y demás instrumentos de manejo y control ambiental, dentro de los cuales se encuentra la suscripción de los contratos de acceso a los recursos genéticos.

- *Concepto Sala de Consulta y Servicio Civil del Consejo de Estado.* Ante la necesidad de tener claridad sobre el régimen jurídico del dominio aplicable a los recursos genéticos, el Ministerio del Medio Ambiente elevó una consulta a la Sala de Consulta y Servicio Civil del Consejo de Estado, la cual fue resuelta mediante Concepto de fecha agosto de 1997. Rad. No. 977. Consejero Ponente: Cesar Hoyos Salazar, en la cual concluyó:

"El régimen jurídico de propiedad aplicable a los recursos genéticos, de utilidad real o potencial, es el establecido para los bienes de dominio público, en forma general en la Constitución Política, y de manera particular, en la decisión 391 de la Comisión del Acuerdo de Cartagena, en el decreto ley 2811 de 1974, la ley 165 de 1994 y las disposiciones legales que en el futuro se expidan sobre la materia.

El tratamiento jurídico de los recursos genéticos no es el mismo que le da la legislación colombiana a los recursos naturales no renovables, porque estos tienen un régimen legal especial, el cual no dispone que sus normas se apliquen también a los recursos naturales renovables. Por el contrario, existe un Código Nacional de Recursos Naturales Renovables y disposiciones que lo adicionan y complementan.

Al recurso genético puede dársele un tratamiento jurídico de propiedad independiente al previsto para el recurso biológico, aunque este contiene al primero, mientras formen unidad o estén integrados, la función ecológica impuesta a la propiedad privada y el interés nacional garantizan la propiedad pública de la nación y una vez separados cada uno se sujeta al régimen jurídico que le es propio".

ENGLISH TRANSLATION

Decision VIII/4 on ABS: International Regime on Access to Genetic Resources and Benefit-Sharing

Legal Regime Governing Genetic Resources in Colombia's Legislation

- With regard to the legal status of genetic resources in national legislation, Colombia has a broad legal framework through which the Government seeks to guarantee the conservation and sustainable use of biodiversity and other renewable natural resources on the country's territory. This framework is supported by policies, strategies, projects, programs and actions for the viable fulfilment of the legislation's general objectives.
- According to subsection 2 of Article 81 of the Political Constitution, the Colombian State is the only entity with the power to regulate the use of genetic resources and their passage into and out of the country. Taking this mandate into account, subsection 21 of Article 5 of Law 99 of 1993 bestows on the Ministry of the Environment the duty to "regulate, according to the Law, activities to obtain, handle, research, import and export wild plant and animal genetic species and stock; and to regulate the import, export and trade of said genetic material, establish monitoring and control mechanisms and procedures, and do everything necessary to claim payment or recognition for the rights or royalties arising from the use of genetic material for the benefit of the nation."
- It is likewise important to take into account Decision 391 of the Cartagena Agreement for a Common Regime on Access to Genetic Resources, which went into effect on 17 July 1996, the date it was published in the Official Gazette of the Agreement. Andean Decision 391 is the first regional legal framework regulating access to genetic resources and their by-products. In addition to establishing the procedure for obtaining access to said resources, it should be highlighted that its stipulations meet the provisions of the Convention on Biological Diversity. Obviously, this framework also recognizes and values communities' rights and decision-making powers with regard to their traditional knowledge, innovations and practices associated with genetic resources and their by-products.
- Through Decree 730 of 1997, the National Government designated the Ministry of the Environment (now the Ministry of the Environment, Housing and Territorial Development) as the Competent National Authority, under the terms and for the purposes of Decision 391 of the Cartagena Agreement Commission regarding the Common Regime on Access to Genetic Resources. As set out in said legislation, the Ministry of the Environment (now the Ministry of the Environment, Housing and Territorial Development) is responsible for issuing the necessary internal administrative regulations to comply with said decision; receiving, processing and authorizing or refusing applications for access to genetic resources, and negotiating and signing, as appropriate, the respective access contracts; supervising and monitoring fulfilment of access contract terms; and establishing the necessary follow-up and evaluation mechanisms, among other things.
- Through Resolution 0620 of 1997, a series of duties were assigned within the Ministry of the Environment (now the Ministry of the Environment, Housing and Territorial Development) with regard to access to genetic resources, and an internal procedure was established to process applications for access to genetic resources and their by-products. This resolution therefore clearly stipulates the authority of each of the Ministerial bodies involved in processing potential applications in this area.
- Decree 2366 of 2004 modified the structure of the Ministry of the Environment, Housing and Territorial Development, and assigned to the Department of Licenses, Permits and Procedures the task of carrying out the procedure with regard to licenses and other

instruments for environmental management and monitoring. The approval of contracts for access to genetic resources falls within this department's duties.

- *Opinion of the Consultation and Civil Service Tribunal of the Council of State.* Given the need for clarity with regard to the legal regime for the domain that applies to genetic resources, the Ministry of the Environment submitted a consultation to the Consultation and Civil Service Tribunal of the Council of State, which gave its ruling in its Opinion of August 1997. Rad. No 977. Representing Councillor: Cesar Hoyos Salazar, with the following conclusion:

"The applicable legal regime for genetic resources for which there is an actual or potential use is the regime established for goods in the public domain, in a general manner in the Political Constitution, and specifically in Cartagena Agreement Commission Decision 391, Decree Law 2811 of 1994, Law 165 of 1994 and any legal provisions issued on this matter in future.

The legal treatment of genetic resources is not the same as that given to non-renewable natural resources in Colombian legislation. Non-renewable resources have their own special legal regime, which does not provide for extending the application of its regulations to renewable natural resources as well. To the contrary, there is a National Code of Renewable Natural Resources, with additional and complementary provisions.

Genetic resources can be given independent legal treatment from that provided for biological resources, although the latter contain the former, and as long as they are within the same unit or are integrated, the ecological function's precedence over private property, combined with the national interest, guarantee public ownership thereof. Once separated, each resource is subject to its own legal regime."

COSTA RICA

RÉGIMEN JURÍDICO DE LOS RECURSOS GENÉTICOS EN LA RESPECTIVA LEGISLACIÓN NACIONAL, Y EN PARTICULAR SOBRE LA LEGISLACIÓN DE PROPIEDAD:

El tema del régimen jurídico de los recursos genéticos y bioquímicos en Costa Rica, ha sido regulado bajo los objetivos y procedimientos que se describen a continuación:¹

1) LEY DE BIODIVERSIDAD N° 7788², vigente a partir del 27 de mayo de 1998, regula a nivel nacional, los principios establecidos en el Convenio sobre la Diversidad Biológica, firmado en Río de Janeiro en el año 1992 y ratificado por el Gobierno de Costa Rica mediante la Ley 7416 de fecha 30 de junio de 1994.

A. ACCESO A RECURSOS GENÉTICOS Y BIOQUÍMICOS EN LA LEGISLACIÓN NACIONAL:

a) Objetivos:

El Artículo 10 de esta ley, establece los objetivos que se pretenden alcanzar con su aplicación:

1. Integrar la conservación y el uso sostenible de los elementos de la biodiversidad en el desarrollo de políticas socioculturales, económicas y ambientales.
2. Promover la participación activa de todos los sectores sociales en la conservación y el uso ecológicamente sostenible de la biodiversidad, para procurar la sostenibilidad social, económica y cultural.
3. Promover la educación y la conciencia pública sobre la conservación y la utilización de la biodiversidad.
4. Regular el acceso y posibilitar con ello la distribución equitativa de los beneficios sociales ambientales y económicos para todos los sectores de la sociedad, con atención especial a las comunidades locales y pueblos indígenas.
5. Mejorar la administración para una gestión efectiva y eficaz de los elementos de la biodiversidad.
6. Reconocer y compensar los conocimientos, las prácticas y las innovaciones de los pueblos indígenas y de las comunidades locales, para la conservación y el uso ecológicamente sostenible de los elementos de la biodiversidad.
7. Reconocer los derechos que provienen de la contribución del conocimiento científico para la conservación y el uso ecológicamente sostenible de los elementos de la biodiversidad.

¹ En este documento se utilizarán los siguientes acrónimos:

AC:	Áreas de Conservación
ATM:	Acuerdos de Transferencia de Material
CBD:	Convención sobre Diversidad Biológica
CONAGEBIO:	Comisión Nacional para la Gestión de la Biodiversidad
CONAREFI:	Comisión Nacional de Recursos Fitogenéticos
CPI:	Consentimiento Previamente Informado
MINAE:	Ministerio del Ambiente y Energía
OIT:	Organización Internacional del Trabajo
SINAC:	Sistema Nacional de Áreas de Conservación

² El texto completo de la Ley de Biodiversidad, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

8. Garantizarles a todos los ciudadanos la seguridad ambiental como garantía de sostenibilidad social, económica y cultural.
9. No limitar la participación de todos los sectores en el uso sostenible de los elementos de la biodiversidad y el desarrollo de la investigación y la tecnología.
10. Promover el acceso a los elementos de la biodiversidad y la transferencia tecnológica asociada.
11. Fomentar la cooperación internacional y regional para alcanzar la conservación, el uso ecológicamente sostenible y la distribución de beneficios derivados de la biodiversidad, especialmente en áreas fronterizas o de recursos compartidos.
12. Promover la adopción de incentivos y la retribución de servicios ambientales para la conservación, el uso sostenible y los elementos de la biodiversidad.
13. Establecer un sistema de conservación de la biodiversidad, que logre la coordinación entre el sector privado, los ciudadanos y el Estado, para garantizar la aplicación de esta ley.

b) Creación de la Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO):

La Ley N° 7788, crea a la Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO) como la Autoridad Nacional competente en Costa Rica, para proponer las políticas sobre el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad y el conocimiento tradicional asociado, que aseguren la adecuada transferencia científico-técnica y la distribución justa y equitativa de los beneficios derivados del acceso; y administrativamente la clasifica como un órgano desconcentrado con personalidad jurídica instrumental, del Ministerio del Ambiente y Energía.

Esta Comisión está integrada por el Ministro de Ambiente y Energía, quien la preside, el Ministro de Agricultura y Ganadería, el Ministro de Salud o sus representantes, el Director Ejecutivo del Sistema Nacional de Áreas de Conservación (SINAC) y un representante del Instituto Costarricense de Pesca y Acuicultura (INCOPECA), del Ministerio de Comercio Exterior, de la Asociación Mesa Nacional Campesina, de la Asociación Mesa Nacional Indígena, de la Federación Costarricense para la Conservación del Ambiente y de la Unión Costarricense de Cámaras de la Empresa privada.

Es decir, esta Comisión está conformada por representantes de Instituciones tanto del Gobierno como de sectores involucrados con el tema de la biodiversidad y de conformidad con el artículo 16 de esta Ley, ejecuta sus acuerdos y resoluciones, así como instruye sus procedimientos, por medio del Director Ejecutivo de la Oficina Técnica.

Cuando se habla de que la CONAGEBIO es un Órgano Desconcentrado traemos a colación lo que señaló el ilustre Profesor Eduardo Ortiz Ortiz, redactor de la Ley General de la Administración Pública costarricense, en el seno de la Comisión Legislativa que tramitó el proyecto correspondiente, quién manifestó que la **“Desconcentración es el fenómeno que consiste en atorgar a una autoridad inferior o subordinada a título propio, la capacidad de decidir un asunto”**³

Sobre el tema de desconcentración que posee la CONAGEBIO y sus competencias, es importante transcribir una pequeña parte del análisis realizado por la Procuraduría General de la República de Costa Rica, en el Dictamen C320-2002 del 28 de noviembre del 2002 en donde se explica : ..”*La competencia de una organización administrativa puede ser transferida internamente mediante el proceso de desconcentración. En este sentido, la desconcentración de competencias implica una distribución de éstas dentro de una misma persona jurídica, por la cual un órgano inferior recibe una competencia de decisión en forma exclusiva, para que la ejerza como propia, en nombre propio y bajo su propia responsabilidad. Por este proceso, el órgano inferior se ve dotado de la capacidad jurídica para decidir en nombre propio de la materia desconcentrada, de modo que el reparto administrativo se especializa*

³ Oficio OT-431-2004. Lic. Maribel Alvarez Mora, Asesora Legal de la Oficina Técnica de la CONAGEBIO

como un medio para mejor satisfacer los cometidos públicos. Ese proceso con lleva que el jerarca resulte incompetente para emitir los actos relativos a la materia desconcentrada”.

Con relación a los recursos financieros que dan sustento al quehacer de la CONAGEBIO y su Oficina Técnica, la Contraloría General de la República⁴ ha determinado que tratándose de un órgano de la Administración Pública, la ejecución de sus recursos presupuestarios debe realizarse de conformidad con las funciones que la Ley de Biodiversidad le ha otorgado y debe respetar el marco jurídico que todo órgano de la Administración debe considerar, entre ello la Ley General de la Administración Pública N° 6227, Ley de Administración Financiera de la República y Presupuestos Públicos, Ley N° 8131, la Ley de Contratación Administrativa Ley N° 7494, la Ley General de Control Interno, Ley N° 8292 y más recientemente la Ley Contra la Corrupción y el Enriquecimiento Ilícito en la Función Pública N° 8422 .

La CONAGEBIO y su Oficina Técnica se financian de conformidad con lo establecido en los artículos 19 y 43 la Ley de Biodiversidad, constituyéndose como la principal fuente de financiamiento, la correspondiente al 10% del Timbre de Parques Nacionales.

c) Elementos y recursos genéticos y bioquímicos declarados bienes de dominio público:

El legislador estableció expresamente en el artículo 6 de la Ley de Biodiversidad N° 7788, la declaración de que las propiedades bioquímicas y genéticas de los elementos de la biodiversidad silvestres o domesticados son de **dominio público**; y que **el Estado** es el que autorizará la explotación, la investigación, la bioprospección, el uso y el aprovechamiento de estos elementos de la biodiversidad, así como la utilización de todos los recursos genéticos y bioquímicos por medio de las normas de acceso que se establecen en el capítulo V de dicha ley.

Además nuestra Constitución Política, tal y como lo menciona la Sala Constitucional de la Corte Suprema de Justicia en sus Votos, regula expresamente el tema del dominio público en los artículos 6, 50, 89 y 121 inciso 14), estableciéndose según las discusiones que constan en sus Actas, la premisa de que su protección y administración corresponden al Estado, para alcanzar como objetivo final, el bien común y no un interés particular.

Partiendo del marco legal constitucional, no existe entonces duda alguna en torno a cuál es el fundamento legal para que a la Comisión Nacional para la Gestión de la Biodiversidad y específicamente a su Oficina Técnica, como parte del aparato estatal, se le atribuyera la función de tramitar, aprobar, rechazar y fiscalizar las solicitudes de acceso a los elementos y recursos genéticos y bioquímicos; máxime que el artículo 6 en relación con los artículos 2 y 3 de la Ley de Biodiversidad, y en concordancia con los artículos de la Constitución Política, determina específicamente esta afectación a los elementos genéticos y bioquímicos de la biodiversidad sujeta a un fin público.

Específicamente, tal y como lo ha reiterado la Sala Constitucional de la Corte Suprema de Justicia costarricense en su jurisprudencia, respecto a la definición, características y naturaleza jurídica: de los bienes de dominio público, es necesario señalar los siguientes elementos:

- Voto N° 2306-91, emitido a las catorce horas cuarenta y cinco minutos del seis de noviembre de mil novecientos noventa y uno:
 - a) .El dominio público se encuentra integrado por bienes que manifiestan, por voluntad expresa del legislador, **un destino especial de servir a la comunidad, al interés público.**

⁴ Contraloría General de la República. División de Fiscalización Operativa y Evaluativa. Área de Servicios Agropecuarios y de Medio Ambiente. Oficio 12729 del 20 de octubre 2004.

- b) Son los llamados bienes dominicales, bienes dominiales, bienes o cosas públicas o bienes públicos, que no pertenecen individualmente a los particulares y que están destinados a un uso público y sometidos a un régimen especial, fuera del comercio de los hombres.-
 - c) Son inalienables, imprescriptibles, inembargables, no pueden hipotecarse ni ser susceptibles de gravamen en los términos del Derecho Civil y la acción administrativa sustituye a los interdictos para recuperar el dominio.-
 - d) No pueden ser objeto de posesión, aunque se puede adquirir un derecho al aprovechamiento, aunque **no un derecho a la propiedad**. El permiso de uso es un acto jurídico unilateral que lo dicta la Administración, en el uso de sus funciones y lo que se pone en manos del particular, es el dominio útil del bien, reservándose siempre el Estado, el dominio directo sobre la cosa.-
 - e) Todo permiso de uso es a título en precario, es decir, alude a la posibilidad que la administración unilateralmente en cualquier momento lo revoque, por razones de necesidad o de interés general, todo ello en la medida que si llega a existir una contraposición de intereses entre el fin del bien y el permiso otorgado, debe prevalecer el uso natural de la cosa pública.
- Voto N° 10466-00 emitido a las diez horas dieciséis minutos del veinticuatro de noviembre del dos mil:
 - a) En los términos de nuestra Constitución Política, **el patrimonio nacional se conforma por los bienes definidos en los artículos 6, 50, 89 y 121 inciso 14) constitucionales**; son las aguas territoriales, las costas, el espacio aéreo, la plataforma continental, el zócalo insular, **los recursos y riquezas naturales del agua del suelo y del subsuelo, las bellezas naturales, el derecho a un ambiente sano y ecológicamente equilibrado**, el patrimonio histórico y artístico de la Nación, las fuerzas que puedan obtenerse de las aguas del dominio público en el territorio nacional, los yacimientos de carbón, las fuentes o yacimientos de petróleo, sustancias hidrocarbурadas, depósitos de minerales radioactivos, servicios inalámbricos -lo que modernamente se conoce como espacio electromagnético-, ferrocarriles, muelles y aeropuertos que estén en servicio.
 - b) Es importante señalar que estos bienes gozan de especial protección a través del Estado, de manera que no son susceptibles de ser apropiados por particulares y ni siquiera por la Administración Pública; ni ser destinados a fines distintos de los que determinan su propia esencia y naturaleza.
 - c) Los bienes de la Nación pueden ser objeto de explotación racional por el Estado o por los particulares *"de acuerdo con la ley o mediante concesión especial otorgada por tiempo determinado y con arreglo a las condiciones y estipulaciones que establezca la Asamblea Legislativa"* (inc. 14 del artículo 121 de la Constitución Política). La jurisprudencia de esta Sala -sentencia 06240-93-, examinó la posibilidad de que la Asamblea Legislativa acuda a la técnica, comúnmente conocida como el dictado de una ley marco, para cumplir con la exigencia de la norma constitucional.
 - d) No debe perderse de vista que la especial afectación de los bienes de la Nación tiene sentido, únicamente, en tanto se garantice a todos los habitantes el derecho a una calidad de vida dentro de un ambiente sano y ecológicamente equilibrado. La explotación de los recursos naturales impone, con rango constitucional, un uso racional de los mismos (adecuado, planificado), para beneficio de los actuales y de los futuros habitantes del país (derechos de la tercera generación).

d) Competencias de la CONAGEBIO y su Oficina Técnica:

La Ley N° 7788, le asigna a la CONAGEBIO, el papel de Autoridad Nacional, para formular y coordinar las políticas sobre el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad y el conocimiento tradicional asociado, que aseguren la adecuada transferencia científico-técnica y la distribución justa y equitativa de los beneficios derivados del acceso.

