The Next Generation of Environmental Monitoring: Environmental DNA in Agency Practice

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Federal and state agencies have begun using residual genetic information taken from the environment—environmental DNA or eDNA—to help make management and regulatory decisions. Environmental DNA can provide information from water, soil, or air samples about the living parts of ecosystems with unprecedented scope, in some cases providing broad surveys of the species present and in others pinpointing hard-to-find species. However, standards for analysis and interpretation have only recently begun to arise in the nascent field of eDNA analysis. As this new and valuable source of information begins to influence the implementation of environmental laws, we survey existing federal uses of eDNA and review federal information requirements relevant to natural resource management—in particular, under the data-hungry Endangered Species Act and National Environmental Policy Act. We find that some agencies are already using eDNA data, and, for the most part, these uses are likely to meet the legal requirements of the controlling statutes and regulations. Though legally acceptable, social factors influence the degree to which a technology becomes widespread in agency practice. We survey likely future scenarios for eDNA uptake and offer recommendations for

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driving broader adoption of this useful technology and enabling management and regulatory decisions grounded in eDNA as a data source.

I. INTRODUCTION

In 2010, researchers working for the U.S. Army Corps of Engineers (Corps) detected the DNA of the highly-invasive Asian carp in waters near the Great Lakes.[1] Asian carp would seriously threaten the ecology and the commercial and recreational uses of the Great Lakes if they became established there, especially harming the fishing industry.[2] In surveying the water for Asian carp DNA—rather than for individuals of the species themselves—scientists made a conceptual leap that has offered other federal agencies a blueprint for employing this type of survey as a basis for decision-making.

The technique used by the Corps scientists is known as environmental DNA (eDNA) analysis. By collecting samples of water, soil, or air and performing a genetic assay of those samples, it is possible to identify species or groups of species that have shed DNA into the environment. A liter of water might contain cells sloughed off by thousands of different species, from fungi to worms to mammals.[3] Academic and industry scientists now routinely analyze genetic information from those cells,[4] yielding a catalog of species present at

1. *See* Michigan v. U.S. Army Corps of Eng'rs, No. 10–CV–4457, 2010 WL 5018559 at *6–8 (N.D. Ill. Dec. 2, 2010), *aff'd* 667 F.3d 765 (7th Cir. 2011) [hereinafter Michigan I]. The Corps' ultimate management decision was challenged by states, a tribe, and citizen groups, resulting in the first opportunity for an American court to consider the use of eDNA data in environmental management. *Id*. In the case, there were two species of concern: silver carp (*Hypophthalmichthys molitrix*) and bighead carp (*H. nobilis*), referred to collectively as Asian carp. *Id*. at *3. The movement of Asian carp has been monitored by multiple government agencies since they were listed as "Injurious Wildlife Species" in 2007 because of the threats these large fish pose to boaters and wildlife. Michigan v. U.S. Army Corps of Eng'rs, 667 F.3d 765, 772 (7th Cir. 2011), *aff'g* Michigan I, *supra* (circuit court ruling on the denial of a motion for preliminary injunction; the circuit court also decided an appeal in 2014 after the district court granted a motion to dismiss).

2. "Based upon testing conducted by the United States Army Corps of Engineers (USACE), the Asian carp is presently migrating toward the Great Lakes through the Chicago Sanitary and Ship Canal and connected tributaries. If these aquatic nuisance species reach the Great Lakes in sufficient numbers, scientists are concerned that they might devastate the Great Lakes commercial and sport fishing industries." Safety Zone, Brandon Road Lock and Dam to Lake Michigan, 75 Fed. Reg. 26095 (May 11, 2010) (to be codified at 33 C.F.R. pt. 165). *See also* Michigan I, *supra* note 1, at *4 n. 6.

3. Microbial diversity, in which individual organisms may only have one cell to begin with, contributes the majority of genetic information to any given environment. In that case, the microbes themselves are sampled. For larger-bodied species, cells are left behind as a result of metabolism or other ongoing life activities. *See, e.g.*, Kenneth J. Locey & Jay T. Lennon, *Scaling Laws Predict Global Microbial Diversity*, 113 PROC. OF THE NAT'L ACAD. OF SCI. 5970 (2016).

4. *See, e.g.*, Kristy Deiner et al., *Environmental DNA Metabarcoding: Transforming How We Survey Animal and Plant Communities*, 26 MOLECULAR ECOLOGY 5872 (2017).

a given time in a given environment. Federal agencies have begun to follow suit.

For example, in 2018, the U.S. Fish and Wildlife Service (FWS) listed the black warrior waterdog (not a dog, but rather a species of salamander)[5] as endangered under the Endangered Species Act,[6] and used eDNA as one form of evidence by which to identify and designate its critical habitat.[7] In the context of endangered species, as with the invasion of nonnative species illustrated in the Asian carp case, eDNA can be particularly useful in detecting rare or difficult-to-detect species. The 2018 waterdog rulemaking, though, also highlights agencies' current practice of combining this novel technology with other methods. For example, the final rulemaking took some pains to respond to public comments surrounding the danger of false-positive detections.[8] Moreover, the agency hedged its use of survey techniques in a way that conspicuously does *not* rely on eDNA alone: "[w]e used eDNA to narrow our focus on sites where additional sampling was more likely to capture live waterdogs, but we are not designating any streams as critical habitat, nor are we determining listing status, solely based on eDNA."[9]

These examples are representative of the current state of a powerful technology in practice: Agencies are using eDNA, but at present those uses tend to be in combination with existing data streams or in research, rather than to fulfill nondiscretionary duties as a sole source of information. Scientists gather information about "the environment" from a broad array of sources ranging along a technological continuum from satellites (remote sensing for temperature, precipitation, photosynthesis, etc.) to manual and visual counts of individual species. Environmental data is, therefore, the sum of many bits of more targeted information, collected for various purposes, the emergent trends of which form a synoptic but incomplete view of the whole. Environmental DNA, as a data source, cuts across some of the technological continua, making retail species

5. *Necturus alabamensis*.

6. Endangered Species Status for Black Warrior Waterdog and Designation of Critical Habitat, 83 Fed. Reg. 257 (Jan. 3, 2018) (to be codified at 50 C.F.R. pt. 17) [hereinafter Waterdog Designation].

7. *Id*. at 262 ("Only through the use of eDNA have we been able to determine that the waterdog is likely present at some historical locations."); *Id.* at 270 ("Based on eDNA detections, the Black Warrior waterdog could be using streams as narrow as 4 m (13 ft) wide.").

8. *Id*. at 258–59. Given that false-positive detections would mean the spurious detection of a species where it is not, in fact, present—and given that such detections would result in larger critical habitat areas—such errors would have practical (and not just statistical) significance.

9. *Id*. at 259.

detection and quantification into a wholesale activity more akin to remote sensing than to visual surveys.[10] eDNA methods are poised to make contributions across a wide spectrum of natural-resources applications relevant to the government. These include monitoring species of interest, tracking the species composition of whole ecosystems, detecting invasive species, detecting rare or threatened species, and estimating the abundance of species to inform the management of harvests. In any application in which an agency requires information about a living (or recently living) species, genetic techniques are very likely to play a role in the near future.

Since the 2010 litigation over eDNA surveillance of Asian carp near the Great Lakes (among other issues),[11] the science of eDNA has advanced rapidly, with a concomitant increase in the reliability of analysis and a decline in costs.[12] Scientists have cross-validated eDNA assays against traditional monitoring techniques in many settings, and a broad understanding of the behavior of DNA in the environment has begun to emerge.[13] eDNA analysis today is capable of supplementing, and may in time supplant, traditional methods used in the identification of microbial pathogens or little-known rare species, which now require careful, costly—and consequently infrequent—work by a limited number of experts. The sensitivity, accuracy, and declining cost of eDNA analysis could yield information that is far cheaper and more reliable than the information currently used in decision-making for environmental management.

The core methods of generating and analyzing eDNA data have rapidly gained credibility in the scientific community, and the only court yet to rule on the matter found it a legitimate form of evidence.[14]

10. Which is to say, rather than detecting species one or a few at a time (as with traditional methods), eDNA detects many species at once.

11. Michigan I, *supra* note 1.

12. *See generally* Deiner et al., *supra* note 4. Note also there are two entire scientific journals now dedicated to eDNA studies: *Environmental DNA* and *Metabarcoding and Metagenomics*.

13. *See, e.g.*, Matthew A. Barnes & Cameron R. Turner, *The Ecology of Environmental DNA and Implications For Conservation Genetics*, 17 CONSERVATION GENETICS 1 (2016); Matthew C. Yates et al., *The Relationship Between eDNA Particle Concentration and Organism Abundance In Nature Is Strengthened by Allometric Scaling*, 30 MOLECULAR ECOLOGY 3068 (2021); Matthew A. Barnes et al., *Environmental Conditions Influence eDNA Particle Size Distribution In Aquatic Systems*, 3 ENV'T DNA 643 (2021); Andrew Olaf Shelton et al., *Toward Quantitative Metabarcoding*, 104 ECOLOGY e3906 (2022).

14. *See* Michigan I, *supra* note 1, 2010 at *28; Michigan v. U.S. Army Corps of Eng'rs, 738 F.3d 892, 896 (7th Cir. 2014), *aff'g* Michigan v. U.S. Army Corps of Eng'rs, 911 F.2d 739 (N.D. Ill. 2012) [hereinafter Michigan II] (accepting that eDNA evidence is sufficiently reliable for the court to interpret it as "indicat[ing] immediate presence of the carp"). *See infra* Part III for a discussion of the courts' application of Federal Rule of Evidence 702 to the admissibility of eDNA analyses.

Given the trajectory of eDNA tools over the past decade, in this Article we assess the legal context in which eDNA methods are likely to be adopted, focusing on the Endangered Species Act (ESA) and the National Environmental Policy Act (NEPA) as motivating statutory examples. Both statutes require credible and reliable information in decisions touching many economic interests and affecting environments across the nation. Does eDNA, in fact, meet the legal requirements of these statutes? And, if so, what are the contours of its acceptability with respect to existing forms of data? Finally, what are the likely paths forward for its adoption into routine practice in federal agencies?

Below, in Part II, we briefly describe the methods behind the collection of eDNA data and introduce the demonstrated and potential uses of that data before surveying existing federal uses of eDNA to highlight the current state of adoption across federal agencies. In Part III, we synthesize the federal legal requirements for biological information, finding eDNA is likely to meet existing statutory and administrative requirements. Part IV concludes by suggesting reasonable steps to support the efficient adoption of molecular methods.

II. WHAT IS ENVIRONMENTAL DNA?

Broadly, eDNA[15] is the residual genetic information left behind from the living parts of an ecosystem. Because all living things make DNA,[16] and because the sequence of this DNA makes species distinguishable from one another, individual cells contain a vast storehouse of biological information. It is a potential goldmine of information for environmental management. If eDNA is the free-ranging genetic material itself, it is the analysis of such material that yields useful information. Analysis of eDNA, to date, has proceeded down one of two pathways, depending upon the management or research question of interest. If the question focuses on a single species, researchers develop assays unique to that species, with the result being a quantitative estimate of the species' DNA present in a sample; this

15. And its cousin, environmental RNA (eRNA), which is the more ephemeral reflection of genes that an organism is actually expressing at a given time. *See generally*, Matthew C. Yates et al., *Environmental RNA: A Revolution in Ecological Resolution?*, 36 TRENDS IN ECOLOGY & EVOLUTION 601 (2021).

16. Or RNA. For example, many viruses use RNA, rather than DNA, as their transmittable genetic material. *See RNA Virus*, WIKIPEDIA, https://en.wikipedia.org/wiki/RNA_virus [https://perma.cc/N7SF-8UL8] (last accessed Jan. 30, 2023).

technique is called quantitative PCR (qPCR).[17] If instead the question focuses on a cross-section of many species present, a second technique—known as amplicon sequencing or metabarcoding—reveals this information but is not usually designed to provide quantitative estimates of abundance.[18] Either or both of these techniques might be applicable to a given management question, and in general, the term "eDNA analysis" refers to both interchangeably.

A. Single-Species Analysis (qPCR)

Quantitative PCR (qPCR) is an appealingly simple technique that yields fast, reliable results. A researcher first designs an assay consisting of short stretches of DNA that precisely match a DNA sequence in a target species—for example, an endangered waterdog or a viral pathogen. The assay then works by a PCR analysis of a sample. Where the target template is present, PCR generates many copies of that template, and where it is absent, PCR produces no result. A fluorescent reporter-molecule, read by a laser and reflecting the number of copies produced, makes visible the rate at which the PCR reaction generates copies; the greater the template concentration in the sample, the faster the copies accrue. The result is a specific, quantitative measurement of the concentration of any template DNA of interest.

In the context of eDNA, scientists can apply qPCR assays to samples obtained from water, soil, or air, searching for a given species of interest. As with any survey method, interpretation of the results of a qPCR test benefits from understanding the particular assay's sensitivity and specificity. A low-sensitivity test has a high rate of false-negative results; a low-specificity one has a high rate of false-positive results.

qPCR assays have become ubiquitous during the COVID-19 pandemic as a sensitive and rapid way of establishing the presence of the virus in a biological sample. In that context, pharmacies and sample-processing centers generally treat qPCR assays as a positive/negative test for the presence of the virus in a sample of cells from, for

17. PCR stands for Polymerase Chain Reaction; PCR is a foundational tool of molecular biology that produces billions of copies of a small fragment of DNA of interest to a given research question or application. *See, e.g.,* Randall K. Saiki et al., *Primer-Directed Enzymatic Amplification of DNA With a Thermostable DNA Polymerase*, 239 SCI. 487 (1988).

18. This technique amplifies a broad spectrum of DNA present in the environment (typically the DNA from hundreds or thousands of species simultaneously) via PCR with generalized primers (rather than species-specific primers).

example, a nasal swab because the average patient does not particularly care about the precise concentration of viral DNA in their nose. Manufacturers of the assay simply set a threshold of viral DNA concentration, above which the sample is deemed "positive" for the virus.

But qPCR inherently provides quantitative information about the underlying concentration of target DNA, and this information is often relevant in the environmental context. For example, a state wildlife agency may wish to map the density of an invasive species over space,[19] or a time series of eDNA samples may efficiently track changes in the population of a species of management concern. And because generating qPCR data is straightforward—for example, COVID tests often return results within 24 hours—this kind of data is broadly attractive in the environmental context.

Wastewater testing is a technique for public-health surveillance that rose to prominence early in the COVID pandemic, neatly linking the ideas of eDNA analysis and now-familiar COVID testing. Wastewater streams contain biological information about the human population in the surrounding area, and consequently, they integrate the genetic signals of disease in that population. Routinely probing a city's wastewater with a COVID qPCR assay[20] quantitatively reflects the rise and fall of COVID infections in the human community over time.[21] In a more general environmental context, precisely the same approach yields information on populations of any particular species of management interest.

