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ACCESS TO GENETIC RESOURCES REGIME OF
THE UNITED STATES NATIONAL PARKS

Document submitted by the Delegation of the United States of America

1. On December 6, 2002, the Delegation of the United States of America submitted a document to the fourth session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

2. The document is entitled "Access to Genetic Resources Regime of the United States National Parks." The document is reproduced in the form received and published in the Annex.

3. The Intergovernmental Committee is invited to take note of this document and the Annex to it.

[Annex follows]

ANNEX

INTRODUCTION

1. In December of 2001, during the second session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, the United States of America introduced document WIPO/GRTKF/IC/2/13 which included examples of agreements entered into by agencies of the United States Government. Specifically, document WIPO/GRTKF/IC/2/13 included the Memorandum of Understanding between the National Cancer Institute (NCI) and various source country organizations, the list of Letter of Collection Agreements entered into by NCI, the Natural Products Repository Material Transfer Agreement of the NCI, information on the International Cooperative Biodiversity Group (ICBG) Program and the Fiscal Year 2002 Guidelines for Germplasm Exchange Proposals and for Plant Exploration Proposals.

2. Document WIPO/GRTKF/IC/2/13 was submitted in the spirit of sharing experiences of the United States in drafting access and benefit sharing agreements, the countries with which the United States had entered into agreements. Essentially, the United States believes that these and other similar agreements show the way forward in how the relevant provisions of the Convention on Biological Diversity (CBD) [1] might be implemented to benefit both the source communities and researchers.

3. The present document is now being submitted to amplify how these and other agreements might be used to implement relevant provisions of the CBD, consistent with the TRIPs Agreement, particularly through the use of an access regime for genetic resources based upon contracts. The present document suggests that, *inter alia*, contracts authorizing collection of genetic materials include provisions requiring reporting and benefit sharing and that parties to such access agreements be obliged to notify the appropriate authorities in the event an invention was developed using genetic materials collected under the contract. The document also advocates including a contractual obligation on the party being granted access to identify the contract and the source of the genetic resources in any patent application claiming that invention filed anywhere in the world. Finally, the present document describes in detail, the experience of the U.S. National Park Service with the use of access and benefit sharing procedures.

BACKGROUND

4. As much of the discussion of access to genetic resources, traditional knowledge, and benefit sharing related to such access arose in connection with the Convention on Biological Diversity, this paper is organized in accordance with the relevant provisions of that Convention. The use of contracts in connection with various forms of traditional knowledge, however, also could be applicable to other knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles.

[1] Specifically, Articles 8(j), 15, 16 and 19.

5. The Preamble of the Convention on Biological Diversity states the intention of the Contracting Parties in entering into the Convention as a desire to enhance and complement existing international arrangements for the conservation of biological diversity and the sustainable use of its components, and expresses their determination to conserve and sustainably use biological diversity for the benefit of present and future generations. The objectives of the CBD, as stated in Article 1 of the Convention,[2] are threefold: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. The third objective, according to the text, relates to appropriate access to genetic resources, to appropriate transfer of relevant technologies, and to appropriate funding. Determinations of what is "appropriate" in relation to access to genetic resources and transfer of technology are to be made, taking into account all rights over those resources and technologies.

Knowledge, Innovations and Practices of Indigenous and Local Communities: Maintenance and Benefit Sharing

6. Article 8(j)[3] of the CBD deals with particular knowledge, innovations and practices of indigenous and local communities that embody traditional lifestyles. Article 8(j) appears to establish three obligations. First, Contracting Parties are to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity". Second, Contracting Parties are to promote the wider application of such knowledge, innovations and practices. Third, Contracting Parties are to encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices. Two phrases modify these obligations. Article 8's chapeau conditions "shall" with the phrase "as far as possible and as appropriate"[4], and subsection (j) begins with the phrase, "Subject to its national legislation."