Además le asigna otras competencias establecidas expresamente, entre las que citaremos las siguientes: formular las políticas nacionales referentes a la conservación, el uso ecológicamente sostenible y la

restauración de la biodiversidad, sujetándose a la Convención sobre la Diversidad Biológica y otros convenios internacionales; formular las políticas y responsabilidades establecidas en los capítulos IV, V y VI de la Ley y coordinarlos con los diversos organismos responsables de la materia; formular la estrategia nacional de la biodiversidad y darle seguimiento y asesorar a otros órganos del Poder Ejecutivo, instituciones autónomas y entes privados, a fin de normar las acciones para el uso ecológicamente sostenible de los elementos de la biodiversidad.

Asimismo la Ley de Biodiversidad, establece que la CONAGEBIO contará con una Oficina Técnica de apoyo, la cual realizará entre otras funciones las siguientes: tramitar, aprobar, rechazar y fiscalizar las solicitudes de acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad; coordinar con las Áreas de Conservación, el Sector Privado, los Pueblos Indígenas y las Comunidades Campesinas, lo relativo al acceso y Organizar; mantener actualizado un registro de solicitudes de acceso a los elementos de la biodiversidad, colecciones ex situ, y de las personas físicas o jurídicas que se dediquen a la manipulación genética. La información registrada será de carácter público, excepto los secretos industriales, que deberán ser protegidos por el Registro, salvo que razones de bioseguridad obliguen a darles publicidad y autorizar los convenios y contratos suscritos entre particulares, nacionales o extranjeros, o entre ellos y las instituciones registradas para el efecto, si contemplaren acceso al uso de los elementos genéticos y bioquímicos de la diversidad costarricense.

e) Procedimiento para el acceso a elementos y recursos genéticos y bioquímicos:

e1) Ámbito de Aplicación:

El Artículo 3°, establece el Ámbito de aplicación de la Ley, de forma que se aplicará sobre los elementos de la biodiversidad que se encuentran bajo la soberanía del Estado, así como sobre los procesos y las actividades realizados bajo su jurisdicción o control, con independencia de aquellas cuyos efectos se manifiestan dentro o fuera de las zonas sujetas a jurisdicción nacional. Esta ley regulará específicamente el uso, el manejo, el conocimiento asociado y la distribución justa de los beneficios y costos derivados del aprovechamiento de los elementos de la biodiversidad.

Sin embargo también se establecen las siguientes exclusiones a su ámbito de aplicación: a) No se aplicará al acceso al material bioquímico y genético humano, que continuará regulándose por la Ley General de Salud, N° 5395 del 30 de octubre de 1973, y por las leyes conexas.

b) Tampoco se aplican estas disposiciones al intercambio de los recursos bioquímicos y genéticos ni al conocimiento asociado resultante de prácticas, usos y costumbres, sin fines de lucro, entre los pueblos indígenas y las comunidades locales y

c) Lo dispuesto en esta ley no afecta la autonomía universitaria en materia de docencia e investigación en el campo de la biodiversidad, excepto si las investigaciones tuvieren fines de lucro.

e2) Declaratoria de Dominio Público:

El artículo 6 establece además de la declaratoria de dominio público, señalada anteriormente, la obligación del Estado de autorizar la exploración, la investigación, la bioprospección, el uso y el aprovechamiento de los elementos de la biodiversidad que constituyan bienes de dominio público, así como la utilización de todos los recursos genéticos y bioquímicos, por medio de las normas de acceso establecidas en el Capítulo V de la Ley. Asimismo el artículo 69 regula expresamente que todo programa de investigación o bioprospección sobre material genético o bioquímico de la biodiversidad que pretenda realizarse en el territorio costarricense, requiere un permiso de acceso.

e3) Definiciones:

En el artículo 7, se establecen varias definiciones, por medio de las cuales deberá ser interpretada esta Ley. Algunas de estas fueron tomadas de la Convención sobre Diversidad Biológica, en su artículo 2, pero también existen otras innovadoras como las siguientes:

“Acceso a los elementos bioquímicos y genéticos: Acción de obtener muestras de los elementos de la biodiversidad silvestre o domesticada existentes, en condiciones ex situ o in situ y obtención del conocimiento asociado, con fines de investigación básica, bioprospección o aprovechamiento económico.”

“Bioprospección: La búsqueda sistemática, clasificación e investigación para fines comerciales de nuevas fuentes de compuestos químicos, genes, proteínas, microorganismos y otros productos con valor económico actual o potencial, que se encuentran en la biodiversidad.”

“Permiso de acceso: Autorización concedida por el Estado costarricense para la investigación básica, la bioprospección, la obtención o comercialización de materiales genéticos o extractos bioquímicos de elementos de la biodiversidad, así como su conocimiento asociado a personas o instituciones, nacionales o extranjeras, solicitado mediante un procedimiento normado en esta legislación, según se trate de permisos, contratos, convenios o concesiones.”

“Elemento bioquímico: Cualquier material derivado de plantas, animales, hongos o microorganismos, que contenga características específicas, moléculas especiales o pistas para diseñarlas.”

e4) Capítulo V: Acceso a los elementos genéticos y bioquímicos y protección del Conocimiento asociado:

1) Específicamente encontramos que el CAPÍTULO V de la Ley, regula el tema del Acceso a los elementos genéticos y bioquímicos y protección del Conocimiento asociado, y establece entre otros aspectos:

“Artículo 62.- **Competencia:** Corresponde a la Comisión proponer las políticas de acceso sobre los elementos genéticos y bioquímicos de la biodiversidad ex situ e in situ. Actuará como órgano de consulta obligatoria en los procedimientos de solicitud de protección de los derechos intelectuales sobre la biodiversidad.

Las disposiciones que sobre esta materia acuerde constituirán las normas generales para el acceso a los elementos genéticos y bioquímicos y para la protección de los derechos intelectuales sobre la biodiversidad, a las que deberán someterse la administración y los particulares interesados. Para ser eficaces frente a terceros deben ser publicadas previamente en La Gaceta”.

2) El artículo 63 de esta Ley, regula los requisitos básicos para el acceso, entre los cuales se establecen los siguientes: el Consentimiento previamente informado; el refrendo de este consentimiento previamente informado por parte de la Oficina Técnica de la Comisión y la designación de un representante legal residente en el país, cuando se trate de personas físicas o jurídicas domiciliadas en el extranjero y el artículo 72 establece los requisitos generales que deberá contener la solicitud de acceso, como por ejemplo: Nombre e identificación completa del interesado; si no es el propio interesado, deberá indicar los datos de identificación del titular y el poder bajo la cual gestiona; cronograma descriptivo de los alcances de la investigación y los posibles impactos ambientales; objetivos y finalidad que persigue y manifestación de que la declaración anterior ha sido hecha bajo juramento. Todos estos requisitos, fueron

desarrollados plenamente, en el Decreto Ejecutivo N° 31514-MINAE, publicado en el Diario Oficial La Gaceta N° 241 de 15 de diciembre de 2003, lo cual facilita en la práctica su aplicación.

3) Respecto a las normas de Procedimiento, la Ley estipula aspectos generales que deben cumplirse en todo permiso de acceso, entre ellos;

- la Oficina Técnica de la Comisión tramitará todas las gestiones que realice en virtud de las competencias indicadas en este título, a través de un expediente oficial.

- Plazo: El permiso de acceso se establecerá por un plazo máximo de tres años, prorrogables a juicio de la Oficina Técnica de la Comisión.

- Los permisos de acceso son personales e intransmisibles, están limitados materialmente a los elementos genéticos o bioquímicos autorizados y sólo podrán ser utilizados en el área o territorio que expresamente se indique en ellos.

- Los permisos de acceso para la investigación o bioprospección no otorgan derechos ni acciones ni los delegan, solamente permite realizar tales actividades sobre elementos de la biodiversidad previamente establecidos.

-En los permisos de acceso se estipularán claramente: el certificado de origen, la posibilidad o la prohibición para extraer o exportar muestras o, en su defecto, su duplicación y depósito; los informes Diarios, la verificación y el control, la publicidad y propiedad de los resultados, así como cualquier otra condición que, dadas las reglas de la ciencia y de la técnica aplicables, sean necesarias a juicio de la Oficina Técnica de la Comisión.

- En la resolución respectiva la Oficina Técnica, de conformidad con las Normas Generales de Acceso a los elementos y recursos genéticos y bioquímicos, se establecerá la obligación del interesado de depositar hasta un diez por ciento (10%) del presupuesto de investigación y hasta un cincuenta por ciento (50%) de las regalías que cobre, a favor del Sistema Nacional de Áreas de Conservación, el territorio indígena o el propietario privado proveedor de los elementos por acceder; y además, se determinará el monto que en cada caso deberán pagar los interesados por gastos de trámites, así como cualquier otro beneficio o transferencia de tecnología que forme parte del consentimiento previamente informado.

e5) Convenios Marco y Concesiones:

Se reconoce:

- la figura de los **Convenios Marco**, por medio de los cuales, las universidades públicas y otros centros de investigación, podrán suscribir en forma periódica convenios marco para la Comisión, para tramitar los permisos de acceso y los informes de operaciones.

- y la **Concesión**: Cuando la Oficina Técnica autorice la utilización constante del material genético o de extractos bioquímicos con fines comerciales, se exigirá al interesado obtener una concesión para explotarlos; para ello, se aplicarán las Normas Generales que dicte la Comisión.

B. PROTECCIÓN DE LOS DERECHOS DE PROPIEDAD INTELECTUAL E INDUSTRIAL:

En Costa Rica, la protección a los derechos de propiedad intelectual es un principio constitucional, pues se encuentra regulado expresamente en el artículo 47 de nuestra Constitución Política: “Todo autor, inventor, productor o comerciante gozará temporalmente de la propiedad exclusiva de su obra, invención, marca o nombre comercial, con arreglo a la ley.” La atribución exclusiva de dictar las leyes, reformarlas, derogarlas y darles interpretación auténtica, le corresponde de conformidad con el artículo 121 de la Carta Magna, a la Asamblea Legislativa.

Por su parte, la Sección III, del Capítulo V, de la Ley de Biodiversidad, regula el tema de la protección a la propiedad intelectual relacionada con la biodiversidad, regulando entre otros aspectos los siguientes:

a) Que el Estado reconoce la existencia y validez de las formas de conocimiento e innovación y la necesidad de protegerlas, mediante el uso de los mecanismos legales apropiados para cada caso específico.

b) Que el Estado otorgará la protección, entre otras formas, mediante patentes, sectores comerciales, derechos del fitomejorador, derechos intelectuales comunitarios *sui géneris*, derechos de autor, derechos de los agricultores. Pero se exceptúan expresamente:

1. Las secuencias de ácido desoxirribonucleico *per se*.
2. Las plantas y los animales.
3. Los microorganismos no modificados genéticamente.
4. Los procedimientos esencialmente biológicos para la producción de plantas y animales.
5. Los procesos o ciclos naturales en sí mismos.
6. Las invenciones esencialmente derivadas del conocimiento asociado a prácticas biológicas tradicionales o culturales en dominio público.
7. Las invenciones que, al ser explotadas comercialmente en forma monopólica, puedan afectar los procesos o productos agropecuarios considerados básicos para la alimentación y la salud de los habitantes del país.

c) La Oficina Nacional de Semillas de Costa Rica como el Registro Nacional de la Propiedad Intelectual, obligatoriamente deberán consultar a la Oficina Técnica de la CONAGEBio, antes de otorgar protección de propiedad intelectual a las innovaciones que involucren elementos de la biodiversidad, recalándose que la oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.

d) Como un requisito esencial, siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo, al solicitar protección de propiedad intelectual a las innovaciones que involucren elementos de la biodiversidad.

e) Los particulares beneficiarios de protección de la propiedad intelectual o industrial en materia de biodiversidad cederán, a favor del Estado, una licencia legal obligatoria que le permitirá en casos de emergencia nacional declarada, usar tales derechos en beneficio de la colectividad, con el único fin de resolver la emergencia, sin necesidad del pago de regalías o indemnización.

f) Se reconocen y protegen expresamente “**Los derechos intelectuales comunitarios *sui géneris*”**, por lo que esta legislación es también pionera respecto a la regulación de este tema en específico:

1. El Estado reconoce y protege expresamente, bajo el nombre común de derechos intelectuales comunitarios *sui géneris*, los conocimientos, las prácticas e innovaciones de los pueblos indígenas y las comunidades locales, relacionadas con el empleo de los elementos de la biodiversidad y el conocimiento asociado. Este derecho existe y se reconoce jurídicamente por la sola existencia de la práctica cultural o el conocimiento relacionado con los recursos genéticos y bioquímicos; no requiere declaración previa, reconocimiento expreso ni registro oficial; por tanto, puede comprender prácticas que en el futuro adquieran tal categoría.
2. Este reconocimiento implica que ninguna de las formas de protección de los derechos de propiedad intelectual o industrial regulados en este capítulo, las leyes especiales y el Derecho Internacional afectarán tales prácticas históricas.
3. La Oficina Técnica, en asocio con la Mesa Indígena y la Mesa Campesina, deberá definir un proceso participativo con las comunidades indígenas y campesinas, para determinar la naturaleza, los alcances y requisitos de estos derechos para su normativa definitiva. Asimismo el proceso participativo determinará la forma en que el derecho intelectual comunitario *sui géneris* será utilizado y quien ejercerá su titularidad, e identificará a los destinatarios de sus beneficios.
4. Mediante el procedimiento indicado en el artículo anterior, se procederá a inventariar los derechos intelectuales comunitarios *sui géneris* específicos que las comunidades solicitan

proteger, y se mantendrá abierta la posibilidad de que, en el futuro, se inscriban o reconozcan otros que reúnan las mismas características. El reconocimiento de esos derechos en el Registro de la Oficina Técnica de la Comisión, es voluntario y gratuito; deberá hacerse oficiosamente o a solicitud de los interesados, sin sujeción a formalidad alguna.

5. La existencia de tal reconocimiento en el Registro obligará a la Oficina Técnica a contestar negativamente cualquier consulta relativa a reconocer derechos intelectuales o industriales sobre el mismo elemento o conocimiento. Tal denegación, siempre que sea debidamente fundada, podrá hacerse aun cuando el derecho *sui géneris* no esté inscrito oficialmente.

Además en el artículo 66 de este cuerpo normativo, se reconoce el Derecho a la objeción cultural, por medio del cual, las comunidades locales y los pueblos indígenas se pueden oponer al acceso a sus recursos y al conocimiento asociado, por motivos culturales, espirituales, sociales, económicos o de otra índole.

A la fecha, aún no se ha finalizado el proceso de consulta para la definición de los derechos intelectuales comunitarios y su regulación, por lo que tanto en el Decreto Ejecutivo N° 31514-MINAE, como en el Reglamento para el acceso a los elementos y recursos genéticos y bioquímicos, en condiciones *ex situ*, se ha incluido el siguiente Transitorio:

“Conocimientos, innovaciones y prácticas de las comunidades locales y los pueblos indígenas. Los permisos de acceso de investigación básica, de bioprospección o de aprovechamiento económico, que involucren conocimientos, innovaciones y prácticas de las comunidades locales y los pueblos indígenas sobre el uso de los recursos genéticos y bioquímicos de la biodiversidad, se otorgarán conforme a lo establecido en los artículos 66 y del 82 al 85 de la Ley de Biodiversidad y el Convenio 169 sobre Pueblos Indígenas y Tribales, aprobado mediante Ley N°. 7316 del 03 de noviembre de 1992, publicada en La Gaceta N° 234 del 04 de diciembre del 1992.”

Es importante mencionar que la Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, N° 6867 del 25 de abril de 1983, reformada por la Ley N° 7979 de 6 de enero del 2000, regula también exclusiones de patentabilidad, las cuales no coinciden plenamente con lo establecido en la Ley de Biodiversidad, por lo que deberá en corto plazo, definirse en nuestro país, una sola interpretación legal respecto a este tema.

2) NORMAS GENERALES PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENETICOS Y BIOQUIMICOS DE LA BIODIVERSIDAD⁵: Decreto Ejecutivo N° 31514-MINAE publicado en el Diario Oficial La Gaceta N° 241 de 15 de diciembre de 2003:

a) Ámbito de aplicación:

En forma concordante con la Ley de Biodiversidad, estas Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad, en adelante denominadas Normas, establecen que el acceso se aplicará sobre los elementos y recursos genéticos y bioquímicos de la biodiversidad, ya sean silvestres o domesticados, terrestres, marinos, de agua dulce o aéreos, *in situ* y *ex situ*, que se encuentren en el territorio nacional definido en el Artículo 6 de la Constitución Política, ya sea propiedad pública o privada. Asimismo tutelan y regulan la protección del conocimiento tradicional

⁵ El texto completo del Decreto Ejecutivo N° 31514-MINAE, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

asociado y la distribución justa y equitativa de los beneficios derivados del aprovechamiento de dichos elementos y recursos.

Se excluyen de su ámbito de aplicación, el uso de los elementos de la biodiversidad utilizados como recursos orgánicos, que continuarán regulados por la Ley Forestal, la Ley de Conservación de la Vida Silvestre, la Ley de creación del INCOPESCA, la Ley de Pesca y otras leyes especiales.

b) Tipos de Permisos de Acceso:

En estas Normas se especifican cuatro tipos de permisos de acceso:

Investigación básica: Permiso para indagar, examinar, clasificar o aumentar los conocimientos sobre las características genéticas o bioquímicas de los elementos de la biodiversidad, sin un interés inmediato en la comercialización de sus resultados.

Bioprospección: Búsqueda sistemática, clasificación e investigación para fines comerciales de nuevas fuentes de compuestos químicos, genes, proteínas, microorganismos y otros productos con valor económico actual o potencial que se encuentren en la biodiversidad.

Aprovechamiento económico comercial: Es la autorización personal e intransferible, no exclusiva ni excluyente para que la parte interesada haga uso de los elementos y recursos genéticos y bioquímicos con fines comerciales, sin que necesariamente esté precedido de un programa de investigación básica o bioprospección como parte de la solicitud.

Concesión: En los casos de otorgamiento de un permiso de acceso para aprovechamiento económico que adquiriera la característica de constante es decir, que el interesado haya solicitado el acceso al menos seis veces en un período de cinco años sobre el mismo recurso genético o bioquímico con fines comerciales se requiere en lo sucesivo obtener una concesión. La Oficina Técnica de la CONAGEBIO tramitará la solicitud y remitirá el expediente con la recomendación al despacho del Ministro para su eventual aprobación y firma.

c) Definiciones:

Además de las definiciones que se encuentran en la Ley de Biodiversidad, estas Normas Generales de Acceso, incluyen aquellas que se usarán como referencia en su aplicación. Entre estas definiciones se encuentran las siguientes:

“Certificado de origen o de legal procedencia: Documento oficial emitido por la Oficina Técnica de la CONAGEBIO donde se certifica la legalidad del acceso a elementos o recursos genéticos o bioquímicos de la biodiversidad y el cumplimiento de los términos en los que fue autorizado al interesado el permiso de acceso correspondiente”

“Concesión: Autorización para el acceso con fines comerciales y de manera constantes a ciertas propiedades bioquímicas o genéticas de los elementos o recursos de la biodiversidad, que el jerarca del Ministerio del Ambiente y Energía otorga a la parte interesada, nacional o extranjera, una vez que su solicitud ha sido revisada y transferida por la Oficina Técnica de la CONAGEBIO. Para los efectos de la aplicación de esta definición, se entenderá el término “utilización constante” cuando el interesado solicite el acceso al menos seis veces en un período de cinco años sobre el mismo recurso genético o bioquímico. Además las concesiones no son exclusivas ni excluyentes.”

