BUILDING BETTER SPECIES: ASSISTED EVOLUTION, GENETIC ENGINEERING, AND THE ENDANGERED SPECIES ACT

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On December 10, 2020, Elizabeth Ann, a black-footed ferret, was born. This was a momentous occasion, as it was the first time a native species listed under the Endangered Species Act ("ESA") had been cloned. This is the first major attempt to use biotechnology to aid in the conservation of an endangered species, but it will certainly not be the last. While cloning may only be relevant for a small subsection of species, other forms of biotechnology, like genetic engineering, could be used to restore lost diversity or make novel changes to genomes. Projects to modify coral to withstand warmer oceans, or to create resistance against chronic disease in amphibians, are already in progress in academic and industry labs. Despite the promise, the application of these techniques to wildlife conservation is controversial. The use of genetic engineering to intervene in evolution is contentious because it challenges humanity's assumptions about the very meaning of Nature. Genetic interventions pit the goals of protection of species and preservation of functioning ecosystems against deeply ingrained views that wildlife should exist apart from our influence. Many threats that listed species face are unlikely to be abated using traditional conservation approaches, forcing us to perpetually manage rather than truly recover.

In this Article, I argue that genetic engineering can facilitate the recovery of biodiversity. Our actions have already permanently modified "natural" genomes, and many of our

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management strategies clearly impinge upon the "wildness" of these species. With this in mind, taking a more informed and active role in that modification, limiting the temporal scope of management, is important for the future of wildlife conservation. Additionally, even though the Coordinated Framework does a poor job regulating conservation engineering, the ESA could provide regulatory oversight for the creation and release of these organisms through the use of: (1) recovery permits; (2) the Controlled Propagation regulations; (3) the 10(j) experimental population procedures; and (4) special 4(d) rules. I conclude by making recommendations to improve this oversight and suggest factors to guide the Services in using these technologies.

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INTRODUCTION

On December 10, 2020, Elizabeth Ann was born.[1] At first glance, she looks just like the rest of her siblings, writhing around, tiny, and pink. However, within a few weeks, she develops distinctive black markings on her face and feet. The rest of the kits in her litter remain pale, just like their parents. While her siblings and surrogate mother are domestic ferrets (*Mustela putorius furo*), Elizabeth Ann is a black-footed ferret (*Mustela nigripes*), cloned from cryopreserved tissue stored in a "frozen zoo" since the late 1980s.[2] Although a number of different animal species have been cloned in the last two decades, Elizabeth Ann is the first native species listed under the Endangered Species Act ("ESA") to be cloned.[3] Further, Elizabeth

1 *Innovative Genetic Research Boosts Black-footed Ferret Conservation Efforts by USFWS and Partners*, U.S. FISH & WILDLIFE SERV. (Feb. 18, 2021) [hereinafter *Innovative Genetic Research*], https://www.fws.gov/press-release/2021-02/genetic-research-boosts-black-footed-ferret-conservation-efforts [https://perma.cc/8AER-6LKH].

2 *See* Samantha M. Wisely, Oliver A. Ryder, Rachel M. Santymire, John F. Engelhardt & Ben J. Novak, *A Road Map for 21st Century Genetic Restoration: Gene Pool Enrichment of the Black-Footed Ferret*, 106 J. HEREDITY 581, 587 (2015); *The Black-footed Ferret Project*, REVIVE & RESTORE, https://reviverestore.org/projects/black-footed-ferret/ [https://perma.cc/KK8K-9EKU].

3 *See generally* Robert P. Lanza et al., *Cloning of an Endangered Species (*Bos Gaurus*) Using Interspecies Nuclear Transfer*, 2 CLONING 79 (2000) (cloning of gaur); Martha C. Gómez et al., *Birth of African Wildcat Cloned Kittens Born from Domestic Cats*, 6 CLONING & STEM CELLS 247 (2004) (cloning of African wildcat); Min Kyu Kim et al., *Endangered Wolves Cloned from Adult Somatic Cells*, 9 CLONING & STEM CELLS 130 (2007) (cloning of grey wolf); Martha C. Gómez et al., *Nuclear Transfer of Sand Cat Cells into Enucleated Domestic Cat Oocytes is Affected by Cryopreservation of Donor Cells*, 10 CLONING & STEM CELLS 469 (2008) (cloning of sand cat); J. Folch et al., *First Birth of an Animal from an Extinct Subspecies (*Capra Pyrenaica Pyrenaica*) by Cloning*, 71 THERIOGENOLOGY 1026 (2009) (cloning of Pyrenean ibex); M. Hajian et al., *"Conservation Cloning" of Vulnerable Esfahan Mouflon (*Ovis Orientalis Isphahanica*): in Vitro and in Vivo Studies*, 57 EUR. J. WILDLIFE RSCH. (2011) (cloning of Esfahan mouflon); Jonathan Wosen, *San Diego Zoo Scientists Revive Cells from 40-year Deep Freeze to Clone Endangered Horse*, L.A. TIMES (Oct. 13, 2020), https://www.latimes.com/california/story/2020-10-

Ann now holds a special place in the black-footed ferret family tree, as she is the only black-footed ferret alive that is not a descendent of the same seven ancestors.[4]

Over the last 150 years, black-footed ferrets have routinely been among the most endangered mammals in North America.[5] Black-footed ferrets are almost entirely reliant upon prairie dogs as their source of food and habitat.[6] Since the early 1900s, prairie dogs have faced intense persecution; widespread poisoning schemes and conversion of prairies to croplands led to a nearly 98% reduction in their range.[7] As the prairie dog population declined, so did the ferrets. Moreover, introduced sylvatic plague has ravaged both of these species.[8] On two separate occasions, black-footed ferrets were believed to be extinct.[9]

In 1986, the United States Fish and Wildlife Service ("FWS"), in cooperation with the Wyoming Game and Fish Department, made the decision to capture all remaining wild black-footed ferrets and bring them into a captive breeding program.[10] Eighteen individuals were captured, but only seven of these reproduced.[11] Elizabeth Ann is cloned from a ferret that died in the 1980s without leaving any progeny. As a result, her nuclear genome contains nearly three times more unique genetic variation than the entire living population of black-footed ferrets, which today numbers in the thousands.[12] If Elizabeth Ann could be successfully integrated back into the broader black-footed ferret species,[13] it could help add new genetic variation into the gene pool, a process known as genetic

13/san-diego-zoo-scientists-use-cells-frozen-away-for-40-years-to-clone-endangered-przewalskis-horse [https://perma.cc/T3VU-7JX4] (cloning of Przewalski's horse).

4 *Innovative Genetic Research*, *supra* note 1.

5 *See* Wisely, Ryder, Santymire, Engelhardt & Novak, *supra* note 2, at 582.

6 *Id.* at 584.

7 Brian Miller, Gerardo Ceballos & Richard Reading, *The Prairie Dog and Biotic Diversity*, 8 CONSERVATION BIOLOGY 677, 678 (1994).

8 Wisely, Ryder, Santymire, Engelhardt & Novak, *supra* note 2, at 585.

9 *Id.* at 584.

10 *Id.* at 585.

11 *Id.*

12 *Innovative Genetic Research*, *supra* note 1.

13 At this point, there are no plans to integrate Elizabeth Ann into the broader ferret population. She will be monitored in captivity to learn more about the long-term effects of cloning in this species. Additionally, by virtue of the cloning procedures used to birth her, her mitochondrial genome is actually that of her surrogate mother, a domestic ferret. The important thing is that her birth has proven that cloning is possible in this species and opens the door for future projects using black-footed ferrets as surrogates. *Id.*

rescue. By doing so, the overall adaptability of the black-footed ferret population could be increased.[14]

While the concept of genetic rescue as a conservation tool has been around for decades,[15] the utilization of biotechnology in this fashion is novel.[16] Assisted reproductive techniques ("ARTs"), such as in vitro fertilization and cloning, might be the first biotechnological techniques used in wildlife conservation, but they certainly will not be the last. Synthetic conservation, also known as conservation engineering, is the use of genetic engineering techniques for the protection of biodiversity, and these synthetic conservation tools are now being developed in laboratories around the world. Conservation engineering allows us to do more than just rescue—we can change and modify genomes, hijacking evolution to direct the evolutionary trajectory of a species. For example, Revive & Restore, one of the partner organizations responsible for cloning Elizabeth Ann, is currently investigating the use of genetic engineering to introduce plague resistance into black-footed ferrets.[17] Disease resistance is not the only trait likely to be added or modified. Adaptive traits, such as heat and drought tolerance, are already being suggested, and in some cases tested in laboratories, as a mechanism for adapting species to a rapidly changing climate.[18] This process of manipulating the evolution of species is called assisted evolution.[19]

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14 For a background on the process of genetic rescue, see generally Donovan A. Bell et al., *The Exciting Potential and Remaining Uncertainties of Genetic Rescue*, 34 TRENDS ECOLOGY & EVOLUTION 1070 (2019) (discussing misunderstood aspects of genetic rescue); Andrew R. Whiteley, Sarah W. Fitzpatrick, W. Chris Funk & David A. Tallmon, *Genetic Rescue to the Rescue*, 30 TRENDS ECOLOGY & EVOLUTION 42 (2015) (discussing the impact of genomics on recent studies in gene rescue).

15 For example, the theory behind genetic rescue extends back to the early days of the field of population genetics. *See* Sewall Wright, *Evolution in Mendelian Populations*, 16 GENETICS 97, 97 (1931); Sewall Wright, *Breeding Structure of Populations in Relation to Speciation*, 74 AM. NATURALIST 232, 233 (1940). In practice, genetic rescue was first being used in the early 1990s. *See* Thomas Madsen, Richard Shine, Mats Olsson & Håkan Wittzell, *Restoration of an Inbred Adder Population*, 402 NATURE 34, 34 (1999); Warren E. Johnson et al., *Genetic Restoration of the Florida Panther*, 329 SCIENCE 1641, 1642 (2010).

16 Wisely, Ryder, Santymire, Engelhardt & Novak, *supra* note 2, at 582.

17 *The Black-footed Ferret Project*, *supra* note 2; Ben Novak et al., *A Proposal for Genomically Adapting Black-footed Ferrets for Disease Immunity*, N.Y. TIMES (Jan. 4, 2016), https://cdn1.nyt.com/packages/pdf/opinion/greenhouse/BF-FUSFWSproposal2.pdf.pdf [https://perma.cc/82GR-BZJG].

18 For an example in coral, see Phillip A. Cleves, Marie E. Strader, Line K. Bay, John R. Pringle & Mikhail V. Matz, *CRISPR/Cas9-mediated Genome Editing in a Reef-building Coral*, 115 PROC. NAT'L ACAD. SCI. U.S. 5235, 5236 (2018).

19 *See infra* Section I.

Despite the potential benefits of conservation engineering, manipulating wildlife in this manner is, and will likely always be, contentious. Outside of use in basic scientific research, genetic engineering has generally failed to gain widespread public acceptance.[20] For example, despite decades of research and widespread approval within the scientific community, only 37% of American adults believe that it is safe to consume genetically modified foods.[21] Acceptance of genetic engineering for conservation is still largely in its infancy. Around 37.3% of respondents in a recent study agreed that it was "[m]orally acceptable to improve survival" of endangered species via genetic engineering, while 29.4% of respondents disagreed.[22] At the same time, between half and three-quarters of respondents in that same study believed that gene editing wildlife "messes with nature" and "allows humans to play God."[23]

Battles over which forms of conservation are ethically sound and over the proper scope of conservation goals are nothing new; many of the issues brought to the forefront by conservation engineering are just high-tech versions of conversations from our past. The fundamental question of "modern environmentalism" is determining the appropriate level of "'correct' human stewardship."[24] This is the same question we have been asking since the days of Pinchot and Muir—is nature a place full of resources for us to control or a place that

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20 *Public and Scientists' Views on Science and Society*, PEW RES. CTR. (Jan. 29, 2015), https://www.pewresearch.org/science/2015/01/29/public-and-scientists-views-on-science-and-society/ [https://perma.cc/6WUZ-58DH].

21 *Id.*

22 P.A. Kohl, D. Brossard, D.A. Scheufele, & M.A. Xenos, *Public Views About Editing Genes in Wildlife for Conservation*, 33 CONSERVATION BIOLOGY 1286, 1291 (2019). It is worth noting that these surveys are notoriously reliant on the exact wording of the question asked. For example, the same study found that only 31.8% of respondents agreed that it was "morally acceptable to decrease or eliminate wildlife populations," while a recent Pew survey instead found that 70% of respondents felt that genetically engineering "mosquitos to prevent their production and therefore the spread of some mosquito-borne diseases" was an "appropriate use of technology." *Compare id.* (describing how survey respondents were split regarding whether it would be beneficial to edit wildlife genomes), *with* Cary Funk & Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals That Benefits Human Health, but Many Oppose Other Uses*, PEW RES. CTR. (Aug. 16, 2018), https://www.pewresearch.org/science/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses/ [https://perma.cc/AF6U-G79E] (describing how survey respondents' views vary widely on the benefits of editing animal genomes).

23 Kohl, Brossard, Scheufele & Xenos, *supra* note 22.

24 A. Dan Tarlock, *Is There a There There in Environmental Law?*, 19 J. LAND USE & ENV'T L. 213, 222–23 (2004).

must be left exactly as it was found?[25] For wildlife conservation, this ultimately boils down to asking how much and what kinds of intervention are warranted and acceptable.

Today, our collective answers to these questions must be given in light of the condition of the world we are trying to conserve. We are firmly in the midst of a mass extinction event; among the survivors, there are widespread population declines, range contractions, and extirpations.[26] The climate is warming at an unprecedented rate.[27] Habitat is being destroyed, developed, and fragmented across the globe.[28] Plastic has worked its way into every conceivable nook and cranny of the globe,[29] and organisms from across the taxonomic spectrum have been moved, either purposefully or accidentally, into new locations and ecosystems.[30] The epoch of man, the Anthropocene, is here to stay, and our conservation actions and goals will need to be reconsidered with this mass global change in mind.

In the face of this global change, we are left with just three pathways for conservation to proceed: do nothing, respond passively, or actively manage changing ecosystems.[31] Clearly, doing nothing is not a viable solution to meeting our biodivers-

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25 For a comparison of the philosophies of Gifford Pinchot, John Muir, and Aldo Leopold, see J. Baird Callicott, *A Brief History of American Conservation Philosophy*, in SUSTAINABLE ECOLOGICAL SYSTEMS: IMPLEMENTING AN ECOLOGICAL APPROACH TO LAND MANAGEMENT 10, 11–13 (1993).

26 Gerardo Ceballos, Paul R. Ehrlich & Rodolfo Dirzo, *Biological Annihilation via the Ongoing Sixth Mass Extinction Signaled by Vertebrate Population Losses and Declines*, 113 PROC. NAT'L ACAD. SCI. U.S. E6089, E6094 (2017).

27 *See generally* INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE 2021: THE PHYSICAL SCIENCE BASIS (2021), https://report.ipcc.ch/ar6/wg1/IPCC_AR6_WGI_FullReport.pdf [https://perma.cc/2UFF-D6PT].

28 *E.g.*, Kevin R. Crooks et al., *Quantification of Habitat Fragmentation Reveals Extinction Risk in Terrestrial Mammals*, 114 PROC. NAT'L ACAD. SCI. U.S. 7635, 7635 (2017).

29 Matthew MacLeod, Hans Peter H. Arp, Mine B. Tekman & Annika Jahnke, *The Global Threat from Plastic Pollution,* 373 SCIENCE 61, 61 (2021).

30 *See e.g.*, Ben J. Novak, Ryan Phelan & Michele Weber, *U.S. Conservation Translocations: Over a Century of Intended Consequences*, 3 CONSERVATION SCI. & PRAC. 1, 2 (2021) (discussing how conservation translocations can restore ecological dynamics).

31 Alejandro E. Camacho, *Assisted Migration: Redefining Nature and Natural Resource Law Under Climate Change*, 27 YALE J. REG. 171, 211 (2010) ("In addressing the effects of climate change on biological systems, natural resource managers ultimately will have the choice of four basic options. The first is doing nothing, allowing existing biological communities and landscapes to change and often decline in ecological function and biodiversity without human management. Another is to rely on passive resource management strategies . . . [which] focus on increasing the capacity of native species and biological communities to better accommodate and adapt to climate changes, but would involve little active human management of such interactions. Third, managers could actively manage biological communities and landscapes . . . .").

ity conservation goals; the vast majority of species protected under the ESA are judged to be reliant on management in order to survive.[32]

Passive management has historically been the de jour strategy for wildlife management. For centuries wildlife conservation was approached through either "hook-and-bullet" management, such as restrictions on harvest, trafficking, and take, or through land use regulations on habitat, such as the establishment of reserves and wilderness area, conservation easements, wildlife connectivity corridors.[33] While these passive strategies are not going to be fully supplanted any time soon, there is a growing acceptance that the management tools of the past will not be enough to overcome the sheer scale and intensity of the problems we face today.[34]

Active management, on the other hand, places humanity in a position of primacy. We created the catastrophe; we drove these population declines, extirpations, and extinctions. Therefore, we might believe that the only way to fix the mess we made is through further intervention. Active management is not a new phenomenon; Aldo Leopold claimed that "game [could] be restored by the creative use of the same tools which have heretofore destroyed it—axe, plow, cow, fire, and gun."[35] During Leopold's era, active management was largely used to increase available game through aggressive predator removal schemes, artificial propagation of game, and the introduction of

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[32] J. Michael Scott, Dale D. Goble, Aaron M. Haines, John A. Wiens & Maile C. Neel, *Conservation-reliant Species and the Future of Conservation*, 3 CONSERVATION LETTERS 91, 93–94 (2010); Dale D. Goble, John A. Wiens, J. Michael Scott, Timothy D. Male & John A. Hall, *Conservation-reliant Species*, 62 BIOSCIENCE 869, 870 (2012).

[33] Dale D. Goble, *Evolution of At-risk Species Protection*, *in* 2 THE ENDANGERED SPECIES ACT AT THIRTY: CONSERVING BIODIVERSITY IN HUMAN-DOMINATED LANDSCAPES 6, 6 (J. Michael Scott, Dale D. Goble & Frank W. Davis eds., 2006) ("Wildlife conservation has historically employed two sets of tools. The first, 'hook-and-bullet' game management, relies on take restrictions such as closed seasons and bag limits to maintain huntable populations; its use can be traced back nearly a millennium. The second, habitat protection, is equally ancient. Both the king in Parliament and colonial American legislatures routinely restricted land uses to conserve habitat." (internal citations omitted)).

[34] For example, a recent International Union for Conservation of Nature ("IUCN") report suggests that meeting the United Nations' target of protection for 30% of all lands and seas would still be insufficient to halt current trends of biodiversity loss. *See* Executive Secretary of the Secretariat of the Convention on Biological Diversity, *Expert Input to the Post-2020 Global Biodiversity Framework: Transformative Actions on all Drivers of Biodiversity Loss are Urgently Required to Achieve the Global Goals by 2050*, at 71, U.N. Doc. CBD/WG2020/3/INF/11 (Jan. 14, 2022).

[35] Goble, *supra* note 33, at 12 (emphasis omitted) (quoting ALDO LEOPOLD, GAME MANAGEMENT xxxi (1933)).

non-native fish and wildlife to increase available sporting opportunities.[36] Today, instead, active management strategies tend to be focused on captive breeding, habitat restoration, and management of invasive or predatory species.[37]

Active management is contentious because it requires us to make choices—often difficult choices.[38] It requires us to make decisions about humanity's role in nature and how much intervention is acceptable. We are forced to grapple with whether or not the wildlife and landscapes we set out to protect are still the same when our management ends. Moreover, it requires us to make decisions about the end goals of management. Do we try to return the environment to some approximation of a pre-Columbian baseline? Do we accept that our world is heating up and, as such, make decisions based on adaptation rather than preservation? Active management brings these thorny issues to the forefront.

We must act with humility[39] and an understanding that we do not, and never will, completely understand.[40] But, whether we like it or not, we must act.[41] We find ourselves in the epoch

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36 *Id.*

37 Scott, Goble, Haines, Wiens & Neel, *supra* note 32, at 93 (grouping active management of endangered species into five different groups of strategies: control of other species; active habitat management; control of direct human impacts; artificial recruitment; and pollution control).

38 I contend that this distinction is not entirely true nor fair. Passive management also requires us to make many of these choices. Choices about which species to offer protections for or which to purchase habitat for are every bit as difficult and value-laden as choices about captive breeding or evolutionary rescue schemes. Pretending that passively managing allows us to make less difficult choices, in my view, just puts us in the position of the ostrich with his head in the sand.

39 John Copeland Nagle, *Humility and Environmental Law*, 10 LIBERTY U. L. REV. 335, 336–37 (2016) (arguing for humility towards both the environment, "the need for restraint and for care in light of our lack of knowledge about the environmental impacts of our actions," and towards the law, taking "cautions against exaggerated understandings of our ability to create and implement legal tools that will achieve our intended results"); Karrigan Börk, *Governing Nature:* Bambi *Law in a* Wall-E *World*, 62 B.C. L. REV. 155, 160–61 (2021) (When discussing active ecosystem management "[w]e must approach this process with humility, but nevertheless, we must approach it because many, maybe most, ecosystems now require ongoing human intervention at a massive scale to maintain a semblance of their historic conditions or to protect their desirable traits.").

