

CONVENTION ON BIOLOGICAL DIVERSITY

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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 BY PARTIES ON EXPERIENCES IN DEVELOPING AND IMPLEMENTING ARTICLE 15 OF THE CONVENTION AT THE NATIONAL LEVEL AND MEASURES TAKEN TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT AND MUTUALLY AGREED TERMS

Note by the Executive Secretary

INTRODUCTION

1. In paragraph 2 of decision VIII/4B, the Conference of the Parties invited “Parties to submit reports on their experiences in developing and implementing Article 15 of the Convention at the national level, including obstacles encountered and lessons learned, four months prior to the fifth meeting of the Working Group on Access and Benefit-sharing”.
2. In paragraph 3 of the same decision, the COP has requested the Secretariat “to prepare a compilation of the information provided in accordance with the paragraph above and make it available for the work of the Working Group on Access and Benefit-sharing at its fifth meeting”.
3. Further to that request, notification 2006-044 of 25 May 2006 was sent to Parties and Governments, and a reminder (notification 2007-030) was sent on 9 March 2007.
4. In paragraph 3 of decision VIII/4D, the Conference of the Parties requested “the Working Group on Access and Benefit-sharing at its fifth and sixth meetings to further consider measures to ensure compliance with prior informed consent in cases where there is utilization of genetic resources or associated traditional knowledge, in accordance with Article 15 of the Convention and national legislation, and with the mutually agreed terms on which access was granted.”
5. Notification 2006-041 invited Parties and Governments to submit to the Secretariat information regarding measures taken to support compliance with prior informed consent and mutually agreed terms on which access was granted, where there is utilization of genetic resources or associated traditional knowledge. A reminder (Notification 2007-030) was sent to Parties and Governments on 9 March 2007.
6. In light of the above, this document contains a compilation of submissions provided by Parties on: 1) experiences in developing and implementing Article 15 of the Convention at the national

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level, including obstacles encountered and lessons learned; and 2) measures taken to support compliance with prior informed consent and mutually agreed terms on which access was granted.

7. The contributions have been reproduced in the form and language in which they were received. In addition, contributions provided in a language other than English have been translated into English.

1) EXPERIENCES IN DEVELOPING AND IMPLEMENTING ARTICLE 15 OF THE CONVENTION AT THE NATIONAL LEVEL, INCLUDING OBSTACLES ENCOUNTERED AND LESSONS LEARNED.

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**1) EXPERIENCES IN DEVELOPING AND IMPLEMENTING ARTICLE 15 OF THE
CONVENTION AT THE NATIONAL LEVEL, INCLUDING OBSTACLES ENCOUNTERED
AND LESSONS LEARNED**

I. SUBMISSIONS FROM PARTIES

ARGENTINA

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31 ENE. 2007 11:25AM P2



*Intendencia de Gabinete de Ministros
Secretaría de Ambiente y Desarrollo Sustentable*

"2006- Año de Homenaje al Dr. Ramón Carrillo"

BUENOS AIRES, 07 AGO 2006

SRA. DIRECTORA:

Me dirijo a Ud. en respuesta a v/nota LETRA DIGMA N° 1618/2006, por la cual se pone en conocimiento acerca de la Notificación de la Secretaría Ejecutiva del Convenio sobre Diversidad Biológica en el que se solicita de las partes informes acerca de sus experiencias al desarrollar e implementar el art. 15 del CBD a nivel nacional, así como los obstáculos encontrados y las lecciones aprendidas.

A este respecto, las normas nacionales y provinciales sobre acceso al material genético proveniente de los recursos biológicos silvestres son escasas y dispares.

En el orden nacional, teniendo en cuenta las facultades de poder de policía que la Ley 22.421 de Conservación de la Fauna confiere a la Autoridad de Aplicación en lo relativo a la fiscalización y contralor del comercio internacional e interprovincial, existe la Resolución 620/1998 de esta Secretaría que contiene pautas específicas para estos supuestos y que ha sido aplicada en numerosas oportunidades desde su entrada en vigor.

Uno de los obstáculos lo encontramos en lo concerniente a la flora silvestre, tema en el cual la ausencia de un marco legal imposibilita la sanción de normas de cumplimiento obligatorio a nivel nacional, pudiendo sólo regular su uso mediante normas provinciales, las cuales son escasas.

Por otra parte, son cada vez más frecuentes las solicitudes de acceso al material genético de recursos silvestres, en un contexto en el que tanto usuarios como proveedores poseen una importante confusión sobre las normas jurídicas aplicables, cuando no salen del país con el material sin mayores restricciones, atento la ausencia de regulaciones.

A raíz de ello se encuentra elaborado un proyecto de directrices para las cuales se ha tomado como referencia lo decidido en la Decisión VI/24 de la Sexta Reunión de la Conferencia de las Partes del Convenio sobre Diversidad Biológica, en la cual se adoptan las Directrices de Bonn sobre acceso a los recursos genéticos y distribución justa y equitativa de los beneficios provenientes de su utilización, y obviamente las leyes y regulaciones nacionales aplicables.

Los objetivos de las mismas en base a las necesidades planteadas precedentemente son:

- Propiciar el cumplimiento de las normas nacionales y provinciales aplicables sobre la materia.
- En los casos que los recursos genéticos se encuentren bajo el dominio público o privado de los estados nacionales o provinciales o sus entidades autárquicas o

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"2006. Año de Homaje al Dr. Ramón Carrillo"

Secretaría de Gabinete de Ministros
Secretaría de Ambiente y Desarrollo Sustentable

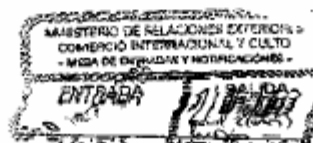
descentralizadas, propiciar que la distribución de beneficios esté prioritariamente orientada a aquellos beneficios de mayor interés o utilidad pública.

- Compatibilizar el dominio civil de las personas de derecho privado sobre los recursos de la fauna y flora silvestre con los propósitos y finalidades del Convenio sobre Biodiversidad, principalmente en lo concerniente al consentimiento fundado previo y la distribución de beneficios, considerando de manera especial aquellos aspectos sobre los que no exista una regulación específica.
- Ofrecer criterios homogéneos a seguir por parte de proveedores y solicitantes de acceso a los recursos genéticos tanto a nivel nacional como provincial.

Saludo a Ud. atentamente,

VICTORIA LICHTSCHEIM
COORDINADORA DE COOPERACIÓN
DE LA BIODIVERSIDAD

A LA SEÑORA DIRECTORA GENERAL DE GENERAL DE ASUNTOS
AMBIENTALES DEL MINISTERIO DE RELACIONES EXTERIORES, COMERCIO
INTERNACIONAL Y CULTO
EMBAJADORA MARIA ESTHER BONDANZA
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"2007 - Año de la Seguridad Vial"

Buenos Aires, 9 de enero de 2007.

INFORME SOBRE LA IMPLEMENTACIÓN DEL ARTÍCULO 15 DE LA CONVENCIÓN SOBRE LA DIVERSIDAD BIOLÓGICA A NIVEL NACIONAL.

Con el fin de responder a la información solicitada por la Dirección General de Asuntos Ambientales de Cancillería (LETRA DIGMA NOTA N° 1618), en el ámbito de la SAGPyA se realizó una reunión de la CONARGEN. De la misma participaron, por el INTA, el Ing. Marcelo Ferrer; por la Dirección Nacional de Mercados la Dra. Vanesa Lowenstein, la Lic. Mariana Tognon y la Lic. Daniela Guarás; por la Dirección de Ganadería el Ing. Miguel Iribarren, por la Oficina de Biotecnología, el Lic. Martín Lema, por la Dirección de Forestación, la Dra. Marcela Bongianino; y por la Dirección de Agricultura la Ing. Carla Pascale Medina y el Ing. Javier Boquete.

A continuación se presentan los siguientes comentarios:

En la Letra DIGMA NOTA N° 1618 se solicita información sobre las experiencias al desarrollar e implementar el artículo 15 de la Convención sobre la Diversidad Biológica a nivel nacional, los obstáculos y las lecciones aprendidas.

En tal sentido cabe aclarar que la Secretaría de Agricultura, Ganadería, Pesca y Alimentos no es la autoridad de aplicación para la implementación del artículo 15 de la CDB. Sin embargo, el INTA ha llevado adelante actividades de intercambio de recursos genéticos en forma regular desde hace varias décadas.

Este intercambio se ha visto dificultado y por consiguiente disminuido como consecuencia de normas restrictivas de acceso a los recursos genéticos implementadas por diversos países, como por ejemplo, la Decisión 391 del Acuerdo de Cartagena de 1996 de los Países del Pacto Andino, la Ley de Acceso de Brasil (Medida Provisoria N° 2052, actual MP N° 2186/2001), entre otros.

La dificultad señalada afectó el intercambio entre instituciones de investigación equivalentes entre los países, como por ejemplo los institutos de investigación nacionales o las universidades.

Asimismo, es esperable que la implementación del Acuerdo de Transferencia de Materiales (ATM) del Tratado Internacional sobre Recursos Fitogenéticos para la Alimentación y la Agricultura de FAO, facilite el intercambio de estos recursos genéticos.

Actualmente el INTA adoptó el ATM de FAO en los intercambios de recursos genéticos que ha realizado recientemente como forma de difundir la aplicación del mismo, dejando de lado otros modelos de ATM propios.

Ante la carencia de instrumentos legales en el orden nacional el INTA adoptó e impulsó la aplicación de las directrices de Bonn como un instrumento válido para implementar la aplicación del artículo 15 del CDB.

ENGLISH TRANSLATION

I am writing you in response to your LETTER DIGMA NOTE No. 1618/2006, regarding the notification issued by the Secretariat of the Convention on Biological Diversity requesting the Parties to report on their experience developing and implementing Article 15 of the Convention at the national level, and on obstacles encountered and lessons learned.

In this respect, national and provincial regulations regarding access to genetic material from wild biological resources are scarce and uneven.

At the national level, taking into account the policing role that Law 22.421 on Wildlife Conservation bestows on the Enforcing Authority with regard to supervising and controlling international and interprovincial trade, we have Resolution 620/1998 of this Secretariat that contains specific guidelines for these cases and has been applied in various opportunities since it went into effect.

One of the obstacles we have encountered is linked to wild flora, an area where the lack of a legal framework makes it impossible to approve regulations of mandatory compliance at the national level. The use of wild flora can only be regulated through provincial regulations, which are scarce.

Furthermore, requests for access to genetic material from wild resources are increasingly frequent. This is taking place in a context in which both users and providers experience significant confusion regarding applicable legal regulations; not to mention situations in which they simply leave the country with the material without major restrictions, owing to the lack of regulations.

This situation has led to the development underway of draft guidelines based on the contents of decision VI/24 of the Sixth Meeting of the Parties to the Convention on Biological Diversity, which adopts the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization and, of course, the relevant national laws and regulations.

The objectives of the guidelines, based on the above-mentioned needs, are:

- To encourage compliance with national and provincial regulations in this area
- In cases where the genetic resources are under the public or private control of the national or provincial governments or their independent and decentralized bodies, to encourage a sharing of benefits that is geared, as a priority, toward the greatest public interest or use.
- Calculate civil control of private person's rights over wild fauna and flora resources, for the purposes of the Convention on Biological Diversity and with its objectives in mind, mainly with respect to priori informed consent and benefit sharing, paying special attention to those aspects for which there is no existing, specific legislation.
- Provide uniform criteria that providers and applicants may follow for access to genetic resources, both at the national and provincial level.

REPORT ON NATIONAL IMPLEMENTATION OF ARTICLE 15 OF THE CONVENTION ON BIOLOGICAL DIVERSITY

In order to respond with the information requested by the General Directorate of Environmental Affairs of the Foreign Ministry (DIGMA LETTER NOTE No. 1618), the SAGPyA held a meeting with CONARGEN. Participants in the meeting were Marcelo Ferrer, Eng., from INTA; Dr. Vanesa Lowenstein, Mariana Tognon and Daniela Guarás, from the National Markets Directorate; Miguel Iribarren, Eng., for the Livestock Directorate. Martin Lema from the Biotechnology Office; Dr. Marcela Bongianino from the Forestry Directorate; and Carla Pascale Medina, Eng. and Javier Boquete, Eng., from the Agriculture Directorate. Herewith are the comments obtained:

/...

DIGMA LETTER NOTE No. 1618 requests information on experience developing and implementing Article 15 of the Convention on Biological Diversity at the national level, as well as obstacles encountered and lessons learned.

In that respect, it is worth clarifying that the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA) is not the enforcing authority for the implementation of Article 15 of the CBD. However, the INTA has been undertaking genetic resource exchange activities on a regular basis for several decades. This exchange has been hampered and has therefore decreased as a result of restrictive regulations regarding access to genetic resources implemented by various countries. One example of this is Decision 391 of the 1996 Cartagena Agreement between Andean Pact Countries, and Brazil's Access Law (Provisional Measure No. 2052, currently MP No. 2186/2001), among others.

The above-mentioned difficulties have affected exchanges among equivalent research institutions in the different countries, such as, for example, national research institutions or universities.

It is therefore hoped that the implementation of the Material Transfer Agreement (MTA) under the International Treaty on Plant Genetic Resources for Food and Agriculture of the FAO will facilitate the exchange of these genetic resources.

The INTA has adopted the FAO's MTA for the exchanges of genetic resources that it has undertaken recently, as a way of extending its application, leaving aside its own MTA models.

Given the scarcity of legal instruments at the national level, the INTA has approved and is fostering the implementation of the Bonn Guidelines as a valid instrument for the application of Article 15 of the CBD.

AUSTRALIA

Australian Government Submission on Implementation of ABS provisions under the CBD

National implementation of Article 15 of the Convention on Biological Diversity (CBD) is an indispensable step in establishing a system to govern access to genetic resources and ensure the fair and equitable sharing of benefits arising out of their utilisation. As both a user and provider of genetic resources Australia appreciates the need for a robust domestic regime, and has taken policy and legislative steps to implement the CBD's provisions.

The CBD's provisions on access and benefit sharing (ABS) set out a basic framework for managing access to and benefit sharing of genetic resources. But the Convention does not provide a detailed system for ABS. There are a number of legitimate ways to implement ABS within a general framework. This is one of the Convention's strengths, because it clearly foresees the need for ABS systems to be established within existing national legislative contexts.

For example, when implementing the CBD's provisions in Australia, legislators had to take into account a number of legislative and administrative challenges arising out of our complex system of government with one federal government and eight state and territory governments, and the operation of existing laws relating to property rights in each jurisdiction.

The process Australia adopted is outlined in detail later in this submission, but it is worth noting at the outset three particular issues which arose and which other Parties may also have to resolve.

The first issue is the problem of how to design a system to regulate access to genetic resources without disrupting transfers of biological resources for purposes unrelated to the utilisation of their genetic resources, for instance for commercial fishing, agriculture or forestry. The Convention does not govern access to all biological resources, but rather it addresses the use of genetic resources extracted from biological resources and the fair and equitable sharing of benefits arising from their use. In does this in the context of reaffirming the sovereign rights of states over their own biological resources. States are likely to arrive at different ways for defining use and delimiting the transfers to which ABS requirements apply.

The three Australian jurisdictions with operating ABS systems differentiate access to biological resources for the purpose of research and development of genetic or biochemical compounds within the biological resource from other intended uses. For the sake of clarity and certainty, the federal and Northern Territory regulations also list a number of activities which are specifically excluded from the scope of their access regimes to genetic resources.

A second and related problem is the definition of 'genetic resources'. While article 15 of the CBD covers only genetic resources, the three Australian jurisdictions with regulations in place included access to 'biochemical compounds' as well as 'genetic resources' in their ABS systems. Given developments in biotechnology and the rate of technological change, ABS systems would not have been effective if they limited domestic systems to genetic resources alone.

Australia's ABS systems don't, however, expressly cover other types of derivatives (products arising from research and development on the acquired resources), which are dealt with through contracts. Since access is based on the existence of a contract (or mutually agreed terms), the provider has the authority to negotiate terms with a user that covers the range of uses of genetic resources and ensures the return of benefits from 'derivatives' or 'products' from such uses.

The third issue is the extent of coverage of access to genetic resources that is actually mandated by the CBD. Given the complexity of Australian legal arrangements, and the choices made by Australian governments, ABS legislation does not cover all access to native genetic resources in all circumstances (for example, biological resources on private land in Queensland). This situation is fully compatible with the Convention because it recognises the sovereignty of states and their subsequent authority to determine access to genetic resources, but does not require ABS systems to regulate all access. Prior informed consent for access is not necessarily required in all instances, as article 15(5) provides that access shall be subject to prior informed consent 'unless otherwise determined by that Party'.

Process to achieve a nationally consistent approach

Australia has a federal system of government with a national government, six sovereign states and two self-governing territories. In a federal structure, a coherent legal framework requires either a single law, 'mirror' or 'model' legislation, where each jurisdiction passes essentially the same law, or a law based on an agreed nationally consistent approach.

Legislative systems for the management of lands, waters and resources are already in place in Australia's states and territories. To allow the implementation of CBD ABS obligations in harmony with the natural resource management decisions made in each jurisdiction, Australia decided to establish a nationally consistent approach.

Following the adoption of the Bonn Guidelines, Australia's 'Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources' (NCA) was agreed to provide guidance for Australian governments when developing or reviewing legislative, administrative or policy measures on access and benefit sharing. This, together with the establishment of an inter-governmental working group for implementation, ensures that all jurisdictions develop a complementary approach to implementation of the Convention on Biological Diversity, and the Bonn Guidelines

Under the NCA legislative, policy and administrative frameworks governing access to and utilisation of Australia's biological resources shall:

1. give effect to Australia's obligations under the Convention on Biological Diversity in relation to access to Australia's native biological resources;
2. be consistent with Australia's responsibilities and interests arising from other international agreements;
3. develop terms of access to resources that encourage local, national and international investment in Australia's biotechnology R&D capabilities, including, biodiscovery research, bioprocessing and product development;
4. be consistent with:
 - a. National Competition Policy;
 - b. the *Trade Practices Act 1974*;
 - c. the *Native Title Act 1993*;
 - d. the National Strategy for the Conservation of Australia's Biological Diversity; and
 - e. the Intergovernmental Agreement on the Environment
5. facilitate the ecologically sustainable access and use of biological resources;
6. enable the fair and equitable sharing of benefits derived from the use of Australia's genetic and biochemical resources;
7. recognise the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms;
8. enhance biodiversity conservation and the valuing of biodiversity by ensuring that, as appropriate, some of the benefits derived from all access to and use of the genetic and biochemical resources

- are, where possible, used for biodiversity conservation, in the area from which the resources were taken;
9. introduce terms and conditions of access to Australian resources that Australia would be prepared to meet if applied by other countries;
 10. ensure that all applicants for access to resources are treated fairly and without prejudice, with all applications judged against transparent criteria and according to law;
 11. be developed in consultation with stakeholders, indigenous peoples and local communities;
 12. facilitate continued access for non-commercial scientific research, particularly taxonomic research;
 13. be integrated into biotechnology development policies and strategies to ensure the continued development of these industries in Australia; and
 14. recognise the differences between commercial scientific research and non-commercial scientific research and their needs.

Australia's consultation with industry has shown that access in accordance with the NCA, and particularly through the legislation already in place in Queensland, the Commonwealth and the Northern Territory provides commercial and scientific users of genetic resources with the certainty they need to engage in research and development that generates benefits for Australia.

The *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* is available at:

<http://www.environment.gov.au/biodiversity/publications/access/nca/index.html>.

Legislation

Legislation to govern access to genetic resources and ensure benefit-sharing has been established in the State of Queensland, the Commonwealth and the Northern Territory. The other state and territory governments in Australia are considering, or are well-advanced in the process of developing similar frameworks.