“Distribución justa y equitativa de beneficios: Participación de los beneficios económicos, ambientales, científico-tecnológicos, sociales o culturales resultantes de la investigación, la bioprospección o el aprovechamiento económico de los elementos y recursos bioquímicos y

genéticos de la biodiversidad entre los actores involucrados en el acceso y en la conservación de los recursos bioquímicos y genéticos, con atención especial a las comunidades locales y los pueblos indígenas.”

“Investigación básica en biodiversidad: Actividad para indagar, examinar, clasificar o aumentar los conocimientos que existen sobre los elementos biológicos en general o sus características genéticas o bioquímicas en particular, sin un interés inmediato en la comercialización de sus resultados”

“Permiso de acceso para el aprovechamiento económico comercial: Autorización personal e intransferible, no exclusiva ni excluyente para que la parte interesada haga uso de los elementos y recursos bioquímicos y genéticos de la biodiversidad con fines comerciales, sin que necesariamente esté precedido de un programa de investigación básica o bioprospección como parte de la solicitud. El permiso de acceso ocasional será otorgado por la Oficina Técnica de la CONAGEBIO y cuando éste adquiera características de constante se requerirá la obtención de una concesión de conformidad con el Artículo 11 del presente reglamento.”

“Proveedor de los elementos o recursos genéticos o bioquímicos de la biodiversidad: Persona física o jurídica que sea dueña, responsable o posea bienes donde se encuentran contenidos los elementos o recursos genéticos o bioquímicos de la biodiversidad, o sea dueña del conocimiento tradicional asociado a ellos y pueda autorizar su acceso, previo cumplimiento de los procedimientos legales establecidos en estas normas.”

“Recurso orgánico: Cualquier material de organismos vivientes, silvestres o domesticados, que se aprovechado como tal, en su totalidad o en sus partes macroscópicas.”

“Recurso bioquímico: Cualquier material derivado de organismos vivientes, buscando o utilizado por su valor actual o potencial, que posee ciertas características específicas, moléculas especiales o pistas para diseñarlas. A diferencia del uso orgánico de los recursos, el recurso bioquímico sufre una mayor transformación y aprovechamiento técnico-industrial, y cuenta en general con un mayor número de ingredientes activos”

“Recurso genético: Cualquier material de organismos vivientes que contenga unidades funcionales de la herencia y que sea manejado e innovado convencionalmente por los campesinos y los fito o zoomejoradores, o bien investigado o aprovechado por medio de procedimientos biotecnológicos modernos, modernos con valor actual o potencial”

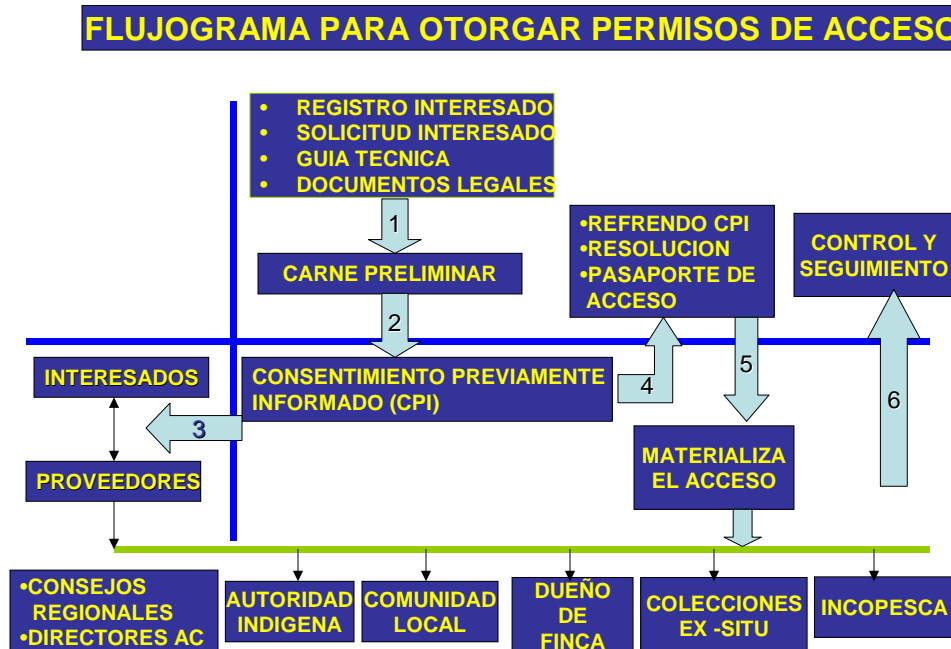
d) Procedimiento:

El Consentimiento Previamente Informado y las Condiciones Mutuamente Acordadas para el acceso a los elementos y recursos genéticos y bioquímicos, constituyen los dos elementos básicos, que diferencian actualmente el procedimiento que se debe cumplir para el otorgamiento de un permiso de acceso, respecto al procedimiento anterior que se aplicaba a la luz de la Ley de Conservación de la Vida Silvestre.

Estos elementos o requisitos, se estipulan en concordancia con el Artículo 15 del Convenio de Diversidad Biológica, en donde se establece el reconocimiento de los derechos soberanos de los Estados sobre sus recursos naturales, el requisito de que el acceso estará sometido al consentimiento previamente informado de la Parte Contratante que proporciona estos recursos genéticos y la necesidad de que se compartan en forma justa y equitativa los beneficios derivados de su uso, con la parte contratante que los aporta.

Debe entenderse que el Consentimiento Previamente Informado, en adelante CPI, constituye un mecanismo mediante el cual los Proveedores de los Recursos genéticos o bioquímicos o del conocimiento asociado a ellos (Consejo Regional o el Director del Área de Conservación - cuando se trate de acceso en propiedad estatal-, los dueños de fincas, las autoridades de las comunidades locales o pueblos indígenas y los dueños o responsables de los materiales mantenidos en condiciones *ex situ*), previa negociación con el Interesado, consienten en permitir este acceso, estableciéndose entre las partes, las condiciones mutuamente convenidas y la distribución justa y equitativa de los beneficios.

Con la finalidad de que el procedimiento para el otorgamiento de un permiso de acceso en la legislación nacional, se comprenda con mayor facilidad, se incorpora el siguiente flujograma:



Fuente: Oficina Técnica, CONAGEBIO. 2005

a. Los interesados deben registrarse ante la Oficina Técnica antes de solicitar cualquier tipo de permiso de acceso, para lo cual se estableció el respectivo formulario. Una vez inscritos es necesario completar el formulario de la solicitud de permiso y el formulario de la guía técnica, adjuntando varios documentos legales, dependiendo de si se trata de personas físicas o personas jurídicas (Paso 1 del flujograma)

b. Una vez presentados estos documentos, la Oficina Técnica entrega al interesado, un carné de identificación preliminar como usuario potencial, que le autoriza para que se presente ante los proveedores de los recursos genéticos o bioquímicos, a establecer el consentimiento previo informado o CPI. La Oficina Técnica ha dispuesto un documento guía de CPI, con la finalidad de agilizar y facilitar la negociación entre las partes. (Pasos 2 y 3 del flujograma)

Para realizar la negociación, y por lo tanto discutir a fondo, el significado y alcances del acceso, los términos de la protección del conocimiento asociado y los aspectos prácticos, económicos y logísticos del acceso, el Interesado o su Representante Legal, se dirigirá a los Representantes del lugar (Proveedores) donde se materializará el acceso a los elementos o recursos genéticos y bioquímicos de la biodiversidad, los cuales podrían ser: el Consejo Regional, el Director (a) del Área de Conservación, en caso de que la

propiedad sea estatal, los dueños de fincas, las autoridades de las comunidades locales o pueblos indígenas y lo dueños o responsables de los materiales en condición *ex situ*.

Si el acceso se va a materializar en un área costero-marina, que no esté comprendida en la definición de humedal del Artículo 40 de la Ley Orgánica del Ambiente, o no esté comprendida dentro de los límites de un área protegida declarada como tal, el consentimiento previamente informado debe ser tramitado ante el INCOPECA, quien para ello pedirá asesoramiento a la Comisión Científico-Técnica adscrita a esa Institución. Pero si el acceso se va a materializar a orillas de caminos públicos y aceras, o en ríos, lagunas y humedales, el consentimiento previamente informado deberá ser tramitado ante el Consejo Regional o el Director del Área de Conservación correspondiente. En el caso de territorios indígenas, la información se registrará por lo que establece el Convenio 169 de la OIT, Ley N° 7316. El consentimiento previamente informado deberá presentarse, además en el idioma indígena correspondiente, si así lo exigen los involucrados.

c. Una vez que el interesado obtiene el Consentimiento Previamente Informado del proveedor del recurso genético o bioquímico se dirige nuevamente a la Oficina Técnica y ésta debe refrendar dicho acuerdo, considerando los principios y objetivos de la Convención sobre Diversidad Biológica y la Ley de Biodiversidad, así como lo establecido en el ordenamiento jurídico costarricense y en el caso en que la Oficina Técnica considere necesario, podrá realizar diferentes consultas y solicitar a las partes involucradas en la negociación del consentimiento previamente informado, la información adicional que estime imprescindible.

Seguidamente, de conformidad con el Artículo 13 de las Normas, la Oficina Técnica emite una resolución donde se indica claramente si la solicitud fue aprobada o rechazada y las justificaciones técnicas, sociales o ambientales en que se fundamentó ese acto. Una vez aprobado el permiso de acceso la Oficina Técnica, extiende un “pasaporte de acceso” que acredita al interesado para ingresar al lugar en donde se materializarán las actividades que le fueron autorizadas mediante la resolución correspondiente (Pasos 4 y 5 del flujograma).

d. En cuanto a los aspectos de verificación y control, la Oficina Técnica, de conformidad con los términos del permiso otorgado, realiza estas funciones y cuando lo considere necesario, coordinará con el interesado o el proveedor del recurso. Los funcionarios de la Oficina Técnica, pueden realizar inspecciones en el predio o lugar en que se materializa el acceso, en cualquier momento en que esté vigente el respectivo permiso o una vez finalizadas las actividades contempladas en el mismo. (Paso 6 del flujograma).

e) Certificado de origen o certificado de legal procedencia:

El Certificado de origen o legal procedencia, emitido por la Oficina Técnica de la CONAGEBIO, ha sido regulado en forma pionera, en la Ley de Biodiversidad, N° 7788 artículo 80, como un requisito esencial que junto al consentimiento previamente informado, siempre el interesado deberá aportar ante la Oficina Nacional de Semillas o el Registro Nacional de Propiedad Intelectual, al solicitar protección de propiedad intelectual, a innovaciones que involucren elementos de la biodiversidad.

Con la finalidad de desarrollar y precisar este instrumento, para facilitar su aplicación a nivel nacional, en este Decreto Ejecutivo se incluye en su artículo 6, la definición de certificado de origen o certificado de legal procedencia y se establece en su artículo 19:

Artículo 19: A efectos de certificar la legalidad del acceso, la Oficina Técnica extenderá al solicitante un certificado de origen denominado también “certificado de legal procedencia” que incluye: el lugar y fecha del acceso, propietario de los elementos o recursos de la biodiversidad, el material obtenido, cantidad y la persona, la comunidad o

comunidades que han contribuido o contribuirán con su conocimiento asociado, innovaciones y prácticas tradicionales. Además indicará si el interesado cumplió con la normativa establecida para el consentimiento previamente informado y las condiciones mutuamente acordadas de la investigación básica, la bioprospección o el aprovechamiento económico, así como la fecha y número de la resolución correspondiente. La Oficina Técnica diseñará el formato correspondiente.

f) Distribución justa y equitativa de beneficios derivados del uso de los recursos genéticos:

Los beneficios derivados por el uso de los recursos genéticos y bioquímicos de la biodiversidad pueden ser clasificados como beneficios monetarios y no monetarios. Nuestra legislación establece en cuanto a beneficios monetarios la obligación del Interesado de depositar hasta un 10% del presupuesto de investigación o de bioprospección, Este porcentaje será establecido de conformidad con la voluntad de las partes, y puede oscilar de cero a diez por ciento; y hasta un 50% de las regalías que obtenga el Interesado a favor del proveedor de los recursos en los casos de un aprovechamiento comercial. En general podríamos clasificar los beneficios de la siguiente forma.

Beneficios monetarios

- Pagos iniciales
- Pagos por cada etapa
- Tasas de licencia en caso de comercialización
- Tasas especiales en apoyo de la conservación y utilización sostenible de la diversidad biológica.
- Salarios
- Financiación de investigación
- Empresas conjuntas
- Propiedad conjunta de derechos de propiedad intelectual pertinente

Beneficios no monetarios

- Participación en los resultados de la investigación
- Cooperación y contribución en programas de investigación y desarrollos científicos preferiblemente en el país.
- Participación en desarrollo de productos
- Formación y capacitación
- Admisión a las instalaciones de colecciones *ex situ* y a bases de datos
- Fortalecimiento de las capacidades de las comunidades locales y pueblos indígenas para conservar y utilizar en forma sostenible sus recursos genéticos.
- Creación de capacidad institucional
- Recursos humanos y materiales para fortalecer las capacidades en especial al persona responsable de la administración y ejecución de las leyes sobre acceso a recursos genéticos.
- Contribución a la economía local
- Investigación dirigida a necesidades prioritarias tales como la seguridad alimentaria, la salud humana considerando los usos nacionales de los recursos genéticos
- Infraestructura
- Acceso a la información científica relacionada con la conservación y utilización sostenible de la diversidad biológica.
- Otros.

g) Acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, en condiciones *ex situ*:

En el caso de acceso a recursos genéticos en condición *ex situ*, el Transitorio 1. del Decreto Ejecutivo N° 31514-MINAE, como normativa general, estableció que mientras no existiere el procedimiento necesario, no se otorgarían permisos de acceso para bioprospección o aprovechamiento económico, de elementos y recursos genéticos y bioquímicos de la biodiversidad mantenidos en condiciones *ex situ*.

Sin embargo, recientemente se ha logrado terminar este procedimiento, emitiéndose el respectivo Reglamento para el Acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, en condiciones *ex situ*.

3) REGLAMENTO PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENÉTICOS Y BIOQUÍMICOS DE LA BIODIVERSIDAD EN CONDICIONES *EX SITU*⁶: Decreto Ejecutivo N° 33697-MINAE, del 6 de febrero del dos mil siete, publicado en el Diario Oficial La Gaceta N° 74 del 18 de abril del 2007.

Recientemente, comenzó a regir en nuestro país este nuevo Decreto Ejecutivo, pionero a nivel mundial, el cual pretende garantizar la aplicación ágil y eficaz del procedimiento necesario para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, mantenidos en condiciones *ex situ*, de conformidad con los artículos 6, 17 inciso 3, 62 y 69 de la Ley N° 7788, el Transitorio 1. del Decreto Ejecutivo N° 31514- MINAE y su Reforma y el Convenio sobre Diversidad Biológica, específicamente en su artículo 9.

Respecto a la emisión de esta normativa, es importante destacar que este Reglamento en borrador fue consultado en varias oportunidades a diversas instancias nacionales, expertos y personas involucradas con el tema, con la finalidad de que se le incorporaran sus comentarios y apreciaciones, y así enriquecer el documento final.

En el mundo, muy pocos países se encuentran en este momento, en el proceso de regular este tema específico, por lo que el Decreto Ejecutivo N° 33697-MINAE, será un insumo importante, para aquellas naciones interesadas en normar esta materia.

a) Análisis detallado del Decreto Ejecutivo N° 33697-MINAE:

a1) Artículo 1º: **Ámbito de aplicación:** Se aplicará sobre los elementos y recursos genéticos y bioquímicos de los componentes de la biodiversidad, ya sean silvestres o domesticados, terrestres, marinos, de agua dulce o aéreos, en condiciones *ex situ*, ya sea en colecciones de personas físicas o jurídicas, públicas o privadas, ubicadas en cualquier parte del territorio nacional según lo define el artículo 6 de la Constitución Política, o en formas no sistematizadas, según el artículo 5 de este Decreto. Asimismo, este Decreto Ejecutivo tutelaré y regularé la protección del conocimiento tradicional asociado y la distribución justa y equitativa de los beneficios derivados del uso de dichos elementos y recursos y/o del conocimiento tradicional.

a2) Artículo 2º: **Exclusiones:** Se establece claramente que sin perjuicio de lo dispuesto en la Ley de Biodiversidad en materia de exclusiones, este reglamento no se aplicará:

⁶ Para conocer el texto completo del Decreto Ejecutivo N° 33697-MINAE, ver el Anexo 1 de este documento.

- a) a los elementos y recursos de la biodiversidad en condiciones *ex situ* utilizados como recursos orgánicos
- b) al intercambio de los recursos genéticos y bioquímicos y el conocimiento asociado resultante de prácticas, usos y costumbres sin fines de lucro, entre los pueblos indígenas y las comunidades locales de conformidad con el artículo 4° de la Ley de Biodiversidad.
- c) al acceso a elementos y recursos genéticos y bioquímicos de la biodiversidad animal domesticada, que se regulará de conformidad con el Transitorio I de este Decreto Ejecutivo.

a3) Artículo 3°: Autoridad Competente: La CONAGEBIO es la Autoridad Nacional competente para proponer las políticas sobre el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad y a su conocimiento asociado, que aseguren la adecuada transferencia científico-técnica y tecnológica, así como la distribución justa y equitativa de los beneficios derivados del acceso; y la Oficina Técnica de la CONAGEBIO, será la encargada de tramitar, aprobar, rechazar y fiscalizar las solicitudes de acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *ex situ*, así como al conocimiento tradicional asociado en los términos del presente Reglamento.

a4) Definiciones: Para la aplicación e interpretación de este Decreto Ejecutivo, además de las definiciones que constan en el artículo 7° de la Ley de Biodiversidad en el artículo 6° del Decreto Ejecutivo N° 31514-MINAE de 3 de octubre de 2003, el artículo 2 de la Ley de Conservación de la Vida Silvestre N° 7317 de 30 de octubre de 1992, y el artículo 2 del Reglamento a la Ley de Conservación de la Vida Silvestre, Decreto Ejecutivo N° 32633-MINAE, del 10 de marzo del 2005, publicada en La Gaceta N° 180 de 20 de setiembre de 2005, se incluyeron 58 definiciones, entre las cuales encontramos:

“**ACCESIÓN:** Es el conjunto de uno o más especímenes mantenidos en una colección viva o preservada para su conservación o uso, los cuales pueden ser muestras de una planta, cepa, línea celular u otros organismos; originarias de una misma población, hábitat y ubicación geográfica. Se conoce también como entrada.”