40 For example, *see* Reed F. Noss, *Some Principles of Conservation Biology, as they Apply to Environmental Law*, 69 CHICAGO-KENT L. REV. 893, 898 (1994) (Professor Noss outlines principles from conservation biology that apply to environmental law. His first principle is that "[e]cosystems are not only more complex than we think, but more complex than we can think." (emphasis omitted)).

41 Evelyn Brister, J. Britt Holbrook & Megan J. Palmer, *Conservation Science and the Ethos of Restraint*, 3 CONSERVATION SCI. & PRAC. 1, 4 (2021) (arguing that the ethos of restraint should be replaced with an ethos of responsible conservation action).

of human influence. Humanity has, intentionally or unintentionally, reached out and touched every corner of the Earth.[42] The kinds of problems that assisted evolution could help alleviate are all hallmarks of the Anthropocene: a warming climate, introduced diseases, invasive species, and small and isolated populations. Despite the promise, assisted evolution will certainly be contentious, even by active management standards. Conservation engineering is upfront about its goals and objectives—that species we value will go extinct unless we help them adapt to the world we are headed towards. It requires us to admit that nature will not fix itself and accept that sometimes the best solution is for us to pick a different evolutionary path for these species to tread.

Yet, this Article is not written to portray bioengineering as a panacea for wildlife conservation. Nor is genetic engineering some technofix that absolves us from humanity's role in biodiversity loss. Reintroducing ancestral genetic diversity or adapting species to a changing climate will prove little more than a temporary salve if the loss of habitat is so complete as to bar recovery. Many threats that endangered species face will simply not be solved by any amount of genetic tinkering.

Despite these limits, I argue that genetic engineering can facilitate the recovery of some listed species. Many threats that listed species face are unlikely to be abated using traditional conservation approaches, forcing us to perpetually manage. Conservation engineering could offer a path to recovery. Further, I argue that our actions have already permanently modified "natural" genomes. Our current management strategies also clearly impinge upon the "wildness" of these species. With this in mind, taking a more informed and active role in that modification, limiting the temporal scope of management, is important for the future of wildlife conservation.

In Section I of the Article, I give a background on genetic intervention and assisted evolution, explaining how they work, how they are connected to biotechnology, and demonstrating that we have been engaging in assisted evolution for much longer than we like to admit. In Section II, I introduce the general provisions of the ESA and argue that genetically engineered ("GE") variants of listed species can be protected under the ESA. In Section III, I contend that assisted evolution is contentious because it pits the goals of protection of species and preservation of functioning ecosystems against deeply in-

42 *See infra* Section III.

grained views that wildlife fit into discrete, genetically "pure" types that should exist "wild" and "natural" outside of our influence. In Section IV, I demonstrate that current biotechnology regulations offer spotty, imperfect regulatory coverage of conservation engineering. In Section V, I focus on regulation of genetic engineering for listed species under the ESA, by narrowing in on the recovery permitting process, the Controlled Propagation regulations, the Section 10(j) experimental population procedures, and special 4(d) rules. Finally, in Section VI, I make suggestions to improve the regulation of GE listed organisms under the ESA and suggest factors for how the implementing agencies should utilize and implement this permitting power.

I
DEFINING ASSISTED EVOLUTION

Assisted evolution is human intervention to drive evolutionary change in a species.[43] Generally, the targeted organisms, without intervention, are unlikely to be able to adapt to some specific threat.[44] Typically, these threats are novel, on an evolutionary timescale, and, like most of the threats endangered species face, anthropogenic in nature.[45] Threats are also likely to be persistent and intractable, making them unlikely to be resolved in the near future.[46] Therefore, the idea behind an

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43 Karen Filbee-Dexter & Anna Smajdor, *Ethics of Assisted Evolution in Marine Conservation*, 6 FRONTIERS MARINE SCI. 1, 2 (2019) ("Assisted evolution is a conservation strategy that involves manipulating the genes of organisms in order to enhance their resilience to climate change and other human impacts. . . . Assisted evolution strategies aim to accelerate the rate of naturally occurring evolutionary processes."); Thomas A. Jones & Thomas A. Monaco, *A Role for Assisted Evolution in Designing Native Plant Materials for Domesticated Landscapes*, 7 FRONTIERS ECOLOGY & ENV'T 541, 546 (2009); Madeleine J.H. van Oppen, James K. Oliver, Hollie M. Putnam & Ruth D. Gates, *Building Coral Reef Resilience Through Assisted Evolution*, 112 PROC. NAT'L ACAD. SCI. U.S. 2307, 2307 (2015).

44 van Oppen, Oliver, Putnam & Gates, *supra* note 43.

45 One exception to the "threats are anthropogenic in nature" rule of thumb is the ongoing spread of devil facial tumor disease ("DFTD") in populations of Tasmanian devils. DFTD is an emerging infectious disease and one of just a handful of transmissible cancers ever discovered. Since the emergence of DFTD in the mid-1990s, the population has declined by 80%. Conservation efforts have involved setting up a captive population away from Tasmania and attempting to discover and spread DFTD-resistant genotypes. *See* Paul A. Hohenlohe et al., *Conserving Adaptive Potential: Lessons from Tasmanian Devils and Their Transmissible Cancer*, 20 CONSERVATION GENETICS 81, 82 (2019); Amanda R. Stahlke et al., *Contemporary and Historical Selection in Tasmanian Devils (*Sarcophilus Harrisii*) Support Novel, Polygenic Response to Transmissible Cancer*, 288 PROC. ROYAL SOC'Y B 1, 2 (2021).

46 Tiffany A. Kosch et al., *Genetic Approaches for Increasing Fitness in Endangered Species*, TRENDS ECOLOGY & EVOLUTION 332, 332 (2022) ("Threats such as

assisted evolution project is that an intervening action will stimulate an evolutionary response.[47] The intervention will change not only the individual organisms in the present, but also the descendants of these organisms into perpetuity.[48] Thus, the genetic intervention is an attempt to redirect the current evolutionary trajectory of the species. Assisted evolution bucks conventional evolution by adding an orthogenetic bent to proceedings; we are instilling "purpose" and an "end goal" into an otherwise directionless system.[49]

While natural history is filled with stories of species rapidly adapting to new selective constraints,[50] this tends to be the exception rather than the rule.[51] Most species simply do not possess the requisite life strategies or standing genetic diversity to be able to respond to rapid change.[52] The ability of a species to respond to novel threats is tied into how much

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emerging infectious diseases and climate change have increased the number of conservation-reliant species, but no effective methods have been developed to restore threatened species in the wild if the threats cannot be mitigated.").

47 Filbee-Dexter & Smajdor, *supra* note 43.

48 Not all modifications will persist truly into perpetuity. Genetic drift will result in variation being lost. Additionally, if the selective landscape changes, then other variants could be selected for instead.

49 One of the central tenets of the modern evolutionary synthesis is the rejection of teleology in evolution. For example, George Gaylord Simpson stated that evolution was not a "steady progression towards a discernible goal." Julian Huxley argued that there was no "predetermined goal" in evolution. George Stebbins argued that "evolution is devoid of purpose." *See* F.J.K. Soontiëns, *Evolution: Teleology or Chance?*, 22 J. GEN. PHIL. SCI. 133, 134–35 (1991); Colin Allen & Jacob Neal, *Teleological Notions in Biology*, STAN. ENCYC. PHIL. (Feb. 26, 2020), https://plato.stanford.edu/entries/teleology-biology/ [https://perma.cc/G44X-CDNY].

50 The peppered moth is perhaps the most famous example. Peppered moths rely on camouflage. Prior to the late 1800s the most common coloration for a peppered moth was a white-bodied morph, allowing them to blend in with the tree bark and lichen they upon which they primarily rested. However, during the Industrial Revolution in England, many of their resting places became covered in soot. The dark-colored morph then grew in frequency because the dark coloration was better camouflage. For a general overview of the peppered moth story, see Michael E.N. Majerus, *Industrial Melanism in the Peppered Moth,* Biston Betularia*: An Excellent Teaching Example of Darwinian Evolution in Action*, 2 EVOLUTION: EDUC. & OUTREACH 63, 63–64 (2009). Darwin's famed finches in the Galapagos serve as another example of rapid evolution. Adaptive radiation is a process through which a species evolves into multiple new species very quickly, often in response to changes in the environment or open ecological niches. Today, there are fifteen recognized species of Darwin's finches in the Galapagos, and all are believed to have evolved from a single ancestor within the last one to three million years. *See* Sangeet Lamichhaney et al., *Evolution of Darwin's Finches and Their Beaks Revealed by Genome Sequencing*, 518 NATURE 371, 371 (2015).

51 *See generally* DOUGLAS J. FUTUYMA & MARK KIRKPATRICK, EVOLUTION (4th ed. 2017) (explaining the basic principles of evolutionary biology).

52 *See* Ary A. Hoffman & Carla M. Sgrò, *Climate Change and Evolutionary Adaptation*, 470 Nature 479, 479 (2011).

standing genetic diversity already exists in the species—effectively, how diverse and how large is the already existing gene pool.[53] Generally, the more individuals in a species, the more unique genetic material will exist.[54] Further, species that have shorter generation times are most likely to be able to evolve more quickly, as there are more opportunities for selection to occur and new mutations to arise.[55] Unsurprisingly, endangered and threatened species tend to have lower genetic diversity, fewer individuals, and longer generation times, making them the most likely to be in need of assisted evolution.[56]

A. Mechanisms of Assisted Evolution

To truly understand how assisted evolution is both similar to and wholly unique from other active management strategies requires an understanding of the mechanisms of evolution. There are two different ways to affect the evolutionary trajectory of a species or population: changing the selective forces that are acting upon the species or changing the underlying genetic material that selection acts upon.

1. *Artificial Selection Techniques*

The first way involves changing the external forces that are selecting for specific phenotypes; this is artificial selection. We have wielded selection as a tool for millennia as we have domesticated farm animals and created plants that are un-

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53 *See generally* RICHARD FRANKHAM, JONATHAN D. BALLOU & DAVID A. BRISCOE, INTRODUCTION TO CONSERVATION GENETICS 42 (2d ed. 2010) ("[G]enetic diversity is needed for populations to evolve to adapt to environmental change. . . . Genetic diversity in a population reflects its evolutionary potential.").

54 Under the neutral theory, a population's genetic diversity depends on the effective population size and mutation rates. *See* Motoo Kimura, *Evolutionary Rate at the Molecular Level*, 217 NATURE 624, 626 (1968); M.T.J. Hague & E.J. Routman, *Does Population Size Affect Genetic Diversity? A Test with Sympatric Lizard Species*, 116 HEREDITY 92, 92 (2016). Like any rule, there are exceptions. For example, species like cheetahs or northern elephant seals have undergone historical population declines and bottlenecks leaving them genetically depauperate, despite recovered population sizes. *See* S.J. O'Brien et al., *Genetic Basis for Species Vulnerability in the Cheetah*, 227 SCIENCE 1428, 1429 (1985); Diana S. Weber, Brent S. Stewart, J. Carlos Garza & Niles Lehman, *An Empirical Genetic Assessment of the Severity of the Northern Elephant Seal Population Bottleneck*, 10 CURRENT BIOLOGY 1287, 1287 (2000).

55 Tomoko Ohta, *An Examination of the Generation-time Effect on Molecular Evolution*, 90 PROC. NAT'L ACAD. SCI. U.S. 10676, 10678 (1993).

56 *See* Janna R. Willoughby et al., *The Reduction of Genetic Diversity in Threatened Vertebrates and New Recommendations Regarding IUCN Conservation Rankings*, 191 BIOLOGICAL CONSERVATION 495, 495 (2015) ("We found that both heterozygosity and allelic richness are reduced in threatened species . . . .").

recognizable from their ancestors.[57] From wolf-shaped clay, we have directed into existence everything from Chihuahuas to Great Danes by introducing selective pressures for certain traits we desire.[58] In the wild, selective pressures on food finding, environmental tolerance, and mate-winning result in the fittest individuals having the most offspring, allowing the perpetuation of those traits that confer higher fitness.[59] However, which species are the most "fit" and the traits that confer higher fitness are context specific.[60] Notably, changes in temperature, disease loads, or predator population densities can all change which traits are being selected for in a given population.[61]

The vast majority of our conservation actions change selective pressures, despite their intended focus on affecting demographic, rather than evolutionary, change. In order to protect species, we remove selective pressures in the hopes that species will be allowed to recover more quickly under weaker selection.[62] For example, we historically utilized widespread predator removal in order to supplement certain game populations. Supplemental feeding, captive breeding, translocations, and assisted migration all change the traits that are being selected.[63] Even passive management can change the selective forces at play. For example, regulations that remove the pressures of harvest are also modifying the selective regimes for which listed species would otherwise be subjected.[64]

Artificial selection strategies are now being employed in efforts to save endangered species. In laboratories, scientists are raising animals in captivity and subjecting them to extremely strong selective forces in hopes that those that survive will pass on winning genes. For example, in Australia, biolo-

57 For example, the corn that we eat today looks very little like the teosinte that it was domesticated from over 6,000 years ago. *See* George W. Beadle, *The Ancestry of Corn*, 242 SCI. AM. 112, 112 (1980).

58 *See* Joshua M. Akey et al., *Tracking Footprints of Artificial Selection in the Dog Genome*, 107 PROC. NAT'L ACAD. SCI. U.S. 1160, 1160 (2010).

59 *See generally* FUTUYMA & KIRKPATRICK, *supra* note 51.

60 *Id.*

61 *Id.*

62 For example, 66% of species covered by the ESA require control of other species. Scott, Goble, Haines, Wiens & Neel, *supra* note 32, at 93–95.

63 Atle Mysterud, *Still Walking on the Wild Side? Management Actions as Steps Towards 'Semi-domestication' of Hunted Ungulates*, 47 J. APPLIED ECOLOGY 920, 921 (2010) ("Natural and sexual selection in man-made environments may differ, and some management actions such as harvesting, feeding, fencing and predator control. . . . may cause development of phenotypes with traits closer to a semi-domestic stage.").

64 *Id.* at 922.

gists are attempting to force bilbies and bettongs to evolve defense strategies against feral cats and foxes.[65] To date, the emphasis has been on removing invasive species through aggressive eradication schemes.[66] However, biologists are now exploring the idea that these invasive predators will never be successfully removed from the landscape. Therefore, if native marsupials are ever going to survive outside of human management, coexistence will be needed.[67]

Similarly, many species exhibit narrow bands of climactic tolerance and will soon find swaths of their current distribution unhabitable.[68] One potential solution is assisted migration, the physical moving of species to areas where the future climate will be tolerable, but even this has proven to be a contentious tool.[69] Assisted migration essentially takes a species and moves it to a new geographical location that matches its current ecological niche.[70] Assisted evolution, on the other hand, would see species expand their present tolerances to adapt to the threats affecting their current geographical habitat.[71] For example, researchers have begun to breed coral in hotter water in laboratory settings in the hopes of developing heat-tolerance.[72] Unfortunately, these artificial selection methods rely on the genes that confer the desired trait to already exist in the

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65 Ashely Braun, *Fear the cats! Bold Project Teaches Endangered Australian Animals to Avoid Deadly Predator*, SCI: SCIENCEINSIDER (May 15, 2019), https://www.science.org/news/2019/05/fear-cats-bold-project-teaches-endangered-australian-animals-avoid-deadly-predator [https://perma.cc/BSU7-BUBU]; Katherine Moseby, *So You Want to Cat-proof a Bettong: How Living with Predators Could Help Native Species Survive*, U. NEW SOUTH WALES: NEWSROOM (Jan. 5, 2022), https://newsroom.unsw.edu.au/news/science-tech/so-you-want-cat-proof-bettong-how-living-predators-could-help-native-species [https://perma.cc/D6DZ-DGJG].

66 Braun, *supra* note 65.

67 *Id.*

68 John A. Wiens, Diana Stralberg, Dennis Jongsomjit, Christine A Howell & Mark A. Snyder, *Niches, Models, and Climate Change: Assessing the Assumptions and Uncertainties*, 106 PROC. NAT'L ACAD. SCI. U.S. 19729, 19729 (2009).

69 *See* O. Hoegh-Guldberg et al., *Assisted Colonization and Rapid Climate Change*, 321 SCIENCE 345, 345 (2008); Malcolm L. Hunter Jr., *Climate Change and Moving Species: Furthering the Debate on Assisted Colonization*, 21 CONSERVATION BIOLOGY 1356, 1356 (2007); Anthony Ricciardi & Daniel Simberloff, *Assisted Colonization is Not a Viable Conservation Strategy*, 24 TRENDS ECOLOGY & EVOLUTION 248, 248 (2009); Camacho, *supra* note 31, at 173.

70 In some ways, assisted evolution acts opposite of something like assisted migration, because we are preserving species in the ecosystems in which they evolved, instead of preserving species by taking them out of their natural ecosystems.

71 Filbee-Dexter & Smajdor, *supra* note 43.

72 Adriana Humanes et al., *An Experimental Framework for Selectively Breeding Corals for Assisted Evolution*, 8 FRONTIERS MARINE SCI. 1, 1 (2021).

population. No matter how much pressure put on a population, you cannot merely will new genes into existence—selection can only act on the genetic material available.

2. *Gene Flow Techniques*

The second way to affect evolution is by changing the raw material that selection is acting upon—this is the manner in which biotechnology can be used to assist evolution. Changes in the gene pool allow for populations to take different evolutionary directions. Additions to the gene pool arise through novel mutations or through gene flow, the influx of genes from a different population or species.[73] Gene pools can also lose variation simply through random chance, known as genetic drift.[74] Our biotechnological assisted evolution techniques build off of the principles of either gene flow or mutation.

Genetic rescue is a form of assisted evolution where gene flow is used to combat the detrimental effects of inbreeding depression and small population size by introducing variation into a population to facilitate recovery.[75] For example, by the early 1990s, the Florida panther population had shrunk to fewer than thirty adults.[76] The population was exhibiting signs of inbreeding depression; kittens were born with crooked tails, heart defects, and poor sperm quality.[77] In order to reverse these deleterious genetic effects, pumas from Texas were brought in to interbreed with the Florida panthers.[78] The influx of genes from the outside population completely changed the evolutionary trajectory of the population.[79] Instead of spiraling further down the extinction vortex, the negative fitness effects were alleviated and the population began to recover.[80]

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73 *See generally* FUTUYMA & KIRKPATRICK, *supra* note 51.

74 *Id.*

75 Bell et al., *supra* note 14, at 1071; Whiteley, Fitzpatrick, Funk & Tallmon, *supra* note 14, at 42.

76 Johnson et al., *supra* note 15, at 1642.

77 *Id.*

78 *Id.* FWS considers the Florida panther (*Puma concolor coryi*) to be a separate subspecies from the pumas in Texas (*Puma concolor cougar*). However, most scientist now consider them part of the same subspecies. M. Culver, W.E. Johnson, J. Pecon-Slattery & S.J. O'Brien, *Genomic Ancestry of the American Puma (*Puma Concolor*)*, 91 J. HEREDITY 186, 190 (2000).

79 Johnson et al., *supra* note 15; Alexander Ochoa, David P. Onorato, Robert R. Fitak, Melody E. Roelke-Parker & Melanie Culver, *De Novo Assembly and Annotation from Parental and F_1 Puma Genomes of the Florida Panther Genetic Restoration Program*, 9 G3 GENES GENOMICS GENETICS 3531, 3532 (2019).

80 Johnson et al., *supra* note 15, at 1642.

By translocating pumas from Texas to south Florida, and hybridizing the two together, the Florida panther was saved.[81]

Traditionally, genetic rescue has been used to alleviate deleterious effects seen in small, isolated populations.[82] Recently, however, the strategy has been suggested to spread specific desirable traits from one population or species to another. For example, Tasmanian devils suffer from an infectious cancer that has rapidly spread across the island of Tasmania, decimating devil populations.[83] One strategy for dealing with the cancer is to use genomic screens to find devils that might possess some genetic immunity to the cancer.[84] Once these variants are discovered, the devils that possess these traits can be used for captive breeding and translocation efforts to introduce immunity genes into other populations.[85] Similarly, as previously mentioned, other researchers are working to apply extreme selective pressure, such as warm water for coral[86] or predation from invasive cats for marsupials,[87] to a captive population. The idea is that this will select for useful standing variation and that the progeny can then be translocated back into wild populations to spread those genes.

Translocations and hybridization are ways to spark a genetic rescue, but recently biotechnology has also been suggested. In vitro fertilization using cryopreserved zygotes and somatic cell cloning using bio-banked tissues are now being used to mine the past for lost genetic variants.[88] The evolutionary process at work is identical to the traditional genetic rescue example of the Florida panther; genetic diversity can be supplemented by the addition of variation that was lost over time due to population declines.[89]

Genetic engineering can also be used to approximate gene flow. Traditionally, genetic engineering involved taking a gene from one organism and splicing it into the genome of a different

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81 *Id.*

82 Bell et al., *supra* note 14, at 1072; Whiteley, Fitzpatrick, Funk & Tallmon, *supra* note 14, at 43.

83 Hohenlohe et al., *supra* note 45.

84 *Id.* at 82.