B. Multi-Species Analysis (Amplicon Sequencing)

Given that living things constantly shed information-dense DNA into the environment, interrogating an environmental sample for a single species at a time leaves a vast amount of ecological information on the table. Rather than designing qPCR assays for one or a few species of interest, it is also possible to amplify DNA from a sample using a more general assay that matches many species at once—all

19. Or, more precisely, the DNA of this invasive species. The relationship between the abundance of a species and the abundance of its DNA can be complicated, but as a rule, more of a species implies more of its DNA in a sample.

20. Or monkeypox, or whatever other disease of interest might be important.

21. *See, e.g.*, Aliza Aufrichtig & Emily Anthes, *How Wastewater Can Help Track Viruses Like COVID*, N.Y. Times (Aug. 17, 2022), https://www.nytimes.com/interactive/2022/08/17/health/wastewater-polio-covid-nyc.html [https://perma.cc/B9TQ-T6F2].

vertebrates, for example. The result of the amplification reaction is a mix of amplified fragments (amplicons) from many species. Researchers can then read the sequence of each of these small fragments using a DNA sequencer, and match the resulting reads back to a database of sequences from known species, revealing the identity of many species from the original environmental sample.

The advantages of this multi-species technique are obvious, inasmuch as one can see hundreds or thousands of species out of a single sample of water, soil, or air. Particularly for broader-spectrum environmental management—as in the case of NEPA, discussed below—amplicon sequencing seems poised to become a core tool of resource agencies.

However, the many complicated details of interpretation exact a cost here: Multi-species data is not nearly as easily interpreted as qPCR data. Chief among these complicating details is the fact that every species will amplify at a slightly different rate. In a community of many hundreds of mixed species, these different rates and the exponential nature of the PCR reaction mean that species' proportions are distorted in the process of amplicon sequencing. One can correct for this distortion, but easy methods for doing so are just now emerging.[22]

A second key detail is that the mix of species in amplicon sequencing means that the resulting data are proportions,[23] rather than absolute concentrations. While qPCR provides estimates of the absolute DNA concentration in a sample, multi-species amplicon sequencing yields a pie chart, in essence. One can know the proportions of individual species represented by DNA present in a sample, but without further information, there is no indication of the quantity of that DNA.

The results therefore can be counterintuitive. For example, a given salmon run may peak in a river in early fall, increasing the salmon DNA present in water samples by orders of magnitude. It is quite possible for the proportion of, say, coho salmon to decrease relative to Chinook during the fall run, even though the absolute concentrations of both species have skyrocketed relative to other times of the year. The absolute concentration of coho can be

22. *See, e.g.*, Justin D. Silverman et al., *Measuring and Mitigating PCR Bias In Microbiota Datasets*, PLOS COMPUTATIONAL BIOLOGY (July 2021); Michael R. McLaren et al., *Consistent and Correctable Bias in Metagenomic Sequencing Experiments*, eLife (Sept. 10, 2019); Shelton, *supra* note 13.

23. The proportions observed will generally be inaccurate because of the differences in amplification described above.

massively increasing while its proportion is decreasing, and the DNA sequences would accurately report a decline in proportion.

Again, additional information in the analysis (such as overall run size or estimates from a calibrating qPCR) can overcome this limitation, but the point is to underscore the added complexity that comes with multi-species sequencing data. Federal agencies have generally adopted qPCR more readily than multi-species sequencing data, presumably because the latter technique is both newer and requires more equipment and expertise. Below, we relate the scope of federal uptake of molecular environmental data to motivate our subsequent legal analysis.

C. Existing Federal Agency Use of eDNA

Federal agencies have been using eDNA to inform complex environmental decisions since at least 2009.[24] A non-exhaustive sampling of agency uses of eDNA as a data source (Table 1) underscores the breadth of federal interest and the state of acceptance. Across the executive branch, agencies are funding eDNA work for purposes ranging from invasive-species management (United States Geological Survey (USGS)) to endangered species detection (FWS, National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS)) to environmental-impact assessment for offshore energy leasing (Bureau of Offshore Energy Management (BOEM)). And although, as we discuss in Part III, federal adoption has been faster in exploratory and non-regulatory scenarios than to support regulatory decisions, agencies are increasingly treating eDNA as simply another data stream on which to base decisions. Moreover, since *Michigan v. Army Corps*,[25] agency use of eDNA has provoked little other federal litigation.[26]

24. Michigan I, *supra* note 1, at *6–8. There, the outcome of the case did not rely on the eDNA evidence, but rather eDNA was one of several lines of evidence the agencies—and later, the court—considered. *Id.* at *6–8, 27–28.

25. Michigan I, *supra* note 1; Michigan II, *supra* note 14.

26. The only other federal case touching on eDNA has been *Appalachian Voices v. U.S. Dep't of Interior*, 25 F.4th 259 (4th Cir. 2022), which found that USFWS had not acted in an arbitrary and capricious manner in using eDNA surveys, among other data sources, in a critical habitat designation under the ESA.

Table 1: Representative Federal Agency eDNA Activities and Programs Reflecting a Substantial Degree of Uptake for a Cross-Section of Applications.

Agency	Parent Agency	Application	Locations/programs
National Invasive Species Council (NISC)	Interior (with membership made up of multiple cabinet-level agencies)	Invasive species	2022 framework for using eDNA,[27] white paper,[28] technical report[29]
United States Geological Survey (USGS)	Interior	Invasive species, ecosystem recovery (Elwha River recovery post-dam removal)[30]	Great Lakes, Yellowstone National Park, Florida Everglades[31]
Bureau of Offshore Energy Management (BOEM)	Interior	Environmental Impact Statement (EIS)	Offshore energy leasing[32]
Fish and Wildlife Service (FWS)	Interior	Invasive species, Endangered species	Aquatic Nuisance Species Task Force (ANS Task Force) Aquatic eDNAtlas Project[33]

27. Jeffrey Morisette et al., *Strategic Considerations for Invasive Species Managers in the Utilization of Environmental DNA (eDNA): Steps for Incorporating this Powerful Surveillance Tool*, 12 Mgmt. of Biological Invasions 747 (2021); for a summary of the Framework, *see* U.S. Dep't of Agric., Shedding Light on Shedded Cells: Using eDNA Sampling for Surveillance of Invasive Species (2022).

28. U.S. Dep't of Interior, Environmental DNA As a Tool for Invasive Species Detection and Management (2022).

29. Morisette, *supra* note 27, at 12.

30. Jeffrey J. Duda, Marshal S. Hoy, Dorothy M. Chase, George R. Pess, Samuel J. Benkman, Michael M. McHenry, & Carl O. Ostberg, *Environmental DNA is an Effective tool to Track Recolonizing Migratory Fish Following Large-Scale Dam Removal*, 3 ENV'T DNA 121 (2020).

31. *USGS Science Is Refining eDNA Techniques and Developing New Applications*, U.S. Geological Survey (Mar. 4, 2022), https://www.usgs.gov/news/featured-story/environmental-dna-research-sheds-light-invasive-species [https://perma.cc/BC8C-H9AE].

32. Bureau of Offshore Energy Mgmt., 2022-0021, Ocean Wind 1 Offshore Wind Farm Draft Environmental Impact Statement (2022).

33. Morisette, *supra* note 27, at 12.

National Oceanic and Atmospheric Administration (NOAA) and National Marine Fisheries Service (NOAA NMFS)	Commerce	Invasive species, nearshore fish assessments,[34] public outreach	Aquatic Nuisance Species Task Force (ANS Task Force) Aquatic eDNA Atlas Project,[35] NOAA's Atlantic Laboratory video series on eDNA,[36] NOAA's Fisheries Strategic Initiative to use eDNA libraries,[37] offshore energy leasing with BOEM.
Forest Service (USFS)	Agriculture	Invasive and endangered species	National Genomics Center for Wildlife and Fish Conservation, eDNA Atlas, the Range-Wide Bull Trout eDNA Project,[38] Hiawatha National Forest[39]
Environmental Protection Agency (EPA)	N/A	Water quality	EPA Region 3 in collaboration with West Virginia, Maryland and Pennsylvania[40]

34. *Scientists Use Innovative DNA Technology to Characterize Nearshore Marine Fish Communities in Southeast Alaska*, NOAA FISHERIES (Mar. 30, 2022), https://www.fisheries.noaa.gov/feature-story/scientists-use-innovative-dna-technology-characterize-nearshore-marine-fish [https://perma.cc/B6K2-WYHG].

35. *The Aquatic eDNAtlas Project*, U.S. FOREST SERV., https://www.fs.usda.gov/rm/boise/AWAE/projects/the-aquatic-eDNAtlas-project.html [https://perma.cc/P8AE-5GWT] (last visited Nov. 20, 2022).

36. *Exploring Environmental DNA*, ATL. OCEANOGRAPHIC & METEOROLOGICAL LAB (Apr. 27, 2022), https://www.aoml.noaa.gov/news/exploring-environmental-dna [https://perma.cc/9WWA-F84B].

37. *How Environmental DNA Can Help Our Ocean*, NOAA FISHERIES (Mar. 4, 2022), https://www.fisheries.noaa.gov/feature-story/how-environmental-dna-can-help-our-ocean [https://perma.cc/A57E-Z6LC].

38. *eDNA*, U.S. DEP'T OF AGRIC. (Mar. 4, 2022), https://www.fs.usda.gov/rmrs/ngc/edna [https://perma.cc/U46U-U54C]. *See also The Range Wide eDNA Bulltrout Project*, U.S. DEP'T OF AGRIC., https://www.fs.usda.gov/rm/boise/AWAE/projects/BullTrout_eDNA.html [https://perma.cc/KKU9-W2RP] (last visited Nov. 20, 2022).

39. Jack Hall, *Hiawatha National Forest Launches eDNA Project*, RADIO RESULTS NETWORK (Nov. 25, 2019), https://www.radioresultsnetwork.com/2019/11/25/hiawatha-national-forest-launches-edna-project/ [https://perma.cc/4P4T-TDNL].

40. *Detecting Sensitive Aquatic Species Using Environmental DNA*, U.S. EPA, https://19january2021snapshot.epa.gov/innovation/detecting-sensitive-aquatic-species-using-environmental-dna_.html [https://perma.cc/HY29-4YTS] (last visited Nov. 20, 2022).

Department of Defense (DoD)	N/A	Invasive species	DoD Environmental Security Technology Certification Program (ESTCP) and DoD Legacy Resource Management Program; Army Corps of Engineers, Army Environmental Command[41]
Department of Defense Office of Naval Research	Defense	Protected species	Multidisciplinary University Research Initiative[42]
Federal Highway Administration	Transportation	Endangered species	In conjunction with Virginia Department of Transportation[43]

While a detailed review of these programs is beyond our scope, several points are relevant. First, federal agencies are using eDNA data for a variety of purposes, with single-species (qPCR) methods being the most common technique and invasive species detection being the most common application.[44] In this regard, the National Invasive Species Council (NISC)[45] has played a role in coordinating

41. Adrian Salinas, *Environmental DNA Provides Key to Identifying, Protecting Endangered Species*, U.S. ARMY (June 8, 2021), https://www.army.mil/article/247319/environmental_dna_provides_key_to_identifying_protecting_endangered_species [https://perma.cc/8RCL-SYBV].

42. *See, e.g.*, *Department of Defense Announces University Research Funding Awards*, U.S. DEP'T OF DEF. (Mar. 3, 2022), https://www.defense.gov/News/Releases/Release/Article/2953234/department-of-defense-announces-university-research-funding-awards/ [ttps://perma.cc/XK9G-NWC9]. Here, the Navy program focused on "Environmental DNA-based Monitoring of the Marine Environment" for purposes of detecting whales and other marine mammals potentially imperiled by Naval activities.

43. Rodney J. Dyer & Bonnie A. Roderique, Development and Testing of Environmental DNA (eDNA) Protocols for the Endangered James Spiny mussel (Pleurobema collina) (2017).

44. Table 1, *supra*.

45. In 1999, President Clinton established the council by Executive Order. Exec. Order No. 13,112, 3 C.F.R. 13112 (1999). President Obama amended and broadened the original Order with Executive Order 13,751, maintaining the NISC. Exec. Order No. 13,751, 3 C.F.R. 13751 (2016). The council sits within the Department of the Interior and has representation from a broad range of federal agencies. *See About the Council*, U.S. DEP'T OF THE INTERIOR, https://www.doi.gov/invasivespecies/about-nisc [https://perma.cc/H5H7-JWPE] (last visited Nov. 13, 2022).

federal agency eDNA use via its framework and cross-agency White Paper and Technical Report.[46] The NISC is led by the Department of the Interior and includes that Department's Secretary as well as the Secretaries of nine other departments and heads of additional agencies, facilitating interdepartmental coordination on federal invasive species actions.[47]

Of particular interest, the NISC works with the Council on Environmental Quality (CEQ), within the Executive Office of the President, to develop guidance to federal agencies regarding invasive species pursuant to NEPA.[48] As eDNA gains currency as an attractive form of data among agencies, NISC and CEQ may find it useful to develop CEQ guidelines for using eDNA data in environmental-impact reporting under NEPA, in an effort to harmonize eDNA data requirements across federal agencies.[49]

Second, we observe that a wide range of federal agencies are using eDNA—including, as might be expected, the key resource agencies whose duties include producing and analyzing biological data. The involvement of the NISC signals at least an awareness of the rise of eDNA data across the federal government, given that the committee is composed of thirteen agencies.[50] The Department of Defense's involvement is noteworthy because of its regulatory role through the Army Corps of Engineers and its research programs,[51] not to mention the sheer size of military budgets and scope of military environmental activities around the world.[52]

46. For descriptions of further federal eDNA programs, *see* U.S. Dep't of the Interior, *supra* note 28.

47. *See* U.S. Dep't of the Interior, *supra* note 45 (NISC is co-chaired by the Secretaries of the Interior, Agriculture, and Commerce. NISC members include the Secretaries of State, Defense, Homeland Security, Treasury, Transportation, Health and Human Services, the U.S. Trade Representative (USTR), as well as the Administrators of the Environmental Protection Agency, National Aeronautics and Space Administration, and Agency for International Development. NISC provides high-level interdepartmental coordination of federal invasive species actions and works with other federal and non-federal groups to address invasive species issues at the national level.).

48. Exec. Order No. 13,112, 3 C.F.R. 13112 (1999).

49. We develop this suggestion further in Part IV.

50. Exec. Order No. 13,112, "Invasive Species," 64 Fed. Reg. 5183 (Feb. 3, 1999).

51. One recent example of the Department of Defense's commitment to eDNA research is a substantial award to survey marine mammals using eDNA, with the goal of avoiding harm to the species and thereby minimizing the risk of Navy liability under the Marine Mammal Protection Act and the Endangered Species Act. *See* U.S. DEP'T OF DEF., *supra* note 42. Full disclosure: author R.P. Kelly was the recipient of this award.