“**BANCO DE GENES:** Colección de materiales propagativos que se encuentran almacenados bajo condiciones que mantienen su viabilidad por largos períodos. Estos pueden incluir semillas, polen, cultivo de tejidos, material vegetal de propagación, ADN e incluso plantas enteras creciendo como plantaciones, así como genes animales.”

“**COLECCIÓN BASICA O COLECCIÓN DE BASE:** La más amplia y completa colección de accesiones de germoplasma almacenada durante períodos largos, con fines de conservación. Sólo se usa para suplir vacíos en la colección activa”

“**LÍNEA CELULAR:** Linaje celular de un grupo de individuos relacionados por un antepasado común- que puede mantenerse en un cultivo *in vitro* o que puede ser reconocido *in vivo*”

“ **MARCADOR GENÉTICO O MOLECULAR:** Es un segmento de ADN cuya herencia se puede rastrear. Un marcador puede ser un gen, o puede ser un segmento de ADN sin función conocida o no codificante.

Los marcadores se usan a menudo como formas indirectas de rastrear el patrón hereditario de genes que no han sido aún identificados pero cuyas ubicaciones aproximadas se conocen.”

a5) Artículo 6°: Registro de colecciones *ex situ* sistematizadas: De conformidad con los artículos 17 inciso 3, 62 y 69 de la Ley N° 7788 y el Transitorio I. del Decreto Ejecutivo N° 31514-MINAE y su Reforma, se desarrolla el procedimiento para realizar el Registro de colecciones *ex situ* sistematizadas, regulándose: la información que deberá contener el respectivo formulario; los diferentes plazos estipulados tanto para la Administración como para el administrado y los recursos ordinarios que el administrado podrá interponer contra la resolución correspondiente. Además en el Transitorio III, se

estipula que los propietarios o responsables de colecciones *ex situ*, o sus representantes legales, tendrán un plazo máximo de diez meses a partir de la publicación de este decreto, para registrar sus colecciones ante la Oficina Técnica de la CONAGEBIO.

Se definen dos modalidades de permanencia de los elementos y recursos genéticos y bioquímicos de la biodiversidad en condición *ex situ*:

a) Colección *ex situ* sistematizada: cualquier colección sistemática de especímenes, partes u órganos de ellos, vivos o muertos, representativos de plantas, animales, microorganismos u otros seres vivos. Estas colecciones pueden ser entre otras, herbarios, extractotecas, ADN total, macerados, viveros, jardines botánicos, bancos de semillas, bancos de germoplasma o de genes, *in vitro*, huertos semilleros, zoológicos, zocriaderos, acuarios, centros de rescate, bancos de semen animal, colecciones de microorganismos, hongos o artrópodos o colecciones de otros materiales de propagación. Se trata de colecciones sistematizadas en que se identifican los ingresos o accesiones y otro tipo de información relacionada, como el nombre científico, la procedencia o el origen. El Decreto Ejecutiva establece respecto a esta modalidad que los propietarios o responsables, sean personas físicas o jurídicas, públicas o privadas, o sus representantes, deberán registrar estas colecciones en la Oficina Técnica, tal y como se mencionó anteriormente.

b) Recursos genéticos y bioquímicos *ex situ* en forma no sistematizada: Cualquier conjunto de especímenes, partes u órganos de ellos, vivos o muertos, representativos de plantas, animales, microorganismos u otros seres vivos que no se encuentra organizado bajo los parámetros y la rigurosidad de una colección *ex situ* sistematizada. Respecto a esta modalidad, se establece que la Oficina Técnica promoverá en lo posible y en cooperación con otros entes públicos y privados, nacionales e internacionales, el registro voluntario de los recursos genéticos y bioquímicos *ex situ* en forma no sistematizada.

a6) Artículo 7º: Requisitos: Se establecen los requisitos necesarios para solicitar el permiso de acceso para investigación básica, bioprospección o aprovechamiento económico, específicamente a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *ex situ*:

- el interesado o su representante, deberán completar adecuadamente y en lo que sea aplicable, los formularios y los documentos que se señalan en los artículos 8 y 9 del Decreto Ejecutivo N° 31514-MINAE.
- Si el interesado presentara un acuerdo privado de transferencia de material, tal como está definido en el artículo 6 del Decreto Ejecutivo N° 31514-MINAE y según lo establecido en el artículo 22 de esa misma normativa, la Oficina Técnica recomienda ajustarse al acuerdo modelo incluido en el Anexo I de este Decreto Ejecutivo. En los casos en que sea posible determinar la procedencia y el origen de los materiales que van a ser accesados de una colección establecida previamente a la entrada en vigencia de este decreto, los beneficios podrán compartirse también con los proveedores originales de los mismos.
- En el caso de un acceso a colecciones sistematizadas nuevas –de conformidad con el artículo 8º de este Decreto Ejecutivo- o acceso a las accesiones nuevas en colecciones establecidas previamente a la entrada en vigencia de este Decreto Ejecutivo, los beneficios se compartirán, de conformidad con lo establecido en el consentimiento previamente informado y en las condiciones mutuamente acordadas, también con los proveedores originales de los mismos; y en este caso, el interesado y/o el propietario, responsable o representante de los materiales mantenidos en condiciones *ex situ*, aportará a la Oficina Técnica como uno de los documentos necesarios para darle curso a la solicitud del permiso de acceso, una copia del consentimiento previamente informado y las condiciones mutuamente acordadas con el proveedor original de los recursos.
- Desde el momento del registro de interesados y para cualquier tipo de solicitud, el interesado se compromete bajo la fe de juramento a respetar el código de conducta que se incluye en el anexo II de este Decreto Ejecutivo, el cual será revisado periódicamente por la Oficina Técnica. Este

compromiso será señalado también por la Oficina Técnica en la resolución que aprueba el respectivo permiso de acceso o en el convenio marco. El interesado deberá suscribirse a las modificaciones que surjan de la revisión del código de conducta.

a7) Artículo 8º: Establecimiento de nuevas colecciones *ex situ* sistematizadas: Se regula que la Oficina Técnica exigirá a los poseedores, propietarios y representantes de nuevas colecciones *ex situ* sistematizadas –establecidas a partir de la publicación de este Decreto Ejecutivo-, indicar el origen y/o procedencia de los materiales accedidos. Se clarifica además que entre las condiciones mutuamente acordadas y el consentimiento previamente informado negociados entre los propietarios, poseedores o administradores de la nueva colección y los proveedores originales de los elementos y recursos genéticos y bioquímicos de la biodiversidad, la Oficina Técnica recomienda preveer, un acuerdo sobre posibles beneficios que pudieran derivarse a partir de un acceso posterior a estos elementos y recursos genéticos y bioquímicos por parte de un tercero..

a8) Artículo 9º: Resolución de aprobación o rechazo: Congruentemente con el Decreto Ejecutivo N° 31514-MINAE, se estipula que la resolución que emita la Oficina Técnica, deberá indicar claramente si la solicitud fue aprobada o rechazada y las justificaciones técnicas, sociales o ambientales en que se fundamenta este acto; se establecen los recursos ordinarios que el administrado podrá interponer contra la resolución emitida y finalmente, se especifica que en los casos de acceso a elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *ex situ*, la Oficina Técnica determinará la necesidad de emitir el pasaporte correspondiente.

a9) Artículo 10º: Exportación y certificado de legal procedencia: Con la finalidad de desarrollar lo establecido en el artículo 19 del Decreto 31514-MINAE, se establece que cuando se pretenda acceder a los recursos genéticos y bioquímicos de materiales mantenidos en condiciones *ex situ*, pero que por diversas razones se requieran exportar estos materiales para su uso fuera del país, el interesado deberá solicitarse necesariamente un certificado de legal procedencia para que acompañe en todo momento al material, el cual le será expedido en los términos estipulados por el artículo 19 del decreto 31514-MINAE por la Oficina Técnica en un plazo no mayor de diez días hábiles a partir de la solicitud.

a10) Artículo 11º: Convenios Marco: Se aclara expresamente que la finalidad de estos convenios marco, es facilitar los trámites y la gestión de permisos de acceso a entidades que se dedican a la investigación básica, a la bioprospección y al aprovechamiento económico de los elementos y recursos genéticos y bioquímicos de la biodiversidad y que para ello se podrán seguir para su redacción, el modelo incluido en el anexo III.

a11) Artículo 12º: Depósito de duplicados: con el fin de promover la conservación *ex situ* en el país, de conformidad con el artículo 9 de la Convención sobre Diversidad Biológica y los artículos 55 y 57 de la Ley de Biodiversidad, la Oficina Técnica en las resoluciones sobre permisos de acceso a elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *in situ*, podrá solicitar al interesado que deposite duplicados del material accedido en alguna de las colecciones *ex situ* existentes, considerando el espacio físico y disponibilidad de recursos financieros y científicos, de quienes mantienen las colecciones registradas según este Decreto Ejecutivo. El acceso posterior a estos recursos genéticos y bioquímicos se permitirá sólo con la finalidad de investigación básica.

a12) Artículo 13º: Repatriación de información o de material de colecciones: Por medio de solicitud de los interesados o de oficio, la Oficina Técnica podrá solicitar a propietarios o responsables de colecciones *ex situ* ubicadas en el extranjero que mantienen material de origen costarricense o accedido en el país, la repatriación de la información respectiva, y en los casos establecidos en el artículo 57 de la Ley de Biodiversidad, también podrá solicitar la repatriación de muestras o material de las colecciones. La Oficina Técnica buscará la colaboración de otras instancias para el manejo de la información obtenida o el mantenimiento del material repatriado.

a13) Artículo 14°: Mantenimiento de las colecciones: Estipula que en el caso de que un propietario, poseedor o responsable de una colección *ex situ*, decida abandonar, destruir o exportar una parte o la totalidad de esa colección, notificará a la Oficina Técnica, quien podrá buscar la colaboración de otras instancias para el mantenimiento de material de interés proveniente de estas colecciones, en concordancia con el artículo 57 de la Ley de Biodiversidad.

a14) Artículo 15°: Promoción de la conservación *ex situ*: Para la promoción de la conservación *ex situ*, la Oficina Técnica, por propia iniciativa o a solicitud del interesado, en coordinación con entes públicos o privados, nacionales o internacionales, podrá apoyar iniciativas, programas o proyectos, gestión de recursos, difusión de tecnologías, incentivos, asistencia técnica, capacitación, entre otros, para promover la conservación *ex situ*.

a15) Artículo 16°: Normas supletorias: En todos los demás aspectos no regulados por el presente decreto, rige lo estipulado por el Decreto Ejecutivo N° 31514-MINAE, publicado en el Diario Oficial La Gaceta del 15 de diciembre de 2003 y en la Ley de Biodiversidad N° 7788.

a16) Modificaciones al Decreto Ejecutivo N° 31514-MINAE de 3 de octubre de 2003 publicado en el Diario Oficial La Gaceta N° 241 del 15 de diciembre del año 2003: Se incluyeron algunas reformas a varios de sus artículos, con la cuales se pretende mejorar y aclarar los procedimientos establecidos, con cambios sustancialmente formales y no de fondo, para garantizar con mayor precisión y claridad los objetivos y fines de la Ley N° 7788.

a17) Disposiciones Transitorias: Por su importancia y tomando en consideración sus particularidades, se incluyó dentro de estas Disposiciones como competencia prioritaria de la CONAGEBIO, el promulgar el reglamento específico que regulará el acceso a recursos genéticos de la biodiversidad animal domesticada, en un plazo máximo de veinticuatro meses a partir del 18 de abril del 2007, fecha de publicación del Decreto Ejecutivo N° 33697-MINAE. Para la elaboración de este reglamento de acceso a recursos genéticos de la biodiversidad animal domesticada, la CONAGEBIO contará con la asesoría y apoyo de personas y grupos técnicos especializados y mientras no exista este reglamento no se otorgarán permisos de acceso de bioprospección o de aprovechamiento económico para el material que se encuentre en estas condiciones.

Se incluye otro Transitorio, respecto al acceso a los recursos fitogenéticos para la alimentación y agricultura en condiciones *ex situ*, en el cual se establece textualmente: “En tanto no exista una normativa jurídica específica para la implementación del Tratado Internacional de Recursos Fitogenéticos para la Alimentación y la Agricultura ratificado mediante Ley N° 8539 del 17 de julio del 2006 publicada en La Gaceta N° 185 del 25 de setiembre del 2006, que pudiera establecer otra disposición al respecto, la Autoridad Nacional para la aplicación de dicho Tratado en el tema de acceso a los recursos fitogenéticos para la alimentación y la agricultura, será la Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO) y su Oficina Técnica, de conformidad con la Ley de Biodiversidad N° 7788 y el Decreto Ejecutivo MINAE- N° 31514, para lo cual la CONAGEBIO y su Oficina Técnica utilizarán como órgano de consulta a la Comisión Nacional de Recursos Fitogenéticos (CONAREFI)”

Además se reitera al igual que en el Decreto Ejecutivo N° 31514-MINAE, el Transitorio que establece respecto a los Conocimientos, innovaciones y prácticas de las comunidades locales y los pueblos indígenas lo siguiente “ Los permisos de acceso de investigación básica, de bioprospección o de aprovechamiento económico, que involucren conocimientos, innovaciones y prácticas de las comunidades locales y los pueblos indígenas sobre el uso de los recursos genéticos y bioquímicos de la biodiversidad, se otorgarán conforme a lo establecido en los artículos 66 y del 82 al 85 de la Ley de Biodiversidad y el Convenio 169 sobre Pueblos Indígenas y Tribales, aprobado mediante Ley N° 7316 del 03 de noviembre de 1992, publicada en La Gaceta N° 234 del 04 de diciembre del 1992”.

a18) Anexos: Se incluyeron tres anexos: un modelo de convenio marco, un modelo de Acuerdo de Transferencia de Material (ATM) y un Código de conducta para el acceso a elementos y recursos genéticos y bioquímicos de la biodiversidad, con la finalidad primordial de facilitar los procedimientos a los Interesados y Proveedores.

Específicamente el Código de Conducta, tiene como objetivo General: promover el acceso racional y la utilización sostenible de los elementos y recursos genéticos y bioquímicos de la biodiversidad tanto en condiciones *in situ* como *ex situ*, reducir los riesgos de erosión genética y proteger los intereses tanto de los usuarios como de los proveedores de esos elementos y recursos. El interesado en realizar el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, mantenidos en condiciones *ex situ*, se compromete bajo la fe de juramento a respetar el código de conducta, el cual será revisado periódicamente por la Oficina Técnica. Este compromiso será señalado también por la Oficina Técnica en la resolución que aprueba el respectivo permiso de acceso o en el convenio marco.

ENGLISH TRANSLATION

LEGAL REGIME FOR GENETIC RESOURCES IN THE RESPECTIVE NACIONAL LEGISLATION, PARTICULARLY WITH REGARD TO PROPERTY LEGISLATION:

The issue of the legal regime for genetic and biochemical resources in Costa Rica has been regulated by the objectives and procedures described below:¹

1) BIODIVERSITY LAW 7788², in effect since May 27, 1998, regulates, at the national level, the principles established in the Convention on Biological Diversity, signed in Rio de Janeiro in 1992 and ratified by the Government of Costa Rica through Law 7416 on June 30, 1994.

A. ACCESS TO BIOCHEMICAL AND GENETIC RESOURCES IN THE NATIONAL LEGISLATION:

a) Objectives:

Article 10 of this law establishes the objectives pursued through its implementation:

1. To integrate the conservation and use of the components of biodiversity into the development of socio-cultural, economic and environmental policies.
2. To promote the active participation of all sectors of society in the conservation and ecological use of biodiversity, in the pursuit of social, economic and cultural sustainability.
3. To promote education and public awareness about biodiversity conservation and use.
4. To regulate access and, in so doing, make possible the equitable distribution of environmental, economic and social benefits to all sectors of society, paying special attention to indigenous and local communities.
5. To improve administration for effective management of the components of biodiversity.
6. To recognize and provide compensation for the knowledge, practices and innovations of indigenous and local communities in the conservation and sustainable ecological use of the components of biodiversity.
7. To recognize the rights deriving from the contribution of scientific knowledge to the conservation and sustainable ecological use of the components of biodiversity.
8. To ensure environmental safety to all citizens as a guarantee of social, economic and cultural sustainability.

¹ The following acronyms will be used in this document:

CA:	Conservation Areas
MTA:	Material Transfer Agreement
CBD:	Convention on Biological Diversity
CONAGEBIO:	National Commission for the Management of Biodiversity
CONAREFI:	National Commission on Plant Genetic Resources
PIC:	Prior Informed Consent
MINAE:	Ministry of the Environment and Energy
ILO:	International Labour Organization
SINAC:	National System of Conservation Areas

² The complete text of the Biodiversity Law is available online at: www.conagebio.go.cr in both Spanish and English.

9. To not limit the participation of any sector in the sustainable use of the components of biodiversity or in the development of research and technology.
10. To promote access to the components of biodiversity and the associated transfer of technology.
11. To promote international and regional co-operation to achieve the conservation, ecologically sustainable use and the distribution of benefits derived from biodiversity, especially in frontier areas or from shared resources.
12. To promote the adoption of incentives and the reward of environmental services for the conservation, sustainable use and components of biodiversity.
13. To establish a system of conservation of biodiversity that will achieve co-ordination between the private sector, the citizens and the State, to guarantee the application of this law.

b) Creation of the National Commission for the Management of Biodiversity (CONAGEBIO):

Law N° 7788 establishes the National Commission for the Management of Biodiversity (CONAGEBIO) as the competent national authority in Costa Rica to propose policies regarding access to the genetic and biochemical components of biodiversity and associated traditional knowledge, to ensure proper scientific and technology transfer, and the fair and equitable sharing of benefits arising from access. At the administrative level, the Law classifies CONAGEBIO as a decentralized organ of the state, with instrumental legal identity, reporting to the Ministry of the Environment and Energy.

This Commission is made up of the Minister of the Environment and Energy, who is its President, the Minister of Agriculture, the Minister of Health or a representative, the Executive Director of the National System of Conservation Areas (SINAC), and a representative of: the Costa Rican Institute of Fishing and Agriculture (INCOPECA); the Minister of Foreign Trade; the National Small Farmers Board; the National Indigenous Peoples Board; the Costa Rican Federation for the Conservation of the Environment; and the Costa Rican Union of Chambers of Commerce.

In other words, this Commission is composed of representatives of government institutions and of institutions in other sectors concerned by the issue of biodiversity. In accordance with Article 16 of the Law, the Commission performs its agreements and resolutions and instructs its procedures by means of the Executive Director of the Technical Office.

