OMG, IT'S A GMO: AN ANALYSIS OF USING BIOTECHNOLOGY ON ANIMALS TO MITIGATE BIODIVERSITY LOSS

NOTE

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Around the world, ecosystems of all types are suffering from rapid biodiversity loss, and it is critical to employ novel strategies to limit this unprecedented decline in species diversity. One conservation method not traditionally utilized by conservationists is biotechnology. Biotechnology, such as genetic engineering, genome editing, and animal cloning, could provide a much-needed solution to help tackle the world's current biodiversity loss problem. Though biotechnology was recently used to successfully clone an endangered species, there remain many unanswered questions concerning the legality, viability, and practicability of using this technology as a mainstream method to mitigate biodiversity loss. Accordingly, this Note examines the legal and regulatory frameworks in place in the United States that guide the use of biotechnology for conservation purposes. In light of the legal backdrop, this Note further discusses practical considerations, ethical concerns, and issues of public mistrust that must be accounted for before employing biotechnology for conservation purposes.

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INTRODUCTION

"Non-GMO" is a label you can find on nearly every product at your local grocery store. The label conjures images of artificially large, lab-altered fruits, vegetables, and grains—images of genetically modified organisms ("GMOs") infiltrating our food pyramid are strewn across the media. However, genetic modification has far surpassed the idea of making "super" foods and has moved on to making "super" animal species. In fact, the U.S. Fish and Wildlife Service ("FWS") has already used cloning, a technology similar to genetic modification, to help conserve an endangered species.

In recent years, biotechnology innovations like animal cloning have leapt from the pages of far-fetched sci-fi tales to contemporary science. However, there is a prominent lack of literature that explores the use of genetic engineering, genome editing, and animal cloning for conservation purposes. As it stands, conservation-based biotechnology has not been used long enough for substantial, well-rounded information to reach mainstream public media. But certain types of biotechnology, particularly animal cloning, have been used in the commercial sector. For example, animal cloning has been used for years to duplicate beloved pets or livestock with particularly favorable traits.[1] Yet, from a conservation perspective, literature on the subject remains lackluster.[2]

This Note contributes to the current body of literature surrounding animal biotechnology and biodiversity conservation by highlighting the opportunities presented by biotechnology methods in the battle against biodiversity loss and analyzing the remaining gaps before these technologies may be successfully leveraged. As a part of this analysis, this Note provides an overview of the existing—yet uncertain—legal regime for biotechnology in the conservation sector.

This Note considers genetic engineering, genome editing, and animal cloning as three potential biotechnology methods to reduce biodiversity loss and proceeds in six parts. Part I begins by examining the need to take immediate action towards mitigating biodiversity loss. Part II provides an overview of the genetic engineering, genome editing, and animal cloning processes available for conservation use, and Part III elaborates on a recent success story of using these forms of biotechnology on an endangered species—the black-footed ferret. Next, Part IV explains areas of regulatory concern, presenting an overview of the primary U.S. federal agencies and statutes that may be implicated in regulating biotechnology in the conservation sphere. Part V proceeds to explore the uncertainties and potential negative outcomes associated with biotechnology use for conservation purposes. Finally, Part VI concludes that despite the complexities and ongoing challenges, biotechnology has the potential to emerge as an important tool to mitigate and/or limit biodiversity loss.

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[1] Science Magazine, *The Precious Genes of the World's First Cloned Ferret Could Save Her Species*, YOUTUBE, at 01:25 (Feb. 11, 2022), https://www.youtube.com/watch?v=s7M-lrMTFLs.

[2] Video Interview with Ben Novak, Lead Scientist, Revive & Restore (Mar. 9, 2022) [hereinafter Ben Novak Interview I].

I. BIODIVERSITY CONSERVATION IN THE STATUS QUO

A. Biodiversity in Today's World

Biodiversity is vital to any ecosystem. In fact, scientific literature has established that ecosystems suffer significant negative consequences from biodiversity loss.[3] According to Dr. Josef Settele, Head of the Department of Conservation Biology & Social-Ecological Systems at Helmholtz-Centre for Environmental Research:[4]

> "Ecosystems, species, wild populations, local varieties and breeds of domesticated plants and animals are shrinking, deteriorating or vanishing. The essential, interconnected web of life on Earth is getting smaller and increasingly frayed . . . . This loss is a direct result of human activity and constitutes a direct threat to human well-being in all regions of the world."[5]

A rich species variation and high biodiversity metrics allow ecosystems to function properly, and, from an anthropocentric perspective, provide a range of cultural, medicinal, economic, and public health benefits.[6] Decreased biodiversity, however, directly harms ecosystem stability and the subsequent benefits humans reap from these ecological systems.[7]

Yet, Earth is becoming increasingly less biodiverse every year.[8] A recent study estimates that many species are declining in population, while only a handful trend towards an increasing population size; in conjunction, the study also showed an overall decline in species biodiversity.[9] These unprecedented rates of extinction[10] are largely a

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[3] *See, e.g.*, Bradley J. Cardinale et al., *Biodiversity Loss and Its Impact on Humanity*, 486 NATURE 59, 60–61 (2012); J. A. Godbold & M. Solan, *Relative Importance of Biodiversity and the Abiotic Environment in Mediating an Ecosystem Process*, 396 MARINE ECOLOGY PROGRESS SERIES 273, 273 (2009); John P. Rafferty, *Biodiversity Loss*, ENCYCLOPEDIA BRITANNICA (July 19, 2023), https://www.britannica.com/science/biodiversity-loss/additional-info#history.

[4] *Prof. Dr. Josef Settele*, HEMHOLTZ CTR. FOR ENV'T RSCH., https://www.ufz.de/index.php?en=38572 (last updated Jun. 4, 2021).

[5] *U.N. Report: Nature's Dangerous Decline 'Unprecedented'; Species Extinction Rates 'Accelerating'*, U.N. SUSTAINABLE DEV. GOALS (May 6, 2019), https://www.un.org/sustainabledevelopment/blog/2019/05/nature-decline-unprecedented-report/ (citing THE GLOBAL ASSESSMENT REPORT ON BIODIVERSITY & ECOSYSTEM SERVICES, IPBES (2019))).

[6] *See Biodiversity and Health*, WORLD HEALTH ORG. (June 3, 2015), https://www.who.int/news-room/fact-sheets/detail/biodiversity-and-health.

[7] Philip J. Seddon et al., *Reversing Defaunation: Restoring Species in a Changing World*, 345 SCIENCE 406, 409 (2014).

[8] Caitlin Looby, *For Species on the Very Brink of Extinction, Cloning Is a Loaded Last Resort*, MONGABAY (Jan. 5, 2022), https://news.mongabay.com/2022/01/for-species-on-the-very-brink-of-extinction-cloning-is-a-loaded-last-resort/.

[9] Catherine Finn et al., *More Losers than Winners: Investigating Anthropocene Defaunation Through the Diversity of Population Trends*, BIOLOGICAL REVS. (forthcoming) (manuscript at 1, 4). Researchers looked at the global population trends of more than 71,000 animal species,

result of human behaviors such as hunting,[11] intentional or unintentional habitat destruction,[12] the introduction of invasive species,[13] and, most significantly, increased fossil fuel emissions.[14] As continued emissions of harmful greenhouse gases cause and worsen climate change, species loss will be further exacerbated due to drastic changes to the habitat and climactic conditions in which species optimally survive.[15] Combined, these factors have led to a declaration that the world is currently experiencing its sixth mass extinction event.[16] Widespread human-caused species loss warrants the use of unique, innovative methods to potentially mitigate and reverse these harmful trends.

B. Current Conservation Tools

Traditional methods used to preserve or increase biodiversity generally do not directly interfere with species on an individual level. Some of the conservation tools used to protect biodiversity at the *species-level* include keystone population restoration and the

revealing that 48% of the species in the analysis were declining and only 3% were increasing in population size. *Id.*

[10] Erin Okuno, *Frankenstein's Mammoth: Anticipating the Global Legal Framework for De-Extinction*, 43 ECOLOGY L.Q. 581, 585 (2016) ("Although scientists do not agree about the exact rates, species extinction rates are much higher now than the background extinction rates that would exist without humans—some studies suggest at least 1000 times higher.").

[11] Justin Worland, *Research Shows Just How Much Hunting Reduces Animal Populations*, TIME (Apr. 13, 2017), https://time.com/4736526/hunting-reduces-animal-populations/.

[12] William F. Laurance, *Habitat Destruction: Death by a Thousand Cuts*, *in* CONSERVATION BIOLOGY FOR ALL 73, 73–86 (Navjot S. Sodhi & Paul R. Ehrlich eds., 2010). The definition of habitat destruction is "when a natural habitat, such as a forest or wetland, is altered so dramatically that it no longer supports the species it originally sustained. Plant and animal populations are destroyed or displaced, leading to a loss of biodiversity." *Id.* at 73.

[13] *See, e.g.*, Daniel Simberloff, *Invasive Species*, *in* CONSERVATION BIOLOGY FOR ALL, *supra* note 12, at 131–37.

[14] INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE 2022: IMPACTS, ADAPTATION, AND VULNERABILITY: SUMMARY FOR POLICYMAKERS at 9–10, 12 (2022), https://www.ipcc.ch/report/ar6/wg2/downloads/report/IPCC_AR6_WGII_SummaryForPolicymakers.pdf; Catrin Einhorn, *Warning on Mass Extinction of Sea Life: 'An Oh My God Moment'*, N.Y. TIMES (Apr. 28, 2022), https://www.nytimes.com/2022/04/28/climate/global-warming-ocean-extinctions.html.

[15] *Id.*; *see also* Karlsruher Institut für Technologie, *Climate Change Exacerbates Biodiversity Loss*, SCIENCEDAILY (Dec. 8, 2020), www.sciencedaily.com/releases/2020/12/201208111634.htm; INT'L UNION FOR CONSERVATION OF NATURE, SPECIES AND CLIMATE CHANGE (2019), https://www.iucn.org/resources/issues-briefs/species-and-climate-change.