7. It should be noted that Article 8(j) does not encompass all knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles. Article 8(j) refers only to knowledge, innovations and practices "relevant for the conservation and sustainable use of biological diversity." Nothing in the Convention, however, would preclude countries from extending the application of the provision to other knowledge, innovations and practices of indigenous and local communities. If such knowledge, innovations and practices

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2 Article 1, entitled "Objectives" states: "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

3 Article 8(j) states: "Each Contracting Party shall, as far as possible and as appropriate; […] Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices."

4 This same phrase is also included in Articles 5, 7, 9, 10, 11, 14.

are to be respected, preserved and maintained and if their wider use is to be promoted, they must be identified.

8. Seeking information on such knowledge, innovations and practices should necessarily involve seeking the approval and assistance of the indigenous and local communities in possession of the knowledge, innovations and practices. Seeking such information would also provide an opportunity to educate any communities that are unfamiliar with the basics of negotiations, contracting, various forms of intellectual property, etc., that might be relevant to them in marketing their knowledge, innovations, and practices, should they choose to do so, for use by those outside their communities, and for obtaining an equitable share of the benefits arising from the utilisation of their knowledge, innovations and practices. The gathering of information would be directed toward achieving all three objectives of Article 8(j). Likewise, it also would provide an opportunity for indigenous and local communities to indicate that they did not want their knowledge, innovations and practices disclosed or shared with the larger community. That would be an appropriate time to provide information on the use of trade secret law as a tool for maintaining limitations on the circulation of the knowledge, innovations and practices.

9. Creating organized databases of knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity, searchable over the Internet, would be valuable in a number of ways. It would create sources of information that could be used by potential licensees searching for knowledge, innovations and practices that might relate to their field of work and could indicate contact points, qualifications for licensees, conditions for licensing, etc. That would go toward the second and third objectives of Article 8(j), *i.e.*, to promote the wider application of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity with the approval and involvement of such communities, and would encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices. Suitable national or local legislation or regulations could establish the legal basis for such contractual arrangements between those seeking to develop knowledge, innovations and practices into commercial products and those providing the knowledge, innovations and practices.

10. Organized, searchable databases of the knowledge, innovations and practices of indigenous and local communities also could provide a source of information that could be used by patent examiners worldwide when examining applications for patents relevant to conservation and sustainable use of biological diversity, in particular, and to other fields as well, if additional information is available on data bases. This would, therefore, aid in improving examination of patent applications in relevant fields to ensuring that inventions granted patents are new and do involve an inventive step.

Access to Genetic Resources and Access to and Transfer of Technology

11. Article 15 of the CBD is entitled “Access to Genetic Resources”. The first paragraph in that Article states that, because States have sovereign rights over their natural resources, they are responsible for determining access to their genetic resources in accordance with their

national law.[5] Contracting Parties are charged with endeavouring to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention.[6] Where access is granted, it is to be on mutually agreed terms as provided for in the Article.[7] Access to genetic resources is subject to prior informed consent of the Contracting Party providing the resources, unless that Party decides otherwise.[8] Contracting Parties are to endeavour to develop and carry out research on genetic resources acquired from other Parties with the full participation and, where possible, in the supplying Contracting Party.[9] Finally, Contracting Parties are to take legislative, administrative or policy measures with the aim of sharing fairly and equitably with the Contracting Party supplying the resources, the results of research and development and any benefits arising from commercial or other use of those genetic resources.[10]

12. Article 16 is entitled "Access to and Transfer of Technology." The first paragraph of the Article requires Contracting Parties, in accordance with the provisions of Article 16, to provide and /or facilitate access for and transfer to other Contracting Parties technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources while not causing significant damage to the environment.[11] Such access and transfer of technology to developing countries are to be provided or facilitated on fair and most favourable terms or, where mutually agreed, on concessional and preferential terms and, where necessary, using the financial mechanism established under Articles 20 and 21. Terms for technology protected by patents or other forms of intellectual property are to be consistent with adequate and effective protection of intellectual property rights.[12] Paragraph 3 requires

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5 Article 15(1) states: "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation."