52. In 2021, the United States spent around 800.67 billion U.S. dollars on its military. This figure is an increase from 2010, when U.S. military spending amounted to 738 billion U.S. dollars. *See U.S. Military Spending 2000–2021*, STATISTA (Oct. 12, 2022),

The involvement of the Army Corps of Engineers is particularly relevant to the legal standing of eDNA data because Corps activities often trigger NEPA and ESA provisions. The Corps issues permits under the Clean Water Act (Section 404 Dredge and Fill)[53] and the Rivers and Harbors Act (Section 10)[54], which each require review and consultation under NEPA and the ESA.[55] In addition, the Corps is likely to commit federal funding to many construction projects in which they are involved; such funding triggers NEPA and the ESA.

Third, Table 1 shows how federal agencies collaborate with each other, with state agencies, and with academic institutions in using eDNA and developing best practices and new techniques. Examples of this collaboration include the eDNA Atlas, National Genomic Center, and Aquatics Nuisance Species Task Force.[56] Many smaller-scale interagency grants and collaborations do not require the same level of spending or public-facing profile, but function effectively as research and development instruments for federal agencies.[57]

https://www.statista.com/statistics/272473/us-military-spending-from-2000-to-2012/#:~:text=In%202021%2C%20the%20United%20States,to%20738%20billion%20U.S.%20dollars [https://perma.cc/HV8T-2SU2]. For information about the Army Environment Command, one example of the military's environmental programs, *see* U.S. Army Environmental Command website at https://www.army.mil/aec [https://perma.cc/STG4-VLSL].

53. 33 U.S.C. § 1344.

54. 33 U.S.C. § 403.

55. The 2021 bipartisan Investment and Infrastructure and Jobs Act will likely increase the number of federal permits issued.

56. *See supra* tbl.1. The National Genomics Center for Wildlife and Fish Conservation (NGC) partners with North American natural resource organizations to provide technical assistance for eDNA assay development and field sampling designs for fish, amphibians, crustaceans, mussels, mammals, and birds. These partnerships collect thousands of samples annually, which are analyzed at the NGC, creating a database that is growing in geographic extent and species diversity. *The Aquatic eDNAtlas Project*, U.S. DEP'T OF AGRIC. (Feb. 2018), https://www.fs.usda.gov/rmrs/projects/aquatic-ednatlas-project [https://perma.cc/P3XS-3EEL]. Congress established the Aquatic Nuisance Species Task Force, comprised of thirteen federal and thirteen ex-officio members, in the 1990 Nonindigenous Aquatic Nuisance Prevention and Control Act to protect U.S. waters by raising awareness and taking action to prevent and manage aquatic nuisance species. Aquatic Nuisance Species Task Force, *About Us*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/program/aquatic-nuisance-species-task-force/about-us [https://perma.cc/SNJ9-TKVR] (last visited Feb. 5, 2023).

57. For example, USGS works with local governments and academic institutions nationally to develop eDNA work. Coauthor RPK works closely with NOAA's Northwest Fisheries Science Center. NOAA's 'Omics Working Group has many connections to related research groups nationwide. *What Is 'Omics?*, NAT'L OCEANIC & ATMOSPHERIC ADMIN., https://sciencecouncil.noaa.gov/NOAA-Science-Technology-Focus-Areas/NOAA-Omics [https://perma.cc/T4BA-BTTF] (last visited Feb. 5, 2023). Many other examples exist.

Finally, NOAA and FWS, the two federal agencies responsible for protecting threatened and endangered species under the ESA,[58] are both using eDNA to do so. NOAA's uses have focused primarily on research rather than regulation,[59] but FWS has programs for listed species, such as bull trout,[60] and for designating critical habitat for listed species.[61] BOEM also collaborates with NOAA to use eDNA for ESA and NEPA review of offshore energy projects.[62] Part III reviews these efforts in detail.

In sum, federal agencies are familiar with and are developing and employing techniques to use eDNA as a source of information on which to base their decisions. Given this broad interest, we investigate in the next section this new technology's legality. We use two statutes—the ESA and NEPA—as motivating examples under which agencies are beginning to make use of eDNA data in carrying out their duties, and assess whether the resulting data meets statutory and regulatory requirements.

III. FEDERAL INFORMATION STANDARDS UNDER THE ESA AND NEPA

Part II identified federal agencies already using eDNA for a variety of purposes—including the Clean Water Act,[63] Magnuson-Stevens Act,[64] National Invasive Species Act,[65] and Endangered Species Act.[66] This agency use is not surprising given the importance of biological data to a constellation of statutes within U.S. environmental law. For example, Magnuson-Stevens demands information on the abundance

58. A sub-agency within NOAA, the National Marine Fisheries Service (NMFS), also called NOAA Fisheries, is responsible under statute for enforcing the ESA. *See infra* note 70 for further explanation.

59. *See, e.g.*, Andrew Olaf Shelton et al., *Environmental DNA Provides Quantitative Estimates of a Threatened Salmon Species*, 237 BIOLOGICAL CONSERVATION 383 (July 24, 2019).

60. *See, e.g.*, *The Rangewide Bull Trout eDNA Project*, U.S. DEP'T OF AGRIC., https://www.fs.usda.gov/rm/boise/AWAE/projects/BullTrout_eDNA.html#:~:text=The%20bull%20trout%20is%20an,nonnative%20species%2C%20and%20habitat%20degradation [https://perma.cc/CRS4-U9K8] (last visited Feb. 12, 2023). eDNA has also been used to evaluate habitats for threatened Coastal Cutthroat Trout. *See* Brooke E. Penaluna et al., *Better Boundaries: Identifying the Upper Extent of Fish Distributions in Forested Streams Using eDNA and Electrofishing*, 12 ECOSPHERE e03332 (Jan. 2021).

61. *See supra* notes 6–9.

62. *See* Part III(2)(C).

63. 33 U.S.C. §§ 1251–1389.

64. 16 U.S.C. §§ 1801–1891(d).

65. 16 U.S.C. § 4701–4751.

66. 16 U.S.C. §§ 1531–1544.

of fish stocks,[67] the National Forest Management Act requires managers to survey indicator species as a proxy for larger forest trends,[68] and the Clean Water Act's effects-based standards[69] depend heavily on biological data—all of which are the kinds of information about the living parts of ecosystems to which eDNA speaks.

This Part examines agency use in more detail under the Endangered Species Act and the National Environmental Policy Act. We focus on these two statutes because both include explicit information requirements, and because both are heavily litigated based on the information used. We examine each statute and its implementing regulations, as well as the judicial standards courts use to review agency information-use under each. Finally, we look at ways in which agencies are presently using eDNA to meet standards under each of these statutes.

A. The Endangered Species Act

The Endangered Species Act (ESA) establishes a protective regulatory regime for species that the federal government lists as "threatened" or "endangered." The ESA's protective framework begins with FWS or NMFS (the "resource agencies" or "the Services")[70]

67. 16 U.S.C. § 1881(c). We also note the qualitative difference between surveys for the presence or absence of a species—for which researchers have routinely used eDNA—and the more quantitative demands of natural-resources statutes such as Magnuson-Stevens, which demand abundance estimates. This is a frontier of eDNA research, at present. *See, e.g.,* Andrew Olaf Shelton, et al., *Environmental DNA Provides Quantitative Estimates of Pacific Hake Abundance and Distribution in the Open Ocean*, 289 PROCEEDINGS ROYAL SOC'Y B 20212613 (2022).

68. 16 U.S.C. § 1604 et seq.; 36 C.F.R. § 219.19.

69. These are the water-quality standards—themselves consisting of water-quality criteria, designated uses, and non-degradation plans—rather than the better-known input-based standards of the National Pollutant Discharge Elimination System. 33 U.S.C. § 1313. Numeric water-quality criteria arise out of biological monitoring and ecological literature; narrative criteria, by contrast, often depend on ongoing biological surveys. 40 C.F.R § 131.11(b)(2). For a review and discussion of some narrative water-quality criteria and related monitoring programs, *see generally* Stephen B. Weisberg, et al., *Water Quality Criteria for an Acidifying Ocean: Challenges and Opportunities for Improvement*, 126 OCEAN & COASTAL MGMT. 31 (2016).

70. The statute charges the two agencies with implementation. 16 U.S.C § 1532(15). The two divide responsibility on the basis of species' primary habitats, with some exceptions. FISH AND WILDLIFE SERVICE & NATIONAL MARINE FISHERIES SERVICE, MEMORANDUM OF UNDERSTANDING BETWEEN U.S. FWS AND NMFS REGARDING JURISDICTIONAL RESPONSIBILITIES AND LISTING PROCEDURES (1974). The National Marine Fisheries Service (NMFS) is an agency within the National Oceanic and Atmospheric Administration (NOAA) that is also known as NOAA Fisheries. NMFS has generally publicly "re-branded" as NOAA Fisheries, such as for purposes of its website, https://www.fisheries.noaa.gov/, but the sub-agency continues to refer to itself as NMFS in the regulatory context, *see, e.g.,* Draft 2022 Marine Mammal Stock Assessment Reports, 88 Fed. Reg. 4162 (Jan. 24, 2023).

"listing" a species as threatened or endangered and identifying the "critical habitat"[71] of the species. Listed species subsequently enjoy federal protection from "take" of all kinds,[72] and all federal agencies must consult with the listing agency to ensure that any of their actions will not "jeopardize the continued existence of the species" or adversely affect "critical habitat."[73]

The above ESA framework creates two distinct pathways for using scientific information. The first is when FWS and NMFS make decisions regarding (a) whether to list species as threatened or endangered, (b) the designation of critical habitat, and (c) whether a federal action is likely to jeopardize a listed species or adversely affect the species' designated critical habitat. These decisions are subject to review on the administrative record developed by the Services.

The second pathway for the use of scientific information is under the ESA's prohibition against taking a listed species. "Take" means to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect," or an attempt to do the same.[74] Furthermore, FWS interprets "harm" to include "significant habitat modification or degradation," an interpretation upheld by the Supreme Court.[75] Thus, the habitat and the endangered animal are both protected from private action. The Services bring these cases directly to court in a *de novo* trial and submit evidence that the defendant has taken the listed species. The ESA also authorizes private parties to stand in the government's shoes to bring these cases.[76] Such actions are known as citizen suits.

1. The First Pathway: ESA's Statutory Best Available Science Standard

The text of the ESA itself establishes a standard for the scientific information in decision-making, requiring that the resource agencies solely rely on the Best Available Science (BAS)[77] for the key decisions

71. 16 U.S.C. § 1533.
72. 16 U.S.C. § 1538(a)(1)(B) –(C).
73. 16 U.S.C. § 1536.
74. 16 U.S.C. § 1532(19).
75. Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687 (1995).
76. 16 U.S.C. § 1540(g)(1).
77. *See generally* Natalie Lowell & Ryan P. Kelly, *Evaluating Agency Use of "Best Available Science" under the United States Endangered Species Act*, 196 BIOLOGICAL CONSERVATION 53 (2016); Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENV'T L. 397 (2004).

they make under the Act, including listing[78] and designating critical habitat,[79] and throughout the consultation between the Services and the action agencies (those agencies proposing actions subject to review for impacts to listed species and their habitats).[80] Under the ESA's statutory BAS requirement, the question isn't whether the agency is using information in a reasonable way, but whether the agency is basing its decisions on the best available information.[81] Perhaps because of this explicit information requirement, and because of the often-controversial nature of ESA decisions, the resource agencies' use of scientific data has been an ongoing focus of analysts and policymakers, including Congress.[82]

2. Judicial Review of the ESA's Best Available Science Standard

The ESA offers an example of an explicit statutory information standard to which courts will hold the relevant agencies. Stakeholders, including project proponents and environmental organizations, frequently challenge agency ESA decisions in court, typically basing these challenges on the administrative record under the Administrative Procedure Act (APA) rather than in a *de novo* trial.[83] This procedural posture has two important consequences.

First, because there is no trial, the court rarely considers new evidence, and the judge does not need to make evidentiary rulings on the admissibility of scientific information as occurred in *Michigan v. Army Corps* (the Asian carp case).[84] Thus, while the *Michigan* court's

78. 16 U.S.C. § 1533(b)(1) ("The Secretary shall make determinations required by subsection(a)(1) solely on the basis of the best scientific and commercial data available to him . . .").

79. 16 U.S.C. § 1533(b)(2).

80. 16 U.S.C. § 1536(a) (2011) ("In fulfilling the [consultation] requirements of this paragraph, each agency shall use the best scientific and commercial data available.").

81. Here, we consider the acceptability of agency decisions that rest on eDNA data; we leave for another time the question of whether collection of eDNA itself—as a biological material derived from a listed species—has the potential to violate the ESA's prohibition on "take."

82. *See, e.g.,* PERVAZE A. SHEIKH. CONG. RSCH. SERV., RL32992, THE ENDANGERED SPECIES ACT AND "SOUND SCIENCE" (2013). *See also* Dennis Murphy & Paul Weiland, *Independent Scientific Review under the Endangered Species Act*, 69 BIOSCI. 198 (Mar. 2019); Doremus, *supra* note 77, at, 408–409. Beyond the existing statutory and regulatory limitations on relevant information, the wildlife agencies have issued internal policies over the years regarding best available science, including policies directing the Services to give preference to primary sources and to use peer review from independent specialists for listing and other decisions.

83. For examples (and analyses) of such claims, see *supra* notes 81-82.

84. For example, parties challenging a Service decision under the ESA may not present their own (novel) findings at the time of challenge; the legal challenge is a narrow one, focused on whether the Service's decision met the applicable statutory requirements, given the information

acceptance of eDNA indicates the credibility of molecular information, the *Daubert* evidence standard[85] relevant in that *de novo* procedural posture does not apply to review of agency decisions under the ESA or NEPA. In considering an ESA or NEPA challenge, the court instead rules based on the administrative record, considering all evidence that was before the agency at the time of its challenged decision.

Second, when plaintiffs bring on-the-record claims challenging agency ESA or NEPA decisions, courts apply the "arbitrary and capricious" standard of review.[86] We discuss the application of this standard in environmental law thoroughly in Part III(2)(B) below. There is a robust academic discussion on the arbitrary and capricious standard generally[87] and specifically as it applies to the ESA;[88] here we briefly summarize central points from this literature.

As a general matter, the "arbitrary and capricious" standard is a deferential one, under which the reviewing court does not substitute its judgment for the agency's scientific determination.[89] Recent reviews of courts' application of this standard to agency decisions regarding the ESA's best available science have argued that the courts have been so deferential as to make the concept of best available science meaningless, calling the Services' use of science "inconsistent

available to the Service at the time of its decision. Consequently, legal challenges are unlikely to be a fruitful avenue by which eDNA proponents may force agencies to use eDNA as a data source if such data were unavailable to the Service when originally making its decision—for example, during a decision's required public comment period.

85. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993) (setting out standards for admission of expert testimony); *see infra* Part III(2)(C) for a discussion of Federal Rule 702 and *Daubert*.

86. *See, e.g.*, *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 481 (9th Cir. 2010) ("Irrespective of whether an ESA claim is brought under the APA or the citizen-suit provision, the APA's 'arbitrary and capricious' standard applies."). For a detailed discussion of the interplay between suits against agencies under the ESA and its interplay with the APA arbitrary and capricious standard, *see* Kirsten Nathanson et al., *Developments in ESA Citizen Suits and Citizen Enforcement of Wildlife Laws, Natural Resources & Environment*, NATURAL RESOURCES & ENVIRONMENT, Winter 2015 at 15.

87. Elizabeth Kuhn, *Science and Deference: The "Best Available Science" Mandate Is a Fiction in the Ninth Circuit*, ENV'T L. (Oct. 21, 2016), syndicated on Env't. L. Rev. Syndicate, https://www.ecologylawquarterly.org/currents/science-and-deference-the-best-available-science-mandate-is-a-fiction-in-the-ninth-circuit/ [https://perma.cc/SAB6-Q7RR].

88. *Id.*; *see also* Jonathan H. Adler, *The Science Charade in Species Conservation*, 24 SUP. CT. ECON. REV. 109 (2016).

89. Doremus, *supra* note **Error! Bookmark not defined.**, at 56 n.191 ("when examining 'a scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.'") (citing Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983)).

and improper,"[90] a "charade,"[91] and a "fiction."[92] One critical review characterized a federal appeals court's reversal of a district court's more rigorous holding against an agency as concluding that "the judiciary is not capable of taking a hard look at even elementary scientific arguments on their merits, and seems to have found that any justification for an agency determination should suffice, no matter how unsubstantial."[93]

To the extent that judicial review of ESA decisions tends to favor the agency, this criticism suggests that the courts are unlikely to require a new technology— here, eDNA—in this context, and therefore may not play a significant role in technology-forcing,[94] which would effectively require agencies to use eDNA data in implementing the ESA. Nevertheless, the same analysis of court rulings on BAS concluded that: "In the ESA context, judicial review has been far from a rubber stamp. Indeed, courts have been far tougher than scientific peer review on wildlife agencies."[95]

To support this conclusion, the author notes that 78% of reported decisions reviewing Service listing decisions ruled against the Services.[96] This seemingly contradictory information suggests courts are likely to defer to the Services on scientific questions, but the courts are prepared to scrutinize agency decision-making quite closely in terms of the effects of those decisions on substantive policy outcomes. The Services, therefore, are ever mindful of litigation risks, and it is

90. Travis O. Brandon, *Fearful Asymmetry: How the Absence of Public Participation in Section 7 of the ESA Can Make the "Best Available Science" Unavailable for Judicial Review*, 39 HARV. ENV'T. L. REV. 311, 311 (2015).

91. Adler, *supra* note 88, at 116.

92. Kuhn, *supra* note 87.

93. Dennis D. Murphy & Paul S. Weiland, *Guidance on the Use of Best Available Science under the U.S. Endangered Species Act*, 58 ENV'T MGMT. 1 (2016). In one case reviewed by Murphy and Weiland, the district court ruled against the Service based on input from court-appointed technical experts. An appeals court reversed the lower court while acknowledging that FWS could have better assessed the effects as recommended by a commissioned peer review. *See infra* Part III(2)(B) for a detailed discussion of the "hard look" standard.

94. In some environmental contexts, courts may encourage or require new technologies in response to technology-based statutory standards, a phenomenon known as "technology-forcing." *See, e.g.*, David Gerard & Lester B. Lave, *Implementing Technology-Forcing Policies: The 1970 Clean Air Act Amendments and the Introduction of Advanced Automotive Emissions Controls in the United States*, 72 TECH. FORECASTING & SOC. CHANGE 761 (2005). Because the ESA requires no particular form of technology for monitoring or implementation, and because of the evidence we cite of courts' deference to the agencies on scientific questions, the dynamics surrounding eDNA adoption appear to be different than those in the case of the catalytic converter described by Gerard and Lave.

95. Doremus, *supra* note 77, at 431.

96. *Id.*

reasonable to expect that as eDNA gains currency, litigation is likely where an action agency or the Services could have used, but declined to use, eDNA in the listing decision, critical habitat designation, or consultation processes.

Setting aside the harshness of this particular criticism, the following guiding principles emerge from scholarly reviews of the courts' application of the "arbitrary and capricious" standard to the best available science mandate: First, in addressing the quality of information agencies use, courts hold that "an agency cannot ignore relevant available data."[97] Thus, without getting into whether eDNA is the "best" information, an agency would be vulnerable to legal challenge if it did not consider "relevant" eDNA data. Second, as to "availability," "an agency does not have an obligation to generate new data, even if only relatively weak data is available."[98] In other words, "available" means actually "available," not technically possible to generate.

These principles make it even more unlikely that litigation itself will drive eDNA adoption under the ESA: during administrative review, courts will not demand the agency generate new data, and so long as an agency is not ignoring existing data relevant to the issue at hand, the ESA's information requirement does not seem to impose much of a burden on agency decision-making. Where eDNA data exists, the agency must use such data appropriately, but on the whole, factors other than litigation risk-management will be important in accelerating eDNA use within agencies. In the next section, we explore how FWS, in particular, has elected to generate and use eDNA information for its ESA decision-making, to identify factors that support eDNA use in conserving endangered species.

3. The Second Pathway: Litigation Over Takings of ESA-Listed Species

In their *de novo* proceedings, federal courts apply Federal Rule of Evidence 702, Testimony by Expert Witnesses, to declarations and live testimony by scientific experts. The rule provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

97. Kuhn, *supra* note 87.

98. *Id.*; Doremus, *supra* note 77, at 425 (citing Sw. Ctr. for Biological Diversity v. Babbitt, 215 F.3d 58 (D.C. Cir. 2000)).

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.[99]

In admitting eDNA information, the district court in *Michigan v. Army Corps* discussed Rule 702 and the application of the U.S. Supreme Court opinion in *Daubert v. Merrell Dow Pharmaceuticals*.[100] The district court, after a detailed review, admitted the eDNA evidence, but concluded that this evidence was insufficient to demonstrate the irreparable harm necessary to grant the plaintiffs' requested injunction.[101] The court of appeals upheld the district court's decision to admit expert testimony regarding eDNA, concluding it was a "proper application of Federal Rule of Evidence 702."[102] The Asian carp case was not an ESA case. However, it illustrates how a court would likely review eDNA evidence in trials under the ESA. Specifically, a plaintiff bringing a citizen suit might base it on eDNA evidence gathered by the plaintiff, as discussed in the next Part. A defendant might seek to exclude the evidence. The judge would apply Rule 702, as illustrated above.

4. Real-World Examples: Using eDNA Under the ESA

As a practical matter and as noted above, FWS and NMFS already use eDNA in implementing the ESA: Evidence from eDNA studies has featured in management and ESA-related research involving an array of species since 2018. A few examples illustrate this use: bull trout, black warrior waterdog, and snail darter.

Bull trout (*Salvelinus confluentus*), for example, is an ESA-threatened[103] species with a broad historical range across the northwestern United States, mainly in freshwater. Given the large number of possible habitats in which the fish can exist, researchers

99. Fed. R. Evid. 702.

100. Michigan I, at *25 (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)).

101. *Id.* at *25–27.

102. Michigan v. U.S. Army Corps of Eng'rs, 667 F.3d 765, 772 (7th Cir. 2011), *aff'g* 2010 WL 5018559 (N.D. Ill. 2010).

103. Endangered and Threatened Wildlife and Plants; Determination of Threatened Status for Bull Trout in the Coterminous United States, 64 Fed. Reg. 58910 (Nov. 1, 1999).

from the U.S. Forest Service (USFS) developed[104] and deployed a qPCR eDNA assay for the species, along with a quantitative framework to analyze detection probabilities and the resulting statistical power to detect a fish in the wild.[105]

This eDNA work has led, in turn, to a substantive change in Section 7 consultation for the species, illustrating an important dynamic that could lead to wider eDNA support from agencies making regulatory decisions as well as private parties seeking federal permits. In one example,[106] centered in western Montana, USFS proposed a restoration project involving vegetation treatments for fuels and road improvements: Bull trout had historically been identified and documented in the project area in the 1990s but not detected since then despite considerable electrofishing sampling.[107] Based on the historical evidence, FWS considered the project area to be occupied and wanted USFS to consult on the impact on the bull trout species.[108] In response, USFS presented eDNA sampling evidence that the project presented a low risk of adverse effects to bull trout.[109] USFS offered to systematically sample the area using eDNA during the project's duration and to add design or mitigation criteria if the agency detected the species.[110] FWS accepted the proposal and determined that a time-consuming, formal consultation was not necessary for the restoration project to proceed.[111]

Looking forward, the eDNA analysis generated for this broad area is now "available" in the parlance of the ESA, and FWS will undoubtedly use it during project-level consultations for federal actions where bull trout is present in the action area. Failure to use this information for these purposes would expose the agencies to legal challenges for failing to consider available and "relevant" information. FWS itself has begun to use eDNA in ESA listing and critical habitat designation decisions, as discussed briefly above in Parts I and II. The

104. Taylor M. Wilcox et al., *Robust Detection of Rare Species Using Environmental DNA: the Importance of Primer Specificity*, 8 PLOS ONE e59520 (2013); MICHAEL K. YOUNG ET AL., SPECIES OCCURRENCE DATA FROM THE RANGE-WIDE BULL TROUT EDNA PROJECT (2017).

105. K. S. McKelvey et al., *Sampling Large Geographic Areas for Rare Species Using Environmental DNA: A Study of Bull Trout Salvelinus Confluentus Occupancy in Western Montana*, 88 J. FISH BIOLOGY 1215 (2016).

106. Sue Miller, Black and White and Shed All Over: How eDNA Analysis Can Help to Answer Your Species Question, Science You Can Use Bulletin, May/June 2020 at 5.

107. *Id*.

108. *Id.*

109. *Id.* at 6.

110. *Id*.

111. *Id*.

black warrior waterdog critical habitat designation illustrates such a use.[112] There, significantly, a federal agency and several public commenters questioned the Service's use of eDNA. The Service defended its decision:

> Since the Black Warrior waterdog is difficult to capture, sampling for eDNA in the historical range of the species is an appropriate tool, bolstering confidence in assessing whether occupancy is likely. We used eDNA to narrow our focus on sites where additional sampling was more likely to capture live waterdogs, but we are not designating any streams as critical habitat, nor are we determining listing status, solely based on eDNA. That said, based on the comment, we have added more discussion about eDNA to the final rule.[113]

The Service's explanation highlights eDNA's potential value when species are hard to capture—one of the key advantages of eDNA over traditional detection methods, and the one that first inspired the use of molecular monitoring that led to *Michigan v. Army Corps*.[114] The black warrior waterdog example also illustrates the pushback from the regulated community where eDNA's use would lead to increased areas of critical habitat subject to the Act's regulatory bite.

A final example is especially noteworthy because it features the snail darter (*Percina tanasi*), the small fish that played a starring role in *TVA v. Hill*, the first ESA case to come before the U.S. Supreme Court.[115] FWS recently used eDNA data in combination with traditional surveys to support its de-listing of the snail darter, after positive eDNA detections demonstrated the species' presence in several Alabama rivers.[116] The agency's use of eDNA in the above examples indicates under what circumstances the agency considers it to be the "best" science. They also illustrate where the data is "available."

NMFS, too, has made some substantial use of eDNA data in research to support its role in implementing the ESA. Agency research showed eDNA to be as effective as traditional net sampling in tracking ESA-threatened chinook salmon populations,[117] with the molecular

112. Endangered and Threatened Wildlife and Plants; Endangered Species Status for Black Warrior Waterdog and Designation of Critical Habitat, 83 Fed. Reg. 257 (Jan. 3, 2018) (to be codified at 50 C.F.R. § 17).

113. *Id.* at 259.

114. Michigan II, *supra* note 14, 758 F.3d at 896.

115. Tenn. Valley Auth. v. Hill, 437 U.S. 153 (1978).

116. Endangered and Threatened Wildlife and Plants; Removing the Snail Darter from the List of Endangered and Threatened Wildlife, 86 Fed. Reg. 48953, 48956 (proposed Sept. 1, 2021) (to be codified at 50 C.F.R. § 17).

117. *Genetic 'Nets' Detect DNA as Accurately as Real Ones, New Research Shows*, NOAA FISHERIES (July 29, 2019), https://www.fisheries.noaa.gov/feature-story/genetic-nets-detect-

tool providing "virtually identical information" to the nets. In further reviewing the advantages and disadvantages of eDNA, NMFS explained:

> Scientists can reliably use eDNA to assess the movement and habitat use of threatened and endangered fish populations. Scientists can use eDNA to examine and assess fish populations at a much lower cost than netting fish individually. There are tradeoffs, however. For example, eDNA does not provide some information that netting does, such as the age and size of the salmon detected.[118]

Analogous work by some of the same authors scaled up the eDNA survey technique, mapping hake (*Merluccius productus*)—the subject of the largest commercial fishery in the United States—along the entire West Coast.[119] Here again, the agency did this work in a research context, rather than a regulatory one, and to support its role under statutes other than the ESA, including the Magnuson-Stevens Act and Marine Mammal Protection Act.[120]

NOAA has also collaborated with BOEM to begin using eDNA during the Section 7 Consultation Process. In 2022, BOEM's Biological Assessment for the Empire Wind Lease Sale specified that eDNA sampling would occur during each year of the two-year pre-construction monitoring period, with 160 samples collected each

dna-accurately-real-ones-new-research-shows [https://perma.cc/56CC-9XG6]. The press release describes research done for a peer-reviewed publication: Andrew Olaf Shelton et al., *Environmental DNA Provides Quantitative Estimates of a Threatened Salmon Species*, 237 BIOLOGICAL CONSERVATION 383 (2019). Scientists collected environmental DNA by dipping one-liter bottles into the Skagit River and estuary. Then they analyzed the samples for the DNA of Puget Sound Chinook salmon. They simultaneously cast seine nets to collect fish in certain areas. According to NOAA, they found "that eDNA analysis identified the state of the population as well as seine net sampling—and sometimes even more accurately." *Id.* Note that one of the present authors, Ryan P. Kelly, was an author of the original scientific publication.

118. *Id.* Age and size can be important in understanding the life stage of the species present, which in turn bears on issues such as juvenile habitat needs, prey avoidance, or other factors relevant to appropriate management measures. *See, e.g.*, Thomas Miller et al., *Scientific Considerations Informing Magnuson–Stevens Fishery Conservation and Management Act Reauthorization: AFS Special Committee*, 43 FISHERIES 533, 539 (2018) ("Studies have demonstrated the value of fisheries management measures that preserve stock size and age structure, protect reproductive females and spawning congregations, and maintain abundance for enhancing the resilience of fish and invertebrate populations to climate impacts.").

