



IFRA-IOFI Guidance Document
for the Flavor and Fragrance Industry
for dealing with the Nagoya Protocol
and Access and Benefit Sharing (ABS) Regulations

Annex – United States of America



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1. Applicable Legislation

The United States of America ('US') is not a party to the Nagoya Protocol and does not formally have a proper or comprehensive ABS Legislation in place.

This being said, regardless of the US being a Party to the Nagoya Protocol or not, **companies located in the US accessing and using natural resources originating from countries that are parties to the Nagoya Protocol and have ABS legislations in place shall comply with the applicable ABS rules.**

Moreover, **some rules and principles related to the acquisition and use of natural resources originating from the US or to the sharing of benefits arising from such activities are implemented in the US through various pieces of legislation at different levels** (local, state, regional, and national) and shall be complied with by individual companies.

Below is a non-exhaustive list of legislation in place at national/federal level (1.1) and State and local levels (1.2).

For the stake of this fiche, 'access' is understood broadly and possibly covering various intended activities such as research and development, use and/or trade (imports/exports/sale).

NB: Moreover, despite not being a party to the Nagoya Protocol, US is party to the following international treaties relevant for ABS principles:

- International Treaty for Plant Genetic Resources for Food and Agriculture ('ITPGRFA')¹;
- International Union for the Protection of New Varieties of Plants Convention ('UPOV')²;
- Convention on International Trade in Endangered Species of Wild Fauna and Flora ('CITES')³.

Furthermore, US is part of the WIPO's (World Intellectual Property Organisation) Intergovernmental Committee ('IGC')⁴, which is an ongoing process of negotiations with the objective of reaching agreement on international legal instrument(s) which will ensure the effective protection of traditional knowledge, traditional cultural expressions and genetic resources.

1.1. The National level

1.1.1. National legislations on natural resources

Since the beginning of the XXth century, US has issued various Acts which *de facto* regulate access to genetic resources, the most important of which are listed below.

- **The Lacey Act, 1900**⁵: conservation law which prohibits trade in wildlife, fish, and plants that have been illegally taken, possessed, transported, or sold. It regulates the import of any species protected by international or domestic law and prevents the spread of invasive, or non-native, species.

¹ International Treaty on plant genetic resources for food and agriculture of 29 June 2004 (2400 U.N.T.S. 303).

² International Convention for the Protection of New Varieties of Plants of 2 December 1961 (815 U.N.T.S. 89).

³ Convention on International Trade in Endangered Species of Wild Fauna and Flora of 3 March 1973 (993 U.N.T.S. 243).

⁴ Source, WIPO website: <https://www.wipo.int/tk/en/igc/>

⁵ Full text available at the following link: <https://www.fws.gov/le/pdf/files/Lacey.pdf>

- **The Endangered Species Act ('ESA'), 1973⁶:** provides a framework to conserve and protect endangered and threatened species and their habitat (notably implementing the CITES).
- **The Pelly Amendment, 1978,** to the Fishermen's Protective Act of 1967 which added the authorisation for the US President "*to embargo wildlife products (including all fish not previously covered) whenever the Secretary of the Interior or the Secretary of Commerce certifies that nationals of a foreign country are engaging in trade or taking that diminishes the effectiveness of an international program in force with respect to the United States for the conservation of endangered or threatened species*"⁷.
- **Various others legislations on biodiversity,** e.g. the Marine Mammal Protection Act ('MMPA')⁸; the Wild Bird Conservation Act ('WBCA')⁹; the Multinational Species Conservation Acts¹⁰; the Migratory Bird Treaty Act¹¹.
- **Codification:**

There are two main relevant sources of codification of applicable US national rules on natural resources, *i.e.* the **US Code ('USC')**¹² and the Code of Federal Regulations ('CFR').