When referring to CONAGEBIO as a Decentralized Organ, we would like to mention the words of illustrious Professor Eduardo Ortiz Ortiz, who wrote Costa Rica's General Law on the Public Administration, who said, when the corresponding draft was being passed in the Legislative Assembly, that **“Decentralization is the phenomenon by which an inferior or subordinate body is granted the capacity to decide a matter on its own authority.”**³

On the issue of the decentralization of CONAGEBIO and its authority, it is important to reproduce part of the analysis carried out by the Attorney General of the Republic of Costa Rica, in Ruling C320-2002 of November 28, 2002, which explains: *...“The authority of an administrative organization can be transferred internally through a process of decentralization. In this respect, the decentralization of authority involves a distribution of said powers within the same legal entity, which is why an inferior organ receives the authority to make decisions in an exclusive manner, so that it may make its own decisions, under its own name and under its own responsibility. Through this process, the inferior organ is given the legal capacity to decide, on its own behalf, on the decentralized subject, resulting in an administrative segment specialized in better fulfilling public tasks. This process leads to a situation in which the leaders are not competent to issue acts relative to the decentralized subject.”*

³ Official letter OT-431-2004. Maribel Alvarez Mora, Legal Advisor of CONAGEBIO's Technical Office

With regard to the financial resources that support the activities of CONAGEBIO and its Technical Office, the Comptroller General of the Republic⁴ has determined that, seeing as it is a public administration organ, its budget resources must be executed according to the functions bestowed upon it by the Biodiversity Law, and must respect the legal framework to which all public administration organs are subject, including the General Law on the Public Administration No. 6227, Law on the Financial Administration of the Republic and Public Budgets, Law No. 8131, Administrative Contracting Law No. 7494, the General Law on Internal Auditing, Law No. 8292 and, more recently, the Law against Corruption and Illegal Enrichment in the Public Service No. 8422 .

CONAGEBIO and its Technical Office are financed according to the stipulations of articles 19 and 43 of the Biodiversity Law, with 10% of the National Parks Stamp Duty being its main source of funding.

c) Biochemical and Genetic Resources Declared Goods in the Public Domain:

The legislator expressly established, in Article 6 of Biodiversity Law No. 7788, the statement that the genetic and biochemical properties of the components of wild or domesticated biodiversity are **in the public domain** and that it is up to **the Government** to authorize the research, bioprospecting, use and exploitation of said components of biodiversity, as well as the use of all genetic and biochemical resources through the regulations for access established in Chapter V of the Law.

Furthermore, our Political Constitution, as stated by the Constitutional Tribunal of the Supreme Court of Justice in its Verdicts, expressly regulates the issue of public domain in Articles 6, 50, 89 and 121 subsection 14), establishing, according to the discussions appearing on the record, the premise that the protection and administration of the public domain is up to the State, to achieve the ultimate goal of the common good, not individual interest.

Given the constitutional legal framework, therefore, there is no doubt whatsoever about the legal basis for granting the National Commission for the Management of Biodiversity, and its Technical Office in particular, as part of the government apparatus, the role of processing, approving, rejecting and examining applications for access to genetic and biochemical resources, particularly as Article 6, in relation to articles 2 and 3 of the Biodiversity Law, and in accordance with the articles of the Political Constitutions, specifically determines that the genetic and biochemical components of biodiversity are subject to a public purpose.

Specifically, as reiterated by the Constitutional Tribunal of the Supreme Court of Justice in its jurisprudence, with regard to the definition, characteristics and legal nature of goods in the public domain, it is necessary to point out the following elements:

- Verdict No. 2306-91, issued at two forty-five p.m. on November six, nineteen ninety one:
 - a) .The public domain comprises goods that, through the express will of the legislator, are **specially destined to serve the community, the public interest.**
 - b) They are those goods that are called dominical goods, dominial goods, public goods or items, or public assets, which do not belong personally to individuals and are destined for public use and subject to a special regime, outside of human commerce.-
 - c) They are inalienable, imprescriptible, nonseizable, cannot be mortgaged nor subject to encumbrance under the terms of Civil Law, and administrative action replaces prohibitions when it comes to recovering the domain.-
 - d) They cannot be an object of possession. A right to exploitation can be obtained, but **not a right to property**. Permission to use is a unilateral legal decision dictated by the Administration, in the

⁴ Comptroller General of the Republic, Operations and Evaluative Auditing, Area of Agriculture and Livestock, and Environment. Official letter 12729 of October 20, 2004.

use of its functions, and what is put in the individual's hands is control over the use the good, with direct control over the good remaining always in the hands of the State.-

e) All permission to use is temporary, alluding to the fact that the administration may, unilaterally and at any time, revoke said permission for reasons of general need or interest. This is insofar as, should the purpose of the good and the permission granted run counter to each other, the natural use of the public item must prevail.

- Verdict No. 10466-00, issued at ten sixteen on November twenty-four, two thousand:
 - a) According to the terms of our Political Constitution, **the national heritage is made up of the goods defined in articles 6, 50, 89 and 121 subsection 14) of the constitution;** they are territorial waters, coasts, the airspace, the continental shelf, the insular base, **the natural resources and wealth of the water and groundwater, natural beauty, the right to a healthy and ecologically balanced environment**, the nation's historical and artistic heritage, the power that can be obtained from the waters in the public domain and on the national territory, deposits of coal, oil wells or fields, hydrocarbon substances, deposits of radioactive minerals, wireless services-what is currently known as electromagnetic space-, railways, ports and airports that are in service.
 - b) It is important to indicate that these goods enjoy special protection from the State, so that they are not susceptible to appropriation by individuals or even by the Public Administration; nor can they be used for purposes other than those that determine their essence and nature.
 - c) The goods of the Nation may be the object of rational exploitation by the State or by individuals *"with or through a special concession granted for a determinate amount of time and according to the conditions and stipulations established by the Legislative Assembly"* (subsection 14 of Article 121 of the Political Constitution). The jurisprudence of this Tribunal -sentence 06240-93-, examined the possibility for the Legislative Assembly to employ the technique of dictating what is commonly known as a framework law to fulfil the requirement of the constitutional regulation.
 - d) It must be kept in mind that the special assignment of the goods of the Nation only makes sense insofar as it guarantees to all inhabitants the right to quality of life in a healthy and ecologically balanced environment. The exploitation of natural resources imposes, with the force of the constitution, rational use of said resources (adapted, planned), for the benefit of the current and future inhabitants of the country (third generation rights).

d) Powers of CONAGEBIO and its Technical Office:

Law No. 7788 gives CONAGEBIO the role of National Authority in charge of formulating and coordinating policies on access to the biochemical and genetic components and resources of biodiversity and associated traditional knowledge that ensure proper scientific and technology transfer and the fair and equitable sharing of benefits arising from access.

It also assigns other, expressly established powers, including the following: formulating national policies on the conservation, sustainable use and restoration of biodiversity, subject to the Convention on Biological Diversity and other international conventions; formulating the policies and responsibilities set out in chapters IV, V and VI of the Law and coordinating them with the various organizations responsible for the subject; formulating the national biodiversity strategy and providing follow-up and advice to other organs of the Executive Branch, independent institutions and private entities, in order to regulate actions for the ecologically sustainable use of the components of biodiversity.

The Biodiversity Law furthermore stipulates that CONAGEBIO should have the support of a Technical Office, to perform the following functions, among others: to negotiate, approve, reject and control applications for access to the genetic and biochemical components and resources of biodiversity; to co-

ordinate anything related to access with the Conservation Areas, the private sector, indigenous peoples and peasant communities; to organize and maintain an updated register of applications for access to the components of biodiversity, *ex situ* collections and on the individuals or legal entities devoted to manipulating genetic matter. The information in the register will be public, except for industrial secrets, which must be protected by the Register, unless biosafety reasons should make it necessary to publicize such information. Another function of the Technical Office is to authorize the agreements and contracts entered into by national or foreign individuals, or between such individuals and institutions registered for that purpose, should said contracts or agreements contemplate the use of genetic and biochemical components of Costa Rica's biodiversity.

e) Procedure for access to genetic and biochemical components and resources:

e1) Scope of Application:

Article 3 establishes the Law's Scope of Application, stating that it will apply to the components of biodiversity that are found under the sovereignty of the State, as well as to the processes and activities carried out under its jurisdiction or control, independently from those effects which manifest themselves inside or outside the zones subject to national jurisdiction. It further states that the law will regulate specifically the use, management, associated knowledge and equitable distribution of the benefits and costs arising from the use of the components of biodiversity.

However, the following exclusions to the law's scope of application are also established: a) it will not apply to access to biochemical or genetic material of human origin, which will continue to be regulated by General Health Law No. 5395, of October 30, 1973, and related laws;

b) neither will these rules apply to the exchange of biochemical or genetic resources among indigenous and local communities, nor to the associated knowledge resulting from their non-profit-making practices, uses or customs; and

c) the arrangements of this law do not affect university autonomy in the matter of teaching or research in the field of biodiversity, unless the research has commercial purposes.

e2) Declaration on the Public Domain:

Article 6 further establishes the above-mentioned declaration on the public domain, establishing that the State will authorize the exploration, research, bioprospecting and use of the components of biodiversity which constitute part of the public domain, as well as the utilization of all genetic and biochemical resources, by means of the rules of access established in chapter V of the law. Article 69 also expressly stipulates that all research programs or bioprospecting related to genetic or biochemical materials of biodiversity to be carried out in Costa Rican territory require an access permit.

e3) Definitions:

A number of definitions are set out in Article 7, on the basis of which the Law should be interpreted. Some of these definitions were taken from Article 2 of the Convention on Biological Diversity, but there are also other innovative definitions, such as:

“Access to biochemical and genetic components: Action to obtain samples of components of biodiversity, wild or domesticated, in *in situ* or *ex situ* conditions, or to obtain associated knowledge, for the purpose of basic research, bioprospecting or commercial use.”

“Bioprospecting: The systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, and micro-organisms, with real or potential economic value, which are found in biodiversity.”

“Permission for access: Authorization granted by the State of Costa Rica for basic research, bioprospecting, obtaining or commercializing genetic materials or biochemical extracts of components of biodiversity, as well as their associated knowledge, to people or institutions, national or foreign, requested by means of the procedure, given the rules in this legislation, whether it concern permission, contracts, agreements or concessions.”

“Biochemical component: Any material derived from plants, animals, fungi or micro-organisms, which contains specific characteristics, special molecules, or elements to design them.”

e4) Chapter V: Access to genetic and biochemical components, and protection of associated knowledge:

1) Specifically, we find that CHAPTER V of the Law regulates the issue of Access to genetic and biochemical components and the protection of associated knowledge, and stipulates, among other things:

“Article 62.- **Competence:** It is a duty of the Commission to propose access policies concerning genetic and biochemical components of *in situ* and *ex situ* biodiversity. It will act as an organ of obligatory consultation in procedures of request for protection of intellectual rights concerning biodiversity.

The provisions concerning this matter will constitute the general rules for access to genetic and biochemical components, and for the protection of intellectual rights concerning biodiversity. The administration and interested parties must comply with these provisions, which should be previously published in the Official Journal in order to be effective for third parties.”

2) Article 63 of this Law regulates the basic requirements for access, including the following: Prior informed consent; approval of the prior informed consent by the Technical Office of the Commission; and the designation of a legal representative resident in the country, when it concerns people or legal persons living outside the country. Article 72 establishes the general requirements for the application for access, including, for example: the name and complete identification of the interested manager; if it is not the self-same interested party, it should indicate the identification data of the official and the power which he/she holds; a descriptive chronogram of the extent of the scope of the research and its possible environmental impact; the objectives and purpose being pursued; and a statement to the effect that the above declaration has been made under oath. All of these requirements have been fully developed in Executive Decree No. 31514-MINAE, published in Official Gazette No. 241 of December 15, 2003, making it easier to implement them in practice.

3) With regard to the standards of Procedure, the Law establishes the general aspects that must be fulfilled in all access permits, including:

- Scope: By means of procedures formally registered in official records, the Technical Office of the Commission will manage all processes under its responsibilities indicated in this law.
- Access permits will have a maximum validity of three years, renewable at the discretion of the Technical Office of the Commission.
- Such permits are personal and non-transferable. They are materially limited to the authorized genetic or biochemical components, and can only be used in the expressly indicated area or territory.
- Access permits for research or bioprospecting do not grant nor delegate rights. They only allow such activities to be carried out on previously agreed components of biodiversity.
- Access permits will clearly stipulate: the certificate of origin, the possibility or prohibition to take out or export samples, or in its absence, their duplication and deposit; the periodic reports, the verification and control, the publicity and property of the results, as well as any other condition that, given the applicable

rules of science and the technique, are necessary as per the discretion of the Technical Office of the Commission.

- In the respective resolution, the Technical Office, in conformity with the General Standards for Access to Genetic and Biochemical Components and Resources, will establish the obligation of the interested party to deposit up to ten percent (10%) of the research budget and up to fifty percent (50%) of the bonuses which it collects, in favour of the National System of Conservation Areas, the indigenous territory or the private owner providing access to the components. Moreover, it will determine the amount which in each case should be paid by the interested parties for administrative costs, as well as any other benefit or technology transfer which forms a part of the prior informed consent.

e5) Framework agreements and Concessions:

The Law recognizes:

- the role of **Framework agreements**, stating that public universities and other research centres could periodically subscribe framework agreements with the Commission, to process the access permits and reports on operations.

- and Concession: When the Technical Office authorizes the constant utilization of genetic material or biochemical extracts for commercial purposes, it will require that the interested party obtain a concession to exploit them, for which the General Rules set by the Commission shall apply.

B. PROTECTION OF INDUSTRIAL AND INTELLECTUAL PROPERTY RIGHTS:

In Costa Rica, the protection of intellectual property rights is a constitutional principle, as it is expressly regulated in Article 47 of our Political Constitution: "All authors, inventors, producers and businesspersons shall temporarily enjoy exclusive ownership of their work, invention, brand or trade name, according to the law." The power to issue, reform, repeal and authentically interpret laws rests exclusively with the Legislative Assembly, as established in Article 121 of the Magna Carta.

For its part, Section III of Chapter V of the Biodiversity Law regulates the issue of protecting intellectual property linked to biodiversity, regulating the following aspects, among others:

a) The State recognizes the existence and validity of forms of knowledge and innovation and the necessity to protect them by means of the use of legal mechanisms appropriate for each specific case.

b) The State shall grant the protection indicated in the previous article, among other ways, by means of patents, trade secrets, plant breeders' rights, sui generis community intellectual rights, copyrights and farmers' rights. These rights shall not apply to:

8. Sequences of deoxyribonucleic acid per se.
9. Plants and animals.
10. Non genetically modified micro-organisms.
11. Essentially biological processes for the production of plants and animals.
12. Natural processes or cycles as such.
13. Inventions essentially derived from knowledge which is associated with traditional or cultural biological practices in the public domain.
14. Inventions which, if commercially exploited through a monopoly, can affect farming or fishing processes or products which are considered basic for the food and health of the inhabitants of the country.

c) Both the National Seed Office of Costa Rica and the Registers of Intellectual and Industrial Property are obliged to consult with the CONAGEBio's Technical Office before granting protection of intellectual or industrial property for innovations involving components of biodiversity, stressing that justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation.

d) As an essential prerequisite, the certificate of origin issued by the Technical Office of the Commission and the prior informed consent must always be provided when requesting protection of intellectual property for innovations involving components of biodiversity.

e) The individual beneficiaries of intellectual or industrial property protection related to biodiversity will cede, in favour of the State, a compulsory legal license which will allow it, in cases of declared national emergency, to use such rights for the collective good, with the sole purpose of resolving the emergency, without need to pay privileges or compensation.

f) “**Sui generis community intellectual rights**” are expressly recognized and protected, which makes this legislation ground-breaking with regard to regulation of this specific issue:

1. The State expressly recognizes and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition or official registration; therefore it can include practices which in the future acquire such status.
2. This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices.
3. The Technical Office, in association with the Indigenous Peoples Board and the Small Farmers Board, shall define a participatory process with indigenous and small farmer communities to determine the nature, scope and requirements of these rights for their definitive regulation. Furthermore, the participatory process will determine the way in which *sui generis* community intellectual rights will be used and who will be the title holder. It will also identify to whom the benefits should accrue.
4. By means of the procedure indicated in the previous article, an inventory will be made of specific *sui generis* community intellectual rights that communities ask to be protected, and the possibility shall be kept open that, in the future, other ones with the same characteristics will be registered and recognized. The recognition of these rights in the register of the Technical Office of the Commission is voluntary and free. It should be done unofficially or at the demand of the interested parties, without being subjected to any formality.
5. The existence of such recognition in the register will oblige the Technical Office to respond negatively to any consultation concerning the recognition of intellectual or industrial rights over the same component or knowledge. Such rejection, always properly justified, can be made for the same motive even when the *sui generis* right is not officially registered.

Furthermore, in Article 66 of this law, the right of local communities and indigenous peoples to oppose any access to their resources and associated knowledge, be it for cultural, spiritual, social, economic or other motives, is recognized

At the time of writing, the consultation process aimed at defining community intellectual rights and their regulation had not been completed. Therefore, both Executive Decree No. 31514-MINAE and the Regulation for Access to Biochemical and Genetic components and resources in *ex situ* conditions include the following Provisional Clause:

“The knowledge, innovations and practices of indigenous and local communities.
Access permits for basic research, bioprospecting or economic exploitation that

involve the knowledge, innovations and practices of indigenous and local communities regarding the use of genetic and biochemical resources of biodiversity shall be granted in accordance with the stipulations of articles 66 and 82 to 85 of the Biodiversity Law and of Convention 169 on Indigenous and Tribal Peoples, approved by Law No. 7316 of November 03, 1992, published in Official Gazette No. 234 of December 4, 1992.”

It is important to mention that the Law on Patents for Inventions, Industrial Drawings and Models, and Utility Models, No. 6867 of April 25, 1983, amended by Law No. 7979 of January 6, 2000, also regulates exclusions from patent that do not fully coincide with the stipulations of the Biodiversity Law. This means that, in the short term, our country will have to define a single legal interpretation with regard to this issue.

2) GENERAL STANDARDS FOR ACCESS TO THE GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY⁵: Executive Decree No. 31514-MINAE published in Official Gazette No. 241 of December 15, 2003:

a) Scope of Application:

In accordance with the Biodiversity Law, these General Standards for Access to the Genetic and Biochemical Components of Biodiversity, hereafter called Standards, establish that access will apply to the genetic and biochemical components and resources of biodiversity, be they wild or domesticated, terrestrial, marine, freshwater or aerial, *in situ* or *ex situ*, which are found in the national territory as defined in Article 6 of the Political Constitution, be they public or private property. The Standards likewise oversee and regulate the protection of the associated traditional knowledge and the fair and equitable distribution of benefits arising from the use of said components and resources.

Excluded from the scope of application of the Standards is the use of biodiversity components used as organic resources, which will continue to be regulated by the Forestry Law, the Wildlife Conservation Law, the INCOPECA creation Law, the Fisheries Law, and other special laws.

b) Types of Access Permits:

The Standards specify four types of access permits:

Basic Research: Permit to investigate, examine, classify or increase existing knowledge over biological elements in general or their genetic or biochemical characteristics in particular, without immediate interest in commercializing its results.

Bioprospecting: Systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, micro-organisms and other products with actual or potential economic value, found in biodiversity.

Economic commercial exploitation: This is a personal and non-transferable authorization, that is neither exclusive nor excluding, so that the interested party may make occasional or constant use of the biochemical or genetic components and resources of biodiversity for commercial purposes, without necessarily being preceded by a basic research or bioprospecting program as part of the permit application.

⁵ The complete text of Executive Decree No. 31514-MINAE, is available at: www.conagebio.go.cr, in both Spanish and English.