Queensland

The Queensland Government's *Biodiscovery Act 2004* sets out a framework regulating biodiscovery, with the purpose of facilitating sustainable access to Queensland's biodiversity and ensuring the fair and equitable sharing of any benefits derived from these activities with the State of Queensland. The Act applies to resources on land or waters in Queensland that are not owned or possessed privately.

The purpose of the Act is achieved through a benefit sharing regime based on contractual Benefit Sharing Agreements and Biodiscovery Plans (administered by the Department of State Development) and a permitting regime (administered by the Environmental Protection Agency) involving a single Biodiscovery Collection Authority for State lands or Queensland waters.

Operation

The biodiscovery plan is a necessary step that biodiscovery organisation's must agree to with the Queensland Government, prior to collecting native biological resources. The Plans must set out:

- . activities to be undertaken under the Biodiscovery Collection Authority;
- . proposed timetable for carrying out the activities; and
- . benefits that will be provided to the State of Queensland.

It is a requirement that any biodiscovery entity wanting to collect and utilise State native biological resources for biodiscovery purposes must also obtain a collection permit (collection authority) from the Environmental Protection Agency. It is a serious offence under the Act to take native biological resources without a valid collection authority. The collection authority allows the holder of the authority to collect the native biological resources specified on the authority, in accordance with terms and conditions listed in the collection authority and the Compliance Code published by the Environmental Protection Agency (www.epa.qld.gov.au). Collection authorities cannot be transferred or renewed, however, they may be suspended, amended or cancelled.

Collection authority holders, and/or their agents, must be competent and possess the necessary certification, licences, training, skills, experience, equipment and qualifications to collect biodiscovery material.

The purpose of the collection authority is to assist in planning and management of Queensland's native biological resources including the conservation of wildlife, management of national parks and the collection of data to assist with assessment of permit applications and renewals.

Commonwealth areas

Biodiscovery in Commonwealth areas is governed by the *Environment Protection and Biodiversity Conservation Regulations 2000* (the Regulations). Under the Regulations, persons seeking access to biological resources must apply to the Department of the Environment and Water Resources for a permit.

Application

Applications for permits can be made in writing or via the following website: www.environment.gov.au/biodiversity/science/access/index.html. Details must be provided on:

- . the biological resources that will be collected;
- . where the collection will occur;
- . the collection method;
- . the qualifications and experience of persons undertaking the collection;
- . the objective and purpose of the collection including potential for commercial use; and
- . how the collection will benefit biodiversity conservation.

A permit will be granted if there will be no environmental harm, and a satisfactory benefit sharing agreement has been made with the access provider.

If access to the biological resources is for commercial or potential commercial use, the applicant must negotiate a benefit-sharing contract with the provider of the biological resources.

Australia recognises the importance of encouraging access for non-commercial scientific research, particularly taxonomic research.

To that end, the requirements for obtaining access to Commonwealth owned or managed genetic materials for non-commercial scientific research is more flexible and less involved than for commercial scientific research.

In place of an access and benefit-sharing agreement, the permit applicant is simply required to obtain written permission from the access provider of the resource to enter a Commonwealth area and remove samples.

A straightforward statutory declaration must also be made which includes agreeing to certain obligations. These include accepting the obligation to negotiate a full benefit-sharing agreement should the purpose of research and development change, and to obtain permission from the access provider before passing the sample on to anyone else.

Australian Government permits are available at minimal or no cost and issued promptly.

Benefits of both commercial non-commercial research include reports on the results of the research, and the offer of a taxonomic duplicate of each sample to an Australian public institution.

Operation

Once a permit has been granted, applicants are obliged to keep records and samples of the collections. The record must include a unique identifier for each sample, the date the sample was taken, the place from which it was taken, an indication of the quantity or size of the collection, the scientific name of the same and details of any transfers of the samples.

If a permit holder decides to dispose of a biological resource sample that has been recorded, they must offer the sample and record to the access provider of that sample prior to considering disposal. If the access provider does not want the record, the permit holder must send the record and details of the disposal to the Department of the Environment and Water Resources.

Northern Territory

Biodiscovery in the Northern Territory is covered by the *Biological Resources Act 2006* (the Act). Under the Act, a person who wishes to engage in biodiscovery for scientific or commercial reasons in any part of the Northern Territory must obtain a permit.

Application

Applications for a permit can be made to the Parks and Wildlife Commission or the Fisheries Group. A permit will not be issued until the applicant has obtained written prior informed consent from the provider and a benefit-sharing agreement. Unlike in Queensland, this includes situations where the access provider is a private citizen. The Northern Territory government can also issue a certificate of provenance if requested.

Register of permits

A public register has been established to list information about each permit that is issued by the Parks and Wildlife Commission or the Fisheries Group. The register contains information such as the name of the bioprospector, the date and term of the permit, and other information that has been agreed by both parties. The register does not contain information that is culturally sensitive, could damage commercial interests, could result in risk to the environment or could harm the national interest.

Operation

It is a requirement under the Act that holders of permits provide a report on the outcomes of the collection. It is a criminal offence to collect biological resources in the Northern Territory without a permit.

Lessons Learned

In developing the NCA and subsequent legislation, the following lessons have been learned by the Australian Government.

1. The Bonn Guidelines are indispensable in assisting governments to develop practical and useful measures. By providing guidance to governments on how to operationalise the CBD, they have assisted Australia to identify practical issues involved in establishing measures for aspects including mutually agreed terms and compliance.
2. A thorough understanding of existing law is essential to establish a system that fits with domestic structures. In the case of Australia, access to genetic resources is controlled variously by a number of governments, private citizens, indigenous land holders, and lease holders. The complex system of property law, as well as established Constitutional arrangements in Australia, has contributed to the need for each government to establish its own legislation.
3. Governments benefit from the involvement of their industry agencies, as well as their environmental agencies, in the development of legislation. Establishment of a domestic regime requires participation from a number of different actors from the early planning stage – Australian legislation has been firmly based on extensive stakeholder consultation including industry, the scientific community, indigenous people, on-ground resource managers and the broader community. Involvement of these experts from the earliest possible planning stage helped to ensure a fully integrated approach. (For more information see the Voumard Inquiry <http://www.environment.gov.au/biodiversity/science/access/inquiry/index.html>)
4. Tailoring the system to existing administrative circumstances is important. The establishment of a permit system must take into account existing permit requirements for taking wildlife or scientific research. This is also reflected in the fact that some Australian jurisdictions have established an online system for permit applications and databases, whereas others require written applications.
5. Reducing barriers to access is a key to encouraging the sustainable and productive use of Australia's biodiversity. Australia has sought to do this by avoiding duplication, ensuring transparency and accountability, and reducing transaction costs to a minimum. This creates certainty required for investments down the development path.

Australia would be pleased to share experience with implementation of the CBD. For more information please contact the Director of Genetic Resources Management Policy Section in the Department of Environment and Water Resources (grm@environment.gov.au) or visit the following website: <http://www.environment.gov.au/biodiversity/science/access/index.html>

CANADA

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization

Currently, there is no specific ABS framework in Canada at the federal, provincial or territorial level. Some laws and regulations in different jurisdictions cover some elements of ABS (e.g., permitting for the collection of genetic resources in national parks) but, again, no common framework exists.

Federal, provincial and territorial Ministers responsible for Forests, Wildlife, Endangered Species and Fisheries and Aquaculture recognized in the Fall of 2004 the need for collaborative work on approaches to optimizing the management of genetic resources.

In order to safeguard the social and environmental interests associated with genetic resources and to maximize their potential economic benefit, the Federal/ Provincial/ Territorial Working Group on ABS (FPTWGABS) is currently developing ABS policy options on a range of items. This process is being guided by key guiding documents, including the Convention on Biological Diversity and the Bonn Guidelines and by learning from other countries which have implemented ABS domestically.

These policy options will encompass developing mechanisms to ensure the benefits arising from the use of Canada's genetic resources are maximized and fairly shared among those who steward/provide genetic resources, and those who use them.

On-going Policy Development Process

In November 2005, a Deputy Minister/Assistant Deputy Minister-level workshop was held in Gatineau. Participants requested that concrete policy options be developed and assessed.

As a first step, the FPTWGABS developed the *Guiding Principles and Features of ABS Policies in Canada* to serve as a foundation for moving the policy discussion forward within jurisdictions and with stakeholders. The *Guiding Principles and Features* create a balance between environmental, economic, social and legal considerations.

Federal, Provincial and Territorial Ministers responsible for Forests, Wildlife, Endangered Species and Fisheries and Aquaculture endorsed the *Guiding Principles and Features* at their most recent meeting in October 2006. The *Guiding Principles and Features* provide a springboard for in-depth analysis of the various policy options, which will occur over the coming months. However, tangible progress has already been made. It is expected that detailed policy options will be presented at the next Federal/Provincial/territorial Ministerial meeting in the second half of 2007. Following this meeting, Canada should be in a position to establish the orientation of a future domestic ABS regime.

Canadian Stakeholder Engagement

The Government of Canada, in close collaboration with provinces and territories held a range of domestic awareness-raising workshops with the purpose of gathering stakeholder and Aboriginal¹ people's views and interests on ABS. The workshops include: ABS and agriculture, ABS and forest genetic resources, ABS and the science and technology agenda, and the Northern workshop on ABS. Participants at all workshops included policy-makers, lawyers, Aboriginal representatives, scientists, industry representatives, and academics.

¹ In Canada the term "Aboriginal" is used interchangeably with the term "indigenous". The term "Aboriginal peoples of Canada" is used in the *Constitution Act*, 1982, and includes Indian, Inuit and Metis.

A domestic meeting on ABS and certificates was also held in Canada on November 16, 2006. A range of stakeholders and Aboriginal peoples was present at this one-day meeting with the purpose of exchanging views on the issue of certificates of origin/source/legal provenance and inform international discussions on this issue.

Recognizing the importance of early engagement of industry in the policy development process, the Government of Canada is also holding meetings with Canadian Industry Associations. The purpose of these meetings is to raise awareness of the ABS issue and better understand how it might affect industry and the private sector. While these meetings represent an opportunity for industry to provide input to the development of Canadian ABS policies, early engagement of other stakeholders, including research institutes, is also important.

It must be noted that the intersection of indigenous and ABS issues is of key importance to many Canadian jurisdictions. Care is given to ensure that Aboriginal peoples are engaged in this process and that their interests are reflected in ABS policy development discussions.

While there is growing interest in Canada around ABS, greater efforts in engagement are needed to increase overall awareness and to ensure a better understanding of the many socio-economic and environmental considerations around this emerging policy area.

COLOMBIA**Notificación SCBD/SEL/DO/MR/54730
Legislación Nacional de Colombia sobre Diversidad Biológica****2º. Acceso a recursos genéticos.**

Sobre esta materia, es de señalar que 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 al mandato anterior, 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 1996, 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 al Decreto 730 de 1997, 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 en consecuencia los mecanismos de seguimiento y evaluación a que haya lugar; entre otras cosas.

A través de la Resolución 0620 de 1997 del Ministerio del Medio Ambiente (hoy Ministerio de Ambiente, Vivienda y Desarrollo Territorial), se delegaron una serie de funciones al interior de éste Ministerio en lo relacionado con esta materia, 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 2366 de 2004, se modificó la estructura del Ministerio de Ambiente, Vivienda y Desarrollo Territorial y se asignó a la Dirección de Licencias, Permisos y 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

COLOMBIA

Notification SCBD/SEL/DO/MR/54730
Colombia's National Legislation on Biological Diversity

2. Access to Genetic Resources

In this regard, it is worth indicating that, 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."

In this regard, it is worth indicating that, according to paragraph 2 of Article 81 of the Political Constitution, the Colombian State is the sole authority with the power to regulate the use, entry or egress of genetic resources into or out of the country."

In response to the above mandate, Law 99 of 1993, number 21 of Article 15 assigns to the Ministry of the Environment the task of "regulating, according to the Law, the acquisition, use, handling, research, import, export, as well as the distribution and trade of species and genetic stock of wild fauna and flora; regulating the import, export and trade of said genetic material; establishing control and monitoring mechanisms and procedures; and taking all necessary steps to claim payment for or recognition of the rights or royalties accruing to the nation from the use of genetic material."

COSTA RICA

INFORMACIÓN SOBRE SUS EXPERIENCIAS EN EL DESARROLLO Y LA APLICACIÓN DEL ARTÍCULO 15 DEL CONVENIO A NIVEL NACIONAL, INCLUIDOS LOS OBSTÁCULOS Y ENSEÑANZAS

a) Proceso de Redacción de la Normativa Nacional¹:

A partir de 1994, tal y como se ha comentado anteriormente, comienza a regir en nuestro país, el Convenio sobre Diversidad Biológica (CBD), por lo que nace la necesidad de redactar una ley nacional, que aplique de una manera eficaz, clara, simple y precisa, estos principios internacionales.

La 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, se aplicaba de manera general a todo tipo de acceso a la biodiversidad, incluyéndose el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad. Sin embargo, tal y como se desprende de sus datos de publicación, este cuerpo normativo al haberse emitido con anterioridad al CBD, no reflejaba ni refleja aun, ninguno de los objetivos del Convenio, por lo que a través de su aplicación, el país no cumplía con los nuevos los compromisos internacionales adquiridos.

El proceso de redacción y aprobación de la Ley de Biodiversidad N° 7788 del 30 de abril de 1998,² dilató varios años en finalizar, existiendo varios Proyectos de normativa a partir del año 1996, los cuales no tuvieron buena acogida por diferentes sectores sociales. Finalmente la Asamblea Legislativa creó una Comisión Especial Mixta, cuya tarea principal consistía en redactar un nuevo borrador de Ley, que pudiera salvar los obstáculos anteriores.

En esta Comisión Especial, participaron delegados de las Universidades Públicas, de la Mesa Nacional Campesina, Mesa Nacional Indígena, de Partidos Políticos, de la Federación Costarricense para la Conservación del Ambiente, de la Unión Costarricense de Cámaras de la Empresa Privada, de la Comisión Asesora en Biodiversidad y del Instituto Nacional de Biodiversidad, quienes representaban por lo tanto, diferentes sectores involucrados con el tema, lo cual permitió que este borrador fuese ampliamente consultado y discutido, de conformidad con el principio de participación ciudadana.

Esta Comisión entrega a la Asamblea Legislativa un nuevo texto, el cual fue enviado a la corriente legislativa, realizándole varias modificaciones por partes de los señores Diputados y en definitiva se

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 La Ley de Conservación de la Vida Silvestre, la Ley de Biodiversidad N° 7788 y otros documentos adicionales pueden ser consultados en www.conagebio.go.cr

aprueba la 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.

Es importante anotar que además de la Ley de Biodiversidad, nuestro país también emitió la Estrategia Nacional de Biodiversidad y su respectivo Plan de Acción de 1999. Esta Estrategia será actualizada en un corto plazo, a través de un proceso coordinado entre la Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO) y el Sistema Nacional de Áreas de Conservación (SINAC)³,

Pocos meses después de emitida la Ley de Biodiversidad, en el mes de setiembre de 1998, la Procuraduría General de la República promovió la Acción de Inconstitucionalidad número 98-006524-007-CO, contra varios de sus artículos.

Esta Acción fue admitida por Sala Constitucional de la Corte Suprema de Justicia, y se le dio curso mediante la Resolución emitida a las diez horas cuarenta minutos del siete de octubre de mil novecientos noventa y ocho. Los artículos impugnados por estimarlos inconstitucionales fueron: 14, 17 inciso 1, 19, 20, 22, 25 incisos 1), 3), 4), 5) y 8), 36,38 párrafo tercero y 39 de la Ley de Biodiversidad.

Sin embargo los artículos impugnados que específicamente se relacionaban con las funciones de la Comisión Nacional para la Gestión de la Biodiversidad⁴ y su Oficina Técnica, eran únicamente los siguientes: 14, 17 inciso 1, 19 y 20, de la Ley N° 7788. A la largo de varios años existió la incertidumbre jurídica, en cuanto a que si esta Acción paralizaba la función de la Oficina Técnica, regulada en el artículo 17 inciso 1 de dicha Ley, en cuanto a tramitar, aprobar, rechazar y fiscalizar las solicitudes de acceso a los recursos de la biodiversidad. Situación que se agudizaba aun más, toda vez que existían expertos que se inclinaban por interpretaciones en uno y otro sentido.

A pesar de este contexto, una Subcomisión de la CONAGEBIO, denominada Subcomisión de Acceso, empieza el análisis y la consulta de los diversos borradores del primer Reglamento de la Ley de Biodiversidad, denominado “Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad”, ante las diversas instancias nacionales.

Este Decreto Ejecutivo, nace con la finalidad de reglamentar el Capítulo V, Secciones I y II de la Ley de Biodiversidad N° 7788, máxime que la misma Ley en su artículo 6, estableció 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 o aprovechamiento.

A través de este instrumento, pionero en Centroamérica y uno de los pocos existentes a nivel mundial, se desarrollaron y precisaron, los principios establecidos por la Ley, respecto al tema del acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, lográndose la aplicación en la práctica de la ejecución de la normativa.

En el mes de diciembre del año 2003, empiezan a regir estas Normas Generales de Acceso para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad, Decreto Ejecutivo

³ Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO) y el Sistema Nacional de Áreas de Conservación (SINAC), son dos órganos desconcentrados del Ministerio del Ambiente y Energía, a los que la Ley de Biodiversidad encomendó la tarea de coordinar el manejo y la conservación de la biodiversidad en el país.

⁴ 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

Nº 31514-MINAE⁵, sin embargo no fue hasta principios del año 2004, que por medio de un análisis jurídico realizado en la Oficina Técnica, se obtiene la conclusión final, de que la presentación de esta Acción de Inconstitucionalidad, no suspendía el trámite de los asuntos de conocimiento, siempre que la resolución que se estableciera tuviese alzada. Es decir, en el caso particular de las resoluciones de los permisos de acceso, dicho recurso se establece expresamente en el artículo 14 inciso 4) de la Ley de Biodiversidad, por lo que la resolución que emite la Oficina Técnica, no produce por sí, agotamiento de la vía administrativa.

Por lo tanto, a partir del año 2004, partiendo de la existencia de un procedimiento claramente señalado en el Decreto Nº 31514-MINAE, el cual no fue suspendido por la Acción de Inconstitucionalidad en su totalidad, la Oficina Técnica, emite los primeros permisos de acceso a elementos y recursos genéticos y bioquímicos de la Biodiversidad, a pesar de que esta Acción se resolvió hasta el año 2006, mediante la Resolución Nº 2006009563, emitida por SALA CONSTITUCIONAL DE LA CORTE SUPREMA DE JUSTICIA. San José, a las dieciséis horas y seis minutos del cinco de julio del dos mil seis.

En esta Resolución de la Sala Constitucional, después de casi ocho años de su interposición, se concluyó que no se constataban los vicios de inconstitucionalidad alegados, procediéndose a declarar sin lugar la Acción de Inconstitucionalidad.

A mediados del año 2004, se comenzó a plantear en la CONAGEBIO y en su Oficina Técnica la necesidad de emitir un nuevo Decreto Ejecutivo, que complementara el Decreto 31514-MINAE, regulando específicamente el acceso a los elementos y recursos de la biodiversidad, en condiciones *ex situ*. Esta necesidad se manifestó con mayor claridad, toda vez que Transitorio 1. del Decreto Ejecutivo Nº 31514-MINAE, estableció que mientras no existiera 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*.

En el año 2005, una consultoría de servicios profesionales inició el proceso para la emisión de este nuevo Reglamento, el cual concluye recientemente a mediados del mes de abril del 2007, con la publicación en el Diario Oficial, del respectivo “Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en condiciones *ex situ*, Decreto Ejecutivo Nº 33697-MINAE”⁶

Al igual que con el Decreto Nº 31514-MINAE, este nuevo instrumento legal, fue ampliamente consultado y difundido, entre funcionarios públicos, expertos, científicos, instituciones privadas, centros de investigación, universidades públicas y personas en general involucradas con el tema. Estas consultas incluyeron la realización de varios talleres; y las apreciaciones resultantes de los diferentes sectores, se incorporaron en los diferentes borradores.

