



ENVIRONMENTAL
LAW • INSTITUTE®

ENVIRONMENTAL LAW INSTITUTE
RESEARCH REPORT

Protecting Biodiversity:

Legal Mechanisms Concerning
Access to and Compensation for
the Use of Genetic Resources in
the United States of America

1998

**PROTECTING BIODIVERSITY:
LEGAL MECHANISMS CONCERNING
ACCESS TO AND COMPENSATION FOR
THE USE OF GENETIC RESOURCES
IN THE
UNITED STATES OF AMERICA**

**Copyright © 1998
Environmental Law Institute®**

Acknowledgments

This report was prepared by the Environmental Law Institute with financial support from the Tinker Foundation Incorporated, the John D. and Catherine T. MacArthur Foundation, and the Global Environment Facility. ELI staff contributing to this report were Susan Bass, Susan Casey-Lefkowitz, Jessica Jacoby, James McElfish, Sergio Mujica, Elissa Parker, Byron Swift and Jill van Berg. Former ELI staff members Martha Aldana, Nancy Golubiewski and Lorenzo de la Puente also assisted in the project. ELI also acknowledges the numerous people who provided additional information and assistance in preparation of this report.

Legal Mechanisms Concerning Access to and Compensation for the Use of Genetic Resources in the United States

Copyright © 1998 Environmental Law Institute ®. All rights reserved.
ELI Project #913015, 913317, 952005, 971400, ISBN #0-911937-77-3

(Environmental Law Institute®, the Environmental Forum®, ELR®, and the Environmental Law Reporter® are registered trademarks of the Environmental Law Institute.)

Preface

This report is part of a collaborative effort of eight environmental law centers in the Americas to address one of the fundamental conditions threatening the biodiversity of the Americas: the absence of adequate national laws regulating access to and compensation for the use of local genetic resources. The Environmental Law Institute's original partners in the project included: Asociación de Abogados Ambiental (AAA-Paraguay); Canadian Institute for Environmental Law and Policy (CIELAP-Canada); Centro de Derecho Ambiental y de los Recursos Naturales (CEDERENA-Costa Rica); Estudios de Estructura y Administración del Estado (ESTADE-Ecuador); Fundación Ambiente y Recursos Naturales (FARN-Argentina); Fundación para la Defensa del Interés Público (FUNDEPUBLICO-Colombia); and Sociedad Peruana de Derecho Ambiental (SPDA-Peru). Fundación Ambio (Costa Rica) later joined the project to prepare the Costa Rica case study, and the IUCN Environmental Law Centre in Bonn provided the international context for the project. Through a comparative analysis of each country's national legislation, the preparation of publications, and public outreach activities, the groups have sought to promote the development and implementation of effective national systems for regulating access.

The project was conceptualized at a workshop hosted by the Fundación Ambiente y Recursos Naturales in Buenos Aires during the 1994 IUCN General Assembly. The common methodology for the national case studies was later developed at a meeting hosted by ESTADE in the fall of 1995. After the national case studies were prepared, SPDA developed a chart comparing key aspects of the case studies. In May 1997, the groups met in Peru to discuss and develop common findings. A number of outreach activities were then conducted, including seminars in Canada and Paraguay, hosted by CIELAP and AAA, respectively. The International Development Research Centre in Canada has agreed to publish a summary of the case studies and the comparative charts and expects to make them available in English and Spanish in early 1999.

Table of Contents

Preface

Introduction i

Chapter One: Legal Status of Genetic Resources - Ownership and Sovereignty 1

A.	Terrestrial and Aquatic Areas	2
1.	Public Ownership	2
2.	Private Ownership	10
3.	Indigenous Ownership	11
B.	Marine Areas	13
1.	Public	15
	(a) Federal Government	15
	(b) State government	19
2.	Private Ownership	21
3.	Indigenous Interests	21
C.	Ex situ Collections	22
1.	Public Ownership	22
2.	Private Ownership	27

Chapter Two: Access to Genetic Resources 29

A.	Terrestrial and Aquatic Areas	29
1.	Public Ownership	29
2.	Private Ownership	36
3.	Indigenous Ownership - Access Issues	40
B.	Marine Areas	42
1.	Public	42
	(a) Federal Government Areas	42
	(b) State Government Areas	47
2.	Private	48
3.	Indigenous	48
C.	Ex situ Collections	49
1.	Public Ownership - Access Issues	49
2.	Private Ownership - Access Issues	51

Chapter Three: Benefits Derived from Access to Genetic Resources 53

A.	Terrestrial and Aquatic Areas	53
1.	Public - Federal	53
2.	State, Private, Indigenous	57

3.	Intellectual Property Rights in Genetic Resources	58
B.	Marine Areas - Benefits	63
1.	Public	63
	(a) Federal	63
	(b) States	65
2.	Private	65
3.	Indigenous	65
C.	Ex situ Collections - Benefits	65

Chapter Four: Measures to Conserve And Sustainably Use Genetic Resources 67

A.	Terrestrial/Aquatic Areas	67
1.	Public Lands - Federal and State	67
2.	Private Lands	70
3.	Indigenous Lands	72
B.	Marine Areas	73
1.	Public	73
	(a) Federal	73
	(b) State	75
2.	Private	75
3.	Indigenous	76
C.	Ex situ Collections - Conservation	76

Conclusion 79

A.	Mechanisms for Benefit-Sharing on Public Lands and Waters	79
B.	Measures for Conservation and Sustainable Use on Public and Private Lands and Waters	80
C.	Managing Ex situ Collections to Support National Regimes on Access	81
D.	Providing for Access to Genetic Resource on U.S. Indigenous Lands	81

Acronyms

ANILCA	Alaska National Interest Lands Conservation Act
APHIS	Animal and Plant Health Inspection Service
ARS	Agriculture Research Service
BLM	Bureau of Land Management
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CPC	Center for Plant Conservation
CRADA	Cooperative Research and Development Agreement
EA	Environmental Assessment
EFH	Essential Fish Habitat
EFP	Exempt Fishing Permit
EIS	Environmental Impact Statement
ESA	Endangered Species Act
FMP	Fishery Management Plan
FTTA	Federal Technology Transfer Act
FWPCA	Federal Water Pollution Control Act
FWS	U.S. Fish and Wildlife Service
IPGRI	International Plant Genetic Resources Institute
LWCF	Land and Water Conservation Fund
MIRCENS	Microbial Resources Centers
MMPA	Marine Mammals Protection Act

NAGP	National Animal Genome Program
NAGRP	National Animal Genome Research Program
NCI	National Cancer Institute
NEPA	National Environmental Policy Act
NFTGRP	National Forest Tree Genetic Resources Program
NGRDSP	National Genetic Resources Database Support Program
NGRP	National Genetic Resources Program
NIGRP	National Insect Genetic Resources Program
NMGP	National Microbial Germplasm Program
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPGS	National Plant Germplasm System
NSSL	National Seed Storage Library
OCS	Outer Continental Shelf
OPA	Oil Pollution Act
PCT	Patent Cooperation Treaty
PVPA	Plant Variety Protection Act
SSE	Seed Savers Exchange
UPOV	International Convention for the Protection of New Varieties of Plants
USDA	U.S. Department of Agriculture

Introduction

In June 1992, over 150 nations, including 30 from the Americas, made a historic commitment to protection of biodiversity by signing the Convention on Biological Diversity (Convention).¹ The Convention promoted three inter-related goals: the conservation of biological diversity; the sustainable use of its components; and the equitable sharing of benefits from the use of genetic resources. One of the innovative policy tools provided by the Convention for achieving these goals is an international policy framework for regulating access to genetic resources and the sharing of benefits derived from those resources. The Convention also sets out related measures for the conservation and sustainable use of biodiversity.

The United States became a signatory to the Convention in 1993. However, the Convention is not in force in the United States, because it has not yet been ratified by the Senate.² Nevertheless, it is useful for several reasons to determine how existing U.S. laws can be used to implement the portions of the Convention that deal with access to, and compensation for, the use of genetic resources, as well as where there are gaps or conflicts in the laws that could affect implementation. First, U.S. policy makers may decide to support the goals of the Convention independently of, or in preparation for, ratification of the Convention by implementing the access provisions. Second, the U.S. may decide that access mechanisms are necessary to compete commercially with other countries that have such regulations in place. Finally, the U.S. may move to adopt such measures so as not to undermine the use of access regimes in other countries.

The key principles for national regimes on access are set forth in Article 15 of the Convention. The Convention recognizes the "sovereign rights of States over their natural resources," and states that national governments have the authority to determine access to genetic resources.³ The concept of sovereignty and the ability of the

¹ United Nations Convention on Biological Diversity, done at Rio de Janeiro, 5 June 1992, entered into force on 29 December, 1993 (hereinafter the "Biodiversity Convention"). The term "biological diversity" means the "variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." Biodiversity Convention, Art. 2. For a general discussion of approaches on implementing this policy framework, see L. Glowka, A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, Environmental Policy and Law Paper No. 34 (IUCN - Environmental Law Centre 1982).

²U.S. Constitution, Art. II, Section 2, requires a ratification of treaties by a 2/3 vote of the Senate. Absent ratification, the Convention has the status of an Executive Agreement. This means that the federal executive agencies of the United States are expected to conform with the Convention to the extent possible within the performance of their *legal functions*, but the Convention is not binding upon them in the performance of their non-discretionary duties and compliance cannot be compelled by a court. Because a treaty is not in force until it is ratified, the Convention is not recognized as law in the federal and state courts and legislatures, nor does it govern the conduct of private persons or organizations.

³Biodiversity Convention, Art. 15.

national government to regulate genetic resources are intertwined with issues of ownership. Thus, the first area this study examines is the legal status, in terms of sovereignty and ownership, of genetic resources.

A second important principle is that of consent to access. Access to genetic resources, according to Article 15, is to be "on mutually agreed terms" and "subject to the prior informed consent of the Contracting Party providing such resources unless otherwise determined by that Party."⁴ At the same time, parties are to "endeavor to create conditions to *facilitate* access . . . for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of [the] Convention."⁵ Accordingly, the second section of this study examines existing regulations on access. Since the U.S. operates under a federal system, laws at the national, state, and local level are surveyed. The rights of private parties and indigenous communities to control access also are considered.

A third principle is that of equitable sharing of benefits from the use of genetic resources. Each Contracting Party is required to take legislative, administrative, or policy measures with "the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources."⁶ Other benefit-sharing provisions in the Convention address access to the results and benefits arising from biotechnologies based upon the genetic resources provided,⁷ access to and transfer of technologies that make use of those resources,⁸ and participation in scientific research based on those resources.⁹ The third section of this study reviews existing benefit-sharing mechanisms under U.S. law. Although not specifically required by the Convention, the study also examines mechanisms for the sharing of benefits with the peoples or local communities where the resources were discovered.¹⁰

⁴Biodiversity Convention, Art. 15.4, 15.5.

⁵Biodiversity Convention, Art. 15.2.

⁶Biodiversity Convention, Art. 15.7.

⁷Biodiversity Convention, Art. 19.2.

⁸Biodiversity Convention, Art. 16.3.

⁹Biodiversity Convention, Art. 15.6.

¹⁰Article 8(j) of the Biodiversity Convention calls on the Contracting Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." Benefit-sharing measures for local communities may also

A fourth principle concerns conservation and sustainable use. According to Article 10(b), parties are "as far as possible and as appropriate" to take measures to avoid or minimize harm to biological diversity from the use of biological resources. Accordingly, access mechanisms themselves need to provide for conservation and sustainable use of the targeted genetic resources, or independent laws on conservation and sustainable use should provide such protection. Thus, the fourth section of this study focuses on requirements under U.S. law for conservation and sustainable use of genetic resources.

support the conservation objectives of the Convention. Biodiversity Convention, Art. 11.

Chapter One:



Legal Status of Genetic Resources - Ownership and Sovereignty

Ownership issues are closely tied to the legal jurisdiction of the respective governmental entities over biological diversity and natural resources in the United States. The United States is a federal system in which sovereignty resides both in the federal government and in the fifty state governments. As a matter of constitutional law, the federal government has only those powers that are specifically identified in the federal Constitution. Over the years, these powers have been interpreted expansively by the courts, most notably the federal government's power to regulate interstate and international commerce.¹¹ The Constitution also provides that, in the event of a conflict between state law and federal law, federal law is supreme.¹² Among the forms of federal law expressly recognized in the Constitution are "all treaties made, or which shall be made, under the authority of the United States."¹³ Thus, the Convention, once ratified, will bind both federal and state governments.

In contrast with the federal government's specifically identified powers, state governments have general powers to provide for public health, safety, and welfare. Thus, states may enact laws on virtually any subject. However, states also have their own constitutions that may limit these powers, and, as noted, are subject to certain limitations under the federal Constitution. Local governments are regarded as creatures of the state and derive their powers from state law.

The federal government -- and not the states -- has full legal power to deal with and determine the rights of indigenous peoples.¹⁴ Lands and waters related to indigenous peoples are administered in special ownership status with some federal supervision. Federally-recognized Indian tribes exercise a limited form of sovereignty over their own members and their own lands, although all indigenous peoples are also citizens of their state and the nation.

¹¹U.S. Constitution, Article I §8.

¹²U.S. Constitution, Article VI.

¹³*Id.*

¹⁴U.S. Constitution, Article I §8.

A. Terrestrial and Aquatic Areas

Terrestrial and freshwater biological diversity are important in the United States, a nation with substantial habitat diversity. Genetic resources exist on public, private, and indigenous-owned lands and waters throughout the United States. This covers an area of 3.6 million square miles, including inland waters. Although there is no comprehensive inventory of species diversity, substantial information is available on the distribution and conditions of biological resources.¹⁵

U.S. forests are home to more species listed as threatened and endangered than other terrestrial habitat types, while wetlands are associated with over 30 percent of such listed animals and 15 percent of listed plants. Prairies, savannas, coastal sage-scrub, and other habitats are also genetically rich but imperiled by a variety of human activities. Hawaii, a biologically unique island state, is particularly threatened with destruction and displacement of native species.¹⁶ Freshwater environments are home to many species of threatened and endangered mussels and several unique invertebrates. Other habitats, including caves and hot springs, provide unique environments with high degrees of endemism.

1. Public Ownership

Federal Ownership and Sovereignty

Under the U.S. Constitution, the federal government has absolute authority to make laws governing the lands and resources that it owns. This section describes the basic legal and institutional structure for management of federal lands and freshwater resources.

The federal government owns approximately 1/3 of the land surface of the United States -- approximately 650 million acres.¹⁷ Federal ownership is greatest in the states west of the Mississippi River, including Alaska (the state containing the greatest amount of federally-owned acreage). The federal government also owns lands in the

¹⁵See generally, National Biological Service, Our Living Resources (1995).

¹⁶Reed Noss and Robert Peters, Endangered Ecosystems (1995) at 8, 30-31.

¹⁷Figures on acreage in this report are from the General Accounting Office, Land Ownership: Information on the Acreage, Management, and Use of Federal and Other Lands, GAO/RCED-96-40, (March 1996).

eastern states.¹⁸ Federal lands are administered by a wide range of agencies. Congress has enacted separate laws defining the terms under which each of these agencies can manage their lands. Most agencies also have adopted regulations further defining their management authority.

The largest land management agency is the Bureau of Land Management (BLM), part of the Department of the Interior. BLM manages some 267 million acres of federal lands in the western U.S. that are generally referred to as the "public domain." Federal law requires management of the public domain for "multiple use" -- a term that means management for a "combination of balanced and diverse resource uses that takes into account the long-term needs of future generations for renewable and nonrenewable resources, including, but not limited to, recreation, range, timber, minerals, watershed, wildlife and fish, and natural, scenic, scientific and historical values."¹⁹

Most BLM lands are open to any public use by any person except where the use is expressly prohibited by law.²⁰ Some uses are also conditioned by permit or lease. These public domain lands are presumptively open to private collection and exploitation of genetic resources, unless and until a prohibition or limitation is imposed. Once a material (minerals, water, timber, forage) is severed lawfully from the public domain, it is owned by the collector and may be used, sold, or otherwise disposed of.²¹ BLM has the authority to impose various limitations, and certain laws directly impose limitations (such as bans on the unpermitted collection of archeological resources, the harvesting of timber without a lease, or grazing without a grazing permit). BLM also has general authority to adopt regulations to prevent "unnecessary or undue degradation" of the public domain.²²

¹⁸Federal ownership is greater in the west because these states achieved statehood during the period when federal policies changed from an attempt to dispose of all lands into private hands to a policy of retaining certain lands in federal ownership. Most of the eastern lands were acquired by purchase from private owners - primarily in the 20th century.

¹⁹Federal Land Policy Management Act, 43 U.S.C. § 1702(c). Grazing, timbering, mineral exploration, mining, recreation, wilderness, and certain other uses are specifically authorized under a variety of public land-use laws.

²⁰See *United States v. Curtis-Nevada Mines, Inc.*, 611 F. 2d 1277, 10 ELR 20191 (9th Cir. 1980).

²¹However, lawful use of the public domain is not itself an ownership interest; the BLM or Congress may terminate the user's access. *Osborne v. United States*, 145 F. 2d 892 (9th Cir. 1944).

²²Federal Land Policy Management Act, 43 U.S.C. § 1732.

The U.S. Forest Service, part of the Department of Agriculture, manages many federally owned forests and grazing lands. These lands, approximately 192 million acres, are generally managed for multiple use under the Multiple Use Sustained Yield Act, which includes management for "outdoor recreation, range, timber, watershed, and wildlife and fish purposes."²³ National Forests also are managed under the National Forest Management Act, which provides for the preparation of forest management plans that allow for multiple uses of the lands and resources in the national forest system.²⁴ Activities on forest lands that involve removal of materials, such as timber, firewood and forage, require a special use permit, grazing permit, contract, or other authorization from the Forest Service. The public has general access to these lands for recreation.

The U.S. Fish & Wildlife Service, part of the Department of the Interior, manages wildlife refuges covering approximately 87 million acres. The refuges must be managed primarily for the benefit of fish and wildlife. Several other uses are permitted, so long as they are "compatible" with the purpose for which the refuge was established.²⁵ Access to refuges, and uses of refuges, are controlled by regulations and use permits. Activities involving genetic resources (particularly if these involved wildlife resources) would probably require a "compatibility" determination by the Service before they could occur.

The National Park Service manages the national parks -- 368 units comprising 77 million acres. Unlike the other federal lands, park lands are not multiple use lands, but must be managed for conservation and "to provide for the [public] enjoyment . . . in such manner and by such means as will leave them unimpaired for the enjoyment of future generations."²⁶ Collection and removal of materials from a park is unlawful unless specifically authorized by the National Park Service. Hunting of wildlife is prohibited in the parks.²⁷ Fishing is generally authorized.

²³16 U.S.C. § 528.

²⁴16 U.S.C. §§ 1600-1614. Mining and oil & gas development is authorized in certain national forests, subject to a system of permits and/or leases.

²⁵Refuge System Act, 16 U.S.C. § 668dd(d)(1)(A); 50 CFR § 29.1.

²⁶16 U.S.C. § 1.

²⁷36 CFR § 2.2. There are limited exceptions where Congress has specifically authorized it.

Federal laws also provide for the designation by Congress of wilderness areas within National Parks, National Forests, National Wildlife Refuges, and public domain lands. Wilderness lands remain under the management of the agency that managed them prior to the wilderness designation, but uses are strictly controlled. Wilderness must be "protected and managed so as to preserve its natural conditions," and the effect of human influence is to be "substantially unnoticeable."²⁸ Construction of roads and use of motorized vehicles -- either on- or off-road -- within wilderness areas are prohibited.²⁹ Extractive uses, such as mining and timbering, are also prohibited; however, grazing under existing permits and mining of valid existing mining claims are authorized.³⁰ Collection of genetic resources is not flatly prohibited by the Wilderness Act, but the techniques and intrusiveness of the collection process could be problematic because of the paramount requirement for managing wilderness intact.³¹

The Bureau of Reclamation (part of the Department of the Interior) and the U.S. Army Corps of Engineers manage certain dams, reservoirs, and water distribution and irrigation facilities. Some of the reservoirs and adjacent water project lands are managed for multiple uses -- primarily for irrigation, flood control, water supply, hydropower generation, and recreation.

Several other agencies manage federal lands. The Department of Defense manages approximately 30 million acres of military lands and the Department of Energy manages a smaller land area, approximately 2.3 million acres, for weapons production and testing facilities. Access to Department of Defense and Department of Energy lands is generally tightly controlled. However, some of the Department of Defense lands include management for fish and wildlife in cooperation with states and the U.S. Fish & Wildlife Service. Access to these fish and wildlife resources on Department of Defense facilities is controlled on a cooperative basis by the agencies.³²

²⁸16 U.S.C. § 1131(c).

²⁹16 U.S.C. § 1133(c).

³⁰Wilderness Act, 16 U.S.C. §§ 1131-1136.

³¹"Each agency administering any area designated as wilderness shall be responsible for preserving the wilderness character of the area . . . Except as otherwise provided in this Act, wilderness areas shall be devoted to the public purposes of recreational, scenic, scientific, educational, conservation, and historical use." 16 U.S.C. § 1133(b).

³²Sikes Act, 16 U.S.C. § 670h.

The federal government has dominant regulatory power over the navigable waters of the United States derived both from the common law "navigation servitude" and the constitutional power to regulate interstate commerce.³³ The federal government's power is not limited to maintaining navigability, but extends to anything that may affect interstate commerce, including privately-owned waters and related lands.³⁴ However, the beds of navigable rivers and streams are owned by the states.³⁵

Despite this paramount *regulatory* jurisdiction over navigable waters, the federal government is only an ordinary *owner* of water incidental to its ownership of federal lands. Federal government ownership of water is determined in the same way as that of any private land owner -- under state laws.

Two different legal systems are used by the states to determine ownership of waters: the riparian system and the prior appropriation system.