[16] *See* Gerardo Ceballos et al., *Vertebrates on the Brink as Indicators of Biological Annihilation and the Sixth Mass Extinction*, 117 PNAS 13596, 13596; *see also* Ivana Kottasová, *The Sixth Mass Extinction Is Happening Faster Than Expected. Scientists Say It's Our Fault*, CNN (June 1, 2020), https://www.cnn.com/2020/06/01/world/sixth-mass-extinction-accelerating-intl/index.html.

elimination of invasive species.[17] Further, there are ex-situ measures, or methods of preservation by organizations holding wild plants and animals like "zoos, aquaria, botanical gardens, arboreta and seed banks."[18] Modern researchers also engage with conservation tools more directly at the *population level*. For example, scientists explore selective breeding as a method of conserving genetic biodiversity.[19] Selective breeding has a high success rate compared to its laboratory counterparts,[20] but is also an extremely limited method of preserving genetic biodiversity because it is only successful where the population in question has adequate existing genetic variation as well as sufficient time for the species to undergo several generations of natural breeding processes.[21]

While these conservation methods are well known and widely used, as conservationists are met with mounting challenges in maintaining biodiversity, they may need a "bigger toolbox" of tactics to help conservation efforts.[22] One tool that has been historically neglected for conservation purposes is the use of biotechnology to promote biodiversity.

II. OVERVIEW OF BIOTECHNOLOGY

In this Note, "biotechnology" generally refers to three specific technologies: genetic engineering, genome editing, and animal cloning. Part II of this Note provides an overview of each of these biotechnology methods.

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[17] *See, e.g.*, Claudia Donegan, *Leave It to Beavers: Keystone Species Provides Nature-Based Restoration*, MD. DEP'T NAT. RES. (Jan. 1, 2021), https://news.maryland.gov/dnr/2021/01/01/leave-it-to-beavers-keystone-species-provides-nature-based-restoration/ (describing the implementation of "beaver-based restoration approaches" to restore riparian biodiversity); Tim Stephens, *Study Shows Biodiversity Benefits of Removing Invasive Mammals from Islands*, UC SANTA CRUZ (Mar. 21, 2016), https://news.ucsc.edu/2016/03/island-biodiversity.html (noting the great success of invasive species eradication programs).

[18] Diana J. Pritchard et al., *Bring the Captive Closer to the Wild: Redefining the Role of Ex Situ Conservation*, 46 ORYX 18, 18 (2011) (arguing for increased use of ex situ conservation methods to protect global biodiversity).

[19] *See* Norman F. Carlin et al., *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction"*, 33 STAN. ENV'T L.J. 3, 13 (2014).

[20] *Id.* Two recent successful selective breeding projects include the quagga, a subspecies of zebra, and the aurochs, an extinct predecessor of cattle. *Id.* at 15.

[21] *Id.* at 13.

[22] Richard T. Corlett, *A Bigger Toolbox: Biotechnology in Biodiversity Conservation*, 35 TRENDS IN BIOTECHNOLOGY 55, 55 (2017). See Kevin M. Esvelt et al., *Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations*, 3 ELIFE, July 2014, for a discussion of one such tactic: the theoretical use of RNA-guided gene drives to overcome the biomolecular limitations currently present when attempting to alter ecosystems.

A. Methods of Biotechnology Defined

Genetic engineering is the direct manipulation of DNA by adding, rearranging, or deleting genes to modify an organism.[23] Broad in scope, genetic engineering may, but does not necessarily, involve adding foreign gene[s] into an organism's DNA.[24] While genetic engineering allows the insertion of DNA into a genome, scientists can only control the general location of the incision; scientists cannot determine *exactly* where the DNA segment lands.[25] This powerful technology may serve to conserve beneficial alleles that could otherwise be lost in conventional breeding and can produce the desired modified organisms at a low cost and within a short timeframe.[26] In the context of conservation, genetic engineering can be used to bring back an extinct species by filling in the missing segments of any part of the species' genome with genetic information from a closely related species or a synthetic strand of DNA.[27]

Genome editing, in turn, is a more precise variation of genetic engineering that allows scientists to accurately target a *specific* region of the genome to edit.[28] As a result of its acute precision, genome editing is considered more exact than standard genetic engineering methods, allowing for less variability and minimizing unexpected outcomes.[29] Importantly, genome editing does not involve adding in a foreign gene into an organism's DNA, but only precisely edits the organism's preexisting genes.[30]

Cloning, which in this Note references a process called somatic cell nuclear transfer, is different from genetic engineering and genome

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[23] *Agricultural Biotechnology Glossary*, U.S. DEP'T OF AGRIC., https://www.usda.gov/topics/biotechnology/biotechnology-glossary (last visited Sept. 11, 2023).

[24] *Genetic Engineering*, NAT'L HUM. GENOME RSCH. INST. (Oct. 5, 2023), https://www.genome.gov/genetics-glossary/Genetic-Engineering.

[25] *Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2023), https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/qa-fda-regulation-intentional-genomic-alterations-animals#genome.

[26] Jianguo Zhao et al., *Genome Editing in Large Animals: Current Status and Future Prospects*, 6 NAT'L SCI. REV. 402, 403 (2019).

[27] Norman Wagner et al., *De-Extinction, Nomenclature, and the Law: How We Name Resurrected Species Can Have Legal Implications, Particularly for Conservation*, 356 SCIENCE 1016, 1016 (2017).

[28] Naglaa A. Abdallah et al., *Genome Editing for Crop Improvement: Challenges and Opportunities*, 6 GM CROPS & FOOD 183, 184 (2015).

[29] *Id.* at 184–85.

[30] Tien Van Vu et al., *Genome Editing and Beyond: What Does It Mean for the Future of Plant Breeding?*, 255 PLANTA, May 2022, at 9 (citing Jan G. Schaart et al., *Opportunities for Products of New Plant Breeding Techniques*, 21 TRENDS IN PLANT SCI. 438 (2016)) ("The advantage of gene editing over genetic engineering is that the end product acquires no foreign genes.").

editing, because there is no genetic manipulation involved. Instead, the nucleus of a donor somatic cell is inserted into an enucleated egg cell (one without a nucleus) to create and stimulate the development of an embryo.[31] Somatic cell nuclear transfer works best with well-preserved DNA, meaning cloning is only truly a viable possibility for recently extinct species whose tissues have been preserved with modern technology.[32] Further, a closely related species is needed to serve as the egg cell donor and, in mammalian species, as the surrogate mother for the gestation period.[33] Because of the need for a member of another species, animals produced by somatic cell nuclear transfer are technically not exact clones but are extremely close to the member of the extinct species that provided the somatic DNA.[34]

Together, genetic engineering, genome editing, and cloning may provide new opportunities in the fight against biodiversity loss.

B. Humans' History with Biotechnology

Evidence of genetic engineering and genome editing dates back to the 1970s,[35] and research on cloning began even earlier in the late 1800s.[36] One of the first known instances in which humans learned of the potential impacts of biotechnology is the famous cloning of Dolly the sheep in 1996.[37] While Dolly made cloning a more familiar household term, the public's interaction with this technology has been limited, and people remain mistrustful of animal cloning.

Despite public wariness, biotechnology—in particular, animal cloning methods—have been highly successful in the commercial sector. Many private companies around the world—in countries including the U.S., India, Argentina, UAE, Korea, and China—have effectively used the technology for a range of purposes.[38] Companies

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[31] X. Cindy Tian et al., *Cloning Animals by Somatic Cell Nuclear Transfer – Biological Factors*, 98 REPRODUCTIVE BIOLOGY & ENDOCRINOLOGY, Nov. 2003, at 1.

[32] Carlin et al., *supra* note 19, at 8; *see also* Corlett, *supra* note 22, at 61.

[33] Carlin et al., *supra* note 19, at 8.

[34] *Id.* at 9.

[35] *Science and History of GMOs and Other Food Modification Processes*, U.S. FOOD & DRUG ADMIN. (Apr. 19, 2023), https://www.fda.gov/food/agricultural-biotechnology/science-and-history-gmos-and-other-food-modification-processes; Dana Carroll, *Genome Editing: Past, Present, and Future*, 90 YALE J. BIOLOGY & MED. 653, 653 (2017).

[36] Shannon Gunn, *Evolution of Cloning: A Dolly Good Show!*, FRONT LINE GENOMICS (Sept. 14, 2021), https://frontlinegenomics.com/evolution-of-cloning-a-dolly-good-show.

[37] *See The History of Cloning*, GENETIC SCI. LEARNING CTR. (July 10, 2014), https://learn.genetics.utah.edu/content/cloning/clonezone.

[38] *See, e.g.*, Jon Cohen, *Six Cloned Horses Help Rider Win Prestigious Polo Match*, SCIENCE (Dec. 13, 2016), https://www.science.org/content/article/six-cloned-horses-help-rider-win-prestigious-polo-match; Andrés Gambini & Marc Maserati, *A Journey Through Horse Cloning*, 30

like ViaGen Pets & Equine perform cloning services for improved selective breeding and the reproduction of valuable domestic livestock, competition animals, service animals, and companion animals.[39] Success of biotechnology like animal cloning in the commercial sector highlights its promise for expansion into conservation efforts.

By the turn of the twenty-first century, though biotechnology still was not a widespread tool for conservation efforts, scientists had created clones of three endangered species: the gaur (*Bos gaurus*) and European mouflon (*Ovis aries musimon*) in 2001, followed by the banteng (*B. javanicus*) in 2003.[40] None of these clones reached maturity.[41] In 2020, however, conservationists broke new ground with the successful cloning of a black-footed ferret.

III. A MODERN EXAMPLE OF BIOTECHNOLOGY AT WORK: ELIZABETH ANN

A. Background Information on the Black-Footed Ferret Species

The black-footed ferret, scientifically known as *Mustela nigripes*, is the only native ferret species in North America.[42] It is a small, carnivorous mammal, and ninety percent of the black-footed ferret's diet is comprised of prairie dogs (*Cynomys ludovicianus*),[43] which are keystone species for prairie lands.[44] Due to their existence as an important predator and prey in the prairie ecosystem, black-footed ferrets act as a "key indicator" of overall prairieland health—that is, the health of a black-footed ferret population signals the relative health of both its prairie dog prey and its prairieland environment.[45] Notably, the prairielands that black-footed ferrets call home may be significant in

REPROD., FERTILITY & DEV. 8 (2018); Joseph Campbell, *Two of a Kind: China's First Pet Cloning Service Duplicates Star Pooch*, REUTERS (Dec. 17, 2018), https://www.reuters.com/article/us-china-petcloning/two-of-a-kind-chinas-first-pet-cloning-service-duplicates-star-pooch-idUSKBN1OG11J.