119. Andrew Olaf Shelton et al., *Environmental DNA Provides Quantitative Estimates of Pacific Hake Abundance and Distribution in the Open Ocean*, PROCEEDINGS ROYAL SOC'Y B, Mar. 23, 2022, at 1. Note that one of the present authors, Ryan P. Kelly, was an author of the original scientific publication.

120. Kim M. Parsons et al., *Water, Water Everywhere: Environmental DNA can Unlock Population Structure in Elusive Marine Species*, ROYAL SOC'Y OPEN SCI., Aug. 8, 2018, at 1.

year.[121] The agencies are using this information for NEPA review as discussed further below.

At least two citizen suits have used eDNA to establish the presence of a listed species in areas subject to logging.[122] In *Friends of the Gualala River vs. Gualala Timber LLC*, the plaintiffs' Motion for Preliminary Injunction using the ESA to try to halt the defendant's logging proposal alleged that "[t]he occupancy of each [ESA listed species] is well documented, including, in the case of CCC coho, NC steelhead, and CA red-legged frogs, through environmental DNA ("eDNA") sampling conducted by Plaintiffs last year."[123] The District Court denied the motion on grounds unrelated to the eDNA evidence.[124] The second case,[125] brought by the same plaintiffs against the same defendant, also relied on eDNA evidence. The widening availability of eDNA data in accessible data repositories such as those identified in Table 1 increases the likelihood that stakeholder groups may use eDNA in ESA citizen suits, as was done in *Friends of the Gualala*.

5. Likely Future ESA Scenarios

Before leaving the ESA, it is useful to step back and contemplate three general cases where the Best Available Science requirement might apply to eDNA.

Perhaps the easiest case is the one in which eDNA is the *only* available data, although this precise point has yet to be litigated. In practice, there is typically scientific information generated using other methods; however, this hypothetical helps illustrate the analysis and could occur in the future when eDNA use becomes more widespread. Where no other information is available, eDNA is, by

121. BUREAU OF OCEAN ENERGY MGMT., EMPIRE OFFSHORE WIND: EMPIRE WIND PROJECT BIOLOGICAL ASSESSMENT FOR NATIONAL MARINE FISHERIES SERVICE 31–33 (Dec. 2022).

122. Pl.'s Mot. Prelim. Inj. 6, Friends of Gualala River v. Gualala Redwood Timber, LLC, 552 F. Supp. 3d 924 (N.D. Cal. 2021) (Case No. 20-cv-06453-JD). For a discussion of and link to the motion for injunctive relief, *see Protecting Endangered Species: The Case for a Preliminary Injunction*, FRIENDS OF GUALALA RIVER, https://gualalariver.org/forestry/floodplain-logging/protecting-endangered-speciesthe-case-for-a-preliminary-injunction [https://perma.cc/QN59-UDQK] (last visited Nov. 13, 2022).

123. *Id*.

124. Friends of Gualala River v. Gualala Redwood Timber, LLC, 552 F. Supp. 3d 924 (N.D. Cal. 2021) (Case No. 20-cv-06453-JD).

125. Friends of Gualala River vs. Gualala Redwood Timber, LLC, (Jan. 18, 2022) (Case No. 3.2022-cv-00317) https://dockets.justia.com/docket/california/candce/3:2022cv00317/390617 [https://perma.cc/2MXP-G54N].

definition, the best available because, as discussed above in Part III(2)(B), courts have held that the BAS standard does not require generating new data.[126] As eDNA surveys become increasingly common, and particularly where their cost is low relative to other sampling methods, scenarios will arise in which an agency or other party detects the molecules of an endangered species with no corroborating evidence.[127] Such detections may well undergird agency decisions in the near-term future, and for good reason. Camera traps, visual surveys, and many other survey methods are often unaccompanied by further corroborating evidence, and yet form the basis for policy and regulatory decisions.[128] There is nothing fundamentally speculative about eDNA, and little to justify treating this data source differently from dozens of other ways of sensing the world. Moreover, the Services, action agencies and project proponents could rightly argue that based on the case law, there is no obligation to generate information using other methods when such information is not already available.

Where eDNA data exists alongside more traditional data on the species of interest, agencies can use, and have used, the various data streams in concert. For example, in the black warrior waterdog critical area designation discussed above, FWS used eDNA as a coarse-focus tool, identifying sites for more labor-intensive manual sampling.[129] Similarly, in *Appalachian Voices v. U.S. Dep't of the Interior*,[130] the agency permissibly used a combination of traditional

126. We assume for the present purposes that "available" information implies that information is also admissible as evidence under the *Daubert* standard, as was eDNA in the most extensively litigated case featuring this kind of data. *See* Michigan I, *supra* note 1, 2010 WL 5018559 at *25-28.

127. Note this hypothetical avoids the question of whether the *absence* of a species detection is, on its own, evidence of the absence of that species.

128. For perspective, essentially *all* data-based natural-resources decisions were historically grounded in visual survey information or something similar. One might think of visual bird counts or forestry surveys, or of net-based fisheries surveys, as a gold-standard survey technique not requiring corroboration by a secondary data source, these traditional methods are anything but foolproof. Many birds, for example, are notoriously difficult to see in their native habitats, both large and small fish systematically escape nets, and so on. All methods of surveying the living world offer incomplete and biased results; an honest assessment merely reports upon its own shortcomings and may attempt to remedy them statistically. Indeed, there is some justification for the idea that eDNA surveys are more robust than those using other methods, because of the propensity for molecular biologists to replicate assays, yielding quantitative evaluations of the assay's power to detect a given species. Visual surveys, for example, nearly always lack such quantitative rigor.

129. Waterdog Designation, *supra* note 6, at 259 ("We used eDNA to narrow our focus on sites where additional sampling was more likely to capture live waterdogs").

130. Appalachian Voices v. U.S. Dep't of the Interior, 25 F.4th 259 (4th Cir. 2022).

in-stream surveys and eDNA sampling to conclude an ESA-listed fish species, the Roanoke logperch, was absent from a watershed.[131] There, as in *Michigan v. Army Corps*, single-species eDNA assays seem to sit comfortably alongside complementary datasets to animate agency decisions.[132]

The third and harder case is where eDNA data contradicts existing information from other sources. For example, where a survey detects the DNA of a listed species in a given location, but visual surveys fail to turn up the same species (or vice-versa). The rational resolution of such a conflict would be to quantitatively establish the detection power of each of the survey methods, and weigh all of the evidence together: Given all of the observations, and given the underlying power of each method, what is the probability of the species being truly present?[133] In practice, the Services would likely act to minimize the risk of litigation by erring on the side of designating critical habitat whenever any of the available data streams indicated that the species was present. In the absence of case law directly on point, we speculate that a court would likely defer to agency judgment as to the weight of different forms of conflicting evidence.[134]

B. National Environmental Policy Act

1. Statutory and Regulatory Standard

Among environmental statutes, NEPA stands out for its foundational importance, for its ubiquity, and for its multifaceted

131. The court found the agency's reasoning persuasive, and implicitly not arbitrary and capricious: "Given the absence of contrary evidence, when we consider these factors together, we have little trouble concluding that the Fish and Wildlife Service 'provided a [sufficiently] cogent justification' for excluding the Blackwater River watershed from further study." *Id*. at 280 (emphasis removed).

132. We note the different statutory standards at play in *Appalachian Voices*, 25 F.4th 259 (ESA) and in *Michigan v. Army Corps* [Michigan I, *supra* note 1, and Michigan II, *supra* note 14] (APA and common law), but nevertheless the point stands.

133. This kind of analysis is one version of site-occupancy models. *See generally* Andrew Royle & William Link, *Generalized Site Occupancy Models Allowing for False Positive and False Negative Errors*, 87 ECOLOGY 835 (2006). Jointly modeling the probability of a site being occupied by a target species, given multiple data streams, is a feasible and desirable way of combining information into the same statistical framework. An effective and straightforward application of the same ideas is an analysis of the statistical power to detect a target species, given some detection rate. *See, e.g.*, Taylor Wilcox et al., *Understanding Environmental DNA Detection Probabilities: A Case Study Using a Stream-Dwelling Char Salvelinus Fontinalis*, 194 BIOLOGICAL CONSERVATION 209 (2015).

134. As did, for example, Judge Dow in *Michigan v. Army Corps*, in a different legal context. *See* Michigan I, 2010 WL 5018559 at *26.

information demands.[135] We focus on its information requirements as a window into broader administrative standards that eDNA must meet if it is to be a data source for federal environmental decision-making. Because the nature of NEPA analysis goes well beyond single-species management, eDNA analyses for purposes of NEPA may similarly move beyond single-species analysis and into sophisticated multi-species data that provide information about the composition of ecological communities. While agencies have not yet employed multi-species eDNA analyses in the NEPA context, the technology has the potential to reform environmental assessments into a tool for accurately capturing the state of whole ecological communities.

NEPA requires federal agencies to evaluate the impacts of their planned major actions[136] in a "detailed statement,"[137] in the form of either an Environmental Assessment (EA) or Environmental Impact Statement (EIS). The EIS is a disclosure document intended to ensure federal agencies consider the consequences of their actions where such actions will have a significant environmental impact; it is procedural, rather than a mandate for a particular outcome.[138] For actions with less-than-significant impacts, agencies prepare EAs,

135. NEPA requires "a systematic, interdisciplinary approach which will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision making which may have an impact on man's [*sic*] environment." 42 U.S.C. § 4332(A).

136. 40 C.F.R. § 1508.18 (2010) ("Major Federal action includes actions with effects that may be major and which are potentially subject to Federal control and responsibility. . . . Actions include the circumstance where the responsible officials fail to act and that failure to act is reviewable by courts or administrative tribunals under the Administrative Procedure Act or other applicable law as agency action"). Examples of actions include making decisions on permit applications, adopting federal land management actions, and constructing highways and other publicly owned facilities. Federal funding may also constitute a major action that triggers NEPA. *See* EPA, *What is the National Environmental Policy Act?*, https://www.epa.gov/nepa/what-national-environmental-policy-act [https://perma.cc/6D75-GKFK] (last visited Feb. 10, 2023).

137. 42 U.S.C. § 4332(I). The statute requires every recommendation or report on proposals for legislation and other major federal actions significantly affecting the quality of the human environment to include a detailed statement by the responsible official on—(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.

138. Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 558 (1978). For a thorough review of NEPA's procedural characterization, *see* Brian LaFlamme, *NEPA's Procedural Requirements: Fact or Fiction? Kuff v. United States Forest Service*, 7 J. ENV'T & SUSTAINABILITY 16 (1999). *See generally Environmental Impact Assessment Reports*, CAL POLY HUMBOLDT LIBR., https://specialcollections.humboldt.edu/environmental-impact-assessment-reports [https://perma.cc/6TD2-6TWV] (last visited Nov. 14, 2022).

which also require substantial amounts of information and evaluation of the project's effects on the environment, but not as much detail as an EIS.[139] Proponents of private projects that require federal permits may bear the responsibility for preparing EAs or EISs, which the relevant agency ultimately signs off on.

Whether an EIS or EA is required has practical impacts: An EIS is a more in-depth document, taking more time and money to prepare. Project proponents, therefore, often work hard to demonstrate that a proposal's environmental impacts are not significant. In contrast to the ESA, where species presence or absence is the threshold question that affects the time and effort required to review a project proposal, the threshold question under NEPA is whether impacts are "significant."[140] Therefore, a brief explanation of NEPA's process for determining significance is important to understanding eDNA's role under the statute.

Agencies must analyze the manner and degree to which the proposed action would potentially affect the environment, as well as the effects of any connected activities.[141] This analysis considers the affected area's scale (e.g., national, regional, or local) and its resource impacts, "such as listed species and designated critical habitat under the [ESA]."[142] Agencies "should consider" short- and long-term effects, beneficial and adverse effects, effects on public health and safety, and effects that would violate Federal, State, Tribal, or local law protecting the environment.[143] Where such effects add up to a significant potential environmental impact, the agency must prepare an EIS.

An EIS must set out the project area's baseline environmental conditions in a "No Action Alternative" and then forecast project impacts assuming several alternative ways of achieving the project's objectives.[144] The EIS, therefore, puts a premium on information about a project area's existing conditions.

139. An EA is a preliminary evaluation of whether or not a proposed action would significantly impact the environment. 40 C.F.R. §§ 1501.5, 1501.6(a). If a proposed action may indeed have significant impacts, then a full-scale EIS follows, 40 C.F.R. § 1501.3(a)(3), and necessarily includes more detail than the EA.

140. 40 C.F.R. § 1501.3 (2020).

141. 40 C.F.R. § 1501.3(b) (2020) ("In considering whether the effects of the proposed action are significant, agencies shall analyze the potentially affected environment and degree of the effects of the action. Agencies should consider connected actions. . .").

142. 40 C.F.R. § 1501.3(b)(1) (2020).

143. 40 C.F.R. § 1501.3(b)(2) (2020).

144. 40 C.F.R. § 1502.14 (2020). An EIS must analyze at least two alternatives, including the No Action Alternative and any other "reasonable alternatives." Natural Resources Defense

Implementing regulations further prescribe information requirements for the EIS. For example, 40 CFR § 1502.10 presents a recommended format for the EIS which includes a description of the "affected environment and the consequences" of the various alternatives. 40 CFR § 1502.15 elaborates on what this section should include: "The environmental impact statement shall succinctly describe the environment of the area(s) to be affected or created by the alternatives under consideration, including the reasonably foreseeable environmental trends and planned actions in the area(s)." The section further provides that the "[d]ata and analyses in a statement shall be commensurate with the importance of the impact, with less important material summarized, consolidated, or simply referenced."[145]

Finally, NEPA regulations explicitly address how agencies must deal with incomplete or unavailable information regarding reasonably foreseeable impacts.[146] First, the agency must make "clear that such information is lacking."[147] Second, the agency must include the information if the information is "essential to a reasoned choice among alternatives" and if "the overall costs of obtaining it are not unreasonable."[148] The regulation also prescribes the agency's

Council v. Morton, 458 F.2d 827 (D.C. Cir. 1972) (holding that the range of "reasonable" alternatives that must be considered in an EIS is broader where the EIS addresses a proposed action constituting part of a larger coordinated plan; in such a situation, the EIS must evaluate alternatives that would require legislative or executive action beyond what the agency itself can control); Natural Resources Defense Council v. Callaway, 524 F.2d 79 (2nd Cir. 1975) (finding that "reasonable alternatives" generally include those which meet the goals of the proposed action, and the EIS must compare the merits of the various alternatives, not focusing only on the agency's preferred alternative); *but see* Citizens Against Burlington v. Busey, 938 F.2d 190 (D.C. Cir. 1991), *cert denied*, 502 U.S. 994 (1992) (finding that the agency retains the discretion to define the objective of a proposed action in a manner that narrowly limits the range of reasonable alternatives). The number of alternatives evaluated in an EIS can vary based on the nature of the proposed action, and longstanding CEQ guidance informs agencies of their options for complying with this component of the NEPA regulations. COUNCIL ON ENV'T QUALITY, *Memorandum to Agencies: Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations*, 46 Fed. Reg. 18026 (Mar. 23, 1981), *as amended* (1986), at 1a-6b (available at https://www.energy.gov/nepa/articles/forty-most-asked-questions-concerning-ceqs-national-environmental-policy-act).