Under the riparian system, owners of land adjacent to a body of water -- such as a river or lake -- are entitled to make "reasonable use" of the water while allowing all other riparian owners reasonable use. This system is used primarily in the eastern U.S. where water is more plentiful. In the east, ownership of ground water is also usually determined on the basis of riparian rights if the water is believed to flow in underground channels. Ground water that is more dispersed, however, is deemed to belong to the owner of the land surface above the water -- again subject to a condition of reasonable use that does not impair the uses of adjacent land owners.

In the more arid western U.S., where most federal lands are located, the "prior appropriation" doctrine is more often used. This doctrine is often summarized as "first in time, first in right." The first land owner to use water for a beneficial (productive) use is entitled to use that amount of water in perpetuity. The prior appropriation doctrine applies to ground water as well as to surface water. When there is a shortage of water, the senior users are permitted to use all of their allocation before the junior users get any water. A water rights owner (and its successors) can lose a water right only if the

³³The federal "navigation servitude" is sometimes also attributed to national sovereignty considerations. *Scranton v. Wheeler*, 179 U.S. 141 (1900); *U.S. v. Cherokee Nation of Oklahoma*, 480 U.S. 700 (1987).

³⁴For example, the federal government's authority to regulate discharges of material into wetlands on private lands is based on the constitutional power to regulate commerce. *Federal Water Pollution Control Act*, 33 U.S.C. Section 1344; *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121 (1985).

³⁵See discussion accompanying notes 45-46, *infra*.

owner fails to use the water. In "prior appropriation" jurisdictions, the doctrine of federal "reserved water rights" can be important. This doctrine holds that when the federal government specifically creates a designated use of the public lands -- such as designation of a park or wildlife refuge from the public domain -- it is deemed to have "reserved" enough water to support that particular use as of the date of the designation. However, while this reserved right may be senior to that of subsequent users, it is junior to the rights of water users using water prior to the designation.

U.S. law is not conclusive on whether ownership of water rights also confers the rights to genetic materials that might be found in the water. Fish and wildlife, as *ferae naturae*, do not belong to the owner of water rights. Submerged vegetation, mussels and other things affixed to the river bed or lake bed, clearly belong to the states and not to the federal government or a private owner, although they can be disturbed by the federal government pursuant to the navigation servitude.³⁶ It is not clear whether the owner of water rights can claim ownership of bacteria or other material suspended in the water, but in the absence of any regulatory prohibition, this is likely.

The federal government has absolute authority over wildlife on federal lands, but it may defer to state wildlife regulation where such regulation is consistent with federal objectives. The federal government also has power to control the taking or sale of wildlife, whether or not on federal lands, under its commerce power.³⁷ However, state governments usually take the leading role in regulating wildlife-related activities on state and private lands. The federal government has enacted a variety of wildlife-related laws, ranging from prohibitions on the "taking" of threatened and endangered species,³⁸ to prohibitions on transactions involving wildlife or plants taken in violation of state, federal, or international law.³⁹ The federal government also has regulated activities affecting wildlife species in laws implementing international treaties.⁴⁰

³⁶See discussion accompanying notes 33-35, *supra*.

³⁷*Hughes v. Oklahoma*, 441 U.S. 322 (1979).

³⁸Endangered Species Act, 16 U.S.C. §§ 1531 *et seq.*

³⁹Lacey Act, 16 U.S.C. § 3372.

⁴⁰*E.g.*, Migratory Bird Treaty Act, 16 U.S.C. § 701 *et seq.* In the same way, the Endangered Species Act, 16 U.S.C. § 1537, helps implement the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

In addition to its regulatory authority over wildlife and fish, endangered species of plants and animals, and commerce in these items, the federal government, along with states and tribal governments, has authority as a "natural resources trustee" to collect damages for the destruction or impairment of living resources by oil spills or toxic contamination. Federal laws also authorize expenditure of the funds collected as damages for rehabilitation of the resources.⁴¹

Despite this recognition of trusteeship, it is doubtful that the federal government could successfully maintain that it has a public ownership right in all genetic resources. For the most part, even common resources such as air, water, and wildlife are not automatically assumed to be federally owned.⁴² Indeed, the United States never adopted the civil law practice of assigning all mineral rights to the government. Thus, while federal *regulatory* jurisdiction over genetic resources undoubtedly is feasible, federal *ownership* of such resources may not exist, except on federal lands and waters.⁴³

⁴¹The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Oil Pollution Act (OPA) provide for recovery of "damages for injury to, destruction of, loss of, [or loss of use of, - OPA only] natural resources, including the reasonable costs of assessing [the damage]." Recovery is by the federal government, a State government, an Indian tribe, or (in the case of the OPA only) a foreign government. 33 U.S.C. § 2702(b)(2)(A); 42 U.S.C. § 9607(a)(4)(C). The government responsible for collecting the damages is determined on the basis of whether the damaged natural resource is owned, managed, controlled, or "appertains" to that government. 33 U.S.C. § 2706(a); 42 U.S.C. § 9607(f)(1).

⁴²The federal government has asserted plenary jurisdiction over certain diffuse common resources using its Constitutional power to *regulate* commerce. For example, the federal government has total regulatory power over the airways for purposes of allocating and controlling aircraft use. Similarly, the federal government has total regulatory power over the electromagnetic spectrum in order to allocate and regulate access for radio, television, common carrier, and other uses. Indeed, this assertion of jurisdiction has gone so far that in recent years the federal government has auctioned off portions of the spectrum that recently became available, and retained the proceeds just as if it were the "owner" of the spectrum. Despite these examples, it is not clear that the federal government could declare a public sovereignty right in the "genetic resources" of the nation and then *sell* the rights to exploit these resources (while allowing the ordinary owner of the plant, animal, fish, insect, or bacterium to own it for other purposes). Although such a course of action might be constitutionally permissible, it would impinge upon the general presumption in favor of private ownership. It might also be a "taking" of private property rights for which just compensation might need to be paid under the Constitution. U.S. Constitution, Amendment V: ". . . nor shall private property be taken for public use without just compensation." It would also be inconsistent with the previous assignment of some of these rights to private entities through such means as recognition of intellectual property rights in gene patenting.

⁴³Article 15, § 1 of the Biodiversity Convention provides: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." The U.S. federal government's "sovereign rights" over resources on private lands include only the right to regulate commerce involving such resources.

State Ownership

State governments also own lands and waters, including state highway rights-of-way, state parks and forests, and state government campuses and buildings. Hundreds of millions of acres are owned by states, and include approximately 40 million acres set aside for conservation and recreation purposes. Approximately 8 million acres are owned by counties and cities for parks and recreational purposes.⁴⁴ States have plenary authority to manage their lands.

In some western states, several million acres are "state trust lands." These trust lands were granted to these states upon their admission to statehood and must be managed by the state to produce income to support schools or other designated uses; these lands are typically managed for sale of timber and for lease of grazing rights.

States also own the beds of the nation's streams and rivers. "[U]pon the admission of a state to the Union, the title of the United States to lands underlying navigable waters within the state passes to [the state] . . . and is subject only to the paramount power of the United States to control such waters for purposes of navigation in interstate and foreign commerce."⁴⁵ In other words, the states own the beds of navigable streams, rivers, and lakes. This ownership interest is sometimes identified as the "public trust" -- an attribute of sovereignty peculiar to the states. Because these submerged lands are held in trust for the public, they may not be sold -- although they may be leased, or certain other activities involving these lands may be conducted for the benefit of the state's citizens.⁴⁶ The states may have the best claim to ownership of genetic materials found in the waters above or on these submerged lands, and are the owners of the submerged vegetation and shellfish affixed to these lands.

⁴⁴President's Commission on Americans Outdoors, Americans Outdoors: The Legacy, the Challenge at 61 (1987). A recent study identified 142 million acres of lands owned by just 13 western states, including 89 million acres owned by the state of Alaska. General Accounting Office, Land Ownership: Information on the Acreage, Management, and Use of Federal and Other Lands, GAO/RCED-96-40 (March 1996).

⁴⁵United States v. Oregon, 295 U.S. 1, 14 (1935); *see also* Phillips Petroleum Co. v. Mississippi, 484 U.S. 469 (1988).

⁴⁶Illinois Central Railroad Co. v. Illinois, 146 U.S. 387 (1892); Phillips Petroleum Co. v. Mississippi, 108 S. Ct. 791 (1988). *See* David B. Hunter, "An Ecological Perspective on Property," 12 Harv. Env. L. Rev. 311, 369-370 (1988) (state limitations on alienability of public trust lands).

However, in some states, owners of lakeshore property (littoral owners) are the owners of the lakebeds -- usually in instances where the lakes are not very large, not connected to other navigable waters, or are deemed non-navigable under state laws.⁴⁷

States have a substantial role in the management of fish and wildlife. They own many of the lands upon which hunting and fishing occur. States also prescribe the terms under which animals and fish may be taken on private lands. As *ferae naturae*, fish and wildlife are not "owned" by the state or indeed by anyone until they are lawfully taken. Under the common law, however, wildlife and fish are deemed to be held in trust for the people by the state.⁴⁸

States set the terms and lengths of hunting and fishing seasons, bag limits, restrictions, moratoriums, and other related provisions. States have authority to prohibit a land owner from taking wildlife or fish even on the owner's land and for the land owner's own use. Although states have primary jurisdiction over fish and wildlife, the federal government (as noted above) also has substantial power.⁴⁹ Thus, for example, one cannot shoot migratory waterfowl in the United States without both a state hunting license and a federal permit ("duck stamp").⁵⁰ States also have authority to enact laws for the protection of plants, nongame animals, and endangered or threatened species existing within that state.

2. Private Ownership

Most lands in the United States are in private ownership -- owned by individuals and corporations. The general legal rule is that the private owner of lands also owns the plants found upon the lands,⁵¹ and may reduce to possession the animals on the land unless they are protected by state or federal wildlife laws. In general, absent a specific prohibition, a private property owner may collect and exploit any genetic material found on that owner's land, and may sell or lease the right to collect and exploit such material.

⁴⁷Obrecht v. National Gypsum Co., 105 N.W.2d 143 (Mich. 1960).

⁴⁸Martin v. Waddell's Lessee, 41 U.S. (16 Pet.) 367 (1842).

⁴⁹Under the Supremacy Clause of the U.S. Constitution, state law must give way if there is a conflicting federal law. U.S. Constitution, Art. VI.

⁵⁰16 U.S.C. §§ 718-718h.

⁵¹*Fructus naturalis* are the property of the land owner. See G. Thompson, Commentaries on the Modern Law of Real Property, 393-451 (1964). A similar rule applies to crops.

The most significant limitation on this right is the power of the government to enact specific laws which protect certain species or resources from taking, exploitation, or commercial use. A variety of federal and state laws restrict activities concerning particular species. Such laws include the federal Endangered Species Act, other federal laws protecting migratory birds and marine mammals, and state laws protecting endangered species, regulating the taking of game species, and setting limits on the scale of some timber harvests.

Private property is subject to the power of eminent domain -- the power of the federal and state governments to take property from private owners for public use, such as to establish parks or other areas for the conservation of species. Eminent domain is seldom used except for takings of private lands and waters in order to provide necessary public services. The U.S. Constitution requires the government exercising eminent domain to compensate the owner for the full value of the property that is taken; property may not be taken without such payment.⁵² Eminent domain cannot be used to take title to a whole classification of goods or resources; it must specify each property that is to be taken. The eminent domain power of federal and state governments is conceivably relevant to genetic resources, but its use in this area would be unusual.⁵³

3. *Indigenous Ownership*

The laws governing indigenous lands (Indian lands) in the United States are quite complex. Indian lands are not limited to unified reservations with clear exterior boundaries that enclose lands owned only by the tribe and its members. While some reservations conform to this pattern, others consist of a "checkerboard" of tribal land, federal land, private land owned by tribe members, and private land owned by non-Indians or non-tribe members. Indian tribal governments exercise sovereignty over their own members, and over many activities occurring within reservation boundaries.

⁵²U.S. Constitution, Amendments 5 & 14.

⁵³The federal power of eminent domain is limited to purposes enumerated in the Constitution. The most important powers for federal eminent domain purposes are providing for the national defense, and the power to regulate commerce. Eminent domain has been used by the federal government, for example, to acquire lands and waters for dams and reservoirs, for national parks, and for public highways. State governments may exercise eminent domain to take property for any public purpose, limited only by what the state constitution may provide. Local governments are usually given eminent domain powers by state legislatures for only a few purposes -- such as road and public building construction, and for redevelopment of blighted urban areas.

However, tribal authority over activities by non-Indians on privately-owned lands within reservation boundaries is limited in scope.⁵⁴

Much Indian land -- whether communally held by a tribe, or individually owned by Indian allottees -- is held subject to a "trust" relationship administered by the federal government.⁵⁵ Approximately 52 million acres, located in 33 states, are Indian trust lands. The trust responsibility requires the federal government to act in the best interests of the Indians living on or exercising authority over the land. Trust land status means that the federal government must approve transactions that involve the lease, sale, or conveyance of the land or any of the materials located on the land.

Indians also have treaty rights to carry out specific activities on state and federal lands and waters outside the boundaries of reservations -- for example, to harvest fish, wildlife, and wild rice. The nature and extent of these off-reservation rights are determined by the individual terms of the treaties between the Indian tribe and the federal government (often entered into more than 100 years ago). Treaty rights may be unilaterally abrogated by the U.S. Congress. Treaty rights may be relevant to genetic materials to the extent to which they give Indians specific rights to take fish, wildlife, plants and other resources.⁵⁶

Indigenous peoples in Alaska (the northernmost state) have different ownership and sovereignty rights than those in the contiguous states. Substantial lands in Alaska are held for the benefit of indigenous peoples by "native corporations." These private entities, created under the Alaska Native Claims Settlement Act,⁵⁷ operate like private corporate land owners -- buying and selling, managing, and exploiting private property. However, their stock is owned by the indigenous people. This approach to ownership gives indigenous Alaskan peoples greater control than many indigenous

⁵⁴See discussion, *infra* n. 163, and accompanying text.

⁵⁵"Federal action towards Indians as expressed in treaties, agreements, statutes, executive orders, and administrative regulations is construed in light of the trust responsibility." F. Cohen, Handbook of Federal Indian Law, 220-21 (1982). Not all Indian lands are trust lands; some lands are owned outright by tribes and individuals.

⁵⁶See Campbell-Mohn, *et al.*, Sustainable Environmental Law (1993), §§ 6.1(B)(3)(c)- (iv)(bb): "Treaty rights to hunt and fish often have two aspects: (1) the right to hunt and fish in the tribe's usual and accustomed place and (2) the right to a share of the harvest as against nontribal members. Such treaty rights may extend off reservation lands and may affect the hunting and fishing activities of both tribal members and non-Indians."

⁵⁷43 U.S.C. § 1601 *et seq.*

peoples have over the more typical reservations and trust lands found in other parts of the United States. Some have been spectacularly successful in financial terms, while others have performed poorly. Like any private land owner, Alaska native corporations control access to and exploitation of the resources they own.

Apart from activities on lands owned by native peoples or by native corporations in Alaska, the Alaska National Interest Lands Conservation Act (ANILCA)⁵⁸ also establishes a right to "subsistence" uses of fish and wildlife by "rural residents" of Alaska, a term that includes both indigenous peoples and others. The law authorizes subsistence uses by rural residents even on federal wildlife refuges and other federal lands where such uses are normally prohibited and remain prohibited to other citizens.⁵⁹ The State of Alaska is authorized to administer the subsistence regulatory scheme. The access provided by subsistence rights is analogous to "treaty rights" in the other states, but with defined limitations that prevent commercial exploitation. Similarly, under the Marine Mammal Protection Act, certain indigenous groups in Alaska are allowed to take marine mammals without a permit for subsistence purposes.⁶⁰

B. Marine Areas

The U.S. possesses approximately 88,000 miles of tidal shoreline and over 2.2 million square miles of ocean waters. Around 10,700 square nautical miles of sea and 401,000 acres of coastland are classified as federally protected. Commercial fishing is a four billion dollar industry, supporting 300,000 jobs.

While difficult to accomplish, there has been a substantial effort to assess the biodiversity of U.S. marine waters at all three levels: ecosystem, species, and genetic. Using the most general definition of ecosystem diversity (considering only mean water temperature and ocean currents as factors), the U.S. possesses 11 "greater" ocean

⁵⁸16 U.S.C. §§ 3111-3126.

⁵⁹Subsistence hunting and fishing is authorized on all federal lands in Alaska except Glacier Bay National Park, Kenai Fjords National Park, Katmai National Park, and Kenai National Wildlife Refuge. 16 U.S.C. § 3111.

⁶⁰16 U.S.C. § 1371. The Marine Mammal Protection Act is discussed in greater detail in the marine environment section accompanying notes 60-64, *infra*. It is mentioned here, in the discussion of terrestrial and freshwater environments, because the Act extends to animals like polar bears and seals that spend a significant amount of their lives on land.

ecosystems.⁶¹ Within each greater ecosystem, smaller systems (such as tidal pools, mangroves, coral reefs, and seagrass beds) are evident.

Lack of extensive monitoring means that marine species diversity (and the losses it has suffered) prove difficult to quantify. U.S. coastal borders do not reflect the natural distribution of species, nor are many ocean species endemic to one particular region. Nevertheless, some 2,000 species of fish, 50 species of mammals, eight species of sea turtles and crocodiles, more than 400 species of birds, and several thousand species of invertebrates can be found in U.S. waters. At least 40 marine species are currently listed as threatened or endangered. This number includes almost all of the mammals and sea turtles found in U.S. waters, as well as some fish and birds. However, this number does not include the many species that are dependent upon the marine environment during certain stages of their lives.

The genetic diversity of marine species has been greatly affected by human activity. Many commercially harvested fish species are becoming increasingly smaller and maturing at a faster rate than previously noted. Many formerly abundant species now share only a few gene pools, while others have suffered a 60-70% decline in population. In addition to overutilization, threats to species and genetic diversity include unintentional kills (harvesting of non-target species), pollution, and habitat destruction.

The oceans have great potential to provide raw materials for the development of pharmaceuticals. Some scientists have argued that the biodiversity of the oceans may surpass that of tropical rainforests (where much drug research has been focused). While U.S. companies are among the leaders in biodiversity prospecting, most of the species harvested (generally microorganisms and invertebrates, *e.g.* sponges, cnidarians, mollusks and tunicates) for pharmacological purposes are found in tropical waters outside the range of U.S. jurisdiction. Much of the work is done by the National Cancer Institute (NCI) and the Scripps Institution of Oceanography at the University of California at San Diego. The NCI warehouse in Frederick, Maryland, receives thousands of marine organisms from across the globe (one metric ton per annum) and

⁶¹"Greater" ecosystem refers to a very large, regional system. For example, Yellowstone National Park is often referred to as a greater ecosystem, even though many smaller ecosystems exist within it. Greater ocean ecosystems are delineated according to water temperature and current flows. On the east coast of the United States, for example, there are three greater ocean ecosystems: from the Canadian border to Cape Cod; from Cape Cod to Cape Hatteras; and from Cape Hatteras southwards. Each of these regions has distinctly different temperature fluctuations, depending upon seasonal current flows, which in turn dictate the types of species that are present.

tests these for the potential to treat tumors and AIDS. Important anti-tumor compounds already discovered include: didemnin B, from a Caribbean sea squirt (1978); bryostatins, from bryozoans (1980s); and dolastin, from the sea hare. Since 1989, the NCI has identified some 80 compounds that show some activity against cancer.

Ownership and sovereignty over marine resources depend on the type of resource and the geographic location. While federal authority is the rule, in certain cases both the federal government and the state government have concurrent regulatory authority, as will be seen in the following discussion.

1. Public

(a) Federal Government

The United States claims and maintains federal jurisdiction over a territorial sea that extends seaward 12 nautical miles.⁶² Within its "exclusive economic zone,"⁶³ the United States also claims sovereign rights and exclusive fishery management authority over all "finfish, mollusks, crustaceans, and all other forms of marine animal and plant life other than marine mammals, and birds" and over all Continental Shelf fishery resources.⁶⁴ The U.S. exclusive economic zone extends from the seaward boundary of each of the coastal states⁶⁵ to a point that is 200 nautical miles from the coastal baseline from which the territorial sea is measured.⁶⁶ The U.S. also exerts "exclusive fishery management authority" over all anadromous species throughout the migratory range of each species beyond the exclusive economic zone (other than within the waters of a foreign nation), and over all Continental Shelf fishery resources, even beyond the

⁶²Proclamation No. 5928 Dec. 27, 1988, 54 F.R. 777.

⁶³16 U.S.C. § 1811(a).

⁶⁴Continental Shelf fishery resources include certain enumerated species of coral, crab, mollusks and sponges, as well as other sedentary species that the Secretary of Commerce determines are either immobile on or under the seabed, or unable to move except in constant physical contact with the seabed or subsoil. 16 U.S.C.A. § 1802.

⁶⁵The seaward boundaries of the nation's original coastal states extend three geographical miles from the coastline; or, in the case of the Great Lakes, they extend to the international boundary with Canada. 43 U.S.C. § 1312. States admitted after the original states extend their seaward boundaries to three geographical miles from the coastline or to the international boundary. 43 U.S.C. § 1312. On the west coast of Florida and coast of Texas the state maritime boundary has extended three marine leagues, or nine miles. Campbell-Mohn, *et al.* Sustainable Environmental Law (1993), § 7.1(B)(2)(a), note 31.

⁶⁶16 U.S.C. § 1811.

exclusive economic zone.⁶⁷ The U.S. is authorized to cooperate with other nations in the conservation of highly migratory species within and beyond the exclusive economic zone.

Federal authority also extends over marine mammals and marine mammal products.⁶⁸ Regulation directed at marine mammals seeks to maintain these species at their "optimum sustainable population"⁶⁹ and to protect "rookeries, mating grounds, and areas of similar significance for each species of marine mammals from the adverse effect of man's actions."⁷⁰ The taking and importation of marine mammals and marine mammal products are subject to a moratorium.⁷¹ Exceptions are provided for scientific research, subsistence fishing by certain native peoples, and incidental takes in the course of commercial fishing operations.⁷² The taking prohibitions of the Endangered Species Act also extend to fish, plant, and other life forms within the territorial area and on the high seas.⁷³

The Secretary of Commerce has primary responsibility under the Magnuson-Stevens Fishery Conservation and Management Act for the management of ocean fisheries.⁷⁴ This responsibility has been for the most part delegated to the National

⁶⁷16 U.S.C. § 1812.