- ✓ The US Code notably covers conservation of resources in its Title 16 (98 Chapters) as well as various provisions on use of natural resources and respect of traditional knowledge in Alaska (Title 15, Chapters 51 and 67)¹³.
- ✓ The Code of Federal Regulations contains all of the regulations promulgated by executive agencies. It notably deals with the collection of natural resources in National Parks (Title 36, Part 2.1)¹⁴.

1.1.2. The National Park Service ('NPS') principles

Since the NPS Organic Act of 1916¹⁵, the NPS has authority to maintain, restore, and protect the inherent integrity of the natural resources, processes, systems, and values originating from national parks areas.

The NPS deals with 419 Units/Parks¹⁶, which are separate protected areas in every US State (plus the District of Columbia, American Samoa, Guam, Puerto Rico, and the Virgin Islands). These areas include national parks, monuments, battlefields, military parks, historical parks, historic sites, lakeshores, seashores, recreation areas, scenic rivers and trails, and the White

⁶ Full text available at the following link: <https://www.fws.gov/international/pdf/esa.pdf>

⁷ Full text available at the following link: <https://www.fws.gov/laws/lawsdigest/FISHPRO.HTML>

⁸ Full text available at the following link: <https://www.fws.gov/international/pdf/legislation-marine-mammal-protection-act.pdf>

⁹ Full text available at the following link: <https://www.fws.gov/le/USStatutes/WBCA.pdf>

¹⁰ All the acts are available at the following link: <https://www.fws.gov/international/laws-treaties-agreements/us-conservation-laws/multinational-species-conservation-acts.html>

¹¹ Full text available at the following link: <https://www.fws.gov/laws/lawsdigest/migtrea.html>

¹² It consolidates and codifies by subject matter the laws of the USA.

¹³ Source: <https://uscode.house.gov/>

¹⁴ Source: <https://gov.ecfr.io/>

¹⁵ Source: NPS website (<https://www.nps.gov/grba/learn/management/organic-act-of-1916.htm>)

¹⁶ A list of all the areas, Units and Related areas, can be found at the following link: <https://www.nps.gov/aboutus/national-park-system.htm>

House. The NPS is also dealing with 150 'Related Areas' for which it provides technical/financial assistance or directly manage the entire or sections of the area.

Access to Natural Resources and use of the process resulting from the work on these resources are regulated, *i.e.* conditioned to the obtention of a permit or the conclusion by the user of an agreement with the NPS. It is important to note that direct sale or direct commercial use of Natural Resources originating from a NPS area is prohibited.

Rules on the management of benefit sharing for natural resources obtained from areas under the NPS authorities are found in the form of NPS Director's orders (See e.g. the "Director's order #77-10: NPS Benefits Sharing" ('NPS DO')¹⁷).

The latest NPS Director's Order and the NPS handbook¹⁸ notably list fundamental benefits-sharing principles, assign responsibilities for administering benefits sharing, and outline reporting requirements.

In a nutshell, although obtaining a NPS research permit on Natural Resources is not compulsory in every situation, **the commercial use of the results of research conducted on Natural Resources is conditioned by obtaining a NPS authorization, which itself is a prior requirement to conclude a necessary benefit-sharing agreement.** Permits are delivered by the NPS Superintendent of the park concerned, and the negotiation of a benefit-sharing agreement between various NPS representatives and the other party(ies) is lead by the NPS Benefits-Sharing Coordinator of the park concerned¹⁹.

1.2. State and local levels

According to information obtained orally from the US ABS National Focal Point, **States, local entities and landowners can restrict/condition the access to or use of their natural resources.**

However, in absence of a register compiling all the different rules that might apply, complexity can arise in identifying applicable rules.

1.2.1. State governments

Every individual US state has at least one environmental agency, and a vast majority of them have Department of Natural Resources ('DNR'). Those agencies could deliver different kind of permits depending on the nature of the activities conducted on materials originating from those areas.