Concession: For cases of access for economic exploitation that becomes constant, in other words, for cases in which the interested party has requested access to the same genetic or biochemical resource at least six times in a five-year period for commercial purposes, a concession is required. CONAGEBIO's Technical Office will process the application and transmit the file with a recommendation to the Ministry for potential approval and signature.

c) Definitions:

In addition to the definitions found in the Biodiversity Law, these General Standards for Access include definitions to be used as a reference for its application. These definitions include the following:

Certificate of origin or legal provenance: Official document issued by CONAGEBIO's Technical Office certifying the legality of access to genetic and biochemical components and resources of biodiversity and the observance of the terms on which the corresponding access permit was authorized to the interested party.

Concession: Authorization for access for commercial purposes and in a constant manner to certain biochemical or genetic properties of the components and resources of biodiversity, which the head of the Ministry of the Environment and Energy grants to the interested party, either national or foreign, once its application has been revised and transferred to the CONAGEBIO's Technical Office. In order to apply this definition, the term "constant utilization" will mean when the interested party applies for access to the same genetic or biochemical resource at least six times in a period of five years. Furthermore, concessions are neither exclusive nor excluding.

Fair and equitable distribution of benefits: Sharing of the economic, environmental, scientific-technological, social or cultural benefits arising from research, bioprospecting or economic exploitation of the genetic and biochemical components and resources of biodiversity among the parties involved in access to and conservation of biochemical and genetic resources, with special attention to indigenous and local communities.

Basic research in biodiversity: Activity to investigate, examine, classify or increase existing knowledge of biological elements in general or their genetic or biochemical characteristics in particular, without immediate interest in commercializing its results.

Access permit for economic commercial exploitation: Personal and non-transferable authorization, neither exclusive nor excluding, granted by the Technical Office of CONAGEBIO so that the interested party may make occasional or constant use of the biochemical or genetic elements and resources of biodiversity for commercial purposes, without necessarily being preceded by a basic research or bioprospecting program as part of the application. Should utilization be constant, attainment of a concession will be required, in accordance with Article 11 of the present regulation.

Provider of the genetic or biochemical components or resources of biodiversity: Physical or legal entity that is the holder, custodian or owner of goods that contain genetic or biochemical components or resources of biodiversity, or who hold associated traditional knowledge and may authorize access thereto, upon compliance with the legal procedures established in these standards.

Organic resource: Any material from living beings, wild or domesticated, which be exploited as such, as a whole or in its macroscopic parts

Biochemical resource: Any material derived from living beings, sought or utilized for its actual or potential value, which has certain specific characteristics, special molecules or clues to design

them. In contrast to the organic use of resources, the biochemical resource undergoes a greater technical-industrial transformation and exploitation, and generally has a greater number of active ingredients.

Genetic resource: Any material from living beings which contains functional units of inheritance and which can be conventionally managed or innovated by farmers and plant or zoo-breeders; as well as researched or exploited through modern biotechnological procedures, with actual or potential value.

d) Procedure:

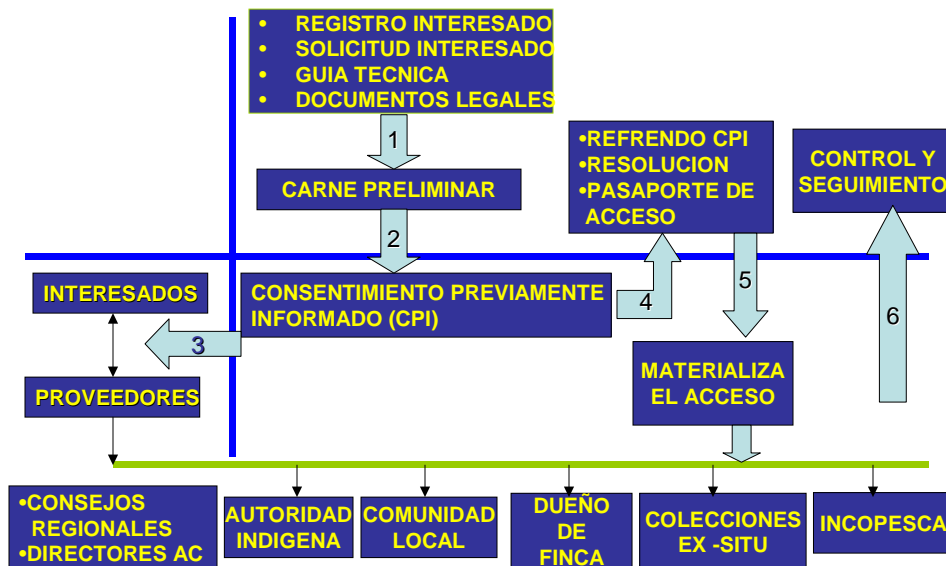
Prior Informed Consent and Mutually Agreed Terms for access to genetic and biochemical components and resources are the two basic elements that currently differentiate the process required for granting an access permit from the previous procedure, which applied under the Wildlife Conservation Law.

These elements or requirements are stipulated in accordance with Article 15 of the Convention on Biological Diversity, which establishes the recognition of States' sovereign rights over their natural resources, the requirement for access to be subject to the prior informed consent of the Contracting Party providing those resources, and the need for sharing in a fair and equitable way the benefits arising from their utilization with the Contracting Party providing such resources.

It should be understood that Prior Informed Consent, hereafter PIC, constitutes a mechanism by which the providers of genetic or biochemical resources, or associated knowledge (Regional Council or Director of the Conservation Area – for government property – and farm owners, the authorities of indigenous and local communities and the owners or custodians of material held in *ex situ* conditions), following negotiations with the interested party, consent to allow access, through the establishment between the parties of mutually agreed terms and of fair and equitable sharing of benefits.

The flow chart below is aimed at making it easier to understand the process for granting an access permit as outlined in the national legislation:

FLUJOGRAMA PARA OTORGAR PERMISOS DE ACCESO



(Flowchart for granting access permits / Interested Party registers; Interested Party applies; Technical guide; Legal documents / 1 Preliminary identification card / 2 Prior Informed Consent (PIC) / 3 Interested Parties / Providers / 4 PIC approval; resolution, access passport / 5 Access becomes effective / Regional councils; Conservation Area Directors / Indigenous Authority / Local Community / Farm Owner / Ex-Situ Collections / INCOPECA / 6 Monitoring and Follow-up)

Source: Technical Office, CONAGEBIO. 2005

a. Interested parties must register with the Technical Office before requesting any type of access permit, for which the corresponding form has been created. Once registered, it is necessary to fill out the permit application form and the technical guide form, attaching various legal documents, based on whether the applicant is an individual or legal entity (Step 1 of the flow chart)

b. Once these documents have been submitted, the Technical Office gives the interested party a preliminary identification card showing that the holder is a potential user, and authorizing the holder to contact the providers of genetic or biochemical resources and establish prior informed consent, or PIC. The Technical Office has provided a PIC guidelines document aimed at speeding up and facilitating negotiations among parties. (Steps 2 and 3 of the flow chart)

In order to carry out the negotiation, and to thoroughly discuss the meaning and scope of the access, the terms for protection of associated knowledge, and the practical, economic and logistical aspects of access, the Interested Party or its Legal Representative must contact the Representatives (Providers) from the place where the access to the genetic and biochemical components or resources of biodiversity will take place, who might include: the Regional Council, the Director of the Conservation Area, in the event that the property is government-owned, the owners of farms, the authorities of indigenous or local communities and the holders or custodians of the material in *ex situ* collections .

If the access is to take place in a coastal or marine areas that does not fall under the definition of wetland contained in Article 40 of the Organic Environment Law, or is in a place that is not within the limits of a protected area declared as such, the prior informed consent must be processed with INCOPECA, with

the advice of its Scientific-Technical Commission. But if the access is to take place on the edges of public roads and sidewalks, or in rivers, lakes and wetlands, the prior informed consent must be processed with the Regional Council or the Director of the corresponding Conservation Area. In the case of indigenous lands, the information will be governed by the stipulations of ILO Convention 169, Law No. 7316. The prior informed consent must furthermore be presented in the corresponding indigenous language if the parties involved so require.

c. Once the prior informed consent of the provider of the genetic or biochemical resource has been obtained, the interested party returns to the Technical Office, which must approve the agreement, taking into account the principles and objectives of the Convention on Biological Diversity and the Biodiversity Law, as well as the stipulations of Costa Rican legislation. Should the Technical Office deem necessary, it may engage in various consultations and request any additional information it considers essential from the parties involved in negotiating the prior informed consent.

Then, in accordance with Article 13 of the Standards, the Technical Office issues a resolution that clearly indicates whether the application for access has been approved or refused, and provides the technical, social or environmental reasons on which the decision is based. Once the Technical Office has approved the access permit, it issues an “access passport” that accredits the interested party to enter the place where the activities authorized by the corresponding resolution are to take place (Steps 4 and 5 of the flow chart).

d. The Technical Office performs monitoring and follow-up in accordance with the granted permit and, when it deems necessary, coordinates with the interested party or the provider of the resource. Technical Office officials may conduct inspections on the estate or in the place where the access is taking place, at any time during the period for which the respective permit is in effect, or once the activities covered by said permit have been completed (Step 6 of the flow chart).

e) Certificate of origin or certificate of legal provenance:

The Certificate of origin or legal provenance, issued by the Technical Office of CONAGEBIO, has been regulated in a groundbreaking manner, in Biodiversity Law No. 7788, Article 80, as a basic requirement that, along with the prior informed consent, must always be presented by the interested party to the National Seed Office or the National Registry of Intellectual Property when applying for intellectual property protection for innovations that involve components of biodiversity.

In order to develop and specify this instrument, to make it easier to apply at the national level, Article 6 of this Executive Decree includes a definition of the certificate of origin or certificate of legal provenance. Furthermore, Article 19 stipulates:

Article 19: In order to certify the legality of access, the Technical Office will issue to the applicant a certificate of origin, also called a “certificate of legal provenance”, which includes: the place and date of access, the owner of the components or resources of biodiversity, the material obtained, the quantity thereof, and the person, community or communities which have contributed or will contribute with their associated knowledge, innovations and traditional practices. Furthermore, it will indicate whether the concerned party fulfilled the regulations established for the previously informed consent and the mutually agreed terms for basic research, bioprospecting or economic exploitation, as well as the date and number of the corresponding resolution. The Technical Office will design the corresponding format.

f) Fair and equitable sharing of the benefits arising from the use of genetic resources:

The benefits arising from the use of genetic and biochemical resources of biodiversity can be classified as monetary and non-monetary benefits. For monetary benefits, our legislation stipulates the interested party's obligation to deposit up to 10% of the research or bioprospecting budget. This percentage will be established in accordance with the will of the parties, and can be anywhere from zero to ten per cent; and up to 50% of the royalties obtained by the Interested Party go to the provider of the resources in the event of commercial exploitation. In general, benefits can be classified as follows:

Monetary benefits

- Up-front payments
- Payments for each step
- License fees in the event of commercialization
- Special fees to support the conservation and sustainable use of biological diversity.
- Salaries
- Research funding
- Joint ventures
- Joint ownership of the relevant intellectual property rights

Non-monetary benefits

- Participation in the results of the research
- Cooperation and contribution to research programs and scientific developments, preferably within the country.
- Participation in product development
- Training and capacity-building
- Entry to the facilities and databases of *ex situ* collections
- Strengthening the capacity of indigenous and local communities to conserve and sustainably use their genetic resources.
- Institutional capacity-building
- Human resources and materials to strengthen capacity, specially for the staff responsible for administering and enforcing the laws regarding access to genetic resources.
- Contribution to the local economy
- Research aimed at priority needs, such as food safety and human health, considering the national uses of genetic resources
- Infrastructure
- Access to scientific information linked to the conservation and sustainable use of biodiversity.
- Others.

g) Access to the genetic and biochemical components and resources of biodiversity in *ex situ* conditions:

In the case of access to genetic resources in *ex situ* conditions, Provisional clause 1 of Executive Decree No. 31514-MINAE establishes, as a general standard, that until the necessary procedure exists, no access permits will be granted for bioprospecting or economic exploitation of genetic and biochemical components and resources of biodiversity maintained in *ex situ* conditions.

However, it was possible to end this procedure recently, with the issuance of the respective Regulation for Access to Genetic and Biochemical Components and Resources of Biodiversity in *ex situ* conditions.

3) REGULATION FOR ACCESS TO GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY IN *EX SITU* CONDITIONS”⁶: Executive Decree No. 33697-MINAE of February 6, two thousand and seven, published in Official Gazette No. 74 of April 18, 2007.

This New Decree, which is groundbreaking legislation worldwide, recently went into effect in our country. It aims to guarantee the quick and effective implementation of the process required for access to genetic and biochemical components of biodiversity in *ex situ* conditions, in accordance with articles 6, 17 subsection 3, 62 and 69 of Biodiversity Law No. 7788, Provisional Clause 1 of Executive Decree No. 31514- MINAE and its Amendment, and the Convention on Biological Diversity, in particular Article 9 thereof.

With regard to the issuance of this legislation, it is important to highlight the fact that this draft Regulation underwent a number of consultations with various national bodies, experts and individuals concerned with this issue, in order to incorporate their comments and opinions and thus enhance the final document.

Very few countries in the world are in the process of regulating this specific issue right now, making Executive Decree No. 33697-MINAE important input for countries interested in regulating this issue.

a) Detailed analysis of Executive Decree No. 33697-MINAE:

a1) Article 1: Scope of application: It shall apply to the genetic and biochemical components and resources of biodiversity, be they wild or domesticated, terrestrial, marine, freshwater or aerial, in *ex situ* conditions, be it in the collections of individuals or legal entities, private or public, located in any part of the national territory as defined in Article 6 of the Political Constitution, or in non-systematized ways, according to Article 5 of this Decree. This Executive Decree likewise oversees and regulates the protection of the associated traditional knowledge and the fair and equitable distribution of benefits arising from the use of said components and resources and/or traditional knowledge.

a2) Article 2: Exclusions: It is stipulated clearly that, without prejudice to the provisions of the Biodiversity Law with regard to exclusions, this regulation shall not apply:

a) to components and resources of biodiversity in *ex situ* conditions used as organic resources

b) to the interchange of genetic and biochemical resources and associated knowledge arising from non-profit practices, uses and customs, among indigenous and local communities, in accordance with Article 4 of the Biodiversity Law.

c) to access to genetic and biochemical components of domesticated animal biodiversity, which shall be regulated in accordance with Provisional clause 1 of this Executive Decree.

a3) Article 3: Competent Authority: CONAGEBIO is the competent National Authority to propose policies regarding access to the genetic and biochemical components of biodiversity and associated traditional knowledge, to ensure proper scientific and technology transfer, and the fair and equitable sharing of benefits arising from access. The Technical Office of CONAGEBIO is in charge of negotiating, approving, rejecting and controlling applications for access to the genetic and biochemical components and resources of biodiversity in *ex-situ* conditions, and associated traditional knowledge according to the terms of this Regulation.

a4) Definitions: For the implementation and interpretation of this Executive Decree, in addition to the definitions set out in Article 7 of the Biodiversity Law, in Article 6 of Executive Decree No. 31514-

⁶ For the complete text of Executive Decree No. 33697-MINAE, please see Annex 1 of the present document.

MINAE of October 3, 2003, in Article 2 of Wildlife Conservation Law No. 7317 of October 30, 1992, and Article 2 of the Regulation of the Wildlife Conservation Law, Executive Decree No. 32633-MINAE of March 10, 2005, published in Official Gazette No. 180 of September 20, 2005, 58 definitions appear in this Executive Decree, including:

“**ACCESSION:** A group of one or more specimens maintained in a live or preserved collection for its conservation or use, which can be samples of a plant, strain, cell line or other organisms; originating from the same population, habitat and geographical location. Also known as entry.”

“**GENE BANK:** Collection of propagating material found stored under conditions that maintain their viability for extended periods. These can include seeds, pollen, tissue cultures, propagating vegetable matter, DNA and even whole plants growing as plantations, as well as animal genes.”

“**BASIC OR BASE COLLECTION:** The broadest and most complete collection of germplasm accessions stored for long periods, for conservation purposes. Only used to fill gaps in the active collection.”

“**CELL LINE:** Cellular lineage of a group of individuals related by a common ancestor – which can be maintained in *in vitro* culture or recognized *in vivo*”

“**GENETIC OR MOLECULAR MARKER:** A DNA sequence whose heredity can be tracked. A marker can be a gene, or a DNA sequence that has no known function or that is non-coding. Markers are often used as an indirect way of tracking the inheritance pattern of genes that have not yet been identified, but whose approximate locations are known.”

a5) Article 6: Registry of systematized *ex situ* collections: In accordance with articles 17 subsection 3, 62 and 69 of Law No. 7788 and Provisional Clause 1 of Executive Decree No. 31514-MINAE and its Amendment, the procedure for creating the Registry of systematized *ex situ* collections is developed, regulating: the information that the respective form must contain; the different time periods stipulated by the Administration and the administered, and the regular recourse that the administered may take against the corresponding resolution. Furthermore, Provisional Clause III stipulates that the owners or custodians of *ex situ* collections, or their legal representatives, will have a maximum time period of ten months from the time of publication of the decree to register their collections with the Technical Office of CONAGEBIO.