145. 40 C.F.R. § 1502.15 (2020).

146. 40 C.F.R. § 1502.21(d) (2013). "For the purposes of this section, 'reasonably foreseeable' includes impacts that have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason." *Id.*

147. 40 C.F.R. § 1502.22 (2017).

148. 40 C.F.R. § 1502.22(a) (2017).

responsibility if the "overall costs of obtaining [the information] are unreasonable or the means to obtain it are unknown."[149]

Thus, NEPA generates a consistent demand for environmental information about the existing environment, a demand that eDNA is already helping to meet in other contexts,[150] and to which multi-species eDNA sequencing data is particularly suited.

Moreover, where essential information about the environmental impacts of a proposed project is lacking, eDNA data may prove a rapid and cost-effective way of filling the information gap. In some cases, project proponents have an affirmative duty to generate such information. The NEPA regulations require the agency to generate new data—for example, eDNA data—when it would be "essential to a reasoned choice among alternatives" and not cost-prohibitive.[151] As discussed below, failure to obtain this information could create legal vulnerabilities on appeal.

2. Judicial Review under NEPA

As with the ESA, courts review agency NEPA decisions under the APA and apply the arbitrary and capricious standard to evaluate the agency's decisions at either of two relevant steps in the process: 1) in accepting the significance determination in an EA/FONSI (Finding of

149. 40 C.F.R. § 1502.21(b)–(c) (2013). "[T]he agency shall include within the environmental impact statement: (c)(1) A statement that such information is incomplete or unavailable; (2) A statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment; (3) A summary of existing credible scientific evidence that is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment; and (4) The agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community." 40 C.F.R. § 1502.21(c) (2013).

150. *See* tbl.1, *supra* Part II(3).

151. *See* 40 C.F.R. § 1502.21, *supra* notes 146 & 149. The costs of DNA sequencing have plummeted in the past two decades, such that sequencing one million nucleotide bases in 2001 cost more than $5,200, and the same sequencing in 2021 cost $0.006. *See DNA Sequencing Costs: Data*, NAT'L HUMAN GENOME RSCH. INST., https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data [https://perma.cc/X5VJ-DDQS] (last visited Jan. 14, 2023). However, the labor and fixed costs of DNA analysis remain fairly high, and it seems unlikely the next two decades will see the same percentage drops in costs as the past two decades have witnessed.

No Significant Impact),[152] or 2) in assessing the adequacy of an EIS.[153] Accompanying this standard in NEPA cases is the concept of "hard look" review, which has a long history of framing courts' assessments of agency's technical determinations.

In all federal circuits, the standard of review for a significance determination in an EA/FONSI is arbitrary and capricious review.[154] The Ninth Circuit has especially abundant case law on review of NEPA decisions, in part because states in the Circuit contain a disproportionate amount of federal land, and a regulation, decision, or contract touching federal land will automatically trigger the "federal action" requirement for NEPA jurisdiction.[155] The arbitrary and capricious standard of review in NEPA cases is often articulated through the "hard look" doctrine. The debate over how far a court's "hard look" should go is largely confined to the Ninth Circuit; the Eighth Circuit offers little additional guidance beyond the APA's

152. CHRISTINE KLEIN ET AL., NATURAL RESOURCES LAW: A PLACE-BASED BOOK OF PROBLEMS AND CASES 143 n. 4, (ASPEN PUBLISHING ed., 4th ed., 2018). An Environmental Assessment (EA) is typically released by an agency simultaneously with a Finding of No Significant Impact (FONSI); the FONSI is generally a component of the larger EA document detailing the agency's scientific research and findings. "Significant impact" on the environment is the threshold between an EA and an EIS, so a finding that there is *no* significant impact is required for an agency to fulfill its NEPA obligations via an EA. An "EA/FONSI" is a final agency action that can be challenged in court. Plaintiffs generally challenge the agency's conclusion (the FONSI) by challenging how it got there (the analysis or data used in the EA that supports the decision between significance or non-significance). In an action challenging an EA/FONSI, a court will rule against the agency if it finds that the agency action does, in fact, create a likelihood of significant environmental impact; the agency must then prepare an EIS. A final EIS may be challenged for its adequacy, the remedy for which is re-writing the EIS to cure its deficiencies.

153. KLEIN ET AL., *supra* note 152. The standard for adequacy of an EIS is similar to that for sufficiency of an EA/FONSI (arbitrary and capricious); this is discussed further later in this section. *See*, *e.g.*, Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 376 (1989); DANIEL MANDELKER ET AL., *Later Lower Court Cases*, in NEPA LAW AND LITIGATION § 10:17 (2d ed. 2022) (NEPALL).

154. The Supreme Court has not spoken specifically on this question, KLEIN ET AL., *supra* note 152, at 143 n.4, but has held that the arbitrary and capricious standard applies to its review of an agency's determination of "significance" for the purpose of whether a supplemental EIS will or will not be required. *See Marsh*, 490 U.S. at 376 (holding determination of significance is "a factual dispute" rather than a question of law). The 5th Circuit in 1992 overturned a stricter "reasonableness" standard for reviewing significance determinations by agencies under NEPA, bringing it in line with other circuits. Sabine River Auth. v. U.S. Dep't of Interior, 951 F.2d 669, 677–78 (5th Cir. 1992).

155. *See* Michael Blumm & Keith Mosman, *The Overlooked Role of the National Environmental Policy Act in Protecting the Western Environment: NEPA in the Ninth Circuit*, 2 WASH J. ENV'T L. & POL'Y 194, 198 (2012) (recognizing the volume and prominence of the Ninth Circuit's body of NEPA law); Dustin Glazier, *When the "Hard Look" Is Soft: Reconciling Center for Biological Diversity v. Department of the Interior within Ninth Circuit Environmental Precedent*, 2010 BYU L. REV. 965, 968 ("Federally owned lands constitute an average of 47.5% of the land within the states of the Ninth Circuit compared to an average of 9.1% in all other states").

general arbitrary and capricious standard.[156] The Ninth Circuit's rulings on the standard of review for NEPA cases have therefore directed the course of NEPA law nationwide.[157]

The "hard look" standard derives from the foundational case of *Citizens to Preserve Overton Park v. Volpe*, wherein the Supreme Court held that while courts' review of agency actions under the APA's arbitrary and capricious standard was "narrow," courts' "inquiry" into the facts underlying the decision must nonetheless be a "searching and careful" one.[158] The term "hard look" appeared in administrative law around the same time as *Overton Park*[159] and, beginning around 1973, "hard look" developed rapidly in federal courts' decisions on NEPA as a tool for articulating the appropriate role of a court in reviewing agency-prepared documents requiring substantial scientific expertise to understand or to challenge.[160] Confusingly, both the agency and the courts may be required to engage in a "hard look." Initially, the question was whether the agency had "take[n] a 'hard look' at the problem, as opposed to making bald conclusions."[161] Courts will also sometimes describe their role in judicial review as necessitating a "hard look" at the agency's decision-making process.[162]

The Ninth Circuit articulated the "hard look" standard in 2001 as follows:

> In reviewing an agency's decision not to prepare an EIS under NEPA, we employ an arbitrary and capricious standard that requires us to determine whether the agency has taken a 'hard look' at the

156. Kyle Hoffmeister, *Taking a "Hard Look": The Legality and Policy Implications Surrounding the PolyMet Mine Land Transfer*, 40 MITCHELL HAMLINE L. J. PUB. POL'Y & PRAC. 212, 222 (2019).

157. *See* Glazier, *supra* note 155, at 965.

158. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971).

159. For a thorough history, *see* Patrick Garry, *The Values and Viewpoints Affecting Judicial Review of Agency Actions: A Focus on the Hard-Look Doctrine*, 53 WASHBURN L. J. 71, 73 (2013); *see also* NEPALL § 3:8.

160. *See*, *e.g.*, Md.-Nat'l Cap. Park and Plan. Comm'n v. U.S. Postal Serv., 487 F.2d 1029, 1039 (D.C. Cir. 1973).

161. *Id.*; *see also* Nat'l Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 730–31 (9th Cir. 2001) (holding that the National Park Service's decision not to prepare an EIS was arbitrary and capricious because it was clear the action met the threshold for significance based on CEQ regulations defining "intensity," along with the judge-made rule that where an action "*may* have a significant effect . . . an EIS must be prepared," deriving from 9th Circuit case law going back at least to 1980) (*NPCA v. Babbitt*). This interpretation of when an EIS is required is replicated in the 8th Circuit. Minn. Pub. Int. Rsch. Grp. v. Butz, 498 F.2d 1314, 1320 (8th Cir. 1974); *see* Found. for N. Am. Wild Sheep v. U.S. Dep't of Agric., 681 F.2d 1172, 1178 (9th Cir. 1982).

162. NEPALL § 3:8 ("courts must take a hard look to ensure that the agency took a hard look").

> consequences of its actions, 'based [its decision] on a consideration of the relevant factors,' and provided a 'convincing statement of reasons to explain why a project's impacts are insignificant.'[163]

Ninth Circuit courts have pulled back in recent years from performing a thorough "hard look" at agency determinations under NEPA and other environmental laws, emphasizing the "narrow" character of judicial review under the arbitrary and capricious standard.[164] In *Lands Council v. McNair*, the Ninth Circuit, *en banc*, rejected earlier opinions which had scrutinized agencies' scientific methodology and not granted them adequate "latitude" to demonstrate compliance with the relevant law.[165] The *en banc* panel held that courts should avoid making "fine-grained judgements" about an agency's decision or reports, and that NEPA documents in particular did not need to "present every uncertainty" to survive judicial review.[166] After *Lands Council*, NEPA "hard look" review is satisfied where an agency "'did not ignore' potential adverse [environmental] impacts but instead responded to comments . . . with studies that supported its claim . . .";[167] courts will find that "an action is arbitrary and capricious only if the record 'plainly demonstrates' that the agency made a 'clear error in judgment' . . ."[168] Hard look review survived the *Land Council* decision,[169] especially as a tool for

163. *NPCA v. Babbitt* at 730–31 (citing *Metcalf v. Daley*, 214 F.3d 1135, 1141–42 (9th Cir. 2000) (citing *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 348 (1989) (holding agency's "hard look" requires no mitigation action, merely consideration of the consequences))).

164. Michael Blumm & Maggie Hall, *Lands Council, Karuk Tribe, and the Great Environmental Divide in the Ninth Circuit*, 54 NAT. RES. J. 1, 15–18 (2014) (discussing Lands Council v. McNair, 537 F.3d 981, 992 (9th Cir 2009) (*en banc*)). *But see* Karuk Tribe of Cal. v. U.S. Forest Serv. 681 F.3d 1006 (9th Cir. 2012) (*en banc*) (an ESA case, which per Blumm & Hall, represents, with *Lands Council*, a division among Ninth Circuit judges over how much deference to afford agencies in environmental cases. ESA actions may get less deference than NEPA ones. *Karuk Tribe* specifically addressed the issue of what constituted "agency action" within mining law.).

165. Blumm & Hall, *supra* note 164, at 14–15 (quoting *Lands Council*, 537 F.3d at 992).

166. *Id.* at 15–16 (quoting *Lands Council*, 537 F.3d at 992).

167. *Id.* at 16 (quoting *Lands Council*, 537 F.3d at 992). The articulation of hard look review in *Lands Council* emphasizes the importance of each agency's obligation under the APA to respond to public comments in a meaningful way. In science-driven agency assessments, such as the EA/FONSI determinations and EIS analyses performed under NEPA, one of the public's most powerful levers to pull is to submit data to the agency which the agency did not, but should have, considered in its analysis.

168. *Lands Council*, 537 F.3d 981 at 994. In other words, courts should not judge agency reports at "fine-grained" level. *See* Blumm & Hall, *supra* note 164, at 15.

169. "Other courts have viewed *Lands Council* as allowing judges to inquire into *the adequacy of the Forest Service's methodology*, while giving effect to *Lands Council's* other rulings, like not requiring site-specific soil studies." Blumm & Hall, *supra* note 164, at 22 (emphasis added). Thus, an EIS may be deficient where agency's methodology does not implement the leading science, at least where the agency's own scientists have warned them of that and the agency

courts to evaluate agencies' efforts in the context of relevant science, but now generally does not extend beyond the "narrow" bounds of arbitrary and capricious review overall.[170]

Courts' application of "hard look" review serves to identify what aspects of an agency's methodology should be scrutinized under the arbitrary and capricious standard, and what areas of agency decision-making should be afforded more deference. For example, to survive arbitrary and capricious review, an agency must have taken a hard look at the data available to them and responded to comments questioning or supplementing that data; when performing new studies, the agency must have complied with basic scientific standards, but need not have followed a particular scientific method or resolved every possible uncertainty before making a decision.[171] Courts will inquire into the overall sufficiency of an agency's approach to science and the administrative process, but not make "fine grained" judgments about the agency's conclusions.[172]

Federal courts reviewing an EIS apply a similar standard to determine whether it is "adequate" for the purposes of NEPA as they do when judging whether an EA/FONSI is "sufficient".[173] Courts review the agency's preparation of the EIS for arbitrariness and capriciousness, often citing the "hard look" doctrine especially when affirming the adequacy of the EIS, i.e., if the agency appears to have taken a hard look at the environmental considerations, the court will not question its conclusions or the nature of the data used to prepare the EIS.[174]

Thus, in reviewing an agency's failure to use existing eDNA evidence, courts will generally ask whether that failure precluded the agency from taking a hard look at a project's impacts. It seems likely an agency decision that *failed* to use existing eDNA data would be

offers no explanation for its opposite choice. *See* Native Ecosystems Council v. Weldon, 848 F.2d 1207, 1217 (D. Mont. 2012), vacated, CV 11-99-M-DWM, 2012 WL 5986475 (D. Mont. Nov. 20, 2012) (vacating as moot because the Forest Service withdrew implementation of the project after a forest fire burned the project area). Blumm & Hall interpret *Weldon* as saying "hard look" review survives *Lands Council*. Blumm & Hall, *supra* note 164, at 23.

170. Blumm & Hall, *supra* note 164, at 18. *But see* Alaska Wilderness League v. Kempthorne, 548 F.3d 815 (9th Cir. 2008) (holding that where the defendant agency's conclusion that there were no significant impacts and so an EIS was not necessary was "not supported by the studies relied upon," the agency's decision was arbitrary and capricious). For a detailed discussion of *Alaska Wilderness League*, *see* Keith Baurle, *The Ninth Circuit's 'Clarifications' in Lands Council v. McNair: Much Ado About Nothing?*, 2 GOLDEN GATE UNIV. L. J. 203, 247 (2009).