[39] Genetic Science Learning Center, *Why Clone?*, UNIV. OF UTAH, https://learn.genetics.utah.edu/content/cloning/whyclone#cite (last visited Oct. 8, 2023).

[40] Rachel Fritts, *Cloning Goes Wild: A Ferret Named Elizabeth Ann Could Become the First Cloned Mammal to Help Save an Endangered Species*, 375 SCIENCE 134, 136 (2022).

[41] *Id.*

[42] *Black-Footed Ferret: Facts*, WORLD WILDLIFE FUND, https://www.worldwildlife.org/species/black-footed-ferret (last visited July 28, 2023).

[43] *Can't Live Without 'Em: Black-Footed Ferrets*, DEFS. OF WILDLIFE (Sept. 22, 2011), https://defenders.org/blog/2011/09/cant-live-without-em-black-footed-ferrets.

[44] *Prairie Dog*, DEFS. OF WILDLIFE, https://defenders.org/wildlife/prairie-dog (last visited Aug. 27, 2023).

[45] *Can't Live Without 'Em*, *supra* note 43.

mitigating climate change as they are more effective at reabsorbing expelled carbon in the air (say, for example, from a wildfire) than forests.[46]

Despite its significance, the black-footed ferret is also a listed endangered mammal in the U.S.—in fact, it was at one point thought to be extinct.[47] The sylvatic plague and significant habitat loss ravaged the species' population size.[48] In 1981, however, eighteen wild black-footed ferrets were discovered in Wyoming.[49] Soon after, the Wyoming Game and Fish Department ("WGFD") created a conservation and captive breeding program in an effort to protect the population.[50] Subsequently, more than 9,000 black-footed ferret offspring have been bred at conservation centers.[51] Though the species' reintroduction back into its natural prairie habitat has been successful to an extent,[52] conservationists remained (and continue to remain) far from their goal of sustaining a wild black-footed ferret population of at least 3,000.[53] In order to reach population goals, conservationists turned to the use of biotechnology to protect black-footed ferrets.

B. Saving the Black-Footed Ferret

The two greatest challenges to the black-footed ferret's population recovery are a strong susceptibility to sylvatic plague bacteria (*Yersinia pestis*)—carried in their primary prey, the prairie dog—and a lack of genetic diversity.[54] All black-footed ferrets today come from just seven distinct cell lines, which means their genetic diversity is severely bottlenecked; the ferrets are therefore likely to spiral into an "extinction vortex," where survival is threatened by issues like genetic drift and inbreeding.[55] Consequently, while prairie dog populations are

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[46] Allie Weill, *Anyone Thinking About Planting Grasslands to Fight Climate Change? They Should*, KQED (July 10, 2018), https://www.kqed.org/science/1927097/to-fight-climate-change-grasslands-may-be-a-safer-bet-than-forests.

[47] *Black-Footed Ferret: Facts*, *supra* note 42.

[48] *Can't Live Without 'Em*, *supra* note 43.

[49] *The Black-Footed Ferret Project: About the Project*, REVIVE & RESTORE [hereinafter *About the Project*], https://reviverestore.org/projects/black-footed-ferret/ (last visited July 28, 2023).

[50] *The Black-Footed Ferret Project: About the Species*, REVIVE & RESTORE, https://revive restore.org/projects/black-footed-ferret/about-the-species/ (last visited July 28, 2023).

[51] *Id.*

[52] *Id.* The Black-Footed Ferret Recovery Implementation Team has reintroduced more than 4,300 captive black-footed ferrets to 30 sites across North America since 1992. About 150 to 220 captive black-footed ferrets are reintroduced into the wild every year. *Id*.

[53] *Id.* Today, there are roughly 300 black-footed ferrets living in the wild. *Id*.

[54] *Id.*

[55] *Id.*

sufficiently large and diverse enough to adapt to the sylvatic plague, the black-footed ferret is not capable of such resistance.[56]

The plight of the black-footed ferret presented a uniquely feasible opportunity for biotechnology intervention.[57] Researchers possess detailed knowledge about both the black-footed ferret and the domestic ferret, a closely related species.[58] In addition, researchers have been working for roughly forty years to save the black-footed ferret, meaning the existing rescue infrastructure for the species is extensive.[59] Keeping in mind the novelty of biotechnology in the conservation field, FWS[60] needed to select a species with an elaborate conservation foundation as a starting point for the application of this new technology. Moreover, public perception of ferrets as "cute" species worthy of preservation[61] along with favorable views from ranchers—who would have opposed conservation of a peskier species like the prairie dog[62]—further provided support for this conservation effort.

After determining the black-footed ferret was a good candidate for the use of conservation biotechnology, FWS contacted Revive & Restore, a conservation organization whose mission is "to enhance biodiversity through the genetic rescue of endangered and extinct species."[63] Revive & Restore, in partnership with ViaGen Pets & Equine and the San Diego Zoo Wildlife Alliance, determined cloning the cell lines of a deceased black-footed ferret was a viable method of maximizing genetic diversity in the existing population.[64] Since Revive & Restore's proposed cloning idea would involve taking DNA from an extinct black-footed ferret and placing it in a domestic ferret for incubation—a groundbreaking use of biotechnology—Revive & Restore required a unique permit.[65]

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[56] *Id.*

[57] Ben Novak Interview I, *supra* note 2.

[58] *Id.*

[59] *Id.*

[60] See discussion *infra* Part IV.A.1 on FWS regulatory authority in the area of biotechnology for wildlife conservation.

[61] Susan Morse, *New Hope for Ferrets: Recovery Efforts are Giving Wiry Mammals a New Chance at Survival*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/story/new-hope-ferrets (last visited Aug. 30, 2023) (listing the charismatic nature of the species as one of several traits that made it a compelling conservation story).

[62] Associated Press, *Ranchers Sought to Help Black-Footed Ferret*, DENVER POST (Apr. 30, 2016), https://www.denverpost.com/2013/02/17/ranchers-sought-to-help-black-footed-ferret/.

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

[64] *Id.*

[65] *About the Project*, *supra* note 49. As the organization with the optimal capacity for the laboratory work (and the organization approached by FWS), Revive & Restore was the entity best

In 2018, FWS granted Revive & Restore a first-of-its-kind Endangered Species Recovery Permit for laboratory research concerning the black-footed ferret conservation project.[66] Part of the permit authorized Revive & Restore to research the viability of cloning cryopreserved cell lines to restore the black-footed ferret's genetic diversity.[67] In addition, the permit was subject to the public review requirements of the National Environmental Policy Act ("NEPA").[68]

During the cloning process, a legal concern arose—the potential for a lawsuit in the name of genetic purity and species classification concerns.[69] In somatic cell nuclear transfer, the resulting clone would have its domestic ferret mother's mitochondrial DNA. Mitochondrial DNA is only inherited through the maternal cell line and is different from the nuclear genome.[70] The presence of domestic ferret mitochondrial DNA in a clone of a black-footed ferret could cause legal issues, because species have historically been classified according to their mitochondrial DNA (as opposed to their nuclear DNA).[71] FWS does not have official guidelines on how cloned species should be classified.[72] Due to this ambiguity, genetic purists could bring a lawsuit arguing that any clone produced via somatic cell nuclear transfer is not a *true* clone, but a closely related species. Such a case could lead to protection issues under the Endangered Species Act ("ESA") and risk the future of biotechnology for species preservation.[73]

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positioned to obtain the Endangered Species Recovery Permit, among the various organizations involved. *See id.*

66 *Id.*; *see also* discussion *infra* Part IV.A.1 (discussing FWS permits for conservation).

67 *About the Project*, *supra* note 49.

68 *Id.*; *see also infra* Part IV.B.2 (discussing NEPA requirements for biotechnology interventions).

69 *See* discussion *infra* Part V.A.3.

70 *Mitochondrial DNA*, NAT'L HUM. GENOME RSCH. INST. (Oct. 5, 2023), https://www.genome.gov/genetics-glossary/Mitochondrial-DNA.

71 Maxime Merheb et al., *Mitochondrial DNA, A Powerful Tool to Decipher Ancient Human Civilization from Domestication to Music, and to Uncover Historical Murder Cases*, 8 CELLS, May 2019, at 14 ("MtDNA [mitochondrial DNA] has been shown to be an ideal marker for molecular diversity. The reasons for this are its ability to be clonally inherited, neutral or near neutral molecular evolution, and that its constant accumulation of neutral or slightly deleterious mutations with time enables accurate dating of samples."); N. Galtier et al., *Mitochondrial DNA as a Marker of Molecular Diversity: A Reappraisal*, 18 MOLECULAR ECOLOGY 4541, 4546–47 (2009).

72 Kimberly Willis, *Wildlife Is Not Crying Wolf: How Fish & Wildlife Service Can Utilize the Endangered Species Act to Mitigate Hybridization Threats to Listed Species*, 26 HASTINGS ENV'T L.J. 255, 264 (2020).

73 If a clone with different mitochondrial DNA is not classified as the endangered species its nuclear DNA comes from, then it will not receive the legal protections of the ESA. Further, issues concerning future protections could arise as the endangered species' population grows with the introduction of clones. To determine if a species should be classified as endangered under the ESA, FWS looks for one, or more, of the following five justifications: (1) loss of a species'

Despite the regulatory and legal complications, Revive & Restore successfully cloned the black-footed ferret in December 2020, naming the clone Elizabeth Ann.[74] While Elizabeth Ann is unable to produce offspring herself, [75] if clones like Elizabeth Ann are someday able to produce viable offspring, they will contribute much-needed genetic diversity to the black-footed ferret population. Based on the significant success and progress seen with the recent cloning of the black-footed ferret, scientists should consider the use of biotechnology as a more viable tool to combat biodiversity loss.

IV. REGULATORY CONCERNS ASSOCIATED WITH USING BIOTECHNOLOGY FOR BIODIVERSITY CONSERVATION

However, if animal cloning—like that of Elizabeth Ann—and other biotechnology is to become a more popular tool in the fight against biodiversity loss, there must be a robust legal regime to support this new method of conservation. As suggested by the case study of the black-footed ferret, many legal and regulatory regimes will likely apply to genetically engineered, genome edited, or cloned species at each stage of conservational intervention. This Part details the particular administrative agencies and federal statutes relevant to biotechnology use for the purposes of wildlife conservation.

habitat or range, (2) over-exploitation of a species, (3) disease or predation, (4) failure of other regulations or measures to protect a species, or (5) other natural or manmade factors that threaten the species. Andrew Carter, *How Is a Species Added to the Endangered Species List?*, DEFS. OF WILDLIFE (Mar. 20, 2023), https://defenders.org/blog/2023/03/how-species-added-endangered-species-list. If the existence of clones takes away some of the above factors, the formerly endangered animal will stop receiving legal protection, and the entire cycle of a non-endangered animal becoming endangered again may ensue. *See also* discussion *infra* Part IV.B.1.