Two ways of keeping the genetic and biochemical components and resources of biodiversity in *ex situ* conditions are defined:

a) **Systematized *ex situ* collection:** any systematic collection of specimens, parts or organs thereof, live or dead, which represent plants, animals, micro-organisms or other living beings. These collections may be, among other things, herbariums, extract libraries, total ADN, brewhouses, greenhouses, botanical gardens, seed banks, germplasm banks or gene banks, *in vitro*, seed gardens, zoos, zoo breeding centres, aquariums, rescue centres, animal semen banks, micro-organism, fungi or arthropod collections, or collections of other propagating material. These are systematized collections for which information has been identified, such as entries and accessions and other types of related information, like scientific name, provenance or origin. The Executive Decree establishes, with regard to this type of collection, that the owners or custodians, be they public or private individuals or legal entities, or their representatives, must register these collections with the Technical Office, as mentioned above.

b) ***Ex situ* genetic and biochemical resources in non-systematized form:** Any group of specimens, parts or organs thereof, live or dead, that represent plants, animals, micro-organisms or other living beings, that is not organized according to the parameters and with the rigorousness of a systematized *ex*

situ collection. With regard to this type of collection, the Regulation stipulates that the Technical Office will encourage the voluntary registration of *ex situ* genetic and biochemical resources in non-systematized form insofar as possible and in cooperation with other public and private bodies at the national and international level.

a6) Article 7: Requirements: The regulation establishes the necessary requirements for applying for the access permit for basic research, bioprospecting or economic exploitation, specifically for genetic and biochemical components and resources of biodiversity in *ex situ* conditions:

- The interested party or its representative must duly complete the applicable forms and documents indicated in articles 8 and 9 of Executive Decree No. 31514-MINAE.
- Should the interested party present a private material transfer agreement, as defined in Article 6 of Executive Decree No. 31514-MINAE and according to the stipulations of Article 22 of that same regulation, the Technical Office recommends adjusting the model agreement included in Annex I of this Executive Decree. In cases where it is possible to determine the provenance and origin of the material to be accessed in a collection established prior to the entry to effect of this decree, the benefits could also be shared with the original providers of the material to be accessed.
- In the case of access to new systematized collections—according to Article 8 of this Executive Decree—or access to new accessions in collections established prior to the entry into effect of this Executive Decree, the benefits shall be shared, in accordance with the stipulations of the prior informed consent and mutually agreed terms, with the original providers of the material; and, in this case, the interested party and/or the owner, custodian or representative of the material maintained in *ex situ* conditions, shall submit to the Technical Office a copy of the prior informed consent and mutually agreed terms with the original provider of the resources, as part of the documents required to process the application for an access permit.
- From the time of registration, and for any type of application, the interested party commits under oath to respecting the code of conduct contained in Annex II of this Executive Decree, which will be revised periodically by the Technical Office. This commitment will also be indicated in the Technical Office resolution approving the respective access permit, or in the framework agreement. The interested party must observe any amendments arising from revisions of the code of conduct.

a7) Article 8: Establishment of new systematized *ex situ* collections: It is stipulated that the Technical Office shall require the holders, owners and representatives of new systematized *ex situ* collections—established after the date of publication of this Executive Decree—to indicate the origin and/or provenance of the accessed material. It is furthermore clarified that the Technical Office recommends including, among the mutually agreed terms and prior informed consent negotiated by the owners, holders or administrators of the new collection and the original providers of genetic and biochemical components and resources of biodiversity, an agreement on potential benefits that might arise from ulterior access to said genetic and biochemical components and resource by a third party.

a8) Article 9: Resolution of approval or refusal: Consistently with Executive Decree No. 31514-MINAE, this Decree stipulates that the resolution issued by the Technical Office must indicate clearly whether the application has been approved or refused, and provide the technical, social or environmental reasons for that decision; it outlines the regular recourse available to the administered party against the issued resolution and, finally, specifies that in cases of access to genetic and biochemical resources of biodiversity in *ex situ* conditions, the Technical Office will determine the need to issue the corresponding passport.

a9) Article 10: Exportation and certificate of legal provenance: For the purpose of developing the stipulations of Article 19 of Decree 31514-MINAE, it is established that, when there is the intent to access the genetic and biochemical resources of material maintained in *ex situ* conditions but, for various

reasons, it is necessary to export said material for use outside of the country, it is mandatory for the interested party to request a certificate of legal provenance to accompany the material at all times. The certificate will be issued by the Technical Office according to the terms stipulated in Article 19 of Decree 31514-MINAE, within a time period not exceeding ten working days from the application.

a10) Article 11: Framework Agreements: It is expressly clarified that the purpose of these framework agreements is to facilitate the processing and management of access permits for entities devoted to basic research, bioprospecting and economic exploitation of the genetic and biochemical components of biodiversity, and that the model contained annex III can be used to draft such agreements.

a11) Article 12: Deposit of copies: in order to promote *ex situ* conservation in the country, in accordance with Article 9 of the Convention on Biological Diversity, the Technical Office, in resolutions regarding permits of access to genetic and biochemical components and resources of biodiversity in *in situ* conditions, may request the interested party to deposit copies of the accessed material in one of the existing *ex situ* collections, taking into consideration the physical space and availability of financial and scientific resources of those maintaining the collections registered according to this Executive Decree. Subsequent access to these genetic and biochemical resources will only be allowed for basic research purposes.

a12) Article 13: Repatriation of information or material from collections: At the request of the interested parties, or on its own initiative, the Technical Office may request the owners or custodians of *ex situ* collections located abroad that maintain material of Costa Rican origin or that was accessed in the country, to repatriate the respective information, and, in the cases set out in Article 57 of the Biodiversity Law, may also request the repatriation of samples or material in the collections. The Technical Office will seek the collaboration of other bodies to deal with the information obtained or to maintain the repatriated material.

a13) Article 14: Maintenance of collections: the regulation stipulates that, should a holder, owner or custodian of an *ex situ* collection decide to abandon, destroy or export the entire collection or a part thereof, it shall notify the Technical Office, which may request the collaboration of other bodies to maintain the material of interest in said collections, in accordance with Article 57 of the Biodiversity Law.

a14) Article 15: Promotion of *ex situ* conservation: For the promotion of *ex situ* conservation, the Technical Office, on its own initiative or at the request of the interested party, in coordination with public or private entities at the national or international level, may support initiatives, programs or projects, manage resources, disseminate technologies, incentives, technical assistance or training, among other measures, to promote *ex situ* conservation.

a15) Article 16: Additional regulations: All other aspects not regulated by the present decree are governed by the stipulations of Executive Decree No. 31514-MINAE, published in the Official Gazette of December 15, 2003, and in Biodiversity Law No. 7788.

a16) Amendments to Executive Decree No. 31514-MINAE of October 3, 2003, published in Official Gazette No. 241 of December 15, 2003: There were some amendments to a number of its articles, with the intent of improving and clarifying established procedures, with significant changes in form but not in substance, to guarantee greater accuracy and clarity with regard to the objectives and purposes of Law No. 7788.

a17) Provisional Clauses: Given its importance and taking into account its special characteristics, these provisional clauses include, as a priority power of CONAGEBIO, that of enacting the specific regulation governing access to the genetic resources of domesticated animal biodiversity, within a maximum time

period of twenty-four months starting April 18, 2007, which is the date of publication of Executive Decree No. 33697-MINAE. In developing this regulation for access to the genetic resources of domesticated animal biodiversity, CONAGEBIO will draw on the advice and support of expert individuals and specialized technical groups, and no permits of access for bioprospecting or economic exploitation for such material will be granted until this regulation is passed.

The regulation features another Provisional Clause regarding access to plant genetic resources for food and agriculture in *ex situ* conditions, which establishes, verbatim: “As long as there is no specific legal regulation for the implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture, ratified through Law No. 8539 of July 17, 2006, published in Official Gazette No. 185 of September 25, 2006, that might establish other provisions in this regard, the National Authority for the implementation of said Treaty with regard to access to plant genetic resources for food and agriculture will be the National Commission for the Management of Biodiversity (CONAGEBIO) and its Technical Office, in accordance with Biodiversity Law No. 7788 and Executive Decree MINAE- No. 31514, for which purpose CONAGEBIO and its Technical Office will use, as an advisory body, the National Commission on Plant Genetic Resources (CONAREFI)”

The regulation also reiterates, like Executive Decree No. 31514-MINAE, the Provisional Clause that establishes, with regard to the knowledge, innovations and practices of indigenous and local communities, the following stipulations: “Permits of access for basic research, bioprospecting or economic exploitation that involve the knowledge, innovations and practices of indigenous and local communities regarding the use of genetic and biochemical resources of biodiversity, shall be granted according to the stipulations contained in articles 66 and from 82 to 85 of the Biodiversity Law and Convention 169 on Indigenous and Tribal Peoples, approved through Law No. 7316 of November 03, 1992, published in Official Gazette No. 234 of December 04, 1992”.

a18) Annexes: The regulation includes three annexes: a model framework agreement, a model Material Transfer Agreement (MAT), and a Code of Conduct for access to genetic and biochemical components of biodiversity, with the main purpose of facilitating procedures for Interested Parties and Providers.

The Code of Conduct in particular has the general objective of: promoting rational access to and the sustainable of the genetic and biochemical components of biodiversity, both in *in situ* and *ex situ* conditions, reducing the risk of genetic erosion, and protecting the interests of the users and providers of these components and resources. The party interested in accessing the genetic and biochemical resources of biodiversity maintained in *ex situ*, conditions commits under oath to respecting the code of conduct, which will be revised periodically by the Technical Office. This commitment will also be indicated by the Technical Office in the resolution approving the respective access permit or framework agreement.

CZECH REPUBLIC

Detailed reports for all focus areas are annexed to this Report, containing present status of in situ and ex situ conservation measures, including legislation (a), specific threats to biological diversity (b), monitoring programmes (d), agriculture biodiversity (e), incentive measures (f) and ABS (g). In this chapter main results are summarized regarding present status of genetic resources, their access and use.

AGRICULTURAL AND GARDEN CROPS

Detailed inventory of crop genetic resources has been carried out and current data were completed by newly obtained information, including recent data on viability and accessibility of accessions and regeneration needs (see chapter 2.3 Status of agricultural and garden crop genetic resources in 2005 of the detailed report). In addition, monitoring system on plant genetic resources conserved in the Czech Republic ex situ as well as in situ has been developed in the framework of the National Programme on Conservation and Utilization of Genetic Resources of Plants and Micro-organisms Important for Agriculture. This system serves also as early warning system on plant genetic resources. The aim is to avoid losses of genetic resources and/or genetic erosion (in the sense of the Act No. 148/2003). The system is linked to national information system on plant genetic resources (EVIGEZ). Steps have been taken to diminish hazards to plant genetic resources, to increase their safety and availability as essential preconditions to guarantee access to plant genetic resources. Strategy has been elaborated for particular groups of crops with respect to the status of genetic resources (bred cultivars, landraces, wild relatives), with special attention to resources of local origin. To reach these goals, effective methodology has been worked out, as a part of Methodology for the National Programme (see detailed information on http://genbank.vurv.cz/genetic/nar_prog/ where Annual Report, Methodology of the National Programme, adopted priorities and other relevant information are available). Further related information can be found on: <http://www.pgrfa.org/selectcountry.aspx> or: <http://www.pgrfa.org/gpa>

Measures were suggested how to enhance access to plant genetic resources (including prompt and appropriate regeneration, safe conservation and effective evaluation and documentation). The results and recommendation were discussed with stakeholders and adopted by the participants of the National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization to strengthen the capacity building in the framework of the Programme. Access to PGRFA will be guaranteed under the terms of the International Treaty on PGRFA and in harmony with national legislation. In line with international and national legislation, a Material Transfer Agreement has been prepared (see Annex to the Report) and recommended to all providers of plant genetic resources in the country. Relationship between providers and users has been clearly defined, with respect to access and benefit sharing principles.

FARM ANIMALS

Access to animal genetic resources is so far not subject to any legally binding multilateral agreements and according to the EU Patent Directive animals are patentable under the Directive provided there is an invention and that it fulfils the patent terms. The term animal variety is not clearly legally defined (as plant variety is in the UPOV conventions). Report analyses status in the Czech Republic where access to and exchange of animal genetic resources is not specifically regulated by national legislation, respecting global principles of private ownership of animals. This property right implies a right to the physical material, e.g. the right to use and sell it for propagation purposes. As a large part of the genome of each individual is common within the breed, the owner of an animal cannot prevent others from using the same genetic components if they are found in their individuals. However, if the individual animal expresses a very specific inherent combination of genes, its owner will have a practical possibility to exclude others from using this genetic combination. The access to animal genetic resources is based on the exchange of propagating material regulated by private (commercial) law agreements and a common understanding among breeders of the rights associated with the material, and is functional. The Government activity is

largely limited to ensuring that various breeders societies that wish to be recognised under the EU breeding legislation covering livestock species, meet the necessary requirements. These set out basic rules regarding entry of animals into herd books, animal identification and recording, testing, and also set rules for production and trade propagating (genetic) materials. So far no internationally negotiated standard Material Transfer Agreement exists and parties can impose and undertake obligations regarding the use of the transferred material. (MTA proposed for stakeholders discussion annexed to the Report in detail). The health status of the herd might be an example of what can ban export of live animals or genetic material. Export of live animals claimed as genetic resources requires Ministry permission.

In such cases access to animals supported by the National Programme might be limited. Main information sees: <http://www.vuzv.cz>

FOREST TREES

Gene resources of forest tree species represent sets of reproductive material of all tree species, regional, local and artificially bred populations used in forest regeneration and reforestation, and in scientific research. The sources are represented in situ by: genebases (reserves), certified stands for seed material collection (phenotype class A and class B), selected trees, and ex situ by: reproductive (seed) stands, seed orchards, mother stands, clone-archives and collections of reproductive material.

The genetic resources of forest tree species are considered to be freely accessible, with the exception of some poplar and willow clones, which are patented. Nevertheless in practice, certain limitation of access may exist, particularly to in situ sources, where the collection could be a little problematic and complicated due to field accessibility, legislation and necessity to follow of owners' law. In some other cases satisfactory amount of reproduced material is not always available. The database of forest reproductive material in the Czech Republic is available on the web site of FGMRI, Research

Station Uherské Hradiště (<http://www.vulhmuh.cz>) on the web-site FGMRI (<http://www.vulhm.cz>) the database of explants archives of forest trees can be found. The existing legislation does not cover the National Programme of Preservation and Use of Forest Genetic Resources, which causes a problem, partly solved by Act No. 149/2003. Another problem represents a complicated practical access to genetic resources of small private owners. The applying for exception from European Commission is needed for the genetic resources certified before entering into force of the Act No. 149/2003. The forest Act No. 289/1995 does not allow using reproductive material of forest trees from EU countries even for research purposes, which requires amendment of the Act. Full recognition of forest genetic resources within the National Programme could support protection and use of forest genetic resources.

BOTANIC GARDENS

Botanic Gardens have long tradition in the territory of the Czech Republic for centuries and played an important role in introduction of useful and decorative plants, as well as in education and public awareness. Activities, including conservation of certain plants, were coordinated in the period 1968 – 2001 by the Advisory Committee of Botanic Gardens. Recently established Union of Botanic Gardens of the Czech Republic (2005) prepared the survey of the present status of the Czech Botanic Gardens collections. The Union has 26 members, but number of the Czech BG exceeds 50. The total number of registered taxa is 73 100, but some of them are registered in two or more BG (due to missing digitalisation of data in many BG duplications cannot be excluded) and therefore the real number of taxa can be some 40 000. Cultivated decorative plants represent more than 50 %. Introduced exotic species are highly represented, especially succulent and carnivorous plants. 12 BG conserve in their ex situ collections several critically endangered and endangered plant species. 9 BG participate in re-introduction programmes, in cooperation with National Park (1) or Protected Landscape Areas (2). Conservation activities, including ancient domestic cultivars of decorative plants, should be extended. A new computer programme on BG plant registers is under development. National legislation on Botanic Gardens, their activities and collections conservation is missing, as well as a special common programme on genetic resources. Exchange of plant material exists through Index Seminum. Adoption of rules enabling membership in International Plant Exchange Network (IPEN) are discussed with responsible

staff of BG, supported by the Union of Botanic Gardens. Topical information can be found on the Union web-site: <http://www.ubzcr.cz>

ZOOLOGICAL GARDENS

Zoos play an important role in preserving world fauna biodiversity, however their possibilities are limited by a number of factors, such as insufficient space, funds or restricted cooperation with other institutions, including scientific ones. 15 Czech zoos (out of existing 16) together with 4 Slovak zoos are organized in the Union of the Czech and Slovak Zoological Gardens, which helps them to overcome certain restrictions. Since 1984 the Union edited the Yearbook containing data on kept animals. The zoos associated in the UCSZ bred in total 2621 animal taxa (species, subspecies) and domesticated animal breeds (as of 1.1.2005). All zoos participate in international breeding and conservation programmes primarily through the European Endangered Species Programme (EEP) of the European Association of Zoos and Aquaria (EAZA), and some Czech zoos are members of the Eurasian Association of Regional Zoos and Aquariums (EARAZA). The Czech and Slovak zoos participate in reintroduction of extinct animal species back into the wild or in strengthening dwindling populations or those with low numbers in situ. Over the past decade they have taken part in reintroduction projects for European fauna (Lynx, Grouse, Aurochs, Bearded Vulture and the Griffon Vulture) and for exotic species (Przewalski Horse, Scimitar-horned Oryx). In 2005 the cooperation between Czech zoos on in situ projects was intensified (European Bison, Bearded Vulture, European Ground Squirrel, Barn Owl, Little Owl, Black Stork and Przewalski Horse). The genetic resources of Czech zoos (particularly those of endangered species) are considered to be a part of the global population and, in the framework of the international conservation programmes, are available to all subjects expressing an interest. However, a certain limitation in providing breeding material to foreign breeders exists, stemming from the specifics of the national legislation and the guidelines of the regional and state veterinary administration. Czech zoos have a long-term experience in conserving biodiversity and genetic resources of the world fauna. They contributed to preservation of many animal species from extinction and even now they are involved in international programmes. Nevertheless, use of modern methods, such as DNA analysis, is a prerequisite for successful development of these activities for which wider cooperation with other research institutions and corresponding ministries is necessary. (Information on history, present status and activities of the Czech zoos see publication prepared within the BEA Project – Jiroušek V.: Zoological Gardens of the Czech Republic and their Contribution to Biodiversity Conservation, and the Union of the Czech and Slovak Zoos website: <http://www.zoo.cz>)

FUNGI

The research on the biodiversity of fungi in-situ is performed by educational institutions, namely by universities (competence of the Ministry of Education) and by cultural institutions, namely by museums (competence of the Ministry of Culture). The voluntary group of scientifically oriented experts, both professionals and well educated amateurs, drala with different scientific aspects of mycology. They are associated in the Czech Scientific Society for Mycology (CSSM), dealing both with microfungi and macrofungi, supervised by the Council of Scientific Societies of the Czech Republic. Diversity of macrofungi is focus of activities of its Section for mycofloristics. Recently members of the CSSM prepared the Red List of threatened and endangered species of macrofungi. Several members participated in projects on inventory research of macrofungi in protected areas. The number of macromycetes in CR may be estimated to about 4 000 - 6 000 species according to estimates in neighbouring countries. Well protected nature areas, old grown forests, steppes, peat bogs etc. represent to some extent natural collection of fungi in situ. In only two nature protected areas of the Czech Republic macrofungi are the main object of protection. Twenty ex situ fungi collections have been registered in the Czech Republic, supervised by different national and international organisations (details see Annex to the Final Project Report - Report on Fungi). Main legislation tool protecting fungi in-situ represents the Act No. 114/1992, on Nature Conservation and Landscape Protection, amended as Act No. 218/2004 and corresponding Decree No. 395/1992, which contains about 40 protected macrofungi. The new list consisting of 100 species of macrofungi has been prepared for the amendment of this Decree. NATURA 2000 does not

contain any rules for fungi. The only possibility to use this legislative regulation for protection of fungi concerns the protection of habitats. In the Red Book of the Slovak and Czech Republic (Kotlaba 1995) only macrofungi are listed. The Act No. 148/2003 on Conservation and Use of Genetic Resources of Plants and Microorganisms Important for Food and Agriculture defines conditions and procedures of preservation, conservation and utilisation of ex situ collections. Conditions and procedures are adjusted in the National Programme on Conservation and Use of Genetic Resources of Plants and Microorganisms Important for Food and Agriculture.

Fungi Genetic resources (Anna Lepšová)

Knowledge on fungi in-situ, e.g. in natural habitats, is low. Inventory research on macrofungi has been carried out in about 35 protected areas but the number of species has not been defined yet. The knowledge on microfungi in-situ is limited as well Ex-situ genetic resources are maintained in 20 culture collections. They comprise about 1.620 species in 470 genera of macro- and microfungi filamentous and yeast fungi included. Most of collections belong to state institutions for the purposes of human and veterinary medicine, for dairy and brewery industry, and for scientific research and education. The rules concerning accessibility and sharing of fungi ex-situ are not developed sufficiently. Main difficulties exist concerning pathogenicity of fungi, patent protection and funding the collections. The existing national legislation does not cover all fungi genetic resources and needs to be amended in line with European regulations.