85 *Id.* at 83.

86 Humanes et al., *supra* note 72, at 1.

87 Braun, *supra* note 65.

88 Wisely, Ryder, Santymire, Engelhardt & Novak, *supra* note 2, at 582; Oliver A. Ryder et al., *Exploring the Limits of Saving a Subspecies: The Ethics and Social Dynamics of Restoring Northern White Rhinos (*Ceratotherium Simum Cottoni*)*, 2 CONSERVATION SCI. & PRAC. 1, 1 (2020) [hereinafter Ryder et al., *Exploring the Limits*]

89 Ryder et al., *Exploring the Limits*, *supra* note 88, at 3.

organism, creating a transgenic organism. Whereas hybridization requires a full mixing of genomes, transgenic engineering inserts just the targeted gene. This allows for gene flow from species that would ordinarily be too evolutionarily distant to hybridize without assistance. The targeted insertion of a single gene also minimizes the transfer of unwanted genetic material into the gene pool of the recipient. This technique is being used to insert a gene from wheat into the American chestnut (*Castanea dentata*) genome in order to fight the introduced chestnut blight (*Cryphonectria parasitica*).[90] The gene that is inserted codes for an enzyme called oxalate oxidase; this enzyme breaks down the chemical the fungus secretes that kills plant tissue.[91] These transgenic chestnuts will still be infected by the blight, but they are significantly less likely to die.[92] They will live to spread this gene onto the next generation, and the trait will persist due to the fitness benefits it bestows.

3. *Mutation Techniques*

Until recently, our reach has been limited to shuffling around the building blocks we find in nature, relying on mimicking gene flow in order to intervene and direct evolution. Cloning allows us to bring back genetic pieces we lost, and transgenic engineering allows us to move genetic pieces around from one species to another. The last decade, however, has seen a boom in genome editing technologies, with CRISPR/Cas systems infiltrating nearly every area of biological research.[93] These technologies work by cutting DNA at specific, targeted sites and allowing the organism's own DNA repair system to fix the cuts based on the inserted sequence.[94] These tools allow researchers to delete or modify existing sequences or to insert new sequences at a single site or on a larger scale.[95] Cloning is, essentially, making a photocopy of a document, while transgenic engineering methods are the copy-and-paste function on

90 William A. Powell, Andrew E. Newhouse & Vernon Coffey, *Developing Blight-tolerant American Chestnut Trees*, COLD SPRING HARBOR PERSP. BIOLOGY 1, 1 (2019); Andrew E. Newhouse & William A. Powell, *Intentional Introgression of a Blight Tolerance Transgene to Rescue the Remnant Population of American Chestnut*, CONSERVATION SCI. & PRAC. 1, 2 (2021).

91 Powell, Newhouse & Coffey, *supra* note 90, at 6.

92 *Id.* at 7.

93 *See* Le Cong et al., *Multiplex Genome Engineering Using CRISPR/Cas Systems*, 339 SCIENCE 819, 822 (2013); Martin Jinek et al., *A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE 816, 816 (2012).

94 Cong et al., *supra* note 93, at 820–21.

95 *Id.* at 822.

a word processor. Gene editing, on the other hand, operates like the find-and-replace function, allowing researchers to make highly specific edits to add, modify, or delete base pairs.[96]

Gene editing can be used to approximate both gene flow and mutation. The advent of novel sequencing and DNA extraction techniques has allowed us to dig into the past like never before. Using museum collections and paleontological discoveries, we can explore at least a portion of the genetic diversity that may have been lost over time.[97] For most species, cryopreserved tissues for cloning and assisted reproduction simply do not exist. However, CRISPR and related gene editing technologies could be used to affect genetic rescue using sequences discovered in these museum samples and recreated via CRISPR.

Finally, more novel uses of CRISPR allow us to mimic mutation, rather than gene flow, and add completely novel variation into genomes. With CRISPR, we can make site-specific edits in a genome, meaning we are no longer constrained to paint within the proverbial lines. For example, CRISPR might be used to fight introduced diseases; assisted evolution projects using CRISPR are being considered to help black-footed ferrets evolve to deal with sylvatic plague,[98] to endow a number of endemic Hawaiian birds with the capability to resist avian malaria,[99] and to fight chytrid fungus in amphibians.[100] These diseases were introduced by human activity and

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96 *Id.* at 820.

97 Richard T. Corlett, *A Bigger Toolbox: Biotechnology in Biodiversity Conservation*, 35 TRENDS BIOTECH. 55, 57 (2017) ("Museum and herbarium specimens provide historical information that can be used to assess recent genetic changes and inform decisions on conservation interventions, such as translocations and assisted gene flow."); Michael P. Phelps, Lisa W. Seeb & James E. Seeb, *Transforming Ecology and Conservation Biology Through Genome Editing*, 34 CONSERVATION BIOLOGY 54, 62 (2019) ("To save species from extinction, genome editing and other synthetic biology approaches may provide a tool to rebuild lost beneficial genetic traits or remove deleterious recessive mutations from inbred populations. . . . [S]ynthetic biology or genome editing would enable the introduction of genetic adaptations that cannot be obtained through direct breeding, such as genetic traits that have been lost through extinction.").

98 *The Black-footed Ferret Project*, *supra* note 2.

99 Michael D. Samuel, Wei Liao, Carter T. Atkinson & Dennis A. LaPointe, *Facilitated Adaptation for Conservation – Can Gene Editing Save Hawaii's Endangered Birds from Climate Driven Avian Malaria?*, 241 BIOLOGICAL CONSERVATION 1, 3 (2020).

100 Lindsay Renick Mayer, *Queensland Lab Turns to Chytrid-fighting Genes to Save Species on the Brink*, AMPHIBIAN SURVIVAL ALL. (Apr. 2, 2019), https://www.amphibians.org/news/chytrid-fighting-genes-to-save-species-on-the-brink/ [https://perma.cc/CF9Z-5F87].

threaten to eradicate these species because they have no naturally evolved defense mechanisms.[101] Given enough time and individuals, genetic variants that code for resistance to the disease would likely spread throughout the population, but frankly, many species do not have enough time. Beneficial mutations are incredibly rare, and the likelihood of evolving a specific novel trait is astronomically low.[102] Instead, assisted evolution aims to introduce and spread this resistance on a conservation-relevant timescale. Similarly, climate adaptation has been targeted as a trait that might be instilled into wild species, especially coral, using CRISPR.[103] This is a more direct method for achieving the same goal, the ability to persist in warmer water, that the stress-test breeding and hybridization programs are seeking, while also minimizing the overall change in the genome.

B. Genetic Intervention Outside of Assisted Evolution

Genetic intervention can also be used outside of the context of assisted evolution.[104] For example, CRISPR could be used to add "barcodes" into the genome, thus allowing scientists to track individuals and populations for research purposes or for anti-wildlife trafficking purposes.[105] In theory, these barcodes are selectively neutral, so this technique falls outside the realm of assisted evolution.

Additionally, assisted evolution is a direct genetic intervention technique—the organism that is being modified is also the organism gaining the conservation benefit.[106] On the other hand, instead of manipulating the genetics of the targeted spe-

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101 For sylvatic plague, see Michael F. Antolin et al., *The Influence of Sylvatic Plague on North American Wildlife at the Landscape Level, with Special Emphasis on Black-footed Ferret and Prairie Dog Conservation*, TRANSACTIONS 67TH N. AM. WILDLIFE & NAT. RESOURCES CONF. 105, 105 (2002). For avian malaria, see Charles van Riper III, Sandra G. van Riper, M. Lee Goff & Marshall Laird, *The Epizootiology and Ecological Significance of Malaria in Hawaiian Land Birds*, 56 ECOLOGICAL MONOGRAPHS 327, 327 (1986).

102 FRANKHAM, BALLOU & BRISCOE, *supra* note 53, at 55.

103 Cleves, Strader, Bay, Pringle & Matz, *supra* note 18, at 5235.

104 *See* Corlett, *supra* note 97, at 55; Phelps, Seeb & Seeb, *supra* note 97, at 54.

105 Phelps, Seeb & Seeb, *supra* note 97, at 60.

106 John A. Erwin, *Changing Genes for a Changing Climate: Genetic Intervention as a Tool for Biodiversity Conservation in an Era of Climate Change*, *in* HANDBOOK ON BIODIVERSITY LAW AND CLIMATE CHANGE (Richard Caddell & Phillipa McCormack eds., forthcoming); Nicolas O. Rode, Arnaud Estoup, Denis Bourguet, Virginie Courtier-Orgogozo & Florence Débarre, *Population Management Using Gene Drive: Molecular Design, Models of Spread Dynamics and Assessment of Ecological Risks*, 20 CONSERVATION GENETICS 671, 671 (2019).

cies, there are proposals to manipulate other species for the benefit of the target species; this is an indirect genetic intervention.[107] A number of proposals would see microbes or other symbiotes genetically modified to benefit their host species;[108] for example, the microbiome on the skin of amphibians could be modified to fight chytrid,[109] or algae could be modified to help coral withstand bleaching.[110] Invasive species could also be modified to make them less threating to native fauna, such as modifying cane toads to reduce their toxicity[111] or modifying mosquitos to make them less likely to carry disease.[112] Alternatively, the use of genetic engineering to exterminate populations of invasive species[113] or disease vectors[114] is gaining significant attention, especially when coupled with gene drive technology. These techniques will only indirectly relate to the ESA and are largely outside the scope of this Article.

Finally, de-extinction is one of the most talked about uses of synthetic biology in wildlife. The resurrection of long extinct dinosaurs and wooly mammoths has captured the popular narrative on genetic engineering and cloning in wildlife.[115]

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107 Erwin, *supra* note 106.

108 *See* Se Jin Song et al., *Engineering the Microbiome for Animal Health and Conservation*, 244 EXPERIMENTAL BIOLOGY & MED. 494, 495 (2019).

109 Matthew H. Becker et al., *Genetically Modifying Skin Microbe to Produce Violacein and Augmenting Microbiome Did Not Defend Panamanian Golden Frogs from Disease*, 1 ISME COMMC'NS 1, 1(2021).

110 Warren Cornwall, *Researchers Embrace a Radical Idea: Engineering Coral to Cope with Climate Change*, SCIENCE (Mar. 21, 2019), https://www.science.org/content/article/researchers-embrace-radical-idea-engineering-coral-cope-climate-change [https://perma.cc/UV87-B3N5]; van Oppen, Oliver, Putnam & Gates, *supra* note 43, at 2310.

111 Kia Handley, *Controlling Cane Toads Through Genetic Editing*, AUSTL. BROAD. CORP., (Feb. 7, 2021), https://www.abc.net.au/radio/newcastle/programs/mornings/editing-cane-toad-genes-to-make-them-less-toxic/13131938 [https://perma.cc/7LSA-T7UA]; Reid Tingley et al., *New Weapons in the Toad Toolkit: A Review of Methods to Control and Mitigate the Biodiversity Impacts of Invasive Cane Toads (*Rhinella Marina*)*, 92 Q. REV. BIOLOGY 123, 142 (2017).

112 Astrid Hoermann et al., *Converting Endogenous Genes of the Malaria Mosquito into Simple Non-autonomous Gene Drives for Population Replacement*, 10 ELIFE 1, 1 (2021).

113 Antonio Regalado, *First Gene Drive in Mammals Could Aid Vast New Zealand Eradication Plan*, MIT TECH. REV. (Feb. 10, 2017), https://www.technologyreview.com/2017/02/10/5666/first-gene-drive-in-mammals-could-aid-vast-new-zealand-eradication-plan/ [https://perma.cc/8GJ4-RJDL].

114 For example, see Andrew Hammond et al., *Gene-drive Suppression of Mosquito Populations in Large Cages as a Bridge Between Lab and Field*, 12 NATURE COMMC'NS 1, 2 (2021).

115 De-extinction has featured prominently in popular media. For just a few examples, see generally JURASSIC PARK (Universal Pictures 1993); Sherryn Groch, *'The De-extinction Club': Could We Resurrect Mammoths, Tassie Tigers and Dinosaurs?*, SYDNEY MORNING HERALD (July 25, 2021), https://www.smh.com.au/national/the-de-extinction-club-could-we-resurrect-mammoths-tassie-tigers-and-

Venture capital groups are rushing ahead to resuscitate more recent losses, like the thylacine or the dodo.[116] Much of the legal scholarly literature related to synthetic biology and wildlife has similarly been focused on de-extinction.[117] While de-extinction utilizes some of the same techniques and harnesses some of the same evolutionary forces,[118] these are fundamentally different exercises. De-extinction is premised around returning reproductions of organisms that potentially no longer have habitats or ecological niches, and they certainly do not have viable population sizes. However, the ESA instructs the Services to prevent extinction and to recover threatened and endangered species, not further stretch their paper-thin budgets to bring back organisms that look like lost species.[119] Conversely, assisted evolution is focused on recovery, not resurrection. It is intervening to allow species to persist sans human-provided life support. This is addressing real, contemporary conservation problems, not creating facsimiles of species to add onto the life support system.

Ultimately, we have a variety of different techniques for manipulating evolutionary forces to build better species. Our conservation actions approximate natural selection, gene flow,

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dinosaurs-20210703-p586jg.html [https://perma.cc/9749-8NEL]; W.S. Roberts, *The Booming Call of De-extinction*, THESCIENTIST (Oct. 19, 2020), https://www.the-scientist.com/news-opinion/the-booming-call-of-de-extinction-68057 [https://perma.cc/2CXP-ZF5F].

116 Colossal Biosciences has been vocal about their current de-extinction projects with mammoths, thylacines, and dodos. Efforts to reintroduce the thylacine are perhaps the best-case use for de-extinction: a recently extinct keystone species. The reintroduction of this apex predator could help restore ecosystems in Tasmania and beyond. Kate Evans, *De-extinction Company Aims to Resurrect the Tasmanian Tiger*, SCI. AM. (Aug. 16, 2022), https://www.scientificamerican.com/article/de-extinction-company-aims-to-resurrect-the-tasmanian-tiger/ [https://perma.cc/9UVZ-DVHG]; Katie Hunt, *Scientists Plot the Resurrection of a Bird That's Been Extinct Since the 17th Century*, CNN (Jan. 31, 2023), https://www.cnn.com/2023/01/31/world/dodo-bring-back-from-extinction-colossal-scn/index.html [https://perma.cc/JC3Z-HAKD].

117 *See generally* Norman F. Carlin, Ilan Wurman & Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-extinction"* 33 STAN. ENV'T L.J. 3, 7–15 (2013); Alejandro E. Camacho, *Going the Way of the Dodo: De-extinction, Dualisms, and Reframing Conservation*, 92 WASH. U. L. REV. 849, 852–62 (2015); Hope M. Babcock, *The Genie is Out of the De-extinction Bottle: A Problem in Risk Regulation and Regulatory Gaps*, 37 VA. ENV'T L.J. 170 (2019); Erin Okuno, *Frankenstein's Mammoth: Anticipating the Global Legal Framework for De-extinction*, 43 ECOLOGY L.Q. 581 (2016).

118 For instance, many of the techniques are similar. De-extinction, or at least the creation of a similar looking organism, can be accomplished through selective breeding, cloning, transgenesis, and genetic editing. *See* Beth Shapiro, *Pathways to De-extinction: How Close Can We Get to Resurrection of an Extinct Species?*, 31 FUNCTIONAL ECOLOGY 996, 996 (2017).

119 16 U.S.C. § 1531(b).

or mutation, and each changes the genetic composition and evolutionary trajectory of wild species. These techniques can be low-tech, like artificial selection, or make use of cutting-edge biotechnologies, such as CRISPR. Additionally, they can be used in an attempt to return the gene pool to a state seen in the past or to prospectively direct evolution to prepare for future conditions. Assisted evolution could be a useful tool for conservation of listed species, but it will require us to take a hard look at the way the ESA is structured and the values at the heart of that law.

II
THE ENDANGERED SPECIES ACT

In this Section, I will explain that the act of bioengineering, or the fact that an organism descends from a modified ancestor, should not make that individual ineligible for protection based on the statutory language of the ESA, Congress's intent behind the ESA, and the manner in which the agencies have implemented the ESA in the past.

A majority of the projects that utilize biotechnology for wildlife conservation in the United States will almost certainly run through the ESA.[120] The species for which genetic engineering would be worth the time, cost, and social enterprise will likely be already on the brink of extinction. Congress intended the ESA "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, [and] to provide a program for the conservation of such endangered species[.]"[121] To achieve these lofty goals, the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS") (collectively "the Services") are charged "to use . . . all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which [the protections under the Act] are no longer necessary."[122] Generally, these measures include those found in Sections 7 and 9. Section 9 prohibits the harm, transport, sale, and "take" of listed species.[123] "Take" is defined broadly and makes it illegal to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to

120 It is certainly possible that this prediction falls flat. In that case, I do think it is safe to say that the majority of assisted evolution projects will fall under the regulatory authority of the ESA, presuming the Act has not been significantly gutted.

121 16 U.S.C. § 1531(b).

122 *Id.* § 1532(2).

123 *Id.* § 1538.

attempt to engage in any such conduct" without a permit.[124] While Section 9 is a general prohibition against all, Section 7 only applies to federal agencies. Section 7 requires that federal agencies must consult with the Services to ensure that their actions do not jeopardize the continued existence of listed species or adversely modify designated critical habitat.[125] The ESA also authorizes the agencies to undertake active management strategies such as captive breeding, controlled propagation, reintroductions, and translocations as long as they contribute to recovery.[126]

The Section 7 and 9 protections only apply once a species has been listed under the ESA. Section 4 outlines the procedures for listing a species under the ESA.[127] A species can be listed as endangered, when it is "in danger of extinction throughout all or a significant portion of its range,"[128] or threatened, when it is "likely to become an endangered species within the foreseeable future."[129] This determination is to be based on "best scientific and commercial data available"[130] and the Secretary is to consider factors such as habitat loss, overutilization, disease, predation, and the adequacy of existing regulation when making the listing decision.[131]

While this seems like a straightforward statutory scheme, much of the legal complexity of the Act is involved with this initial listing decision.[132] Determining what constitutes a "spe-

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124 *Id.* § 1532(19).

125 *Id.* § 1536(2).

126 *Id.* § 1532(3) ("The terms 'conserve', 'conserving', and 'conservation' mean to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this chapter are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.").

127 *Id.* § 1533.

128 *Id.* § 1532(6).

129 *Id.* § 1532(20).

130 *Id.* § 1533(b)(1)(A).

131 *Id.* § 1533(a)(1) ("The Secretary shall by regulation promulgated in accordance with subsection (b) determine whether any species is an endangered species or a threatened species because of any of the following factors: (A) the present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (B) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.").

132 ERIC T. FREYFOGLE, DALE D. GOBLE & TODD A. WILDERMUTH, WILDLIFE LAW: A PRIMER 238 (2d ed. 2019) ("A surprising portion of the legal complexity of the Endangered Species Act deals with the initial step in the conservation process, the

cies" under the ESA has become one of the most contentious parts of the listing process,[133] and questions about how modified organisms fit into this scheme will certainly do nothing to ameliorate the conflict. Listing essentially proceeds in three steps: (1) determine if the population is a "species" under the Act; (2) determine if that "species" is threatened or endangered; and (3) determine what levels of protection will be applicable.[134]

A. Are GE Organisms Separate "Species"?

The listing process begins by determining if the population is a "species" under the Act.[135] The ESA defines species as including "any subspecies of fish or wildlife or plants, and any distinct population segment ["DPS"] of any species of vertebrate fish or wildlife which interbreeds when mature."[136] Notably, Congress gave no further definition for the terms species and subspecies, leaving it up to the discretion of the agencies.

To determine whether or not a taxon qualifies as a species or subspecies, the Services rely heavily on existing scientific consensus.[137] However, scientists often disagree about taxonomic groupings. Though philosophers and biologists alike have toiled since the days of Aristotle on the question, there still exists no consensus as to the meaning of "species."[138] Today, as many as twenty-six different species concepts are actively competing for use within biological circles.[139] The defi-

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step of identifying and the listing species that are imperiled. Much of the controversy has surrounded three key subissues: what unit of life will be protected (i.e., the 'species'), how we decide whether a species qualifies as threatened or endangered, and how agencies allocate their limited funds for studying species when hundreds of species await their attention.").

133 For example, see Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L.Q. 1029, 1088 (1997) (discussing in part the difficult task of solving the "taxonomy problem" in listing decisions and arguing that improved science will not ultimately solve the problem).

134 Trout Unlimited v. Lohn, 559 F.3d 946, 949–50 (9th Cir. 2009).

135 *Id.*

136 16 U.S.C. § 1532(16).

137 Doremus, *supra* note 133, at 1111 ("Instead, they typically emphasize deference to taxonomists in the relevant field. The agencies' joint listing regulations, for example, call for reliance on 'standard taxonomic distinctions' and the agencies' own biological expertise in determining whether a group of organisms qualifies as a statutory 'species.'"). On the other hand, the agencies will at times substitute their own judgment when they see fit. *Id.* at 1112 ("They have generally deferred to the taxonomic community but occasionally, without explanation, departed from an apparent taxonomic consensus.").