6 Article 15(2) states: "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

7 Article 15(4) states: "Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article."

8 Article 15(5) states: "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."

9 Article 15(6) states: "Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties."

10 Article 15(7) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

11 Article 16(1) states: "Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

12 Article 16(2) states: "Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms,

Contracting Parties to take appropriate legislative, administrative or policy measures aimed at providing, on mutually agreed terms, access to and transfer of technology making use of genetic resources, including technology protected by patents or other intellectual property rights, to Contracting Parties that supplied the genetic resources, particularly those that are developing countries.[13] Contracting Parties also are to take appropriate legislative, administrative or policy measures with the aim of having the private sector facilitate access to, joint development and transfer of technology covered by paragraph 1 for the benefit of governmental institutions and the private sector of developing countries. These measures also are to impose the obligations of paragraphs 1, 2 and 3 on the private sector.[14] Finally, Contracting Parties are to cooperate, subject to national legislation and international law, to ensure that patents and other intellectual property rights support and do not run counter to the objectives of the Convention.[15]

13. Articles 15 and 16 are best discussed together because the most effective means for providing access to genetic resources, and for ensuring that any benefits that arise from their use are shared fairly and equitably, would be through contracts between those granting access to the resources and those to whom access is granted. CBD Contracting Parties can provide, through legislation or regulations, systems that permit parties seeking access to genetic resources to enter into contracts with the sovereign entity or private party responsible for granting access. To be effective, such contracts should spell out in detail the terms and conditions under which access is granted, including such things as any requirements for joint research and development or for transfer of technology developed from or using the genetic resources to which access was to be granted. Obviously, questions of jurisdiction of courts and conditions required to be included in contracts with any third parties licensed to make use of the genetic resources obtained would also have to be spelled out. A contract granting access also should define expressly terms that are not clear on their face, such as the definition of the term genetic resources.

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including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms that recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below."

[13] Article 16(3) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, or mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below."

[14] Article 16(4) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above."

[15] Article 16(5) states: "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

14. Those seeking access to genetic resources likely would welcome such a regime, because it would clarify rights and obligations on both sides at the outset. Such clear rules would help to avoid misunderstanding and confusion. By making transparent the requirements for being granted access to genetic resources, CBD Contracting Parties could encourage greater use of their genetic resources in a sustainable way. Where genetic resources can be obtained from a number of sources, of course, the party seeking access likely would seek the resources from the territory that provides more favorable terms, so that an incentive would exist for balance between the access to genetic resources granted and the terms and conditions on which access is based.

15. Such a contract system also might include a requirement that a party to which access is to be given identify the contract in the specification of any patent application it files claiming an invention developed through use of the genetic resources obtained. Obtaining patents around the world for commercial products that serve to conserve biological diversity would provide benefits that could be shared in accordance with the terms of the contract. Absent patent protection, others who were not bound by contract, would be free to use the technology without any obligation to share the benefits with the Contracting Party that provided the genetic resources on which the invention was based. Finally, in the event of a breach of obligations on either side, contracts can be litigated in the specified jurisdiction and judgements enforced around the world under international agreements regarding the recognition of judgements.

16. Some have said that contractual systems would not work in ensuring that benefit sharing results from access to genetic resources, because some individuals might not respect a requirement that parties seeking access to genetic resources enter into a contract with the sovereign entity or private individual as provided under the laws of a country. It is possible that a few individuals could ignore the legal requirements and simply put an herb in their pocket, in the same way that some individuals counterfeit trademarks or pirate copyrighted works, but this does not negate the value of a contractual system that would apply to the vast majority of those seeking access, just as trademark and copyright laws apply in their spheres. Just as is done in the case of trademark counterfeiting and pirated copyrighted works, criminal provisions and/or civil liability for failure to comply with a country's regime for granting access can be included in the country's laws for those few who might take genetic resources without entering into an access agreement with the appropriate party.