Este Decreto Ejecutivo Nº 33697-MINAE, pretende cumplir con los siguientes objetivos generales:

- a) mejorar y aclarar los procedimientos establecidos, en el Decreto Ejecutivo Nº 31514-MINAE.
- b) tramitar sin ningún obstáculo, las solicitudes de personas físicas o jurídicas, de permisos de acceso para investigación, bioprospección o aprovechamiento económico, que correspondan a material que se encuentre en condiciones *ex situ*.
- c) brindar mayor seguridad jurídica, al regular específicamente el acceso a los elementos y recursos genéticos y bioquímicos en condiciones *ex situ*, cumpliéndose con lo establecido en la Ley de

⁵ El texto completo del Decreto Ejecutivo Nº 31514-MINAE, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

⁶ Para conocer el texto completo del Decreto Ejecutivo Nº 33697-MINAE, ver el Anexo 1 de este documento.

Biodiversidad y en el Decreto N° 31514-MINAE y aplicando los principios de la Convención sobre Diversidad Biológica.

d) establecer formalmente el Registro de las colecciones *ex situ* sistematizadas.

En cuanto al tema de la distribución justa y equitativa de los beneficios, el nuevo Decreto establece claramente las siguientes pautas:

- 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.
- Cuando las colecciones se hayan establecido a partir de la entrada en vigencia de este decreto, se pactará también con el proveedor original de los recursos para compartir beneficios.

Por su importancia y tomando en consideración sus particularidades, se incluyó dentro de las Disposiciones Transitorias, como competencia prioritaria de la CONAGEBIO, 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.

En estas Disposiciones Transitorias, también se especifica respecto a la competencia en el tema de acceso a los recursos fitogenéticos para la alimentación y agricultura, que mientras no exista una normativa jurídica específica para la implementación nacional del Tratado Internacional de Recursos Fitogenéticos para la Alimentación y la Agricultura, 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, utilizando como órgano de consulta a la Comisión Nacional de Recursos Fitogenéticos (CONAREFI).

Con respecto al tema de la protección del conocimiento tradicional, la Oficina Técnica, proseguirá con la tarea de definir el procedimiento participativo en asocio con la Mesa Indígena y la Mesa Campesina, con la finalidad de determinar la naturaleza, la forma en que estos derechos serán utilizados, los destinatarios de sus beneficios, los titulares, los alcances y los requisitos de los derechos intelectuales comunitarios *sui generis* para su regulación definitiva.

Lamentablemente, este proceso ha caminado lentamente, tanto por factores económicos como por factores sociales, sin embargo hasta la fecha, tanto la Mesa Indígena como la Mesa Campesina, han logrado realizar varios talleres a nivel nacional. A través de estos talleres, se han redactado y validado los primeros borradores para la normativa de los Derechos Intelectuales comunitarios *sui generis*.

Estos borradores de normativa, aun deben ser revisados, modificados y nuevamente consultados a los pueblos indígenas y comunidades locales, por lo que la Oficina Técnica, junto con la Mesa Indígena y la Mesa Campesina, buscan mejorar la metodología hasta ahora utilizada, con la finalidad de que se avance con mayor agilidad en este proceso de consulta, incluyendo además el elemento de la capacitación, en los diversos temas relacionados con el acceso y el conocimiento tradicional.

A nivel nacional, hemos concluido que una limitante tanto en la redacción de la Ley de Biodiversidad, como en la redacción de los Decretos Ejecutivos: **NORMAS PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENÉTICOS Y BIOQUÍMICOS DE LA BIODIVERSIDAD Y**

REGLAMENTO PARA EL ACCESO A LOS ELEMENTOS Y RECURSOS GENÉTICOS Y BIOQUÍMICOS DE LA BIODIVERSIDAD EN CONDICIONES *EX SITU*, la constituye la situación de que a nivel mundial existe muy poca legislación o insumos que pudieran utilizarse como referencia o modelo, en la preparación de normativa.

Aunado a ello, de las pocas legislaciones existentes a nivel mundial, ninguna refleja una realidad comparable a la nuestra, por lo que no existen verdaderos modelos o guías que se pudiesen utilizar: Estos inconvenientes influyeron en cierta medida en el tiempo de redacción, pues al constituirnos como pioneros en generar estas normativas, y al empezar en cierta forma de cero, es necesario que los procesos se realicen de forma clara y con una verdadera participación ciudadana.

A la fecha, con la aplicación del marco nacional legal existente, se han aprobado en total 77 permisos de acceso a elementos y recursos genéticos y bioquímicos de la biodiversidad. El siguiente cuadro refleja el número de permisos por año que la Oficina Técnica de la CONAGEBIO, ha aprobado a partir del año 2004 y su respectiva clasificación.

Cuadro 1. Permisos de Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad aprobados durante el periodo 2004-Abril 2007.(*)

<i>Tipo</i>	<i>2004</i>	<i>2005</i>	<i>2006</i>	<i>2007</i>	<i>Total</i>
<i>Investigación Básica</i>	<i>2</i>	<i>25</i>	<i>27</i>	<i>11</i>	<i>65</i>
<i>Bioprospección</i>	<i>2</i>	<i>4</i>	<i>4</i>	<i>2</i>	<i>12</i>
<i>Total</i>	<i>4</i>	<i>29</i>	<i>31</i>	<i>13</i>	<i>77</i>

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Es interesante aclarar, que hasta el momento, el mayor porcentaje de los permisos de acceso en condiciones *in situ*, han sido solicitados para ser realizados en áreas silvestres protegidas declaradas por el Estado y pertenecientes al Patrimonio Natural del Estado, cuya administración es responsabilidad del SINAC, las cuales se hallan ubicadas en Áreas de Conservación, sin embargo también han existido accesos en propiedades privadas, o en áreas costero-marinas, que no están dentro de los límites de Áreas protegidas estatales.

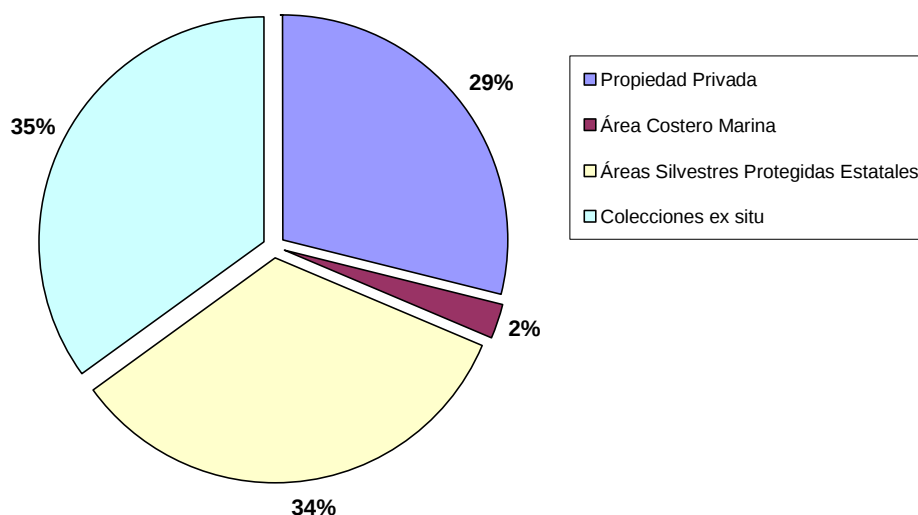


Figura 1. Lugares de Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad entre el periodo 2004- Abril 2007.

Todos los Consentimientos Previamente Informados, en apego al principio de que los elementos y recursos genéticos y bioquímicos, son de dominio público, han sido refrendados por la Oficina Técnica, 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.

En estos consentimientos previamente informados, se han negociado entre las partes, tanto beneficios monetarios (hasta el 10% del presupuesto de investigación o bioprospección) como no monetarios, por ejemplo: dar constancia de origen y otorgar los créditos respectivos, en referencia a las muestras recolectadas cuando elabore cualquier publicación escrita, electrónica, informes u de otro tipo y en cualquier trámite o uso posterior que se le dé a lo recolectado o a la información generada por estas; brindar cualquier tipo de información, derivada de este proyecto, cuando lo considere necesario el Proveedor; presentar la información que permita aumentar el conocimiento de la biodiversidad investigada y los potenciales usos que se descubran, a través de informes o diferentes formas de capacitación y remitir copia de todas las publicaciones que se realicen a partir del proyecto de investigación, entre otros.

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

A nivel institucional, la Ley de Biodiversidad crea 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. Administrativamente, se clasifica a la Comisión como órgano adscrito al Ministerio del Ambiente y Energía con desconcentración máxima y personería jurídica instrumental.

En cuanto al tema de recursos financieros, a pesar de que la Ley regula en sus artículos 19 y 20, el tema de financiamiento de la Comisión y la Oficina Técnica, el primer presupuesto formal se ejecutó en el año 2002, por lo que anteriormente existieron problemas de relevancia operativa, lo cual afectó en gran medida el proceso de consolidación de la CONAGEBIO, y el proceso de emisión del Decreto N° 31514-

MINAE, pues en sus inicios, la Comisión, no contaba con los instrumentos administrativos y recurso humano necesario.

Actualmente la Oficina Técnica aún presenta limitantes en cantidad personal, lo que dificulta el desarrollo de sus funciones específicas establecidas en el ordenamiento jurídico nacional.

c) Novedad de la regulación:

Otro inconveniente que la CONAGEBIO ha tenido que vencer poco a poco, es la oposición al cambio, muchas personas físicas y jurídicas, no lograron visualizar, la regulación del acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, como un avance regulatorio para el país, con el cual se aplicarían a nuestra realidad, los principios establecidos en el Convenio sobre Diversidad Biológica. Por el contrario, interpretaban que su aplicación atrasaría los procesos de investigación y no era comprensible para algunos, la diferencia entre el acceso a los elementos y recursos genéticos y el acceso a la biodiversidad, como recurso orgánico, lo que generó que diferentes grupos sociales, solicitaran a los Jerarcas Ministeriales, seguir aplicando la Ley de Conservación de Vida Silvestre para todo tipo de acceso.

Ante esta falta de comprensión de algunos sectores, la CONAGEBIO y su Oficina Técnica, han consultado ante diferentes instancias nacionales, expertos y personas involucradas, cada uno de los borradores de los Decretos Ejecutivos vigentes a la fecha, y en la medida de lo posible, sus aportes han sido incorporados dentro de la redacción de estos Decretos. Además se incentiva a que la población en general remita sus dudas o interpretaciones, las cuales son evacuadas con fundamentos técnicos y legales.

Lamentablemente, aún existe la resistencia de algunos investigadores y personas jurídicas, de cumplir con los requisitos exigidos legalmente, a pesar de que la normativa nacional aplica los compromisos internacionales adquiridos por el país. Sin embargo cada vez esta población disminuye, y en contraposición las solicitudes de permisos de acceso aumentan año con año, tal y como se refleja en la información mencionada anteriormente.

Se ha continuado con el proceso de negociación dirigido a Universidades Públicas y Centros de Investigación, 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, para que estos opten por la constitución de Convenios Marco con la CONAGEBIO, lo cual les permite agilizar y facilitar la gestión administrativa de permisos de acceso. Actualmente la CONAGEBIO ha firmado Convenios Marco con el Instituto Nacional de Biodiversidad (INBio), la Asociación Organización para Estudios Tropicales Incorporada (OET) y la Escuela de Agricultura de la Región Tropical Húmeda (EARTH); y se encuentran en trámite de negociación los Convenios Marco con las siguientes instituciones: el Centro Agronómico Tropical de investigación y Enseñanza (CATIE) y el Instituto Tecnológico de Costa Rica (ITCR).

A pesar de que el marco legal nacional, se ha desarrollado y aplicado en estos últimos años, con mayor claridad que en otros países miembros del CBD, tal y como consta en este documento, aún existe el gran reto de crear capacidad y entendimiento en la población, sobre temas tan específicos y novedosos como: derechos intelectuales comunitarios *sui generis*, negociación del consentimiento previamente informado, acuerdos de transferencia de material, Convenios Marco, entre otros.

En relación al tema de la negociación del consentimiento previamente informado y las condiciones mutuamente acordadas, se refleja la carencia de capacidad de negociación, la cual se ha reflejado en el procedimiento que los Interesados y Proveedores llevan a cabo para el acuerdo de sus voluntades y la emisión del contrato correspondiente. Por ello actualmente la Oficina Técnica en coordinación con el Sistema Nacional de Áreas de Conservación (SINAC), ha preparado un cronograma de Talleres, a

realizarse durante este año, cuya finalidad principal es lograr que este instrumento, cumpla fielmente los objetivos para los cuales fue creado.

Estos talleres estarán dirigidos en su primera etapa, únicamente a los Encargados de Investigación, Abogados y Directores de las Áreas de Conservación, ya que las Áreas Protegidas estatales, se han constituido en los últimos períodos, en los lugares preferidos por los investigadores para realizar el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad.

En la práctica se ha manifestado también la necesidad de dilucidar el ámbito de aplicación de varios instrumentos jurídicos nacionales, relacionados con el tema de acceso a la biodiversidad, con la finalidad de evitar traslapes de competencias entre instituciones públicas.

Particularmente la CONAGEBIO, a través de su Oficina Técnica, en los últimos meses, ha coordinado acciones en este sentido, con instituciones estatales como: Sistema Nacional de Áreas de Conservación (SINAC), Servicio Nacional de Salud Animal (SENASA), Servicio Fitosanitario del Estado, Oficina Nacional de Semillas y Registro de la Propiedad Intelectual, lo que ha permitido delimitar con mayor claridad el ámbito de aplicación de la normativa que regula el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, y consolidar las funciones atribuidas a la CONAGEBIO y a la Oficina Técnica, tanto dentro del Ministerio del Ambiente y Energía como externamente.⁷

⁷ Como fuente bibliográfica adicional, sobre este tema en específico, se podrá contactar a la Licenciada Eugenia Wo Ching Sancho, quien se encuentra realizando el documento: **SISTEMATIZACION DEL PROCESO DE ELABORACION DE LA POLITICA DE ACCESO A RECURSOS GENETICOS Y BIOQUIMICOS DE LA BIODIVERSIDAD DE COSTA RICA**, a los correos electrónicos :eugeniaws@gmail.com y/o eugeniaws@inet.co.cr

ENGLISH TRANSLATION

INFORMATION ON EXPERIENCE DEVELOPING AND IMPLEMENTING ARTICLE 15 OF THE CONVENTION AT THE NATIONAL LEVEL, INCLUDING OBSTACLES AND LESSONS LEARNED

a) Process of drafting national regulations:¹

Starting in 1994, as mentioned earlier, the Convention on Biological Diversity (CBD) came into force in our country, giving rise to the need to draft a national law that would implement those international principles in a clear, simple and precise manner.

Wildlife Conservation Law No. 7317 of October 30, 1992, published in Official Gazette No. 235 of December 7, 1992, applied in a general manner to all types of access to biodiversity, including access to the genetic and biochemical components of biodiversity. However, as can be deduced from the information on its publication, this legislation was issued before the CBD. It therefore did not, and still does not, reflect any of the Convention's objectives, and the implementation of that Law did not enable the country to fulfill the new international obligations it had acquired.

The process of drafting and approving Biodiversity Law No. 7788 of April 30, 1998,² took several years to complete. There were various draft regulations in existence as of 1996, but they were not well received by different social sectors. Finally, the Legislative Assembly created a Special Joint Commission, which was given the main task of writing a new draft Law that would be able to overcome past obstacles.

The members of this Special Commission included delegates from public universities, the National Farmers Board, the National Indigenous Board, Political Parties, the Costa Rican Federation for Environmental Conservation, the Costa Rican Union of Chambers of Commerce, the Biodiversity Advisory Commission and the National Biodiversity Institute, who represented the various sectors concerned by the issue. This made it possible for this draft to undergo widespread consultation and discussion, in accordance with the principle of citizen participation.

This Commission submitted to the Legislative Assembly a new text, which was forwarded to the legislative branch and underwent a number of amendments from the deputies there, leading to the definitive approval of Biodiversity Law No. 7788 of April 30, 1998, published in Official Gazette No. 101 of May 27, 1998.

It is important to point out that, in addition to the Biodiversity Law, our country issued the National Biodiversity Strategy and its respective 1999 Plan of Action. This Strategy will be updated in the short

¹ The following acronyms will be used in this document:

CA: Conservation Areas

MTA: Material Transfer Agreements

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)

ILO: International Labour Organization

SINAC: Sistema Nacional de Áreas de Conservación (National System of Conservation Areas)

² The Wildlife Conservation Law, Biodiversity Law No. 7788 and other, additional documents can be consulted at www.conagebio.go.cr

term through a coordinating process between the National Commission for the Management of Biodiversity (CONAGEBIO) and the National System of Conservation Areas (SINAC).³

A few months after the Biodiversity Law was issued, in September 1998, the Attorney General's Office of the Republic brought Unconstitutionality Lawsuit No. 98-006524-007-CO against several of its clauses.

This Lawsuit was admitted by the Constitutional Tribunal of the Supreme Court of Justice, and was taken for consideration through the Resolution issued at ten forty on October seventh, nineteen ninety eight. The clauses contested because they were thought to be unconstitutional were clauses 14, 17 subsection 1, 19, 20, 22, 25 subsections 1), 3), 4), 5) and 8), 36, 38 paragraph three and 39 of the Biodiversity Law.

However, the contested clauses linked specifically to the functions of the National Commission for the Management of Biodiversity⁴ and its Technical Office were solely the following: 14, 17 subsection 1, 19 and 20 of Law No. 7788. There was legal uncertainty for a number of years regarding whether this Lawsuit paralyzed the operations of the Technical Office, regulated in Article 17, subsection 1 of said Law, with regard to processing, approving, refusing and supervising applications for access to biodiversity resources. This situation was made even more difficult by the fact that the experts leaned toward two opposite interpretations.

Despite this context, a Sub-Commission of CONAGEBIO, called the Access Sub-Commission, began analyzing the Biodiversity Law's first Regulation, entitled "General Standards for Access to the Genetic and Biochemical Components of Biodiversity", and submitted it to various national bodies for consultation.

This Executive Decree arose for the purpose of regulating Chapter V, Sections I and II of Biodiversity Law No. 7788, especially since Article 6 of that same law established that the biochemical and genetic properties of wild or domesticated components of biodiversity are in the public domain, and that the State must authorize any research, use or exploitation involving them.

This instrument, which was a first in Central America and one of only a handful worldwide, developed and specified the principles established by the Law with regard to the issue of access to the genetic and biochemical components and resources of biodiversity, thus achieving practical implementation of the legislation's enforcement.

During the month of December 2003, these General Standards for Access to the Genetic and Biochemical Components and Resources of Biodiversity, Executive Decree No. 31514-MINAE,⁵ went into effect. However, it was not until early 2004 that, following legal analysis carried out by the Technical Office, the final conclusion was reached that the Unconstitutionality Lawsuit did not suspend the process underway, as long as the resolution establishing it remained in effect. In other words, in the particular case of resolutions regarding access permits, said recourse is expressly established in Article 14, subsection 4) of

³ The National Commission for the Management of Biodiversity (CONAGEBIO) and the National System of Conservation Areas (SINAC), are two decentralized bodies of the Ministry of the Environment and Energy, upon which the Biodiversity Law bestowed the task of coordinating the management and conservation of biodiversity in the country.

⁴ Competent National Authority in Costa Rica, to promote policies on access to the genetic and biochemical components of biodiversity and related traditional knowledge, which ensures proper scientific and technology transfer, and the fair and equitable sharing of benefits arising from access.

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

the Biodiversity Law, meaning that the resolution issued by the Technical Office does not, in and of itself, preclude further administrative proceedings.