¹⁷ Director's order #77-10: NPS Benefits Sharing, 19 December 2013, US Department of the Interior, can be found at the following link: https://www.nps.gov/policy/DOrders/DO_77-10.pdf

¹⁸ Benefits-sharing handbook, 18 August 2014, updated on 16 October 2018, NPS, can be found at the following link: [https://www.nps.gov/policy/DOrders/Benefits-Sharing_Handbook_\(2018\).pdf](https://www.nps.gov/policy/DOrders/Benefits-Sharing_Handbook_(2018).pdf)

¹⁹ For park-specific enquiry, the contact details can be found at the following link (listed by States): <https://www.nps.gov/aboutus/upload/NPIndex2012-2016.pdf>

Example: State of Wisconsin

The Wisconsin DNR delivers a permit to collect and research²⁰ within the state's natural areas, and also, among others²¹, a license to harvest the wild ginseng plant which is regulated under the Wisconsin laws (Wisconsin Statutes 29.611²² and Chapter NR 28 Wisconsin Administrative Code²³).

Therefore to harvest wild ginseng in Wisconsin²⁴, various conditions apply, among which²⁵:

1. Having a valid permit to harvest wild ginseng issued by the Wisconsin DNR, harvest licenses are available online (at gowild.wi.gov) and at DNR license sales locations;

2. Having the permission of the land owner or public land manager if the lands are not belonging to the state of Wisconsin;

3. Respecting the harvesting period: only from September 1 - November 1;

4. Respecting the limitation on type of plants: wild ginseng plants shall only be harvested if they possess three or more true leaves and a flowering/fruited stalk, and all of their seeds shall be planted in the vicinity of the parent plants in a way that will encourage their germination and growth.

1.2.2. Indigenous rules

The importance of Indigenous rights is growing in the US as the following elements demonstrate.

As a preliminary remark, the terms '**Native Americans**', '**Indians**', or '**Tribes**' are commonly used in literature. Moreover, under US Regulations on natural resources or traditional knowledge, the term '**Indigineous**' or '**Tribes**' are not precisely defined and may cover a large population. For those reasons, the terms are interchangeably used for the purpose of this fiche.

There is no direct availability of information on Indigenous rules on natural resources rules. Their identification may therefore require specific investigations.

As a principle, **Native Americans have rights on the natural resources found on their lands.**

There are two major types of Native American lands:

- **Trust land**, for which the legal title is hold by the federal government but the beneficial interest remains with the tribe; and,
- **Fee land**, for which the legal title pertains to the tribe.

²⁰ Source, Wisconsin DNR: <https://dnr.wi.gov/files/PDF/forms/9400/9400-379.pdf>

²¹ Source, Wisconsin DNR: <https://dnr.wi.gov/topic/endangeredresources/permits.html#tabx6>

²² Source, Wisconsin State legislature: <https://docs.legis.wisconsin.gov/statutes/statutes/29/IX/611>

²³ Source, Wisconsin State legislature: http://docs.legis.wisconsin.gov/code/admin_code/nr/001/28.pdf?o=n

²⁴ Source, Wisconsin DNR: <https://dnr.wi.gov/topic/endangeredresources/ginseng.html>

²⁵ For more detailed conditions see the Guide to Wisconsin Wild Ginseng Regulations : <https://dnr.wi.gov/files/PDF/pubs/LE/LE0005.pdf>

Native American natural resource ownership is fundamentally similar to Native American land ownership, *i.e.* the natural resources can be held in trust for a tribe or individual, or may be owned by them as part of a fee land²⁶.

This **does not necessarily mean however that only Tribe rules will apply on those land and/or resources**. Indeed, for most tribes **federal government approval may remain necessary** at some point in the process.