[74] *About the Project*, *supra* note 49.

[75] Revive & Restore scientist, Ben Novak, revealed: "Elizabeth Ann will not have offspring in her lifetime, but she is in excellent health and will likely have a good long life as a conservation biotech ambassador." During the mating process, researchers, "found that her uterus was swollen and filled with fluid, a condition known as hydrometra" and "ultimately for her safety an ovariohysterectomy was performed. She recovered well and rapidly and is her normal self today." In addition, Novak notes, "We have no reason to suspect Elizabeth Ann's condition is related to her being a clone, however, the causes of hydrometra in mammals are unknown. With only one cloned animal so far, it is scientifically impossible to rule out epigenetic or genetic factors, but we do know currently that Elizabeth Ann's genomic methylation profile (just one measure of epigenetics) is consistent with that of naturally conceived black-footed ferret females, which notably differ from the methylation profiles of males. No disrupted genes have yet been identified in her genome, but analyses are ongoing." As of 2023, Revive & Restore continues to attempt to birth clones from the same cell line that produced Elizabeth Ann. Email from Ben Novak, Lead Scientist, Revive & Restore (Feb. 14, 2023) (on file with author).

A. Federal Agencies

There are a range of federal agencies that may be implicated when biotechnology is employed to preserve a species. The discussion below provides an overview of the potential agencies with jurisdiction over the various stages of a conservation-based biotechnology intervention.

1. U.S. Fish and Wildlife Service ("FWS")

The U.S. Fish and Wildlife Service ("FWS") grants permits for conservation groups to engage in specific conservation efforts with endangered species.[76] As previously discussed, before Revive & Restore could clone the endangered black-footed ferret, FWS had to grant Revive & Restore a special biotechnology permit.[77] The permit considered Revive & Restore's proposed laboratory experiment plan, initially put forth in 2016, and served to authorize the organization to do the lab work needed to address the central causes of reduced black-footed ferret populations—to increase genetic diversity and improve resistance to the sylvatic plague.[78]

The FWS permitting process is subject to a public comment period under NEPA.[79] For example, FWS's permit for Revive & Restore's plan was subject to NEPA requirements, including appropriate public engagement.[80] Regarding the public comment period for the black-footed ferret cloning project, lead Revive & Restore scientist Ben Novak noted there was no explicit opposition against the general idea of cloning—rather, the primary concerns were about the potential efficacy of the technology.[81] While Revive & Restore's 2018 permit was "a first-of-its-kind Endangered Species Recovery Permit from the [FWS] to initiate the foundational laboratory research for the genetic rescue of the [b]lack-footed ferret,"[82] as such interventions become more common, FWS will likely have a continued role in the process as the central permit-granting entity for endangered species recovery projects.

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[76] Endangered Species Act, 16 U.S.C. § 1539(a)(1)(A); *see also* Endangered and Threatened Wildlife and Plants; Enhancement of Survival and Incidental Take Permits, 88 Fed. Reg. 8380 (proposed Feb. 9, 2023) (to be codified at 50 C.F.R. §§ 13, 17).

[77] U.S. Endangered Species; Receipt of Recovery Permit Application, 83 Fed. Reg. 15597, 15597 (Apr. 11, 2018).

[78] *The Black-Footed Ferret Project: Major Milestones*, REVIVE & RESTORE [hereinafter *Major Milestones*], https://reviverestore.org/projects/black-footed-ferret/major-milestones/ (last visited Aug. 27, 2023).

[79] *See infra* Part IV.B.2 (discussing NEPA and biotechnology interventions).

[80] *Major Milestones*, *supra* note 78.

[81] Ben Novak Interview I, *supra* note 2.

[82] *About the Project*, *supra* note 49.

2. Food and Drug Administration ("FDA")

The scope of the U.S. Food and Drug Administration's ("FDA") authority in the context of biotechnology for conservation purposes is less clear. As an initial matter, it is unclear whether the FDA has authority to regulate all forms of biotechnology on animals.[83] While FDA has published several guidelines relating to genetically engineered and genome edited animals,[84] its guidance for cloned species is minimal.[85]

With respect to genetically engineered or genome-edited animals, FDA views the "heritable genetic construct" in such organisms as a "new animal drug."[86] Under the Food, Drug, and Cosmetic Act ("FDCA"), the FDA has authority to regulate all "drugs" and "devices."[87] The definition of a "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[88] FDA justifies its authority over genetically engineered or genome-edited animals on the basis that, "[t]he rDNA construct in a [genetically engineered] animal that is intended to affect the structure or function of the body of the [genetically engineered] animal, regardless of the intended use of products that may be produced by the [genetically engineered] animal, meets the FFDCA drug definition."[89] While species resulting from genetic engineering and genome editing are not "drugs" in the common sense, according to FDA, "animals produced through the

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[83] *See* U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY #187; REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS (2017) [hereinafter GUIDANCE FOR INDUSTRY #187], https://www.fda.gov/media/74614/download.

[84] *See, e.g., id.*; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS (2015) [hereinafter 2015 GUIDANCE], https://www.fda.gov/media/135115/download.

[85] *See., e.g.*, *Animal Cloning*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/safety-health/animal-cloning (last updated Apr. 10, 2023) (listing the few FDA memoranda and guidance documents on the topic of cloning).

[86] Margaret Foster Riley, *One Health Pandemic Prevention and Mitigation: The Role of FDA*, 76 FOOD & DRUG L.J. 200, 230–31 (2021) (citing 21 U.S.C. § 321(g)(1) (2019)).

[87] 21 U.S.C. §§ 301 *et seq.*; 21 U.S.C. § 321(g)(1) (2019).

[88] 21 U.S.C. § 321(g)(1).

[89] 2015 GUIDANCE, *supra* note 84, at 6; *see also* BIOTECH. WORKING GRP., MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY (2017) [hereinafter 2017 UPDATE TO CFRB], https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf.

use of genome editing technologies and genetic engineering" are within the scope of the Agency's regulatory power.[90]

As of 2017, FDA asserts its authority over the "intentionally altered genomic DNA in animals" both relating to the animal that has been genetically engineered or undergone genome editing and its offspring with the inheritable genetic modification.[91] This is important because it implies that FDA not only has authority to regulate the initially genetically engineered animal but the Agency also maintains its authority for generations of that animal's reproductive line.[92] Nevertheless, it is important to note that FDA explicitly and repeatedly states that its guidance is not legally binding and merely constitutes industry recommendations.[93]

Genetically engineered or genome edited animals that are regulated by other government agencies are generally not subject to the enforcement of FDA's Investigational New Animal Drug ("INAD") or new animal drug application ("NADA") requirements, both of which merely take NEPA's requirement of an environmental impact assessment into consideration prior to approval.[94] Most species considered for genetic engineering or genome editing for conservation purposes are likely to be endangered species (and therefore also regulated by FWS), or extinct species (which may also be regulated by FWS). If the genetically engineered animal project is not regulated by another federal agency, it is important to note that NADAs are generally "deemed unsafe" until the FDA approves the application for the project's specific use; genetically engineered animals do not qualify for conditional approval or indexing like some other new animal drugs.[95] Regardless, FDA states it is allowed to "exercise enforcement discretion," mainly based on the level of environmental and safety risks associated with the genetic modification of the animal and its intended long-term use.[96]

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90 *Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, *supra* note 25.

91 GUIDANCE FOR INDUSTRY #187, *supra* note 83, at 3.

92 *Id.*

93 *Id.* FDA chooses to work via guidance in this area—instead of proposing firm, legal rules for genetic engineering and genome editing—likely for two reasons: (1) biotechnology is constantly evolving and industry guidelines are more broadly applicable than strict rules, and (2) guidance over legal substance effectively keeps the courts out of this area of regulation.

94 *Id.* at 9.

95 *Id.* at 6–7. See 21 U.S.C. § 360b for the definition of "new animal drug."

96 GUIDANCE FOR INDUSTRY #187, *supra* note 83, at 8.

3. U.S. Department of Agriculture ("USDA")

The U.S. Department of Agriculture ("USDA") has a regulatory purview separate from FDA that may be helpful in addressing the risks that cloned or bioengineered species could pose to livestock by transmitting pests or other diseases. Veterinary biologics, including vaccines and biologic treatments for animals, as well as risk assessments analyzing risk of biotech-created organisms on livestock health, fall under broad authority granted to USDA under the Animal Health Protection Act ("AHPA").[97] Specifically, the Secretary of Agriculture has the "authority to prohibit or restrict imports or entry of any animal, article, or means of conveyance into the United States if the Secretary determines this is necessary to prevent the introduction or dissemination of any pest or disease of livestock."[98] This is done via a permit procedure carried out by the USDA's Animal and Plant Health Inspection Service ("APHIS"), which may grant or deny permits for the interstate movement of organisms—including genetically engineered species—that could "cause or transmit animal disease."[99] Accordingly, while it is unlikely that USDA has authority over all cloned populations of endangered or threatened species that are released back into the environment, USDA does have limited power where risk to livestock is involved.[100]

USDA also regulates the use of biotechnology in plants, which may provide some insight on how the USDA could similarly approach the use of biotechnology in animals under the Agency's regulatory umbrella.[101] In USDA's most recent Amended Policy on Biotechnology, the Agency exempts the following types of genetically engineered plants from regulatory oversight:

> 1) "[where] the genetic modification is solely a deletion of any size; or
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> 2) the genetic modification is a single base pair substitution; or

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[97] 7 U.S.C. § 8301 (2002). *See also* U.S. DEP'T OF AGRIC., ANIMAL AND PLANT HEALTH INSPECTION SERVICE FRAMEWORK FOR THE REGULATION OF GENETICALLY ENGINEERED ANIMALS AND INSECTS PURSUANT TO THE ANIMAL HEALTH PROTECTION ACT (2018) [hereinafter *APHIS Framework*], https://www.aphis.usda.gov/animal_health/downloads/framework-ee-ahpa.pdf; *What FDA Does and Does Not Regulate*, U.S. FOOD & DRUG ADMIN. (Oct. 19, 2017), https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate.