⁶⁸The term "marine mammal" means any mammal which (a) is morphologically adapted to the marine environment (including sea otters and members of the order Sirenia, Pinnipedia and Cetacea) or, (B) primarily inhabits the marine environment (such as the polar bear); and, for the purposes of this chapter, includes any part of any marine mammal, including its raw, dressed, or dyed fur or skin. 16 U.S.C. § 1362(5). The term "marine mammal product" means any item of merchandise which consists, or is composed in whole or in part, of any marine mammal.

⁶⁹ The term "‘optimum sustainable population’, means, with respect to any population stock, the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element." 16 U.S.C. § 1362(9)).

⁷⁰16 U.S.C. § 1361(2).

⁷¹16 U.S.C. § 1371.

⁷²16 U.S.C. § 1371.

⁷³See discussion accompanying note 159, *infra*.

⁷⁴For an overview of the various agency roles in regulating ocean fisheries generally, see, Eldon V.C. Greenberg, Ocean Fisheries, in Sustainable Environmental Law 413-418 (Celia Campbell-Mohn *et al.* eds.,

Marine Fisheries Service (NMFS), an agency within the Commerce Department. The five regional NMFS offices focus on management of fisheries, and enforcement of management plans. Eight regional councils are responsible for preparing fishery management plans. The councils have jurisdiction over the fisheries in the exclusive economic zone seaward of the coastal states that make up the membership of each council.

NMFS and the Department of Interior's Fish and Wildlife Service (FWS) administer the Marine Mammal Protection Act's provisions relevant to the species under their respective jurisdiction. The Endangered Species Act also requires federal agencies to consult with the NMFS and FWS in the case of proposed activities affecting listed species.

The United States also has adopted legislation implementing its various treaty obligations for specific species. These statutes -- including, for example, the Atlantic Tunas Convention Act, the Tuna Conventions Act of 1950, and the northern Pacific Halibut Act -- provide the U.S. authority to issue regulations implementing the recommendations of international fisheries commissions.

The Secretary of Commerce is authorized to designate areas of coastal and ocean waters, the Great Lakes and their connecting waters, and submerged lands over which the United States exercises jurisdiction, as national marine sanctuaries.⁷⁵ Although Congressional approval is not required, Congress can disapprove the designation of a sanctuary by a concurrent joint resolution adopted within 60 session days after a designation.⁷⁶ State governors can disapprove the designation of any sanctuary within their territorial waters.⁷⁷ The National Oceanic and Atmospheric Administration (NOAA) within the Department of Commerce is responsible for establishing and overseeing marine sanctuaries.

1993).

⁷⁵16 U.S.C. § 1433.

⁷⁶16 U.S.C. § 1434(a).

⁷⁷16 U.S.C. § 1434(b).

Marine resources are also subject to a general ban against the import, export, transport, sale, receipt, acquisition, or purchase of any fish, wildlife and plants that have been taken or possessed in violation of any law, treaty, or regulation of the United States or in violation of any Indian tribal law.⁷⁸ It is also illegal to import, export, transport, sell, receive, acquire, or purchase in interstate or foreign commerce any fish, wildlife or plant taken, possessed, transported, or sold in violation of any law or regulation of any State (or, in the case of fish and wildlife, in violation of any foreign law).⁷⁹ Within the maritime and territorial jurisdiction of the United States, it is also illegal for any person to possess any fish, plant, or wildlife taken, possessed, transported or sold in violation of any State law or regulation (or, in the case of fish and wildlife, in violation of any foreign or Indian tribal law). Activities regulated by the Tuna Convention Acts and the harvesting of highly migratory species taken on the high seas (if such species are taken in violation of the laws of a foreign nation and the U.S. does not recognize the jurisdiction of such nation over the species) also are exempt from these provisions.

The Federal Water Pollution Control Act (FWPCA) indirectly asserts jurisdiction over marine resources via its requirement for the issuance of a federal permit for the dredging and filling of wetlands.⁸⁰ The U.S. Army Corps of Engineers is responsible for issuing these permits in consultation with the NMFS and the FWS.

The Coastal Zone Management Act⁸¹ sets up a voluntary program that encourages states to exercise their own authority in establishing and implementing state coastal management programs. If developed and submitted, state coastal management plans must be approved by NOAA. Plans must include: an identification of the boundaries of the coastal zone; a definition of permissible land and water uses within the zone; an inventory and designation of particular areas of concern; an identification of means by which states propose to exert control over land and water uses; broad guidelines on priority uses in particular areas; and a description of the organizational structure proposed to implement the management program. Federal activities must be

⁷⁸16 U.S.C. § 3372. Activities regulated by a fishery management plan are exempt from these provisions. 16 U.S.C. § 3377.

⁷⁹16 U.S.C. § 3372.

⁸⁰FWPCA, § 404, 33 U.S.C. § 1344; Rivers and Harbors Act, § 10, 33 U.S.C. § 403.

⁸¹16 U.S.C.A. §§ 1451-1464.

"consistent" with approved state coastal management plans.⁸² These include activities undertaken directly by federal agencies (including development projects), activities requiring federal licenses or permits, outer continental shelf (OCS) exploration, development, production plans, and federal assistance to state and local governments.

(b) State government

The inherent authority of the state to promote the health and welfare of the public extends to the management of fishery resources, particularly within the territorial sea.⁸³ Constitutional limits on the exercise of state power include prohibitions against measures that unduly burden interstate commerce, measures that discriminate against non-citizens in favor of citizens, and measures that conflict with federal laws and are therefore preempted under the federal supremacy clause.⁸⁴ Thus, for example, state measures that have conflicted with fishery management plans have generally been superseded.⁸⁵ Within their jurisdiction, states have developed a wide range of regulatory measures for fisheries, including provisions on gear specifications, prohibited gear, bag limits, size limits, sales restrictions, protected species closed areas, quality control, and seasons. States usually have an executive branch agency in charge of the management and enforcement of these measures.

The traditional authority of States to regulate fisheries within their boundaries within the territorial sea was reaffirmed in the Magnuson Fishery Conservation and Management Act of 1976. However, the Secretary of Commerce may preempt state authority after an adjudicatory hearing when the Secretary finds that the fishing covered by a fisheries management plan occurs predominantly within the exclusive economic zone (and beyond) and the state has taken action or omitted to take action which will substantially adversely affect the carrying out of the fishery management plan.⁸⁶

⁸²16 U.S.C.A. § 1456(c).

⁸³Historically, state jurisdiction has extended from zero to three miles offshore, within the territorial sea, except on the west coast of Florida and the coast of Texas where the state maritime boundary has extended three marine leagues, or nine miles.

⁸⁴*See generally*, Louisiana Seafood Management Council v. Foster, 917 F.Upp. 439 (E.D. La. 1996).

⁸⁵*See e.g.*, Southeastern Fisheries Association, Inc. v. Chiles, 979 F.2d (11th Cir. 1992), Vietnamese Fishermen Assn. Of America v. California Department of Fish and Game, 816 F. Supp.1468 (N.D.Cal. 1993).

⁸⁶16 U.S.C. § 1856.

States are authorized to regulate fishing vessels outside of their boundaries in the following limited circumstances.⁸⁷ First, a State can regulate vessels registered under the law of that State if there is no fishery management plan or other federal fishing regulations for the applicable fishery in place, or if the State's laws and regulations are consistent with the applicable fishery management plan and federal laws. Second, a fishery management plan can delegate management of the fishery to a State. Third, the State of Alaska can regulate non-Alaskan vessels operating in the exclusive economic zone off Alaska in which there is no fishery management plan in place and where there is a legitimate interest of Alaska in the conservation and management of such fishery. The States of Washington, Oregon and California also have interim authority to enforce their respective laws governing fish harvesting and processing against any vessel operating in the exclusive economic zone off that State in a fishery for dungeness crab for which there is no fishery management plan.⁸⁸ In addition, Maine can approve lobster fishing in certain federal waters off Maine for persons holding a valid Maine license.⁸⁹

States have title to and ownership of, and consequently authority to manage, the lands beneath navigable waters within their boundaries.⁹⁰ Because these lands are held in public trust, a state may not sell these submerged lands -- although they may be leased or certain other activities may be conducted with or on them for the benefit of the state's citizens.⁹¹

State claims of ownership over the seabed and subsoil of the OCS beyond the three mile marginal sea have historically been rejected in favor of paramount federal jurisdiction.⁹²

As described above, through the consistency requirement provided for under the Coastal Zone Management Act, states gain a measure of control over federal actions affecting their coastal zones.

⁸⁷Sustainable Fisheries Act, Pub. L. No. 104-297, § 112 (1996) (to be codified at 16 U.S.C. § 1856(a)(3)).

⁸⁸Sustainable Fisheries Act, Pub. L. No. 104-297, § 1229(d).

⁸⁹Sustainable Fisheries Act, Pub.L. No. 104-297, § 809 (1996).

⁹⁰43 U.S.C. § 1311.

⁹¹See discussion on public trust doctrine in Section I.A.1, State Ownership.

⁹²United States v. Maine, 420 U.S. 515, 43 L.Ed. 2d 363, 95 S.Ct. 1155 (1975).

2. Private Ownership

The seabed and subsoil generally are not subject to private ownership. Moreover, under current legislation, the federal government probably lacks statutory authority to lease the seabed and subsoil under its jurisdiction for biodiversity prospecting.⁹³ However, Congress has authority to create such a program, as it has for mineral exploration on the OCS.

In the case of submerged lands subject to state jurisdiction, the public trust doctrine probably limits the state's right to transfer fee title interest to these lands. As discussed above, the states have the right to lease the seabed and subsoil within their jurisdiction.

3. Indigenous Interests

The treaty rights of Indian tribes commonly include the right to hunt and fish in the tribe's usual and accustomed place and the right to a share of the harvest as against nontribal members.⁹⁴ By requiring the provisions of fishery management plans to be consistent with "other applicable law", the Magnuson-Stevens Act accommodates these treaty rights, as well as relevant case law on indigenous rights.⁹⁵ Recently, Congress established a western Alaska community development quota program, under which a percentage of the total allowable catch of any Bering Sea fishery is allocated to the program. Communities eligible for the program must be certified as a native village and must consist of residents who conduct more than one-half of their commercial or

⁹³The Magnuson-Stevens Fishery Conservation and Management Act is silent as to whether the federal government can lease the seabed and subsoil under its jurisdiction. Leasing is not specifically listed as one of the discretionary tools that can be incorporated in a fishery management plan. 16 U.S.C. § 1853(b). However, the government is authorized to prescribe such other measures, requirements, or conditions and restrictions as are determined to be necessary and appropriate for the conservation and management of the fishery. 16 U.S.C. § 1853(b)(12), as amended by the Sustainable Fisheries Act, Pub. L. 104-297, § 108(c)(6) (1996). Another factor indicating that leasing may not be a permissible tool is the Act's limitation on the collection of fees to the administrative costs of issuing permits and other program expenses. 16 U.S.C. § 1854(d), as amended by the Sustainable Fisheries Act, Pub. L. 104-297, § 109 (1996). In addition, the leasing program authorized by the Outer Continental Shelves Land Act is currently limited to mineral resources. 43 U.S.C. §§ 1331(c), 1334.

⁹⁴C. Campbell-Mohn, *et al.*, Sustainable Environmental Law § 6.1(B)(3)(bb) (1993).

⁹⁵ 16 U.S.C. § 1853(a)(1)(C).

subsistence fishing effort in the waters of the Bering Sea or those surrounding the Aleutian Islands.⁹⁶

Indian tribes also have an opportunity to present their interests through the indigenous representative to the Pacific Council, one of the eight regional councils set up by the Magnuson-Stevens Act. The Secretary of Commerce is required to appoint to the Pacific Council one representative of an Indian tribe with federally recognized fishing rights from California, Oregon, Washington, or Idaho. The representative is to be selected from a list of not less than three individuals submitted by the tribal governments. Representation on the council is rotated among the tribes.⁹⁷

C. Ex situ Collections

1. Public Ownership

Federal Ownership

The conservation of components of biological diversity outside their natural habitat is known as "*ex situ*" conservation. Plant germplasm for crop species has been collected for decades by the U.S. government and others as a means of strengthening agriculture. In the mid-1980s, attention was focused on collecting plant germplasm and animal genetic resources. Additional programs for coordinating *ex situ* collection and conservation have been established.

The National Genetic Resources Program

The 1990 Farm Bill formally instituted the National Genetic Resources Program (NGRP) to promote the collection, preservation, and distribution of those types of germplasm that are important to American food and agricultural production.⁹⁸ NGRP builds on well-established plant genetic resource collection, preservation, and exchange activities, and extends them to other life of importance to food production and agriculture: forest trees, animals, aquatic organisms, insects, and microbes. Through cooperative efforts between government and industry, NGRP targets those genetic

⁹⁶Sustainable Fisheries Act, P.L. 104-297, § 111(a)(I) (to be codified at 16 U.S.C. § 1855(I)).

⁹⁷Sustainable Fisheries Act, P.L. 104-297, § 107(b) (1996) (to be codified at 16 U.S.C. § 1852(b)(5)).

⁹⁸7 U.S.C. §§ 5841-5844.

resources "economically important to agriculture"⁹⁹ for preservation and productive use.

The U.S. Department of Agriculture's (USDA's) Agricultural Research Service (ARS) serves as the lead agency for the federal government component of the NGRP and functions as the coordinating unit for the loose association of sites and collections of which the program is comprised. The NGRP includes program components for plant germplasm, plant genome, forest tree, animal germplasm, animal genome, insect germplasm, microbial germplasm, and database support.

The National Plant Germplasm System (NPGS) is the nation's most well-established *ex situ* collection program and currently it is the only NGRP component operating beyond a start-up phase. It serves as the model for the programs in the NGRP which focus on other life forms. Beginning in the 1940s, the NPGS began to coordinate the network of government and industrial seed and crop collections assembled by USDA and State Agricultural Experiment Stations. Federal and state government agencies, for-profit businesses, non-profit organizations, and private entities all contribute germplasm to the NPGS.

The mission of the NPGS involves providing germplasm to scientists for "plant improvement, research, teaching, or extension programs" through exploration, exchange, collection, introduction, increase/regeneration, evaluation, and documentation.¹⁰⁰ Its responsibilities also include preserving and maintaining collections and distributing samples. Essentially, germplasm collection has been for the purpose of national self-sufficiency. Concern about global biodiversity also has become important in the operations of the NPGS during the last 20 years.

The federal government "owns" and controls almost all of the plant germplasm within the NPGS regardless of origin or location, acting as its custodian and distributor; but the material is held for free distribution. Exceptions to federal ownership involve plant varieties which are registered under the Plant Variety Protection Act (PVPA) and unusual cases that occasionally arise where records are missing or incomplete. For

⁹⁹"The National Genetic Resources Program" information sheet, 1. (Hereafter noted as NGRP.)

¹⁰⁰National Research Council, *Managing Global Genetic Resources: the U.S. National Plant Germplasm System*. (Hereafter noted as MGGR: NPGS.) 43.

varieties registered under the PVPA, the NPGS simply acts as a repository and distributor while the owner of the variety retains rights to the germplasm.¹⁰¹

At present, NPGS embodies one of the most extensive collections of plant germplasm in the world¹⁰² with over 450,000 accessions of plant material.¹⁰³ It receives about 12,000 new accessions every year. NPGS engages in plant exploration to acquire specific kinds of germplasm. Any scientist can make exploration proposals through a Crop Germplasm Committee, but proposals also can be developed by a crop committee, the National Germplasm Research Laboratory, or the ARS National Program Staff. In addition, NPGS participates in cooperative exploration efforts with other countries. While plant exploration is important for NPGS, it is not a central activity. Sometimes large seed companies contribute samples to the national system. Seventy-five percent of NPGS acquisitions arrive from collections located throughout the world; most of these are acquired through exchange.¹⁰⁴ The collections contain over 8,000 species of plants, including food, feed, and natural fiber crops and ornamentals, including almost all crops pertinent to U.S. agriculture.¹⁰⁵ Most species are not native to the United States. The NPGS annually supplies about 160,000 samples of plant genetic resources to scientists, 30,000 of which go to foreign countries.¹⁰⁶ Between 1990 and 1994, 145 countries received germplasm from NPGS.¹⁰⁷ This activity qualifies NPGS as the world's largest distributor of plant germplasm.¹⁰⁸ Twenty-one storage locations comprise the NPGS collections. These include the National Seed Storage Laboratory in Fort Collins, Colorado, and 20 other collections at regional centers and land-grant public universities.

¹⁰¹It is easier for an owner to let NPGS handle distribution. Meanwhile, NPGS furthers its mission by distributing the germplasm.

¹⁰²Philip H. Abelson, "Resources and Plant Germplasm" *Science*, 23 August 1991, 833.

¹⁰³Henry L. Shands, Informational Memorandum for the Under-secretary of Research, Education, and Economics, 12 December 1995, Table 3.

¹⁰⁴MGGR: NPGS, 47.

¹⁰⁵MGGR: NPGS, 3.

¹⁰⁶Communication with Dr. Henry Shands, 10 May 1996.

¹⁰⁷*Ibid.*

¹⁰⁸Abelson, at 833. The National Small Grains Collection, one of NPGS' components, holds some of the most frequently distributed accessions in the world.

In addition, State Agricultural Experiment Stations, usually located at public universities, support plant genetics, breeding, and germplasm enhancement activities. Some examples include the native prairie grass collection at South Dakota State in Brookings, South Dakota and the Lettuce Genetic Stock Center in Salinas, CA.¹⁰⁹

The *National Animal Genome Program (NAGP)* is the most developed NGRP component after NPGS. The program eventually will consist of storage repositories for gametes, embryos, and stem cells of animals important to agriculture, including aquatic species. It will run a genetic resource database system on all food animals and research activities. It seeks to optimize access to those genetic resources which "will contribute to the future food and fiber supply."¹¹⁰ Currently, the program lacks a secured budget for completing its infrastructure and formalizing its components. The construction of the animal gene bank is complete, but the Bank is not yet operative. USDA labs in Beltsville, Maryland and Nebraska store some samples of semen and embryos for research or because they are unique germplasm. The database is partially completed.

Other planned components include the *National Animal Genome Research Program (NAGRP)*, which will seek to genetically improve animal species and to establish animal genomic (gene map) databases; the *Plant Genome Research Program*, which will have the purpose of improving crops by discovering and integrating economically important traits into species and to establish plant genomic databases; the *National Forest Tree Genetic Resources Program (NFTGRP)*, which will categorize and preserve forest tree genetic resources in protected areas, *ex situ* collections, and/or orchard collections; the *National Insect Genetic Resources Program (NIGRP)*, which will identify and protect existing and proposed collections of insects and arthropods important to agriculture; the *National Microbial Germplasm Program (NMGP)*, now in early stages of development, which will consist of collections of microorganisms which are both beneficial to agriculture and pharmaceutical use, as well as pathogens; and the *National Genetic Resources Database Support Program (NGRDSP)*, intended to be established to inventory genetic information about all life forms.

¹⁰⁹Calestous Juma, *Gene Hunters* (Princeton U. Press, 1989), at 248 (hereafter noted as Juma).

¹¹⁰"About National Animal Germplasm (Including Aquatics)," <http://www.ars-grin.gov/nag/about.nagp>.

Other Federal Ex situ Programs

The National Cancer Institute's (NCI's) Developmental Therapeutics Program maintains a collection of genetic materials within its Natural Products Branch. Its collection includes plant extracts, microbial cultures, fungi and other life forms. They are held primarily for use in the discovery and development of new agents for the treatment of cancer and AIDS. NCI, as an agency of the federal government, considers the materials within the collection to be its own property. NCI normally retains title to material provided to researching organizations pursuant to a Material Transfer Agreement.¹¹¹

NCI enters into contracts with other countries for collecting their resources. It has been active in collection and screening since 1960, with a six year break from 1980 to 1986. Its collectors include: USDA (1960-1980); Missouri Botanical Garden; New York Botanical Garden; University of Illinois; Kunming Institute of Botany, China; Central Drug Research Institute, India; Brigham Young University; Harbor Branch Oceanographic Institute; Australian Institute of Marine Sciences; Coral Reef Research Foundation; Smithsonian Oceanographic; University of Connecticut; University of Hawaii at Manoa; University of Miami; Michigan Biotechnology Institute; and Tel Aviv University. Between 1960 and 1980, NCI received almost 35,000 species of plants, 16,000 marine extracts, and 180,000 microbe extracts. Currently, it receives almost 10,000 plant, marine, invertebrate, fungi, and algae samples each year. NCI also collects for private industry, including Eli Lilly and Glaxo Group Research.

The U.S. National Herbarium was founded in 1848 and is a part of the National Museum of Natural History of the Smithsonian Institution, a museum created and funded by Congress. It contains about 4.5 million plant specimens from around the world and is among the ten largest herbaria worldwide. It represents about 8% of the plant collection resources of the United States. The collections encompass all major groups of plants including algae, bryophytes, lichens, pteridophytes and flowering plants. Viable seed occasionally is produced from plants being prepared for the herbarium and is available for distribution.

¹¹¹*Natural Products Repository Material Transfer Agreement*, Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment, Diagnosis and Centers, National Cancer Institute, National Institutes of Health.

State Ownership

Several state universities and associated research institutions maintain collections of plant and animal genetic resources. Many of these are affiliated with the NGRP, but may undertake collection and access certain resources in different ways with respect to at least part of their collections (e.g., through collection agreements, cooperative research contracts, *etc.*).