In that regard, it is interesting to note that there are two types of tribes²⁷:

- Federally recognized tribes (at present 573 tribes): Native American or Alaska Native tribal entities that is recognized as having a government-to-government relationship with the US, possessing certain inherent rights of self-government (*i.e.* tribal sovereignty) and is entitled to receive certain federal benefits, services, and protections because of their special relationship with the US government.
- Non-federally recognised groups: can be recognised by US States or can have rights granted federally notably the right to be consulted.²⁸

2. National Authorities and Relevant institutions

At the **National level**, the **U.S. Fish & Wildlife Service ('FWS')** is "*the only agency in the federal government whose primary responsibility is management of fish and wildlife for the American public*"²⁹. The FWS enforces the CITES and the Endangered Species Act ('ESA')³⁰.

For areas under the authority of the **National Park Service**, details of the competent offices for a given area can be found in an index edited by the NPS³¹.

At the **US federated states level**, environmental agencies have jurisdiction over land under state authority, mostly called **Department of Natural Resources ('DNR')**.

The Division of natural resources within the **Office of Trust Services** of the **Bureau of Indian Affairs**, could provide information on the authority to contact regarding **Native American lands**.

3. An example: Access to Genetic Resources under the NPS rules

The NPS Director's Order (NPS DO) dated 19 December 2013³² and the NPS handbook of 18 August 2014³³ provide for benefit sharing rules and procedures for resources found in National Parks. Below is a description of the applicable rules.

The definitions of the terms mentioned below can be found in point 3 of the NPS DO.

²⁶ Source, US DOI website: <https://revenuedata.doi.gov/how-it-works/native-american-ownership-governance/>

²⁷ Source, US BIA: <https://www.bia.gov/frequently-asked-questions>

²⁸ Another interesting source of information for the relation between the US and the Tribes is the Bureau of Land Management (BLM) Manual 1780 Tribal Relations: https://www.blm.gov/sites/blm.gov/files/uploads/H-1780-1_0.pdf

²⁹ Source: US Fish & Wildlife Service website (https://www.fws.gov/help/about_us.html).

³⁰ Full text available at the following link: <https://www.fws.gov/international/pdf/esa.pdf>

³¹ Source, NPS website: <https://www.nps.gov/aboutus/upload/NPIIndex2012-2016.pdf>

³² Director's order #77-10: NPS Benefits Sharing, 19 December 2013, US Department of the Interior, can be found at the following link: https://www.nps.gov/policy/DOrders/DO_77-10.pdf

³³ Benefits-sharing handbook, 18 August 2014, updated on 16 October 2018, NPS, can be found at the following link: [https://www.nps.gov/policy/DOrders/Benefits-Sharing_Handbook_\(2018\).pdf](https://www.nps.gov/policy/DOrders/Benefits-Sharing_Handbook_(2018).pdf)

3.1. Definition of Natural Resources

The NPS DO foresees two categories of Natural Resources: **Natural Products** and **Materials**.

3.1.1. Natural Products

The broad definition of a Natural Product under the NPS DO covers “*naturally occurring items collected from a park*”.

First, “*Specimens*” of such resources are Natural Products.

Moreover, any modification of or extraction from a collected Specimen is also considered as a Natural Product: *i.e. “if the researcher slices, polishes, or otherwise prepares or removes a part of the collected specimen, the prepared specimen or component remains a “natural product” (emphasis added)*³⁴.

3.1.2. Materials

Materials can be understood as the derivative of one of the different forms of collected Specimens. Following that definition, are considered as Materials:

- Progeny, defined as “*(u)nmodified descendant from a collected specimen or Material*”³⁵;
- Unmodified derivatives of collected specimens, examples are “*copies of cells of the collected specimen, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA extracted from the collected specimen or Material*”³⁶;
- Museum specimens, which are permanently retained in a park museum collection and are non-living³⁷;
- Living collections, which are retained in an NPS or non-NPS repository³⁸.

3.2. Utilisation of Natural Resources

Access to Natural Resources and use of the process resulting from work conducted on it are conditioned to the obtention of a permit and/or the conclusion by the user of an agreement with the NPS.