138 Richard Frankham et al., *Implications of Different Species Concepts for Conserving Biodiversity*, 153 BIOLOGICAL CONSERVATION 25, 26 (2012).

139 *Id.*

nition of a subspecies is even more contentious, with drastically different standards applied across even the Animal Kingdom.[140]

In order for a modified organism to fall under the regulatory gamut of the ESA, these organisms need to be listed separately as their own "species" or need to be included as part of an already-listed species. The first option, in which we would define modified organisms as species or subspecies separately from the non-modified organisms, makes little sense. Editing a single gene of a black-footed ferret does not make the offspring a new species, in the same way conservators at the Louvre adding new paint to the Mona Lisa has not caused us to question if she is still the work of DaVinci.

Despite over two dozen species concepts, the addition, removal, or modification of small numbers of genes will not result in the splitting of a species. The exception to this rule would be if the engineering resulted in reproductive isolation, either immediately, through genomic incompatibility, or through ecological speciation over time. Genomic incompatibility is unlikely because these organisms would be useless in terms of rescuing a population. Similarly, for ecological speciation to occur in a rescue scenario, interbreeding would have to be severely limited; this would be a failed rescue as well. The entire point of engineering for conservation is to rescue imperiled populations by spreading the novel trait via interbreeding. Unless the addition of the gene is causing an evolutionary divergence that would eventually lead to speciation through reproductive isolation, then GE organisms should not be classified as separate species or subspecies.

Alternatively, the Services could attempt to list modified organisms as a separate DPS. Congress left it up to the Services to define "DPS" but directed them to use their DPS listing authority "sparingly."[141] Existence of a DPS is determined based on the discreetness and significance of the population segment.[142] For a population to be considered "discreet," it must be "markedly separated from other populations of the

140 Susan M. Haig et al., *Taxonomic Considerations in Listing Subspecies Under the U.S. Endangered Species Act*, 20 CONSERVATION BIOLOGY 1584, 1586 ("Furthermore, we found use of subspecies in modern taxonomy differed by taxonomic group. In general, more subspecies have been described for vertebrates and plants than the less-studied invertebrates and fungi . . . .").

141 Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act, 61 Fed. Reg. 4722, 4724 (Feb. 7, 1996) [hereinafter Joint DPS Policy].

142 *Id.* at 4725.

same taxon as a consequence of physical, physiological, ecological, or behavioral factors."[143] The added or modified genetic material, and the phenotypic changes associated with that genetic material, would make these organisms demonstrably different from other populations. However, it is unclear if a change at a single gene or the change of a single trait is enough to be "markedly separated."

Significance is likely an even more difficult claim to make. Significance can be demonstrated in four different manners: (1) persistence in unusual or unique ecological settings; (2) if the loss of the DPS would result in a significant gap in the range of the taxon; (3) if the DPS is the only natural occurrence of a taxon left in its historic range; and (4) if the DPS differs markedly from other populations in its genetic characteristics. Similar to the discreetness analysis, the question would be whether the changes to a single or small number of genes is enough to differ "markedly."[144] Ultimately, however, the DPS provision is supposed to protect evolutionarily divergent populations.[145] While a small number of changes might have noticeable functional effects, such as disease immunity, the overall patterns of genetic variation in this new DPS would be identical to the population in which the non-modified parents belonged. Additionally, listing GE organisms as a separate DPS would defeat the purpose of creating these organisms in the first place. The goal of using genetic engineering to affect a genetic rescue would be to spread the trait, not to isolate it in a singular, discrete population.

B. Including GE Organisms in the Same "Species"

Attempting to separate GE organisms from their parent taxa by categorizing them as separate species, subspecies, or DPS's is unlikely to be legally defensible, as it diverges so drastically from scientific consensus. Moreover, it is unlikely to help achieve the goals of the conservation engineering.

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143 *Id.* Alternatively, discreteness can be based on whether the population segment is "delimited by international government boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant." *Id.* This avenue seems even less likely to apply.

144 Joint DPS Policy, *supra* note 141, at 4725.

145 The term "DPS" was based on the biological concept of an Evolutionarily Significant Unit ("ESU"). Robin S. Waples, *Distinct Population Segments*, *in* 2 THE ENDANGERED SPECIES ACT AT THIRTY: CONSERVING BIODIVERSITY IN HUMAN-DOMINATED LANDSCAPES 127, 150 (J. Michael Scott, Dale D. Goble & Frank W. Davis eds., 2006) (discussing the creation of the DPS policy and its relation to the ESU framework set forth by Dr. Waples).

Instead, the Services can and should use their discretion to interpret the term "species" in a manner which covers GE organisms. The plain text of the statute clearly supports this interpretation. "Fish or wildlife" are specifically defined as including "[a]ny member of the animal kingdom . . . or . . . offspring thereof."[146] This approach is consistent with how other agencies have defined bioengineered organisms.[147]

This approach is also in line with recent agency actions and case law dealing with captive populations. FWS has stated that its "default practice" is "extending the same listing status to all individuals of a listable entity."[148] For example, the D.C. District Court upheld FWS's decision when it declined to list captive ranched populations of three antelope species as a DPS that was separate from wild antelopes.[149] Similarly, the Ninth Circuit was forced to grapple with whether or not hatchery-raised steelhead were to be included with "natural" fish as part of the same "species" for listing purposes.[150] They held that hatchery steelhead derived from the "natural" population, shared the "same evolutionary . . . legacy," and thus were to be included in the same ESU.[151] In the wake of these cases, FWS combined captive and wild chimpanzees into a single endangered species,[152] and NMFS relisted the Southern Resident Killer Whale DPS to include captive animals.[153] This same logic should bind the Services to include modified organisms in the same "species" with non-modified organisms from the same

146 50 C.F.R. § 81.1(d) (2023). However, this has not always been interpreted faithfully. This rationale was originally used to include hybrids under the Act in the late 1970s before the Solicitor learned about genetic swamping and reversed the policy. *See* Kevin D. Hill, *The Endangered Species Act: What Do We Mean by Species?*, 20 B.C. ENV'T AFF. L. REV. 239, 244 (1993).

147 For example, when biotech crop producers submit letters of inquiry to the Animal and Plant Health Inspection Service, they give a taxonomic description of their product. The species is always listed as the species that was modified, not some new species. *See Regulated Article Letters of Inquiry*, ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/Regulated_Article_Letters_of_Inquiry [https://perma.cc/E22P-LYGA] (last visited June 1, 2023).

148 Safari Club Int'l v. Jewell, 960 F. Supp. 2d 17, 63 (D.D.C. 2013), *appeal dismissed*, 2017 WL 11663346 (D.C. Cir. 2017).

149 *Id.* at 65.

150 Trout Unlimited v. Lohn, 559 F.3d 946, 947 (9th Cir. 2009).

151 *Id.* at 956.

152 Endangered and Threatened Wildlife and Plants; Listing All Chimpanzees as Endangered Species, 80 Fed. Reg. 34,500, 34,500 (June 16, 2015) (codified as amended at 50 C.F.R. pt. 17) [hereinafter Chimpanzee Listing Petition].

153 Listing Endangered or Threatened Species: Amendment to the Endangered Species Act Listing of the Southern Resident Killer Whale Distinct Population Segment, 80 Fed. Reg. 7380, 7380 (Feb. 10, 2015) (codified as amended at 50 C.F.R. pt. 224).

population. The only current examples of split or exclusionary listings involve fish that are endangered in their native range but have invasive, naturalized populations outside of that range.[154]

Finally, this approach best serves the goals of the ESA. When the Services set forth the DPS policy, they stated that "the Services understand the Act to support the interrelated goals of conserving genetic resources and maintaining natural systems and biodiversity over a representative portion of their historic occurrence."[155] These dual purposes were also used as justification for relisting captive and wild organisms together.[156] If the modification of a few genes for climate change adaptation can ensure the persistence of a keystone species, then the rest of the ecosystem as a whole would benefit. Similarly, the use of biotechnology for the reintroduction of genetic diversity could, for many species, be the only way to actually restore lost diversity on a non-evolutionary time scale. Persistence of the species is critical to conserving the most genetic resources available, even if that means triage for the original gene that is being edited and changed.

Ultimately, the same listing status should be extended to all organisms, both modified and non-modified; this interpretation of the Act is most consistent with its purpose and current precedent.

III
Assisted Evolution Challenges Assumptions

While it seems clear to me that organisms modified by a genetic intervention can be covered by the ESA based on the statutory language, for many this is not a satisfying answer. Other scholars have argued that the despite the textual and purposive arguments in favor, protection under the ESA should not extend to modified organisms because "the ESA was not intended to provide protection for new organisms invented by human beings *ab initio*."[157] This "artificiality" is viewed as

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154 This includes the Arkansas River shiner, the arctic grayling, the Santa Ana sucker, and the California golden trout. *Safari Club Int'l*, 960 F. Supp. 2d at 63; Endangered and Threatened Wildlife and Plants; 12-month Findings on Petitions To Delist U.S. Captive Populations of the Scimitar-horned Oryx, Dama Gazelle, and Addax, 78 Fed. Reg. 33,790, 33,790 (June 5, 2013) (codified as amended at 50 C.F.R. pt. 17) [hereinafter Antelope Listing Petition].

155 Joint DPS Policy, *supra* note 141, at 4723.

156 Chimpanzee Listing Petition, *supra* note 152, at 34,504–05.

157 *See* Carlin, Wurman & Zakim, *supra* note 117, at 22 ("[C]onsider the GloFish . . . . The text of the statute might seem to justify ESA listing, but, in our

disqualifying GE organisms from protection under the Act. I argue that this line of logic derives from two erroneous, outdated presumptions: (1) that species are static, genetically pure entities that should not change; and (2) that humanity exists separately and apart from nature. These presumptions have plagued the implementation of the ESA since its inception but were likely foundational for many of the drafters.[158] Professor Alejandro Camacho asserted that assisted migration is controversial because "it challenges foundational tenets of conservation law and ethics" by pitting one set of goals against another.[159] In the same vein, assisted evolution feels wrong because it pits the goals of protection of species and preservation of functioning ecosystems against deeply ingrained views that wildlife should belong in discrete, unchanging types that should exist "wild" and "natural" outside of our influence.

A. The Myth of Genetic Purity

If my claim that a genetically modified black-footed ferret is still a black-footed ferret bothers you, then you may possess an essentialist or typological view of species. Do not worry though; you are in good company. Plato, Aristotle, and Linnaeus all understood the natural world in a similar manner.[160]

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view, it should not be forthcoming in such cases, because the ESA was not intended to provide protection for new organisms invented by human beings *ab initio*."). In fairness to Carlin, Wurman & Zakim, in a later footnote, they argue that using cloning to reintroduce lost genetic diversity with cryopreserved tissue and that "[p]resumably doing so should not endanger their ESA listing status." *Id.* at 22 n.72. Other scholars do not take a strong position on the matter. *See* Jonas J. Monast, *Governing Extinction in the Era of Gene Editing*, 97 N.C. L. REV. 1329, 1345 (2019) ("In order for the ESA to apply, the FWS or NMFS must determine whether the species is threatened or endangered and, if so, how to respond. The agencies have discretion when deciding whether listing is appropriate . . . . It is not clear how federal agencies will apply this discretion when considering a genetically modified organism."); Sadie Grunewald, *CRISPR's Creatures: Protecting Wildlife in the Age of Genomic Editing*, 37 UCLA J. ENV'T L. & POL'Y 1, 45 (2019) ("It is unclear, however, whether the ESA would protect threatened or endangered wildlife that have been edited, regardless of whether such edits were intentional.").

158 Holly Doremus, *The Endangered Species Act: Static Law Meets Dynamic World*, 32 WASH. U. J.L. & POL'Y 175, 201 (2010) ("Static (or essentialist) and evolutionary views of species coexisted easily in the legislative reports and statements that preceded the Act's passage. It is entirely possible that many legislators held both views of species simultaneously.").

159 Camacho, *supra* note 31, at 176. In the same vein, assisted evolution likewise pits the same goals of "the protection of endangered species, the maximization of future ecological health, and active management to maintain and improve natural resources" against the goals "to preserve and restore preexisting biological systems and shield them from human interference." *Id.* at 176–77.

160 Sierra M. Love Stowell, Cheryl A. Pinzone & Andrew P. Martin, *Overcoming Barriers to Active Interventions for Genetic Diversity*, 26 BIODIVERSITY CONSERVATION 1753, 1757 (2017).

For all of history, we have used categorization to reduce the complexity of the natural world, yet typological thinking, and the associated rigid fixation on categorization, can result in erroneous beliefs that: (1) there is a singular "type" for a taxon; (2) that this type is fixed and immutable; and (3) that changes in this type make those organisms less pure. Despite decades of evidence to the contrary, these fallacies remain imbedded in our collective cultural conscience and impede the effective implementation of our conservation law and policy.[161]

1. *Typological Thinking*

Typological thinking invokes the belief that organisms are naturally grouped together based on shared traits.[162] This view could be part of a deeper essentialist narrative, where each species or "kind" has been imbued with its own discrete essence when it was first created by God.[163] However, even those accepting of evolutionary theory often fall into the typological trap. Under this typological view, we might accept that evolution has occurred, and that evolutionary processes created the variation we see in the world, but we might still think that an individual organism or a set of diagnostic traits can be used to define the entire group.

While few people today consider themselves essentialists, this typological thinking still permeates our cultural understanding of biology. For example, think back to when we sequenced "*the* Human Genome."[164] When the Human Genome Project was complete, it was widely trumpeted that we had successfully sequenced "*the* Book of Life."[165] However, we actually just sequenced the genome of an anonymous donor from Buffalo and claimed that it was representative of the entire Homo sapiens species.[166] There is no singular "human genome"—instead there have been well over 100 billion human

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161 *Id.*

162 *See* Marc Ereshefsky, *Species*, STAN. ENCYC. PHIL. (Aug. 29, 2017), https://plato.stanford.edu/archives/fall2017/entries/species/ [https://perma.cc/FD7C-CD9M].

163 *Id.*

164 Jasmine Lee, *The Complete Human Genome: A "Book of Life,"* COLD SPRING HARBOR LAB'Y (Feb. 24, 2021) (emphasis added), https://www.cshl.edu/the-complete-human-genome-a-book-of-life/ [https://perma.cc/A27S-ZZQ4].

165 *See, e.g.*, *id.* (emphasis added).

166 This is admittedly a slight exaggeration. Many donors were used for the project, but over 70% of the final draft sequences belonged to a single anonymous donor. This more accurate portrayal of the draft being cobbled together from a handful of donors does nothing to refute the typological narrative. *See* Kazutoyo Osoegawa et al., *A Bacterial Artificial Chromosome Library for Sequencing the Complete Human Genome*, 11 GENOME RSCH. 483, 483 (2001).

genomes since our species evolved into existence.[167] This is just one semantic example of the continued persistence of typological thinking.

Despite the widespread incongruency in delineating species, biologists today think along evolutionary lines, with a focus on "population thinking;"[168] as such, species are groups of organisms that share an evolutionary history and interbreed naturally.[169] Instead of a single type that all members of the species are compared against, the focus has shifted onto the importance of variation within a species. To make this clear, let me recontextualize and extend the "book of life" metaphor. The typological view would see all of life as a library; we can call it Noah's Ark-hive.[170] Here we could house each extant species' "book of life" and adequately capture each living "kind." Instead, modern evolutionary thinking might give each extant species its owns section of this library. Each book is now representative of a different living individual's genome. Over time, old books are removed and new books are added; each section as a whole changes.

2. *Static Approximations Of Dynamic Reality*

Just like the changing composition of books in a library, species have evolved and will continue to evolve. To leave the library behind and make the metaphor explicit, over time descendants begin to look and act differently than their ancestors, and this can lead to species splitting or even merging in the future.[171] Modification by descent is one of the foundational tenets of evolutionary biology.[172] The nature of Nature is

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167 Toshiko Kaneda & Carl Haub, *How Many People Have Ever Lived on Earth?*, POPULATION REFERENCE BUREAU (May 18, 2021), https://www.prb.org/articles/how-many-people-have-ever-lived-on-earth/ [https://perma.cc/5EK7-TSZC] ("About 117 billion members of our species have ever been born on Earth." (emphasis omitted)).

168 Ernst Mayr, *Typological Versus Population Thinking*, *in* CONCEPTUAL ISSUES IN EVOLUTIONARY BIOLOGY 155, 157 (Elliot Sober ed., 2nd ed. 1994).

169 *See* Frankham et al., *supra* note 138, at 26–27.

170 Alternatively, a metaphor as a museum has been used. *See* Natalie Jacewicz, Note, *Protecting Evolutionary Potential: Can the Endangered Species Act Save Species Before They Exist?*, N.Y.U. L. REV. 472, 475 (2019) ("But biodiversity is not a museum diorama to be dusted off and fussed over by scientists and policymakers. This conception ignores that evolution is a constant, dynamic process. If nature were a museum diorama, it would be one that changed every evening and surprised curators the next morning.").

171 FUTUYMA & KIRKPATRICK, *supra* note 51, at 213–44.

172 *See* CHARLES DARWIN, THE ORIGIN OF SPECIES 71 (J.W. Burrow ed., Penguin Books 1968) (1859).

change, and, as such, law that treats species as static entities is problematic.

A static view of species forces us to ignore the fact that species evolve on timescales that are relevant to policy, creating a fixed target for protection. Yet the more we explore genomes of wild species, the more we have found examples of rapid evolution.[173] We have known about the concept of adaptive radiation, where a species will diverge quickly into many different species filling newly opened ecological niches, since Darwin landed in the Galapagos to study finches. However, today we keep finding examples that species can change very quickly under certain selective pressures. For example, body sizes across a wide range of taxa are shrinking in response to climate change.[174] Trophy characteristics[175], such as horn size in bighorn sheep,[176] body size in fish,[177] or the presence of tusks in elephants,[178] have begun to shift in response to harvest pressures. Urban foxes are diverging from their rural conspecifics

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173 *See, e.g.*, Simon P. Hart, Martin M. Turcotte & Jonathan M. Levine, *Effects of Rapid Evolution on Species Coexistence*, 116 PROC. NAT'L ACAD. SCI. U.S. 2112, 2112 (2019) (discussing "[i]ncreasing evidence for rapid evolution").

174 *See* Jennifer A. Sheridan & David Bickford, *Shrinking Body Size as an Ecological Response to Climate Change*, 1 NATURE CLIMATE CHANGE 401, 403 (2011); Brian C. Weeks et al., *Shared Morphological Consequences of Global Warming in North American Migratory Birds*, 23 ECOLOGY LETTERS 316, 323 (2020); Jorinde Prokosch, Zephne Bernitz, Herman Bernitz, Birgit Erni & Res Altwegg, *Are Animals Shrinking Due to Climate Change? Temperature-Mediated Selection on Body Mass in Mountain Wagtails*, 189 OECOLOGIA 841, 846–47 (2019); Michelle Tseng et al., *Decreases in Beetle Body Size Linked to Climate Change and Warming Temperatures*, 87 J. ANIMAL ECOLOGY 647, 656 (2018); R. Eugene Turner, *Smaller Size*-at-Age Menhaden with Coastal Warming and Fishing Intensity, 4 GEO: GEOGRAPHY & ENV'T 1, 8 (2017); Sara Ryding, Marcel Klaassen, Glenn J. Tattersall, Janet L. Gardner & Matthew R.E. Symonds, *Shape-Shifting: Changing Animal Morphologies as a Response to Climatic Warming*, 36 TRENDS ECOLOGY & EVOLUTION 1036, 1036 (2021).

175 Fred W. Allendorf, Phillip R. England, Gordon Luikart, Peter A. Ritchie & Nils Ryman, *Genetic Effects of Harvest on Wild Animal Populations*, 23 TRENDS ECOLOGY & EVOLUTION 327, 331 (2008); Fred W. Allendorf & Jeffrey J. Hard, *Human-induced Evolution Caused by Unnatural Selection Through Harvest of Wild Animals*, 106 PROC. NAT'L ACAD. SCI. U.S. 9987, 9987 (2009).

176 David W. Coltman et al., *Undesirable Evolutionary Consequences of Trophy Hunting*, 426 NATURE 655, 655–56 (2003); Gabriel Pigeon, Marco Festa-Bianchet, David W. Coltman & Fanie Pelletier, *Intense Selective Hunting Leads to Artificial Evolution in Horn Size*, 8 EVOLUTIONARY APPLICATIONS 521, 528 (2016).

177 Nina O. Therkildsen et al., *Contrasting Genomic Shifts Underlie Parallel Phenotypic Evolution in Response to Fishing*, 365 SCIENCE 487, 487 (2019); Silva Uusi-Heikkilä et al., *The Evolutionary Legacy of Size-selective Harvesting Extends from Genes to Populations*, 8 EVOLUTIONARY APPLICATIONS 597, 598 (2015).

178 Patrick I. Chiyo, Vincent Obanda & David K. Korir, *Illegal Tusk Harvest and the Decline of Tusk Size in the African Elephant*, 5 ECOLOGY & EVOLUTION 5216, 5226 (2015).

and seemingly domesticating themselves.[179] This is evolutionary change occurring across just a few generations. Effectively, species have already evolved and changed since they went onto the endangered species list back in the 1970s.