2. *Private Ownership*

Private companies throughout the United States operate their own collection, storage, and screening programs. They represent a variety of industries, including commercial breeders, seed firms, pharmaceutical manufacturers, and biotechnology companies. Some companies run their own operations, while others contract with collector companies, individuals, or research and non-profit organizations. Proponents of private collections argue that companies best know their own needs and can meet the high costs of maintaining inventories and facilitate limited production with their own finances, field resources, and personnel.¹¹² Most non-profit organizations involved in germplasm conservation pursue very specific types of plant germplasm, often for gardening or historical interest.

Identifying the variety of non-governmental germplasm conservation activity is difficult: there is no single source of data or statistics that expresses current activity. Non-governmental germplasm collection is not strictly coordinated with NPGS, but many feel the two sectors do not duplicate each other's work. One institution that does cooperate with the national system is the Crop Science Society, which has arranged to register and secure individual genetic stocks with National Seed Storage Library (NSSL).

One important group of private institutions are botanical gardens, most of which are non-profit organizations. Most U.S. botanical garden germplasm collections contain few crop species, but the gardens are increasingly placing more emphasis on collection

¹¹²Henry Shands, "Plant Genetic Resources Conservation: The Role of the Gene Bank in Delivering Useful Genetic Materials to the Research Scientist," *Journal of Heredity*, January 1990, at 9. For example, although Eli Lilly does not own all of the materials in its collections, the company has obtained rights to use them in research. Many were obtained through the American Type Culture Collection and the Agricultural Research Service's Microbial Germplasm Resource Collection in Peoria, Illinois. Many others were obtained from scientists and others in the research community.

of wild plant species, especially those that are endangered. The Center for Plant Conservation (CPC) is an association of U.S. botanical gardens which owns and maintains rare and endangered U.S. plant species. The cooperating gardens acquire and maintain seeds from their respective regions. Its collections are not part of NPGS, although NPGS supports CPC efforts by providing backup storage of seeds.

The New York Botanical Garden, the Missouri Botanical Garden, and the University of Chicago contract with private pharmaceutical companies and public research organizations to provide samples for pharmaceutical development as private non-profit "intermediaries."¹¹³ Other universities and botanical gardens also keep collections.¹¹⁴

Other private plant-related groups include the Seed Savers Exchange (SSE), which promotes the preservation of heirloom vegetables through diffused conservation; member gardeners conserve most of the germplasm themselves. The Northern Nut Growers Association is an 85-year old group interested in finding, propagating, and improving nut-bearing trees. The Native Seeds/SEARCH in southern Arizona is a grass-roots education, research, and conservation organization that specializes in the survival and propagation of regional native and heirloom plants.

The American Livestock Breeds Conservancy is the only private, non-profit institution in the United States seeking to preserve genetic resources of North American livestock. It keeps animals in *ex situ* habitats and preserves genetic resources cryogenically. Some universities store animal germplasm as part of their research efforts, but not for the purpose of collection. Breeding associations and for-profit businesses also keep animal germplasm collections; their activities revolve around selling a product rather than conserving genetic resources.

Several U.S. centers participate in the world network of Microbial Resources Centers (MIRCENs), including the NifTAL project (rhizobium) at the College of Tropical Agriculture, University of Hawaii; Cell Culture and Nitrogen Fixation Lab (rhizobium) at Maryland; and the Department of Microbiology (marine biotechnology) at the University of Maryland. The American Type Culture Collection and the Culture Collection of the Hopkins Marine Research Station also collect microbial germplasm resources.

¹¹³Walter V. Reid, "The Economic Realities of Biodiversity," *Issues in Science and Technology*; Winter 1993-94, 51.

¹¹⁴Juma, 95.

Chapter Two:



Access to Genetic Resources

United States law implements what may be regarded as a system of access to genetic resources based primarily on ownership. Biodiversity prospectors are generally free to gain access to and exploit genetic resources upon private lands, so long as they have obtained the agreement of the private landowner. This system relies on private property law to determine the rights and conditions of access.

Access to genetic resources on government lands generally is conditioned upon obtaining the appropriate permit for access to natural resources in which the genetic resources are embodied. Similar permitting requirements apply to the natural resources found in the territorial sea, over which the federal government exerts primary jurisdiction. Both private and public collections of *ex-situ* genetic resources also generally operate on an open system of access.

The principal laws that currently constrain rights of access in the United States are those designed for the conservation of specific species. If these laws, such as the Endangered Species Act, apply, then access to the genetic resources found within these species may be limited. Similarly, if certain lands are designated as having special conservation value, such as wilderness areas or marine sanctuaries, then access to the genetic resources found within these lands for commercial exploitation may be denied.

A. Terrestrial and Aquatic Areas

1. Public Ownership

Federal Government Areas

Access to most resources on federally-owned lands is controlled by permit requirements, leases, or other legal authorizations. However, access limitations vary widely depending upon the applicable land management law. For much federal land, such as the public domain controlled by the Bureau of Land Management or National Forests, access for the purposes of collecting and exploiting resources is subject to few restrictions. Such access may be more restricted in national parks, wilderness areas, and similar lands designated for conservation purposes.

This section reviews the existing federal laws and regulations governing access to genetic resources on federal lands. These laws were not written specifically to address collecting or prospecting for potentially valuable genetic materials. Typically, the laws concerning access address scientific collecting, harvesting timber, private collection of common plants, or hunting and fishing.

Before examining the specific laws applicable to each federal land-management agency, we note that, in some cases, collection of materials on federal lands may be subject to an environmental evaluation under the National Environmental Policy Act (NEPA).¹¹⁵ NEPA applies if the action is considered a "major Federal action[] significantly affecting the quality of the human environment,"¹¹⁶ in which case a detailed environmental impact statement (EIS) must be prepared. If an EIS is needed, it must address:

- (i) the environmental impact of the proposed action;
- (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented;
- (iii) alternatives to the proposed action;
- (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and
- (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.¹¹⁷

Any application for a permit or other authorization to collect materials on federal lands must be evaluated to determine whether it triggers the need for an EIS. In many cases, an agency would have to prepare an environmental assessment (EA) in order to determine whether an action is of sufficient scope for an EIS to be necessary. However, low impact collection permits might be categorically excluded by federal agencies from the EIS process.¹¹⁸ A categorical exclusion may apply, for example, if no lands will be disturbed and no populations of non-rare plants, animals, insects, or microorganisms will be affected.

¹¹⁵42 U.S.C. §§ 4321-4332.

¹¹⁶42 U.S.C. § 4332(2)(C).

¹¹⁷*Id.*

¹¹⁸Categorical exclusions are categories of actions "which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency . . . and for which, therefore, neither an environmental assessment, nor an environmental impact statement is required." 40 CFR § 1508.4.

Apart from environmental impact analysis requirements, the substantive laws and regulations governing administration of federal lands establish the basis on which access may be granted or denied.

The *National Park Service* operates under laws and regulations which generally prohibit removal of any living or formerly living material from a National Park.¹¹⁹ However, certain materials, including genetic materials, may be collected and removed for *research purposes* if a specimen collection permit is obtained from the National Park Service.¹²⁰ Authority to issue a permit rests with the park superintendent.¹²¹ However, permits requiring an EA or an EIS must be reviewed at the regional level of the Park Service. Few specimen collection permits are subjected to such assessments by the Park Service. A specimen collection permit may be issued only to "an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display, when the superintendent determines that the collection is necessary to the stated scientific or resource management goals of the institution or agency."¹²² "Specimens and data derived from consumed specimens" must be "made available to the public and publications resulting from a research specimen collection permit shall be filed with the [park] superintendent."¹²³

In 1997, the Park Service relied on a novel interpretation of the Federal Technology Transfer Act (FTTA) to allow a for-profit company, Diversa, to develop commercial products from bacteria collected in the hot springs of Yellowstone National Park.¹²⁴ The actual collection of the bacteria by Diversa was authorized under a specimen collection permit, with the permit actually prohibiting commercial use of the specimens.¹²⁵ However, a separate agreement, entered into under the FTTA, allows the Company to use the *results* of the research conducted on the specimens for commercial

¹¹⁹36 CFR § 2.1. Fishing is authorized in many parks; hunting and trapping is allowed in a few parks where Congress has specifically authorized it. 36 CFR §§ 2.3, 2.2.

¹²⁰36 CFR § 2.5.

¹²¹36 CFR § 1.6.

¹²²36 CFR § 2.5(b).

¹²³36 CFR § 2.5(g)(2).

¹²⁴See discussion accompanying notes 222-226, *infra*.

¹²⁵Since specimen collection permits may only be issued to "an official representative of a reputable scientific or educational institution or a state or federal agency," the Park Service is presumably taking the position that the company in this instance is a reputable scientific institution.

purposes. On March 5, 1998, several citizen groups filed suit challenging the Park Service's use of this law in this manner.¹²⁶

The *Bureau of Land Management* (BLM) has broader discretion to authorize access. Apart from the specific laws relating to access to minerals, grazing, and other uses of the public domain, the BLM has general authority under the Federal Land Policy Management Act to provide for the use, occupancy, and development of public domain lands through permits, leases, and easements.¹²⁷ This authority could be applied to manage access to genetic resources. Under the law, any use not specifically forbidden by law may be authorized.¹²⁸ Permits are the preferred mechanism where the authorized use is to extend for less than three years and there will be little disturbance of the land.¹²⁹ Land use authorizations may be issued only if there is payment of "fair market value" to the government, and the uses must conform to BLM land-use plans, objectives, and management programs. Fair market value may or may not reflect the potential development value of genetic material. It is more likely that the value that must be recovered is the value of the access (for example, payment for occupancy, or ingress and egress) or the basic value of the specimens.¹³⁰ However, regulations could be adopted to assure that greater economic returns are realized. Under the current regulations, competitive bidding may be required at the option of the government, but noncompetitive land-use authorizations are allowed where there is no competitive interest, or where competitive bidding would unfairly "disadvantage..the originator of the unique land-use concept."¹³¹ Requests for a permit must be submitted in writing and must disclose the intended use in sufficient detail to allow evaluation.

Any land use authorized by BLM under its general authorities must "minimize damage to scenic, cultural and aesthetic values, fish and wildlife habitat and otherwise protect the environment," and must require compliance with all environmental and health and safety standards; the authorization also must contain any provisions BLM considers necessary to protect federal property and economic interests, protect the interests of local persons relying on the fish, wildlife, and other biotic resources of the

¹²⁶Edmonds Institute v. Babbitt, No. 1:98CV00561 (filed March 5, 1998, D.D.C.).

¹²⁷43 U.S.C. §§ 1732, 1733, 1740; 43 CFR Part 2920.

¹²⁸43 CFR §§ 2920.0-6, 2920.1-1.

¹²⁹43 CFR § 2920.1-1(b).

¹³⁰The regulations contemplate payment of a "rental fee" and payment for any "vegetative materials . . . to be cut, removed, used or destroyed." 43 CFR §§ 2920.8, 2920.7(d).

¹³¹43 CFR § 2920.5-4.

area for subsistence purposes, and otherwise protect the public interest.¹³² The BLM may require the posting of a bond or other security to assure fulfillment of the terms and conditions of the permit.¹³³ The authorization may be terminated by BLM for noncompliance with its terms and conditions, failure to use the authorization for the purpose authorized, non-use of the authorization for two years, nonpayment of rent for two consecutive months, or whenever the public lands are needed for another public purpose.¹³⁴

Access to wilderness areas is more restrictively managed. Certain uses are specifically prohibited in wilderness areas, including commercial enterprises, motorized equipment and structures, and cutting of trees. BLM wilderness areas are, however, open to uses "consistent with the preservation of their wilderness character and their future use and enjoyment by the American people as wilderness, including, but not limited to . . . scientific study."¹³⁵ The BLM may require permits for any use of particular wilderness areas. "[A]ny person desiring to conduct any activity for purposes of gathering information about natural resources in wilderness may do so," provided that the activity is consistent with the maintenance of the environment as wilderness and any necessary permits or authorizations are obtained.¹³⁶

The *Bureau of Reclamation*, which manages certain dams and water projects, may grant various "rights of use:" on project lands. These rights, broadly defined, include "easements, leases, permits, licenses, or agreements," but do not include leases for grazing, agriculture, or "any other purpose where a greater return will be realized by the United States through a competitive bidding process."¹³⁷ The Bureau is entitled to recover from applicants the value of rights of use, plus the administrative costs associated with granting the rights. However, rights of use may be granted to non-profit organizations with a charge only for the administrative costs and not the use value. In this case, the Bureau must also determine that "the use will not interfere with the authorized current or planned use of the land by the Bureau."¹³⁸ It is not clear

¹³²43 CFR § 2920.7.

¹³³*Id.*

¹³⁴43 CFR § 2920.9-3.

¹³⁵43 CFR § 8560.1-1.

¹³⁶43 CFR §§ 8560.1-2, 8560, 4-5.

¹³⁷33 CFR Part 429, § 429.2(d).

¹³⁸43 CFR § 429.4.

whether the existing provision for recovery of value could encompass possible returns from the development of products from genetic resources collected on Reclamation lands.

Like the Bureau of Reclamation, the *Army Corps of Engineers* has some control over access to resources at its water resource development projects. Occupancy and construction activities must be expressly authorized by permit. However, these lands are open for hunting, fishing, and trapping, except where specifically prohibited.¹³⁹ Destruction, removal, or any alteration of public property (including vegetation) is prohibited unless in accordance with written permission of the District Engineer.¹⁴⁰ There are no provisions regarding recovery of value, suggesting that this may be discretionary.

Access to national wildlife refuges is controlled by the *U.S. Fish & Wildlife Service*. The primary purposes of the refuges are to restore, preserve, develop, and manage wildlife and habitat; to protect and preserve endangered and threatened species and their habitat; and to manage for the maximum benefits from wildlife and wild lands.¹⁴¹ Refuge managers, the director of the Service, or the Secretary of the Interior may issue permits for various activities on refuges, including the collection of genetic materials. The law and regulations do not currently specify conditions for permitting activities, except for the general rule that all activities must be "compatible with the major purposes" for which the refuge was established.¹⁴² The Service has substantial discretion in setting conditions. At this time, hunting and fishing is allowed in most refuges.

The *U.S. Forest Service* controls access to the resources of the national forests. All uses of these lands and resources, except those provided for in the regulations governing sale of timber, leasing of grazing rights, and disposition of minerals, are defined as "special uses" and require a special use permit.¹⁴³ Thus, if genetic materials are to be collected in the course of an activity other than logging or grazing, a special

¹³⁹*E.g.*, 36 CFR § 327.8 (hunting, fishing, trapping).

¹⁴⁰36 CFR § 327.14.

¹⁴¹50 CFR § 25.11.

¹⁴²16 U.S.C. § 668dd(d)(1)(A).

¹⁴³36 CFR § 251.50. Noncommercial recreational uses do not generally require a special use permit.

use permit may be required by the Forest Service.¹⁴⁴ Written applications are required for special use permits, and these must include detailed information. The holder of a special use permit is authorized only to occupy the area and conduct the activities specified in the permit, but does not possess a property right. The holder must pay in advance the value of any vegetative materials removed, used, or destroyed in connection with the special use.¹⁴⁵

On both *federal and non-federal lands*, the U.S. Fish and Wildlife Service also requires permits for collection and transportation of certain regulated categories of plants and animals.¹⁴⁶ In general, this authority is used to regulate export traffic in wildlife or to protect endangered species or species that have special protection under state laws. An applicant may not receive a permit if that applicant has previously been assessed a civil penalty or convicted of a criminal offense for a related activity. Permit applicants must fully disclose all material information about the project, including demonstration of responsibility, and a valid justification for the activity. The activity must not threaten a wildlife or plant population.¹⁴⁷ Special requirements apply to the export of wildlife or wildlife parts.¹⁴⁸

The Service also may issue permits for the taking of a limited number of threatened or endangered species for scientific purposes.¹⁴⁹ The Endangered Species Act provides that such permits may be granted only if the Service finds, and publishes in the Federal Register a finding, that the permitted activity has been applied for in good faith, that it will not operate to the disadvantage of the species, and that it will be consistent with the conservation and restoration purposes of the Act.¹⁵⁰

State Government Areas

The ways in which state governments control access to their lands and resources vary. Western states administering state trust lands are required to maximize revenues

¹⁴⁴The regulations do not identify a statutory authority that speaks directly to this kind of use in national forests. 36 CFR § 251.53. However, the Forest Service has recognized a broad variety of special uses.

¹⁴⁵36 CFR § 251.55.

¹⁴⁶50 CFR Part 13.

¹⁴⁷50 CFR § 13.21.

¹⁴⁸50 CFR Part 14.

¹⁴⁹50 CFR §§ 17.22, 17.32, 17.62, 17.72.

¹⁵⁰16 U.S.C. § 1539.

from these lands, usually to support spending on public education. Ordinarily, these trust lands require competitive bidding for timber cutting and grazing rights. Other states have forest lands, which may be offered for timber cutting under competitive bidding procedures. States could use a similar approach with respect to access to genetic materials on these lands.

Access to other state lands will be managed in different ways under state laws. Generally, state laws limit the kinds of activities that may be carried out on state park and other conservation lands. New York's Adirondack Park, for example, is subject to a state constitutional provision that the state-owned lands within the park be maintained "forever wild."

State conservation lands that have been acquired with federally-contributed funding under the federal Land and Water Conservation Fund (LWCF) Act must remain in conservation uses and cannot be converted to other uses without the consent of the federal Secretary of the Interior.¹⁵¹ Subject to these constraints, access to state lands can be as broad as state legislatures choose to make it.

Approximately 15 states have laws that require them to conduct environmental impact assessments for state or private activities occurring on state lands. Only California, Washington, New York, and Massachusetts apply such requirements to private activities on private lands that need state or local permits.¹⁵² However, in the majority of states, no environmental impact assessments are required in connection with the collection and exploitation of genetic resources on state lands.

2. Private Ownership

In general, in the absence of explicit regulation, a private property owner has complete control over access to any genetic material that may be found on his or her own property. There is no requirement under state or federal law to obtain a special permit to conduct research or obtain access to any genetic resource. In general, any restrictions the government places on private rights are due to concerns for the

¹⁵¹Such consent may be granted if other conservation lands of equivalent value are substituted by the state for the lands that will undergo development. *See* *Friends of the Shawangunks, Inc. v. Clark*, 754 F.2d 446 (2d Cir. 1985) (requiring the Secretary of the Interior to review the proposed conversion of a scenic easement area acquired by the state of New York with LWCF funds to a private golf course); *see also* *Sierra Club v. Davies*, 955 F. 2d 1188 (8th Cir. 1992) (allowing commercial exploration for diamonds in an Arkansas state park acquired and improved with LWCF funds provided that land disturbances remained minimal and temporary).

¹⁵²*See generally*, J. McElfish, "State Law and Programs" Section 6.03[1][c], in S. Novick *et al.*, eds., *Law of Environmental Protection* (Clark, Boardman, Callaghan, 1987, updated annually).

conservation of specific species, such as endangered species, or to ensure the sustainable harvest of certain economically important species.

The strength of private rights over property originate in common law concepts. The power to exclude others is "one of the most essential sticks in the bundle of rights that are commonly characterized as property."¹⁵³ The owner may control access by granting or denying permission to others to enter and collect material; or the owner may sell or lease the right to collect and exploit such material. Both the common law and state statutes grant the owner the power to eject trespassers and to recoup any material taken by trespassers.¹⁵⁴

Private land owners have power to prevent entry to their property by government officials as well. Both the U.S. Constitution¹⁵⁵ and state constitutions protect land owners from "unreasonable searches and seizures" of property by government agents. Government agents may not enter private property or remove any material from it without either the consent of the land owner, or a warrant issued by a judge based upon a showing that either, (1) there is probable cause to believe that a crime has been committed or, (2) a pervasive regulatory inspection scheme authorizing the intrusion is in place.¹⁵⁶ Thus, if government agents are to collect any genetic material from private lands for research or exploitation, they need to obtain the consent of the land owner. The land owner can deny the government access *even if* the relevant laws do not allow the owner to exploit a particular resource found on the property. For

¹⁵³Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979).

¹⁵⁴Some states have, by statute, created a limited exception to the presumption that entry upon private property without the express consent of the owner is trespassing. These states provide in their hunting laws that rural, privately-owned lands are presumed to be open for lawful hunting of wildlife during hunting season, unless the landowner expressly posts notices on the land to exclude hunters (*e.g.*, Maryland, Pennsylvania).

¹⁵⁵U.S. Constitution, Amendment IV.

¹⁵⁶Certain regulatory programs include a "consent" to entry by government inspectors as a condition of receiving a government permit. However, if a land owner bars entry even after granting such general consent in a permit application, the government agents may not force their way onto the premises, but must obtain a warrant. There are also a few exceptions to the warrant requirement -- such as entry by police in "hot pursuit" of a felon, or seizure of evidence in "plain view" when the agent has the right to be where he or she can see the evidence. In any case, any material seized by a government agent must be listed on an inventory and a copy of the inventory must be provided to the owner. The material must eventually be returned to the owner at the end of any legal proceedings unless it is deemed to be contraband automatically forfeit to the government, or unless the government initiates formal forfeiture proceedings. Forfeitures are intended to punish a wrongdoer by forcing him or her to give up instrumentalities with which crimes have been committed (*e.g.*, weapons, houses, cars, businesses) and the ill-gotten benefits of property acquired through the pursuit of criminal activity (*e.g.*, money, buildings, businesses, consumer goods).

example, even though a land owner may not lawfully reduce to possession or sell a bald eagle nesting on the owner's property, the owner cannot be compelled to allow government agents to enter the property for the purpose of capturing the eagle or sampling its genetic material.

Subject to possible regulation, land owners have substantial leeway in granting access. Typical legal mechanisms that could be used by land owners to control access and achieve a financial return include contracts, leases, options, revocable licenses (e.g., fees for hunting), and joint ventures (where the landowner becomes a partner in the enterprise doing the prospecting in return for some share of the proceeds). These instruments are typically valid for a limited period of time.