[98] *APHIS Framework*, *supra* note 97, at 1; *see* 2017 UPDATE TO CFRB, *supra* note 89, at 23.

[99] *APHIS Framework*, *supra* note 97, at 2; *see also* 9 C.F.R. § 122 (2023).

[100] *See* Lauren Corey, *A Black-Footed Ferret and U.S. Law: Lessons Learned from the First Successful Clone of a Native U.S. Endangered Species*, 23 N.C. J.L. & TECH. 338, 366–68 (2021).

[101] *Animal and Plant Health Inspection Service: Program Overview*, U.S. DEP'T OF AGRIC. (Jan. 18, 2023), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/program-overview.

> 3) the genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or
>
> 4) [t]he plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent."[102]

The third type of genetically engineered plant exempted involves a type of genome editing that can also be used to reintegrate lost alleles into endangered animal species, an activity that Revive & Restore is pursuing to increase genetic diversity of adaptive alleles.[103] Given the parallels between the genetic engineering methods for plants that are exempted from USDA oversight and the similar genome editing process that could be used for animal species, it is possible that USDA could extend the same regulatory exemptions to genetically engineered animals. Such regulatory exemptions would be in line with USDA policy—according to former Secretary Perdue, "USDA seeks to allow innovation when there is no risk present."[104]

As the use of biotechnology becomes more popular, agencies implementing regulations for genetically modified animals may look to USDA's Amended Policy as a template for how to regulate biotech-animal species.[105] USDA's regulatory model—foregoing parameters for plant species that could have been derived via traditional breeding techniques but were created using biotechnology—could be adopted by other federal agencies and applied to animal species. For example, FWS could also embrace a stance in which the Agency does not oversee animals created or enhanced with biotechnology if the animal could have been produced through traditional breeding. Regulations like USDA's Amended Policy on Biotechnology, though not directly applicable to the use of biotechnology in the conservation of animal species, provide a foundation that future regulators can use as a model for creating regulations more specific to biotechnology and conservation efforts.

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[102] Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29790, 29791 (May 18, 2020).

[103] Email from Ben Novak, Lead Scientist, Revive & Restore (Apr.1, 2023) (on file with author).

[104] Press Release, Sonny Perdue, Secretary, U.S. Dep't of Agric., Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (Mar. 28, 2018), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation.

[105] *See* Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29790, 29791 (May 18, 2020).

4. U.S. Environmental Protection Agency ("EPA")

The U.S. Environmental Protection Agency ("EPA") is another agency that may have regulatory oversight over species created or enhanced with biotechnology. Under the Toxic Substances Control Act ("TSCA"), EPA has the authority to regulate chemicals that present unreasonable risks to human health and the environment—specifically, EPA may require reporting, record-keeping, testing, and/or prohibitions relating to chemical substances and/or mixtures.[106] A "chemical substance" is outlined in TSCA as "any organic or inorganic substance of a particular molecular identity, including . . . any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and . . . any element or uncombined radical."[107] Under this broad definition, the DNA, rDNA, and nucleic inserts into animals for conservation purposes could constitute "chemical substances" subject to EPA's regulatory oversight under the statute. In fact, EPA itself has confirmed that the term "chemical substance" is wide-reaching.[108] This exercise of regulatory authority is further bolstered because under TSCA, EPA can "regulate *all* microorganisms produced for environmental, industrial, or consumer uses."[109] A separate statute, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") also allows EPA to "to regulate genetically-engineered microorganisms formed by deliberate combinations of genetic material from dissimilar source organisms," showing that genetically-engineered organisms can fall under EPA authority.[110] Based on these considerations, the broad language present in TSCA may give EPA authority to regulate biotechnology used for conservation purposes where a "chemical substance" exists.

5. U.S. Coordinated Framework for the Regulation of Biotechnology ("CFRB")

Finally, all federal genetic engineering regulations need to follow the guidelines of the Coordinated Framework for the Regulation of

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106 15 U.S.C. § 2603 (2019); *see also Summary of the Toxic Substances Control Act*, U.S. EPA, https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act (last updated Oct. 4, 2022).

107 15 U.S.C. § 2602(2)(A).

108 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, 189–90 (2019).

109 *Id.* at 189 (emphasis added) (quoting Rekha K. Rao, Note, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish™*, 57 ADMIN. L. REV. 903, 910 (2005)).

110 *Id.* (quoting Rekha K. Rao, Note, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish™*, 57 ADMIN. L. REV. 903, 910–11 (2005)).

Biotechnology ("CFRB"), a document published by the Executive Office of the President's Office of Science and Technology Policy in 1986.[111] The CFRB provides an overview of genetic engineering policies from federal agencies.[112] More specifically, CFRB connects the regulatory regimes of the FDA, USDA, and EPA to collectively regulate biotechnology, "cover[ing] the full range of plants, animals and microorganisms derived from biotechnology in an integrated and coordinated manner."[113] Each of the three main federal agencies in the CFRB plays a specific role in contributing to the comprehensive regulation of the use of biotechnology for biodiversity conservation.[114]

The CFRB updated its policy in 1992 to clarify that its regulation of biotechnology products in the environment "focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created."[115] More recently, in 2017, the CFRB again updated its policy, explicitly outlining the statutory authority and goals of each agency in relation to the CFRB.[116]

Though the CRFB could be the most comprehensive regulatory tool the U.S. currently has for biotechnology as it relates to biodiversity conservation, there are also individuals opposed to relying on this cross-agency structure. Some critics believe that even a seemingly cooperative regulatory framework for biotechnology shared between current government agencies would lead to major gaps in regulation.[117] When examining the motley web of laws and regulations the CRFB relies on, one journalist notes the laws were "all written for other purposes" besides the specific regulation of biotechnology.[118] As a result, it can be difficult to apply these laws to modern genetic engineering, genome editing, or animal cloning contexts.[119] In light of these complexities, in 2019, the Trump Administration issued Executive Order 13874, which

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111 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302 (June 26, 1986).

112 *Id.*

113 *About the Coordinated Framework*, UNIFIED WEBSITE FOR BIOTECH. REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about (last visited May 6, 2022).

114 *Id.*

115 Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6753 (Feb. 27, 1992).

116 See 2017 UPDATE TO CFRB, *supra* note 89, at 9 tbl.1 for more specifics about the statutes used by each agency.

117 *See* Babcock, *supra* note 108, at 190–91 (discussing critics of the CFRB).

118 Rosie Mestel, *Genetic Modification Strains Old Food and Drug Laws*, L.A. TIMES (Mar. 23, 2013), https://www.latimes.com/science/la-xpm-2013-mar-23-la-sci-gmo-regulations-20130324-story.html.

119 *Id.*

recognizes that biotechnology has the powerful potential to "revolutionize" agricultural practices and asks CFRB to create a science-based regulatory framework for this growing area of technology.[120]

B. Traditional Environmental Statutes

In addition to the statutes like FDCA, APHA, and TSCA that confer authority on agencies to regulate biotechnology-derived species and/or processes, there are also additional statutory mandates under bedrock environmental statutes that may be applicable to bioengineered species.

1. Endangered Species Act ("ESA")

One avenue of protection afforded to endangered animals is the federal Endangered Species Act ("ESA"), a 1973 statute enacted to protect endangered and threatened species from extinction.[121] The statute establishes protections for animals and plants that are listed as threatened or endangered; delineates a process for adding or removing species from the threatened and endangered species lists; and ensures that both private parties and government entities avoid "taking" listed species.[122] The cusp of new biotechnologies raises the question: do cloned or genetically modified versions of endangered animals enjoy the same ESA protections as their non-biotech counterparts? The protections provided under ESA are not freely doled out to any species, but instead only apply to species that are listed as "endangered" by FWS or the National Marine Fisheries Service.[123] Looking at legal precedent, a recent case concluded that the *creation* of genetically engineered species must comply with ESA regulations, but the court's opinion did not discuss whether the genetically engineered *species themselves* would be protected by the ESA.[124] When the ESA was implemented, Congress could not have accounted for the modern biotechnology scientists have today, and the statute therefore includes no express provisions about such technology. Consequently, there is a debate over whether the statute allows for the regulation and protection of

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120 Exec. Order No. 13,874, 84 Fed. Reg. 27899 (June 11, 2019).

121 Cynthia F. Hodges, *Brief Summary of the Endangered Species Act (ESA)*, MICH. STATE UNIV. ANIMAL LEGAL & HIST. CTR. (2010), https://www.animallaw.info/article/brief-summary-endangered-species-act.

122 16 U.S.C. §§ 1531–44.

123 Carlin et al., *supra* note 19, at 18; *see also* 16 U.S.C. § 1532(6) (defining "endangered species" for the purposes of the statute).

124 *Inst. for Fisheries Res. v. FDA*, 499 F. Supp. 3d 657, 661–62 (N.D. Cal. 2020).

genetically engineered, genome edited, or cloned endangered or threatened species.

In reviewing the ESA, there are several provisions that could be applicable to biotechnology-derived species. For instance, genetically modified or cloned versions of existing endangered species may be afforded ESA protections as an "experimental population." Section 10(j) of the ESA serves as a tool to facilitate the reintroduction of experimental populations of endangered species placed back into parts of their habitat they no longer naturally occupy—this section could be extended to bioengineered species.[125] An "experimental population" is defined as a geographically separate group that is "isolated from other existing populations of the species."[126] The species must be released to an area that is "wholly separate geographically from the nonexperimental populations of the same species" as to prevent interbreeding between the experimental and current wild populations.[127] The purpose of having a provision for the reintroduction of experimental populations is to give conservationists a tool to navigate rigid ESA rules and to decrease conflicts the reintroduction might cause with local hunting, fishing, livestock, or agricultural practices.[128] Genetically modified and cloned versions of endangered species could constitute experimental populations; however, whether these populations can be granted ESA protections is dependent on if they are released into an area separate from existing populations of the endangered species at issue. Though perhaps not originally intended by writers when the ESA was first implemented, this provision covering experimental populations could potentially apply to bioengineered species as well.

Another way the ESA could afford protections for genetically modified or cloned versions of endangered species is under the "similar species" provision in Section 1533(e) of the statute.[129] Under this section, a species that is not endangered may be treated as endangered if it "so closely resembles in appearance" an endangered species "that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species."[130] It may be most practical for administrative purposes to list genetically engineered,

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125 *Designating Experimental Populations under the Endangered Species Act: Section 10(j)*, NOAA FISHERIES, https://www.fisheries.noaa.gov/designating-experimental-populations-under-endangered-species-act-section-10j (last visited July 28, 2023).

