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Protecting Biodiversity:

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

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

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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: Asociacón 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.

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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

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[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

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:

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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.

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[11]U.S. Constitution, Article I §8.

[12]U.S. Constitution, Article VI.

[13]*Id.*

[14]U.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

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

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

[17]Figures 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 rehı˝T*o nage their landi finepeci1 Tfı˝1oralTpte

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[18]Federal 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.

[19]Federal 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.

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

[21]However, 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).

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

[23]16 U.S.C. § 528.

[24]16 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.

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

[26]16 U.S.C. § 1.

[27]36 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]

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[28]16 U.S.C. § 1131(c).

[29]16 U.S.C. § 1133(c).

[30]Wilderness 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).

[32]Sikes Act, 16 U.S.C. § 670h.

[33]The 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).

[34]For 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

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

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

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

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

[39]Lacey 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).

[44]President'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

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

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

[49]Under 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.

[50]16 U.S.C. §§ 718-718h.

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.

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

[53]The 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

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[54]*See* 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.

[56]*See* 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."

[57]43 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

[58]16 U.S.C. §§ 3111-3126.

[59]Subsistence 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.

[60]16 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

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.

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

[63]16 U.S.C. § 1811(a).

[64]Continental 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.

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[67]16 U.S.C. § 1812.

[68]The 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 "

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).

[75]16 U.S.C. § 1433.

[76]16 U.S.C. § 1434(a).

[77]16 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

[78]16 U.S.C. § 3372. Activities regulated by a fishery management plan are exempt from these provisions. 16 U.S.C. § 3377.

[79]16 U.S.C. § 3372.

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

[81]16 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]

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[82]16 U.S.C.A. § 1456(c).

[83]Historically, 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).

[86]16 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.

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

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

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

[90]43 U.S.C. § 1311.

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

[92]United 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

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[93]The 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 Shelfs Land Act is currently limited to mineral resources. 43 U.S.C. §§ 1331(c), 1334.

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

[95] 16 U.S.C. § 1853(a)(1)(C).

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

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

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

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

[100]National 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 world[102] 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]

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

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

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

[104]MGGR: NPGS, 47.

[105]MGGR: NPGS, 3.

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

[107]*Ibid.*

[108]Abelson, 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

[109]Calestous 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.

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[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

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[112]Henry 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.

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

[114]Juma, 95.

Chapter Two:

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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

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

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[115]42 U.S.C. §§ 4321-4332.

[116]42 U.S.C. § 4332(2)(C).

[117]*Id.*

[118]Categorical 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 gen926 rby scienti8etions v

[119]36 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.

[120]36 CFR § 2.5.

[121]36 CFR § 1.6.

[122]36 CFR § 2.5(b).

[123]36 CFR § 2.5(g)(2).

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

[125]Since 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

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

[127]43 U.S.C. §§ 1732, 1733, 1740; 43 CFR Part 2920.

[128]43 CFR §§ 2920.0-6, 2920.1-1.

[129]43 CFR § 2920.1-1(b).

[130]The 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).

[131]43 CFR § 2920.5-4.

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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

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[151]Such 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. Constitution[155] 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

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

[154]Some 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).

[155]U.S. Constitution, Amendment IV.

[156]Certain 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).

[157]Conveyance 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

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

[158]Berman 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).

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

[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

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

[165]Black 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).

[166]16 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.

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[167]61 Fed. Reg. 32,541, 32,542 (1996) (to be codified at 50 C.F.R. § 600.10).

[168]16 U.S.C. § 1801(b)4.

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

[170]50 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)).

[171]16 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 72

[172]16 U.S.C. § 1854(d), as amended by Sustainable Fisheries Act, P.L. 104-297, § 109 (1996).

[173]16 U.S.C. § 1823.

[174]16 U.S.C. §§ 1821-1827, as amended by Sustainable Fisheries Act, P.L. 104-297, § 105 (1996).

[175]16 U.S.C. § 1802.

[176]61 Fed. Reg. 32,541, 32,543 (1996)(to be codified at 50 C.F.R. § 600.10).

[177]The 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).