Legislative aspects of access to genetic resources and benefit sharing (Eva Tošovská)

The study in its first chapter summarises the most important sources of international law that adjust the access to genetic resources. International conventions which commitments are obligatory for the Czech Republic are analyzed. The second chapter provides an update of existing approaches to assist European Parties and stakeholders with access and benefit-sharing implementation. The attention is focused to actions undertaken by the European Commission to implement the Bonn Guidelines and to experience of individual countries. The debate on “disclosure of origin” of genetic resources and traditional knowledge in patent application is also mentioned. The third chapter summarizes the current Czech legislation which relates to access to genetic resources in the field of plant varieties, farm animals and forest reproductive material. As a real progress in breeding is sustainable and productive in a long term perspective only if protected varieties and animal species are available for breeding (so called “breeder exemption”), the Czech legislation was analyzed from that point of view. The final part outlines comparison between protection of an invention by patent and protection of a variety of plant by plant variety protection based on the International Convention on Protection of New Varieties of Plants.

ZOOS and their conservation of biodiversity (Evžen Kůs)

During the past two centuries zoos of the world have changed in principle: In the 20th century it became centres for education, ethology, study and conservation. Many zoos keep species as a part of cooperative a coordinated international breeding programmes collaborating with others zoos and others breeding facilities within the zoos association such as EAZA, WAZA, BIAZA or EARAZA. Zoos role in preserving the biodiversity of world fauna is however limited by a number of factors. Zoos spatial and operational capacities are limited and only some of the zoos have breeding stations available outside of the cities. Majority of zoos, where economic results and grants are derived from the number of visitors, have to exhibit rare and above all, attractive species, this frequently being to the detriment of more needy species, which may be facing a critical situation in the wild (including of many domestic animals, stocks without perspective in the modern farms condition). Conservation breeding ex situ represents, from the evolutionary standpoint, a unique biological experiment. Preservation of biological diversity ex situ requires new techniques primarily in the area of determining and mapping the gene pool of world fauna (taking samples for DNA, analyses. used for later taxonomic and genetic purposes, processing the cadavers of deceased animals for museums): Some zoos are starting to take samples for DNA profiles of certain species, thus forming a sample bank in cooperation with the , zoological institution, e.g. CRES (Conservation and Research for Endangered species) in San Diego USA. Therefore enhanced cooperation between the zoos and research institutes and universities and establishment of a Central database of DNA

samples for selected species are necessary steps. Further efforts aim at reinforcing the quality of conservation breeding and at support of their efforts to link up to in situ conservation projects a zoos possibilities are limited by an almost exclusive orientation on the breeding of vertebrates in particular mammals, birds and reptiles, i.e. groups representing only a fraction of the species richness of the world fauna. Thanks to their huge experience and trained staff zoos play an important role in ensuring the transport, quarantine and acclimatization of animals caught in the wild and designated for repatriation or reintroduction in the wild. Many of the world zoos are moreover interesting through their green places and their plant composition. . Key words: Zoos, conservation, biodiversity, breeding programmes rare specie's, reintroduction, repatriation, ex situ and in situ projects, genetic analyses, gene pool, refuges, bio-corridors.

National Biosafety Framework of the Czech Republic (Jan Káš, Milena Roudná)

The Czech Republic joined the UNEP/GEF Project Development of the National Biosafety Framework since July 1, 2002 up to March 2004. The National Coordinating Committee consisting of representatives of biosafety related sectors and institutions, Czech Commission for the Use of Genetically Modified Organisms and Products, non-governmental organizations and private sector coordinated activities. The results were summarized in the Final Report (Ministry of the Environment, 2004) structured into 5 main chapters: Description of the national biosafety policy, its priorities, relations to sectoral policies and strategies, mainly State Environmental Policy Description of regulatory regime, principal acts related to biosafety and main decrees in force, institutions responsible for their implementation. System to handle notifications or requests for authorisation of certain activities, competent authorities. Systems for enforcement and monitoring of impacts on the environment and human health, responsible institutions. System and measures to enhance public education, awareness and participation, relation to national strategic documents, competent authorities basic information on the Biosafety Clearing-House and related websites. In the framework of Project 15 workshops were organized for different groups of stakeholders and 17 publications prepared. The Project has helped to establish the basis for the Cartagena Protocol implementation in the Czech Republic. Its second implementation phase has to be started.

Agriculture crops genetic resources, their access and use (Ladislav Dotlačil, Zdeněk Stebno, Iva Faberová, Karel Jan Štolc)

The present status of crop genetic resources in the Czech Republic is described and analyzed, with respect to access to plant genetic resources and benefit sharing. There are 48 thousands of accessions maintained in the Czech collections among them 8 532 accessions belong to vegetatively propagated species. Seed-propagated species are maintained in the Gene Bank in IUCP Prague (at present 91% of accessions). Vegetatively propagated species are maintained in field collections (potatoes in vitro). Cryo-preservation is being developed in selected species. In Czech Republic, legislation on PGR has been developed (Act. No. 148/2003 and Regulation No.458/2003) and is fully compatible with international documents. This legislation is implemented mainly through National Programme on Plant genetic Resources and Agri-biodiversity. National standards and model MTA have been developed and implemented. More than 75% of accessions are available to users, under internationally agreed terms. Reciprocal services with local and foreign partners, inputs "in kind" to international efforts, participation in international activities and 'assistance .to developing countries are envisaged as prospective tools for benefit sharing.

The legal status of plant genetic resources and genetic resources (PGR) of micro-organisms for food and agriculture (MFA GR) is embedded in the Act on conservation and utilization of genetic resources of plants and micro-organisms important for food and agriculture No. 148/2003 Coll. The state support stockholders of genetic resources of FAnGR, MFA GR, PGR via a special program formed and administrated by the Ministry of Agriculture. It is the National Program on Conservation Genetic Resources for Food and Agriculture No. 20139/2006-13020 (NP). The National Program follows the regulations, International Treaty on Plant Genetic Resources FAO signed up by Czech Republic (2001) and Global Plan of Action FAO (1996). Seed is collected in a central gene bank and also in the small working gene banks of stockholders. Some genetic material is kept as meristem tissues in kryo bank and

in vitro cultures. Collections of micro-organisms are kept in vivo cultures or conserved in inactive forms (frozen, etc.). State support the collections of all types. Nevertheless samples still remain in ownership of stockholders and both their acquisition and transfer to any third party are subject to the model MTA designed and verified since 2005 in practice. MTAs contain also specifications on benefit sharing issues.

In plant genetic resources, The Czech Republic has a satisfactory and well structured system of the national legislation (Act No. 148/2003 coll. on “Conservation and Utilization of Genetic Resources of Plants and Micro-organisms Important for Food and Agriculture”, as well as Regulation No. 458/2003, which executes this Act.). These documents and Methodology of the National Programme provide detailed rules, fully linked to the CBD, IT and other international documents. Therefore, we can consider the legal system as a strong point of the system, giving good conditions for international collaboration on ABS. Also the organization structure is fully satisfactory (existing functional National Programme and Frame Methodology, the Board on Plant Genetic Resources has been established, and the National Information System and Gene Bank are fully functional). Another precondition for sharing international system on ABS is effective international collaboration, especially with ECP/GR, IPGRI and FAO. In general, Czech Republic is able to follow present international regime on ABS.

Botanic Gardens genetic resources (Pavel Sekerka, Petr Hanzelka, Vladimír Řehořek)

About 40 000 species and cultivars of plants are in collections of the Czech botanic gardens. These plants are used as genetic resources, for ex situ conservation programmes and ‘for scientific research in cooperation with universities’ and research ‘institutes. Botanic gardens play also an important role as urban green areas or in ecological education. Beyond conservation of wild plants, botanic gardens should take care about cultural heritage in area of genetic resources conservation especially as to historical cultivars and hybrids, which are in danger “of lost just because of lower commercial attraction. Some improvement is necessary in plant evidence and taxonomy research in cooperation with universities, as well as in cooperation with state institutions and government bodies (such as Ministry of the Environment, phytosanitary offices). No Act on Botanic Gardens exists regulating activities and plants collection protection in botanic gardens. Index Seminum represents a traditional way for plants and seeds exchange, quite liberal and free The IPEN system seems to be a good way how to implement commitments of the Convention on Biological Diversity. The main aim of the Union of the Czech Botanic Gardens ‘established in 2005 is to help botanic gardens in creating unique plant database and compatible information system, and, enable information sharing about national and especially international activities.

Forest trees genetic resources – their conservation and access (Václav Buriánek, Josef Frýdl, Jana Malá)

The first systematic collections of forest tree species reproductive material had already started in 19th century. Considerable extension of international cooperation is possible to chronicle in the same time, too. Concepts of forest tree species protection and reproduction (selection, establishment and management of gene bases, standards seed orchards, parental trees, clonal archives) have been proposed with the aim to factor them in the Czech Republic forestry legislative rules. During the eighties and nineties of last century, there had been an attention concentrated problems connected with genetic parameters of forest tree Species (gene transfers, genetic correlations, general and specific combining ability) with the aim to use obtained findings in selection and realization of breeding strategies. These activities used to be realized on the base of EU and OECD International directives. There is an increased attention paid’ to broadleaved species, especially as for some threatened species and populations too. Activities are aimed to protection of both forest stands and forest trees in situ treatments. Forest tree species reproductive material used to also be collected as samples to be stored in seed banks and bank of explains continuously, modern biotechnological methods are being to use, as well. In accordance with both the Czech Republic international commitments and state forest policy there have also been worked out the National program of forest genetic sources conservation and , utilization. Preservation, documentation and reproduction of forest tree species genetic resources, including shrubs, used to be currently realized on the base of this program, together with definition and realization of specific treatments aimed to forest

regeneration and provision of forest stands stability, including assurance of their species and genetic variability quality. Especially local ecotypes of forest tree species, used to be studied and utilized to enrichment of forest stands biodiversity.

Genetically Modified Organisms and Legislative Framework of their Use (Zuzana Doubková)

The use of genetically modified organisms is regulated on the national, EU and international levels on the national level in the Czech Republic the Act No. 78/2004 Coll., on the Use of Genetically Modified Organisms and Genetic Products applies. The Act covers the contained use, deliberate release of GMOs' into the environment and placing on the market of GMOs as or in products. Directly applicable European regulations set rules for traceability and labeling of GMOs and of food and feed produced from GMOs. Cartagena Protocol of Biosafety deals with transboundary movement of living modified organisms. Field trials with GM crops are assessed by the national competent authority; trials with maize, potatoes, flax and prune have been carried out in the Czech Republic. The placing of GMOs on the market is authorized at EU level, authorized or notified GM crops include maize, cotton, oilseed rape, and others, most frequent traits are herbicide tolerance and insect resistance.

The legislation and other information are made available to the public on the website of the Ministry of the Environment, Czech Republic, at the address: www.env.cz.

Farm Animals Genetic Resources – their access and use (Věra Mátlová)

The program on conservation of farm animal genetic resources has started in 1994 and until now it has been successful in underpinning various populations of traditional farm animal breeds. Contrary to plant genetic resources, using simple ex-situ conservation and regeneration methods is not possible because of different reproduction patterns and biological features and the most effective conservation method is the in-situ breeding combined by collecting cryopreserved reproduction material and/or DNA samples.

The preservation project coordinated by the Research Institute of Animal Production covers monitoring breeds, collecting data on their characters and utility traits and implementing sustainable breeding functional system operating within other relevant national bodies (veterinary service, central animal recording scheme). Since 1994 the project aimed at breed stabilization and introducing targeted breeding methods with a support of the state subsidy scheme. The number of supported subjects ranges around 800. Some negative factors influence in situ conservation, especially declining numbers of traditional breeders. Utilization of traditional national breeds is disadvantaged by lack of marketing strategies and poor consumer knowledge. Generally public awareness on importance of preservation domestic animal products and knowledge on traditional breeds is inadequate and the educational system is not addressing this issue at all.

The access to and utilization of farm animal genetic resources through regular ABS principles is supported by a favourable legislative frame with exception as to property and disposition rights to existing cryomaterial. Breeding animals as well as the reproduction material are available on standard market principles with an exemption of exporting directly supported individuals. However as for cryopreserved reproduction material, deficient amounts in some species and accreditation status of samples collected before 1.4.2004 are still limiting the exchange or providing samples. Personal, vocational and technical capacities need to be strengthened to comply with all commitments. On the other hand, based on more than 10 years of experience, Czech specialists are able to train in the given activities personnel from developing countries.

The legal status of farm animal genetic resources (FAnGR) is embedded in the Breeding Act No. 344/2006 Coll., with special paragraphs related to the National program on genetic resources (i.e. para 14) and further implemented through the Regulations No. 447/2006 Coll. No. 448/2006 Coll.

On principle, FAnGR are privately owned and managed within limits given by veterinary, hygienic and welfare legislation in force.

The state supported NP is opened to all owners of breeds and populations recognized and listed in the NP as national genetic resources and, in fact, poses a kind of agreement between the owner and the State. Upon this agreement supported participants are obliged to offer on request of the National Coordinating

Centre genetic material (tissue samples for research, semen samples for cryoconservation) for gene banks. Samples still remain their ownership and both their acquisition and transfer to any third party are subject to the model MTA designed and verified since 2005 in practice. MTAs contain also specifications on benefit sharing issues.

There are also samples of genetic material in gene banks procured by the State from FAnGR owners during the past period (previous NP in force during the 2003-2006) and so being a state ownership. These are accessible upon the same MTA conditions.

However, some samples (ram and bucks semen doses collected before 2006) do not convene specific requirements as to labeling (registration number of the laboratory producing the material is not indicated on the straw) and hence cannot be delivered abroad.

More information can be found in the Workshop Proceedings from 4 November 2005 – Conservation of Plans and animal resources of the Czech Republic, their access and biosafety issues and from 28 February 2006 – Genetic resources - their conservation and access (Ministry of the environment 2006, Roudná (ed.)

And the final project report:

Assessment of Capacity-building Needs: Access to Genetic Resources and Benefit-sharing, Conservation and Sustainable Use of biodiversity Important for Agriculture, Forestry and Research – Czech Republic (Roudná M., Ed., Ministry of the Environment, Prague, 2006)

The Report can be downloaded on the Ministry of the Environment website:

<http://www.env.cz/osv/edice.nsf/e26dd68a7c931e61c1256fbe0033a4ee/543095a457f030bdc125719c0030d9bb?OpenDocument>

For other information see the previous submission of the Czech Republic in last year and the third national report.

ETHIOPIA

Laws and experiences:-

In the national law of Ethiopia, the ownership of genetic resources is vested in the state and the Ethiopian people.

NORWAY

Notification No. 2006/045 –Information on the legal status of genetic resources in national law – Norwegian submission

Information on the legal status of genetic resources in national law

Norway would like to refer to our submission to Notification No. 2006/041 (please see document UNEP/CBD/WG-ABS/5/INF/2). In this submission our work on a new law on the protection of the natural environment, landscape and biological diversity and on a new draft act from an expert committee on the management of living marine resources is described.

We would furthermore like to refer to our submission dated October 26, 2005, where the new provisions in the Norwegian Patents Act on disclosure of origin in patent applications are described.

POLAND

INFORMATION ON THE LEGAL STATUS OF THE GENETIC RESOURCES IN THE POLISH LAW

The legal status of the genetic resources in Poland is regulated by the following acts:

The Nature Conservation Act of 16 April 2004 (Dz.U. of 2004, No. 92, item 880 with later amendments),
Act on the Legal Protection of Plant Varieties of 23 June 2003 (Dz.U. of 2003, No. 137, item 1300 with later amendments),

Act on the Forest Reproductive Material of 27 June 2001 (Dz.U. of 2001, No. 73, item 761 with later amendments),

The Hunting Law Act of 13 October 1995 (Dz.U. of 2005, No. 175, item 1462).

Issues concerning wild animal, plant and fungi species are, to a limited degree, regulated by The Nature Conservation Act. That concerns mainly collecting biological material (individuals) from legally protected species in the wild. With respect to species covered with strict protection, the consent for collection may be granted by the Minister of the Environment, whereas for species covered with partly protection by the Province Governor (Wojewoda) (art. 56). Minister of the Environment may allow collection of species from the national parks and nature reserves, inter alia, for scientific researches or education purposes. The permission for scientific researches may be granted only with the agreement of the manager of a national park or nature reserve (art. 15). Import and export of species regulated by the European Union law require the consent of the Minister of the Environment in the consultation with the State Council for Nature Conservation (art. 61). Collecting of wild species not covered with legal protection and/or outside national parks and nature reserves does not require any permits.

The Act on the Legal Protection of Plant Varieties regulates issues of plant variety legal protection, in particular:

the procedure and mode of granting and invalidating the right to preservation of newly bred or discovered and developed by a breeder varieties and also making commercial use of it;

the scope of the legal protection.

The breeder can apply for granting for the exclusive right to a plant variety, if the variety is distinct, uniform, stable and new. The exclusive right is granted by the Research Centre for Cultivar Testing. The exclusive right can't be granted if the variety is already protected by the Community Plant Variety Office in the European Union. (art. 4). The exclusive right includes: production and reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, stocking (art. 21).

The Act on the Forest Reproductive Material regulates (in the adaptation to the European Union Council Directive 1999/105/EC on the marketing of forest reproductive material) the issues of, inter alia, registration of the basic forest material and marketing of forest reproductive material. The basic forest material means seed sources (trees), stands, seed orchards, parents of tree families, clones or clonal mixtures. The forest reproductive material means: seed units (cones, infructescences, fruits and seeds intended for the production of planting stock), parts of plants intended for the production of planting stock and planting stock – plants raised from seed units, from parts of plants or from plants from natural regeneration.

The basic forest material shall undergo its registration in the National Register of the Basic Forest Material, managed by the Minister of the Environment (art. 15).

Import of the forest reproductive material from the States outside the European Union shall require the consent to be granted by the Minister of the Environment (art. 44).

Marketing of the forest reproductive material can be carried out exclusively by the Suppliers, who are registered in the Register of Suppliers, that is managed by the Minister of the Environment (art. 45).

The Hunting Law Act regulates, inter alia, rules of the harvesting of game. Hunting is based on the annual hunting plans, developed by the leaseholder of the controlled hunting reverts, in the consultation with the head of municipal government, and approved by a proper district forester in the agreement with the Polish Hunting Association (art. 8). Minister of the Environment in agreement with the Minister of Agriculture and Rural Development, in the consultation with the State Council for Nature Conservation, lays down in regulation the hunting seasons for game animals. Minister of the Environment, in the consultation with the State Council for Nature Conservation, may allow game harvesting (shooting or capture) for research purposes irrespective of the protection seasons (art. 44).

SWITZERLAND

2. Information on the legal status of genetic resources:

A study aiming at establishing an "inventory" of the Swiss legislation applicable to access to genetic resources was conducted in 2003 by the Swiss Federal Office for the Environment. The major outcomes of this study demonstrated that, despite a large mosaic of diverse legal texts (enacted prior to the ratification of the CBD as well as enacted with aims distinct from those of the CBD), Swiss legislation broadly conforms to Article 15 of the CBD. Indeed, the majority of restrictions on access to genetic resources imposed by Swiss law are motivated by concerns for nature conservation, and are thus a priori compatible with the CBD's objectives.

The study is available in French (including an abstract and a summary in English) under:

http://www.bafu.admin.ch/publikationen/index.html?lang=en&action=show_publ&id_thema=27&series=SRU&nr_publ=359