3. *Genetic Purity*

The next issue with an essentialist view of species is that organisms that are different from the fixed and static "type" can be seen as less "genetically pure." This logic especially troubles conservation practice. For example, despite the theoretical and empirical evidence that genetic rescue is an effective tool for restoring genetic diversity to small and inbred populations, it has rarely been used by conservation managers.[180] Genetic rescue has only been used as a desperate act of last resort, rather than the default in situations dealing with small inbred populations.[181] While concerns related to outbreeding depression and loss of local adaption are legitimate, a growing body of evidence suggests they are overblown or easily controlled.[182] Instead, much of the opposition to genetic rescue is focused on maintaining "taxonomic integrity," a scientific euphemism for not diluting the purity of gene pools.[183] For this reason, genetic rescue across named taxonomic units has been especially rare.[184] Our fear of mixing gene pools is actively harmful to species where their "genetic purity" is part of the problem, such as those that have accumulated negative fitness traits or lack the ability to evolve.[185]

The fixation on purity especially creates impediments for organisms that may best be described as fitting multiple types, such as hybrids or transgenic organisms. Yet fundamentally, the issue is that species, no matter how you define them, are not discrete.[186] They mix and interbreed with far more regular-

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179 K.J. Parsons et al., *Skull Morphology Diverges Between Urban and Rural Populations of Red Foxes Mirroring Patterns of Domestication and Macroevolution*, 287 PROC. ROYAL SOC'Y B 1, 1 (2020).

180 *See* Katherine Ralls et al., *Call for a Paradigm Shift in the Genetic Management of Fragmented Populations*, 11 CONSERVATION LETTERS 1, 5 (2018).

181 *See id.* at 2–3.

182 *Id.* at 2; Ary A. Hoffmann, Adam D. Miller & Andrew R. Weeks, *Genetic Mixing for Population Management: From Genetic Rescue to Provenancing*, 14 EVOLUTIONARY APPLICATIONS 634, 645 (2021).

183 Love Stowell, Pinzone & Martin, *supra* note 160, at 1756–57.

184 *See id.* at 1756.

185 *Id.* at 1756–57.

186 See Benjamin M. Fitzpatrick, Maureen E. Ryan, Jarrett R. Johnson, Joel Corush & Evin T. Carter, *Hybridization and the Species Problem in Conservation*, 61 CURRENT ZOOLOGY 206, 208 (2015).

ity than we once believed.[187] This is especially true for intraspecific categories like subspecies or DPSs, where gene flow is assumed yet seemingly discouraged.[188] By trying to privilege purity and the mythical gene pool of yesterday, we are actually fighting against evolution and the natural order.

4. *Hybridization as an Example*

Despite the fluidity and change that is inherent in nature, the Services have often taken this essentialist or purist view of "species."[189] The manner in which the Services have dealt with hybridization provides the clearest understanding of how this typological, essentialist view has been baked into the ESA since its inception.

Hybridization is a process where one individual from one species or population interbreeds with an individual from another species or population, creating a "hybrid" organism.[190] These hybrid individuals defy categorization—essentially belonging to no defined species or, alternatively, both of their parent species. While this might be a simple annoyance for taxonomists, it creates a serious issue for the ESA.[191] The ESA is, at its core, a species-based conservation law; it is built around categorizing organisms in order to list and protect them.[192] For a species to be protected it has to be listed, and an individual organism must fit into that discrete 'species' bin to be covered under the Act. Hybrids complicate protection under the ESA by pushing against well-defined species barriers.

During the early decades of conservation biology, this was not a problem. Hybridization was generally viewed as an "unnatural" threat to endangered species.[193] Hybridization evoked lingering thoughts about sterile mules and ligers in zoos, and biologists feared that rare species might be hybridized out of existence by invasive or more common species.[194] However, as our understanding of evolutionary biology and genetics grew,

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187 John A. Erwin, *Hybridizing Law: A Policy for Hybridization Under the Endangered Species Act*, 47 ENV'T L. REP. 10615, 10617–18 (2017).

188 *Id.*

189 Doremus, *supra* note 158, at 182.

190 *See* Fitzpatrick, Ryan, Johnson, Corush & Carter, *supra* note 186, at 207; Robert K. Wayne & H. Bradley Shaffer, *Hybridization and Endangered Species Protection in the Molecular Era*, 25 MOLECULAR ECOLOGY 2680, 2680–82 (2016).

191 *See* Erwin, *supra* note 187, at 10615.

192 *Id.* at 10618.

193 *Id.* at 10621–22. Threats include: genetic swamping, outbreeding depression, and competition with non-hybrids.

194 *Id.*

our understanding of hybridization changed. The more we looked into the genomes and evolutionary history of species, the more common we found hybridization to be. Biologists came to recognize that gene flow between supposedly distinct groups happens far more frequently than we ever realized and is instead an important part of the evolutionary process. Today, hybridization is perhaps better understood as simply the invasion of the genome.[195]

Scholars, in both the legal[196] and scientific literature,[197] have frequently criticized the handling of hybrids under the ESA. Though the issue of hybridization was seemingly not considered when the law was first passed, within a few short years it became a point of contention.[198] By the late 1970s, concerns that purebred endangered species might interbreed with common species, invasive species, or even other endangered species were brought to the forefront.[199] During the 1980s, FWS

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195 *See* James Mallet, *Hybridization as an Invasion of the Genome*, 20 TRENDS ECOLOGY & EVOLUTION 229, 234–35 (2005).

196 *See, e.g.*, Doremus, *supra* note 158, at 176–188 (discussing the ESA's passage and subsequent failure to adequately address hybrids); Erwin, *supra* note 187, at 10618–20, 10624–26 (addressing the ESA's shortcomings and proposing a hybrid policy); Oliver Frey, *When Science and the Statute Don't Provide an Answer: Hybrid Species and the ESA*, 26 DUKE ENV'T L & POL'Y F. 181, 182 (2015) (examining the ESA and its inability to address hybrids); Hill, *supra* note 146, at 240–43 (explaining the creation of and issues related to the ESA); Nina Lincoff, *Looking to Hybrid Species for the Future of Coral Reefs*, 108 CALIF. L. REV. 1597, 1618–23 (2020) (detailing how the ESA does not protect hybrid species including hybrid corals).

197 *See, e.g.*, Norman C. Ellstrand et al., *Got Hybridization? A Multidisciplinary Approach for Informing Science Policy*, 60 BIOSCIENCE 384, 384 (2010) (criticizing U.S. conservation policy and proposing a science-based conservation policy that addresses hybridization); Susan M. Haig & Fred W. Allendorf, *Hybrids and Policy*, *in* 2 THE ENDANGERED SPECIES ACT AT THIRTY: CONSERVING BIODIVERSITY IN HUMAN-DOMINATED LANDSCAPES 150, 150 (J. Michael Scott, Dale D. Goble & Frank W. Davis eds., 2006) (reviewing discussions related to listing hybrids in the ESA); Raeya N. Jackiw, Ghada Mandil & Heather A. Hager, *A Framework to Guide the Conservation of Species Hybrids Based on Ethical and Ecological Considerations*, 29 CONSERVATION BIOLOGY 1040, 1042 (2015) (reviewing hybrid management policies and creating a flexible framework that can be applied to any hybrid); Stephen J. O'Brien & Ernst Mayr, *Bureaucratic Mischief: Recognizing Endangered Species and Subspecies*, 251 SCIENCE 1187, 1187 (1991) (explaining how the U.S. Endangered Species Act of 1973 should discourage hybridization between species, but not between subspecies); Sarah Piett, Heather A. Hager & Chelsey Gerrard, *Characteristics for Evaluating the Conservation Value of Species Hybrids*, 24 BIODIVERSITY & CONSERVATION 1931, 1933 (2015); Astrid V . Stronen & Paul C. Paquet, *Perspectives on the Conservation of Wild Hybrids*, 167 BIOLOGICAL CONSERVATION 390, 391 (2013) (noting the urgent need to advance conservation policies that utilize current understandings of ecology and evolution); Wayne & Shaffer, *supra* note 190, at 2680 (highlighting the nuances of hybridization as a conservation problem).

198 *See* Doremus, *supra* note 158, at 188.

199 *See* Hill, *supra* note146, at 243–44.

even allowed the dusky seaside sparrow to go extinct rather than hybridize it in an attempt to save the species.[200] The population had dwindled down to just five male sparrows that had been brought into captivity.[201] While scientists had suggested a system of hybridization and backcrossing in order to save the sparrow, FWS declared that any hybridized sparrows would not be protected under the Act, making the entire venture pointless.[202] In 2006, after decades of viewing hybridization as a threat to endangered species[203] and a failed attempt at crafting a more flexible rule,[204] the Services laid out their current stance on this issue in a listing decision for the westslope cutthroat trout.[205]

Today, the Services determine how to deal with hybridization by "evaluat[ing] the long-term conservation implications" on a case-by-case approach.[206] This case-by-case approach has led to hybrids being tolerated in some cases, where hybridization appears to be ancestral or natural, and still viewed as a threat in most other scenarios.[207] Further, the Controlled Propagation regulations that exist today recognize hybridization as a management tool if it is: (1) part of an approved recovery plan and genetic management plan; (2) implemented in a scientifically controlled manner; and (3) used for a genetic rescue.[208] While the Services have certainly taken a more flexible view of hybridization over time, there is still substantial uncertainty about where hybrids fit into the ESA scheme.[209]

Ultimately, what the ESA's torrid history on hybridization demonstrates is a struggle over how much to value the "type." At times in the past, the Services essentially treated the genome like a wilderness area, emphasizing the protection of its

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200 Erwin, *supra* note 187, at 10619–20.
201 *Id.*
202 *Id.*
203 For a history of the early hybrid decision making process *see* Hill, *supra* note 146.
204 Endangered and Threatened Wildlife and Plants; Proposed Policy and Proposed Rule on the Treatment of Intercrosses and Intercross Progeny (the Issue of "Hybridization"); Request for Public Comment, 61 Fed. Reg. 4710 (Feb. 7, 1996) (codified as amended at 50 C.F.R. pt. 424) [hereinafter Intercross Policy].
205 Endangered and Threatened Wildlife and Plants: Reconsidered Finding for an Amended Petition to List the Westslope Cutthroat Trout as Threatened Throughout Its Range, 68 Fed. Reg. 46,989, 46,989 (Aug. 7, 2003) (codified as amended at 50 C.F.R. pt. 17).
206 *Id.* at 46,992.
207 Erwin, *supra* note 187, at 10624.
208 *See* Policy Regarding Controlled Propagation of Species Listed Under the Endangered Species Act, 65 Fed. Reg. 56,916, 56,920 (Sept. 20, 2000) [hereinafter Controlled Propagation Policy].
209 Erwin, *supra* note 187, at 10619–20.

purity over all other concerns. Hybridization was not to be tolerated because it diluted the essence and could change the type. A preservationist approach to the current genomic makeup of a species is completely out of line with our understanding of evolution. Thus, despite the improvement, assisted evolution will likely remain controversial, at least in part, because it challenges implicit assumptions about genetic purity. Assisted evolution brings change to the forefront and highlights the malleability of species. Even though the Services have slowly moved away from expressly making decisions based on these views, the general uncertainty surrounding hybrids persists and will certainly carry over to bioengineered organisms.

B. The Separation of Man and Nature Myth

Along with a static concept of species, the use of assisted evolution also cuts against the deeply ingrained separation of man and nature. The false dichotomy between nature and humanity has been explored extensively in the environmental law literature,[210] especially in relation to the ways in which we manage wilderness areas.[211] In relation to wildlife, this problematic dualism appears in the differential treatment of non-native species that are introduced by humans and those that migrate to new areas on their own.[212]

The ESA is certainly not immune to these criticisms either.[213] Section 10(j) of the ESA covers the reintroduction of experimental populations.[214] In an effort to diffuse political concerns, experimental populations are provided fewer protections under Section 7 and Section 9 than naturally occurring

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210 *See generally* J.B. Ruhl, *Climate Change Adaptation and the Structural Transformation of Environmental Law*, 40 ENV'T L. 363, 393 (2010); Camacho, *supra* note 117, at 871–72; Karrigan Börk, *Guest Species: Rethinking our Approach to Biodiversity in the Anthropocene*, 2018 UTAH L. REV. 169, 169 (2018) [hereinafter Börk, *Guest Species*]; Börk, *supra* note 39, at 209; Katrina Miriam Wyman, *Rethinking the ESA to Reflect Human Dominion Over Nature*, 17 N.Y.U. ENV'T L.J. 490, 490 (2008); Christine A. Klein, *Preserving Monumental Landscapes Under the Antiquities Act*, 87 CORNELL L. REV. 1333, 1366–84 (2002).

211 Camacho, *supra* note 117, at 871–72; Peter Landres, Beth A. Hahn, Eric Biber & Daniel T. Spencer, *Protected Area Stewardship in the Anthropocene: Integrating Science, Law, and Ethics to Evaluate Proposals for Ecological Restoration in Wilderness*, 28 RESTORATION ECOLOGY 1, 1 (2020).

212 Camacho, *supra* note 117, at 871; Börk, *Guest Species*, *supra* note210, at 169.

213 Camacho, *supra* note 117, at 872; Klein, *supra* note 210, at 1378; Federico Cheever, *From Population Segregation to Species Zoning: The Evolution of Reintroduction Law under Section 10(j) of the Endangered Species Act*, 1 WYO. L. REV. 287, 287 (2001); Holly Doremus, *Restoring Endangered Species: The Importance of Being Wild*, 23 HARV. ENV'T L. REV. 1, 11–14 (1999).

214 16 U.S.C. § 1539(j).

populations.[215] To enforce these more lax protection standards, experimental populations are to be kept "wholly separate geographically from nonexperimental populations of the same species."[216] The Services actively work, through physically capturing and relocating animals, to ensure that the experimental populations and nonexperimental populations do not mix. As Professor Camacho points out, "the purpose of establishing this division may have been to facilitate reintroduction efforts . . . .[h]owever, it nevertheless reinforces a fallacious duality between those biological resources that are human managed and those that are not."[217]

1. *Wild and Natural versus Controlled and Artificial*

If my earlier claim that a black-footed ferret which possesses an edited gene can be protected under the ESA bothers you, your issue could be that you feel that this animal is no longer wild or is inherently artificial. These concerns may boil down to a deeply ingrained feeling that humanity should remain separate from nature. Both "wildness" and "naturalness," however you define them, are predicated on keeping humanity away. Assisted evolution ultimately breaks the mirage that we are somehow separate because we are directly inserting ourselves into evolutionary processes.

The value of "wildness" and "naturalness" is not necessarily made explicit by the statute, but rather it has been implied and understood by the agencies, courts, and commentators alike.[218] For example, the Ninth Circuit held in *Trout Unlimited* that "the [Act's] primary goal is to preserve the ability of *natural* populations to survive in the *wild*."[219]

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215 *Id.* § 1539(j)(2)(C) ("[E]ach member of an experimental population shall be treated as a threatened species; except that—(i) solely for the purposes of [Section 7] of this title . . . , an experimental population determined . . . to be not essential to the continued existence of a species shall be treated, except when it occurs in an area within the National Wildlife Refuge System or the National Park System, as a species proposed to be listed under [Section 4] of this title; and (ii) critical habitat shall not be designated under this chapter for any experimental population determined . . . to be not essential to the continued existence of a species.").

216 16 U.S.C. § 1539(j)(1).

217 Camacho, *supra* note 117, at 872.

218 *See, e.g.*, Doremus, *supra* note 213, at 13 ("In crafting the ESA's findings, then, Congress made it fairly clear that the Act is aimed at preserving wild, natural creatures.").

219 Trout Unlimited v. Lohn, 559 F.3d 946, 957 (9th Cir. 2009) (emphasis added).

Though "wild" and "natural" are facially similar, and they are often conflated,[220] for the purposes of this Article I believe these represent two distinct, yet interconnected values. Each is just a different side of the same human/nature separation coin. As such, I have assigned fundamentally different definitions for each.[221] "Wildness" refers to the amount of management and control (or lack thereof) humans apply to the species in the present. It is effectively how separate the animal is from humanity contemporaneously. On the other hand, "naturalness" refers to the consistency with which the species matches the evolutionary trajectory it would take without anthropomorphic influence. "Naturalness" essentially boils down to the extent of humanity's role in shaping the species, its gene pool, or its ecological functions. Naturalness, therefore, seems to require an examination of the past. Naturalness is effectively a measure of how much past human intervention can be detected in the present. Both naturalness and wildness are values operating on a spectrum, as relative rather than absolute or binary concepts.[222]

So we could describe wild horses, dingoes, or even invasive Burmese pythons in the Everglades as being "wild," even though we would not consider them "natural" because they were anthropogenically introduced into their current homes.[223] On the other hand, endangered red wolves, black-footed ferrets, or California condors brought into captive breeding programs would not be "wild" while in the breeding program, though we would still consider them mostly "natural." I say mostly "natural" because captive breeding certainly reduces the "naturalness" of a population over time. Species adapt to

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220 For example, Professor Doremus perhaps defined wildness best as "the degree to which a species or ecosystem is free, over the long term, both of dependence on human handouts for its basic needs and of deliberate human control[.]" This clearly incorporates both of my definitions. Doremus, *supra* note 213, at 16.

221 Other definitions for these values are certainly possible. For example, Professor Clare Palmer discusses the effects of gene editing on what she refers to as dispositional wildness, self-willed wildness, and constitutive wildness. She also examines how releasing gene edited organisms could impact the wildness of ecosystems/landscapes. *See* Clare Palmer, *Saving Species but Losing Wildness: Should We Genetically Adapt Wild Animal Species to Help Them Respond to Climate Change?*, MIDWEST STUD. PHIL. 234, 238–39 (2016).

222 Noss, *supra* note 40, at 899.

223 FWS recently determined that the Pryor Mountain mustang population was ineligible for listing under the ESA. This was in part due to their unnaturalness, with the agency specifically stating "feral horses are nonnative and may impede the conservation of ecosystems upon which endangered and threatened species depend." Endangered and Threatened Wildlife and Plants; 90-Day Findings for Four Species, 87 Fed. Reg. 51,635, 51,638 (Aug. 23, 2022) (codified as amended at 50 C.F.R. pt. 17).

captivity both behaviorally and genetically, and each subsequent generation in captivity will decrease the overall "naturalness" of the population.[224] It is worth nothing that both "wildness" and "naturalness" operate on sliding scales; no organism is likely to ever be fully "wild" or "natural."

2. *The Impossibility of Being Wild*

In one of her many seminal contributions, *Restoring Endangered Species: The Importance of Being Wild*, Professor Holly Doremus argued that "[p]rotecting wild species and ecosystems means preserving them in a condition that permits them to function, to the greatest extent possible, without human intervention."[225] Similarly, the Ninth Circuit found "[t]hat the purpose of this [Act] is to promote populations that are self-sustaining without human interference."[226] I think most, myself included, would find that to be a laudable goal. But frankly, as aspirational as that may be, it is not the reality most listed species face.

Listed species are among the most heavily managed species on Earth. Eighty-four percent of listed species are considered conservation reliant and will require active management even after they "recover" for the purposes of the ESA.[227] A species is considered conservation reliant when the threats that it faces "cannot be eliminated but only controlled."[228] For conservation reliant species, recovery will only be achieved "through continuing management intervention."[229] The statistics are particularly bleak when you look at the kinds of interventions being required. Sixty-six percent of listed species require human management of other species, such as predator control or the removal of invasive competition.[230] Fifty-one percent require active habitat management, such as prescribed cuts and burns or controlled releases from dams, just to keep

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224 Doremus, *supra* note 213, at 12 ("More fundamentally, species in captivity rapidly diverge from their wild forebears. Captive animals experience different selection pressures than wild ones. As a result, their progeny exhibit characteristics different from those of animals born and reared in the wild.").

225 *Id.* at 16.

226 Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List *Phoenix Dactylifera* 'Sphinx' (Sphinx Date Palm), 77 Fed. Reg. 71,757, 71,758 (Dec. 4, 2012) (codified as amended at 50 C.F.R. pt. 17) (alteration in original) (citing to Trout Unlimited v. Lohn, 559 F.3d 946 (9th Cir. 2009)).

227 Scott, Goble, Haines, Wiens & Neel, *supra* note 32, at 93–94; Goble, Wiens, Scott, Male & Hall, *supra* note 32, at 869–70.

228 Goble, Wiens, Scott, Male & Hall, *supra* note 32, at 870.

229 *Id.*

230 Scott, Goble, Haines, Wiens & Neel, *supra* note 32, at 93–94.

them alive.[231] Even worse, 42% require artificial recruitment, such as captive breeding and translocations.[232] Of the 951 species determined to be conservation reliant, 618 (65%) of them required multiple kinds of management interventions.[233] It is difficult to argue, based on any definition of the word "wild," that species that will "slid[e] back toward extinction"[234] as soon as active management stops are "wild." They might not all be all kept in zoos or captive breeding programs, but they certainly are not "function[ing] . . . without human intervention."[235] Therefore, if "wildness," in this case an escape from persistent human intervention, is the ultimate goal for recovery of species, then we need to find methods that will remove seemingly intractable threats.