Handling of Biotechnology and Distribution of its Benefits

17. Article 19 is entitled "Handling of Biotechnology and Distribution of its Benefits." Paragraph 1 requires Contracting Parties to take appropriate legislative, administrative or policy measures to permit participation in biotechnological research by the Contracting Parties providing the genetic resources for the research and, where feasible, in those Contracting Parties' territories.[16] Paragraph 2 requires Contracting Parties to take "all practicable measures" to "promote and advance" priority access, on a fair and equitable basis and on mutually agreed terms, to Contracting Parties that provided genetic resources to results

[16] Article 19(1) states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties."

and benefits arising from biotechnologies based on those resources.[17] Paragraph 3 requires Parties to consider whether a protocol is needed establishing procedures for safe transfer, handling and use of genetically modified organisms that might adversely affect biological diversity.[18] Paragraph 4 requires Contracting Parties themselves, or through natural or legal persons within their jurisdictions, to provide any available information on safety, handling and use of genetically altered organisms to Contracting Parties into the territory of which such organism is being introduced.[19]

18. These obligations also are better met through contractual arrangements between the Contracting Party giving access to genetic resources from which a modified genetic organism is developed and the party to which access to those genetic resources is given. The party creating the genetically modified organism from genetic resources provided by the Contracting Party would be most likely to have the relevant information. If another Contracting Party created the genetically modified organism from genetic resources provided by a Contracting Party, there would be no need for a separate agreement, since the provisions of Article 19 would apply. If the creator of the organism is a private party, the requirement to provide the relevant information regarding any genetically modified organism, including information regarding any adverse effects the organism might have on the conservation and sustainable use of biological material, should be included in the contract between the party and the Contracting Party or private party giving access to the genetic resources.

19. The existence of a patent would help to ensure that the genetically modified organism was within the control of the patent owner or its licensee, thereby minimizing the likelihood that the organism would be widely distributed or mishandled in ways that could have undesirable effects. Such control also would ensure that liability could be established should an accident occur with the organism. As mentioned before, such arm's-length contracts ensure that both the party receiving access and the Contracting Party or private party granting access clearly understand their rights and obligations at the outset of the relationship and such contracts can be enforced in courts in the jurisdiction agreed upon, with judgements enforceable in courts in other jurisdictions as provided in international agreements.

20. The collection of biological specimens for scientific research in U.S. national parks is not new. The first research permit in the national park system, which authorized collection of

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[17] Article 19(2) states: "Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

[18] Article 19(3) states: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

[19] Article 19(4) states: "Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced."

microbial specimens from hot springs at Yellowstone National Park,[20] was issued over a century ago. In 1916, legislation was enacted creating the U.S. National Park Service to administer U.S. national parks, in particular to "conserve the scenery and the national and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations."

21. Over the years, research permits have continued to be granted authorizing collection of specimens from the parks. The National Park Service's current regulations governing the collection of specimens for scientific research were put in place in 1983.[21] A single case study should suffice to demonstrate the public benefits of permitting access to genetic resources. In 1966, Thomas Brock was studying microorganisms living in Yellowstone's hot spring pools. In the laboratory, he named one of the curious organisms he had discovered *Thermus aquaticus* and submitted a living sample for safekeeping to the American Type Culture Collection, an organization that collects and maintains microorganisms.[22]

22. Two decades after Dr. Brock's academic work in Yellowstone, his discoveries produced a practical application that he had never imagined. In 1985, a biotechnology company named Cetus Corporation was seeking to develop a new way to duplicate genetic material. At the time, chromosomes were very difficult to study because they are made of genes and genes are composed of DNA, but DNA was too small to study effectively. Dr. Kary Mullis, a Cetus scientist, invented a useful method for DNA duplication, called Polymerase Chain Reaction (PCR),[23] but, unfortunately, the high temperatures required by PCR destroyed the polymerase enzymes, requiring laboratory technicians to add fresh enzymes throughout the PCR process, making that process tedious and resource intensive.

23. Other scientists at Cetus added to PCR an enzyme, named Taq polymerase, isolated from a sample of *Thermus aquaticus* obtained from the American Type Culture Collection. Taq polymerase had the unusual ability to keep working even at high temperatures. The scientists learned to reproduce the enzyme in the laboratory so that it would not be necessary to use original samples. PCR using Taq polymerase was so effective that a whole new scientific field flourished as scientists finally had a convenient way to reproduce and study DNA.