126 *Id.*

127 16 U.S.C. § 1539(j)(1).

128 Carlin et al., *supra* note 19, at 19 (citing 16 U.S.C. § 1539(j)).

129 16 U.S.C. § 1533(e).

130 *Id.*

genome edited, or cloned versions of endangered species as endangered under the "similar species" section of the ESA, as this is a concept already embedded within the statute itself.

Notwithstanding these potential avenues for ESA coverage, the applicability of the ESA grows murkier when considering the reintroduction of previously extinct species. It is logical to assume that once a de-extinct species is ready to be reintroduced back into its previous natural habitat, groups supporting the resurrection would want the species to have some sort of federal protection in order to increase its odds of population growth and survival—even though doing so would subsequently require a mountain of permits, paperwork, and other bureaucratic requirements.[131] While the ESA has not yet been applied to a de-extinct animal, such an application would support the fundamental purpose of the ESA by providing for "the conservation and recovery of species that otherwise would be lost."[132] It would thus be rational for de-extinct species to be afforded ESA protections.

One theory suggests de-extinct species are "essential to the continued existence of an endangered species or a threatened species" and thus automatically meet the ESA requirements for protection.[133] However, there may be opposition to this idea, given that most de-extinct species will be the product of mere genetic modification (as opposed to full cloning) because of degraded DNA samples. So, conversely, if de-extinct species are legally considered members of an already-protected species with some genetic modifications, then the de-extinct species would not be "essential" to the survival of that species.[134] This latter reasoning is likely to prevail, given it is more in line with the scientific process of creating a de-extinct species.

Another issue presented for de-extinct species is the ESA requirement that reintroduced, experimental populations be placed in an area away from the current habitat range of other existing populations of the same species.[135] An extinct species has no wild populations for the de-extinct experimental population to interbreed with, leading one to believe the project managers could reintroduce the de-extinct species in any part of its historic range. This loophole in the ESA could pose a problem: what if the de-extinct species interbreeds with the relative

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131 Carlin et al., *supra* note 19, at 19.

132 *Id.*

133 *Id.* at 20; 16 U.S.C. § 1539(j)(2)(B) ("Before authorizing the release of any population under subparagraph (A), the Secretary shall by regulation identify the population and determine, on the basis of the best available information, whether or not such population is essential to the continued existence of an endangered species or a threatened species.").

134 Carlin et al., *supra* note 19, at 20.

135 16 U.S.C. § 1539(j)(1).

species that it was genetically engineered from? For example, imagine passenger pigeons—a currently extinct species—were resurrected using genetic engineering with DNA from its close relative, the band-tailed pigeon. If these resurrected passenger pigeons were reintroduced in part of their historic range that is now occupied by wild band-tailed pigeons, it is possible the passenger pigeon would interbreed with the band-tailed pigeon;[136] such hybridization, however, could undermine the point of resurrecting the extinct species. Though this kind of intercross between de-extinct and closely related species does not violate the ESA, it could pose serious ecological problems—those that would have to be considered under NEPA[137]—because the environmental impacts of species intercrossing in the wild are often unpredictable and potentially adverse.[138]

2. National Environmental Policy Act ("NEPA")

To regulate bioengineered species, agencies could also take an environmental risk approach, like that seen under the National Environmental Policy Act ("NEPA"). NEPA is a federal statute that requires the consideration of the environmental impacts of all "major Federal actions significantly affecting the quality of the human environment."[139] Such "major Federal actions" include the actions of federal agencies themselves, along with state, local, and private actions that federal agencies fund, lease property to, or for which they provide permits and other authorizations.[140] Actions that trigger NEPA require the federal actor to complete an environmental assessment ("EA") or an environmental impact statement ("EIS") to examine how the action will affect the environment and to provide reasonable alternatives.[141] The EIS or EA is also subject to a public comment period.[142]

The use of biotechnology on endangered or de-extinct species will likely require the responsible agency or actor to conduct an EA or EIS as it will constitute a "major Federal action[] significantly affecting the quality of the human environment."[143] Generally, an EA or EIS is required for the reintroduction of species into their former habitat; an example of this is illustrated by FWS's reintroduction of the gray wolf

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136 Carlin et al., *supra* note 19, at 20.

137 See *infra* Part IV.B.2 for discussion of NEPA process for biotechnology interventions.

138 Carlin et al., *supra* note 19, at 40–42.

139 National Environmental Policy Act, 42 U.S.C. § 4332(C) (1970).

140 40 C.F.R. § 1508.1(q) (2022); *see also* 88 Fed. Reg. 49924, 49962 (July 31, 2023) (to be codified at 40 C.F.R. 1508.1(u)).

141 42 U.S.C. § 4332(C).

142 40 C.F.R. 1503.1(a) (2020).

143 42 U.S.C. § 4332(C).

to Yellowstone National Park.[144] The EIS for the reintroduction of the gray wolf was conducted by the responsible agency, FWS, and looked to impacts such as effects on local deer populations and livestock, changes to visitation rates of deer hunters, and potential conflicts on public lands.[145] In the case that a federal agency like FWS—or any other agencies previously mentioned in this Note—is in charge of a biotechnology-related intervention, it would likely need to assess similar impacts on ecosystems, patterns in and changes to predator-prey relationships, effects on impacted stakeholders, etc.

However, even the use of environmental risk assessments poses a problem for the reintroduction of genetically engineered, genome edited, or cloned versions of de-extinct species because part of the evaluation process requires predictions—which are difficult to perform with accuracy when working with a species that has not lived in an area for a long time. Requiring conservationists to conduct an EA or EIS before a conservation biotechnology project is approved is logical and precautionary, but any predictions about the degree of the ecological risks of reintroduction will likely be uncertain.[146]

C. Regulatory Conclusions

There are already many questions as to which agency, if any, has regulatory control over species enhanced with biotechnology. For example, in practice, if the species being genetically modified or cloned is considered a plant pest or a pesticide, its management may be subject to agricultural regulations put forth by various federal agencies. This is assuming the animal species is not an endangered species (regulated by FWS under the ESA) and it does not involve DNA insertion (regulated by FDA or potentially EPA). However, without a defined use linked to the scope of a federal agency, there are no explicit federal laws that govern species enhanced with biotechnology.[147] This gap in federal legislation may encourage states and localities to create their own set of laws that apply to biotechnology either generally or for conservation purposes specifically.

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[144] U.S. FISH & WILDLIFE SERV., THE REINTRODUCTION OF GRAY WOLVES TO YELLOWSTONE NATIONAL PARK AND CENTRAL IDAHO: FINAL ENVIRONMENTAL IMPACT STATEMENT (1994), https://www.sierraclub.org/sites/www.sierraclub.org/files/sce/rocky-mountain-chapter/Wolves-Resources/The%20Reintroduction%20of%20Gray%20Wolves%20to%20Yellowstone%20National%20Park%20and%20Central%20Idaho%20-%20Final%20Environmental%20Impact%20Statement.pdf.

[145] *Id.* at v–xxiii.

[146] Corey, *supra* note 100, at 357.

[147] Carlin et al., *supra* note 19, at 46.

The scientific community at large has already begun self-regulation in this sphere. In May 2016, the Species Survival Commission—a body of over 8,500 experts dedicated to the goal of reducing biodiversity loss[148]—of the International Union for Conservation of Nature ("IUCN") published guidelines for how de-extinct species, or their proxies, should be handled by the scientific community.[149] However, the report seems to present a list of items parties interested in de-extinction should consider, rather than a firm set of guidelines that outlines the steps a party must take to receive international approval for the project.[150] Further, it is unclear how these guidelines interact with current U.S. domestic law, and such additional guidelines only add to the already existing mix of non-binding guidance and recommendations.

Currently, it seems as though self-regulation of biotechnology within the scientific community lacks formidable framework and enforcement mechanisms, which should prompt federal agencies to step up and fill in the regulatory gaps as necessary. When authorities are ready to propose and enforce regulations for conservational biotechnology, there are a plethora of prescriptive issues that these provisions must consider, as discussed in Part V.

V. THE UNCERTAINTIES AND CONCERNS OF BIOTECHNOLOGY USE FOR BIODIVERSITY CONSERVATION: PRACTICAL, ETHICAL, AND PUBLIC OPINION CONSIDERATIONS

After establishing the conservation potential that lies in biotechnology with the case study of the black-footed ferret and demonstrating the potential legal framework that could apply to these technologies and their implementation, it is also important to discuss remaining practical uncertainties as well as ethical and public opinion concerns that will emerge with the increased use of biotechnology in the wildlife preservation field.

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148 *About*, INT'L UNION FOR CONSERVATION OF NATURE, https://www.iucn.org/our-union/commissions/species-survival-commission/about (last visited on May 6, 2022).

149 INT'L UNION FOR CONSERVATION OF NATURE, IUCN SSC GUIDING PRINCIPLES ON CREATING PROXIES OF EXTINCT SPECIES FOR CONSERVATION BENEFIT 1 (2016) [hereinafter IUCN SSC GUIDING PRINCIPLES], https://portals.iucn.org/library/sites/library/files/documents/Rep-2016-009.pdf.

150 *Id*. at 13. For example, Section VII, titled "Legal and Other considerations," merely notes that "[p]roxy species will be categorized differently by different authorities" and "[i]t is unclear" how de-extinct species will be handled by international conventions. The document does little to provide parties looking to perform a de-extinction project information about the legalities of such an undertaking.