Therefore, as of 2004, based on the existence of a procedure clearly set out in Decree No. 31514-MINAE, which was not suspended in its entirety by the Unconstitutionality Lawsuit, the Technical Office issued the first permits of access to genetic and biochemical components and resources of Biodiversity, despite the fact that the Lawsuit was not resolved until 2006, through Resolution No. 2006009563, issued by the CONSTITUTIONAL TRIBUNAL OF THE SUPREME COURT OF JUSTICE in San José, at six minutes after four p.m. on the fifth of July, two thousand and six.

In this Resolution handed down by the Constitutional Tribunal, almost eight years after the lawsuit was brought, it was concluded that the alleged unconstitutionality errors had not been found, leading to dismissal of the Unconstitutionality Lawsuit.

Halfway through 2004, the need to issue a new Executive Decree began to be felt within CONAGEBIO and its Technical Office. This new Executive Decree would complement Decree 31514-MINAE by specifically regulating access to the components and resources of biodiversity in *ex situ* conditions. This need was made even clearer by Provisional Clause 1 of Executive Decree No. 31514-MINAE, which established that, as long as the necessary procedure did not exist, permits of access for bioprospecting or the economic exploitation of genetic and biochemical components of biodiversity maintained in *ex situ* conditions would not be granted.

In 2005, a professional service consultancy firm began the process for issuing this new Regulation, which recently culminated in mid April 2007, with the publication in the Official Gazette of the respective “Regulation for Access to Genetic and Biochemical Components of Biodiversity in *ex situ* conditions, Executive Decree No. 33697-MINAE.”⁶

Like Decree No. 31514-MINAE, this new legal instrument was submitted to broad consultation and distributed to public officials, experts, scientists, private institutions, research centres, public universities and people involved with this issue in general. These consultations included the holding of various workshops. The resulting opinions of the different sectors were incorporated into the various drafts.

This Executive Decree No. 33697-MINAE, aims to achieve the following general objectives:

- a) improve and clarify the procedures set out in Executive Decree No. 31514-MINAE.
- b) process, without any obstacles, the applications of individuals or legal entities for permits of access for research, bioprospecting or economic exploitation, in relation to material kept in *ex situ* conditions.
- c) provide greater legal security by specifically regulating access to genetic and biochemical components and resources in *ex situ* conditions, thus complying with the stipulations of the Biodiversity Law and of Decree No. 31514-MINAE, and implementing the principles of the Convention on Biological Diversity.
- d) formally establish the Registry of Systematized *ex situ* collections.

With regard to the issue of fair and equitable sharing of benefits, the new Decree establishes the following guidelines:

- In cases where it is possible to determine the provenance and origin of the material to be accessed from a collection set up before the entry into effect of this decree, the benefits may also be shared with the original providers of said material.

⁶ For the full text of Executive Decree No. 33697-MINAE, see Annex 1 of this document.

- For collections established after this Decree came into effect, a benefit-sharing agreement will also be entered into with the original provider of the resources.

Given its importance and taking into account its special characteristics, the decree's Provisional Clauses were made to include, as a priority, CONAGEBIO's power to promulgate the specific regulation governing access to the genetic biodiversity resources of domesticated animals, within a maximum time period of 24 months starting on April 18, 2007, the date of publication of Executive Decree No. 33697-MINAE. In developing this regulation on access to the genetic biodiversity resources of domesticated animals, CONAGEBIO will receive advice and support from specialized technical groups and individuals. No permits of access for bioprospecting or economic exploitation will be granted for the material in these conditions until this regulation exists.

The Decree's Provisional Clauses also specify that, as long as there is no specific legal regulation for national implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture, CONAGEBIO and its Technical Office, in consultation with the National Commission for Plant Genetic Resources (CONAREFI), will be the national authority for the implementation of said treaty with regard to access to plant genetic resources for food and agriculture.

With regard to protecting traditional knowledge, the Technical Office will continue the task of defining the participatory procedure, in association with the Indigenous Board and the Small Farmers Board, for the purpose of determining the nature, the way in which the rights involved will be used, the recipients of their benefits, and the scope and requirements of *sui generis* community intellectual rights, in order to provide definitive regulation.

Unfortunately, this process has moved slowly, owing to both economic and social factors. However, so far the Indigenous Board and the Small Farmers Board have managed to hold various national workshops. These workshops have led to the drafting and validation of the first drafts of the regulation respecting *sui generis* Community Intellectual Rights.

These drafts of the regulation still need to be revised, amended and submitted once again to consultation with indigenous and local communities, so that the Technical Office, with the Indigenous Board and the Small Farmers Board, can find a way to improve the methodology used so far, in order to move forward more quickly in this consultation process, and add a capacity-building component to the various issues linked to access and traditional knowledge.

At the national level, we have concluded that one of the constraints on drafting both the Biodiversity Law and the Executive Decrees: **STANDARDS FOR ACCESS TO GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY, AND REGULATION FOR ACCESS TO THE GENETIC AND BIOCHEMICAL COMPONENTS AND RESOURCES OF BIODIVERSITY IN *EX SITU* CONDITIONS** is the fact that there is very little legislation or input at the global level that can be used as reference or as a model for preparing this legislation.

In addition to this, of the few examples of legislation that exist worldwide, none reflect a comparable situation to ours, which means that there are no real models or guides that could be used. These hurdles had a certain influence on the time it took to draft, seeing as it was necessary to carry out the pioneering process of generating this legislation, basically starting from scratch, in a clear manner and with true citizen participation.

So far, through implementation of the existing legal framework, a total of 77 permits of access to genetic and biochemical components and resources have been granted. The table below reflects the number of permits granted by CONAGEBIO's Technical Office since 2004, with their respective classification.

Table 1. Permits of Access to Genetic and Biochemical Resources of Biodiversity, Approved during the 2004-April 2007 Period (*)

Type	2004	2005	2006	2007	Total
Basic Research	2	25	27	11	65
Bioprospecting	2	4	4	2	12
Total	4	29	31	13	77

* For more details and information, please contact: marta.jimenez@sinac.go.cr and/or johernan@costarricense.cr,

It is interesting to point out that, up until now, the greatest percentage of permits of access in *in situ* conditions have been requested for State-declared protected wild areas that are part of the State's Natural Heritage, which are located in Conservation Areas and administered by SINAC. However, there has also been access on private property, or in coastal and marine areas, which are not within the confines of State Protected Areas.

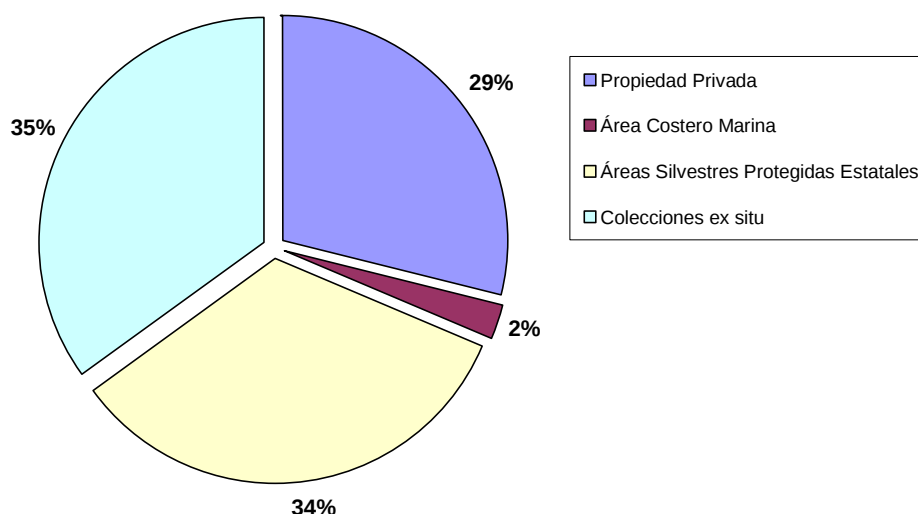


Figura 1. Lugares de Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad entre el periodo 2004- Abril 2007.

(Tr.: Private Property / Marine and Coastal Area / State Protected Wild Areas / Ex Situ Collections / Figure 1. Places of Access to Genetic and Biochemical Components and Resources of Biodiversity in the 2004-April 2007 period)

Based on the principle that genetic and biochemical components and resources belong to the public domain, all Prior Informed Consents have been approved by the Technical Office, taking into account the principles and objectives of the Convention on Biological Diversity and the Biodiversity Law, as well as the stipulations of the Costa Rican legal code.

In these instances of Prior Informed Consent, both monetary benefits (up to 10% of the research or bioprospecting budget) and non-monetary benefits have been negotiated, including, for example: declaring origin and giving respective credit and reference to the collected samples when drafting any written or electronic publications, reports or other documents, and in any subsequent process or use in /...

which the collected material is involved, or the information generated from said process or use; giving any kind of information arising from the project, when deemed necessary by the Provider; presenting information that makes it possible to increase knowledge about the researched biodiversity and any potential uses that are discovered, in reports or various types of training, and forwarding a copy of all publications arising from the research project, among other things.

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

At the institutional level, the Biodiversity Law created the National Commission for the Management of Biodiversity (CONAGEBio), as the Competent National Authority in Costa Rica, to propose policies regarding access to genetic and biochemical elements of biodiversity and related traditional knowledge that ensure proper scientific and technology transfer and the fair and equitable sharing of benefits arising from access. Administratively, the Commission is classified as a body that is attached to the Ministry of the Environment and Energy, with maximum decentralization and instrumental legal status.

With regard to financial resources, despite the fact that Articles 19 and 20 of the Law regulate the issue of financing the Commission and the Technical Office, the first formal budget was implemented in 2002. There were therefore operational difficulties before that, which affected, to a large extent, the process of consolidating CONAGEBIO, as well as the process of issuing Decree No. 31514-MINAE, owing to the fact that, in the beginning, the Commission did not have the necessary administrative tools and human resources.

Even now the Technical Office has limited staff, making it difficult to carry out its specific functions established through national legislation.

c) Novelty of the Regulation:

Another inconvenience that CONAGEBIO has had to overcome gradually has been resistance to change. There were many individuals and legal entities who were not able to see the regulation of access to the genetic and biochemical components of biodiversity as legislative progress for the country, through which the principles established by the Convention on Biological Diversity could be applied to our situation. Quite the contrary, their interpretation was that its implementation would slow down research processes, and it was impossible for some to understand the difference between access to the genetic and biochemical components, and access to biodiversity as an organic resource, which led various social groups to lobby Ministry Leaders to continue implementing the Wildlife Conservation Law for all types of access.

Given this lack of understanding from some sectors, CONAGEBIO and its Technical Office consulted with the different national bodies, experts and individuals involved, regarding each of the drafts of the Executive Decrees currently in effect and, to the extent possible, their input has been incorporated into the text of these Decrees. There has also been encouragement to have members of the general public transmit their doubts or interpretations, which are dispelled using technical and legal arguments.

Unfortunately, some researchers and legal entities still resist complying with legal requirements, despite the fact that the national legislation implements the international commitments acquired by the country. However, this population is in constant decline. Conversely, applications for permits of access are increasing on a yearly basis, as reflected in the above-mentioned information.

The negotiation process with public universities and research centres devoted to basic research, bioprospecting and economic exploitation of the genetic and biochemical resources of biodiversity, to have them choose to enter into Framework Agreements with CONAGEBIO that would enable them to speed up and facilitate the administrative management of access permits, is still underway. So far, CONAGEBIO has signed Framework Agreements with the *Instituto Nacional de Biodiversidad*

(INBio - National Biodiversity Institute), the *Organización para Estudios Tropicales Incorporada* (OET - Incorporated Tropical Studies Organization) and the *Escuela de Agricultura de la Región Tropical Húmeda* (EARTH – Tropical Humid Region Agriculture School); and is currently negotiating Framework Agreements with the following institutions: the *Centro Agronómico Tropical de Investigación y Enseñanza* (CATIE – Tropical Agronomy Research and Teaching Centre) and the *Instituto Tecnológico de Costa Rica* (ITCR – Technology Institute of Costa Rica).

Despite the fact that the national legal framework has been developed and implemented over the last few years in a clearer way than in other member countries of the CBD, as shown in this document, there is still the major challenge of creating capacity and understanding among the population, on issues as specific and new as *sui generis* community intellectual rights, the negotiation of prior informed consent, material transfer agreements, and framework agreements, among other things.

Lack of capacity comes through with regard to negotiating prior informed consent and mutually agreed terms, when it comes to the procedure that Interested Parties and Providers undertake to reach agreement in this area and generate the corresponding contract. That is why the Technical Office, in coordination with the National System of Conservation Areas (SINAC), has prepared a timetable of workshops to be conducted throughout this year. Their main purpose is to enable this instrument to comply faithfully with the objectives for which it was created.

These workshops are initially geared only toward those in charge of research, lawyers and the directors of conservation areas, seeing as State Protected Areas have become, over the last few years, the places where the greatest access to the genetic and biochemical elements and resources of biodiversity has taken place.

In practice, the need has also arisen to distinguish the scope of application of the various national legal instruments linked to the issue of access to biodiversity, to avoid overlapping of jurisdiction between public institutions.

CONAGEBIO in particular, through its Technical Office, has undertaken activities to this effect over the last few months, in coordination with state institutions like the National System of Conservation Areas (SINAC), the Servicio Nacional de Salud Animal (SENASA – National Animal Health Service), The State Service for Plant Health, the National Seed Office and Intellectual Property Registry. This has made it possible to determine more clearly the scope of application of the legislation regulating access to the genetic and biochemical components and resources of biodiversity, and to consolidate the functions attributed to CONAGEBIO and the Technical Office, both within the Ministry of the Environment and Energy and outside of the Ministry.⁷

⁷ For additional bibliographical references on this specific issue, please contact Eugenia Wo Ching Sancho, who is currently writing: **SISTEMATIZACION DEL PROCESO DE ELABORACION DE LA POLITICA DE ACCESO A RECURSOS GENETICOS Y BIOQUIMICOS DE LA BIODIVERSIDAD DE COSTA RICA (SYSTEMIZING THE PROCESS OF DRAFTING COSTA RICA'S POLICY FOR ACCESS TO THE GENETIC AND BIOCHEMICAL RESOURCES OF BIODIVERSITY)**, at the following e-mail addresses: eugeniaws@gmail.com y/o eugeniaws@inet.co.cr

ETHIOPIA

Laws and experiences:

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

A proclamation to provide for Access to Genetic Resources and Community Knowledge, and Community Rights has been developed and approved by the parliament in February 2006. The proclamation addresses issues of Protection of community rights; conditions of access to genetic resources, follow up and compliance measures, exploration of genetic resources and administration of access. The full document of this proclamation has been sent to your office beforehand (and attached with this message for your reference).

The Institute of Biodiversity Conservation has made agreements with two foreign companies. One of these companies from the Netherlands [Health and Performance Food International (HPFI)] has the right to exploit on selected **teff** (*Eragrostis tef* (Zucc.) Trotter) varieties and the other company from UK (Venique Biotech) has got the right to commercialize **Vernonia** (*Vernonia galamensis* L. ssp. *galamensis* var. *ethiopica* (Noya) as a chemical. Progress on these agreements will be reported in the future.

Creating awareness and participatory approach:

In October 2006, a workshop on “participatory biodiversity conservation and sustainable Utilization in Ethiopia” has been held for two days. The main aims of the workshop were:

- To raise the level of awareness and provide up-to-date information on Biodiversity Conservation and sustainable utilization to stakeholders
- To reach a level of understanding on how to organize focal points that work on biodiversity in different regions and levels
- And to review on the draft implementation regulation on Access to Genetic Resources and Community Knowledge. The regulation has been reviewed and participants make comments on:

* The conditions and the procedure in accordance to which local communities shall give prior informed consent for access to their community knowledge

* The procedure in accordance to which benefit arising out of the utilization of community knowledge and genetic resources shall be used for the common advantage of local communities.

* The conditions and procedure in accordance with which access applications shall be presented examined and prior informed consent shall be given shall be specified by regulations.

* on how the remaining portion of the monetary benefit from access to genetic resources, after deducting the share of the local community shall be allocated for conservation of biodiversity and the promotion of community knowledge.

With comments made on these issues, the regulation will be submitted to the council of ministers for approval. We will report the development in the future.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

Information provided by the Czech Republic, Denmark, Finland and the Netherlands on their experience with the Bonn Guidelines

A. Czech Republic

In the Czech Republic, the principles of Bonn Guidelines are advertised among livestock keepers to aware them on their rights and appreciate all values of the stocks kept. We used them also when preparing a model MTA for animal gene banks. The same situation is for plant and micro-organisms genetic resources keepers.

As a part of the UNEP/GEF Project: 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 the analysis was done for Agricultural and garden crops, farm animals, forest trees, Botanic Gardens, Zoological Gardens, Fungi

For more information see 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>

IMPLEMENTATION OF THE BONN GUIDELINES

Within the Project implementation of the Bonn Guidelines was analysed in the main focused areas: agricultural crops, farm animals, forest tree species, botanic gardens (BG) and zoological gardens (ZOO), partly fungi. The result of the survey can be summarized as follows.

GENERAL MEASURES

Frame

for implementation of ABS principals is done by national legislation in case of agricultural crops, partly in farm animals, forest trees and fungi. As to BG and ZOO the national frame is missing so far, but international principles are respected.

Terms – their definition and use

Basic terms are defined in national legislation (in areas where it exists) and in part within Glossary of the Czech Academy of Agricultural Sciences (under preparation). As to ZOO the terminology is based on this used in The World Zoo and Aquarium Conservation Strategy(WAZA 2005, Czech translation 2005).

Goals for ABS support

are defined as to agricultural crops, farm animals, forest trees and partly fungi within the National Programmes launched and guaranteed by the Ministry of Agriculture. Goals are not satisfactorily so far defined as to BG and ZOO. National frame and goals in general are in relation to international treaties and documents, namely Cartagena Protocol on Biosafety, legal documents of UPOV, international phytosanitary measures, IPEN – International Plant Exchange Network (BG) and corresponding Council of European Union Directives.

ROLES AND RESPONSIBILITIES IN ABS

Competent National Authorities

CNAs and corresponding NFPs (contact persons) were nominated for agricultural crops (Research Institute for Crop Production), farm animals (Research Institute for Farm Animals Production) and forest trees (Forestry and Game Management Research Institute). On the basis of the Project outcomes nomination was done of the CNAs and corresponding NFPs for BG (in the framework of recently established Union of Botanic Gardens) and ZOO (Prague ZOO – centre for editing of the Czech and Slovak ZOO Yearbook, among others).

Responsibilities of users and providers

are legally defined in case of agricultural crops, farm animals and forest trees, not sufficiently as to fungi. In ZOO are indirectly done by existing national legislation and take into account existing international treaties. In BG international principles are respected, but they are not clearly defined at national level. A model Material Transfer Agreement exists for agricultural crops and farm animals.

PARTICIPATION OF STAKEHOLDERS

National Councils on Genetic Resources as consultative bodies were established at the Ministry of Agriculture with competency in agricultural crops, farm animals, forest trees and microorganisms utilized in agriculture. The Commission for Zoological Gardens at the Ministry of the Environment fulfils the similar function. No corresponding body has been established so far for BG but it will be solved in connection with establishment of the Union of the Czech Botanic Gardens. Sharing activities have been relatively good developed (specialized publications, exhibitions, presentations for public etc.).

STEPS IN ABS PROCESS

Overall strategy

is defined for agricultural crops, farm animals and forest trees within the National Programmes, together with identification of steps (in different details). The Strategy is not so far sufficiently defined for ZOO and it is missing in case of BG.

Prior Informed Consent

System of PIC is not officially established at national level. Nevertheless some agreements and decrees at national level can be considered as contribution to such system. Principles of PIC are included in model MTAs for agricultural crops and farm animals. Principles are implemented in case of ZOO and BG on the basis of international treaties and rules, especially in international cooperation and exchange. The outcomes of the BEA Project are aiming at support of these steps.