For some species, biotechnology might be that method. The potential use of genetic engineering in black-footed ferrets is the perfect example; the use of genetic engineering could result in a speedier return to the "wild" state. Today, the management of sylvatic plague in prairie dog and ferret populations already significantly impacts the "wildness" of black-footed ferrets. Extensive management of the prairie dog colonies where ferrets are found is done to accommodate this endangered species.[236] Wildlife managers routinely dust prairie dog colonies with insecticides in order to kill the fleas that carry the plague bacteria.[237] This is an invasive procedure where technicians walk around on the colony spraying deltamethrin into each burrow opening.[238] It must be repeated at least annually and has an effect on arthropod biodiversity and on non-target mammal species.[239] Recent evidence even suggests that fleas

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231 *Id.*

232 *Id.*

233 *Id.*

234 *Id.* at 92.

235 Doremus, *supra* note 213, at 16.

236 *See* Rachel C. Abbott, Jorge E. Osorio, Christine M. Bunck & Tonie E. Rocke, *Sylvatic Plague Vaccine: A New Tool for Conservation of Threatened and Endangered Species?*, 9 ECOHEALTH 243, 244–47 (2012); Daniel J. Salkeld, *Vaccines for Conservation: Plague, Prairie Dogs & Black-footed Ferrets as a Case Study*, 14 ECOHEALTH 432, 432–36. (2017).

237 David B Seery et al., *Treatment of Black-tailed Prairie Dog Burrows with Deltamethrin to Control Fleas (*Insecta: Siphonaptera*) and Plague*, 40 J. MED. ENTOMOLOGY 718, 718–20 (2003); Lenora Marilyn Dombro, Ecological Effects of Deltamethrin Insecticide in Prairie Dog Colonies of Western South Dakota 2 (May 7, 2016) (M.S. thesis, Auburn University); Amanda Goldberg et al., *Deltamethrin Reduces Survival of Non-target Small Mammals*, 49 WILDLIFE RSCH. 698, 698–706 (2022).

238 Dombro, *supra* note 237.

239 *Id.* at 3.

are developing resistance to these insecticides.[240] More recently, an oral vaccine has been developed for prairie dogs; however, this still requires consistent active intervention to spread the vaccine chews around the colony.[241] Additionally, ferrets are routinely given an injectable vaccine themselves.[242] All captive-born ferrets are given two shots of the sylvatic plague vaccine before they are released into the wild.[243] In many populations, ferrets born in the wild are routinely collected and vaccinated as well.[244] Clearly, these ferrets are not truly "wild." There is constant human intervention, and there will continue to be constant human intervention. Recovery implies a state of wildness, where the species can exist without constant human intervention.[245] Can a species like the black-footed ferret ever truly recover if they will rely on FWS and state agencies to always fight back against sylvatic plague?

On the other hand, let us say the efforts to use gene editing to increase immunity to sylvatic plague in ferrets are successful. During the early years, the species will continue to exist in a state of mixed captivity and "wildness," just like it does now in the current captive breeding program. The difference, however, is that colonies where the novel genes can be found will no longer require active plague management in perpetuity. No more dusting, no more shots, and no more vaccines baited to look like free food. These black-footed ferrets are the ones that will be "wild" again. These ferrets can actually recover their "wildness."

3. *The Absolute Impossibility of Being Natural*

Professor Doremus went further to define wildness as:

> [L]eaving the future of those species or ecosystems to the ordinary processes of evolution, rather than steering them deliberately toward some human vision of usefulness or beauty . . . . Human control of species inevitably, even if subtly, turns their evolutionary path in ways responsive to

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240 David A. Eads et al., *Resistance to Deltamethrin in Prairie Dog (*Cynomys Ludovicianus*) Fleas in the Field and in the Laboratory*, 54 J. WILDLIFE DISEASE 745, 745 (2018).

241 *See* Daniel W. Tripp, Tonie E. Rocke, Jonathan P. Runge, Rachel C. Abbott & Michael W. Miller, *Burrow Dusting or Oral Vaccination Prevents Plague-associated Prairie Dog Colony Collapse*, 14 ECOHEALTH 451, 452–54 (2017).

242 Tonie E. Rocke et al., *Recombinant F1-V Fusion Protein Protects Black-footed Ferrets (*Mustela nigripes*) Against Virulent* Yersinia Pestis *Infection*, 35 J. ZOO & WILDLIFE MED. 142, 142–46 (2004).

243 *Id.*

244 *Id.*

245 *See* Doremus, *supra* note 213, at 16.

> human interests. It thereby represents a form of human domination, inconsistent with truly wild nature.[246]

Instead of "wildness," this is a perfect definition of what I referred to above as "naturalness."

While I can make the argument that engineered organisms can be "wild," it is much more difficult to argue that they will be "natural." Professor Leslie Paul Thiele has argued that genetic engineering can be seen to "stretch, if not tear apart, the very meaning of nature."[247] Frankly, there is no getting around the fact that genetically intervening to make heritable changes to a species will alter its evolutionary trajectory. The point of assisted evolution is to change the evolutionary path a species is already on, which, by my own definition, will make these organisms and their descendants "unnatural."

Certainly, some genetic interventions may be viewed as more "natural" than others. Organisms modified through selective breeding are unlikely to be viewed with the same skepticism as organisms carrying transgenes. Ironically, from a purely mathematical perspective, artificially selecting for traits via traditional breeding is likely to result in a more quantitatively "artificial" genome than a targeted intervention into a single gene! Organisms derived from cloning might also be viewed as more natural, since they do not possess novel DNA. Gene editing is particularly perplexing. Regulatory bodies, including the Animal and Plant Health Inspection Service ("APHIS"), have begun using a legal fiction to deregulate gene edited agricultural products.[248] Crops that could have been produced through "traditional breeding methods" are being exempted from regulation.[249] Because gene editing does not add any exogenous DNA to the genome, CRISPR edited crops are covered by this exemption.[250] This effectively relies on a fiction that, at some point in time, the change being made occurred in

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246 *Id.*

247 Leslie Paul Thiele, *Nature 4.0: Assisted Evolution, De-extinction, and Ecological Restoration Technologies*, 20 GLOBAL ENV'T POLS. 9, 10 (2020).

248 *See* Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29,790, 29,791 (2020) [hereinafter SECURE rule] (codified as amended at 7 C.F.R. pts. 330, 340, 372).

249 *See* John A. Erwin & Robert Glennon, *Feeding the World: How Changes in Biotech Regulation Can Jump-start the Second Green Revolution and Diversify the Agricultural Industry*, 44 WILLIAM & MARY ENV'T L. & POL'Y REV. 327, 385 (2020); Neil E. Hoffman, *Revisions to USDA Biotechnology Regulations: The SECURE Rule*, 118 PROC. NAT'L ACAD. SCI. U.S. 1, 2–5 (2021).

250 This category of "traditional breeding methods" extends to deletions of any size, small modifications of just a single base pair, and any change that recreates sequences already found within that species' gene pool. Effectively, APHIS is making a distinction between gene edited organisms, which possess no exoge-

the genome of a member of this species, and therefore the editing can still be considered natural.[251]

While some modifications will mirror genetic variants already found in the species, or can be explained away through legal fiction, in many cases, the genes added or modified will fall outside of the scope of what conceivably could have happened "naturally." For these sorts of modifications, I offer no argument that these organisms are "natural." This kind of manipulation will certainly reduce the "naturalness" of the species by any definition used. Instead, I question whether the species we currently protect are actually anymore "natural" than those resulting from genetic intervention.

Just as the natural landscape has been irrevocably altered by humanity, so too have the genomic landscapes of the species found in those natural landscapes. While we might like to pretend that the evolutionary trajectory of a species falls outside of humanity's long reach, a vast body of contemporary scientific research strongly refutes that presumption. A species' evolutionary trajectory is going to be defined by the selective pressures being applied. Any condition that affects which individuals contribute viable offspring will play a role in directing the genomic and phenotypic future of a species. The more we look, the more we have found that humanity has already put our collective thumbs on the scale, changing the selective forces to which each species is subjected.

We have already irrevocably altered the evolutionary trajectory of wild species. Humanity is the most dominant evolutionary force on the planet.[252] Hunting and overharvesting has

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nous DNA, and transgenic organisms, which contain DNA from distantly related species. SECURE rule, *supra* note248.

251 *Id.* at 39,792.

252 *See* Stephen R. Palumbi, *Humans as the World's Greatest Evolutionary Force*, 293 SCIENCE 1786, 1786 (2001) (arguing humanity has become the largest selective force on the planet); J.W. Bull & M. Maron, *How Humas Drive Speciation as Well as Extinction*, 283 PROC. NAT'L ACAD. SCI. U.S. 1, 1 (2016) (recognizing that human-mediated speciation is occurring through "relocation, domestication, hunting, and novel ecosystem creation"); Andrew P. Hendry, Kiyoko M. Gotanda & Erik I. Svensson, *Human Influences on Evolution, and the Ecological and Societal Consequences*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1 (2017) (categorizing and contextualizing the myriad ways in which humanity influences evolution of wild species including: "hunting, harvesting, fishing, agriculture, medicine, climate change, pollution, eutrophication, urbanization, habitat fragmentation, biological invasions and emerging/disappearing diseases"); George H. Perry, *How Human Behavior Can Impact the Evolution of Genetically-mediated Behavior in Wild Non-human Species*, 206 J. COMPARATIVE PHYSIOLOGY A 337, 337 (2020) (reviewing evolutionary scenarios in "which human behavior might have impacted the evolution of genetically mediated behavior in non-human, non-domestic species").

caused reductions in the size of trophy-related traits.[253] Similarly, our CO_2 emissions and warming planet are causing significant morphological and genetic changes to wildlife around the world—body sizes are shrinking,[254] animals are changing colors,[255] and species are moving into new areas and habitats.[256] Climate change is even driving up the albatross divorce rate![257] Species have been forced to adapt and coevolve with introduced and invasive species.[258] Emerging and exotic diseases have caused changes in species abundance and behavior and have driven the evolution of resistance.[259] Both agricultural[260] and urban areas[261] have sprung up, creating novel ecosystems and novel ecological niches for species to spread into. Many species have evolved tolerances to chemical pollutants, herbicides, or insecticides.[262] Even habitat fragmenta-

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253 *See supra* notes 176–178 and accompanying text.

254 *See supra* note 174 and accompanying text.

255 *See* L. Scott Mills et al., *Winter Coat Polymorphisms Identify Global Hot Spots for Evolutionary Rescue from Climate Change*, 359 SCIENCE 1, 1–3 (2018); Michael P. Moore et al., *Sex-specific Ornament Evolution is a Consistent Feature of Climatic Adaptation Across Space and Time in Dragonflies*, 118 PROC. NAT'L ACAD. SCI. U.S. 1, 1 (2021).

256 *See* J. Eric Williams & Jessica L. Blois, *Range Shifts in Response to Past and Future Climate Change: Can Climate Velocities and Species' Dispersal Capabilities Explain Variation in Mammalian Range Shifts?*, 45 J. BIOGEOGRAPHY 2175, 2183–87 (2018).

257 Francesco Ventura, José Pedro Granadeiro, Paul M. Lukacs, Amanda Kuepfer & Paulo Catry, *Environmental Variability Directly Affects the Prevalence of Divorce in Monogamous Albatrosses*, 288 PROC. NAT'L ACAD. SCI. U.S. 1, 8. (2021).

258 *See* Richard A. Lankau, *Coevolution Between Invasive and Native Plants Driven by Chemical Competition and Soil Biota*, 109 PROC. NAT'L ACAD. SCI. U.S. 11240, 11240 (2012) (discussing an example in plants where native populations in areas with introduced species are forced to coevolve to adapt to the introduced species in the community); Sharon Y. Strauss, Jennifer A. Lau, & Scott P. Carroll, *Evolutionary Responses of Natives to Introduced Species: What Do Introductions Tell Us About Natural Communities?*, 9 ECOLOGY LETTERS 357, 357 (2006) (analyzing a review of evolutionary responses of native plant species to introduced species).

259 *See* Mary A. Rogalski, Camden D. Gowler, Clara L. Shaw, Ruth A. Hufbauer & Meghan A. Duffy, *Human Drivers of Ecological and Evolutionary Dynamics in Emerging and Disappearing Infectious Disease Systems*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1–7 (2017).

260 *See* Martin M. Turcotte, *The Eco-evolutionary Impacts of Domestication and Agricultural Practices on Wild Species*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1 (2017).

261 *See* Marina Alberti, John Marzluff & Victoria M. Hunt, *Urban Driven Phenotypic Changes: Empirical Observations and Theoretical Implications for Eco-evolutionary Feedback*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1 (2017).

262 *See* Patrick B. Hamilton, Gregor Rolshausen, Tamsyn M. Uren Webster & Charles R. Tyler, *Adaptive Capabilities and Fitness Consequences Associated with Pollution Exposure in Fish*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1–7 (2017) (discussing adaptive tolerance to chemical pollutants in fish); Nichola J. Hawkins, Chris Bass, Andrea Dixon & Paul Neve, *The Evolutionary Origins of Pesticide*

tion has a massive effect on the evolutionary trajectory of species, as the loss of gene flow will decrease genetic diversity.[263] Frankly, the signatures of anthropogenic selection are everywhere in the genomes of wild species—no species is truly "natural."

Even if we were able to remove all of the selective forces caused by humanity, the mere reduction in population sizes of species is enough to alter their evolutionary trajectories. As populations become smaller, the effects of selection become weaker and weaker, while the effects of genetic drift become stronger.[264] Genetic drift is essentially the random chance that diversity will be lost each generation.[265] Smaller populations are more likely to lose diversity simply because fewer individuals will carry fewer copies of each gene.[266] Endangered species are already depressed in number and will tend to lose genetic variation over time.[267] This loss of genetic variation correlates with a loss of raw genetic material for selective forces to act upon.[268] This too leads to "unnatural" species.

Further, our traditional management actions leave their own evolutionary marks on species. As discussed in Section I, actions such as predator control and habitat management certainly change which traits are favored in a population. For a number of endangered species, we literally have "stud books" and detailed pedigrees directing mangers on which animals should be bred together.[269] We might like to pretend that these actions are just cancelling out the "negative" anthropogenic selective forces, but in reality we are still "unnaturally" altering the evolutionary trajectory of species.

The reality is that true "naturalness" would require a total removal of human influence; we would actually have to fully separate humanity from nature. With this in mind, the ques-

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Resistance, 94 BIOLOGICAL REVS. CAMBRIDGE PHIL. SOC'Y 135, 143–51 (2019) (discussing rapidly evolving pesticide resistance in crops).

263 Pierre-Olivier Cheptou, Anna L. Hargreaves, Dries Bonte & Hans Jacquemyn, *Adaptation to Fragmentation: Evolutionary Dynamics Driven by Human Influences*, 327 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1 (2017).

264 *See* FRANKHAM, BALLOU & BRISCOE, *supra* note 53, at 199.

265 *See id.* at 184.

266 *See id.* at 199.

267 *Id.*

268 *Id.*

269 *See* U.S. FISH & WILDLIFE SERVICE, BIOLOGICAL REPORT FOR THE MEXICAN WOLF (*Canis Lupus Baileyi*) (2017) https://www.fws.gov/sites/default/files/documents/2017MexicanWolfBiologicalReportFinal_0.pdf [https://perma.cc/SVC2-D9ZS]; U.S. FISH & WILDLIFE SERVICE, BLACK-FOOTED FERRET MANAGED CARE OPERATIONS MANUAL (2016), https://assets.speakcdn.com/assets/2332/bff_fieldoperationsmanual.pdf [https://perma.cc/ZTC2-64DQ].

tion really becomes how much "unnaturalness" is acceptable. Let us consider the black–footed ferrets again. Black-footed ferrets are still struggling to recover in the wild. Captive breeding programs are still being used to establish new populations and to supplement existing populations. Despite meticulous management and a near perfect pedigree, ferrets in captivity are adapting to their new captive surroundings over time. The longer the captive breeding goes on, the more serious the effects will be. This makes them increasingly "unnatural." Even further, both the plague and our plague management tactics have altered the trajectory of the species. As mentioned above, this will likely continue indefinitely. If a genetic intervention occurred, where we were able to develop and spread plague resistance, ferrets might be able to escape their conservation-reliant existence. They would escape the selective pressures of the captive breeding and the active plague management, and possibly the plague itself. The question then becomes whether these ferrets, those carrying a gene that was inserted into their ancestor's genome by scientists, would be any less "natural" than ferrets forced to indefinitely deal with the long-term repercussions of captive breeding and an introduced plague? From a purely genomic composition standpoint, the "natural" ferrets are the ones that would certainly pick up more anthropogenically–induced genetic changes.

4. *Purposes of the Act*

Further, how much value should we actually put on "naturalness?" Professor Doremus argued that our control over wild animals will always bend them towards our own interests, something incompatible with "wildness."[270] However, the express purposes of the ESA are all based on our interests—specifically the benefits we glean from listed species. When Congress first passed the ESA, it made its raison d'être clear: biodiversity was worthy of protection because species were "of esthetic, ecological, educational, historical, recreational, and scientific value to the Nation and its people."[271] That laundry list of justifications hints at protecting species due to their value to humanity.[272] We protect species because we enjoy

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270 Doremus, *supra* note 213, at 16.

271 16 U.S.C § 1531(a)(3).

272 Some commentators have dubbed these as "instrumental" justifications. See Andrew E. Wetzler, *The Ethical Underpinnings of the Endangered Species Act*, 13 VA. ENV'T L.J. 145, 168 (1993). Andrew Wetzler, Professor J. Baird Callicott, and others have argued that the ESA is also implicitly committed to protection for endangered species based on intrinsic value. I do not find their arguments en-

bird watching, fly fishing, sport hunting, and photo safaris, and, even if we don't, we enjoy the money recreationalists put into the economy.[273] We also protect species because they allow us to learn more about the world we inhabit and the forces that have shaped both it and us. We protect species because they remind us of a time when we were more directly dependent upon them or because our cultural identities are so closely intertwined. We even protect species because we like how they look, we like how they act, or we like the incredible or mundane things they do to survive.

Protection of species based on "ecological value" can be tied back to our own needs as well. Biodiversity is important to maintaining the ecosystem services we rely on; if we want clean air, clean water, and a livable climate then we need biodiversity.[274] Even the oft-cited "canary in a coalmine" explanation for the ESA is focused on how these species can be used by us as early warning systems for problems in the ecosystem that might affect us.[275] All of those justifications are essentially tied to how species look and act in the world and how *we* are affected by those looks and actions. "Wild" organisms best serve all of these justifications, but I do not believe "naturalness" plays a significant role here.[276]

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tirely persuasive. Yet, even if we do assume that the ESA implies that species have intrinsic value, I still believe that this value is best preserved through genetic intervention rather than perpetual management. *See also* J. Baird Callicott, Explicit and Implicit Values, *in* 1 THE ENDANGERED SPECIES ACT AT THIRTY: RENEWING THE CONSERVATION PROMISE 36, 36 (J. Michael Scott, Dale D. Goble & Frank W. Davis eds., 2006); *but see,* Ian A. Smith, *Incalculable Instrumental Value in the Endangered Species Act*, PHILOSOPHIA 2249, 2251 (2022) (arguing that Callicott's and Wetzler's readings of the ESA are incorrect, and instead arguing that the ESA is built on an assumption of "incalculable instrumental value" rather than intrinsic value).

273 U.S. FISH & WILDLIFE SERVICE, WHY SAVE ENDANGERED SPECIES? (2005), https://digitalmedia.fws.gov/digital/collection/document/id/1682/ [https://perma.cc/RS9E-KRGH] (discussing how, for example, the Texas Parks and Wildlife Department calls birding "the nation's fasted growing outdoor recreation." It estimates that birders pump an estimated $400 million each year into the state's economy. Moreover, Fish and Wildlife Service estimated that wildlife watching generated $85 billion in economic benefits to the nation in 2001.).

274 *Id.*

275 Oliver A. Houck, *Why Do We Protect Endangered Species and What Does that Say About Whether Restrictions on Private Property to Protect Them Constitute "Takings"?*, 80 IOWA L. REV. 297, 330 (1995).

276 Cultural value is the one exception to this trend. This is especially relevant when dealing with species of cultural value to tribes. Indigenous views on genetic engineering are as varied as those of Western societies, but some tribes have taken aggressive stances against biotechnology. *See* NCAI PTG, *Yurok Tribe Breaks New Ground with Genetically Engineered Organism Ordinance*, INDIAN COUNTRY TODAY (Aug. 8, 2019), https://indiancountrytoday.com/opinion/yurok-tribe-breaks-new-ground-with-genetically-engineered-organism-ordinance

Additionally, as our understanding of molecular genetics has grown, there has been an increased emphasis on the specific protection of certain aspects of a species that cannot be so easily seen: "genetic resources."[277] We still know so little about the biodiversity that exists in the world, but we at least recognize that the loss of genetic variation is essentially permanent, with recovery only coming along evolutionary timescales. We recognize that standing genetic variation is essentially the crucible through which the selective forces of the world have created the universe of useful compounds.[278] Therefore, we do not want to destroy the sources of medicinally useful compounds, or sources of inspiration for new inventions, before we understand them or even realize they exist. Though not explicitly stated in the Act itself, the importance of genetic resources was highlighted extensively in the legislative proceedings building up to the Act and in the first landmark ESA case, *Tennessee Valley Authority v. Hill.*[279] With the rise of molecular genetics, and the oversized effect it had on taxonomy, some began to see species as merely a collection of a specific set of genes which might be useful to humanity.[280] The rise of bio-

[https://perma.cc/DHP4-FQ3Q] (The Yurok tribe passed a resolution that opposes "the approval for production, sale, or consumption of all genetically engineered salmon." One member was quoted as saying you "can have . . . as many Frankenfish as you want, but not in our backyard."). *But see* Maui Hudson et al., *Indigenous Perspectives and Gene Editing in Aotearoa New Zealand*, 7 FRONTIERS BIOENGINEERING & BIOTECHNOLOGY 70, 70 (2019 ("Mâori informants were not categorically opposed to new and emerging gene editing technologies *a priori*.").