24. Today, the DNA copying process, made practical because of the study of a Yellowstone microorganism, has become a major part of DNA studies around the world. Taq polymerase helps permit the uses of DNA that are so familiar today – from matching DNA in criminal investigations, to medical diagnoses or cures, bioremediation of toxic wastes, and research into the basic building blocks of life.

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[20] Established on March 1, 1872, Yellowstone National Park is the first and oldest national park in the world.

[21] These regulations can be found in the U.S. Code of Federal Regulations, Title 36, section 2.5, which can be accessed at http://www.access.gpo.gov/nara/cfr/waisidx_01/36cfrv1_01.html.

[22] The ATCC is also an international depository authority under the WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

[23] Dr. Mullis was awarded a Nobel Prize for his invention.

25. While the results of such research on materials collected from national parks flowed to the world, however, there was no provision for ensuring that benefits flowed back to the parks that supplied the original materials. The National Parks Omnibus Management Act of 1998 expressly authorizes "negotiations with the research community and private industry for equitable, efficient benefits-sharing arrangements" in connection with research conducted in national parks. The Act also mandates increased scientific research in the national parks and the use of science in park management decisions. The law encourages the national parks to be places for scientific study by public as well as private sector researchers, and mandates long-term inventory and monitoring programs that provide baseline information, and document trends relating to the condition of park resources.

26. A lawsuit in 1998 challenged the legality of a cooperative research and development agreement (CRADA) negotiated between the Yellowstone National Park (Yellowstone) and Diversa Corporation (Diversa), a biotechnology company that develops new technologies for discovering and modifying genes. The judge dismissed the case with prejudice to the plaintiff, ruling that benefits-sharing CRADAs are consistent with the National Park Service Organic Act and the Yellowstone National Park enabling act.

27. As an example of benefit sharing under the CRADA between Diversa and Yellowstone, Diversa, in 1999, at no charge to the federal government, developed a DNA pedigree for the endangered Yellowstone wolves, the first such pedigree ever established. This pedigree, which the Yellowstone National Park could not have afforded to pay for, helps in understanding the dynamics of the wolf population, assessing the genetic health of the park's wolf population, identifying wolves that are killed illegally, detecting when wolves from other areas immigrate to Greater Yellowstone, and documenting breeding in the wild. This knowledge is used by Yellowstone staff in carrying out their charge to conserve the wild life in the park so that it can be enjoyed by this and future generations.

General Rules for Doing Research in U.S. National Parks

28. The National Park Services has separate requirements for collecting research materials from parks, depending on the use to which the research is to be put. For collections aimed solely at basic research and education, the superintendent of each national park has authority to issue research permits addressing the resources and needs of the park the superintendent oversees. A Scientific Research and Collecting Permit is required for most scientific activities involving fieldwork or specimen collection, particularly if the research has the potential to disturb resources or visitors. In some instances, other federal or state agency permits or approvals also might be required to be submitted with the application for a Scientific Research and Collecting Permit before the superintendent of the national park will consider the application. For example, research proposals involving threatened or endangered species must be accompanied by a permit from the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. Application materials, including *Guidelines to Researchers for Study Proposals*, can be obtained from the Internet (www.nps.gov) or by contacting the park in which the proposed research is to take place. Specimen collection for scientific research will be authorized only if the collection is necessary for the stated scientific goals included in the written research proposal. The research proposal must detail the activities that will occur in the park together with the analyses that will occur elsewhere, such as in the scientists' laboratory or office.

29. Each proposal is reviewed to ensure compliance with the National Environmental Policy Act and other relevant laws, regulations and policies. Depending on the complexity and sensitivity of the proposal, the superintendent might also require a review by relevant scientific experts, internal or external. Permits may be issued only if the proposed research will not have an adverse impact on public health and safety, environmental or scenic values, natural or cultural resources, other scientific research, management responsibilities, allocation and use of facilities, and visitor activities.