Benefit-sharing

Principles are in different forms and degree implemented in all monitored groups of genetic resources. International rules are respected as international cooperation is relatively well developed. Mechanism of benefit-sharing is not officially defined, most frequently it is based on mutual agreement or joint projects. Non-monetary benefits are mostly provided. Frequently it regards long-term benefits. Benefit-sharing is in most cases implemented through direct contact with recipient, in case of ZOO also through an intermediary (e.g. in ZOO within specialized programmes). Not so far fully used capacity exist in implementation of the Czech Development Assistance for less experienced countries.

OTHER PROVISIONS

Provided services (provided samples for national and foreign users, provided information or know-how) are *monitored* once a year, especially in agricultural crops. These data form part of Annual Reports for a

given group of genetic resources. Activities developed within the National Programmes (agricultural crops, farm animals, forest trees) are *controlled*. In case of BG Index Seminum statistics is made. In ZOO selling and purchase are recorded. Transfer of animals within EEP Programmes is registered by coordinator of corresponding Programme. Rules of collections *ex situ* are done by national legislation (Act on Nature Conservation and Landscape Protection, Act on Genetic Resources for Food and Agriculture Act on Genetic Resources for Food and Agriculture and corresponding decrees, methodology of National Programme). During international expeditions the Code of Conduct (FAO) is implemented. Sanctions are used in case of non-compliance with the National Programme. In agricultural crops the Act defines also remedies controlled by the Ministry of Agriculture. In ZOO sanctions are applied in case of non-compliance with contractual agreement. Settlement of disputes are done by national Acts and in case of agricultural crops and farm animals through MTAs. In ZOO disputes are settled through EAZA.

B. Denmark, Finland and Sweden

In the context of their cooperation amongst the Nordic countries, Denmark, Finland and Sweden contributed in 2006 to a guide introducing and explaining the Bonn Guidelines and their implications for both users and providers of genetic resources. This guide has been translated into the four nordic languages (Swedish, Danish, Finnish and Norwegian).

The full text is available at: <<http://www.norden.org/pub/ovrigt/ovrigt/US2006448.pdf>>.

C. Netherlands

Developments in the Netherlands regarding access and benefit sharing measures form a direct response to the decisions taken in the first meeting of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (the International Treaty).

* The Netherlands regards access and benefit sharing measures not only as a way to implement the decisions of the Governing Body of the International Treaty but also as a contribution to the development of an International Regime on Access and Benefit-Sharing which forms the responsibility of the Parties to the Convention.

* The collections of the Centre for Genetic Resources The Netherlands are under the management and control of the government and in the public domain. All collections of crops listed under Annex 1 of the FAO International Treaty form part of the Multilateral System of Access and Benefit-sharing.

* The Netherlands Centre for Genetic Resources expects to introduce the standard Material Transfer Agreement before the end of 2006 for all its transactions regarding crops listed in Annex 1 of the Treaty. Furthermore, it will use the same Material Transfer Agreement to provide germplasm to users that does not belong to crops listed in Annex 1, which was acquired by CGN before the entry into force of the Convention.

* The Netherlands Centre for Genetic Resources will also offer the option of a click-wrap procedure for the user to accept the terms and conditions of the standard Material Transfer Agreement, having ascertained that such procedure is legally binding.

* Finally, the Netherlands is in the process of approaching other germplasm holders in order to encourage these to bring their collections in the Multilateral System of Access and Benefit-sharing, where appropriate.

D. Finland**ABSTRACT****Background**

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of Their Utilization issued under the Convention on Biological Diversity CBD operationalize the third objective of the CBD concerning the access to genetic resources and benefit sharing (ABS). The guidelines identify in accordance with the article 15 of the CBD the different stages of the access and benefit sharing process, with special emphasis on the obligation of the users to obtain the prior informed consent of the party providing the genetic resources.

At present there is legislation concerning the genetic resources and benefit sharing in force in about 15 countries, while in about 40 countries, including the majority of the European countries, the preparation of such legislation is under way. The first countries to draw up legislation and arrangements concerning the access to genetic resources and benefit sharing were the so-called megadiversity countries in Latin America and Asia. Of the Nordic countries, Norway is preparing an extensive legislative proposal concerning biological diversity, which comprises the genetic resources as well. The guidelines on the access and utilisation of genetic resources issued in Sweden are mainly intended for researchers and scientific purposes. Greenland is also preparing a legislative proposal concerning the use of genetic resources for scientific and commercial purposes.

The Finnish ABS Working Group

The task of the Finnish working group established under the Advisory Board on Genetic Resources on 6 October 2004 was to deal with the national implementation of the Bonn Guidelines, including the drafting of the necessary legislation. The mandate included the examination of the roles and responsibilities in the access to genetic resources and benefit sharing and, where necessary, the obligations set down by other agreements. The working group was to draft a proposal for a national strategy and action plan on the access to genetic resources and benefit sharing as well as prepare the other implementation tasks. The work was to be completed by 1 June 2006.

The background survey presents alternative models for implementing the Bonn Guidelines, as well as the legislative and/or administrative action needed for each of the alternative implementation models. The survey drawn up by the working group focuses on issues relating to the main principles and priorities. The working group considered that these questions need to be settled before any detailed administrative practices can be created.

The background survey is divided into two parts. The first part deals with the development needs in the legislation and administration. The second part describes the different types of genetic resources and the status and value of the national genetic resources as well as the current international and national legislation on genetic resources. It also deals with the national and international activities relating to genetic resources.

The questions addressed in the first part concerning the development of the legislation are: ownership of genetic resources, nature of the system (statutory or not subject to formal requirements), legal relationship between the provider and recipient (user) of the genetic resources, everyman's right (public right of access), prior supervision of the provision of genetic resources (prior informed consent or declaration), certificate of origin, scope of application, role of the intended use, rights and traditional knowledge of indigenous communities, and financial perspectives.

Among the main issues as regards the development of the legislation are whether to choose a statutory system or system that is not subject to formal requirements, and whether the regulation concerning the genetic resources that fall directly within the competence of the State is also extended to the privately-owned genetic resources. A system that is not subject to formal requirements is a much lighter solution in terms of the administration and finances, but very likely some new legislation would have to be drafted. A statutory system requires both new legislation and the establishment of a new official body, whose tasks would include, in addition to those mentioned above, the supervision of the compliance with the agreements.

The implementation of a system that would also apply to wild species included in public and private collections would very likely require new legislative measures concerning at least the content of the agreement, stakeholder participation, prior consent procedure and means for legal protection. The issues to be taken into account in this case include constitutional questions and rules concerning, for example, everyman's right (public right of access).

The continuation of work and clarification of the legislative and financial questions described above is important for the implementation of the administrative measures concerning the access to genetic resources and benefit sharing in Finland. Main issues to be decided nationally will be the definition of the roles and responsibilities relating to the access to genetic resources and benefit sharing and, in particular, the question of prior informed consent and information on origin of genetic resources for access and benefit sharing.

ISLAMIC REPUBLIC OF IRAN

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In The Name of God

January, 17, 2007

XXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXX
Secretariat of Convention on Biological Diversity

Subject: Re- Decision VIII/4 on access and benefit-sharing: Bonn Guidelines on
Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out
of their Utilization

Dear Sir/ Madam,

Pursuant to your notification letter No SCBD/SEL/VN/VP/54834 dated on 25th May
2006, regarding requested information about aim subject, you will find below the
information in question, may be it should be related to capacity_building.

Performed and Ongoing Activities

- 1) Establishment of Genetic Banks and determination of Genetic resources
Identification.
- 2) There are three Plant Gene Bank in Iran which Genetic Identification has
been prepared for some of agriculture digit as well.
- 3) Initiation of an Animal Gene Bank .
- 4) Identification of fauna and flora in Iran and its taxonomy.
- 5) Identification of endemic Plant and Animal species.
- 6) Identification of extinct Animal and Plant species.
- 7) Determination of extinct, endangered, supported and not supported species
under supervision of EPO's protected areas.
- 8) Development of managerial EPO's protected areas to keep and custody of
Genetic Resources.

PAKISTAN

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

Switzerland was closely involved in the development of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization and committed to their effective implementation. Thus several measures have been undertaken on a sector-based approach at the national level in order to support the implementation of the Bonn guidelines.

1. Establishment of a ad hoc Swiss ABS working group

A national working group on ABS was set up in early 2003 by the Swiss Federal Office for the Environment (FOEN) and the Federal Office for Agriculture (FOA). This working group is composed of representatives from governmental and non-governmental stakeholders, including academic research, private sector, seed producers, botanical gardens and NGOs. The major tasks of this working group are to:

- identify the specific needs and activities of each particular stakeholder
- help the stakeholders in the development of sector-based measures
- support the coordination of information exchange (through the CHM) and promote public and professional awareness on topics related to ABS
- develop a national strategy on ABS with coordinated measures
- follow international activities within the CBD (especially on the development of an "international regime on ABS") and the FAO International Treaty.

2. Promote awareness to ABS issues for academic research

A process was undertaken to produce manual "Access and Benefit Sharing - Good practice for academic research on genetic resources".

The FOEN commissioned and sponsored the *Swiss Academy of Sciences (SCNAT)* to sensitize the stakeholders involved in academic research on ABS issues with emphasis on the implementation of the Bonn Guidelines. As a first step, a survey was conducted to determine the level of awareness of the stakeholders with regards to ABS issues and to evaluate the number of research projects involving the use of genetic/biological resources and/or traditional knowledge. As a second step, stakeholders involved in projects dealing with ABS issues were asked more specific questions regarding ABS situation. The outcome of these two studies showed that a vast majority of stakeholders were not aware of the CBD provisions, in particular with those dealing with ABS issues.

Therefore a manual aiming to inform the academic community about the system governing the ABS procedure was developed in the context of an iterative and participative process, and various drafts were evaluated at different stages by members of the Swiss academic community. The resulting manual "Access and Benefit Sharing - Good practice for academic research on genetic resources" was widely distributed among the Swiss scientific community and also presented and distributed at several international meetings and workshops.

Finally, a website dedicated to the ABS issues was launched during the Summer 2006 (<http://abs.scnat.ch/>).

3. Promote awareness to ABS issues for botanic gardens

Botanic gardens are particularly concerned by issues related to ABS. Indeed, one of the main activities of botanical gardens is the collection of plants for the purposes of scientific research, conservation, display and education. Thus botanic gardens are used to collect, document, distribute and exchange a great amount of various biological materials (living plants, seeds, cuttings, bulbs, etc.). This makes botanic gardens stakeholders in the implementation of the CBD provisions.

In order to facilitate these activities and to comply with the CBD, several instruments were developed at the international level, such as the "Principles on ABS" of the Royal Botanic Gardens, Kew and the "Code of Conduct" of the German Ministry of Environment.

A mechanism to implement both instruments, called the "International Plant Exchange Network, IPEN)" was developed under the control of the BGCI (Botanic Gardens Conservation International, <http://www.bgci.org/worldwide/home>).

At national level, an initiative was developed and supported with the aim to integrate all the Swiss botanic gardens in the IPEN network, by assisting them in the development of databases to keep tracks of all relevant materials coming in and out of the gardens. By the end of 2006, all Swiss botanic gardens of importance had integrated the IPEN mechanism.

4. Promote awareness to ABS issues for the private sector to support the implementation of the Bonn Guidelines on ABS through an ABS Management Tool.

The ABS Management Tool is a voluntary guide, which was developed by the International Institute for Sustainable Development and Stratos Inc. on behalf of the State Secretariat for Economic Affairs. The aim of this instrument is to support the implementation of the principles of the Bonn Guidelines on access and Benefit sharing of genetic resources. It puts at disposal a practical guidance for providers and users of genetic resources and facilitates mutually beneficial relationships between both sides. It helps the providers and users in the negotiation of agreements and their implementation as well as monitoring.

In a first phase, the ABS Management Tool has been elaborated as it is available at the moment (http://www.iisd.org/pdf/2005/standards_abs_mt_user_guide.pdf). In a second phase, this guideline has been tested for its practicability by some field tests in Australia, Malaysia, Cameroon and Bolivia.

The results of the tests will flow in the new edition of the ABS Management Tool, which will be available within the next few months.

Besides this Management Tool SECO in the frame of economic development co-operation, SECO, supports the BioTrade Facilitation Programme (BTFP) UNCTAD, which brings together sustainable economic use and protection of biodiversity. The genetic resource should have an economic value and the local community should profit from the international trade of their genetic resource. Pilot programs are currently implemented in Bolivia, Peru, Colombia, Southern Africa and Vietnam. The SECO in Switzerland launched a pilot case in this context. Between a Swiss retailer and the government of Bolivia an agreement was settled, that farmers in Switzerland plant a variety of potatoes from Bolivia and sell them to the retailer. Five percent of the benefits from the sales will be reimbursed to the local community in Bolivia (cultivator of the potato varieties), the national potato institute and the national directorate for natural reserves. The first sales of these potatoes are expected to take place in spring 2008.

5. Promote awareness to other stakeholders

Other potential sectors are concerned by ABS issues including industry (agro-food, agro-chemicals, pharmaceuticals and cosmetic industry), as well as horticulture and garden centers. Several projects are under way to evaluate the precise involvement and awareness of these sectors in relation with the ABS issues. First data will be available at the end of 2007.

**2) MEASURES TAKEN TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT
AND MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED.**

I. SUBMISSIONS FROM PARTIES

CANADA

Measures to Support Compliance with PIC and MAT

While no specific ABS measures for PIC and MAT exist yet in Canada, the domestic policy process, launched about two years ago, is exploring the many aspects of PIC and MAT and will eventually develop measures that will address concerns of both users and providers of genetic resources.

As a first step, the Federal/Provincial/Territorial Working Group on ABS (FPTWGABS) has developed a scoping paper which sets out the policy questions that arise when implementing ABS, including some applicable to PIC and MAT.

Building on this document, and mindful of the Bonn Guidelines, the group recently undertook an in-depth discussion and exploration of the many legal and socio-economic aspects associated with the elaboration of a PIC system and the negotiation of MAT.

At the heart of this discussion are considerations around ownership of genetic resources and associated traditional knowledge in Canada and question of who would have the authority to grant PIC and negotiate MAT. The group also discussed issues such as how PIC might relate to existing land claim agreements, what the appropriate role of governments in determinations of MAT might be, and the need to ensure the transparency and efficiency of PIC and MAT systems.

The contribution of a number of Canadian jurisdictions, either at the federal, provincial or territorial level, is crucial for ensuring the relevancy of the system and the ability of all involved in the system to comply with it.

Canada has also undertaken a stakeholder outreach exercise in which the views and interests of a broad range of Canadian stakeholders were gathered. These dialogues with stakeholders are helping policy-makers understand the context in which genetic resources are currently being used and provided in Canada and the potential positive and negative impacts of PIC and MAT.

As policy work continues to advance thinking in Canada on these issues, Canada welcomes any contribution from other Parties who have implemented PIC and MAT in federated states. Below are some general thoughts on PIC and MAT.

Prior-informed consent

PIC is crucial to the credibility and legitimacy of an ABS regime. Its efficiency will be measured on the basis of whether there is continued access to genetic resources (GR) and associated traditional knowledge (TK) and whether users of genetic resources can obtain PIC without undue delays or excessive administrative burdens. Its effectiveness will be judged on the basis of how confident providers are that the system allows them to protect their interests in genetic resources.

While it appears that the various questions relating to PIC will be resolved at the national level, it is clear that the functioning of an international ABS regime could greatly depend on the capacity of provider countries to establish an efficient PIC system which will be transparent enough to allow users to easily comply with it.

Recent domestic discussions have highlighted the fact that the functioning of ABS measures, and the capacity of all actors (users and providers) to comply with them, will depend on the appropriate, transparent, non-discriminatory, practical, and timely nature of the measures as well as the level of

awareness amongst Canadian and non-Canadian users of genetic resources and associated traditional knowledge.

In multi-jurisdictional countries, where the management of GR and the development of policies to support the preservation, maintenance and promotion of TK are shared by different government agencies, developing a transparent yet credible and efficient mechanism for PIC is challenging. The first step to be undertaken when trying to develop a domestic system for PIC is the identification of appropriate PIC granting authorities, taking into consideration the need to facilitate access and respect for domestic legal and social realities. In Canada, addressing this issue is complex as it implies extensive discussions and a common understanding at various levels of governments and amongst a broad range of different resource management authorities.

Domestic discussions have also brought to light other questions central to the concept of PIC, including when PIC should be granted in the ABS process, how it should be granted (orally or in writing), whether and under what conditions PIC might be withdrawn, and how to proceed in the apparent absence of a PIC granting authority, to name a few. On-going domestic discussions at the federal, provincial, territorial levels aim to suggest possible answers to such questions.

Developing a PIC system that is respectful of the decision-making processes of indigenous communities and their spiritual and cultural values is important. This is particularly challenging in countries with multiple jurisdictions and pluralistic legal systems. Developing a PIC system that can accommodate traditional knowledge of indigenous communities associated with genetic resources must start from three key considerations:

- The need to ensure the proper identification of the knowledge holder(s) (i.e. community, family, individual, “caste” or sub-community associated with a work sector (e.g. hunters, healers), etc.),
- The importance of respecting the various decision-making processes of indigenous communities,
- And, the importance of clarity, fairness and a common understanding of the implications of granting PIC, both for the providers and users of the TK.

Mutually-agreed terms

Canada would like to underline the fact that the negotiation of MAT will greatly depend on the capacity of users and providers of genetic resources and associated TK to identify and ensure their respective interests are given due consideration.

Issues around fairness in the negotiation of MAT and equitable sharing of benefits should be carefully considered by national, including sub-national, authorities. In this regard, national authorities may have an important role to play in supporting fair negotiations, for instance through providing technical assistance to certain actors or in furnishing information such as model contracts or clauses. National authorities could also provide legal minimum threshold range related to the future share of benefits, to ensure that a minimum of fairness is included in negotiated MAT. Legal framework could also be needed to ensure that eventual benefits would go to real owners and managers of the GR and TK.

The determination of which elements should be negotiated under contractual agreements between the users and providers of genetic resources and associated traditional knowledge could be done by the appropriate national and/or sub-national authorities, bearing in mind the various elements set out in the Bonn Guidelines. Elaborating model clauses, for the negotiation of MAT and benefit-sharing arrangements, flexible enough to address a range of situations, would help states to achieve key objectives of the CBD such as transparency, facilitated access, etc. Existing international and national MAT models may provide a useful point of departure.

Finally, legal certainty and clarity in the context of MAT could also be ensured by an appropriate awareness raising efforts regarding the legal requirements (at all the various stages of ABS) in provider and user countries. While efficient ABS frameworks will help implement the ABS requirements, their success could prove to be limited if users and providers of genetic resources and associated traditional knowledge are not aware of their existence.

COSTA RICA

INFORMACIÓN RELATIVA A LAS MEDIDAS QUE HAYAN SIDO TOMADAS PARA APOYAR EL CUMPLIMIENTO CON EL CONSENTIMIENTO FUNDAMENTADO PREVIO Y LOS TÉRMINOS MUTUAMENTE ACORDADOS EN LOS QUE SE CONCEDIÓ EL ACCESO, ALLÍ DONDE HAYA USO DE LOS RECURSOS GENÉTICOS O DE CONOCIMIENTO TRADICIONAL ASOCIADO¹.

En referencia a las medidas adoptadas por el país para apoyar el desarrollo del Consentimiento Previamente Informado y las condiciones mutuamente acordadas, para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, se mencionan a continuación aquellas que se consideran de mayor relevancia:

Ante la falta de capacidad nacional, así como la carencia de insumos a nivel internacional, en el artículo 9 Apartado 3 de las Normas Generales para el acceso a los elementos y recursos genéticos de la biodiversidad, Decreto Ejecutivo N° 31514-MINAE: Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad² con la finalidad de crear una guía para la negociación entre el Proveedor y el Interesado, se incluyó un contrato modelo³, en el cual se contemplaron una serie de elementos o cláusulas recomendadas.