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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

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[184]61 Fed. Reg. 32,575, 32,576 (1996) (to be codified at 50 C.F.R. § 600.745(c)).

[185]*Id.*

[186]61 Fed. Reg. 32,541, 32,542 (1996) (to be codified at 50 C.F.R. § 600.10).

[187]61 Fed. Reg. 32,568 (1996) (to be codified at 50 C.F.R. § 600.512(b)).

[188]50 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

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[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

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[194]16 U.S.C. § 1441(f).

[195]16 U.S.C. § 1434(a)(5).

[196]16 U.S.C. § 1434(c).

[197]16 U.S.C. § 1434(d).

[198]42 U.S.C. §§ 4321-4332.

[199]42 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,

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[200]15 C.F.R. § 930.34.

[201]15 C.F.R. § 930.65, 15 C.F.R. § 930.121.

[202]*See* discussion accompanying note 162, *supra*.

[203]50 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 identifiers[207] 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]

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[204] 50 C.F.R. § 216.23(b).

[205] 7 U.S.C. § 5841(d)(4).

[206] http://www.ars-grin.gov/npgs/orders.html.

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

[208] Communication 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

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 availablee seerce1ı˝3 -sa2e

[209]Communication, George Russell July 23, 1996.

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

[211]Communication, 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.

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

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

[214]Convention, 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.

[215]Convention, Article 16.

[221]Jim 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;

"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."

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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

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[231]25 U.S.C. § 81.

[232]Where 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.

[233]U.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 . . .

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[234]28 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).

[235]The 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).

[236]However, 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.

[237]35 U.S.C. § 101.

[238]35 U.S.C. § 102.

[239]35 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).

[240]447 U.S. 303 (1980).

[241]Chakrabarty, 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.

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 Act[247] 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

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[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).

[247]35 U.S.C. §§ 161-164.

[248]35 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.

[249]What 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).

[251]Plant 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

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[252]35 U.S.C. § 163.

[253]7 U.S.C. §§2401-2582. The Plant Variety Protection Act was extended to tuber propogated 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.

[254]International 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.

[255]7 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).

[256]The 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).

[257]7 U.S.C. § 2402(a)(2).

[258]7 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

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[259] 7 U.S.C. § 2402(a)(4).

[260] 7 U.S.C. § 2422(3). The regulations require seeds to be deposited at the National Seed Storage Laboratory at Fort Collins, Colorado.

[261] 7 U.S.C. § 2483.

[262] 7 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.

[263] 7 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

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[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.

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[269] 16 U.S.C. § 1854(d), as amended by Sustainable Fisheries Act, P.L. 104-297, § 109(c).

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

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Chapter Four:

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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 jurisdication 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.

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

[274]16 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.

[275]16 U.S.C. § 1604(g)(3)(B).

[276]36 CFR § 219.19.

[277]16 U.S.C. § 1732.

[278]16 U.S.C. § 1536.

[279]16 U.S.C. § 1532.

[280]16 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.

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

[282]16 U.S.C. §§ 4701-4751 (the Nonindigenous Aquatic Nuisance Prevention and Control Act).

[283]16 U.S.C. § 1331.

[284]40 CFR § 1508.20.

[285]For 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.

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).

[292]16 U.S.C. § 1539(a)(1)(B) & (2).

[293]33 U.S.C. § 1344.

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

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

[299]7 U.S.C. §§ 2801-2814.

[300]16 U.S.C. §§ 3371-3378 (Lacey Act).

[301]*See* discussion accompanying note 157,

[302]16 U.S.C. § 1853, as amended by Sustainable Fisheries Act, P.L. 104-297, § 108 (1996).

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

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[305]61 Fed. Reg. 32575, 32576 (1996) (to be codified at 50 C.F.R. § 600.745(b)(3)).

[306]61 Fed. Reg 32575, 32576 (1995) (to be codified at 50 C.F.R. § 600.745(b)(3)).

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

[308]22 U.S.C. § 1978.

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

[310]50 CFR § 216.31.

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

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[313]NGRP, 2.

[314]Communication 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

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 acess. 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.

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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.