A. Uncertainties

1. On Which Species Should We Use Biotechnology?

One issue that critics raise is how species candidates for bioengineering should be selected. How should conservationists choose which animals to modify or clone—should they select those that society likes to see or those that are most helpful to overall ecosystem health? This is already a problem with funding traditional conservation methods: the limited scientific funding for promoting biotechnology in endangered or de-extinct animals may trend towards saving charismatic animals (like pandas or dolphins), rather than species that would have a more formidable benefit to ecosystem stability or on biodiversity overall.[151] Mollusks, for instance, are vital for ecosystem well-being but often overlooked in traditional conservation efforts.[152]

In addition to selecting *living* species to modify or clone, biotechnology has raised a pressing question: should scientists reintroduce *extinct* species?[153] Due to a lack of complete DNA segments, not all extinct species have enough genetic material to be cloned; however, only "fragmentary" DNA is required for some species to be genetically engineered and resurrected.[154] In these cases, scientists would work to reconstruct as much of the extinct species' genome as possible, and then use the genes of a close relative to fill in the gaps of missing DNA.[155] Especially since DNA rapidly decays after an animal dies, it will be more difficult to "resurrect" species that have been extinct for a long time. For example, it is much more difficult to resurrect a woolly mammoth that died 20,000 years ago than a black-footed ferret that died in the 1980s.[156] About twenty-five different

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[151] *Id.* at 1 (discussing the allure of charismatic species in conservation); Ben Jacob Novak, *De-Extinction*, 9 GENES 548, 562 (2018); Frédéric Ducarme, Gloria M. Luque & Franck Courchamp, *What Are "Charismatic Species" for Conservation Biologists?*, BIOSCIENCES MASTER REVS., July 2013, at 4.

[152] Helena Fortunato, *Mollusks: Tools in Environmental and Climate Research*, 33 AM. MALACOLOGICAL BULL. 1, 1 (2015) (stating that mollusks are very valuable to ecosystems, "helping to structure aquatic bottom environments and providing habitat, protection, and food to a wide array of other taxa"); Charles Lyedard et al., *The Global Decline of Nonmarine Mollusks*, 54 BIOSCIENCE 321, 328 (noting that when management resources are limited, "mollusks and other less charismatic groups are usually ignored.").

[153] *See* Wagner et al., *supra* note 27; *see also* Lynn J. Rothschild, *Seven Reasons We Shouldn't Bring Extinct Animals Back to Life*, QUARTZ (Mar. 15, 2019), https://qz.com/1566083/we-shouldnt-bring-back-extinct-animals-like-the-woolly-mammoth/.

[154] Carlin et al., *supra* note 19, at 11.

[155] Corlett, *supra* note 22, at 61.

[156] Webb Miller et al., *Sequencing the Nuclear Genome of the Extinct Woolly Mammoth*, 456 NATURE 387, 387 (2008) (describing challenges in genome sequencing with "such ancient DNA").

extinct species, selected mostly for their "high public profiles, availability of well-preserved DNA, existence of closely related species who may serve as host or surrogate parents, and availability of suitable habitat" have been suggested as possible de-extinction candidates through the use of biotechnology.[157]

In addition, assuming society *does* support the use of biotechnology on animals, we must then decide to which animals do we owe the highest priority for funding and protection—extinct animals, endangered animals, livestock, or animals enhanced with biotechnology? The interests of these animals are not always aligned with one another. For instance, animals like mice or rabbits are harmed by the exploration of biotechnology, as laboratory experiments are typically conducted on small mammals before employed on more rare species;[158] so, the benefits given to animals enhanced with biotechnology come at the detriment of other, more common species. Likewise, wild animals could be harmed by the sudden reintroduction of de-extinct species who have not inhabited the wild species' ecosystem for decades. Similarly, livestock animals could be harmed by a species' population enhanced with biotechnology.[159]

2. Unclear Impacts of Gene Drives of Biotech-Organisms

Genome-editing technology helps a genetically altered trait to quickly spread through a wildlife population using "gene drives."[160] Gene drives of genetically modified organisms allow for quick genetic transformations of wild populations that can work to increase the fitness of threatened species or decrease the fitness of invasive species.[161]

Gene drives can serve two primary conservation purposes: eliminating an unfavorable species itself or changing genetic

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157 Wagner et al., *supra* note 27.

158 *See, e.g.*, *Research Facility Annual Usage Summary Report*, U.S. DEP'T OF AGRIC. (Oct. 25, 2022), https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_obtain_research_facility_annual_report/ct_research_facility_annual_summary_reports (listing animals like mice, hamsters, guinea pigs, and rabbits that are used in USDA testing).

159 For example, consider how grassland livestock receive a detriment when black-footed ferret populations increase, as the likelihood of a healthy prairie dog population (that can create holes in the ground, which are dangerous for livestock, and that carry the sylvatic plague bacteria, which is harmful to livestock) flourishes.

160 Esvelt et al., *supra* note 22, at 3; *see also* Ethan Bier, *Gene Drives Gaining Speed*, 23 NATURE REVS. GENETICS 5, 5 (2022) ("Gene drives are selfish genetic elements that are transmitted to progeny at super-Mendelian (>50%) frequencies.").

161 Corlett, *supra* note 22, at 60.

characteristics within a species.[162] Though gene drives have the power to spread favorable traits through a population within only one generation, they also carry risks.[163] Foremost, while researchers can perform many online simulations, it is impossible to determine—and evaluate—all of the environmental impacts introducing a biotech-organism via a gene drive.[164] If the gene drive of a modified species produces unintended consequences, how can these negative impacts be mitigated? There are social, ethical, and ecological questions concerning gene drives with biotech species that remain unanswered—even organizations like the National Institute of Health do not currently support "studies involving field release of gene drive modified organisms."[165] Unlike most genomic intervention methods, gene drives are purposefully designed to be spread amongst a population,[166] which adds an additional hurdle in a regulatory world that generally works to contain biotechnology.[167]

3. Scientists are Divided on How to Classify Biotech Species

Previously extinct animals that have been brought back to life via biotechnology are most genetically similar to the extinct species, as only the organelles' DNA (which comes from the non-extinct donor species) differs from the extinct animal's original genome.[168] The cell line used in the cloning process for the black-footed ferret had been cryopreserved in 1988 and was not found among living ferrets.[169]

One concern arising from somatic cell nuclear transfer is the presence of mitochondrial DNA from the surrogate species, which pose a potential biological and regulatory hurdle.[170] The black-footed ferret

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[162] NAT'L ACADS. SCIS., ENG'G & MED., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 16 (2016).

[163] NOVEL & EXCEPTIONAL TECH. & RSCH. ADVISORY COMM., NAT'L INST. HEALTH, GENE DRIVES IN BIOMEDICAL RESEARCH REPORT 5 (Sept. 2021) [hereinafter GENE DRIVES RESEARCH REPORT], https://osp.od.nih.gov/wp-content/uploads/NExTRAC-Gene-Drives-Final-Report.pdf.

[164] Margaret Foster Riley, *One Health Pandemic Prevention and Mitigation: The Role of FDA*, 76 FOOD & DRUG L.J. 200, 230 (2021) ("[Gene drives] may also incur significant ecological costs, and we do not fully understand what those may be.").

[165] GENE DRIVES RESEARCH REPORT, *supra* note 163, at 5.

[166] *See* Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT'L ACAD. SCIS. U.S. 1981, 1981 (1975) (emphasizing containment in biotechnology); NAT'L ACADS. SCIS., ENG'G & MED., *supra* note 162, at 8.

[167] Riley, *supra* note 164, at 230; *see generally* GENE DRIVES RESEARCH REPORT, *supra* note 163.

[168] Wagner et al., *supra* note 27, at 1016.

[169] *Ferret Becomes First North American Endangered Species to Be Cloned*, BBC NEWS (Feb. 19, 2021), https://www.bbc.com/news/world-us-canada-56132410.

[170] Video Interview with Ben Novak, Lead Scientist, Revive & Restore (Mar. 31, 2022) [hereinafter Ben Novak Interview II]; *see also* Progress, Potential, and Possibilities, *Ben Novak*,

clone, Elizabeth Ann, was created using a dead black-footed ferret's cryopreserved cell line and the egg of a domestic ferret, meaning Elizabeth Ann's mitochondrial DNA is from her domestic ferret surrogate mother.[171] The presence of domestic ferret mitochondrial DNA in a cloned species, particularly an endangered species, is significant for classification purposes. The majority of genetic species classifications have historically been made based on mitochondrial DNA.[172] Since mitochondrial DNA only comes from an animal's mother, however, the classification would list a hybrid species as the same species as its mother, though it is only genetically partially related to that species.[173]

While some scientists call for the end of mitochondrial DNA classifications, genetic purists could bring a case arguing that Elizabeth Ann is not a true black-footed ferret, which would result in ESA issues regarding whether the species receives protection.[174] The presence of mitochondrial DNA in a clone made from somatic cell nuclear transfer presents a host of unsolved problems.[175]

4. Will Patents be Required?

When viewing genetic engineering or genome editing as conservation tools, parties may be interested in patenting certain creations derived from biotechnology or the specific sequences or techniques used to produce bioengineered species. In 1980, the U.S. Supreme Court ruled

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Lead Scientist, Revive & Restore – De-Extinction Biotechnology & Conservation Biology, YOUTUBE, at 23:50, 47:50 (Nov. 1, 2021), https://youtu.be/gzRck35bUvE?feature=shared.

171 Ben Novak Interview II, *supra* note 170.

172 Daniel Rubinoff & Brenden S. Holland, *Between Two Extremes: Mitochondrial DNA is Neither the Panacea Nor the Nemesis of Phylogenetic and Taxonomic Inference*, 54 *SYSTEMATIC BIOLOGY* 952, 953 (2005).

173 *Id.* at 955.

174 *See* Carter, *supra* note 73.

175 In addition to classification issues, there were concerns that mitochondrial DNA from a domestic ferret would be harmful to the cloning of the black-footed ferret. Ben Novak Interview II, *supra* note 170. These hesitations are supported by some studies on bison which concluded that bison that contain cattle mitochondrial DNA are smaller and have lower body weight than bison with bison mitochondrial DNA. James N. Derr et al., *Phenotypic Effects of Cattle Mitochondrial DNA in American Bison*, 26 CONSERVATION BIOLOGY 1130, 1135 (2012). However, these results may not be the same for the black-footed ferret, because the research team created a heteroplasmic oocyte (cybrid) with Elizabeth Ann's embryo. Ben Novak Interview II, *supra* note 170. A cybrid occurs when "cytoplasm from the nucleus donor has been inserted along with the nucleus into the donor oocyte," which should decrease any incompatibility between the nuclear and mitochondrial genes responsible for actions like ATP synthesis and some phenotypic expression. Samantha M. Wisely et al., *A Road Map for 21st Century Genetic Restoration: Gene Pool Enrichment of the Black-Footed Ferret*, 106 J. HEREDITY 581, 584 (2015). Cybrids, compared to hybrids, appear to have fewer mitochondrial incompatibility issues and increased efficiency in blastocyst development. *Id.*

that lab-created micro-organisms count as a "manufacture" or a "composition of matter" under 35 U.S.C. § 101 and are therefore patentable.[176] Relatedly, in 2013, the Supreme Court also unanimously declared that human genes are not patentable because DNA segments are natural,[177] which could likely lead to an inference that animal genes—which are natural—are also not patentable. These rulings leave open the possibility that synthetic DNA or rDNA inserts may be patent-eligible. Similarly, de-extinct species brought back via hybridization (like the woolly mammoth) may also be patentable because these DNA sequences no longer are naturally occurring in the wild.[178]

5. Who Claims Legal Liability?

Another significant legal issue surrounding biotechnology-created species stems from the fact that no revived species is *exactly* the same as its original counterpart.[179] Genetically engineered or genome edited species are different from their original predecessor, as the addition of modified DNA predictably has some effect on the species. Similarly, cloned species can be slightly different from their original counterpart if they have different mitochondrial DNA than their cloned counterpart. These differences may produce unfavorable traits that may inflict unintended and unanticipated harms that could result in a question of liability.