Entre estas cláusulas recomendadas encontramos las siguientes: especificar el destino potencial de los elementos o recursos genéticos y bioquímicos y de sus destinos subsecuentes; compromiso formal, por parte del interesado, de dar constancia del origen de los recursos genéticos y del conocimiento asociado, en cualquier publicación, trámite o uso posterior que se les dé; términos acordados sobre el intercambio de conocimientos asociados a características, cualidades, usos, procedimientos y cuidados sobre los elementos y recursos genéticos y bioquímicos de la biodiversidad y cómo estos conocimientos contribuirán a la conservación de las especies y ecosistemas; términos acordados sobre alguna otra condición que la práctica o el resultado del proceso participativo dispuesto en el artículo 83 de la Ley de Biodiversidad N° 7788⁴, de las comunidades locales y los pueblos indígenas, indiquen como necesaria; manifestación expresa por parte del interesado de respetar las medidas de protección del conocimiento, las prácticas y las innovaciones asociadas de las comunidades locales y pueblos indígenas, según lo establecido en el ordenamiento jurídico nacional sobre los derechos intelectuales comunitarios *sui generis*; términos acordados sobre el tipo y formas de transferencia de tecnología o de generación de la información derivados de la investigación, bioprospección o aprovechamiento económico hacia las contrapartes nacionales, las comunidades locales y pueblos indígenas y el proveedor del recurso; términos acordados sobre la distribución equitativa de beneficios ambientales, económicos, sociales, científicos o espirituales, incluyendo posibles ganancias comerciales, a corto, mediano y largo plazo, de algún

¹ En este documento se utilizarán los siguientes acrónimos:
CBD: Convención sobre Diversidad Biológica
CONAGEBIO: Comisión Nacional para la Gestión de la Biodiversidad
CPI: Consentimiento Previamente Informado
MINAE: Ministerio del Ambiente y Energía
SINAC: Sistema Nacional de Áreas de Conservación

² 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.

³ Este Contrato-Modelo puede ser consultado también en la página web: www.conagebio.go.cr

⁴ El texto completo de la Ley de Biodiversidad, se encuentra disponible en: www.conagebio.go.cr tanto en versión en español como en inglés.

producto o subproducto derivado del material adquirido. La Oficina Técnica velará porque estos términos se cumplan de acuerdo con el tercer objetivo del Convenio de Diversidad Biológica; y estimación aproximada de los plazos para la distribución de beneficios.

A partir de este contrato modelo, se han generado nuevas versiones cada vez más elaboradas, tanto por parte de la Oficina Técnica de la CONAGEBIO, con la finalidad de enriquecer su política de educación y capacitación, como por parte del Sistema Nacional de Áreas de Conservación.⁵ Lo que ha producido que el contrato modelo se haya enriquecido, al incorporar específicamente cláusulas más detalladas en temas como por ejemplo Propiedad Intelectual y Transferencia del material a terceros.

Sin embargo, a pesar de experimentar una mejora en la redacción de este contrato modelo, aun se carece de una verdadera cultura de negociación entre las Partes involucradas en el proceso, y muchas veces el Proveedor no le da la importancia necesaria a la posibilidad de poder negociar beneficios tanto monetarios como no monetarios, con el Interesado en realizar el acceso genético o bioquímico.

Por esta razón la Oficina Técnica en los dos últimos años, ha realizado varios talleres de capacitación, convocando a los diferentes Proveedores nacionales. Actualmente en coordinación con el Sistema Nacional de Áreas de Conservación (SINAC), -a quien corresponde la administración de las áreas silvestres protegidas declaradas por el Estado, las cuales se hallan ubicadas en las Áreas de Conservación, fungiendo como uno de los proveedores de los recursos genéticos y bioquímicos de la biodiversidad-, se ha preparado un cronograma de Seminarios, que se realizarán durante este año, cuya finalidad principal es lograr que este instrumento, cumpla fielmente los objetivos para los cuales fue creado y fortalecer las capacidades de negociación.

Particularmente estos Seminarios o Talleres, estarán dirigidos en su primera etapa, únicamente a los Encargados de Investigación, Abogados y Directores de las Áreas de Conservación, pues las Áreas Silvestres Protegidas estatales, se han constituido en estos últimos años, como los lugares en donde se realizan la mayor cantidad de accesos de elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *in situ*.

Además estos espacios de capacitación y discusión, permitirán que el Sistema Nacional de Áreas de Conservación (SINAC), avance en la propuesta y aprobación del procedimiento oficializado para la negociación y firma del Consentimiento Previamente Informado y facilitará en cierta medida, la emisión de la Política Nacional para el acceso a los elementos y recursos genéticos y bioquímicos en Áreas Silvestres Protegidas Estatales.

Hasta el día de hoy, solamente en el SINAC, existe un procedimiento propuesto para la negociación y formalización del Consentimiento Previamente Informado, que se formuló en el año 2005, sin embargo su aplicación no ha sido uniforme ni clara en las diferentes Áreas de Conservación del país, lo que refleja aún con mayor detalle, la necesidad de realizar los Talleres anteriormente citados.

Sin embargo, a pesar de las limitantes anteriormente mencionadas, ya se han reflejado al menos a nivel de Áreas Silvestres Protegidas estatales, los primeros beneficios económicos, producto de la negociación de los Consentimientos Previamente Informados, lo cual recalca una vez más, que la normativa nacional tiene aplicación práctica.

De conformidad con datos que constan en el Primer Informe (período 2004-2006) denominado: LOS FRUTOS ECONÓMICOS DE LA INVESTIGACIÓN Y LOS CONTRATOS DE CONSENTIMIENTO PREVIAMENTE INFORMADO (CPI), realizado en enero del 2007 por el funcionario del SINAC, Lic.

⁵ El Sistema Nacional de Áreas de Conservación (SINAC), integra las once Áreas de Conservación, a las cuales pertenecen las Áreas Silvestres Protegidas estatales. es el órgano desconcentrado estatal, que hasta la fecha

Gustavo Induni Alfaro, los beneficios económicos obtenidos de negociaciones de Consentimientos Previamente Informados, únicamente pactados con el Instituto Nacional de Biodiversidad, oscilan aproximadamente en ₡18.000.000 millones de colones, suma total que equivale a \$38.387 dólares. Específicamente, tal y como se desprende de este informe en el período del 2004 al 2006, el (89,3 %) de los recursos económicos hasta ahora obtenidos, provienen del 10 % de los presupuestos de los proyectos de investigación acordados entre el INBio y las organizaciones socias con quienes trabaja y el restante 10,7 % corresponde al 50 % de las regalías obtenidas por el INBio en los proyectos de bioprospección que involucran al SINAC.

Esta situación permite incentivar a los otros Proveedores de elementos y recursos genéticos y bioquímicos de la biodiversidad, para que desarrollen sus capacidades de negociación y congruentemente apliquen los principios establecidos por el Convenio sobre Diversidad Biológica, desarrollados en esta normativa nacional.

Es importante señalar que a pesar de que el Consentimiento Previamente Informado y las condiciones mutuamente acordadas se formalizan en un contrato privado, en donde existe autonomía de la voluntad de las partes, estos contratos conforme a la legislación nacional, han sido refrendados por la Oficina Técnica, y para ello se han considerado los principios y objetivos de la Convención sobre Diversidad Biológica y la Ley de Biodiversidad N°7788, así como lo establecido en el ordenamiento jurídico costarricense.

Dentro de estos elementos evaluados por la Oficina Técnica de la CONAGEBIO, para otorgar el refrendo a los consentimientos previamente informados, se señalan a manera de ejemplo los siguientes: el principio precautorio señalado en los convenios internacionales, protocolos regionales y leyes nacionales para garantizar entre otros, los objetivos de conservación, utilización sostenible y distribución justa y equitativa de los beneficios derivados del acceso a los elementos o recursos genéticos y bioquímicos; la seguridad y soberanía alimentaria; la conservación de los ecosistemas; la protección de la salud humana; el peligro de extinción de las especies, subespecies, razas y variedades; razones de endemismo, poca abundancia o rareza; condiciones de vulnerabilidad o fragilidad en la estructura o función de los ecosistemas; protección a elementos esenciales de la autonomía o identidad cultural de los pueblos indígenas y comunidades locales y Recursos genéticos o áreas geográficas calificados como estratégicos.

De conformidad con el párrafo anterior, en el caso de 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.

Tanto el Consentimiento previamente informado como 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 requisitos esenciales que 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.

Respecto al Certificado de origen o de legal procedencia, en el artículo 19 del Decreto Ejecutivo N° 31514-MINAE, se regula que en este documento oficial, se 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, el lugar y fecha del acceso, propietario de los elementos o recursos de la biodiversidad, el material obtenido, cantidad y la persona, y la comunidad o comunidades que han contribuido o contribuirán con su conocimiento asociado, innovaciones y prácticas tradicionales;

Adicionalmente a lo establecido en el artículo 19 anteriormente mencionado, el Decreto Ejecutivo N° 33697: Reglamento para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *ex situ*⁶, señala que cuando se pretenda acceder a los elementos y recursos genéticos y bioquímicos de materiales mantenidos en condiciones *ex situ*, y que por diversas razones el interesado requiera exportar los materiales para su uso fuera del país, el mismo deberá necesariamente solicitar un certificado de legal procedencia para que acompañe en todo momento al material, el cual será expedido en los términos señalados en el Decreto Ejecutivo N° 31514-MINAE por la Oficina Técnica, es decir deberá indicar si el interesado cumplió con la normativa establecida para el consentimiento previamente informado y las condiciones mutuamente acordadas, así como el resto de la información anteriormente señalada.

Tal y como se ha mencionado anteriormente, el requisito del consentimiento previamente informado y las condiciones mutuamente acordadas, cumple una función esencial dentro del procedimiento establecido, para otorgar el permiso de acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad, por lo que en el Decreto Ejecutivo N° 31514-MINAE se incluye dentro de las causas que se considerarán incumplimiento grave: la violación sustancial al consentimiento previamente informado y las condiciones mutuamente convenidas, lo cual podrá ser sancionado con la cancelación del permiso de acceso otorgado:

Artículo 27. “Si del debido proceso, la Oficina Técnica llega a comprobar el incumplimiento de las condiciones bajo las cuales se otorgó el permiso, lo suspenderá temporalmente, y le concederá a la parte interesada un plazo perentorio para realizar las medidas correctivas correspondientes. En caso de que el incumplimiento comprobado fuere grave, o que en el plazo otorgado no se realizaron las medidas correctivas, la Oficina Técnica cancelará el permiso otorgado.

Se considera incumplimiento grave, aquél que cause una violación sustancial al consentimiento previamente informado y las condiciones mutuamente convenidas, a los derechos comunitarios *sui generis*, y a la conservación de las especies y de los ecosistemas, o en su lugar exista falsedad comprobada de los documentos fundamento para el otorgamiento del permiso.”

Por su parte en el Decreto Ejecutivo N° 33697: Reglamento para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones *ex situ*, se ha procurado establecer expresamente, respecto al tema de la distribución justa y equitativa de los beneficios, la regulación de ciertas situaciones en las que los beneficios también se compartan con los proveedores originales:

- El consentimiento previamente informado y las condiciones mutuamente acordadas se deberán obtener y negociar con los propietarios, responsables o representantes de los materiales mantenidos en condiciones *ex situ* de acuerdo con el contrato modelo dispuesto por la Oficina Técnica.
- En los casos en que sea posible determinar la procedencia y el origen de los materiales que van a ser accedidos 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.
- Si se trata de un acceso a colecciones sistematizadas nuevas –de conformidad con el artículo 8° 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

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

informado y en las condiciones mutuamente acordadas, también con los proveedores originales de los mismos.

- 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.

Finalmente, se espera que en corto plazo la Oficina Técnica en asocio con la Mesa Indígena y la Mesa Campesina, logre concluir el procedimiento participativo, con la finalidad de determinar la naturaleza y alcances de los derechos intelectuales comunitarios *sui generis*.

Este Decreto Ejecutivo, deberá regular entre otros aspectos relacionados con el consentimiento previamente informado: quién será la autoridad dentro del pueblo indígena, quién se encargará de negociar el Consentimiento Previamente Informado con el Interesado, cuando el acceso a los elementos y recursos genéticos y bioquímicos se solicite realizar dentro de sus territorios o cuando los permisos de acceso solicitados involucren conocimientos, innovaciones y prácticas de las comunidades locales y pueblos indígenas; cómo se realizarán las objeciones a los accesos de recursos o conocimiento asociados, por motivos culturales, espirituales, sociales o de otra índole, entre otros.

Lamentablemente, este proceso ha caminado lentamente, tanto por factores económicos como por factores sociales, sin embargo hasta la fecha, tanto la Mesa Indígena como la Mesa Campesina, han logrado a través de varios talleres, redactar y validar los primeros borradores, para la regulación de la protección de los Derechos Intelectuales comunitarios *sui generis*.

Estos documentos serán nuevamente revisados, modificados y consultados a los pueblos indígenas y comunidades locales, por lo que la Oficina Técnica, junto con la Mesa Indígena y la Mesa Campesina, buscan mejorar la metodología hasta ahora utilizada, con la finalidad de que se avance con mayor agilidad en este proceso de consulta, por lo que consecuentemente, mientras no se emita la regulación específica, se limita la potestad de la Oficina Técnica de otorgar permisos de acceso de investigación básica, bioprospección o aprovechamiento económico, que involucren estos conocimientos, innovaciones y prácticas de las comunidades locales y los pueblos indígenas sobre el uso de los recursos genéticos y bioquímicos de la biodiversidad.

ENGLISH TRANSLATION

INFORMATION REGARDING MEASURES TAKEN TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT AND MUTUALLY AGREED TERMS FOR GRANTING ACCESS FOR USE OF GENETIC RESOURCES OR ASSOCIATED TRADITIONAL KNOWLEDGE¹

Here are some of the most relevant measures adopted by the country to support the development of Prior Informed Consent and mutually agreed terms, for access to the genetic and biochemical components of biodiversity:

Given the lack of national capacity, and scarce input at the international level, a model contract² was included in Article 9, Paragraph 3 of Executive Decree No. 31514-MINAE: General Standards for Access to the Genetic and Biochemical Components of Biodiversity,³ in order to create a guide for negotiations between the Provider and Interested Party. The model contract incorporates a series of recommended elements or clauses.

The recommended clauses include: specifying the potential destination of the genetic or biochemical components or resources and their subsequent destinations; a formal commitment on the part of the interested party to provide proof of origin of the genetic resources and associated traditional knowledge in any subsequent publication, undertaking or use; agreed terms regarding the exchange of knowledge associated with characteristics, qualities, uses, procedures and care of genetic and biochemical resources of biodiversity, and for how this knowledge will contribute to the conservation of biological diversity; agreed terms regarding any other condition that the practice or outcome of the participatory process involving local and indigenous communities, set up pursuant to Biodiversity Law No. 7788,⁴ should indicate as necessary; an express statement on the part of the interested party that measures for protecting the knowledge, practices and innovations of indigenous and local communities, as established in the national legal order regarding *sui generis* community intellectual rights, will be respected; agreed terms regarding how technology transfer will take place or how information arising from research, bioprospecting or economic exploitation will be transmitted to national counterparts indigenous and local communities and the provider of the resource, and what it will consist of; agreed terms on the equitable sharing of environmental, economic, social, scientific or spiritual benefits, including possible commercial gain, in the short, medium and long term, of any product or derivative by-product of the acquired material. The Technical Office shall oversee compliance of these terms in accordance with the third

¹ The following acronyms will be used in this document:

CBD: Convention on Biological Diversity

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

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

PIC: Prior Informed Consent

SINAC: Sistema Nacional de Áreas de Conservación (National System of Conservation Areas)

² This Model Contract can be consulted on the Web page: www.conagebio.go.cr

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

⁴ The complete text of the Biodiversity Law is available at: www.conagebio.go.cr in both Spanish and English.

objective of the Convention on Biological Diversity. The model contract also provides a rough estimate of the timeframe for sharing of benefits.

Using this model contract as a basis, new, increasingly developed versions have been generated by both the Technical Office of CONAGEBIO, as a means of enhancing its education and training policy, and the National System of Conservation Areas.⁵ This has led to an enriched model contract that specifically incorporates more detailed clauses on issues such as, for example, intellectual property and material transfer to third parties.

However, despite improvements in the wording of this model contract, a true culture of negotiation between the parties involved in the process is still lacking. Often, the provider does not grant the necessary importance to the possibility of being able to negotiate both monetary and non-monetary benefits with the party interested in obtaining access to the genetic or biochemical component.

That is why the Technical Office has held various training workshops over the last two years, aimed at the various national providers. The Technical Office has worked in coordination with the National System of Conservation Areas (SINAC), -which is in charge of managing state-designated protected wild areas located within Conservation Areas, acting as one of the providers of genetic and biochemical resources of biodiversity – to prepare a timetable of Seminars that will take place this year, for the purpose of ensuring that this instrument faithfully complies with the objectives for which it was created, and strengthening negotiation capacity.

Specifically, these seminars or workshops will be geared initially only toward those in charge of research, lawyers and the directors of conservation areas, seeing as state protected wild areas have become, over the last few years, the places where the most access to the genetic and biochemical elements and resources of biodiversity in *in situ* conditions have taken place.

Furthermore, these spaces for training and discussion will enable the National System of Conservation Areas (SINAC), to make progress with regard to proposing and approving the official procedure for negotiating and signing Prior Informed Consent. They will also facilitate, to a certain extent, issuance of the National Policy for access to genetic and biochemical components and resources in State Protected Wild Areas.

Up until now, only SINAC has a proposed procedure for negotiating and formalizing Prior Informed Consent, which was formulated in 2005. However, its implementation has been neither uniform nor clear in the country's different Conservation Areas, which illustrates in even greater detail the need to carry out the above-mentioned workshops.

However, despite the above-mentioned limitations, the first economic benefits resulting from the negotiation of Prior Informed Consent have already become apparent, at least at the level of the state protected wild areas, again highlighting the fact that national regulations have a practical application.

According to the data contained in the First Report (2004-2006 period), entitled: THE ECONOMIC FRUITS OF RESEACH AND PREVIOUS INFORMED CONSENT (PIC) CONTRACTS, carried out in January 2007 by SINAC official Gustavo Induni Alfaro, the economic benefits obtained from Prior Informed Consent negotiations with the National Biodiversity Institute alone are approximately ¢18.000.000 million colones in total, which is equivalent to \$38,387 dollars. Specifically, as revealed by this report, in the 2004 to 2006 period, (89.3%) of the economic resources obtained so far come from 10% of the budgets for research projects entered into by INBio and the partner organizations it works with, and

⁵ The National System of Conservation Areas (SINAC), covers eleven Conservation Areas, which belong to State Protected Wild Areas. It is the state body that, so far, has

the remaining 10.7% corresponds to 50% of the royalties obtained by INBio in bioprospecting projects that involve SINAC

This situation makes it possible to create an incentive for other providers of genetic and biochemical resources of biodiversity to develop their negotiation capacity and apply, in a coherent manner, the principles established by the Convention on Biological Diversity and developed in the national regulation.

It is important to point out that, despite the fact that Prior Informed Consent and mutually agreed terms are formalized in a private contract, in which there is the independent will of the parties, these contracts comply with national legislation in that they must be approved by the Technical Office, taking into account the principles and objectives of the Convention on Biological Diversity and Biodiversity Law No. 7788, as well as the stipulations of Costa Rica's legal order.