Easements and other deed mechanisms (such as covenants) may be used to convey permanent interests in land under state law; or they can be structured to exist for a term of years. They can be used to grant access to genetic resources on private lands while assuring their conservation. An easement is created by one land owner and conveyed to another, or retained by a land owner upon conveyance of the underlying parcel of land to another. The easement is a recognized interest in land that obligates the servient estate (the owner of the land and the owner's successors in title) to take certain steps for the benefit of the dominant estate (the owner of the easement and its successors). Unless specifically limited, the easement is perpetual and "runs with the land." A type of easement known as a conservation easement requires the servient estate to limit uses of the land to non-developed uses and to conserve the natural resources on the land. In the genetic resources context, a conservation easement might be used to assure both that the servient estate prevents incompatible development and allows the easement owner regular access to the land for collection purposes.¹⁵⁷

The authority of private property owners to *grant* access is limited by the regulatory power of the states (and, to some extent, the federal government). The states' power may be broadly exercised to benefit the public health, safety, or general

¹⁵⁷Conveyance of an easement interest (creating a relationship between the dominant and servient estates) for collection of genetic resources appears to be feasible under current law, although state laws vary on whether certain kinds of easements can be held by an entity that is not an adjacent property owner, and on who can hold a conservation easement. It is less clear, however, whether a property interest in genetic resources could be permanently severed and conveyed outright by deed. Mineral deeds are well-known ways to sever and convey permanently the right to prospect for and extract minerals, and deeds can sever and convey the air rights to parcels for building purposes. Genetic resources, however, may or may not be seen as a separate estate in land that can be conveyed and recorded in the land records. The issue would have to be resolved under state law.

welfare.¹⁵⁸ Thus, states (and local governments, which are legal subdivisions of states) can affect the terms under which access to genetic resources may occur on private lands, by imposing reasonable zoning or licensing requirements or other regulatory terms and conditions. For example, zoning regulations might limit access for a commercial use or harvest in an area not zoned for that purpose. In addition, state laws regulate the taking of wildlife species.

Federal laws may also limit the abilities of private property owners to exploit resources found on their property. The most significant of these is the Endangered Species Act (ESA) because it may apply to any species, subspecies, or even a discrete population of a species which is threatened with extinction. Its provisions do not apply, however, unless a species is officially listed by the U.S. Fish and Wildlife Service as an endangered or threatened species.

The ESA prohibits anyone from "taking"¹⁵⁹ threatened or endangered animals or fish on private land, but allows the taking of endangered or threatened plants. Such plants cannot, however, be sold, transported, or used in commerce, thus limiting the value of the access.¹⁶⁰ Prohibitions on the export of threatened and endangered species also may seriously limit owners' ability to exploit certain resources.

In addition, the ESA affects private persons through provisions which require federal agencies to deny a request for permits or other agency action if that action would jeopardize the continued existence of a listed species. The Act also provides authority and funding for the government to establish voluntary protective measures with private landowners.

Other significant federal wildlife statutes include the Migratory Bird Act, which prohibits the taking of songbirds and establishes seasons for migratory game birds. There is also a federal law protecting the Bald and Golden eagles, although certain American Indians are allowed to own and use eagle feathers and parts, something

¹⁵⁸Berman v. Parker, 348 U.S. 26, 33 (1954): "The concept of the public welfare is broad . . . The values it represents are spiritual as well as physical, aesthetic as well as monetary. It is within the power of the legislature to determine that the community should be beautiful as well as healthy, spacious as well as clean, well-balanced as carefully patrolled."

¹⁵⁹"Taking" of threatened or endangered species includes causing "harm" to such species. Causing damage to habitat that adversely impacts upon species' breeding, feeding, and shelter requirements falls within the prohibition. Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon, 115 S. Ct. 509 (1994).

¹⁶⁰Endangered Species Act, 16 U.S.C. § 1538.

prohibited to most citizens.¹⁶¹ Thus, state and federal laws may limit the access that private land owners may grant to some genetic resources on their lands.¹⁶²

3. *Indigenous Ownership - Access Issues*

Federally-recognized Indian tribes have authority to control access to reservation lands. However, where privately-owned non-Indian lands are interspersed with Indian lands within a reservation, tribal control over access to private lands is limited.¹⁶³

Where an Indian tribe grants access to its lands and resources in the form of a contract, lease, or deed, the federal Department of the Interior must review the agreement and approve it in order for it to be legally valid.¹⁶⁴ Historically, this power has been used both for the Indians' benefit and to their detriment. In making decisions concerning the approval or disapproval of agreements, the federal government is bound by the "trust" responsibility. In other words, it must act in the best interests of the Indian tribe.

¹⁶¹ Indians cannot sell such parts or feathers, *Andrus v. Allard*, 444 U.S. 51 (1979).

¹⁶² The major limitation on the regulatory power of states and the federal government is the Constitutional provision that private property cannot be taken for public use without payment of "just compensation." U.S. Constitution, Amendments V and XIV. This provision applies not only to governmental expropriations of private property, but also to certain cases in which private property is regulated. The Supreme Court held in 1926 that "while property may be regulated to a certain extent, if a regulation goes too far it will be recognized as a taking." *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1926). The determination of when a regulation has gone "too far" is made case-by-case, and includes an assessment of the purposes of the regulation and, just as importantly, its impact upon the remaining value of the property. In general, if private property retains economic value after regulation is effective -- even if the property's value is diminished -- a compensable taking will not be found. Moreover, personal property (such as genetic resources reduced to possession) may be subjected to a much higher level of regulation before a taking will be found. *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899-2900 (1992), citing *Andrus v. Allard*, 444 U.S. 51 (1979). No federal court case has ever found a wildlife or endangered species regulation to be a "taking" of property without just compensation.

¹⁶³ In *Montana v. United States*, 450 U.S. 544 (1981), the Supreme Court held that the Crow Indian tribe could not prohibit hunting by non-tribal members on privately-owned lands within the Indian reservation. However, "Indian tribes retain inherent sovereign power to exercise some forms of civil jurisdiction over non-Indians on their reservations, even on non-Indian lands." 450 U.S. at 565. Tribes' jurisdiction over non-members includes cases where non-members enter into "consensual relationships with the tribe or its members, through commercial dealings, contracts, leases, or other arrangements . . . [and cases where non-member] conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." 450 U.S. at 565-566. Such cases include the discharge of pollution by non-tribe members. *Montana v. EPA*, Nos. 96-35505, 96-35508 (9th Cir. March 3, 1998).

¹⁶⁴ 25 U.S.C. § 81.

However, the government has substantial discretion in determining what those interests are. For example, an Indian allottee recently authorized fossil hunters to dig up and remove a dinosaur fossil skeleton from his land; the federal government seized the fossil from the fossil hunters because the individual Indian had no power to convey the fossil to the hunters without the permission of the federal government.¹⁶⁵ Eventually the fossil skeleton was auctioned and the proceeds were delivered to the Indian land owner.

In contrast to transactions involving tribal trust lands, which require some degree of federal oversight, Alaska native corporations have the same rights as any other private owners in offering access to, and exploiting, any resources found on their lands and waters.

Indian treaty rights governing off-reservation access to biological resources (usually fish and wildlife, and sometimes native plants) are also relevant to the issue of access to genetic resources. So are the subsistence rights of rural (indigenous and non-indigenous) Alaska residents on federal lands, and the subsistence rights of indigenous Alaskans to take marine mammals. These access rights are guaranteed and can be impaired only by an Act of Congress. Nevertheless, the fact that treaty rights and subsistence rights must be respected does not give people with those rights the ability to grant access to others. One cannot sell or rent a treaty right or subsistence right to someone else. However, treaty rights may allow tribes to sell the things they harvest, such as plants, seeds, animals, or fish. In contrast, Alaska subsistence rights do not include the right to sell harvested resources commercially.¹⁶⁶

Even if the actual fish and wildlife taken under off-reservation treaty rights can be sold, such rights are non-exclusive. Treaty rights simply guarantee tribes access to resources otherwise managed by the state or federal government and that may be exploited by others. Companies that seek access to the genetic material embodied in the living things that are subject to treaty rights may, therefore, deal either with the tribe or with another party that has access to the same materials. Tribal control of access to

¹⁶⁵Black Hills Institute of Geological Research v. South Dakota School of Mines and Technology, 12 F. 3d 737 (8th Cir. 1993), *cert. denied* 115 S. Ct. 61 (1994).

¹⁶⁶16 U.S.C. § 3113: "Subsistence uses" means "the customary and traditional uses by rural Alaska residents of wild, renewable resources for direct personal or family consumption as food, shelter, fuel, clothing, tools, or transportation; for the making and selling of handicraft articles . . .; for barter, or sharing for personal or family consumption; and for customary trade." In addition, no marine mammals taken pursuant to the subsistence provisions of the Marine Mammal Protection Act may be transferred in interstate or foreign commerce. 16 U.S.C. § 1371.

these resources can be assured only if the tribe and the federal or state governments operate in coordination with one another in their dealings with third parties.

B. Marine Areas

1. Public

(a) Federal Government Areas

Access to genetic resources in marine areas is controlled by the federal government under the Magnuson-Stevens Act. This statute comprehensively covers all living genetic resources contained in marine areas because, although its provisions refer to "fish", its definition of fish includes, "any finfish, mollusk, crustacean, or parts, thereof, and all other forms of marine animal and plant life. . ." ¹⁶⁷

Under this Act, access to fishing resources within the exclusive economic zone is governed primarily by the applicable fishery management plan (FMP). The purpose of these plans is to achieve the "optimum yield" from each fishery on a continuing basis. ¹⁶⁸ The plans are to be developed by local councils in accordance with national standards. For certain highly migratory species, the Secretary of the Interior prepares the plan in consultation with the affected councils. ¹⁶⁹ An FMP may propose management measures that allocate fish among different groups of individuals or establish a system of property rights. ¹⁷⁰ Common mechanisms of limiting access include licensing of vessels, gear, or fishermen to reduce the number of units of effort, or dividing the total allowable catch into fishermen's quota's (a stock-certificate system). FMPs may also reserve a portion of the allowable biological catch of the fishery for use in scientific research. ¹⁷¹ FMPs generally are implemented by permit or license subject to the plan's provisions.

¹⁶⁷61 Fed. Reg. 32,541, 32,542 (1996) (to be codified at 50 C.F.R. § 600.10).

¹⁶⁸16 U.S.C. § 1801(b)4.

¹⁶⁹Sustainable Fisheries Act, P.L. 104-297, § 109(g) (1996) (to be codified at 16 U.S.C. § 1854(g)).

¹⁷⁰50 CFR § 602.15(b)(2)(I). New individual fishing quota programs may not be approved or implemented before October 1, 2000. Sustainable Fisheries Act, P.L. 104-297, § 108(e) (1996) (to be codified at 16 U.S.C. § 1853(d)(1)(A)).

¹⁷¹16 U.S.C. § 1853(b), as amended by Sustainable Fisheries Act, P.L. 104-297, § 108(c) (1996).

Federal fees for licenses or permits in excess of administrative costs and taxation are not permitted as mechanisms to limit access.¹⁷²

Foreign fishing within the exclusive economic zone is prohibited unless: (1) a treaty or agreement in effect on April 13, 1976, or a governing international fishery agreement, or Pacific Insular Area fishery agreement¹⁷³ authorizes such fishing; (2) an allocation of fish is available to the foreign government; (3) a valid permit has been issued; and (4) the foreign nation where the foreign vessel is registered extends the same fishing privileges to U.S. vessels.¹⁷⁴ International fishery agreements are subject to review and approval by Congress. The total allowable level of foreign fishing in each fishery is equivalent to that portion of the optimum yield of that fishery which will not be harvested by U.S. vessels. The Secretary of State is authorized to allocate any foreign harvest among eligible foreign nations, based on a number of discretionary criteria. Foreign nations must annually submit an application for permits for its fishing vessels that seek to fish within U.S. waters. A fee is charged in connection with the issuance of the permit. Currently, there is virtually no foreign exploitation of fishery resources within the exclusive economic zone.

One important issue which appears to have been resolved, is whether biodiversity prospecting would be regulated under the Magnuson-Stevens Act. The term "fishing" as defined under the Magnuson-Stevens Act does not generally include scientific research conducted by a scientific research vessel.¹⁷⁵ However, "data collection activities" designed to capture and land quantities of fish or invertebrates for product development, market research, and/or public display ". . . are not considered to be the type of scientific research activities exempt from regulations."¹⁷⁶ Thus, biodiversity prospecting involving collections of quantities of fish¹⁷⁷ by U.S. scientific research vessels -- if such prospecting is conducted for product development -- remains subject to regulation under the Magnuson-Stevens Act. Consequently, these activities must be permitted under the "exempted fishing procedures," which are described below.

¹⁷²16 U.S.C. § 1854(d), as amended by Sustainable Fisheries Act, P.L. 104-297, § 109 (1996).

¹⁷³16 U.S.C. § 1823.

¹⁷⁴16 U.S.C. §§ 1821-1827, as amended by Sustainable Fisheries Act, P.L. 104-297, § 105 (1996).

¹⁷⁵16 U.S.C. § 1802.

¹⁷⁶61 Fed. Reg. 32,541, 32,543 (1996)(to be codified at 50 C.F.R. § 600.10).

¹⁷⁷The term "fish" means "any finfish, mollusk, crustacean, or parts thereof, and all other forms of marine animal and plant life other than marine mammal, and birds." 61 Fed. Reg. 32, 541, 32, 542 (1996) (to be codified at 50 CFR. § 600.10).

Under the exempted fishing permitting procedures, NMFS may authorize the target or incidental harvest of species managed under an FMP or fishery regulations that would otherwise be prohibited.¹⁷⁸ This would include data collection contemplated by biodiversity prospecting.

To receive an exempt fishing permit (EFP), the applicant must submit an application package which includes: a statement of the purposes and goals of the exempted fishing; justification for issuance of the EFP; a listing of the species (target and incidental) expected to be harvested under the EFP; the amount(s) of such harvest necessary to conduct the exempted fishing; the arrangements for disposition of all regulated species harvested under the EFP and any anticipated impacts on marine mammals or endangered species; the approximate time and place of fishing; and gear to be used.¹⁷⁹ A fee to recover administrative expenses may be charged.¹⁸⁰ An EFP may be denied if: (i) the harvest would detrimentally affect the well-being of the stock of any regulated species of fish, marine mammal, or threatened or endangered species in a significant way; (ii) activities to be conducted under the EFP would be inconsistent with the management objectives of the FMP or other applicable law;¹⁸¹ or (iii) the proposed activity could create a significant enforcement problem.

The EFP may be issued with terms and conditions consistent with the purpose of the exempted fishing. These include, the maximum amount of each regulated species that can be harvested and landed during the term of the EFP; the time and place where fishing may be conducted; the type, size and amount of gear that may be used; the conditions under which observers, a vessel monitoring system, or other electronic equipment will be carried on board; and reasonable data reporting requirements and provision for public release of data.¹⁸² Unless otherwise specified in the EFP, the permit is effective for no longer than one year and is not transferable or assignable.¹⁸³

Persons conducting scientific research activities are requested to submit a copy of any cruise report (or the publication created as a result of the cruise), including the

¹⁷⁸61 Fed. Reg. 32,575 (1996) (to be codified at 50 C.F.R. § 600.745(b)(1)).

¹⁷⁹*Id.*

¹⁸⁰61 Fed. Reg. 32,575 (1996) (to be codified at 50 C.F.R. § 600.745(b)(1)).

¹⁸¹See discussion *infra* note 304 and accompanying text on requirements in the FMP for protecting essential fish habitat.

¹⁸²*Id.*

¹⁸³61 Fed. Reg. 32,575, 32,576 (1996) (to be codified at 50 C.F.R. § 600.745(b)(4), 50 C.F.R. § 600.745(b)(6)).

amount, composition, and disposition of their catch, to the appropriate Science and Research Director.¹⁸⁴ Similarly, persons fishing under an EFP are required to report their catches to the appropriate official specified in the EFP.¹⁸⁵

The only permissible way under current regulations for data collection activities to be carried out by foreign vessels under the scientific research exemption is for the foreign vessel to act "in full cooperation with the U.S." and thus qualify for the scientific research exemption. It does not appear that foreign vessels are eligible to receive an EFP; exempted fishing is defined under the regulations as only covering fishing from a vessel of the United States.¹⁸⁶ Data collection by foreign vessels for product development not carried out in full cooperation with U.S. vessels may be considered foreign fishing subject to applicable regulations. After review of the research plan, the authorities will inform the applicant as to whether the proposed activity constitutes fishing rather than scientific research activity, and may recommend revisions necessary to make the cruise acceptable as scientific research activity. Persons conducting scientific research are requested to submit a copy of any cruise report or other publication created as a result of the cruise, including the amount, composition, and disposition of their catch.¹⁸⁷

Special laws protect marine mammals. Under the Marine Mammals Protection Act (MMPA), the taking and importation of marine mammals and marine mammal products is generally prohibited. Permits may only be issued for purposes of scientific research, public display, or enhancing the survival or recovery of a species or stock. In determining whether to issue a scientific research permit under the MMPA, the Secretary of Commerce is to consider, among other criteria, the value of the scientific research and the effect of the proposed taking or importation on the population stock and the marine ecosystem.¹⁸⁸ Permits may contain such terms and conditions as the Secretary deems appropriate, including provisions on the number and kind of marine mammals which may be taken, the transferability or assignability of the permit, and the

¹⁸⁴61 Fed. Reg. 32,575, 32,576 (1996) (to be codified at 50 C.F.R. § 600.745(c)).

¹⁸⁵*Id.*

¹⁸⁶61 Fed. Reg. 32,541, 32,542 (1996) (to be codified at 50 C.F.R. § 600.10).

¹⁸⁷61 Fed. Reg. 32,568 (1996) (to be codified at 50 C.F.R. § 600.512(b)).

¹⁸⁸50 CFR § 216.31.

sale or other disposition of the marine mammal, its progeny, or the marine mammal product.¹⁸⁹ A fee covering the costs of issuance of such a permit may be charged.¹⁹⁰

Certain marine mammal parts are exempt from the prohibitions on takings, such as bones, teeth, or ivory of any dead marine mammal.¹⁹¹ Tissues, fluids, or other marine mammal parts sloughed, excreted, or otherwise naturally discharged may be collected for bona fide scientific research. Collection must not involve the taking of a living marine mammal in the wild. Marine mammal parts collected pursuant to this exception must be registered and identified and are subject to transfer restrictions. In addition, such parts may not be sold or traded for commercial purposes.

Federal laws also create special protection for areas designated as marine sanctuaries, creating a different set of access issues. The Secretary of Commerce can designate marine sanctuaries based on conservation, recreational, ecological, historical research, educational or aesthetic values, and must identify the types of activities that will be subject to regulation to protect those characteristics.¹⁹² The terms of the designation may only be modified by the same procedures as the original designation.

The Secretary of Commerce may issue special use permits which authorize the conduct of activities in a national marine sanctuary if such authorization is necessary to establish conditions of access to and use of any sanctuary resource.¹⁹³ A permit may only authorize activities that are compatible with the purpose for which the sanctuary is designated and with the protection of sanctuary resources. Permits are limited to five years unless renewed. Activities are to be carried out in a manner that does not destroy, cause the loss of, or injure sanctuary resources. Fees may be assessed to cover administrative and monitoring costs and the amount which represents the fair market value of the use of the sanctuary resources and a reasonable return to the U.S. government.

Special use permits are not necessary to conduct fishing activities in a national marine sanctuary; these activities are governed instead by the regulations and permit

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ 50 CFR § 216.26.

¹⁹² 16 U.S.C. § 1434(a)(4).

¹⁹³ 16 U.S.C. § 1441.

requirements of the Magnuson-Stevens Act.¹⁹⁴ Regulations for fishing activities within marine sanctuaries in the exclusive economic zone are to be prepared by the appropriate Regional Fishery Management Council.¹⁹⁵ Although the Secretary of Commerce does not have the right to terminate any valid rights of subsistence use or access in existence on the date of the designation, such instruments and rights are subject to regulation consistent with the purposes for which the sanctuary is designated.¹⁹⁶

In addition, federal agency actions within or outside of a national marine sanctuary, including private activities authorized by licenses, leases, or permits that are likely to destroy, cause the loss or, or injure any sanctuary resource, are subject to consultation with the Secretary of Commerce. If the Secretary finds that the proposed action is likely to destroy, cause the loss of, or injure a sanctuary resource, the Secretary is required to recommend reasonable and prudent alternatives that will protect the sanctuary resources, which may include conducting the action elsewhere.¹⁹⁷

Finally, if collection of materials is contemplated in the waters, seabed, or subsoil under federal jurisdiction, it is possible that an environmental evaluation may be required under the National Environmental Policy Act (NEPA).¹⁹⁸ The determination of whether NEPA applies depends upon the scope of the contemplated activity and its potential impacts. An environmental impact statement must be prepared whenever there is a proposal for a "major Federal action[] significantly affecting the quality of the human environment."¹⁹⁹

(b) State Government Areas

If a state has an approved coastal management plan, federal activities directly affecting the coastal zone and activities affecting the coastal zone that require federal licenses or permits must be consistent with the plan. Federal agencies must provide state agencies with a consistency determination at least 90 days before final approval of the federal activity, unless both the federal agency and the state agency agree to an

¹⁹⁴16 U.S.C. § 1441(f).

¹⁹⁵16 U.S.C. § 1434(a)(5).

¹⁹⁶16 U.S.C. § 1434(c).

¹⁹⁷16 U.S.C. § 1434(d).

¹⁹⁸42 U.S.C. §§ 4321-4332.