As a matter of principle, direct commercial use or direct sale of Natural Resources originating from a NPS area is prohibited. Indeed, according to Article 4.1.1 of the NPS DO:

- ✓ “*the commercial use or sale of natural products, including specimens collected in parks under research permits, is prohibited by regulation (36 CFR 2.1);*
- ✓ *the commercial use or sale of paleontological specimens collected on federal lands is prohibited by law (16 USC 470aaa-5);*
- ✓ *the commercial use or sale of archeological resources collected on federal lands is prohibited by law (16 USC 470ee).”*

³⁴ See Point 3 of the NPS DO, “Natural Products”.

³⁵ See Point 3 of the NPS DO, “Progeny”.

³⁶ See Point 3 of the NPS DO, “Unmodified derivative”.

³⁷ See Point 3 of the NPS DO, “Museum Specimen”.

³⁸ See Point 3 of the NPS DO, “Living collection”.

However “(e)xisting NPS law and policy do not prohibit or authorize commercial use of knowledge and research results derived from collected specimen” (Article 4.1.2 of the NPS DO) (emphasis added).

Therefore **the results of research on Natural Resources can be used for scientific or commercial purposes if the permittee has entered into an agreement.**

3.2.1. Access for research purposes

A NPS authorization is a prior requirement to conclude a benefit-sharing agreement which itself is a condition for the commercial use of the results of research on Natural Resources³⁹.

3.2.1.1. Personal scope

The NPS can enter into an agreement for purposes of scientific study with “*Federal or non-Federal public or private agencies, organizations, individuals, or other entities*”⁴⁰.

3.2.1.2. Type of agreements

There are various forms of agreements for research:

- **Scientific Research and Collecting Permit** is “*required for most scientific activities pertaining to natural resources or social science studies in National Park System areas that involve fieldwork, specimen collection, and/or have the potential to disturb resources, visitors, or park operations.*”
- **Collected Specimen Transfer Agreement** (‘CSTA’) aims to “*provide custody of collected specimens to organizations and their researchers, other than researchers identified in the Scientific Research and Collecting Permit, for purposes of research when a determination has not yet been made on whether the specimens will be permanently retained and incorporated into an NPS museum or living collection.*”
- **Loan agreement** is concluded “*between a lender and a borrower of museum specimens or living collections, specifying the items lent and the terms, conditions, and responsibilities and liabilities of each party. The NPS uses outgoing loan agreements to track loans of cataloged museum specimens and living collections to other institutions, such as research laboratories or repositories.*”
- **Material Transfer Agreement** (‘MTA’) established “*the terms by which one party both provides Material to another party for research use and tracks disposition of the Material.*”

3.2.2. Access for commercial purposes

The NPS DO defines ‘**Commercial use**’ as the : “(u)se of Material or modifications or other research results in a product, service, or process resulting in a product or service that is sold, leased, licensed, or otherwise transferred for value received” (emphasis added)⁴¹.

³⁹ See Point 1.7 of the NPS handbook.

⁴⁰ Source, 54 U.S. Code § 100705 - Availability of System units for scientific study:
<https://uscode.house.gov/view.xhtml?path=/prelim@title54/subtitle1/divisionA/chapter1007&edition=prelim>

⁴¹ See Point 3 of the NPS DO, “Commercial use”.

Prior to the commercialization of the results of research on Natural Resources, the user shall conclude a benefit-sharing agreement with the NPS. The benefit sharing can take the form of both monetary or non-monetary schemes.

3.2.2.1. Personal scope

It is not clear at first glance if the NPS may enter into agreements with individual companies. This constitutes a grey zone which should be clarified with authorities.

First, according to the NPS DO, the NPS can conclude agreements for benefits sharing only with federal and non-federal entities⁴², which the Code of Federal Regulation defines as : “*state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient*”⁴³. Private companies are not mentioned.

However, the US Code states that the DOI Secretary may negotiate for benefit-sharing arrangements with the research community and private industry⁴⁴.