Some of the elements considered by CONAGEBIO's Technical Office when granting approval of Prior Informed Consent include, for example: the precautionary principle indicated in international conventions, regional protocols and national laws to guarantee, among other things, the objectives of conservation, sustainable use and fair and equitable distribution of the benefits arising from access to the genetic and biochemical components or resources; food safety and sovereignty; ecosystem conservation; human health protection; the risk of extinction of species, subspecies, races and varieties; reasons linked to endemism, non-abundance or scarcity; reasons linked to the vulnerability or fragility of ecosystem structures or functions; protection of essential elements of the autonomy or cultural identity of indigenous and local communities; and genetic resources of geographic areas categorized as strategic.

In accordance with the previous paragraph, in the event that the Technical Office should consider it necessary, it may conduct various consultations and request the parties involved in the negotiation of prior informed consent to provide any additional information it deems necessary.

Both Prior Informed Consent and the Certificate of Origin or Legal Provenance issued by CONAGEBIO's Technical Office have been regulated in a pioneering manner through Biodiversity Law No. 7788, Article 80, as essential prerequisites that the interested party must submit to the National Seed Office or the National Intellectual Property Registry, upon requesting intellectual property protection for innovations involving components of biodiversity.

With regard to the Certificate of Origin or Legal Provenance, Article 19 of Executive Decree No. 31514-MINAE stipulates that this official document must indicate whether the interested party has complied with the established regulations governing prior informed consent and mutually agreed terms for basic research, bioprospecting or economic exploitation, with the date and number of the corresponding resolution, the place and date of access, the owner of the biodiversity components or resources; the material obtained, the quantity, and the person and community or communities that have contributed or will be contributing their related traditional knowledge, innovations and practices.

In addition to what was established in above-mentioned Article 19, Executive Decree No. 33697: Regulation for Access to Genetic and Biochemical Components and Resources of Biodiversity in *Ex Situ* Conditions,⁶ indicates that, when attempting to access the genetic and biochemical components of material maintained in *ex situ* conditions in a situation where, for various reasons, the interested party needs to export the material for use outside of the country, it is necessary for that party to apply for a certificate of legal provenance that must accompany the material at all times, to be issued by the Technical Office according to the terms set out in Executive Decree No. 31514-MINAE. In other words, the certificate must indicate whether the interested party has complied with the regulations established for prior informed consent and mutually agreed terms, as well as all of the other information indicated above.

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

As mentioned earlier, the requirement of prior informed consent and mutually agreed terms fulfils an essential function within the procedure set up to grant permits of access to the genetic and biochemical components and resources of biodiversity, which is why Executive Decree No. 31514-MINAE includes, among the causes deemed to be severe non-compliance: substantial violation of prior informed consent and mutually agreed terms, which could be penalized through cancellation of the granted access permit:

Article 27. “If, through due process, the Technical Office should discover non-compliance with the terms under which the permit was granted, said permit will be suspended temporarily, and the interested party will be given a fixed time period in which to carry out the corresponding corrective measures. In the event of severe non-compliance, or failure to undertake corrective measures within the specified period, the Technical Office shall cancel the granted access permit.

Non-compliance is considered severe when it results in a substantial violation of the prior informed consent and mutually agreed terms, of *sui generis* community rights, and of the conservation of species and ecosystems, or when the supporting documents used as a basis for granting the permit are found to be false.”

For its part, Executive Decree No. 33697: Regulation for Access to Genetic and Biochemical Components and Resources of Biodiversity in *Ex Situ* Conditions has managed to expressly stipulate, with regard to the issue of fair and equitable sharing of benefits, the regulation of certain situations in which benefits are also shared with the original providers:

- Prior informed consent and mutually agreed terms must be obtained and negotiated with the owners, custodians or representatives material maintained in *ex situ* conditions, in accordance with the model contract provided by the Technical Office.
- In cases where it is possible to determine the provenance and origin of the material to be accessed from a collection set up before the entry into effect of this decree, the benefits may also be shared with the original providers of said material.
- If it is a question of access to new systemized collections—in accordance with Article 8 of this Executive Decree—or new assent to access collections established prior to the entry into effect of this Executive Decree, the benefits will be shared, in accordance with the provisions of the prior informed consent and mutually agreed terms, and also with the original providers of the material.
- The Technical Office recommends including, among the mutually agreed terms and prior informed consent negotiated between the owners, holders or administrators of the new collection and the original providers of the genetic and biochemical resources of biodiversity, an agreement on possible benefits that could arise from ulterior access to these genetic and biochemical components and resources by a third party.

Finally, it is hoped that, in the short term, the Technical Office, in association with the Indigenous Peoples Board and the Small Farmers Board, will be able to conclude work on the participatory procedure aimed at determining the nature and scope of *sui generis* community intellectual rights.

This Executive Decree should regulate, among other aspects linked to prior informed consent: the authority within the indigenous people who will be in charge of negotiating Prior Informed Consent with the interested party when there is a request for access within indigenous territories to genetic and biochemical components and resources, or when the requested access permits involve the knowledge, innovations and practices of indigenous and local communities; the procedure for objecting to access to resources or related knowledge for cultural, spiritual, social and other reasons, among others.

Unfortunately, this process has progressed slowly, owing to economic and social factors. However, so far both the Indigenous Peoples Board and the Small Farmers Board have managed, through various workshops, to write and validate the first drafts of regulations for the protection of *sui generis* community intellectual rights.

These documents will be revised again, amended and submitted to consultations with the indigenous and local communities. The Technical Office, with the Indigenous Peoples Board and the Small Farmers Board, is therefore seeking to improve the methodology used so far, in order to speed up the consultation process. Until the specific regulations are issued, the Technical Office's powers are limited when it comes to granting access permits for basic research, bioprospecting or economic exploitation that involve the knowledge, innovations and practices of local and indigenous communities in relation to the use of genetic and biochemical resources of biodiversity.

CZECH REPUBLIC

We have reported in many notifications in 2004, 2005 as well as in the third national report about this issue. A lot of information can be found there.

As a part of the UNEP/GEF Project “Development of the National Biosafety Framework” the model MTA for the agricultural and garden crops and farm animals were developed.

These model Agreements were elaborated in 2005 – before the FAO international standard agreements were developed (SMTA, July 2006). Therefore these MTA will have to be further elaborated and linked with these FAO agreements. The model MTA was developed for Agricultural and Garden Crops, Farm Animals, Forest Trees, Botanic Gardens, Zoological Gardens, Fungi. They can be found in the Annex to this Report. This Annex is also annex to this notification.

No access to farm **animal genetic resources** maintained in ex-situ collections (gene banks) has been asked so far, live animals are subject to free trade agreements. For administration genetic material from gene banks see also the Notification No. 45 and previous notification from last and previous year.

As to **plant genetic resources** all access to the collected ex situ genetic resources are operated under special Material Transfer Agreements (FAO) – free for scientific and educational purposes, following the ABS CBD main ideas respecting the relevant laws and claims of original sources. Still there were not stated the claims for benefit sharing. Exchange of genetic resources among gene banks goes on without any problem.

Genetic resources of micro-organisms for food and agriculture follows up standard systems of access and benefit sharing keeping without any problem international agreements on dealing with microorganisms.

For plant genetic resources, prior informed consent and mutually agreed terms on which access was granted are specified in the national version of Material Transfer Agreement. The access is based on the provisions of IT/PGRFA laying down that only the specified PGRFA (Annex 1 of IT) are internationally available under terms of the IT/PGRFA, and exclusively for utilization in research, breeding or education. This means that, in the framework of IT, the samples of PGR are not provided for direct commercial use, as far as the PGR transfer actualizes on mutually agreed terms. Provision of PGR is sometimes restricted by technical circumstances as e.g. limited stock of the propagation material from some genetic resource in collection. Such restrictions are gradually removed by regeneration and replenishment of seed samples in the gene bank, as well as by conservation of a satisfactory quantity of vegetative propagated plants in the field gene banks or *in vitro* collections.

Please find an example of the model MTA (for animals and plants genetic resources) in the Czech Republic on following pages and in the Annex 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)

Report of the UNEP/GEF Project – BEA

Material Transfer Agreement on Plant Genetic Resources for Food and Agriculture

(Recommended MTA model for institutions participating in the “National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization” of the Czech Republic and providing plant genetic resources for users)

Name of the legal subject providing the genetic resources, its address, contact (hereinafter “provider”)

Conserves plant genetic resources (PGR) in accordance with the Act No. 148/2003 and authorization of the Ministry of Agriculture of the Czech Republic. Participant of the National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization is obliged to provide samples of PGR for purposes of breeding, research and education to domestic and foreign users. Samples of PGR are provided under conditions of this agreement, if sufficient stock exists and if sampling will not endanger or damage the genetic resource. Parameters of the provided samples of PGR and extent of services are regulated by the Decree No. 458/2003. In case of foreign users (legal or natural persons) the obligation mentioned above is applied only to subjects and their requirements for providing the samples covered by the International Treaty on Plant Genetic Resources for Food and Agriculture.

Aim of this agreement is to contribute to conservation of plant genetic resources, to ensure access to these resources and their sustainable use respecting fair benefit sharing.

Availability of samples of plant genetic resources for food and agriculture kept by the provider is guaranteed for the following categories of material:

Category 1)

Samples of plant genetic resources for food and agriculture listed in the Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Category 2)

Samples of plant genetic resources for food and agriculture not listed in the Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture and that were:

- either developed (produced, obtained as a property) in the institution that presently maintains these genetic resources or which were obtained by this institution before the Convention on Biological Diversity entry into force and to which no legal protection is applied and/or their availability is not limited in other way (by an author or owner of the given genetic resource – e.g. requirement of reciprocity etc.),
- or obtained after the Convention on Biological Diversity entry into force, however on the basis of an agreement which enables to provide such genetic resources for agricultural (biological) research, breeding and education without any restrictions.

Availability of PGR samples mentioned in the categories 1) and 2) is guaranteed in accordance with provisions of the International Treaty, namely its articles 12.3 and 13.2d.

Plant genetic resources not included in the categories 1) or 2) or to which legal protection is applied and/or their availability is limited in other way by an author, provider or owner of such genetic resource, are not subject of this agreement. Nevertheless, they can be made available on the basis of mutual providing of the same or similar advantages and/or on the basis of a special agreement.

At recognition and respect for his given liabilities, responsibilities and rights, the provider enables access to plant genetic resources in his collections and in the gene bank under the following conditions:

Recipient of plant genetic resources sample(s) agrees herewith that:

- He will enable access to samples of genetic resources exclusively for their conservation and utilisation in research, breeding and education with the aim to ensure food production and agriculture.
- He will not apply on provided plant genetic resources any form of intellectual property rights or other rights that could restrict an easy availability of plant genetic resources for food and agriculture or their genetic segments or components that he obtained on the basis of this agreement.

- He will ensure that all further (third) persons and/or institutions, to that the recipient makes available the respective genetic resources, will guarantee for provided genetic resources and/or materials that were directly and essentially derived from them, that this further (third) person will be bound by the same provisions as in this agreement and will guarantee to transfer the same obligation to possible subsequent recipients.
- If the obtained samples of genetic resources or their segments or components will be further evaluated and characterised by the recipient and any data on their properties will be obtained, the recipient undertakes to provide the data to the sample provider. Upon request of the recipient the provided data can be made publicly available only after a three year's period from their transfer.
- If the results of the use of provided samples of PGR or their segments or components are published, the recipient (user) undertakes to recognise and quote provider of used genetic resources in the publication and send a copy of such publication to the provider.
- In case, that the result of use of provided PGR samples in research or breeding is a material (e.g. cultivar) on which legal protection is applied, the recipient of PGR samples undertakes to inform the provider and send him copies of documents constituting such legal protection.
- Recipient of PGR samples is fully responsible, that transfer of samples will comply with national regulations concerning quarantine and biosafety, as well as import and release of plant genetic resources for cultivation in recipient country.

Phytosanitary state of provided PGR sample(s) is guaranteed only in such a case and extent as specified in Phytosanitary Certificate and only when its copy is enclosed. Provider accepts no liability for safety or correctness of name, nor for accuracy and correctness of any passport or other data provided along with a PGR sample(s). He also does not guarantee quality, viability and purity (genetic and/or mechanical) of provided PGR samples.

In case of disputes within the frame of the agreement, a party of the agreement can require arbitration, at national level or at the International Chambre of Commerce, Paris, France.

The samples of plant genetic resources listed bellow are provided only after recipient acceptance of the agreement conditions. This agreement enters into force immediately after recipient accepts the PGR samples listed bellow.

If the conditions mentioned above are not met by the recipient, provider may refuse future services to this recipient.

List of provided samples of genetic resources (in case of lack of space, please use an annex)

.....
.....

The provider asks the requesting party to fill in and sign this agreement by a statutory representative and return it to provider.

Name of the recipient of the sample(s) of plant genetic resources:

.....

Full address (place, street, number, postal code, phone, e-mail)

.....
.....

On behalf of recipient:

.....
First name, surname, title

.....
Position

Date and place:

On behalf of provider:

.....
First name, surname, title

.....
Position

Date and place:.....

Farm Animals

ANNEX

I. MATERIAL TRANSFER AGREEMENT (GENEBANK TO A THIRD PERSON)

(i) Preamble

This is a legally binding document governing conditions for the transfer of genetic material, hereinafter referred to as the “material,” and any information relating thereto, hereinafter referred to as the “information,” from the National Genebank to the requesting party. The material received under this Material Transfer Agreement (MTA) was collected with the Prior Informed Consent (PIC) and will be used in a *bona fide* and sustainable way, in full respect of the principles laid down in the Convention on Biological Diversity (CBD).

A. Parties to this Agreement:

The provider: National Genebank..... (Address)...., hereinafter referred to as the “provider“

The requesting party hereinafter referred to as the “recipient.”

<i>Name of recipient</i>	
Address	
Identification Number	
End User	

B. Material (to be filled by the provider)

Amount and nature of the material provided (semen, embryo, tissue type, DNA etc., and form – lyophilized, deep frozen etc.,)
Minimum identification data (species, breed, sex of the donor animal, accession number of the gene bank,)
Description (origin, place and date of acquisition from in situ conditions,)
PIC (copy of, or a reference to)

C. Objectives of Use of Genetic Resources Provided Under this Agreement

The material and related information is intended only for use in non-profit research, development, testing and/or evaluation, control, reference and training purposes.

The recipient will use the material for (specified by the recipient)

On completion of these activities any remaining quantities of the material and all the eventual derivatives will be treated as follows:.....(specified by the provider)

D. Conditions of Transfer of the Material

The material and information are provided on the following conditions:

- 1) The recipient agrees neither to claim ownership over the material nor to seek intellectual property rights over them or information passed along.
- 2) The recipient will not sell, distribute or otherwise made available the material and/or information to any other party for any purpose or use this material and/or information in any way for the commercial purposes.
- 3) The recipient will use the material and the information exclusively for the purpose described under Section C above.
- 4) The recipient will ensure that the material will at all times be used and handled in compliance with all relevant laws, rules and regulations applicable, and for the purposes of testing will follow the protocols of standard test and reference procedure.
- 5) The recipient agrees to furnish relevant performance data arising from the evaluation of the material to the provider. Upon request of provider or recipient these data will only be made publicly available after an embargo period of.....years.
- 6) Any other information and/or research results obtained using the material, will be considered proprietary to the recipient. Prior to publication of such results, the recipient will provide the provider with a copy of such intended publication. All such intended publications will contain an acknowledgement of the provider.
- 7) The recipient is free to file patent application(s) claiming inventions made by the recipient through the use of the material but agrees to inform the provider prior to applying for any intellectual property rights related to the use of any received material and notify the provider upon filing a patent application claiming method(s) of manufacture or use(s) of the material.
- 8) The material is provided at no cost, the recipient will – will not* undertake to reimburse the provider for costs associated with distribution of the material to the recipient.
- 9) Except to the extent prohibited by law, the recipient assumes all liability for damages, which may arise from its use, storage or disposal of the material. The provider will not be liable to the recipient for any loss, claim, damage, illness, or injury to person or property whatever the cause may be arising out of or pertaining to recipient's use of the materials, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the provider.
- 10) Any dispute relating to the interpretation of application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the Economic Chamber. The parties will accept the arbitral award as final.
- 11) This agreement shall only be capable of change by written amendment executed by duly authorized officers of the parties.

- 12) The relevant signatories must sign each of three copies of this Agreement, one of which retained by the National Coordinating Center for Farm Animal Genetic Resources, one retained by the recipient and one by the provider.

8) * not accordant text be crossed out

Approval by the NCC:

I hereby warrant that I, as an Authorized Official of the NCC hereby certify my approval of the transfer of the material to the recipient.

Name of Authorized Official (NC):

Signature of Authorized Official

Date

Provider (the gene bank from whom the material will be released)

Name: _____

Address: _____

Signature of Authorized Official of the gene bank

Date

I hereby certify that as the Responsible Administrative Authority of the recipient, I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the material. I hereby warrant that I have the full authority to execute this Agreement and to thereby bind the recipient.

Name of Authorized Official: _____

Signature of Authorized Official

Date

II. REPRODUCTION MATERIAL TRANSFER AGREEMENT (GENEBANK TO A THIRD PERSON)

(ii) Preamble

This is a legally binding document governing conditions for the use of genetic material, hereinafter referred to as the “material” distributed from the National Genebank to the Requesting Party, The material received under this Agreement was collected with PIC and will be used in a *bona fide* and sustainable way, in full respect of the principles laid down in the Convention on Biological Diversity (CBD).

A. Parties to this Agreement:

The provider: Genebank..... (Address)...., hereinafter referred to as the “provider“

/...

The requesting party hereinafter referred to as the “recipient.”

Name of Recipient	
Address	
Identification Number	

B. Material Information (to be filled by the gene bank)

Nature and amount of the material provided (semen dose, embryo)
Minimum identification data (species, breed/line, accession number of the gene bank, identification of the provider)
Description (origin, place and date of acquisition from in situ conditions)
PIC (copy of, or a reference to)

C. Objectives of Use of Genetic Resource Provided Under this Agreement

The distribution of the material is carried out according to the breed reconstruction regulations of the National Program on Farm Animal Genetic Resources, (reference number....., dated) hereinafter referred to as the “National program”.

D. Conditions of Transfer of the Material

The material is provided on the following conditions:

1. The recipient will use the material exclusively for the purpose described under Section C above and will not produce any offspring for other purposes without the permission from the provider.
2. The recipient will not sell, distribute or otherwise made available the material to any other party for any purpose or use this material and/or information in any way for the commercial purposes.
3. Any remaining quantities of the material that was not used for any reason for the objective indicated under Section C above will be returned to the provider.
4. The recipient will ensure that the material will at all times be used and handled in compliance with all relevant laws, rules and regulations applicable.
5. Except to the extent prohibited by law, the recipient assumes all liability for damages, which may arise from its use, storage or disposal of the material. The provider will not be liable to the recipient for any loss, claim, damage, illness, or injury to person or property whatever the cause may be arising out of or pertaining to recipient’s use of the materials, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the provider.
6. Progeny born with the use of the material becomes a property of recipient. The recipient agrees that the progeny will be handled according to the Breed Reconstruction Project (Annex No.1 to the Agreement).
7. The recipient agrees to collaborate in the conservation program by future provision of genetic material of similar type and amount originated from the progeny born according to Breed Reconstruction Project (Annex No.1 to the Agreement). and by provision of scientific information relevant to conservation and sustainable utilization of the genetic material provided.

8. Information provided by the recipient to the provider under, or in connection with, this Material Transfer Agreement, which could be considered as trade secrets of the recipient, would be treated by the provider as confidential and proprietary to the recipient for a period of(5) years after the disclosure of such information to the provider.
9. The material is provided at no cost, the recipient will – will not* undertake to reimburse the gene bank for costs associated with distribution of the material to the recipient.
10. Any dispute relating to the interpretation of application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the Economic Chamber. The parties will accept the arbitral award as final.
11. This agreement sets forth the entire understanding between the parties and supersedes any prior agreements, written or verbal. It shall only be capable of change by written amendment executed by duly authorized officers of the parties.
12. The relevant signatories must sign each of three copies of this Letter of agreement, one of which retained by the National Coordinating Center for Farm Animal Genetic Resources, one retained by the recipient and one by the gene bank from whom the material will be obtained.