¹⁹⁹42 U.S.C. § 4332(2)(C). See discussion accompanying note 115, *supra*.

alternative notification schedule.²⁰⁰ If the state agency disagrees with the federal agency's determination, either party can request mediation assistance from the Secretary of Commerce. In the case of a request for a federal permit or license, the applicant is required to provide a consistency certification with the application. The state may object to the applicant's certification, precluding issuance of the permit or license by the relevant federal agency, unless the Secretary of Commerce finds that the activity is consistent with the objectives of the Coastal Zone Management Act or is necessary in the interest of national security.²⁰¹

States that have laws requiring environmental impact assessments may be required to prepare such assessments in conjunction with their own activities or in connection with state approval of private activities that could have a significant impact upon the state's environment.²⁰²

2. Private

As discussed above, there are very few situations in which marine resources are privately owned. One common situation is the leasing of seabeds under state jurisdiction. In this situation, access would be subject to consent of the lessee and would need to occur in a manner consistent with the terms and conditions of the lease.

3. Indigenous

In terms of access, fishery management plans and their implementing regulations must be consistent with the provisions of treaty obligations with Indian tribes.

Certain indigenous groups are allowed to take marine mammals without a permit. Any Indian, Aleut, or Eskimo who resides on the coast of the North Pacific Ocean or the Arctic Ocean may take a marine mammal without a permit. They are, however, subject to the following limitations.²⁰³ The taking must be by an Alaska Native who resides in Alaska and must be for subsistence purposes; or the taking must be for the purposes of creating and selling authentic native articles of handicraft and clothing. In each of these cases, the taking must not be done in a wasteful manner. In addition, as a general matter, no marine mammals taken pursuant to these exemptions

²⁰⁰15 C.F.R. § 930.34.

²⁰¹15 C.F.R. § 930.65, 15 C.F.R. § 930.121.

²⁰²See discussion accompanying note 162, *supra*.

²⁰³50 C.F.R. § 216.23(a).

may be transferred in interstate or foreign commerce.²⁰⁴ These provisions appear to preclude the taking of marine mammals for biodiversity prospecting purposes pursuant to the permit exemptions.

C. Ex situ Collections

1. Public Ownership - Access Issues

National Genetic Resources Program

Most germplasm within the National Genetic Resources Program (NGRP) is freely available to any person for research purposes. Although commercial use of this germplasm is not permitted, it is distributed without restrictions concerning uses derived from the research.

However, a plant variety that is protected by the Plant Variety Protection (PVP) Act will be made available subject to conditions imposed by the PVP holder. Thus, materials which the National Seed Storage Laboratory (NSSL) receives through the PVP Office are unavailable for distribution. They remain under the control of the PVP Office. Other materials at NSSL that are within NGRP are subject to the distribution policies which apply to the general NGRP system.

Accessing materials in NGRP requires a simple request. By law, NGRP is required to "make available upon request, without charge and without regard to the country from which such request originates, the genetic material which the program assembles."²⁰⁵ Most repositories within NPGS receive and distribute germplasm free of charge through exchanges to other countries, written inquiries, or orders placed through the NPGS internet site.²⁰⁶ The requesting party needs to provide name, organization, address, phone number, special handling instructions, and the accession identifiers²⁰⁷ desired to the appropriate repository. The Plant Introduction Office in Beltsville, Maryland handles foreign exchanges. There are handling and shipping fees and "phytosanitary permit costs" which have been provided free-of-charge to date.²⁰⁸

²⁰⁴50 C.F.R. § 216.23(b).

²⁰⁵7 U.S.C. § 5841(d)(4).

²⁰⁶<http://www.ars-grin.gov/npgs/orders.html>.

²⁰⁷Accession identifier is the term used for a plant variety's identification number.

²⁰⁸Communication with Dr. Henry Shands, May 10, 1996.

Requests from U.S. and Canadian entities are processed through the appropriate collection.

The Agricultural Research Service (ARS) Culture Collection distributes microbial strains to researchers. There is no charge for most cultures. A researcher may request up to 12 strains from a given laboratory, and individuals may request up to 24 strains per year unless they enter into a cooperative research and development agreement. Requests need to be made in writing and include the strain's accession number. Strains held in the ARS Patent Culture Collection may be requested only with a signed original letter.

U.S National Cancer Institute

The materials within National Cancer Institute's (NCI's) Developmental Therapeutics Program Natural Products Branch are available to "selected qualified research organizations," if they will be used in furtherance of the purposes for which they are held by the NCI. Distribution is subject to availability, and materials will not be provided if research programs of NCI would be adversely affected. Research organizations who wish to acquire materials from the collection must submit research proposals. Requests are evaluated on their scientific merits and the relative importance of the work. Although research relating to AIDS and cancer is given preference, other areas of research are considered. NCI also considers the uniqueness of the purpose for the natural product screening, its relevance to the other major research missions of the Institute, the existence of an ongoing operational screen, and demonstration of sufficient scientific expertise to assure that the disposition of the material will be utilized optimally to discover new therapeutic agents.

Approved applicants are not granted unlimited access to repository materials. They may receive samples under the terms of a Material Transfer Agreement. Important aspects of the model Material Transfer Agreement are: (i) recipients must agree to protect the interests of the country providing the material to NCI; (ii) the NCI will retain ownership of the material (which is separate from intellectual property rights); (iii) the recipient will pay the "out-of-pocket" costs of preparing and shipping samples; (iv) unused samples will be disposed of in a manner determined by mutual agreement; (v) a reporting procedure will be established to assure that NCI is kept informed of the usage of the materials; and (vi) research results derived from this material will be transmitted in a timely manner to the NCI. Recipients must publicize findings related to the use of the material.

Smithsonian Institution

Although the Smithsonian's herbarium specimens are not maintained as germplasm, viable seed occasionally is produced. If available, seed is normally freely distributed to researchers upon request. The curator reserves the right to assess the value of the researcher's work, and to evaluate whether it outweighs the loss of value to the collection. Seed will not be distributed if it is an endangered or special historic specimen.²⁰⁹

2. Private Ownership - Access Issues

Access to germplasm held by private, for-profit firms is governed by private agreements. Biotechnology companies engaged in research of microorganisms and DNA face increasingly contentious debates about rights to the access and benefits of the resources they seek.

Private, non-profit organizations have varying policies regarding access. Many operate on a policy of open access or exchange. The Center for Plant Conservation (CPC) will only distribute excess material to researchers, since most of the plants within their collections are rare. Researchers can submit a request to the CPC or to participating institutions. The CPC requires a statement of purpose with a request. The CPC will distribute material for conservation-related research only. Depending upon the species desired, a fee may also be required.²¹⁰

Specimens within the New York Botanical Gardens are available free of charge upon request for almost any research purpose. Requests are submitted to the managers of the Horticulture Department. Requesting parties must provide their name, identify the material they are requesting, and explain why they wish to receive the material and where it will be used. Requests are approved by the Vice President of Horticulture.²¹¹

The Arnold Arboretum of Harvard University also makes specimens from its collections available to researchers. The Arboretum requires that researchers identify themselves and the purpose of their request. A fee is required only to cover costs of collecting the material. If the research might lead to a patent, requesting parties must

²⁰⁹Communication, George Russell July 23, 1996.

²¹⁰Communication, Anukriti Sud, Manager of Conservation Programs July 25, 1996.

²¹¹Communication, R. Schnall, VP Horticulture July 16, 1996.

sign a research agreement that requires a return to Harvard University before commercialization. The Arboretum distributes specimens to nurseries as well.²¹²

The Missouri Botanical Garden maintains ownership of all of its plant material and releases samples only under specific conditions to support research projects. Its Material Transfer Agreement provides that, "Samples in the Garden's DNA Bank have been collected solely for the purpose of supporting molecular phylogenetics and will be released only for the study of relationships of plants or for studies aimed at improving our understanding of evolutionary mechanisms. Samples will not be made available for bioprospecting endeavors, screening for genes of interest in agricultural research, or any other commercial application." A fee of \$25 is charged for each sample requested.²¹³

Issues of access and benefits vary depending on the particular organization's mission. Zoos and university collections of animal resources often operate on an exchange basis. Members of private groups, such as the Seed Savers Exchange, exchange seeds among themselves and publish information about seeds in catalogs and inventories. Those interested in preserving and growing plants can join the Seed Savers Exchange for a modest annual membership fee. Native Seeds/SEARCH invites particular groups to engage in preservation efforts of species native to the Southwest U.S. It provides materials free of charge to Native Americans and to plant breeders; some germplasm is offered for sale to the general public in an annual catalog.

The American Livestock Breeds Conservancy owns the germplasm it stores. Most of the germplasm is kept in long-term storage and will only be made available to help the survival of a breed in the event of a disaster, or to genetically improve breeding efforts of a line experiencing genetic problems. A second, smaller function of the gene bank is to fill breeder orders; breeders are restricted to using germplasm only on pure-bred livestock. For either type of access, recipients are charged for semen at market cost, plus shipping and handling fees.

²¹²Communication, A. Hubble for Bob Cook, Director July 26, 1996.

²¹³Missouri Botanical Garden DNA Bank, Material Transfer Agreement, p. 1.

Chapter Three:



Benefits Derived from Access to Genetic Resources

The Biodiversity Convention requires each party to provide source countries access to the benefits (such as financial benefits) resulting from the exploitation of that country's genetic resources.²¹⁴ The Convention also requires all contracting parties to provide, or facilitate access to, technologies relevant to conservation of biological diversity, technologies relevant to sustainable use of the components of biological diversity, and technologies that make use of genetic resources.²¹⁵ Benefits-sharing requirements -- even for access to genetic materials on government-owned lands and waters -- are not well developed or widely used in the United States.²¹⁶

A. Terrestrial and Aquatic Areas

1. Public - Federal

In the United States, absent new laws, benefit-sharing obligations under the Convention may be implemented by imposing regulatory conditions on access to government-owned lands and Indian trust lands, and by entering into private agreements on private lands. The regulations of many federal land management agencies, however, fail to deal adequately with the issue of potential future compensation for genetic resources, and may leave some agencies in a position of not being able to receive those benefits.

²¹⁴Convention, Article 15, Section 7, and Article 19. Training, sharing of research results, and technical and scientific cooperation are also provided for in Articles 12, 17, and 18.

²¹⁵Convention, Article 16.

²¹⁶Examples of how transfers of benefits might operate under U.S. law are offered by agreements made by U.S. firms with developing countries. Merck's contract with INBio in Costa Rica provided for an initial payment of \$1,135,000 covering various costs, technology transfer, training, overhead, and equipment; an undisclosed royalty rate is to be paid on any commercially successful products. In return, INBio provides samples and extracts for evaluation, using local people trained as parataxonomists. See *generally*, World Resources Institute, Biodiversity Prospecting: Using Genetic Resources for Sustainable Development (1993). The U.S. National Cancer Institute also has a policy for providing benefits to source countries in connection with its evaluation of genetic materials.

The issue of obtaining benefits derived from the exploitation of genetic materials discovered on government-owned lands is not just theoretical. One federal permit issued in the 1960s for research in the hot springs of Yellowstone National Park led to the discovery of the taq-polymerase enzyme in bacteria found in the springs. The bacteria were collected by one researcher and, years later, the enzyme was discovered in representative cultures deposited in the American Type Culture collection and commercialized by a company subsequently acquired by the multinational firm Hoffman-LaRoche.²¹⁷ There was no economic return to the National Park Service because regulations did not provide for revenue-generating provisions in National Park research permits or reserve rights to the fruits of any discoveries.²¹⁸ Regulations for research specimen collection permits continue to provide only that that data and publications resulting from the collection permit must be made available to the public and filed with the park superintendent. The permits do not provide for revenue-generation.²¹⁹

As a result of this experience, the National Park Service considered developing a requirement that researchers at Yellowstone sign a contract that dedicates a portion of any eventual product profits to the Park Service. However, the Park Service was concerned as to whether such agreements were within the Park Service's existing legal authority, which states that "no natural curiosities, wonders, or objects of interest shall be leased, rented, or granted to anyone on such terms as to interfere with free access to them by the public."²²⁰ Moreover, it was not clear that any funds received would go to Yellowstone or the National Park Service rather than to the general federal treasury. To overcome the legal obstacles to revenue-collection presented in the research collection specimen permit regulations, the Park Service created a hybrid arrangement, separating the collection activities from revenue generation. First, the Park Service granted a research specimen collection permit to a U.S.-based bioprospecting firm, Diversa Corporation (Diversa), allowing it to collect samples of thermal microbes from Yellowstone springs. Then, in August 1997, the Park Service entered into a separate agreement with Diversa for commercialization of research based on the collected

²¹⁷Thomas Brock, "The Value of Basic Research; Discovery of *Thermus aquaticus* and other extreme Thermo-philic," Genetics 146:1207-1210 (August, 1997).

²¹⁸National Public Radio, "All Things Considered," March 5, 1996.

²¹⁹36 CFR § 2.5(g)(2).

²²⁰16 U.S.C. Section 3. "[A]t least two [biotechnology companies] have proposed deals to cut the National Park Service in on revenue generated by their discoveries. But park managers say strict laws against the exploitation of park life bar them from making such deals, though they have not barred the collecting that raised the question to begin with." Michael Milstein, "The West's New Prospectors Seek Microbes," High Country News, April 29, 1996, p. 13.

samples. The agreement provides for payments and in-kind contributions to the park totalling \$35,000 per year for five years, plus an undisclosed amount of royalties on any future product. Diversa also agreed to do DNA fingerprinting for a genetic analysis of the wolves recently re-introduced to the parks, train park staff, and to conduct a genetic inventory of park resources.²²¹

The Park Service asserted as the legal basis for the agreement -- and for the Park's collection and retention of cash payments -- the Federal Technology Transfer Act of 1986.²²² That law authorizes the director of any government-operated federal "laboratory" to enter into "cooperative research and development agreements" (CRADAs) with collaborating private parties.²²³ The purpose of a CRADA is to grant to a collaborator the right to "patent licenses or assignments . . . in any invention" made at the laboratory under the terms of the agreement "for reasonable compensation when appropriate." The law defines laboratory as "a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government."²²⁴ The Department of the Interior has taken the position that the national parks fall within this definition, thus authorizing Yellowstone National Park to enter into the CRADA with Diversa.

The Park Service maintains that the CRADA, which is a commercial agreement, is consistent with the limitations on research permits for specimen collection in the parks, which do not allow commercial uses. Diversa has access to the biological resources in the Park under a research specimen collection permit. That permit itself does not provide for collection of materials that will be commercially exploited, but merely for collection for research purposes. Indeed, the research permit conditions recited in the CRADA expressly provide that "sale or commercial use of Natural Products taken from Yellowstone National Park or other park areas is prohibited."²²⁵ At

²²¹Jim Robbins, "Yellowstone's Microbial Riches Lure Eager Bioprospectors," New York Times, Tuesday, October 14, 1997; Michael Milstein, "Microbes for Sale Here," High Country News, September 29, 1997; John Varley, Director, Yellowstone Center for Resources, Speech, February 25, 1998, National Press Club, Washington, D.C.

²²²15 U.S.C. §§ 13710a - 13710d.

²²³15 U.S.C. § 1310a(a).

²²⁴15 U.S.C. § 3710a(d)(2)(A).

²²⁵Cooperative Research and Development Agreement for a Project Between Yellowstone National Park/National Park Service and Diversa Corporation, section 2.2. See also research permit application, Recombinant Biocatalysis (prior name of Diversa Corp.), June 24, 1997, application condition 2:

the same time, however, the CRADA covers the research "results," which are what may be commercially exploited. According to the Park Service, this distinction is critical to the legality of the agreement, since the Service has far less leeway under its organic laws than do other public land management agencies to enter into commercial arrangements involving the resources they manage.²²⁶

The Park Service intends to allow non-profit research to continue in the parks under research permits without requiring benefit-sharing CRADAs; indeed, nearly 40 research organizations currently have permits for research in Yellowstone. In the future, however, the Park Service intends to condition such permits on statements by applicants that they are conducting such research for strictly noncommercial purposes. Companies seeking to develop commercial products -- including bioprospecting companies -- will be directed to negotiate CRADAs with the Park Service to provide a financial return to the park.²²⁷ A Park Service official involved in the negotiation of the Diversa CRADA has estimated that Yellowstone National Park will enter into as many as 6 CRADAs in 1998 and 10-20 over the next ten years; he also noted that up to 100 of the 368 national parks may face this issue in the future.²²⁸

If the Federal Technology Transfer Act is used successfully by the Park Service to achieve the receipt of benefits from bioprospecting, it is likely to be used by other federal agencies as well. Several issues have been raised, however, concerning the use of this law. First, the lands or installations of the other federal agencies must qualify as "laboratories" within the meaning of the law. Second, the National Parks and Conservation Association has maintained that the royalty rates should not be secret, has called for the issuance of regulations setting standards for the use of CRADAs for bioprospecting, has called for careful monitoring of the collection activities and of

"Collections shall be used for scientific or educational purposes only, shall be dedicated to public benefit, and shall not be used for commercial profit, unless explicitly authorized by the superintendent."

²²⁶World Foundation for Environment and Development & Yellowstone Center for Resources, "Bioprospecting at Yellowstone National Park: Some Frequently Asked Questions," (undated pamphlet) [1998], at 3: "The existing prohibition on the 'sale or commercial use' of natural products collected at Yellowstone National Park remains unchanged." But the CRADA, which covers research "results," will "ensure that Yellowstone shares in the economic and scientific benefits resulting from Diversa's research." *Id.*

²²⁷Preston Scott, World Foundation for Environment and Development, personal communication, Feb. 26, 1998. The World Foundation brokered the Diversa agreement, using its familiarity and experience with the InBIO agreement in Costa Rica.

²²⁸John Varley, Director, Yellowstone Center for Resources, Speech, Feb. 25, 1998, National Press Club, Washington, D.C.

royalty agreements, and has expressed concern that funds derived from commercial exploitation of park resources might lead to displacement of public funding for parks rather than augment such funding.²²⁹ In addition, a lawsuit challenging the Diversa agreement was filed by three citizen groups in March 1998. The suit alleges that the Federal Technology Transfer Act does not apply to Yellowstone National Park; that the CRADA violates the National Park Service Organic Act and implementing regulations; that the CRADA violates the terms of the legislation under which Yellowstone was established; that the National Park Service illegally chose not to prepare an environmental assessment or environmental impact statement to evaluate the impact of the CRADA and the cumulative impacts of future CRADAs on the park; and that the CRADA violates the public trust under which Yellowstone National Park and its resources are held for all citizens.²³⁰

It is not clear whether the courts will reach the merits of this suit as the government is likely to contest the standing of the plaintiff organizations to challenge the CRADA. Moreover, because much of the case involves Park Service laws and procedures, even a ruling adverse to the Park Service may not reduce the utility of the CRADA mechanism for bioprospecting conducted on federal lands administered by other agencies.

On federal lands dedicated to multiple uses, such as Bureau of Land Management and Forest Service lands, the permits granting access can be drafted to contain conditions providing for some return of "fair market value" or other benefits to the government for collection of genetic resources. Thus, they might require performance of certain restoration or conservation actions by the permittee, and provide for payment of administrative and processing fees. In general, however, absent specific authorizing legislation, fees and royalties beyond those necessary for administration of a particular permit may not be exacted by federal agencies for uses of the federal lands. Thus, the use of CRADAs may be the logical approach for these agencies as well if they seek to exact financial benefits for genetic resource collection and exploitation on many federal lands.

2. State, Private, Indigenous

There are no obvious impediments to the owners' negotiation for the receipt of benefits for genetic collection on state, private, and indigenous lands. Conditions of

²²⁹Libby Fayed, Counsel to NPCA, remarks, Feb. 25, 1998, National Press Club, Washington, D.C. The NPCA has not opposed the Diversa agreement, however.

²³⁰Edmonds Institute, et al. v. Babbitt, No. 1:98CV00561 (filed March 5, 1998, D.D.C.).

access must be agreed to and all regulatory conditions must be met. Contracts involving resources on Indian trust lands must be reviewed and approved by the Department of the Interior before they become effective, to assure that the Indians are receiving an adequate return.²³¹ According to the provisions of the state law,²³² states may impose charges for collection or exploitation of resources on state lands. Private land owners can negotiate the terms of access to their lands in order to achieve some financial benefits.

Of course, to the extent that genetic resources are dispersed across a wide area and over the land of many different owners, it may be difficult for any one owner (or even group of owners) to successfully exact a significant financial return. Unique resources (such as rare plants confined to a limited geographic area) may be easier to manage in a way that increases the likelihood of the land owner or community receiving a financial benefit.

3. *Intellectual Property Rights in Genetic Resources*

One approach relevant to the extraction of economic benefits from access to genetic materials may be the use of intellectual property rights, a form of private property recognized under federal law.²³³ Intellectual property rights give exclusive

²³¹25 U.S.C. § 81.

²³²Where the genetic resources are found in fish or game animals, a federal provision may constrain state abilities to reap and expend financial benefits. Federal law provides for the allocation of certain federal tax revenues to states to support fish and wildlife conservation and restoration, but requires that in order to receive this federal money, a state must have enacted laws that prohibit hunting and fishing license fees charged by the state from being diverted to any purpose other than the administration of the state's fish and game program. 16 U.S.C. §§ 669, 777. Because of this provision, all states include this limitation on the use of license fees.

²³³U.S. Constitution, Art. 1, Section 8, cl. 8. While the applicable law is national, significant international agreements help define the limits within which national laws operate. The major conventions concerning patents include the Patent Cooperation Treaty (PCT) with 47 members (Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, T.I.A.S. 8733, 9 I.L.M. 978, 35 U.S.C. § 351 *et seq.*) and the Paris Convention for the Protection of Industrial Property with 101 members (Paris Convention for Protection of Industrial Property, March 20, 1883, U.S.T.S. 379, 25 Stat. 1372, 161 S.T.S. 409). Patent granting standards are left up to national laws by the Convention. The General Agreement on Tariffs and Trade (GATT) also has intellectual property provisions. The Trade-Related Aspects of Intellectual Property (TRIPs) under the Uruguay Round of GATT sets minimum standards for intellectual property law, and particularly for trademark protection including protection of geographical indications of origins (GATT (Uruguay Round), TRIPs, pt. II, Section 2, arts. 15-24). TRIPs also provides for the patenting of microorganisms, but allows signatories to deny patents to plants and animals. It also provides that signatories may allow limited, reasonable exceptions to exclusive rights (*e.g.*, provide for compulsory licenses).

access rights to the holder of the rights. These rights normally are exploited by licensing and commercialization agreements where the owner receives either a specific fee or a percentage of net or gross proceeds. Intellectual property rights may also be sold outright. They are not perpetual, but operate for a specific period of time, designed to allow the innovator or discoverer of the protected matter to control access exclusively, and thus reap the financial rewards of the discovery. However, the United States government and its contractors may use patented technology, as long as a reasonable royalty is forwarded to the patent holder.²³⁴ The primary forms of intellectual property relevant to genetic resources are embodied in utility patents, plant patents, and plant variety certificates.