Also, the NPS DO⁴⁵ and the NPS Handbook⁴⁶ state that to share or decline benefits, the NPS may enter into agreements with entities “*who already have NPS authorization for their research*” through the aforementioned research permit (cf. point 3.2.1.2 above) and/or “*other NPS research authorizations*”. As a matter of fact, private companies can apply for permits for scientific research and are under the scope of the US Code provision for benefit-sharing.

It therefore appears that private companies should be able to ask the NPS to enter into an agreement to pursue commercial use of the results of their natural resource research. Nevertheless, the NPS Handbook adds to the confusion by indicating different personal scopes of application for different type of agreements (see below).

In absence of clearer provisions to that end, this should be verified on a case-by-case basis.

The NPS Handbook adds that NPS should enter into only one agreement to share or decline benefits for “*each commercialization of research results*”.

The agreement shall be concluded prior to commercial use of research results⁴⁷.

3.2.2.2. Type of agreements

There are three main types of agreements to implement benefits sharing⁴⁸:

- **Cooperative Research and Development Agreement ('CRADA')**, for parks that are federal laboratories as defined by the FTTA⁴⁹;
- **Cooperative Agreement;**

⁴² NPS DO Point 4.3.2; Definition of non-federal entities can be found in the CFR, 2 § 200.69.

⁴³ See Point 4.3.2. of the NPS DO; and CFR, 2 § 200.69 - Non-Federal entity.

⁴⁴ Source, 54 U.S. Code § 100705 - Availability of System units for scientific study.

⁴⁵ See Point 5.1 of the NPS DO.

⁴⁶ See Point 1.7 of the NPS Handbook.

⁴⁷ See Point 1.1 of the NPS DO.

⁴⁸ See Point 6.1 of the NPS Handbook.

⁴⁹ FTTA is the Federal Technology Transfer Act, it can be found at the following link:
[https://uscode.house.gov/view.xhtml?req=\(title:15%20section:3710%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:15%20section:3710%20edition:prelim))

- **General Agreement.**

NPS may agree on monetary or non-monetary benefit sharing schemes under all types of agreements.

According to the NPS Handbook, the main differences between these agreements are the authority receiving the monetary benefits (the parks or the U.S. Treasury), the level of involvement of the park in the research project and the entities that may enter into them, i.e.:

- A **CRADA** may be entered into by “*any organisation including federal, state and local governments, universities, and the private sector, but each CRADA must involve at least one non-federal partner*” (emphasis added). Under such agreement, the park may provide personnel, services, facilities, equipment, intellectual property, or other resources (but no funds to the non-federal partner);
- A **Cooperative Agreement** may be entered into by “*public or private educational institutions, states, and their political subdivisions*”. Under this agreement, the park will expect to have a substantial participation in a research project likely to develop a commercial use qualified as being in the public interest;
- A **General Agreement** may be entered into by “*any federal and non-federal entities (institutions and organizations, not individuals)*”. Under this agreement, the park does not anticipate substantial involvement.

After operating under one type of agreement for a period of time, the parties may negotiate new terms using another type of agreement.

3.3. Request for Access before the NPS

NPS uses an online system for request for access to natural resources, it is called the Research Permit and Reporting System (RPRS) which is available online⁵⁰.

4. Abbreviations

ABS	Access and Benefit Sharing
BIA	Bureau of Indian Affairs
CBD	Convention on Biological Diversity
CFR	Code of Federal Regulations
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CRADA	Cooperative Research and Development Agreement
CSTA	Collected Specimen Transfer Agreement
DNR	Department of Natural resources
DOI	US Department of the Interior

⁵⁰ The online platform can be found at the following link: <https://irma.nps.gov/RPRS/>



ESA	Endangered Species Act
FWS	US Fish & Wildlife Service
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
MTA	Material Transfer Agreement
NPS	National Park Services
NPS DO	Director's order #77-10 on NPS Benefits Sharing of 19 December 2013
UPOV	International Union for the Protection of New Varieties of Plants Convention
US	United States of America
USC	US Code



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