9) * not accordant text be crossed out

Approval by the NCC:

I hereby warrant that I, as an Authorized Official of the NCC hereby certify my approval of the transfer of the material to the recipient.

Name of Authorized Official (NC):

Signature of Authorized Official

Date

Provider (the gene bank from whom the material will be released)

Name: _____

Address: _____

Signature of Authorized Official of the gene bank

Date

I hereby certify that as the Responsible Administrative Authority of the recipient, I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the material. I hereby warrant that I have the full authority to execute this Agreement and to thereby bind the recipient.

Name of Authorized Official: _____

Signature of Authorized Official

Date

III. MATERIAL ACQUISITION AGREEMENT (PIC – DONOR TO A GENE BANK)

(iii) Preamble

THIS IS A DOCUMENT, WHICH EXPRESSES A PRIOR INFORMED CONSENT OF THE DONOR WITH THE PROVISION OF GENETIC MATERIAL TO THE NATIONAL GENE BANK AND GOVERNING CONDITIONS FOR THE FURTHER USE OF THIS GENETIC MATERIAL, HEREINAFTER REFERRED TO AS THE “MATERIAL”.

A. Parties to this Agreement:

The supplier..... (Address)....., hereinafter referred to as the “donor“

<i>Name of donor</i>	
Address	
Participant Number of the National Program	

The recipient party: Genebank (Address) hereinafter referred to as the “recipient”

<i>Name of the Genebank</i>	
Address	
Corporation Identification Number	

B. Material Information

Nature and amount of the material provided (semen dose, embryo)
Minimum identification data (species, breed/line, identification of the donor’s animal(s), date of acquisition from in situ conditions) – in an attached list

The donor grants material and related information to the recipient under the terms and conditions of this agreement. The material being provided is identified in the attached list, which forms part of this agreement. The donor asks that the recipient agree to the following before the recipient receives the material:

- 1) The above material is the property of the donor and is made available as a service to the research community. Donor warrants that it is legally free to provide the material.
- 2) The recipient will hold the material in trust in its gene bank, periodically check it, and provide long-term conservation in compliance with all applicable statutes and regulations.
- 3) After placing into the gene bank, this material becomes a sample without market value.
- 4) The material will be used for not-for-profit research, education or for the breed reconstruction under the terms of the National Program on Farm Animal Genetic Resources, (reference number....., dated), hereinafter referred to as the “National Program”, only.
- 5) To the extent supplies are available; the provider agrees to make the material for purposes mentioned in the paragraph 3) under a separate Material Transfer Agreement having terms consistent with the terms of this Agreement, and refer any transfer of the material to the donor.

- 6) Unless prohibited by law, recipient assumes all liability for claims for damages against it by third parties, which may arise from the use, storage or disposal of the material except that, to the extent permitted by law, the donor shall be liable to the recipient when the damage is caused by the gross negligence or willful misconduct of the donor.
- 7) The material is provided at no cost - with a transmittal fee* solely to reimburse the donor for its preparation and distribution costs.
(If a fee is requested, the amount will be indicated here: [..... insert fee].)
-

7) * not accordant text be crossed out

The recipient must sign both copies of this Agreement and return one signed copy to the donor. The donor will then supply the material.

Recipient information and authorized signature

Recipient:

.....

Address:

Name of Authorized Official:

Title of Authorized Official:

Signature of Authorized Official:

Date:

EUROPEAN COMMUNITY AND ITS MEMBER STATES

Before the third and fourth meetings of the Ad-Hoc Open-Ended Working Group on Access and Benefit-sharing, the EU already submitted ample information on measures taken by the European Community and its Member States to support compliance with prior informed consent of the contracting party providing genetic resources and of ABS requirements established through mutually agreed terms. In addition, the EU would like to provide the following observations.

Further activities to raise awareness about Access and Benefit-sharing

The EU concurs with the preliminary assessment in document UNEP/CBD/WG-ABS/4/3 that highlights the lack of awareness among ABS stakeholders as one of the major impediments to the effective implementation of access and benefit-sharing frameworks.

In response, the European Community and EU Member States have continued their efforts to raise awareness of ABS issues, particularly amongst users of genetic resources in the EU. Some of the measures and steps that the EU has not previously reported on are briefly described in Annex 2 and 3 to this submission, as well as in the EU's submission to notification 2006-044 on experiences with the Bonn Guidelines.

Discussion on further international measures to enforce PIC and MAT in a trans-national context

CBD parties are currently discussing in the Ad-Hoc Open-Ended Working Group on Access and Benefit-sharing whether there is a need for additional legal measures to ensure that users of genetic resources comply with access and benefit-sharing requirements across different jurisdictions.

In this context, the EU would first like to reiterate its proposal regarding the disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications to the World Intellectual Property Organization as contained in document WIPO/GRTKF/IC/8/11. The EU considers this proposal as an element to support compliance with access and benefit-sharing requirements.

The EU is willing to engage in a substantive discussion on further measures to support compliance with PIC and MAT, not excluding legally binding ones. This could include work on an international definition of misappropriation and a related international obligation to prohibit the use of misappropriated genetic resources. However, a precondition for a discussion on such further measures is that, at the same time, efforts are undertaken to ensure that national access regimes fully conform to the CBD and the Bonn Guidelines and do not discriminate against foreign users of genetic resources. This will require the establishment of international minimum requirements on national access law and practice which serve as reference point for enforcement measures in user countries.

Select overview of recent measures taken by the European Community and its Member States to raise awareness amongst users of Genetic Resources on Access and Benefit-sharing and the Bonn Guidelines

Public research funders in Germany and France are undertaking work to request acceptance of guidance on access and benefit-sharing formulated within the CBD.

Further Member States have established **national web-portals** dedicated to Access and Benefit-sharing issues, particularly with a view to enhancing the ability of users of genetic resources to obtain pertinent information on ABS quickly and at low cost.¹

Further Member States such as **Belgium**² or **France** have undertaken extensive **consultations** with **users of genetic resources** to enhance awareness of Access and Benefit-sharing issues.

In November 2005, **Germany** held an **international user workshop** bringing together representatives from the research community, ex-situ collections and botanical gardens. At this meeting, different ABS compliance measures and activities adopted by botanical gardens and academic research institutions were presented. This meeting also demonstrated the need to consider existing instruments when designing new ABS policies.

In November 2006, a Nordic workshop was held for users from the **Nordic Countries**. The workshop concluded that further information as well as the development of tools to facilitate compliance with access rules is needed. A Nordic project to follow up on these conclusions will be considered in 2007.

Furthermore, **expert meetings** organised by the **Commission** and **Member States** involving users of genetic resources in the EU have become a regular feature of EU preparations prior to CBD meetings on Access and Benefit-sharing.

In part, as a consequence of the above-mentioned activities, users of genetic resources, like the pharmaceutical industry, the biotechnology sector, the botanical gardens and ex-situ collections have already developed or are in the process of developing and implementing **codes of conduct** that establish best practices on access and benefit-sharing for their respective areas of activity.

Belgian User Survey

In 2006, the Belgian DG Environment of the Federal Public Service Health, Food Chain Security and Environment has funded a survey on the extent of knowledge and use of the CBD provision on access and benefit-sharing (and in particular the Bonn Guidelines) by Belgian users of genetic resources.

The study, realised by Research Unit on Biodiversity of the Centre for Philosophy of Law of the Catholic University of Louvain (specialised in ABS issues), started in January 2006 and ended in June of the same year. The full title of this notice of tender is « *Marché relatif à l'analyse du degré de connaissance et de prise en compte par les acteurs belges des dispositions de la Convention sur la Diversité Biologique en matière d'accès aux ressources génétiques et de partage juste et équitable des avantages résultant de leur utilisation.* »

The objective of the study was to consolidate the Belgian ABS national and international policy, and to know the exact situation regarding ABS provision and genetic resources users in Belgium. This aimed at identifying specific measures that need to be taken in order to improve stakeholders involvement. To this end, information's on the subject were gathered from all Belgian potential actors involved in the exchange of genetic resources.

Within the scope of this study only those biological resources, whose **origin is not the Belgian Kingdom**, were studied. They include resources which were taken from their natural habitat (in-situ) or

¹ Netherlands; Germany: <http://www.defra.gov.uk/science/geneticresources>

<http://www.abs.biodiv-chm.de>;

United Kingdom:

² See Annex 3.

from ex-situ collections and on-farm cultivation outside the natural habitat. It does not include human material.

In depth surveys were realised within a sample of 400 random selected organisations. 57 answers were received, with a relatively homogeneous rate of answers throughout the 7 different sectors (Biotechnology, Research, Health, Biological Control, Collections, Agriculture and Processing Industries), with a under representation of the biotechnology sector and an over representation of the research and collections sectors.

Following issues were treated:

- the degree of awareness of the CBD by Belgian users;
- the degree of implementation of the CBD and the Bonn guidelines ABS provisions ;
- the existing institutional models and practices used in exchanging material.

A meeting of an ad hoc expert group of academics and user representatives (social sciences experts' representatives, conservators/distributors' representatives, users' representatives, and directors of national ABS surveys in other countries) was organised in the framework of the study (in June 2006) to discuss the interpretation of the results, the possible policy recommendations and cross-country comparison of the draft report for the Belgian ABS survey.

The main results of the study indicate that the CBD is well known in the collections and research sectors and that the implementation seems more spread for acquisition of PIC than for benefit sharing.

The study also proposes recommendations on **documenting the flow of resources and open access policies in user countries** related to the exchange of resources.

NORWAY

Norway refers to an earlier submission on the topic dated October 26, 2005.

Draft Act on the protection of the natural environment, landscape and biological diversity, including draft regulation on access to and benefit-sharing of genetic resources

As stated in this submission, an expert committee appointed by Royal Decree presented a draft Act on the protection of the natural environment, landscape and biological diversity in December 2004. A summary of the draft, concerning access to and benefit-sharing of genetic resources, was presented in our earlier submission.

The committee's draft Act has now been subject to a broad public hearing, and the government is now in the process of preparing a proposal of law to be presented to Parliament.

Draft Act on the management of living marine resources

June 9, 2005 an expert committee appointed by Royal Decree presented a draft Act on the management of living marine resources.

The committee's Draft Act proposes to regulate all utilization of wild marine resources and genetic material. It will apply to Norwegian internal waters, territorial sea and EEZ.

The proposal includes a chapter on marine bioprospecting and utilization of genetic resources. The marine bioprospecting will require a permit from the Norwegian Fisheries Directorate. General rules of precaution will apply, and more detailed rules will be established later.

According to the proposal, a permit can be given on the condition that parts of the benefits from the utilization of marine genetic resources shall be given to the Norwegian government and that results from the bioprospecting can only be used after consent from the government.

The committee's Draft Act has been on a public hearing, and the government is now in the process of preparing a proposal of law to be presented to Parliament.

The Norwegian Patents Act

Norway would once again like to refer to the earlier submission on the topic, dated October 26, 2005. In 2003 (entered into force February 2004) the Norwegian Patents Act was amended to address disclosure of origin.

A new para. 8 b) states that the patent application shall include information on the country from which the inventor collected or received the biological material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from in-situ sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether

such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall state this in the application.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents.

SWITZERLAND

Our response to that notification will be limited to some considerations of the feasibility to support compliance with prior informed consent.

In the current negotiation – notably in the coming Ad-Hoc Open-Ended Working Group on Access and Benefit-sharing - we will discuss the needs for additional legal measures to ensure that users of genetic resources comply with access and benefit-sharing requirements across different jurisdictions.

In this context, we would like to recall our proposal regarding the disclosure of the source of genetic resources in patent applications to the World Intellectual Property Organization (WIPO) which was reported already at several occasions within the frame of the CBD:

This proposal is described in the following web site address: <http://www.ige.ch/E/jurinfo/j105.shtm#6> with further observations and explanations regarding the declaration of the source.

Switzerland considers this proposal as an element to support compliance with access and benefit-sharing requirements.

THAILAND

Thailand's information, regarding measures taken to support compliance with prior informed consent and mutually agreed terms on which access was granted, where there is utilization of genetic resources or associated traditional knowledge are gathered and regulated under government agencies such as the Department of Agriculture, Ministry of Agriculture and cooperatives the major Act that is pertinent to the measures is the Plant Protection Act 1999 which stipulates the protection of both specific and general native plant and forest species. Department of Agriculture has set up a ministerial regulation concerning access to and utilization of such species. The money earned is deposited to the plant protection fund, which is intended to help and support activities related to the conservation, research and development of plant species. It is also shared with communities that conserve such plant species. The Department is developing guidelines, methods and conditions concerning applying for permits, collecting/gathering general native or forest plant species, and the agreement concerning benefit-sharing. Also, the Department is formulating guidelines and methods for community registration and registration of special native flora, including establishing national mechanism for exchanging data in order to enhance sustainable conservation and use of genetic resources for food and agriculture under a project of the Food and Agriculture Organization (FAO) of the United Nations.

As for the overall regulation on accessing and sharing the benefits of utilizing genetic resources, The Office of Natural Resources and Environmental Policy and Planning (ONEP) studied and evaluated relevant factors in 2004-2005 by looking into the present situation in Thailand and comparing it with relevant international agreements involving regulations and legislations in other countries. The legislation and mechanism for administration of biological resources by government agencies were also taking into account. The Office requested for comments from experts and involved persons and consequently formulated a Draft Regulation of the Committee on Conservation and Use of Biological Resources; concerning guidelines and share benefits from biological resources regulation. The objective is to set up standard guidelines and methods to access biological resources and sharing of benefits from utilizing genetic resources to gather relevant recommendations, the draft concerned agencies, such as National Park, Wildlife and Plant Conservation Department (DONP), Royal Forest Department (RFD), Department of Fisheries (DOF), Department of Livestock Development (DLD), Department of Agriculture (DOA) and universities, including the private sector. The draft will support the creation of awareness among all agencies and will create negotiating mechanisms for benefit-sharing from research on biological resource. In the past, the benefits were intended for a few persons and research institutes only not for the entire nation.

For standard guidelines and methods to access biological resources; the National Committee on Conservation and Sustainable Use of Biodiversity; under the chairmanship of the Natural Resources and Environment Minister is the committee responsible for supervising guideline and methods..

II. SUBMISSIONS FROM RELEVANT ORGANIZATIONS

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Members of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) welcome the decision from the eighth Conference of the Parties requesting information regarding business best practices. As stated in Decision VIII/17, paragraph 3, the Secretariat is requested to “compile information on the business case for biodiversity and good biodiversity practice, and to make this information available through the clearing-house mechanism.” Paragraph 5 of the Decision further invites business to “develop and promote the business case for biodiversity, to develop and promote the wider use of good practice guidelines, benchmarks, certification schemes and reporting guidelines and standards...”

The IFPMA is pleased to submit, with this letter, our Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization issued 7 April 2006. These Guidelines represent our industry’s commitment to compliance with existing legislation relating to access of genetic resources with full prior informed consent, as well as fair and equitable benefit-sharing. Note, however, that the Guidelines also call on Parties to enable our industry to comply through implementation of national laws on access and benefit sharing.

These guidelines reflect our Council’s decision that IFPMA is firmly against the taking of genetic resources without proper authorization. The guidelines also reaffirm IFPMA members’ support of all three objectives of the CBD, as well as our full engagement and participation in discussions relating to the development of an international regime on Access and Benefit Sharing.

We appreciate the Secretariat’s efforts to compile information on industry best practices and to ensure greater participation of industry stakeholders in all CBD negotiations. We look forward to working with you and the CBD Secretariat to achieve constructive progress in the CBD negotiations concerning access and use of genetic resources.

Guidelines¹ for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization Issued 7 April 2006.

I. INTRODUCTION

IFPMA members:

Supporting the objectives of the Convention on Biological Diversity (CBD) and recognizing the national sovereignty of States over biological resources,

Supporting and wishing to participate in the development of a regime on Access and Benefit Sharing (ABS), which would facilitate the sustainable use of genetic resources (GR) and, once clearly defined, associated traditional knowledge (TK) and regulate the rights and responsibilities of users and providers of such resources in a transparent way, taking into account related discussions and outcomes from other relevant international fora,

Aware of the important role the research-based pharmaceutical industry has to play as a stakeholder in informing policy decision-making related to this issue through its unique expertise and practical experience in managing the complex nature of the medical innovation process,

¹ The Guidelines list certain “best practices” which should be followed by companies which will engage in the acquisition and use of genetic resources.

Willing to participate in appropriate technical assistance, in coordination with the CBD Secretariat and CBD parties/observers or other appropriate organizations, to build the legislative, science and negotiating capacity of CBD parties,

Calling on CBD members to ensure continuing education and outreach efforts to facilitate capacity building, either independently or through a body such as WIPO, relating to the development of model and/or national legislation governing prior consent and benefit sharing laws, including model clauses for ABS agreements, keeping in mind that such laws should achieve a satisfactory balance between the conservation of biodiversity and encouragement of access to and use of GR in a way that would promote fair and equitable benefit sharing,

Propose concrete measures to facilitate implementation of CBD provisions relating to access to genetic resources and equitable sharing of the benefits arising out of their utilization and related traditional knowledge.

II. OBJECTIVE

International research-based pharmaceutical companies support a positive approach to CBD implementation consistent with other international obligations and agreements. Successful resolution of issues raised in various fora concerning Access and Benefit Sharing will enable industry to facilitate implementation of CBD provisions relating to access to genetic resources², and equitable sharing of the benefits arising out of their utilisation and reasonably related and clearly defined forms of traditional knowledge³ in the context of (i) CBD obligations on states to facilitate access and not impose restrictions on access that run counter to CBD objectives and (ii) the CBD recognition that access and benefits sharing should be on mutually agreed terms.

The following provides an outline of industry best practices and steps that CBD members should take in order to provide the legal environment necessary to allow such best practices.

III. INDUSTRY BEST PRACTICES

1. To obtain prior informed consent (PIC) to the acquisition and use of genetic resources controlled by a country/indigenous people and provided to the company in accordance with local law.
2. In obtaining PIC, to disclose the intended nature and field of use of the genetic resources.
2. To gain necessary approval to remove materials found *in situ*, and to enter into formal contractual benefit-sharing agreements reflecting the mutually agreed terms (MAT) on the use of the genetic resources obtained through that removal. These agreements may contain conditions on permissible uses of the genetic resources, transfer of the genetic resources to third parties, and appropriate technical assistance and technology transfers.

² Under the CBD, Conference of Parties COP Decision II/11, para. 2, human genetic material is excluded from the scope of the CBD. In addition, materials removed from *in situ* locations prior to 1992 also fall outside the remit of the CBD.

³ As recognized by the recent European Community and Member States Proposal to WIPO: “there are concerns about the possibly unclear scope of the term ‘traditional knowledge’. In order to achieve the necessary legal certainty, a further in-depth discussion of the concept of TK is necessary.” Source: http://www.wipo.int/tk/en/genetic/proposals/european_community.pdf

4. To avoid taking actions, in the course of use or commercialization of genetic resources obtained as specified under these commitments that impede the traditional use of such genetic resources.

5. To agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between the parties.

IV. ENABLING STEPS BY GOVERNMENT

1. Actual enactment of national legislation implementing the CBD.

2. Establishment of Focal Points.

Such national focal points should establish clearly which indigenous groups or other stakeholders possess rights to authorize access to particular genetic resource(s) *in situ* within any CBD member. This would provide transparency and legal certainty to industry and to other interested parties. Such focal points may wish to establish databases recording the existence of genetic resources and its uses.

3. Commitment to enter into good faith negotiations as to the terms of access and benefit sharing contracts with commercial entities.

4. Agreement on dispute resolution as outlined in point III.5. above.