30. Researchers granted permits to work in National Park System areas must complete an Investigator's Annual Report on the required form for each year of the permit, including the final year. This can be done on paper or over the Internet. The reports themselves document the accomplishments of research conducted in the parks. The principal researchers are accountable for the accuracy and content of their reports. In addition to the reports, park research coordinators can request copies of field notes, data, reports, publications and other documents and materials related to studies conducted in the National Park System Areas. The *General Conditions for Scientific Research and Collecting Permit* is attached.

31. As noted above, specimens and components of specimens collected under permit are to be used for scientific or educational purposes only; specimens collected in parks may be loaned by the NPS for scientific purposes but may not be sold for any purpose; research results derived from NPS specimens may not be used for commercial or other revenue-generating purposes without further permission.

Cooperative Research and Development Agreements

32. According to National Park Service policy, any party that submits an application for a Scientific Research and Collecting Permit proposing to use the results of research for commercial or revenue-generating purposes must enter into a CRADA or other approved benefit-sharing agreement with the NPS. Under a CRADA, the National Park Service makes a clear distinction between sale or other transfer to third parties of collected research specimens or materials and the sale or other transfer of the results of research based upon the collected research specimens or materials. The sale or other transfer to third parties of collected specimens or components thereof is strictly prohibited. The party to the CRADA, however, may make commercial or other revenue-generating use of the results of its research, with benefit-sharing to the National Park Service as provided for in the CRADA.

33. The scientific research and collecting permit issued by the National Park Service to the other party spells out the terms and conditions under which that party will be permitted to collect research specimens or other materials from the park and the purposes to which such specimens or other materials may be put. The CRADA or other benefit-sharing agreement would identify the allocation of ownership in any inventions made, and the other rights and obligations of the parties, including reporting requirements and the manner in which any disputes will be handled. Some contracts might provide for express damages in the event of a breach of any of the provisions of the agreement by the party seeking to collect research specimens or other materials. Reporting requirements might include notification of the development of any invention based upon research using research specimens collected in the parks and identification of the contract in any patent application claiming an invention developed as a result of the research on collected specimens or other materials.

34. Only one CRADA has been negotiated by the NPS to date. The litigation in 1998 imposed a requirement to comply with National Environmental Policy Act and the NPS is currently developing an environmental impact statement to consider the effects of benefits-sharing within the National Park System.

Conclusion

35. The United States believes that a similar system, adapted to the legal systems and government structures of other countries, would work well in promoting the sustainable use of genetic resources and in ensuring that benefits resulting from any research using those resources are shared with the source of the resources. Such benefits could include training for scientists, direct application of the research results (as in the example of the genetic pedigree of the endangered Yellowstone wolves), or monetary remuneration. Finally, the United States is currently working to develop a model law that might be adapted to serve as the basis of domestic legislation for countries that are seeking to establish a practical means to regulate access to the resources in their country and ensure benefit sharing.

GENERAL CONDITIONS
FOR SCIENTIFIC RESEARCH AND COLLECTING PERMIT

United States Department of the Interior
National Park Service

1. Authority – The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.

2. Responsibility – The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.

3. False information – The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.

4. Assignment – This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.

5. Revocation – This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.

6. Collection of specimens (including materials) – No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit.

The general conditions for specimen collections are:

- Collection of archeological materials without a valid Federal Archeology Permit is prohibited.
- Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.
- Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.
- New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected,

location collected, specimen status (*e.g*. herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.

- Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.
- Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will provide accession information. It is the permittee's responsibility to contact the park for cataloging instructions and specimen labels as well as instructions on repository designation for the specimens. Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.
- Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a cooperative Research and Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with the NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled, including but not limited to injunctive relief against the permittee.

7. Reports – The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park Service.

8. Confidentiality – The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.

9. Methods of travel – Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.

10. Other permits – The pemittee must obtain all other required permit(s) to conduct the specified project.

11. Insurance – If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.

12. Mechanized equipment – No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.

13. NPS participation – The permittee should not anticipate assistance from the NPS unless specific arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.

14. Permanent markers and field equipment – The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.

15. Access to park and restricted areas – Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is allowed unless authorized in additional park specific stipulations attached to this permit.

16. Notification – The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.

17. Expiration date – Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).

18. Other stipulations – This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.

[End of Annex and of document]