277 Obviously, some genetic changes result in phenotypic changes that can be seen and felt by humanity. But much of the "genetic variation" that is protected is neutral variation—that in which selection is not believed to be acting on and that likely does not result in an appreciably different phenotype.

278 U.S. FISH & WILDLIFE SERVICE, *supra* note 273 ("Each living thing contains a unique reservoir of genetic material that has evolved over eons. This material cannot be retrieved or duplicated if lost. So far, scientists have investigated only a small fraction of the world's species and have just begun to unravel their chemical secrets to find possible human health benefits to mankind.").

279 437 U.S. 153, 177–79 (1978) ("From the most narrow possible point of view, *it is in the best interests of mankind to minimize the losses of genetic variations.* The reason is simple: they are potential resources. They are keys to puzzles which we cannot solve, and may provide answers to questions which we have not yet learned to ask." (citing H.R. REP. NO. 97-412, at 4–5 (1973)).

280 *See* Doremus, *supra* note 213, at 14 (citing Paul Munton, *Concepts of Threat to the Survival of Species Used in Red Data Books and Similar Compilations*, *in* THE ROAD TO EXTINCTION 71, 87–88 (Richard & Maisie Fitter eds., 1987)) ("Surprisingly, not even conservationists have always recognized the fundamental importance of protecting species in nature, rather than simply as genetic entities. One biologist, for example, has seriously suggested that genes deemed worthy of protection could be 'stored as part of a composite living organisms, an animal with multiple features from many species or a vast polyploid plant bearing a hundred different flowers and fruits from its branches.").

technology brought this framing of species to the forefront. During hearings over potential amendments to the ESA, as early as 1982, arguments were made that species functioned as "depositor[ies]" of "potentially transferrable . . . genes" that would be lost forever through extinction.[281] Courts have also picked up on this concept and used the economic value of genetic resources, and specifically their potential in genetic engineering, as a hook for Congress' authority under the Commerce Clause.[282] This rationale turns protected species into resources for exploitation. The policy rationales for the ESA effectively reject the separation of humanity and nature, and instead suggest quite firmly that the conservation of organisms, and their genomes, for our benefit is preferred.

Ultimately, if we make the decision that we must intervene, a targeted, short-term intervention leading to a more rapid recovery should be preferred over continuous interventions in perpetuity that just keep species on life support. These values are best served by recovered species, not "natural" species. Through these targeted genetic interventions, we can promote "wildness" through recovering species.

IV
THE COORDINATED FRAMEWORK

So far, I have argued that genetic intervention is a useful tool for wildlife conservation and that, despite challenging underlying assumptions of the ESA, modified organisms should be covered under the ESA. However, for a synthetic intervention to be successful, conservation law must synergistically interact with biotechnology regulation law in ways the drafters

281 Jacewicz, *supra* note 170, at 496–97 ("'[A] species must now be viewed as more than just a unique conglomerate of genes,' explained one biologist in a hearing before Congress. 'It must be viewed also as a depository of genes that are potentially transferrable . . . . The notion that species extinction means the loss of individual utilizable genes must now be squarely faced.'" (alteration in original)) (citing *Endangered Species Act: Hearing on Endangered Species Act Reauthorization and Oversight Before the Subcomm. on Fisheries & Wildlife Conservation of the H. Comm. On Merch. Marine & Fisheries*, 97th Cong. 130–31 (1982)).

282 Nat'l Ass'n of Home Builders v. Babbitt, 130 F.3d 1041, 1053 (D.C. Cir. 1997) ("Fortifying the genetic diversity of U.S. crops played a large part in the explosive growth in farm production since the 1930s, accounting for at least one-half of the doubling in yields of rice, soybeans, wheat, and sugarcane, and a three-fold increase in corn and potatoes. Genetic diversity provided by wild plants also protects domestic crops from disease and pest damage . . . . Similar genetic engineering can be used with animals. For instance, it is not beyond the realm of possibility that the genes of a wild pollinator species like the [Delhi sands flower-loving] Fly might be inbred with the commercial profit, scientific knowledge, and aesthetic pleasure it can yield.").

of the relevant statutes never would have dreamed. For example, the Endangered Species Act was not designed to protect humanity from endangered species, just as biotechnology laws were not designed to protect modified organisms from humans.[283] Ultimately, we must determine how to perform these interventions to conserve biodiversity while also protecting human health and the environment from unintended consequences.

Generally, biotechnology is regulated under the Coordinated Framework for Biotechnology. During the Reagan administration, when thoughts of editing specific genes were still relegated to science fiction, the White House Office of Science and Technology Policy ("OSTP") drafted the Coordinated Framework, which co-opted pre-existing federal statutes to regulate biotechnology.[284] The Coordinated Framework assigns responsibility of biotechnology to three separate agencies: the Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA"), and APHIS.[285] Consequently, creators of genetically modified organisms must navigate the varying levels of overlapping jurisdiction in order to sell or distribute these organisms.[286] Furthermore, despite being regulated by the same agencies, GE endangered plants and GE endangered animals are likely subject to significantly different regulations. Lastly, the Coordinated Framework was developed to regulate commercial products, not wild releases. This has led to confusion and regulatory uncertainty for the only two organisms that have currently been designed for widespread release: Oxitec's genetically engineered mosquitos and the transgenic American Chestnut.[287]

A. Food and Drug Administration

The FDA oversees the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which likely provides the only regulatory oversight under the Coordinated Framework for most listed GE

283 Erwin, *supra* note 106.

284 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

285 *Id.* at 23, 304–05.

286 *Id.*

287 Joan Conrow, *USDA to Decide Fate of American Chestnut Restoration*, ALLIANCE FOR SCI. (Aug. 25, 2020), https://allianceforscience.cornell.edu/blog/2020/08/usda-to-decide-fate-of-american-chestnut-restoration/ [https://perma.cc/M9NZ-ZURA]; *Oxitec's Friendly™ Mosquito Technology Receives U.S. EPA Approval for Pilot Projects in U.S.*, OXITEC (May 1, 2020), https://www.oxitec.com/en/news/oxitecs-friendly-mosquito-technology-receives-us-epa-approval-for-pilot-projects-in-us [https://perma.cc/32TR-NF6J].

animals.[288] Under the FFDCA, the definition of "drug" includes "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[289] The FDA understands the process of genetic engineering as affecting the structure of an animal's body, and, as such, all bioengineered animals are considered "new animal drugs" ("NADs"), "regardless of the intended use of products that may be produced by the GE animal."[290] Thus, even though these endangered species might have nothing to do with "food," they can be subject to "premarket" permitting under the FFDCA, despite the obviously poor fit for the concept of "premarket review" for an endangered species. Along with premarket review, if FDA requires a new animal drug application ("NADA"), its review and approval of the NADA would implicate the National Environmental Policy Act ("NEPA"), offering a chance for some outside oversight of the process.[291] On the other hand, the FDA has stated that it does not intend to enforce NADA requirements for "non-food-species that are regulated by other government agencies or entities" and non-food-species that remain in research laboratories.[292] Under its newest draft guidance, if FDA chooses not to enforce NADA requirements, then it merely "intends" to consider environmental risks "in determining whether to exercise enforcement discretion."[293] Listed GE plants, on the other hand, would likely fall outside of the FDA's

288 Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301–399.

289 *Id.* § 321(g)(1).

290 FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #187: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 6 (2015), https://www.fda.gov/media/135115/download [https://perma.cc/6KHV-CQKH] ("The rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the FFDCA drug definition.").

291 *Id.* at 8.

292 *Id.* at 7–8 ("For example, FDA has not and does not intend to take enforcement action with respect to INAD and NADA requirements for: (1) GE animals of non-food-species that are regulated by other government agencies or entities, such as GE insects being developed for plant pest control or animal health protection, and that are under APHIS oversight; and (2) GE animals of non-food-species that are raised and used in contained and controlled conditions such as GE laboratory animals used in research institutions. Although we generally intend to exercise enforcement discretion with regard to INAD and NADA requirements for such animals, we retain the discretion to take enforcement action if we learn of safety concerns associated with them.").

293 *Id.* at 9 ("When FDA exercises its enforcement discretion over the INAD or NADA requirements, no NEPA review would take place. As a result, environmental risks are among the factors we intend to consider in determining whether to exercise enforcement discretion.").

regulatory purview, as the FFDCA regulations on GE plants are tied to "adulterated foods."[294]

B. Environmental Protection Agency

The EPA regulates bioengineered organisms through the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which charges the agency to regulate the "distribution, sale, or use" of "pesticides" to the "extent necessary to prevent unreasonable adverse effects on the environment."[295] To meet this statutory goal, EPA regulates "plant incorporated pesticides" ("PIPs"), defined as substances plants produce for protection against pests and the genetic material necessary to produce these substances.[296] Thus, plants that have been genetically engineered to produce pesticidal compounds will be regulated by EPA as PIPs under FIFRA.[297] Additionally, because the definition of "pesticide" is defined based on pesticidal intent rather than actual toxicity, plants that have been genetically engineered to be more resistant against diseases are also classified as PIPs.[298] Disease resistance is likely one of the main traits relevant to listed GE species, making EPA jurisdiction over bioengineered listed plants a possibility. The EPA would likely not be able to regulate listed GE animals, as "new animal drugs" under the FFDCA were explicitly removed from being regulated by FIFRA.[299]

C. Animal and Plant Health Inspection Services

Finally, APHIS regulates GE organisms that are plant or animal "pests" under the Plant Protection Act of 2000 ("PPA")[300] and the Animal Health Protection Act ("AHPA").[301] Both acts define "pests" broadly with a focus on injuring or causing diseasing in either plants or livestock.[302] It is possible that some endangered species could fall into one of these "pest" categories if interpreted broadly. Additionally, new rules passed at APHIS now allow for some genetic modifications to be completely deregulated, including: "deletions of any size," "single base pair substitutions," and introductions of "nucleic acid sequences in

294 21 U.S.C. § 342.
295 7 U.S.C. § 136a(a).
296 40 C.F.R. § 152.3 (2023).
297 *Id.*
298 Erwin & Glennon, *supra* note 249, at 383.
299 40 C.F.R. § 152.6(d)(2).
300 7 U.S.C. § 7711.
301 *Id.* § 8301.
302 *Id.* §§ 8302, 7702.

a plant to correspond to a sequence known to occur in that plant's natural gene pool."[303] This last exemption could be especially relevant to listed GE species where ancestral genetic diversity that has been lost is being recreated through gene editing. APHIS is currently in the process of promulgating new draft regulations that would take over GE animal regulation from the FDA, and it remains unclear how this might affect regulation of listed GE animals.[304]

Thus, the Coordinated Framework provides a labyrinth of regulations for the creators of listed GE species to navigate. There is still much ambiguity regarding what is or is not covered under the Coordinated Framework. Additionally, genetic interventions performed through hybridization, ARTs, or selective breeding are not subject to these laws at all, despite also modifying genomes. Finally, it remains to be seen how appropriate or effective regulations aimed at pre- or post-market reviews will be for endangered species.

V
REGULATION UNDER THE ESA

While the Coordinated Framework offers uncertain coverage for bioengineered listed species, the ESA does provide some regulatory structure that could be used to perform a synthetic intervention. While the ESA was certainly never intended to regulate biotechnology, there is a framework in place that can be utilized to oversee the creation, testing, and release of bioengineered listed species. Under the ESA, recovery permits, the Controlled Propagation regulations, the Section 10(j) procedures for experimental populations, and Section 4(d) rules would all provide some regulatory coverage for listed GE organisms.

However, it is important to make clear that nothing in this section would apply to organisms that are not listed species. There are certainly many applications of biotechnology that simply will not trigger the ESA. The regulation of gene editing for release outside of controlled systems clearly needs to be clarified and strengthened across the board.

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303 Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29,790, 29,791 (May 28, 2020) (codified as amended at 7 C.F.R. pts. 330, 340, 372).

304 *See* Regulation of the Movement of Animals Modified or Developed by Genetic Engineering, 85 Fed. Reg. 84,269 (Dec. 28, 2020).

A. Recovery Permits

The ESA prohibits the taking of a listed species. As discussed earlier, the definition of "take" is quite broad, including to "harass, harm, . . . trap, capture, or collect."[305] In order to legally violate this prohibition against the taking of a listed species, one can petition the Services for permits.[306] The Services may permit the taking of a listed organism either "for scientific purposes or for the enhancement of propagation or survival" of the affected species or if such taking is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.[307] This directive has led to three different permitting schemes: (1) recovery permits; (2) incidental take permits accompanying habitat conservation plans (HCPs); and (3) enhancement of survival permits that correspond with Safe Harbor Agreements ("SHAs") and Candidate Conservation Agreements with Assurances ("CCAAs.")[308]

Recovery permit procedures offer an umbrella of coverage for the Services to regulate modified listed organisms. First, this recovery permitting process gives the Services notice and control over the creation of the modified listed organism. The capture and handling of a listed species clearly falls under the definition of "take." Further, these prohibitions extend to "any part, product, egg . . . or the dead body or parts" of listed species;[309] this means that just possessing the cells or tissue samples needed to begin the project would be a violation of the Act. Thus, a Section 10(a)(1)(A) recovery permit will be required just to perform the research needed to create a GE listed organism. The Section 9 prohibition against take and the recovery permitting process effectively give FWS or NMFS veto power over the very creation of these organisms; only projects that they approve and permit will be legally allowed to proceed.

Secondly, even though research permits have not traditionally been used in this manner, the statutory and regulatory language gives the Services fairly broad discretion to accept or reject permit applications, as long as they can be reasonably tied to recovery, including enhancement of propagation. These permits have routinely been used as the sole authority for per-

305 16 U.S.C. § 1532(19).

306 *Id.* § 1539.

307 50 C.F.R. § 17.22 (2023); 16 U.S.C. § 539(a)(1)(A).

308 William S. Eubanks II, *Subverting Congress' Intent: The Recent Misapplication of Section 10 of the Endangered Species Act and its Consequent Impacts on Sensitive Wildlife and Habitat*, 42 B.C. ENV'T AFFS. L. REV. 259, 259, 281, 284 (2015).

309 16 U.S.C. § 1532(8).

forming reintroductions of captive bred individuals.[310] This statutory language has also been stretched to allow private game ranches to breed and allow hunting of certain listed species.[311]

The general permitting requirements for endangered and threatened animals mandates that "the Director shall issue the appropriate permit unless . . . the authorization requested potentially threatens a wildlife or plant population."[312] For recovery permits specifically, the Director shall consider factors such as: (1) "[w]hether the purpose for which the permit is required is adequate to justify removing from the wild or otherwise changing the status of the wildlife;" (2) "[t]he probable direct and indirect effect which issuing the permit would have on the wild populations of the wildlife;" (3) "[w]hether the permit, if issued, would in any way, directly or indirectly, conflict with any program intended to enhance the survival probabilities of the population from which the wildlife sought to be covered by the permit was or would be removed;" and (4) "[w]hether the purpose for which the permit is required would be likely to reduce the threat of extinction facing the species of wildlife."[313]

For plants, the issuance criteria are even more straightforward—"[w]hether the purpose for which the permit is requested will enhance the survival of the species in the wild" and "enhance the propagation of the species."[314] The Services use "[t]he opinions or views of scientists" or other relevant experts when making permitting decisions.[315] This language effectively requires an assessment of the risks to the rest of the species, ensuring that the genetic intervention will not harm the species as a whole.

The Services also have significant control over the specifics of the permits, and there are safeguards in place to ensure compliance. The Services set the duration of the permits by authorizing "a single transaction, a series of transactions, or a number of activities over a specific period of time."[316] This

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310 Karrigan Börk, *Listed Species Reintroductions on Private Land—Limiting Landowner Liability*, 30 STAN. ENV'T L.J. 177, 197 (2011).

311 *See* Antelope Listing Petition, *supra* note 154, at 33,797 (allowing the issuance of private permits to hunt captive-bred specimens of scimitar-horned oryx, dama gazelle, and addax).

312 50 C.F.R. § 13.21(b)(4) (2023).

313 *Id.* §§ 17.22(a)(2)(i)–(iv).

314 *Id.* § 17.62(b)(1)–(2).

315 *Id.* § 17.22(b)(3).

316 *Id.* § 17.62.

ability to tailor the length and scope of permits could allow the agency to adopt an iterative, adaptive management framework.[317]

The permitting regulations additionally give the Director the discretion to incorporate "any other conditions deemed appropriate and included on the face of the permit."[318] This clause could provide an additional hook to include regulations specific to GE organisms.

The recovery permitting process also has built-in opportunities for public participation and information gathering. The Services will publish descriptions of the permits in the Federal Register and use a thirty-day notice and comment period to accumulate public input.[319]

Because the approval of a permit is a final agency action that must go through notice and comment rulemaking, it implicates additional environmental review. NEPA is implicated anytime a federal agency makes any "major Federal action[ ] significantly affecting the quality of the human environment."[320] NEPA could therefore require the agency to consider broader effects on the environment by preparing an Environmental Assessment (EA) or Environmental Impact Statement (EIS). However, recovery permits generally fall under a categorical exclusion, in which case the agency would not need to prepare a more detailed analysis to comply with the statute.[321]

Finally, intra-agency Section 7 consultation is required prior to an issuance of 10(a)(1)(A) permits, offering one additional level of review.[322] Under Section 7, federal agencies must consult with the Services to ensure that their actions do not jeopardize the continued existence of listed species or adversely modify designated critical habitat.[323] When the federal agency in question is FWS, they will perform an intra-agency consultation to ensure that their actions would not harm listed species. Unlike the rest of the ESA, Section 7 may be also applicable when the modified species is not endangered; for example, a genetic intervention used to eradicate an invasive

317 *See* NAT'L ACADS. SCIS., ENG'G, & MED., FOREST HEALTH AND BIOTECHNOLOGY: POSSIBILITIES AND CONSIDERATIONS 144–45 (2019) (describing a model adaptive management framework) [hereinafter NASEM].

318 50 C.F.R. § 13.21(e)(1).

319 *Id.* § 17.22.

320 National Environmental Policy Act, 42 U.S.C. § 4332(2)(C).

321 Eubanks II, *supra* note 308, at 285.

322 Börk, *supra* note 310, at 194–95.

323 16 U.S.C. § 1536.

species might trigger Section 7 consultation to ensure that closely related endangered species will not also be affected.

B. Controlled Propagation and the Intercross Policy

There are also regulations that could be directly applicable to GE organisms. The Services have promulgated two different sets of rules for artificial propagation. The captive breeding regulations almost exclusively control the breeding of species that are not native to the US.[324] The Controlled Propagation regulations, however, apply to breeding and releasing native species.[325]

The Controlled Propagation regulations allow for captive breeding only in situations where other measures have either failed or are unlikely to be sufficient to achieve full recovery.[326] Controlled propagation is to proceed only on the recommendation of an approved recovery plan, a genetics management plan, and a reintroduction plan, when practical, and periodic evaluations are required. If genetic intervention is seen as fitting within this controlled propagation rule, then this provides a build-in limiting factor for when genetic intervention can be used—only in cases where recovery teams have approved it as a tool and where other measures are unlikely to result in recovery.

The agency will also consider risks associated with the project. NEPA and Section 7 of the Act require specific consideration of the potential ecological and genetic effects of both the breeding program and the introductions.[327] Controlled propagation projects must take "all known precautions" to limit the

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324 50 C.F.R. § 17.21(g) (2023). In theory, these regulations can also apply to native species; however, in practice, only the Laysan duck has been granted eligibility under this set of provisions. *See* U.S. FISH & WILDLIFE SERVICE, CAPTIVE-BRED WILDLIFE REGISTRATION UNDER THE U.S. ENDANGERED SPECIES ACT 1 (2003).

325 Controlled Propagation Policy, *supra* note 208, at 56,918.

326 *Id.* at 56,920 ("Used as a recovery strategy only when other measures employed to maintain or improve a listed species' status in the wild have failed, are determined to be likely to fail, are shown to be ineffective in overcoming extant factors limiting recovery, or would be insufficient to achieve full recovery. All reasonable effort should be made to accomplish conservation measures that enable a listed species to recover in the wild, with or without intervention (e.g., artificial cavity provisioning), prior to implementing controlled propagation for reintroduction or supplementation.").