In the future, it will be important for policymakers to determine who is responsible for genetically created or altered species and what level of liability attaches to these parties. For example, if a reincarnated woolly mammoth clone caused crop damage, would a farmer be able to sue the individual or agency responsible for releasing the mammoth into the area? Would liability be linked to ownership of the animal or to the act of reintroducing the animal to a particular region? Before the use of biotechnology for animal conservation can become widespread, involved parties must be aware of any potential liabilities arising from their work.

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176 Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980); 35 U.S.C. § 101.

177 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591–93, 596 (2013).

178 Matt Reynolds, *You're (Maybe) Gonna Need a Patent for That Woolly Mammoth*, WIRED (Feb. 9, 2022), https://www.wired.com/story/de-extinction-patents/.

179 Carlin et al., *supra* note 19, at 16.

B. Concerns

1. Ethical Concerns: Laboratory Animal Welfare

As with any matter concerning conservation, genetic engineering, genome editing, and animal cloning will require acute resource allocation, which inevitably leads to corresponding animal ethics concerns. Triaging level of concern for animal welfare is a prominent area of ethics that prompts criticism from those opposed to the use of biotechnology for conservation.[180] To better understand biotechnology, processes like genetic engineering, genome editing, and animal cloning are practiced on laboratory animals like mice or rats.[181] In the lab, mice suffer as scientists use them in efforts to improve black-footed ferrets' immunity to the sylvatic plague.[182] To some, the idea of causing suffering to one species for the benefit of another is abhorrent enough to completely disregard the use of these biotechnologies. One stakeholder with an anti-bioengineering view is the People for the Ethical Treatment of Animals ("PETA"), who believes that countless animal lives are lost or harmed in achieving success with this technology.[183] Further, PETA, along with other critics, are skeptical of the efficacy of the use of biotechnology if no other changes are made to further the conservation of the species' habitat or decrease its death rate.[184]

2. Utility Value: Do Costs Exceed Benefits?

Another problem is one rooted in utilitarianism—asking if the costs of genetic engineering are worth its supposed benefits. Even if endangered or extinct species are successfully revived with biotechnology, "as their numbers increase, their low genetic diversity, originating from one or a few individuals created in the laboratory or by selective breeding, will put them at serious long-term risk of accumulating genetic defects as the result of inbreeding."[185] The long-

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[180] Corey, *supra* note 100, at 352. ("Specifically, cloning necessarily involves the imposition of extremely invasive procedures on an individual host, as well as harmful testing on other animals.").

[181] *Research Facility Annual Usage Summary Report*, *supra* note 158.

[182] Video Interview with Alka Chandna, Vice President of Laboratory Investigations, People for the Ethical Treatment of Animals (Apr. 8, 2022) [hereinafter Alka Chandna Interview]; *see also* Corey, *supra* note 100, at 352–53.

[183] Alka Chandna Interview, *supra* note 182; *see also Mice and Rats in Laboratories*, PETA, https://www.peta.org/issues/animals-used-for-experimentation/animals-laboratories/mice-rats-laboratories/ (last visited Aug. 31, 2023).

[184] Alka Chandna Interview, *supra* note 182.

[185] Carlin et al., *supra* note 19, at 26.

term effect of biotechnology use on species with little existing genetic variation might lead to perverse, unintended results.

In addition, the species' old habitat may not be equipped to handle a sharp population increase or change in phenotypic characteristic. For example, if scientists created a clone of the woolly mammoth, a species that has been extinct for over 10,000 years, its previous ecosystem may have adapted in ways that no longer supports the woolly mammoth's traits.[186] As a result, all of the time, money, and effort put into the cloning project could be moot if an endangered or de-extinct species cannot survive, and thrive, in the ecosystem where it is reintroduced.[187]

3. Public Mistrust of Biotechnology

For years, the public has and continues to lack confidence in biotechnology methods.[188] As a result, there are biotechnology proponents who are hesitant to support the use of genetic engineering and animal cloning on species in peril, such as those that are endangered or extinct, because they are worried that any whiff of failure will create negative publicity for future conservation efforts. Under this line of thinking, the public, already skeptical of biotechnology as a tool for population restoration, does not need another reason to fear new technology.

Opponents of genetic engineering, genome editing, and animal cloning for conservation purposes find that biotechnology "threatens to undermine the concept of nature itself."[189] One study of 1,600 adults sought to assess Americans' views on genetic engineering for animal conservation.[190] The results indicated that there is a general skepticism of the outcomes of genetic engineering—about 85 percent of respondents believed that genetic editing would be "risky" for both nature and humans, and about 75 percent of respondents were concerned that biotechnology would be used for the "wrong" purpose.[191] Additionally, most participants felt it was more morally acceptable to use biotechnology to improve the survival of a species compared to decreasing the population of an undesirable species.[192] Interestingly, the

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186 *Id.* at 41–42.

187 *See* Corey, *supra* note 100, at 345.

188 *See* Fritts, *supra* note 40, at 136; Clark Wolf, *Public Trust & Biotech Innovation: A Study of Trustworthy Regulation of (Scary!) Technology*, 38 SOCIAL PHILOSOPHY & POL'Y 29, 31–36 (2022) (tracing the origins of public mistrust in biotechnology methods).

189 William M. Adams & Kent H. Redford, *Fix That Genome?*, 55 ORYX 481, 481 (2021).

190 P.A. Kohl et al., *Public Views About Editing Genes in Wildlife for Conservation*, 33 CONSERVATION BIOLOGY 1286, 1289 (2019).

191 *Id.* at 1291.

192 *Id.*

consensus split fairly evenly on whether using biotechnology for conservation would be beneficial or morally acceptable.[193] The results of this study demonstrate the public's reactions to genetic editing and animal cloning to mitigate biodiversity loss might be correlated with the intent of the scientific intervention—for "good" (increasing species' fitness) or "evil" (decreasing a species' fitness).[194]

Though not fully explored in the study itself, these mixed feelings towards biotechnology interfering with nature may be tied to the long-forged idea of scientists "playing God" in the laboratory. However, this kind of negative backlash was not prominent with the recent successful cloning of the black-footed ferret.[195] One explanation for this outcome is that the black-footed ferret project involved cloning and not genetic engineering or genome editing—and Revive & Restore intends on utilizing conventional breeding techniques to spread the new genetic diversity to the rest of the population.[196]

Beyond considering whether the use of animal biotechnology is "good" or "bad," the public may also learn to view genetic engineering, genome editing, and cloning as metaphorical band-aids for conservation. Biotechnology could "simply become a 'conservation' initiative for humans to bring back species populations in order to feel better about their past ecological destruction, without actually promoting species conservation or animal welfare."[197] Based on this reasoning, using biotechnology on animals does not help protect biodiversity at all and in fact is detrimental to traditional conservation efforts in general.

VI. CONCLUSIONS

The world has known since the time of Darwin that both natural and artificial selection have shaped modern ecosystems.[198] Further

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193 *Id.*

194 *Id.* at 1288.

195 Ben Novak Interview I, *supra* note 2.

196 *Id.*

197 Corey, *supra* note 100, at 360; *see* IUCN SSC GUIDING PRINCIPLES, *supra* note 149, at 2 ("Conservation prioriti[z]ation is a valid means to apportion scarce resources for species conservation, but should not consider technological advances as providing a viable means of even temporarily suspending efforts to avert the extinction of some species in the expectation of later revival, since even if appropriate cryo-preserved samples are kept, the complexity of the original species and its full ecological role and interactions are unlikely to be fully restored.").

198 CHARLES DARWIN, ORIGIN OF SPECIES 18 (2d ed. 1860) ("The key is man's power of accumulative selection: nature gives successive variations; man adds them up in certain directions useful to him.").

intervention in the form of biotechnologies like genetic engineering, genome editing, and animal cloning are needed to aid conservation efforts in the international fight against biodiversity loss. Nevertheless, it is important to emphasize that biotechnology alone cannot save an endangered species—it is merely an additional tool to supplement current conservation efforts. Traditional methods, such as proper land management and habitat preservation,[199] must remain at the core of conservation efforts to ensure maximum success.

While genetic technology may seem like a savior tool for mitigating biodiversity loss, there are a number of reasons why it may be years before genetic engineering, genome editing, or animal cloning become mainstream conservation methods. Foremost, the legal regime is riddled with uncertainties. It is unclear what agencies will regulate these biotechnology interventions and to what degree; it is unclear how traditional environmental statutes such as ESA and NEPA will apply to bioengineered species projects. Even if we can speculate about the legal framework, practical concerns, ethical issues, and public mistrust will present additional hurdles.

This Note outlines the legal and regulatory framework, as well as potential uncertainties, that must be considered in using biotechnology as a method for preserving or enhancing animal biodiversity. Though the notion parallels the imaginary plotline of *Jurassic Park*,[200] using biotechnology to alter ecosystems is now on the frontline of reality. Science is currently able to achieve these feats—even if the law is unprepared.[201]

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[199] *See* Paul Robbins & Ryan Phelan, *To Restore Biodiversity, Embrace Biotech's 'Intended Consequences'*, SCI. AM. (Jun. 15, 2021), https://www.scientificamerican.com/article/to-restore-biodiversity-embrace-biotechs-lsquo-intended-consequences-rsquo/.

[200] JURASSIC PARK (Universal Pictures 1993).

[201] Carlin et al., *supra* note 19, at 4–5.