The most powerful intellectual property right mechanism is a utility patent.²³⁵ A utility patent provides the holder with the exclusive right to make, use, or sell the patented invention for the term of the patent - currently 17 years.²³⁶ An applicant for a utility patent must describe the invention in detail and demonstrate that it distinguishes itself from known inventions by means of its utility,²³⁷ novelty,²³⁸ and non-obviousness.²³⁹ The U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*²⁴⁰ confirmed the patentability of a "human-made, genetically engineered bacterium . . .

²³⁴28 U.S.C. § 1498(a). Courts have interpreted this section as premised on the exercise of eminent domain over patented property. See, e.g., *Tektronix, Inc. v. United States*, 552 F.2d 343, 346 (Ct. Cl. 1977).

²³⁵The availability of utility patents for products of nature varies by country. While the U.S. will allow patents to be granted for products of nature where they have been significantly altered by humans, other countries have denied such patent protection on the grounds that such patents reduce public access to the patented invention or are morally offensive. Michael A. Gollin, *An Intellectual Property Rights Framework for Biodiversity Prospecting*, in *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* (WRI 1993).

²³⁶However, the Patent Term Restoration Act allows patentees of pharmaceuticals up to a 5-year extension to make up for some marketing delays that are due to Food & Drug Administration approval processes. 35 U.S.C. § 155A.

²³⁷35 U.S.C. § 101.

²³⁸35 U.S.C. § 102.

²³⁹35 U.S.C. § 103. If the subject of a patent application has been used by anyone other than the inventor prior to the date claimed for the invention, the patent must be denied for lack of novelty. 35 U.S.C. § 102(a). If, more than one year before date of the application, the subject of the patent application was patented or was described in a printed publication, or was publicly used or sold in the United States, the patent must be denied. The patent must also be denied if the subject of the application was patented in another country or described in a printed publication in another country more than one year before the date of the application. 35 U.S.C. § 102(b).

²⁴⁰447 U.S. 303 (1980).

capable of breaking down multiple components of crude oil."²⁴¹ The bacterium's manufactured quality via a purposeful endeavor, along with the usual patent standards of utility, novelty, and non-obviousness, made it patentable.

The Court established the distinction that utility patents could not be awarded for discovered existing life forms, but that human-engineered life forms could be granted patents if they met the relevant criteria.²⁴² As the Court said in an earlier case, "a modified natural product does not become [patentable] subject matter until its essential nature has been substantially altered."²⁴³ The case law has supported grants of utility patents to genetically engineered bacteria, fungi, microorganisms and even a mouse.²⁴⁴

Ex parte Hibberd,²⁴⁵ an administrative case, extended utility patent protection to new plants produced through conventional breeding techniques. *Ex parte Hibberd* involved an appeal to the Patent and Trademark Office concerning a rejected utility patent for a new maize plant. The appeal board granted a patent to the plant inventors, concluding first, that the Supreme Court had already determined that utility patents could be issued on anything made by humans provided the standards of utility, novelty, and non-obviousness could be met; and second, that there appeared to be no evidence that Congress intended the separate statutes for plant patents, plant variety certificates, and utility patents to be mutually exclusive.

More recently, discoverers of the function and potential utility of specific naturally occurring *gene sequences* have been granted patents. This seems to extend patent protection beyond that recognized in *Chakrabarty* because the gene sequences

²⁴¹Chakrabarty, 447 U.S. at 305.

²⁴²"[A] new mineral discovered in the Earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of nature' . . . here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork but his own; accordingly, it is patentable subject matter." 447 U.S. at 309-310.

²⁴³American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931).

²⁴⁴See Edmund Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 Drake L. Rev. 551 (1989). There are approximately 200 patent examiners (out of a total of 1800) devoted to biotechnology applications. Biotechnology patent applications constitute approximately 6% of the total filed each year; and there were over 12,800 such applications in 1993. Victoria Slind-Flor, *Pending Patent Problems*, Nat'l L. J. May 23, 1994, at A22.

²⁴⁵227 U.S.P.Q. 443 (P.T.O. Bd. Pat. App. & Int'f, 1985).

themselves are naturally occurring and not modified by human ingenuity, although isolated and discovered by such ingenuity. Gene sequences have been deemed patentable where a research firm has first identified their function and how they might be *used* in a unique way.²⁴⁶

A different form of patent protection is explicitly afforded to some types of plants produced through human intervention. In 1930, the U.S. Congress passed the Plant Patent Act²⁴⁷ which grants a patent to "whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state."²⁴⁸ The Plant Patent Act is for asexually reproducing plants. The focus of the Act is on protecting and encouraging the human creation of new plant varieties. The exclusion of "a plant found in an uncultivated state" excludes mere discoveries of natural plants from exclusive appropriation. Human ingenuity and manipulation must be involved -- not in simply appreciating the potential usefulness of an existing plant -- but in developing a new plant.²⁴⁹ The Act protects only "plants" and attempts to patent bacteria under the Plant Patent Act have been rejected.²⁵⁰ For plant patents, the new variety must be novel and non-obvious, but the requirement of "utility" is replaced by "distinctiveness."²⁵¹ The right protected by the plant patent is the right to exclude others from reproducing the plant, or selling or

²⁴⁶*E.g.*, "Human Genome Sciences Granted 3 Gene Patents," Washington Post, April 17, 1996 ("the three patents granted yesterday are for complete genes, the proteins they make and the role that those proteins play in the human body. The patents give the company the right to use the genetic information to make - or sell the rights to make -- diagnostic tests or therapeutic drugs based on the information.") Patenting of genes requires that the patent seeker discover not only the gene, but its usefulness; an early attempt to patent a gene sequence without this information was rejected by the Patent and Trademark Office in 1993 for failure to meet the statutory standards of "novelty" and "utility." See Barbara Looney, "Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement," 26 Law & Policy in International Business 231, 252 (1994).

²⁴⁷35 U.S.C. §§ 161-164.

²⁴⁸35 U.S.C. § 161. The Act's exclusion of tuber plants was included in the Plant Patent Act especially to exclude certain food crops, such as the potato.

²⁴⁹What characterizes a distinct and new variety could be such things as "immunity from disease; resistance to cold, drought, heat, wind or soil conditions; color of flower, leaf, fruit or stems . . . perfume; and ease of asexual reproduction." Minor and temporary differences resulting from a small difference in the situation of cultivation -- *e.g.*, climate or soil induced changes -- are excluded. 35 U.S.C. § 161.

²⁵⁰*In re Arzberger*, 112 F. 2d 834 (C.C.P.A. 1940).

²⁵¹Plant Patent Act 35 U.S.C. § 162.

using the plant so reproduced.²⁵² Plant patents do not protect the cut flowers or products of the plant. The usual patent rights of licensing, royalties, and infringement remedies are available to holders of plant patents.

Congress enacted the Plant Variety Protection Act in 1970 in order to extend intellectual property protection to breeders of sexually reproducing plants.²⁵³ The Act allowed U.S. breeders to abide by the International Convention for the Protection of New Varieties of Plants (UPOV).²⁵⁴ The Plant Variety Protection Act results in issuance of a certificate rather than a patent and the registration is managed by the United States Department of Agriculture rather than the Office of Patents and Trademarks. The U.S. Department of Agriculture issues these certificates to "the breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety."²⁵⁵ The term of protection is 20 years for non-woody plants and 25 years for woody plants.²⁵⁶

To qualify for protection under the Plant Variety Protection Act, a new variety must be characterized by distinctness, uniformity, and stability. "Distinctness" requires "that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge."²⁵⁷ "Uniformity" refers to any variations within the variety being "describable, predictable and commercially acceptable."²⁵⁸ "Stability" requires that "the variety, when reproduced, will remain

²⁵²35 U.S.C. § 163.

²⁵³7 U.S.C. §§2401-2582. The Plant Variety Protection Act was extended to tuber propagated plant varieties by amendment in 1994, enacted "at the request of the potato industry." H. Rep. 103-699, 103 Cong. 2d Sess. 9, 1994 U.S. Code Cong. & Adm. News, 2423, 2425.

²⁵⁴International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961. 33 U.S.T. 2703, 815 U.N.T.S. 89, T.I.A.S. No. 10199.

²⁵⁵7 U.S.C. § 2402(a). A certificate may not be issued if more than one year before the date of application, the variety was sold or exploited, or was sold or exploited outside the U.S. more than 4 years before the application (6 years for trees and vines). 7 U.S.C. § 2402(a)(1).

²⁵⁶The 1970 Act provided for a 17-year term of protection, like that provided for plant patents and other patents. In 1980 plant variety protection was extended to 18 years to conform to the 1978 UPOV amendments; in 1994, the term was extended to conform to the 1991 UPOV amendments. 7 U.S.C. § 2483(b).

²⁵⁷7 U.S.C. § 2402(a)(2).

²⁵⁸7 U.S.C. § 2402(a)(3).

unchanged with regard to [its] essential and distinctive characteristics."²⁵⁹ Additionally, for a certificate to be granted, a "viable sample of basic seed (including any propagating material) must be deposited and replenished periodically in a public repository."²⁶⁰ The Plant Variety Protection Act's protection is broader than that of the Plant Patent Act in that seeds or any part of the plant cannot be sold without proper authorization.²⁶¹ There is, however, a "farmers' exemption," which allows farmers to save the seed from a protected variety for cropping in succeeding seasons without violating the certificate holder's rights to royalties.²⁶² The Secretary of Agriculture has the authority to require a certificate holder to grant a two-year compulsory license when a variety is "necessary" to insure an adequate supply of food, fiber, or animal feed in the nation, and the owner is unwilling or unable to supply the public need at a reasonable price.²⁶³

Intellectual property rights provide a potentially important, but limited, vehicle for the legal exploitation of genetic materials for financial benefit. The property right applies only to materials that have been manipulated by human intervention, or where a unique use has been discovered by such intervention. Anyone seeking to receive recognition of such a right must also meet the required substantive and procedural filing requirements. Currently, there is no U.S. law that would require the holder of intellectual property rights in genetic material to share benefits with local communities or with those that had collected, preserved, or initially identified the genetic material as potentially worthy of investigation.

B. Marine Areas - Benefits

1. Public

(a) Federal

Current law significantly limits the federal government from securing benefits in connection with regulation of fishery resources. Under the Magnuson-Stevens Act, the

²⁵⁹7 U.S.C. § 2402(a)(4).

²⁶⁰7 U.S.C. § 2422(3). The regulations require seeds to be deposited at the National Seed Storage Laboratory at Fort Collins, Colorado.

²⁶¹7 U.S.C. § 2483.

²⁶²7 U.S.C. § 2543. The 1994 amendments eliminated a prior exemption that allowed farmers to sell seed to other farmers without violating the certificate holders' rights. This change conformed to the 1991 UPOV Convention's elimination of this exemption.

²⁶³7 U.S.C. § 2404.

fees that are allowed to be imposed on any fishing vessel of the United States that fishes or wishes to fish in the exclusive economic zone or for anadromous species or for Continental Shelf fishery resources beyond such zone, are limited to the administrative costs incurred in connection with the issuance of the permit and the costs related to the management and enforcement of any individual fishing quota program or community development quota program.²⁶⁴ As discussed above, the permit fee applicable to domestic vessels that are required to secure an Exempt Fishing Permit for data collection is limited to administrative expenses. Thus, the executive branch would probably need clearer legislative authority before administratively imposing any fees in connection with biodiversity prospecting.

In the case of foreign fishing, the Secretary of Commerce, in consultation with the Secretary of State, is to establish a schedule of "reasonable fees" for foreign fishing permits that apply in a nondiscriminatory manner to each foreign nation.²⁶⁵ In general, these fees are to be deposited in the general fund of the Treasury. One unique exception is that funds collected pursuant to a foreign fishing agreement for a Pacific Insular Area are to be forwarded from the U.S. Treasury to the treasury of the appropriate Pacific Insular Area and can be used for implementing a marine conservation plan.²⁶⁶ There does not appear to be any fee applicable to foreign vessels conducting scientific research in full cooperation with the U.S.

The fee that may be assessed in connection with the taking of marine mammals for scientific purposes is limited to the costs of issuance of the permit. However, the permit may include provisions concerning the sale or other disposition of the marine mammal, its progeny, or the marine mammal product.²⁶⁷ This conceivably could be used to secure benefits from the development of genetic resources.

Fees may also be assessed in connection with the issuance of permits for the conduct of specific activities in marine sanctuaries.²⁶⁸ These fees can cover administrative and monitoring costs and the amount which represents the fair market value of the use of the sanctuary resources and a reasonable return to the U.S. government.

²⁶⁴ 6 U.S.C. § 1854(d), as amended by Sustainable Fisheries Act, P.L. 104-297, § 109(c).

²⁶⁵ 16 U.S.C. § 1824(10).

²⁶⁶ Sustainable Fisheries Act, P.L. 104-297, § 104(e) (1996) (to be codified at 18 U.S.C. § 1824(e)).

²⁶⁷ 50 CFR § 216.31.

²⁶⁸ 16 U.S.C. § 1441(c).

(b) States

The Secretary of Commerce is authorized to enter into a cooperative agreement with States under which those States can administer the permit system provided in connection with a fisheries management plan. The cooperative agreement may provide that all or part of the fees collected under the system shall accrue to these States.²⁶⁹

States also can collect fees and taxes pursuant to their authority to promote the health and welfare of the public. This exercise of this authority, however, is subject to both state and federal constitutional restrictions. In general, these fees and taxes can be collected to fund conservation and other welfare programs of the state. States also can collect funds by leasing the seabed subject to their jurisdiction.

2. *Private*

As discussed above, there are very few situations where marine resources are privately-owned. One common situation is the leasing of seabeds under state jurisdiction. In this situation, since access would be subject to consent of the private owner, the owner may be able to collect some type of fee for allowing access.

3. *Indigenous*

Subsistence fishing rights provided by treaty may provide some indigenous communities with access to resources that can be commercially sold. However, the treaty rights themselves may not be sold or transferred.²⁷⁰

Subsistence taking provisions that allow Alaska natives to take some marine mammals do not permit commercial use of the taken mammals and their products.

C. *Ex situ* Collections - Benefits

Most *ex situ* collections do not have formal requirements to return benefits to the place(s) where the genetic materials were originally collected. Many collections do, however, engage in reciprocal exchanges with similar institutions in other parts of the world.

²⁶⁹16 U.S.C. § 1854(d), as amended by Sustainable Fisheries Act, P.L. 104-297, § 109(c).

²⁷⁰See discussion *supra* Section II.A.3.

Because of the usual policy of open access under the National Genetic Resources Program, ordinarily there is no return of benefits, even to the *ex situ* collection itself. However, in a fairly typical requirement, recipients of germplasm from the National Plant Germplasm System are asked to acknowledge the source of germplasm in publications and reports and to evaluate the performance of materials received.²⁷¹

The National Cancer Institute recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders. The Institute's model "Letter of Collection" provides for technology and information transfer, such as helping the source country or local organization to develop the capacity to undertake drug discovery and development,²⁷² as well as for local participation. According to the agreement, if a drug is licensed to a pharmaceutical company, the licensee will make an agreement with the source country about royalties and other compensation. This model agreement also promotes the source country as a long-term supplier. The Institute has entered into such "Letter" agreements with more than 10 countries.

For-profit and non-profit organizations that conserve genetic material *ex situ* may have some return of benefits, but this varies widely. For certain organizations, sales of seed help to support the organization's conservation work.

²⁷¹Personal communication, Henry Shands, 10 May 1996.

²⁷²Technology transfer activities include: providing test results of the screening of the extracts to the source country on a quarterly basis; helping the source country or local organization to develop the capacity to undertake drug discovery and development, including screening and isolation of compounds; inviting senior technicians or scientists to work in laboratories using relevant technology; discussing the participation of source country scientists in development of a specific agent; and consulting with the source country on further development of a promising compound.

Chapter Four:



Measures to Conserve and Sustainably Use Genetic Resources

The United States has a reasonably comprehensive set of laws concerning the conservation of natural resources and species. Conservation laws include both those governing all resources found on public lands, which cover a third of the nation, plus the nation's marine resources, and regulatory laws protecting species. The most important of the latter is the Endangered Species Act, which attempts to ensure that no genetic resources will be lost at the species or subspecies level.

Laws governing the sustainable use of natural resources have become established for traditionally exploited biological resources, such as fish, birds, game animals and timber. There is no general legislation establishing the authority of the government to require that the use of genetic resources is sustainable, as is the case for species protected under the Endangered Species Act. Instead, resource-specific laws are typically passed in response to over-exploitation. The relevant laws are discussed briefly in this section.

A. Terrestrial/Aquatic Areas

1. Public Lands - Federal and State

Almost all federal and state lands are subject to requirements for the conservation of their natural resources and species. In general, there appears to be authority in federal laws to ensure that access to genetic resources on the public lands does not impair the biological integrity of the populations in which the genetic resources are found.

Federally protected conservation areas include areas under the jurisdiction of the National Park Service and the Fish and Wildlife Service, as well as wilderness areas under the jurisdiction of other land management agencies. Although National Wildlife Refuges are managed for a broad variety of purposes, including hunting, fishing, public recreation, mineral development, and others, these activities must be compatible with the purpose of the refuge -- a standard which implies priority for the

conservation of the wildlife resources for which the refuge was established.²⁷³ National Park and wilderness areas are managed primarily for conservation purposes.²⁷⁴

Other lands owned by the federal government are managed by the Forest Service and the Bureau of Land Management (BLM), and their operating statutes are intended to protect natural resources from over-exploitation. The Forest Service is directed by statute to "provide for diversity of plant and animal communities based on the suitability and capability of the specific land area to meet overall multiple use objectives."²⁷⁵ By regulation, the Forest Service must manage all national forests to "maintain viable populations of existing native and desired non-native vertebrate species."²⁷⁶ Requirements such as these provide basic authority that could be used to link conservation of genetic resources and biological communities to the use and exploitation of those resources. BLM lands are managed to prevent "unnecessary or undue degradation," which does not affirmatively state a genetic conservation mandate, but could be construed as such.²⁷⁷

Other laws speak more specifically to species conservation on federal lands. The Endangered Species Act (ESA) imposes special provisions on federal agencies, requiring them to consult with the U.S. Fish and Wildlife Service and to obtain a biological opinion that their activities will cause no jeopardy to threatened or endangered species of plants and animals.²⁷⁸ The ESA also requires federal agencies to use "any and all methods" to conserve and restore listed species to the point where they no longer need the protection of the ESA.²⁷⁹ The Secretary of the Interior must develop recovery plans for all listed species.²⁸⁰ This law applies on both federal lands and non-federal lands.

²⁷³See C. Campbell-Mohn, *et al.*, Sustainable Environmental Law § 6.4(A)(1)(b) (1993).

²⁷⁴16 U.S.C. §§ 1, 1a-1; 16 U.S.C. §§ 1131-1136. The National Park Service Organic Act does state that national parks are to be managed to "conserve the scenery and the natural and historic objects and the wild life therein." 16 U.S.C. § 1.

²⁷⁵16 U.S.C. § 1604(g)(3)(B).

²⁷⁶36 CFR § 219.19.

²⁷⁷16 U.S.C. § 1732.

²⁷⁸16 U.S.C. § 1536.

²⁷⁹16 U.S.C. § 1532.

²⁸⁰16 U.S.C. § 1533(f).

A 1977 presidential Executive Order also requires federal agencies to restrict the introduction of exotic species into lands and waters under federal jurisdiction. This little-used order does not apply if the Secretary of Interior or Agriculture finds that the introduction will not have an adverse effect on natural ecosystems.²⁸¹ Another law attempts to limit and control the spread of exotic species into the Great Lakes, particularly through the regulation of vessels' discharge of ballast water.²⁸²

In addition, wild free-ranging horses and burros on the federal public lands must be protected from "capture, branding, harassment or death," and managed "in a manner designed to achieve and maintain a thriving, natural ecological balance on the public lands."²⁸³

Mitigation of adverse environmental impacts could help minimize damage resulting from potential collection and exploitation of genetic resources on federal lands. The National Environmental Policy Act (NEPA) requires *identification* of mitigation opportunities as part of decisionmaking by federal agencies. The regulations adopted by the Council on Environmental Quality in 1978 define how mitigation is to be achieved if an agency decides to act. NEPA mitigation includes: avoiding the impact altogether by not taking an action or parts of an action; minimizing impacts by limiting the degree or magnitude of the action; rectifying the impact by restoring the affected environment; reducing or eliminating the impact over time; and compensating for the impact by replacing or providing substitute resources.²⁸⁴ This menu of mitigation opportunities provides some protection for the environment if it is incorporated into agency actions and permits. Nevertheless, NEPA does not require active mitigation of impacts; as a statute it requires only identification of impacts, alternatives, and mitigation opportunities. Under NEPA, it is up to the federal agency decisionmaker to decide whether or not to require mitigation. However, several laws that apply to federal agencies expressly require mitigation in some instances.²⁸⁵

State lands are managed under various conservation mandates. A number of states have non-game wildlife and endangered species laws that promote conservation.

²⁸¹E.O. 11,987, reprinted at 42 U.S.C. § 4321.

²⁸²16 U.S.C. §§ 4701-4751 (the Nonindigenous Aquatic Nuisance Prevention and Control Act).

²⁸³16 U.S.C. § 1331.

²⁸⁴40 CFR § 1508.20.