327 *Id.* ("Based on specific consideration of the potential ecological and genetic effects of the removal of individuals for controlled propagation purposes on wild populations and the potential effects of introductions of artificially bred animals or plants on the receiving population and other resident species. Assessments of potential risks and benefits will be addressed, as required, through sections 7 and 10 of the Act and the National Environmental Policy Act (NEPA, 42 U.S.C. 4332) for proposed controlled propagation actions.").

spread of disease or parasites[328] and to prevent the accidental introduction of individuals outside their historic range.[329]

The Controlled Propagation regulations do not directly mention genetic engineering, but they do provide a pathway for "intercrossing" to be used to "compensate for a loss of genetic viability in listed taxa that have been genetically isolated in the wild as a result of human activity."[330] For intercrossing to be used in controlled propagation, it must be "recommended in an approved recovery plan; supported in an approved genetic management plan . . . ; [and] implemented in a scientifically controlled and approved manner."[331] The regulations define "intercross" to include any "genetic exchange between individuals of different species, subspecies, or distinct population segments of a vertebrate species."[332] While the word "intercross" is clearly a euphemism for "hybridization," based solely on this definition, some forms of biotechnologically-assisted evolution would be considered "intercrossing." For instance, transgenic engineering involves moving genes from one species into another, which is essentially a targeted form of hybridization.[333]

There are two limiting factors, however. First, the use of intercrossing appears to be limited to genetic rescue, and many applications of biotechnology for assisting the evolution of adaptive traits would not fit a rigid interpretation of this rule.[334] Second, this rule would seemingly not apply to gene edited organisms. For gene edited organisms, there is no exogenous DNA being incorporated into the genome, so the comparison to hybridization no longer applies.

Interestingly, the Services nearly drafted a rule during the 1990s that would have addressed some forms of genetic engineering for conservation. In 1996, the Services drafted the "Intercross Policy"[335] to deal with hybridization. The policy was never adopted over concerns with how it dealt with natural

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328 *Id.* ("Conducted in a manner that takes all known precautions to prohibit the potential introduction or spread of diseases and parasites into controlled environments or suitable habitat.").

329 *Id.* ("Conducted in a manner that will prevent the escape or accidental introduction of individuals outside their historic range.").

330 *Id.*

331 *Id.*

332 *Id.* at 56,919.

333 Gene edited organisms, on the other hand, still fit outside of this hybrid definition. With gene editing, instead of transferring genetic material from one organism into another, the genetic material within the genome is merely being changed.

334 *See supra* Section I.

335 Intercross Policy, *supra* note 204, at 4710.

hybridization and its focus on the individual rather than the population.[336] The Intercross Policy specifically mentions transgenics and would have offered protection for "organisms resulting from genetic engineering experiments that use genetic material from listed species . . . [if] such organisms are produced for the purpose of recovery of the listed species in accordance with an approved recovery plan."[337] If this rule were ever to be finalized, it would certainly apply.

C. Experimental Populations

Section 10(j) is another useful statutory provision to help the Services direct introductions with modified organisms.[338] Following the 10(j) procedures, the Services could create non-essential experimental populations made up entirely of modified organisms.[339] In theory, this would be useful for two reasons. Firstly, experimental populations were added to the ESA in an attempt to make politically unpalatable reintroductions more bearable.[340] The introduction of GE organisms may well be politically fraught, and the reduced protections that accompany experimental populations may be helpful to increase local buy in.[341] Secondly, experimental populations will be an effective way to essentially field test these organisms. Field testing is a routine part of the risk assessment for genetically modified crops,[342] and this kind of testing in GE organism will likely be necessary as well. As experimental populations are to be kept separate and geographically disjunct from non-experimental populations, and FWS has aggressively enforced this separation,[343] this reduces the chance that introduced genes will

336 Haig & Allendorf, *supra* note 197.
337 Intercross Policy, *supra* note 204, at 4712.
338 16 U.S.C. § 1539(j).
339 *Id.* § 1539(j)(2)(B) ("Before authorizing the release of any population . . . the Secretary shall . . . determine . . . whether or not such population is essential to the continued existence of an endangered species . . . .").
340 Doremus, *supra* note 213, at 23 ("Congress sought, through section 10(j), to reduce political opposition to wildlife reintroduction."); Cheever, *supra* note 213, at 365 ("The justification for section 10(j) is simple: to relax protection for species members in order to reduce political opposition to reintroduction.").
341 *But see* Cheever, *supra* note 213, at 291 (arguing that the politically palatable compromise of Section 10(j) ultimately frustrates recovery because it isolates populations and creates a confusing regulatory variation).
342 *See generally*, M.M. Slot, C.C.M. van de Wiel, G.A. Kleter, R.G.F. Visser & E.J. Kok, *The Assessment of Field Trails in GMO Research Around the World and their Possible Integration in Field Trials for Variety Registration*, 27 TRANSGENIC RSCH. 321, 324 (2018) (comparing various field trials that aimed at assessing the risk of introducing new genetically modified crops).
343 16 U.S.C. § 1539(j)(1) ("[T]he term 'experimental population' means any population (including any offspring arising solely therefrom) authorized by the

spread during the field tests. The experimental population provision would allow the Services to test how the modified organisms fit into the environment while being kept separate from the rest of the species until the risks have been assessed.

D. Section 4(d) Rules

Finally, if the listed taxon is merely threatened instead of endangered, special 4(d) rules could be crafted that would treat GE organisms differently than the non-modified organisms.[344] Section 4(d) allows the Services to adopt customized regulations for threatened species.[345] For instance, under Section 4(d), the Services can apply or withhold Section 9 protections as they see fit. This was essentially how NMFS was directed to deal with hatchery salmon after *Trout Unlimited*; NMFS was free to utilize different protective standards for the hatchery fish and the "natural" fish under a 4(d) rule.[346]

VI
SUGGESTIONS FOR IMPROVEMENT

A. Limiting Factor

One oft repeated concern over the utilization of synthetic biology is that once we cross the threshold of directed modification, we lose sight of a clear line in the sand. As Professor Doremus sagely noted, once the human control begins, it is tempting to continue building up these species in our own image, so to speak.[347] Some commentators have suggested that genetic engineering only be utilized as a last resort or in relation to the conservation status of the species,[348] but I believe this is the wrong approach. Instead, under the Controlled

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Secretary for release . . . but only when, and at such times as, the population is wholly separate geographically from nonexperimental populations of the same species.").

344 *Id.* § 1533(d) ("Whenever any species is listed as a threatened species pursuant to subsection (C) of this section, the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation of such species. The Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 1538(a)(1) of this title, in the case of fish or wildlife, or section 1538(a)(2) of this title, in the case of plants, with respect to endangered species; except that with respect to the taking of resident species of fish or wildlife, such regulations shall apply in any State which has entered into a cooperative agreement pursuant to section 1535(c) of this title only to the extent that such regulations have also been adopted by such State.").

345 *Id.*

346 Trout Unlimited v. Lohn, 559 F.3d 947, 962 (9th Cir. 2009).

347 Doremus, *supra* note 213, at 16.

348 Phelps, Seeb & Seeb, *supra* note 97, at 62.

Propagation regulations, the Services require interventions to be necessary for recovery. This is a more appropriate standard. Genetic engineering should be utilized when it will facilitate recovery and reduce conservation reliance.

When the Services set forth the DPS policy, they stated that "the Services understand the Act to support the interrelated goals of conserving genetic resources and maintaining natural systems and biodiversity over a representative portion of their historic occurrence."[349] This understanding must be the guiding principle through which the Services can apply assisted evolution as a tool. I have argued previously that the Services should adopt a defined, yet flexible, policy for hybridization based on these two factors of conserving genetic resources and maintaining ecosystem functions.[350] I believe that a similar approach should govern the use of synthetic biology under the ESA.

Genetic engineering should be used to conserve genetic resources by promoting recovery over indefinite management. At its core, the ESA is a species-based conservation plan, so the focus will inevitably be on preserving species.[351] Working within this species-based paradigm, modifications should be used, but, because the conservation of genetic resources is the directive, intervention should be used sparingly. Perpetual management should be avoided, but, likewise, interventions outside the scope of ending reliance on management should also be avoided. This essentially requires the services to balance lost genetic resources versus those potentially saved by the recovery of the species. The species-based approach to conservation turns genetic engineering into a form of amputation, where genetic resources are being lost and replaced in the name of saving the whole species. This would be the easiest standard to apply when using genetic engineering for conservation under the ESA.

The Services are also dedicated to preserving the ecosystems in which these species are found. While the preservation

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349 Joint DPS Policy, *supra* note 141, at 4723.

350 Erwin, *supra* note 187, at 10625 ("Thus, at its simplest, the decision of whether or not to protect hybrids should be made based on a simple two-factor test: will protecting hybrids benefit the continued persistence of the endangered taxon, and will protecting hybrids benefit the ecosystem as a whole? If protecting hybrids will benefit the endangered species by protecting the unique genetic lineages or the environment as a whole, that supports protection of hybrids; likewise, if protecting hybrids will harm the endangered taxon or the other organisms in its ecosystem, then that goes against protection of hybrids.").

351 *Id.*

of ecosystems tends to be placed on the back burner, engineering could certainly be used to further this goal. The Services should use genetic engineering to promote functioning ecosystems. This requires that modifications to these organisms will not result in negative impacts to the ecosystem as a whole. Under the narrow species-based paradigm, the Services should promote editing that will allow species to continue to perform their same ecological roles, not editing that pushes species into different ecological niches.

However, the Services could take a more expansive view of their duty to preserve ecosystems, potentially at the expense of their duty to conserve genetic resources. Under an ecosystem-focused paradigm, the Services could use this technology to push listed species into different ecological niches. For example, there is a project underway to modify Asian elephants with genes originating in wooly mammoths to restore the grassland ecosystems of Siberia.[352] This sort of project would not be acceptable under the species-based paradigm. These modifications are not being done with the purpose of "recovery" in mind. However, under a broader ecosystem-based paradigm, projects undertaken to further the goals of ecosystem protection or restoration could be utilized. While these sorts of projects may also be a necessary tool in the future for preservation of ecosystems, under the current species-based paradigm of the ESA, they are less justifiable.

B. Strengthening the ESA Process

Ideally, the Services would clarify and strengthen their regulatory procedures by promulgating a new Genetic Intervention rule or updating the Controlled Propagation rule. This would allow the Services to clarify when modified organisms would be covered under by the Act. Ideally, the Services also need to work with the FDA to determine when, or if, the FDA intends to use its NAD authority to regulate synthetic genetic interventions.[353] Perhaps most importantly, the Services should utilize this rulemaking to create a more formal and robust risk assessment framework, filling the gaps that currently exist. The Services should focus on developing an itera-

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352 Carl Zimmer, *A New Company With a Wild Mission: Bring Back the Woolly Mammoth*, N.Y. TIMES (Sept. 13, 2021), https://www.nytimes.com/2021/09/13/science/colossal-woolly-mammoth-DNA.html [https://perma.cc/GS92-NG79].

353 Coordination with all of the coordinated framework agencies is probably ideal. If APHIS does take control of GE animals from FDA, this will be especially important. Since EPA would be implicated by some modifications to listed plants, they should also be brought into the conversation.

tive, adaptive management approach that incorporates both new knowledge and public comment.[354]

If the Services intend to use the recovery permitting process to create and release GE organisms, then they should focus on bolstering public participation aspects of this process. Expanding public participation and transparency is critical for the acceptance and legitimacy of any reintroduction, as the lack of transparency has contributed heavily to general mistrust of biotechnology.[355] At present, the Act only requires a short thirty-day notice and comment period for scientific recovery permits, as opposed to the sixty days required for incidental take permits.[356] Additionally, the descriptions for scientific recovery permits published in the Federal Register are notoriously short and nondescript, making informed comment difficult.[357] Separate permits should be required for the basic research, the propagation, the field testing, and the eventual release, allowing citizens to weigh in on these projects at multiple steps once additional knowledge has been generated. As part of the permit conditions, permittees could also be required to host public hearings in regions where wild releases are envisioned.

Further, meaningful collaboration with Tribal governments must be made a priority. Though the extent to which the ESA applies to tribal government remains unclear,[358] government-to-government consultation with relevant Indian tribes should be built into this approval process. Under Clinton-era Executive and Secretarial Orders, FWS must consult with tribal offi-

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354 NASEM, *supra* note 317.

355 Kohl, Brossard, Scheudele, & Xenos, *supra* note 22.

356 50 C.F.R. § 17.22 (2023).

357 For example, the recovery permit for the first Phase of research into genetically engineered ferrets reads as follows: "The applicant requests a permit to conduct 'Phase 1' of a multi-phase process to generate disease-resistant black-footed ferrets (*Mustela nigripes*). This phase would involve research in laboratories located in North Rose, NY, and San Diego, CA. The studies aim to develop, test, and optimize model cisgenic and novel disease-resistance pathways in the black-footed ferret, both *in vitro* and *in vivo*, leveraging domestic ferret resources for comparative genomics, comparative proteomics, and interspecies somatic cell nuclear transfer (iSCNT) reproductive techniques for the purpose of enhancing the species' survival. Integration of genetically modified black-footed ferrets into wild populations would require careful execution and constitutes 'Phase 2' of the long-term program." U.S. Endangered Species; Receipt of Recovery Permit Application, 83 Fed. Reg. 15,597, 15,597 (Apr. 11, 2018).

358 MARREN SANDERS, JOINT OCCASIONAL PAPERS NATIVE AFFS. NO. 2007-01, IMPLEMENTING THE FEDERAL ENDANGERED SPECIES ACT IN INDIAN COUNTRY 1 (2007), https://hwpi.harvard.edu/files/hpaied/files/implementing_the_federal_endangered_species_act.pdf?m=1639579032 [https://perma.cc/6SLB-Y2WP].

cials on "policies that have tribal implications."[359] Special solicitation should be given to indigenous peoples whose cultural identities are intertwined with these species.

Additionally, I argue that the use of experimental populations should only be used for field testing and risk assessment. The long-term use of experimental populations, or 4(d) rules, for modified organisms and their descendants would be a short-sighted, and ultimately detrimental, for the recovery of the species. Assisted evolution requires the introduced trait to be spread. Siloing GE organisms indefinitely in experimental populations would defeat the purpose of creating these organisms in the first place. After a period of field testing, the experimental population regulations should no longer apply. It is well established that wild populations can be stocked from captive bred populations without the need for the experimental population designation.[360]

C. Impact Assessments

The most significant issue with applying the current regulatory framework to genetic interventions of listed species is the narrow scope of the impact review. The regulatory mechanisms under the ESA all require that the species being modified does not suffer harm as a result of the modification; however, they are mostly silent in terms of regulating harm to non-target species, human health, or the environment as a whole. Broader environmental impacts are simply not considered under the recovery permitting process. Section 7 intra-agency consultation expands this scope slightly, ensuring that the introduction does not jeopardize any listed species, not just the one modified, but ultimately this too is limited to reviewing effects on listed species. As stated above, biotechnology regulation is also unlikely to fill this gap. Even if these regulations are deemed applicable, their approval processes are generally

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359 Exec. Order No. 13,175, 3 C.F.R. 304 (2000); Dep't of Interior, Secretarial Order 3206: American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act § 4 (June 5, 1997), https://www.doi.gov/sites/doi.gov/files/elips/documents/3206_-american_indian_tribal_rights_federal-tribal_trust_responsibilities_and_the_endangered_species_act.pdf [https://perma.cc/PJ9S-E77R]

360 Doremus, *supra* note213, at 22 ("Nonetheless, Interior conducts and funds reintroduction projects that do not seem controversial without [Section 10(j) experimental population] designation. The California condor, for example, was returned as a nonexperimental population to the Los Padres National Forest in southern California. Similarly peregrine falcons have been re-established at several locations without any reference to section 10(j).").

tied to specific threats to human health and agriculture, not ecological damage.[361]

Both the Services and the Coordinated Framework agencies therefore rely entirely on NEPA for analysis of broader environmental impacts. NEPA requires that agencies evaluate potential environmental impacts and consider alternatives to the proposed action for any "major Federal actions significantly affecting the quality of the human environment."[362] Additionally, NEPA reviews may be too narrow in scope and too qualitative in nature to function as a legitimate ecological risk assessment.[363] Critically, NEPA is traditionally seen as procedural rather than substantive; while it may require the agencies to consider environmental impacts, the agencies are not bound to make substantive decisions based on these assessments.

NEPA does, however, provide the public with an opportunity to comment on the proposed project.[364] Presently, the Services routinely do not prepare an EIS for the issuance of a recovery permit, for controlled propagation projects, or for the use of 10(j) experimental populations; these activities instead tend to be covered under categorical exclusions.[365] For enhancement of survival permits under 10(a)(1)(A), FWS will sometimes perform a NEPA analysis, instead of claiming a categorical exclusion, for agreements that are especially large or controversial.[366] Preparing an EA or EIS instead of utilizing categorical exclusions would be beneficial for public acceptance of the project, and it would be necessary for the Services to fully consider environmental impacts to other species.

D. Factors to Consider

Ideally, the Services would develop a more holistic and formalized impact assessment framework. However, this is possibly outside of the Services' rulemaking authority under the ESA; agency rulemaking is arbitrary and capricious when the agency relies on impermissible factors.[367] Thus, it is unclear

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361 Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitoes and the Coordinated Framework for Biotechnology*, 51 U.C. DAVIS L. REV. 205, 223 (2017).
362 42 U.S.C. § 4332(c).
363 Lin, *supra* note 361.
364 42 U.S.C. §§ 4321–4347.
365 Eubanks II, *supra* note 308, at 285.
366 *See* Börk, *supra* note 310, at 188.
367 Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983).

whether broader ecological and cultural concerns can be incorporated into decision making in the ESA context or if the Services are bound to only consider impacts to listed species. Assuming the Services do have this authority, or that this framework could be incorporated into the Services' NEPA-implementing regulations, I will briefly highlight some of the factors the Services should consider.

Frankly, many of the potential negative impacts related to assisted evolution projects are the same impacts the Services deal with when performing reintroductions, translocations, and captive breeding, such as: the potential introduction of novel diseases; the release of animals that are poorly adapted to the environment; concerns over outbreeding depression; or changes in competitive interactions among species.[368] While history is littered with examples of destructive introduced species, at least one recent study suggests that intentional introductions that were performed for the purposes of conservation have yielded few unintended negative consequences.[369]

When considering the negative effects that genetic engineering might have on the listed organisms, a risk assessment will also need to consider: the function and fitness effects of the trait introduced; novelty of the trait that has been introduced; and whether the modification has been appropriately integrated into the genome. For example, a modification that reintroduces lost variation might be considered less risky than a modification for a novel trait like heat-tolerance. These are factors that are routinely considered by risk assessments performed by the Coordinated Framework agencies.

Broader ecological impacts should also be considered. For example, an assessment will need to consider how the improvement in fitness for the listed species will affect other species in the environment through competition or predation and the potential for transmission of the modified gene to other species through hybridization. Additionally, prudential concerns such as: feasibility; state, tribal, or local ordinances against genetically modified organisms; and international transboundary concerns should be considered.

Finally, ethical concerns inevitably crop up around genetic engineering. Neither the ESA nor NEPA requires a thorough

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368 IUCN Species Survival Comm'n, *Guidelines for Reintroductions and Other Conservation Translocations*, IUCN (2013), https://portals.iucn.org/library/efiles/documents/2013-009.pdf [https://perma.cc/8NP9-QQUT].

369 Novak, Phelan & Weber, *supra* note 30.

consideration of animal welfare or other ethical dimensions.[370] The Animal Welfare Act requires that the Institutional Animal Use and Care Committee ("IACUC") review for biomedical research, but many aspects of conservation engineering projects will fall outside the scope of IACUC review.[371] Bioethicists Professor Ronald Sandler and Professor Lisa Moses teamed up with Dr. Samantha Wisely, one of the prominent biologists involved with the black-footed ferret recovery efforts, to develop a framework for the ethical analysis of conservation cloning projects.[372] Their framework assesses the goals, means, and desirability of the project in order to make recommendations for the ethically responsible use of the technology. This framework could be readily applied to other uses of synthetic biology for wildlife conservation.[373] The Services could predicate the issuance of recovery permits on a condition that an ethical analysis is first performed or incorporate these factors in other ways.

CONCLUSION

The Anthropocene is here. Humanity is already the most significant evolutionary force on the planet. We have two options. We can bury our heads in the proverbial sand and allow our influence to drive species down the road to extinction. Or we can accept that our influence is unlikely to truly abate and that we already direct the evolution of species across the globe. We must acknowledge that species evolve and change, and that we are already the ones directing that change, whether we intend to or not. We can build species that will resist disease and survive in the warmer world we have created. We can build species that will recover their independence, rather than rely upon our persistent human intervention into perpetuity. We must use this power responsibly, but we can and should build better species.

370 David N. Cassuto & Tala DiBenedetto, *Suffering Matters: NEPA, Animals, and the Duty to Disclose*, 42 U. HAW. L. REV. 41, 42, 72 (2020).

371 Ronald L. Sandler, Lisa Moses & Samantha M. Wisely, *An Ethical Analysis of Cloning for Genetic Rescue: Case Study of the Black-footed Ferret*, 257 BIOLOGICAL CONSERVATION 1, 5 (2021).

372 *Id.* at 1.

373 *Id.* at 12.