171. *See* Blumm & Hall, *supra* note 164, at 14–15.

172. *Id*.

173. *See* Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 376 (1989).

174. NEPALL § 3.8 (and included case citations).

vulnerable under the arbitrary and capricious standard, specifically for one of the reasons in the *State Farm* test: "failure to consider an important aspect of the problem."[175] Agencies may not merely ignore data before them that speaks directly to the question at hand, no matter the particular survey method yielding that data.[176] As discussed further below, the risks to an agency rise when the agency ignores stakeholder comments that link data to a reasoned consideration of alternatives and their impacts. In contrast to a failure to consider eDNA evidence, it is hard to imagine a court vacating an agency decision merely because that decision rested upon eDNA evidence.

For a court to consider whether the agency should have used eDNA evidence, a stakeholder would need to have raised the issue during scoping or comments on the draft EIS. Courts will not review issues on appeal that were not raised to the agency during the administrative process.[177] During judicial review, the court would examine whether the agency responded to a stakeholder's comment that eDNA should be used. An agency's failure to respond persuasively by explaining its decision not to use eDNA would be vulnerable to a finding that the agency decision was arbitrary and capricious, as would a failure to respond to the comment at all.

No court has yet reviewed an agency's application of 40 CFR § 1502.21, the specific test requiring a project proponent to generate new eDNA information. A stakeholder would need to raise the issue during the EIS public process.[178] For example, comments on a draft EIS making a compelling argument that eDNA met the various factors in 40 CFR § 1502.21 would be most useful in reviewing the federal agency's consideration of adding eDNA research. This would also set

175. Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.") (*State Farm*).

176. The agency might permissibly choose to weigh other evidence more strongly—as, for example, the Army Corps did in *Michigan v. Army Corps.* Michigan I, *supra* note 1, 2010 WL 5018559 at *7-11. Furthermore, the agency might choose, if doing its own surveying, to exclusively use more traditional monitoring tools, rather than eDNA. But eDNA data is valid and often valuable information, quite equivalent to other forms of biological survey data. The only difference is that eDNA is new, and this does not in itself give agencies license to ignore such data.

177. Jeffrey Lubbers, *Fail to Comment at Your Own Risk: Does Issue Exhaustion Have a Place in Judicial Review of Rules?*, 70 ADMIN. L. REV. 109, 128–131 (2018).

178. *Id.*

up the record for the reviewing court if the agency did not respond to the comment in the Final EIS or agree to conduct the research. If declining to use eDNA, the agency would be wise to give a thoughtful and considered response as to why it concluded that either eDNA information was not "essential" to considering alternatives, unreasonably expensive, or both.

3. Using eDNA Under NEPA

While we have not found widespread agency use of eDNA data in NEPA environmental documents,[179] federal agencies involved in offshore energy development have identified eDNA as an appropriate source of information that could be included in NEPA review of various stages of such development[180] and have identified eDNA monitoring as part of a wind energy lease proposal. In addition, several examples have surfaced under California's state-level NEPA equivalent, CEQA, and a variety of published work describes international examples of NEPA-style assessments using eDNA. We review eDNA uses for environmental review under NEPA and CEQA directly below.

The Bureau of Ocean Energy Management (BOEM)—the Interior Department agency responsible for overseeing offshore energy planning, leasing, and development—requires private lessees to develop Site Assessment Plans (SAPs) for renewable energy activities on their commercial leases on the Outer Continental Shelf.[181] For the last several years, BOEM, collaborating with NOAA, has regularly and with increasing confidence explored using eDNA for making leasing decisions.

In 2018, BOEM's study program noted it had been funding studies on incorporating eDNA in monitoring.[182] The 2019–2020 Study Program proposed additional eDNA research,[183] and in 2020 BOEM solicited study ideas for fiscal years 2022–2023, including this specific statement of interest in eDNA proposals:

179. Very likely, this lag reflects the more recent development of the techniques involved in multispecies sequencing relative to single-species qPCR, as well as the additional expertise required to interpret multispecies data, as we discuss above in Part II(2).

180. See discussion *infra* regarding BOEM.

181. 30 C.F.R. §§ 585.605–18 (2023).

182. BOEM, STUDIES DEVELOPMENT PLAN 2019–2021 19 (2018).

183. *Id.* at 123.

> BOEM is keen to advance innovative technologies that may improve results and potentially reduce costs, such as use of unmanned vehicles in the sea and air, satellite imagery, and eDNA.[184]

The 2022–2023 Study Program included a detailed section on eDNA that described a proposed collaboration with the Smithsonian Institution and NOAA:

> [To] evaluate how well eDNA metabarcoding[185] resolves marine communities using retrospective analyses (persistent communities) and simultaneous observations (observers; net tows; aerial cameras). The main objectives are to identify strengths and weaknesses in methodology, address weaknesses by populating genetic databases where feasible, and guide future BOEM projects across the regions.[186]

Specific questions driving this research included eDNA's ability to (1) reliably detect managed taxa and community structure (e.g., from clams to seabirds) to support NEPA evaluations and BOEM's permitting processes, and (2) predict and confirm multi-species hotspots derived from decades' worth of observations and in-situ sampling.[187] The research also sought to determine whether the agencies could advance best management practices for eDNA use and rely on reference libraries to detect community-level interactions.[188]

By 2022, BOEM was referencing eDNA in a draft EIS for an offshore wind lease. Specifically, the mitigation and monitoring appendix identifies eDNA surveys for marine mammals as one of the proponent-identified mitigation measures.[189]

The State of California has used eDNA in environmental reviews conducted pursuant to the California Environmental Quality Act (CEQA), the state's NEPA equivalent. In each instance thus far, the Environmental Impact Review (EIR) has relied on eDNA information to address potential impacts on species listed under the ESA (giant

184. *BOEM Now Accepting Environmental Study Ideas for Fiscal Years 2022 and 2023*, BOEM (Nov. 10, 2020), https://www.boem.gov/newsroom/notes-stakeholders/boem-now-accepting-environmental-study-ideas-fiscal-years-2022-and-2023 [https://perma.cc/8TNH-G797] (emphasis removed).

185. "Metabarcoding" refers to multispecies eDNA analysis, or amplicon sequencing.

186. BOEM, STUDIES DEVELOPMENT PLAN 2022–2023 76–78 (2022).

187. *Id.*

188. *Id.*

189. BOEM, OCEAN WIND OFFSHORE WIND FARM DRAFT ENVIRONMENTAL IMPACT STATEMENT, App. H (2022).

garter snake,[190] green sturgeon,[191] and the California red-legged frog[192]).[193] These CEQA examples model what we might expect in the coming years under NEPA itself, but in addition, NEPA encourages joint state-federal review that could result in the incorporation of eDNA generated for CEQA purposes into a NEPA document.[194] Moreover, CEQA applies to state actions and, therefore, applies to many projects that do not trigger the federal NEPA. Finally, CEQA requires state agencies, when feasible, to make substantive—rather than merely procedural—decisions reducing the level of environmental impacts.[195] In this regard, CEQA has more "teeth" than NEPA.[196]

Beyond these emerging uses of eDNA data in legally required environmental reviews, several published academic studies have assessed the effects of offshore oil and gas drilling using the kind of multispecies amplicon sequencing that is likely to be applied to domestic NEPA-style analyses in the near future. This work—from

190. eDNA demonstrated the presence of the Giant Garter Snake on the project site. CAL. DEP'T OF WATER RES., DRAFT ENVIRONMENTAL IMPACT REPORT: LOOKOUT SLOUGH TIDAL HABITAT RESTORATION AND FLOOD IMPROVEMENT PROJECT (2019).

191. eDNA demonstrated the presence of green sturgeon at the project site. CITY OF LATHROP, DRAFT ENVIRONMENTAL IMPACT REPORT FOR THE LATHROP CONSOLIDATED TREATMENT FACILITY SURFACE WATER DISCHARGE PROJECT (2020).

192. California red-legged frog was not detected at the project site using eDNA and was determined to be absent. CITY OF VALLEJO CALIFORNIA, FAIRVIEW AT NORTHGATE PROJECT DRAFT ENVIRONMENTAL IMPACT REPORT (2020).

193. These EIRs rely in part on single-species (qPCR) assays, rather than multispecies amplicon sequencing.

194. The CEQ NEPA Regulations encourage cooperation with state and local agencies in an effort to reduce duplication in the NEPA process (40 C.F.R. § 1506.2 (2023)). The regulation states that cooperation shall include: (1) joint planning processes; (2) joint environmental research and studies; (3) joint public hearings (except where otherwise provided by statute); and (4) joint environmental assessments.

195. Cal. Pub. Res. Code § 21002 (West 2022) provides that "public agencies should not approve projects as proposed if there are feasible alternatives or feasible mitigation measures available which would substantially lessen the significant environmental effects of such projects." The statute creates an exception to this requirement if "specific economic, social, or other conditions make infeasible such project alternatives or such mitigation measures."

196. *See* Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 558 (1978) (holding that NEPA is procedural, rather than substantive); *see also* LaFlamme, *supra* note 138.

Italy,[197] New Zealand,[198] and Norway[199]—demonstrates the applicability of the technique for broader use in the context of all kinds of industrial development.

In each study, the authors develop an index of environmental quality (or its inverse, environmental degradation) and observe the changes in the community of species detected by eDNA associated with a change in environmental quality. Moreover, each highlights the cross-cutting nature of eDNA sampling. Hundreds of species, from microbes to fish, show up in the samples—a diversity of detection that far outstrips traditional sampling methods, which generally focus on a few key species as indicators of environmental conditions. Given that microbes are often the most sensitive barometers of environmental change in response to developmental pressures,[200] molecular sampling may be a way to leverage the technique's sensitivity for routine, practical use.

4. Likely Future NEPA Scenarios

The above analysis suggests several situations where agencies might improve decisions and avoid legal vulnerability by using eDNA evidence.

As a first step, agencies could review existing eDNA information that has been generated for other purposes. For example, as discussed in Part III, eDNA data exists regarding a variety of invasive species; this information is included in the eDNA Atlas and other repositories. An action's effects on invasive species—that is, the kind of environmental impact reviewed under NEPA and the kind to which existing eDNA data may speak—is the subject of existing federal guidance on NEPA review.[201] As a routine matter, agencies and

197. Tristan Cordier et al., *Multi-Marker eDNA Metabarcoding Survey to Assess the Environmental Impact of Three Offshore Gas Platforms in the North Adriatic Sea (Italy)* 146 MARINE ENV'T RSCH. 24, 24-34 (2019).

198. Olivier Laroche et al., *Metabarcoding Monitoring Analysis: The Pros and Cons of Using Co-Extracted Environmental DNA and RNA Data to Assess Offshore Oil Production Impacts on Benthic Communities*, PEERJ 1 (May 2017).

199. Anders Lanzén et al., *Benthic eDNA Metabarcoding Provides Accurate Assessments of Impact from Oil Extraction, and Ecological Insights*, ECOLOGICAL INDICATORS, Aug. 2021, at 1.

200. Laroche et al., *supra* note 198. Note also that Laroche and colleagues distinguish between detections of live and dead organisms—a shortcoming of eDNA, because both live and dead organisms have the same DNA—by comparing eRNA to eDNA and making a conservative estimate of which species are both present and alive at the time of sampling.

201. *See, e.g.,* U.S. DEP'T OF THE INTERIOR, NEPA-INVASIVE SPECIES GUIDANCE QUESTIONNAIRE SUMMARY, https://landscapepartnership.org/people/acp-work-group-2.-synthesis-201cstate-of-the-appalachians201d/aquatic-systems/issue-invasives-doi-nepa/index_html

consultants preparing NEPA environmental documents should review various databases for information regarding the presence of invasive species in the action area. Where an appropriate eDNA analysis detects the presence of such species, the agency can assess the project's impact accordingly.

Similarly, agencies could employ in NEPA reviews eDNA evidence already collected for ESA-listed species. Using such data would minimize agencies' litigation risk. The incorporation of such data into the NEPA context should be an easy leap, because federal actions that trigger consultations under ESA Section 7 also trigger environmental review under NEPA. NEPA regulations make it easy to incorporate ESA biological assessments and other studies into NEPA documents, including EISs and EAs. As discussed in the ESA section above, using eDNA information can help ensure that impacts are not overlooked, but can also help show that certain impacts are unlikely by establishing that an invasive or ESA-listed species is not present in an area. The latter finding helps reduce the scope and cost of environmental review.

Second, to avoid legal vulnerability, agencies should consider generating eDNA evidence for NEPA review when such evidence is relevant to choosing among alternatives and when the cost of generating the information is not unreasonable. Projects that are controversial and costly will often satisfy both of these criteria because the cost of the eDNA study is small compared both to the overall project's cost and to the cost of potential litigation delay from failing to conduct the study. Conducting eDNA surveys may also be faster than traditional sampling methods which may depend on larger field crews. In addition, project impact areas are often small compared to areas assessed for other purposes (for example, for invasive or sensitive species). Again, eDNA can help establish that certain species are not present and that therefore a project will not adversely impact them.

Where eDNA instead establishes that species are present, this information enables project proponents to plan for appropriate mitigation. Accurately identifying the presence of invasive or sensitive species helps develop targeted mitigation—for example, formulating an improved project alternative that reduces invasive

[https://perma.cc/6E7G-H6LV] (last visited Feb. 19, 2023); Jhoset Burgos-Rodrıguez & Stanley Burgie, *Federal Legal Authorities for the Early Detection of and Rapid Response to Invasive Species*, 22 BIOLOGICAL INVASIONS 129 (2020); JOHNSON ET AL., CONG. RSCH. SERV., R43258, INVASIVE SPECIES: MAJOR LAWS AND THE ROLE OF SELECTED FEDERAL AGENCIES (2017).

species penetration—which meets NEPA's information standard as well. As discussed in the section on judicial review of NEPA documents, stakeholders can play a key role by commenting during the administrative process on the importance of using eDNA data.

IV. CONCLUSION

As scientists have learned to leverage the mountains of genetic information found in the world's ecosystems, federal and state agencies have recognized the value of this information for environmental management and conservation. The Federal Register has already featured a trickle of entries grounded in eDNA data, and a larger stream is fast approaching.

In light of the foregoing analysis, we conclude that (1) eDNA is likely to meet relevant evidentiary and administrative standards, given that it has been challenged in court twice and survived both times, (2) the relevant information standards (particularly those pertaining to requiring new information) for the ESA and NEPA differ—being focused on single species and multiple species, respectively—and different methods of eDNA analysis are therefore relevant to each, (3) courts are unlikely to play a technology-forcing function that would drive eDNA uptake in agencies, and (4) private parties may encourage this kind of uptake via litigation. We expand upon each of these conclusions briefly below.