²⁸⁵For example, the Fish and Wildlife Coordination Act, 16 U.S.C. §§ 661-667e, led the Fish and Wildlife Service to develop a mitigation policy for use at water resource development projects.

Typically, state wildlife agencies also must manage fish and wildlife populations in order to achieve a stable yield for hunters and fishers. In addition, state forestry agencies must manage forest lands to produce a sustainable yield of forest products. These authorities are relevant to genetic resources, although they do not clearly provide for conservation of such resources. Many states have funds that support conservation on state-owned lands derived from license fees, contributions, and other sources. Federal conservation funds also provide for some state conservation of resources. The Land and Water Conservation Fund Act of 1965 is funded from the proceeds of sales of surplus federal properties, a tax on motorboat fuels, and outer continental shelf oil and gas leasing revenues.²⁸⁶ It is used for federal and state land and water acquisition and management. The Pittman-Robertson Act²⁸⁷ and the Dingell-Johnson/Wallop-Breaux Act²⁸⁸ provide funds derived from taxes on sales of sporting equipment for acquisition and management of fish and wildlife areas. The federal Nongame Act provides some financial and technical assistance to states for the conservation of nongame vertebrate species.²⁸⁹ The Migratory Bird Conservation Fund for the acquisition of refuges and waterfowl production areas is supported by the sale of federal migratory bird hunting licenses ("duck stamps").²⁹⁰ Each of these funds takes advantage of user fees in order to support conservation. They provide models for possible funding of genetic resource conservation with user fees, royalties, or other funds derived from collection and exploitation agreements or permits.

2. Private Lands

Conservation of genetic resources on private lands is regulated to a very limited extent by state and federal laws. Chief among these are the federal and state endangered species acts, together with federal laws protecting migratory birds and marine mammals, and state game laws.

Most of these laws do not explicitly require affirmative activities to conserve species, but simply prohibit the "taking" of listed species.²⁹¹ The federal Endangered

²⁸⁶16 U.S.C. §§ 460l-4 to 460l-11.

²⁸⁷16 U.S.C. §§ 669-669i.

²⁸⁸16 U.S.C §§ 777-777k.

²⁸⁹16 U.S.C. §§ 2901-2911.

²⁹⁰16 U.S.C. §§ 718-718h.

²⁹¹"Take" includes "harm," a term that includes adverse modifications to habitat. *Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon*, 115 S. Ct. 2407 (1995). It is not clear whether adverse

Species Act, as amended in 1982, does provide for "habitat conservation plans" that must be prepared and implemented by private land owners as a condition of federal permits allowing the "incidental take" of threatened or endangered species in the course of a development activity.²⁹² The habitat conservation planning process may provide a model for conservation of genetic resources in the course of activities that involve collection of genetic materials; it would not, however, apply directly if the collection activity were directed at endangered species -- such "takes" would not be "incidental."

Other federal regulatory laws include the Migratory Birds Act, which prohibits the taking of any migratory bird species except in open seasons established for the larger species, and the Marine Mammals Act, which controls the taking of any marine mammal. State fish and game laws limit the ability of land owners to take fish and game animals and establish license requirements. Land owners are not, however, required to provide or maintain habitat for these animals.

There are other regulatory and conservation constraints that apply to private lands, including federal laws prohibiting the dredging or filling of wetlands without a permit²⁹³ and similar state wetlands laws; prohibitions on the discharge of pollution to the waters of the United States or the states;²⁹⁴ state forest practices laws;²⁹⁵ and federal agriculture laws providing for the conservation of highly erodible lands and wetlands.²⁹⁶ A number of the agricultural programs provide for federal lease payments to farmers who voluntarily take lands out of production and manage them for wetlands, forestry, grasslands, or other conservation values. State land use measures and local zoning regulations also may impose conservation obligations over lands and waters that are used for particular purposes. For example, the state of Maryland's Critical Areas Law controls land and water uses that may affect the health of the

modifications to habitat constitute an illegal "take" of migratory birds under the Migratory Bird Treaty Act. *See* Seattle Audubon Society v. Evans, 952 F. 2d 297 (9th Cir. 1991) (adverse modification leading indirectly to bird deaths is not a taking); Sierra Club v. Martin, No. 1:96-CV-926-FMH (N.D.Ga. May 8, 1996) (logging during nesting season is a taking).

²⁹²16 U.S.C. § 1539(a)(1)(B) & (2).

²⁹³33 U.S.C. § 1344.

²⁹⁴*E.g.*, Clean Water Act, 33 U.S.C. § 1311.

²⁹⁵C. Campbell-Mohn, *et al.*, Sustainable Environmental Law § 9.2(A)(3)(a) (1993).

²⁹⁶16 U.S.C. §§ 3821-3823, 3831-3836 (Swampbuster, Wetland Reserve Program, Conservation Reserve Program).

Chesapeake Bay and its biological resources.²⁹⁷ Zoning laws may require protection of fragile ecological areas, or require commercial enterprises to mitigate impacts.

Federal laws also include limitations on the importation and introduction of potentially harmful species. Approximately 20 federal agencies have some role in research, use, prevention, or control of non-indigenous species, with the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) having the primary role.²⁹⁸ The Federal Noxious Weed Act authorizes the Department of Agriculture to quarantine plants before they enter the U.S.²⁹⁹ The U.S. Fish & Wildlife Service is also responsible for listing harmful species that may not be imported.³⁰⁰ These limitations apply both on public and private lands.

Apart from these regulatory constraints and opportunities, private land owners can engage in a variety of voluntary arrangements to conserve or use genetic resources on their lands. The "conservation easement" discussed previously may be a useful model for linking access and conservation.³⁰¹ Contracts and other agreements may also provide enforceable approaches to conservation. Private, non-profit organizations such as The Nature Conservancy, The Trust for Public Land, and numerous other "land trusts" have also engaged in private lands conservation -- either by acquiring key areas, or by acquiring and holding conservation easements on lands that remain in private ownership. To date, these groups have protected approximately 4 million acres.

3. Indigenous Lands

Conservation of genetic resources on indigenous lands may be pursued by tribal governments within the limits of their sovereignty; and, of course, tribes must conform to federal laws, such as the Endangered Species Act, and to some (but not all) state laws.

Conservation activities may be required by the federal government as a condition of approving commercial collection and exploitation agreements by third parties on tribal trust lands. Alaska native corporations, however, are not subject to this

²⁹⁷Md. Nat. Res. Code Ann. § 1801 *et seq.*

²⁹⁸*See generally*, Office of Technology Assessment, "Harmful Non-Indigenous Species in the United States" (1993).

²⁹⁹7 U.S.C. §§ 2801-2814.

³⁰⁰16 U.S.C. §§ 3371-3378 (Lacey Act).

³⁰¹*See* discussion accompanying note 157, *supra*.

federal approval requirement and may act in the same manner as other private land owners, subject only to the normal array of federal and state laws.

B. Marine Areas

1. Public

(a) Federal

The Magnuson-Stevens Act provides the federal government with broad authority for the conservation and sustainable use of fish and other living marine organisms. Under the Act, fishery management plans (FMPs) are to contain conservation and management measures applicable to fishing by both foreign and U.S. vessels which are necessary and appropriate for the conservation and management of the fishery; to prevent overfishing and rebuild overfished stocks; and to protect, restore, and promote the long term health and stability of the fishery.³⁰²

Recent regulations require the regional councils to amend their FMPs to (i) describe and identify essential fish habitat (EFH); (ii) identify adverse impacts to that habitat from both fishing and non-fishing sources; and (iii) identify measures to conserve and enhance that habitat.³⁰³ Since the cumulative impacts of fishing and non-fishing activities are to be considered, biodiversity prospecting may potentially be regulated under these provisions. Federal agencies are required to consult with the National Marine Fisheries Service (NMFS) regarding any action or proposed action that may adversely affect EFH. NMFS must then recommend measures to the appropriate agency to conserve habitat. In addition, the federal agency must respond, detailing the measures to be taken to avoid, mitigate, or offset the adverse effects to EFH and explain the reasons for any actions inconsistent with NMFS' recommendations.

To guard against unsustainable use, NMFS must notify a council when a fish stock in its region is being overfished. The council then has one year to take action to end the overfishing. If the council fails to act, then the NMFS is to act.³⁰⁴ As discussed above, the issuance of an EFP to allow data collection may be denied if the harvest to be conducted under the permit would detrimentally affect the well-being of the stock of any regulated species of fish, marine mammal, or threatened or endangered species in a

³⁰²16 U.S.C. § 1853, as amended by Sustainable Fisheries Act, P.L. 104-297, § 108 (1996).

³⁰³62 Fed. Reg. 66495 (Dec. 19, 1997) amending 50 CFR Part 600.

³⁰⁴Sustainable Fisheries Act, P.L. 104-297, § 109(e) (1996) (to be codified at 16 U.S.C.A. § 1854(e)).

significant way.³⁰⁵ The EFP also can include terms and conditions specifying the maximum amount of each regulated species that can be harvested and landed during the term of the EFP, the time and place where exempted fishing may be conducted, and the type, size, and amount of gear that may be used.³⁰⁶

Prior to entering into an agreement for foreign fishing in a Pacific Insular Area, a 3-year marine conservation plan must be developed by the Western Pacific Council and the appropriate governor. The plan must detail the intended use of funds collected pursuant to the agreement.³⁰⁷

Foreign nations and their fishing vessels must agree in any governing international fishery agreement allowing fishing to abide by all federal regulations concerning fishery conservation.

To support international fishery conservation efforts, the U.S. is authorized to impose economic sanctions against non-complying treaty parties.³⁰⁸ In the event that foreign nationals are conducting fishing operations detrimental to a fishery conservation program, the Secretary of Commerce is to certify that fact to the President. The President then has the discretion to direct the Secretary to prohibit the importation of fish products of the offending country.

Limitations on the taking of threatened and endangered species, as well as the consultation requirements, also serve to protect some marine resources.³⁰⁹ Limitations on the taking of marine mammals promotes conservation of these resources. In addition, permits for the taking of marine mammals for scientific purposes may include terms and conditions that the Secretary may deem appropriate, which could include conservation provisions.³¹⁰

Permitted activities in marine sanctuaries are limited to those that are compatible with the purpose for which the sanctuary is designated and with the protection of sanctuary resources. Fees collected in connection with permits for activities conducted

³⁰⁵61 Fed. Reg. 32575, 32576 (1996) (to be codified at 50 C.F.R. § 600.745(b)(3)).

³⁰⁶61 Fed. Reg. 32575, 32576 (1995) (to be codified at 50 C.F.R. § 600.745(b)(3)).

³⁰⁷Sustainable Fisheries Act, P.L. 104-297, § 105(e) (1996) (to be codified at 16 U.S.C. § 1812 (e)).

³⁰⁸22 U.S.C. § 1978.

³⁰⁹See discussion accompanying notes 73, and 278-280, *supra*.

³¹⁰50 CFR § 216.31.

in marine sanctuaries may be dedicated towards the expenses of designating and managing national marine sanctuaries. As noted above, federal agency actions internal or external to a national marine sanctuary, including private activities authorized by licenses, leases, or permits that are likely to destroy, cause the loss of, or injure any sanctuary are subject to consultation with the Secretary. If the Secretary finds that the proposed action is likely to destroy, cause the loss of, or injure a sanctuary resource, then the Secretary is required to recommend reasonable and prudent alternatives that will protect the sanctuary resources, which may include conducting the action elsewhere.³¹¹

(b) State

Subject to the federal and state constitutional limitations, States can enact a broad range of conservation measures for marine resources within their jurisdiction. Examples of state conservation measures include restrictions on the types of nets used for fishing, banning of commercial fishing for certain species, and harvest limitations. State laws, however, tend to focus on traditionally exploited species. In instances when non-traditional fish or shellfish become exploited, there is generally a lack of regulation until political pressure mounts for state action. This situation occurred in Delaware Bay in the early 1990's, when commercial interests began to harvest horseshoe crabs, an important resource for migratory shorebirds, for use as lobster and fish bait. It took several years for New Jersey to pass emergency legislation regulating this practice, which was uncontrolled in the interim.³¹²

States can include conservation measures in their respective coastal zone management plans. As described above, through the consistency requirement provided for under the Coastal Zone Management Act, states gain a measure of control over federal actions affecting their coastal resources.

2. *Private*

As discussed above, there are very few situations where marine resources are privately-owned. Conservation measures required of landowners adjacent to marine areas, however, may indirectly assist in the protection of these resources. For example, state laws may restrict lot size and the type of commercial development allowable on lands adjacent to the water.

³¹¹16 U.S.C. § 1434(d).

³¹²See, Horseshoe Crab Adopted Emergency Amendment, New Jersey Administrative Code 7:25-18.16 (Aug 18, 1997).

3. Indigenous

Treaty rights may imply a duty on the part of the federal government to insure the conservation of marine resources subject to such rights. While this is certainly true for anadromous fish, it also may extend to some other resources.

Tribal ownership of marine resources is rare for the same reason as is private ownership of such resources: for the most part, the federal and state governments have ownership over the seabeds. However, in the event of indigenous ownership, conservation of resources on indigenous submerged lands may be pursued not only by tribal governments, but may also be required by the federal government as a condition of approving commercial collection and exploitation agreements on tribal lands (except for Alaska native corporations).

C. Ex situ Collections - Conservation

Ex situ collections exist, in part, for the purpose of conservation. For example, the National Plant Germplasm System is involved in international plant conservation insofar as it has accepted responsibility to store international collections. NPGS stores some collections at the National Seed Storage Laboratory which serve as backups to international collections. There is, however, a difficulty with this arrangement in that the collections are stored without agreement for their maintenance or regeneration, so the viability of the germplasm may be lost.

The International Plant Genetic Resources Institute (IPGRI) has designated eighteen U.S. crop collections, including maize, rice, sorghum, wheat, soybean, citrus, tomato, and cotton, as regional or global base collections in its international network. The memoranda of understanding have expired, so the material simply exists in storage rather than being subject to an agreed plan for active caretaking.

Current NPGS needs include "regeneration of fresh germplasm [to maintain their viability], filling gaps in current collections, conducting more evaluations, accelerating quarantine introduction procedures, coordinating research on alternative storage methods, and supporting genetic stock collections."³¹³ NPGS faces continual budgetary problems. There apparently has been no new funding of significance to the program since it was authorized in 1990.³¹⁴ While there is adequate storage space, operations are decreasing due to a shortage of funds, and the backlog of work increases. NPGS lacks

³¹³NGRP, 2.

³¹⁴Communication with Dr. Henry Shands, 10 May 1996.

the visibility and influence to ensure support. Also, the health of certain collections is in danger: the U.S. system has emphasized storage of germplasm over regeneration or evaluation.

Specific non-profit *ex situ* organizations also are interested in promoting the cultivation and use of rare and unusual species, thereby promoting their conservation. The mission of Seed Savers Exchange, for example, is to preserve heirloom vegetables by encouraging member gardeners to grow and protect these species. The North American Fruit Explorers contribute to species protection by documenting its members' collections. The Association for Living Historical Farms and Agricultural Museums seeks to preserve heirloom species; some farms may become sites for large scale germplasm conservation. The mission of Native Seeds/SEARCH links germplasm conservation with agricultural development. The Southwestern Traditional Conservancy Garden supports self-sufficiency using locally-adapted crops, and its mission has been expanded to conserving wild relatives of crops. The American Livestock Breeds Conservancy focuses on preserving North American livestock breeds in productive uses on farms.

Conclusion

The patchwork of laws regulating access to genetic resources in the United States today has resulted in a primarily "open" system of access to genetic resources. This is a system in which, in most cases, the government exercises minimal, if any, control over the regulation of access. This system is the result of policies which historically have had the goal of promoting private rights to develop natural resources, as well as the free exchange of scientific information.

Nevertheless, as the review of laws conducted by this report has shown, the system also already has in place many features that implement the key principles of the Biodiversity Convention. Thus, what is needed is not a wholesale overhaul of laws, nor creation of a new body of laws, but a careful and committed effort to build on existing legal foundations. The following discussion highlights some of the critical gaps and opportunities in U.S. law in terms of implementation of the principles of the Convention on access.

A. Mechanisms for Benefit-sharing on Public Lands and Waters

Although most federal and state land management agencies have the right to control access to properties under their jurisdiction, such access is available under laws that did not contemplate the possible relevance of genetic resources. Compensation to these agencies for access, where available, is generally limited to fees based on their actual administrative costs in regulating access. Mechanisms for financial return to the government based on commercialization of genetic resources vary widely and are absent in the case of many categories of land.

Recently the National Park Service invoked the Federal Technology Transfer Act (FTTA) as legal authority for collecting money and structuring the return of benefits from commercial products that may in the future be developed from bacteria found in the hot springs of Yellowstone National Park. This strategy, however, cannot yet serve as a model for other federal agencies attempting to share equitably in the benefits of product development, in part because of the legal uncertainties involved with applying the FTTA to research conducted on specimens from the National Parks. Only some of these issues will be addressed in the legal challenges that have been brought against the National Park Service. Moreover, on a policy level, the use of this law is not directly linked with safeguards for biological diversity and ecological integrity – which are addressed only through the agency's use of its other conservation-oriented legal authorities. Integration of access, use, recovery of benefits, and conservation is consequently achieved in an ad hoc manner, rather than as a matter of national policy or design. Similar issues that might arise on other federally-owned lands, state-owned

lands, or in waterways, are not clearly covered by any approach that might either control access or limit it in ways that serve conservation ends.

In sum, U.S. law currently lacks the specific legal mechanisms to enable the appropriate governmental authority to recover financial benefits from commercial development of genetic resources collected on public lands and waters. Mechanisms are also lacking that would allow sharing in the technological and research advances that might result from granting access to genetic resources located on government-owned lands and public waters.

B. Measures for Conservation and Sustainable Use on Public and Private Lands and Waters

U.S. law currently contains a number of mechanisms for conservation of natural resources *containing* genetic resources and located on publicly controlled lands and waters. Nevertheless, there is a significant absence of mechanisms focusing on sustainable use, particularly at the level of genetic resources. Moreover, there is no linkage between access to genetic resources and the independently established conservation objectives in such laws as the Federal Lands Policy Management Act or the National Forest Management Act. In addition, financial benefits received by governmental entities in connection with providing access to genetic resources are not directly allocated for programs promoting the sustainable use and conservation of those resources.

U.S. law regarding management of private lands also lacks measures for conservation and sustainable use of genetic resources. Although private landowners may impose these types of measures as a condition of access, this action is discretionary, and current laws and policies lack incentives for private landowners to impose these measures. There is also a lack of incentives for private landowners to channel resources from commercial development of genetic resources to conservation programs.

Finally, regulatory programs that apply on both public and private lands (*e.g.*, endangered species laws, migratory birds laws, hunting and fishing laws, native plants laws) provide some basis for conservation, but apply only to limited categories of living resources. Moreover, while they often address some access and conservation issues (prohibiting or limiting access to the animal or plant) and sometimes compensation (purchase of hunting or fishing licenses supporting wildlife and fishery management programs), more often there is little link between conservation, sustainable use, and the right of access. Examination of these and other laws may be needed if conservation and sustainable use of genetic resources is to be integrated into the general legal framework of laws protecting living resources.

C. Managing *Ex situ* Collections to Support National Regimes on Access

Access to *ex situ* collections controlled by the federal government for research purposes is generally unrestricted and compensation to the collection or the country of origin is not required. Access to private *ex situ* collections is subject to the conditions and compensation required by the particular owner; many of these are also open access. In general, both public and private *ex situ* collections exist for the purpose of conservation. Only a few of these collections appear to require compliance with the benefit-sharing mechanisms of the source country. It may be appropriate to examine whether, or how, access to and use of material in *ex situ* collections should help support technology transfer, benefits sharing, and conservation in the country of origin of the material. Without either private or government mechanisms ensuring conformance of *ex situ* collections with source country laws on access (particularly with respect to material already collected), these national systems may be less effective than the Biodiversity Convention appears to contemplate. This does not mean that the general approach of open access followed in the U.S. should be replaced with a different system, but it does suggest that alternatives may need to be developed in order to support the objectives of the Convention.

D. Providing for Access to Genetic Resource on U.S. Indigenous Lands

Indigenous lands in the U.S., as in many countries, present particularly complex sets of issues in the context of the Biodiversity Convention. Federally-recognized Indian tribes have authority to control access to reservation lands and could adopt access, compensation, and conservation regimes. However, such regimes may be difficult to establish or maintain if open access is the approach maintained by federal and state authorities on surrounding lands with the same or similar genetic resources. If a compensation-generating access regime were established by a tribe, it could be subject to federal review to ensure an adequate return to the tribe. Conservation requirements might be imposed by the tribal authority or as a condition of approval of the commercial collection and exploitation agreement by the federal government. Where privately-owned non-Indian lands are interspersed with Indian lands within a reservation, however, tribal control over access to these private lands is limited, and in all likelihood would not extend to the imposition of an access regime.

Alaska lands held by native corporations are a special case, and are generally subject to the same limitations and opportunities of any private landowner to grant or negotiate access, compensation, etc.

Off-reservation treaty rights guaranteeing access by tribe members to living resources on non-indigenous lands may present a particularly difficult case, as ordinarily their right of access is not exclusive. Hence, access to genetic materials covered by these treaty rights does not readily lend itself to control of access or generation of compensation, although serious legal questions could arise in a variety of scenarios where access to these genetic resources posed the prospect of generating a financial return.

* * *

As a result of the patchwork nature of laws governing access, the process of bringing U.S. law and practice into conformity with the Biodiversity Convention will require a combined approach of legislative, regulatory, and policy action. Legislators and agency officials may need to take stock of the unique and/or potentially valuable genetic resources under their jurisdictions in order to best identify priorities for action. As the recent experience in Yellowstone has shown, biodiversity prospecting is no longer just an abstract concept for the U.S.

Unless natural resource stewards take steps now to set up the legal and policy framework for identifying and properly managing genetic resources, some of the value of these resources may be lost to future generations.