A. Litigation Success

Only two federal cases have featured challenges to eDNA data. In *Michigan v. U.S. Army Corps*, the Northern District of Illinois found admissible the expert-witness testimony of David Lodge, the principal scientist behind the Asian carp eDNA assay.[202] This was the court of first instance, and proceedings were akin to a trial; the parties presented disputed evidence to be reviewed *de novo*. The court undertook a *Daubert* analysis,[203] finding the eDNA testimony admissible for purposes of the matter at hand.[204] In a subsequent

202. Michigan I, *supra* note 1, 2010 WL 5018559 at *26. Note also this wasn't technically a *Daubert* challenge. *Id*. at *25 n. 23.

203. *Id.*, at *25 n. 23, *34 (addressing the issue because intervenors had moved to strike the eDNA testimony).

204. *Id.* at *26 ("Consistent with the Seventh Circuit's guidance for non-jury proceedings and in the interest of expediting the hearing and consideration of the issues, the Court provisionally accepted Dr. Lodge's . . . testimony, with the caveat that the testimony could be disregarded or excluded if upon reflection it proved irrelevant or inadmissible.")

appeal, the Seventh Circuit treated eDNA evidence as completely unremarkable.[205] Thus, eDNA has survived in federal court the only times it has faced an admissibility test.

In a different posture, eDNA featured in an arbitrary and capricious review of agency action, and also survived. In *Appalachian Voices*, the Fish and Wildlife Service had used the non-detection of an imperiled fish species—via both eDNA surveys and traditional sampling surveys—to justify excluding a particular watershed as critical habitat under the ESA. The Fourth Circuit court had "little trouble concluding that the Fish and Wildlife Service provided a sufficiently cogent justification for excluding the. . . watershed from further study."[206] The court, then, found eDNA data acceptable as part of the agency's reasoning.[207]

The legal precedent on eDNA itself is thin,[208] but wholly supports treating eDNA as just another data source that agencies might choose to include in their processes. To date, eDNA has met the legal requirements for the statutes under which it has been used.

B. Different Information Standards and Analytical Needs

The ESA and NEPA have different information standards that bear on eDNA. Under the ESA's Best Available Science test, an agency need only consider available scientific information; there is no need to generate new studies, eDNA or otherwise. In contrast, NEPA's regulations explicitly require an agency to generate new scientific information when such information is essential and not cost-prohibitive. Meeting these criteria may be difficult in the case of eDNA as it may not be clear in the early stages of an administrative review that eDNA is essential to the decision.

205. Michigan II, 758 F.3d at 896 ("The reliability of eDNA was a matter of some contention when we last considered this case, but for present purposes we accept the States' allegation that it indicates immediate presence of the carp."). The court undertook no *Daubert* analysis. *Id*.

206. Appalachian Voices v. U.S. Dep't of Interior, 25 F.4th 259, 280 (4th Cir. 2022) (citing Am. Whitewater v. Tidwell, 770 F.3d 1108, 1116 (4th Cir. 2014)) (internal quotations and punctuation omitted for clarity).

207. *Id*.

208. The record on eDNA itself is thin, but there are volumes of cases dealing with the acceptability of other trace genetic data, such as DNA fingerprinting, in criminal contexts. *See, e.g.,* People v. Wesley, 183 A.D.2d 75, 78 (N.Y. Ct. App. 1992) (walking through analysis of admissibility of "novel scientific evidence," including the threshold requirement that "the scientific theory and the procedures used to obtain the result have gained general acceptance in the scientific community and the result achieved is accepted by that community as reliable"); People v. Lindsey, 868 P.2d 1085, 1090 (Colo. Ct. App. 1993) (citing several states' cases upholding admissibility of DNA forensic evidence).

The single-species nature of the ESA lends itself to single-species eDNA analysis, the form of molecular assay now familiar to the public in a medical context as the qPCR test. This simple assessment often answers a binary question on the part of the researcher: Does this patient have COVID-19 or not? Can I detect this species in the environment or not? As a result, sensitive qPCR assays for single species have first made their way into the Federal Register in the context of either/or determinations under the ESA. For example, FWS has used qPCR results (in combination with other survey methods) as sufficient justification for delineating areas appropriate for critical habitat designation,[209] and has proposed delisting a species on the basis of its being detected in a variety of watersheds.[210] Because single-species qPCR is among the simplest uses of eDNA, its development and field-deployment have preceded the more complicated multi-species methods, which have yet to appear in a federal rulemaking or court decision.

However, it seems likely that, as the analysis of multi-species sequencing becomes easier, these sources of data will begin to inform the decisions that federal statutes require. NEPA, in particular, demands information about the effects of human actions on the biological environment, and multi-species eDNA analysis is capable of measuring those effects quite directly. Given that multi-species eDNA data are increasingly common in academic ecological studies of all kinds, NEPA-required impact assessments cannot be far behind.

C. Judicial Deference

Agencies have broad discretion in choosing the tools with which they do their jobs. Courts will not force them to use any method in particular—be it eDNA, visual surveys, or any other survey technique—so long as the agency's chosen methods are adequate to support decisions that meet the APA's arbitrary and capricious standard and the relevant statutory information standards. As we noted in Part III, it is at least plausible that a court could require eDNA analysis in a NEPA context where information needed to distinguish the effects of different alternatives does not otherwise exist and where the cost of generating such eDNA data is not unreasonable. However, on the whole, courts are unlikely to drive a broad federal

209. Appalachian Voices v. U.S. Dep't of Interior, 25 F.4th 259, 280 (4th Cir. 2022).

210. Endangered and Threatened Wildlife and Plants; Removing the Snail Darter from the List of Endangered and Threatened Wildlife (Final Rule), 87 Fed. Reg. 60298-01 (Oct. 5, 2022).

uptake of eDNA methods, even where those methods might provide better, cheaper, or faster ways of meeting agency mandates.

D. Prospects for Litigation

On the other hand, private litigants may find eDNA analyses meet their needs, leading to broader eDNA uptake both in the private sector and, in response, among agencies. To the extent that pro-conservation groups use data as a sword with which to challenge landowners, development proponents, agencies, and others—or indeed, to the extent any stakeholder uses data to challenge another—courts will find themselves deciding cases grounded in eDNA data. For example, one might imagine an environmental group—such as the Friends of Gualala River, discussed above—surveying a landscape for genetic evidence of an imperiled species, and using the resulting information to bring a citizen suit under Section 9 of the ESA, or to petition for a species' listing and for the agency to designate critical habitat. On the other side, a developer might preemptively survey lands slated for development to evaluate the risk of litigation over species that are present, or to minimize use conflicts.

In short, all available evidence suggests that stakeholders on any side of an environmental issue can wield eDNA assays in their own interest, generating evidence that is likely to stand up in court. Such evidence, in turn, may force agency action under various environmental statutes, and could plausibly inspire the agencies themselves to adopt eDNA methods proactively, so as to better control the sources of information underpinning their own decisions.

E. Recommendations for Efficient Uptake of eDNA Methods

Federal guidance on how to integrate eDNA into existing agency functions would benefit multiple parties. At this point in the evolution of a new data stream that is likely to influence federal decisions in the near-term future, executive branch guidance on eDNA use would minimize the risks associated with any remaining uncertainty surrounding its utility under various statutes. Other nations have developed guidance for the use of eDNA; most notably, Canada's Department of Fisheries & Oceans has done so in the context of

invasive species,[211] and Finland's Ministry of the Environment has set out a more comprehensive eDNA roadmap.[212]

As a practical matter, such guidance would harmonize data standards across agencies, establishing minimum standards while allowing flexibility for eDNA methods to continue to improve. We suggest two complementary paths: (1) a guidance document from the White House Council on Environmental Quality (CEQ) and (2) a multi-agency joint rulemaking to clarify existing practices and define eDNA as relevant to agency decisions under enumerated statutes.

The CEQ is already developing guidance for incorporating new forms of knowledge into NEPA analysis, in part because agencies have long lacked adequate means of impact assessment and site-specific assessment.[213] CEQ guidance on applying eDNA data in the context of NEPA, in particular, would provide much-needed certainty for agencies and private-sector consultants working toward making molecular data a standard part of environmental impact reviews. Such suggestions would also be consistent with CEQ's role under Executive Order 13112 regarding invasive species management.[214]

More generally, beyond what NEPA requires, agencies across the executive branch are using eDNA for their own aims,[215] although final rules resting upon such data are still rare. We suggest that a joint rulemaking would efficiently provide a valuable degree of legal certainty for many presently independent federal activities involving eDNA. Where, for example, eDNA might meaningfully improve the

211. Cathryn Abbot et al., *Guidance on the Use of Targeted Environmental DNA (eDNA) Analysis for the Management of Aquatic Invasive Species and Species at Risk*, FISHERIES & OCEANS CANADA (Mar. 2021).

212. Veera Norros et al., *Roadmap for Implementing Environmental DNA (eDNA) and Other Molecular Monitoring Methods in Finland: Vision and Action Plan for 2022–2025*, REPS. FINNISH ENV'T INST. 20 (2022).

213. *See* National Environmental Policy Act Task Force, 68 Fed. Reg. 55,954 (Sept. 29, 2003) at 10–11. This 2003 NEPA task-force report to CEQ highlights needs that eDNA data meets, such as rapid, site-specific assessments. "Existing information, such as . . . data regarding sensitive environmental resources . . . and the evaluation of potential impacts, can inform new decision-making processes. However, information sources must be supplemented to address the unique aspects of many proposed actions, particularly concerning the need for site-specific detail. Insufficient time, money, or expertise needed to collect data; seasonal field-data collection; and completion of final design alternatives can delay any NEPA process and limit agencies' ability to strategically address data gaps and track environmental trends. Most agencies prefer to use peer-reviewed information; however, timelines are often too short to accommodate the peer-review process. Insufficient availability of resource experts inhibits the ability of agencies to stay abreast of current research, which in turn causes agencies to 'reinvent the wheel' rather than leverage existing information resources." *Id.*

214. Executive Order 13112, "Invasive Species," (Feb. 3, 1999).

215. See Part II, *supra*.

implementation of statutes as diverse as the Clean Water Act, Outer Continental Shelf Lands Act, National Forest Management Act, and Federal Land Policy and Management Act—in addition to the ESA, NEPA, and many others—the relevant federal agencies might agree to harmonize their minimum standards for eDNA data.

There is precedent for such a joint rulemaking elsewhere in the environmental sphere, both for multiple agencies implementing a common statute[216] and, as here, for multiple agencies implementing multiple statutes.[217] Within and across these agencies, scientists are already collaborating via inter-agency eDNA working groups and initiatives.[218] A rulemaking would simply codify the practices that are already arising through such processes.

Both the CEQ and the rulemaking pathways are inter-agency examples of a strategy of technology adoption we call, in a companion paper, "collaborative governance." [219] The strategy recognizes that successful adoption of eDNA methods throughout federal agencies is not a single decision but a social process. For reasons developed in that companion paper, we conclude that two features of eDNA analysis make collaborative governance a useful path forward.

The first of these is technological dynamism. eDNA analysis entails a set of methods that are emerging and changing rapidly, as part of the dramatic evolution of genomics, where research has been fueled by large biomedical investments. Based on the current pace of technology development and institutional adoption, there is reason to believe that continued rapid change is in the offing for eDNA and other genomic methods.[220] Capturing the benefits of eDNA will require a continuing process of learning by doing. Given the differences among agencies' institutional settings and cultures, building and sustaining a collaborative inter-agency approach is important in order to take advantage of continuing improvements in eDNA technology.

216. *See, e.g*., Policy Regarding the Recognition of Distinct Vertebrate Population Segments under the Endangered Species Act, 61 Fed. Reg. 4722-01 (Feb. 7, 1996).

217. For an extensive review of the role of various agencies in shared regulatory space, *see generally*, Jodi Freeman and Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV., 1131 (Mar. 2012).

218. *See supra*, notes 57–58 and accompanying text, for descriptions of interagency eDNA activities.

219. Kai Lee et al., *Adoption of Environmental DNA in Public Agency Practice* (forthcoming in ENVIRONMENTAL DNA, 2023). On file with authors.

220. *See* discussion of ongoing integration of eDNA into state-level and international scientific practices and government-led management processes, Part III.2.C., *supra*; *Lee* et al., *supra* note 219.

A second feature of eDNA methods is their novelty. The research record strongly suggests that, in many settings, eDNA analysis is already competitive with existing methods. But eDNA analysis is different and unfamiliar, and thus accepting it requires institutional change. Environmental science is beginning to bring genetic methods such as eDNA into agency practices that have been grounded heavily in ecology and field observation. In every agency, staff need to be trained, new relationships with contractors need to be built, and guidelines and regulations need to be adjusted in order to reflect the strengths and limitations of eDNA methods, as they take their place in the toolkits of policy implementation. Here, too, a collaborative approach that rewards learning by doing is essential.

F. Concluding Thoughts

As a technology becomes routine, its use follows a predictable arc with respect to the degree of discretion and expertise required of users. At the beginning of that arc, a technology is experimental and likely to be rapidly evolving; as a consequence, the transaction costs of basing decisions upon that technology are likely to be high—the user needs to invest time and money to understand each relevant detail, needs to repeat analyses as those details shift with an evolving technology, and needs to exercise a great deal of discretion in moving from raw data to analytical outcome to policy decision. If such discretion led to unpredictable outcomes across different end-users, any decision resting upon them would be vulnerable to litigation, leading to waste and further high transaction costs.

At the other end of the arc of technological uptake, a technology has become routinized and stable. Implementation entails low transaction costs and requires a small or negligible exercise of discretion on the part of the user. At this stage, agency decisions grounded in the routine technology are unlikely to be challenged on those grounds, and if challenged, the agency is likely to prevail in court.

In this Article, we have focused on a technology in transition between these endpoints. A wide variety of agencies have begun using eDNA data in research and even in regulatory contexts (Part II). Legal disputes over this shift have been rare, and our legal analysis (Part III) suggests eDNA data is likely to withstand judicial scrutiny in many management contexts. The weight of available evidence suggests that eDNA data is, in legal terms, just like any other form of biological data, and is acceptable in the same legal contexts. We have

also identified specific legal requirements and how different stakeholders, including decision-making agencies, might leverage these requirements under NEPA and the ESA to introduce and utilize eDNA evidence.

What lies ahead is adoption of eDNA methods at full scale, and such adoption is inherently a social process. Legal acceptability does not ensure social acceptability within agencies and among their stakeholders, and even the most valuable of technologies do not necessarily diffuse without friction through federal bureaucracy. We suggest that relatively modest federal actions to harmonize uptake across agencies could lead to significant improvements in the ability to inform environmental decision-making. The legal framework to guide this development is already in place. By encouraging federal scientists and managers to take full advantage of eDNA technology, federal leadership can help move environmental management into the 21st century.