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THE CASE FOR ADDRESSING ECOLOGICAL RISK FROM EMERGING BIOTECHNOLOGIES AND AN AGENDA FOR FUTURE REFORMS

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The Case for Addressing Ecological Risk from Emerging Biotechnologies and an Agenda for Future Reforms

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In 2022, President Biden signed an executive order promoting the development of biotechnology, but also suggesting the importance of biodiversity and ecological health in biotechnology regulation. Even after the executive order, however, the Coordinated Framework for biotechnology regulation wholly fails to address the ecological risks posed by what we term "synthetic conservation," that is, the use of genetically engineered organisms created for intentional release into nature. Notably, the Coordinated Framework continues to exclude from any real role agencies that have expertise regarding biodiversity and ecological health. The executive order also in no way challenges an implicit assumption of the Coordinated Framework: that all biotechnology, even genetically engineered animals that may be designed to replace non-engineered species, are "products" that need to be reviewed only for their safety as "products" and even then, only when they are first allowed onto the market. We propose and consider a number of Federal Executive Branch, state law, and international law paths to bringing an ecology-informed realism to U.S. regulation regarding genetically engineered animals created for environmental release—a realism that centers ecological well-being over time as a key goal and counters the hegemony of the product model. Despite its shortcomings, the Biden Order could be the jumping-off point for efforts to achieve the needed reforms to address current and emerging alterations of wildlife and the ecosystems they inhabit and will inhabit.

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I. INTRODUCTION

In 2022, President Biden signed an executive order promoting the development of biotechnology, but also underscoring the importance of considering risks associated with new technologies: "We need to . . . ensure that biotechnology is developed and deployed in ways that align with United States principles and values and international best practices, and not in ways that lead to accidental or deliberate harm[s] . . . ."[1] The core of the United States' regulatory system for biotechnology is the Coordinated Framework, an interagency framework involving the U.S. Department of Agriculture, the Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention, and the Food and Drug Administration.[2] The Executive Order (EO) was an opportunity for the federal government to take account of the criticisms of the Coordinated Framework and revisit its glaring limitations. But, in fact, the EO was a missed opportunity, especially as to one category of risk that the Coordinated Framework as of now is woefully inadequate to address: long-term ecological risk from bioengineered organisms that are released into the environment. At the same time, we argue that the EO could provide some purchase—a modest regulatory launching pad—for efforts to address this inadequacy.

After explaining the Coordinated Framework and its history, we explicate three points. First, the EO potentially opens the Coordinated Framework to meaningful consideration of ecological risks by centering "climate" and "climate change" in biotechnology regulatory review. Because climate change threatens biodiversity and ecological health, and nurturing biodiversity and ecological health is itself an essential measure to mitigate climate change's

[1] Exec. Order No. 14,081, 87 Fed. Reg. 56849 (Sept. 12, 2022).

[2] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986) [hereinafter Coordinated Framework].

effects, the EO in effect centers biodiversity and ecological health as goals of biotechnology regulation.[3] Second, the EO and its subsequent plan to reform the Coordinated Framework[4] fail to serve those goals, inasmuch as they leave untouched or even unmentioned a truly glaring deficiency of the Coordinated Framework as to biodiversity and ecological health: none of the agencies (or in the Environmental Protection Agency's case, office within the agency) with authority under the Coordinated Framework has understanding of, or expertise regarding, biodiversity and ecological health. Third, the EO fails to promote biodiversity and ecological health because it in no way challenges the Coordinated Framework's implicit assumption that biotechnology consists only of products that need to be reviewed for safety before being allowed onto the market, like car or toothpaste. But biotechnology encompasses and can encompass living organisms that unavoidably become part of complex ecosystems over time, with potentially good but also potentially adverse effects on biodiversity and ecological health.[5] Thus, what is needed is a regulatory system that conceives of engineered, living organisms not just as products but as long-term interventions into the environment that necessitate long-term adaptive management, including tracking, assessment, and review.

II. OVERVIEW OF THE COORDINATED FRAMEWORK AND THE EXECUTIVE ORDER

The interagency Coordinated Framework is the core legal infrastructure for the United States' regulatory system on biotechnology.[6] Under the Coordinated Framework, the Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) each take a part in ostensibly regulating risks from biotechnology products.[7] Depending on its characteristics, a biotechnological product may be subject to

[3] Of course, as with any executive order, the EO could be rescinded or disregarded by subsequent administrations. Nonetheless, it represents the most prominent formal acknowledgement by the Executive Branch that climate change should be a driving consideration in the development and regulation of biotechnology.

[4] *See* U.S. DEP'T OF AGRIC., U.S. ENV'T PROT. AGENCY & U.S. FOOD & DRUG ADMIN., THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY: PLAN FOR REGULATORY REFORM UNDER THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 3 (2024) [hereinafter REFORM PLAN], https://usbiotechnologyregulation.mrp.usda.gov/eo14081-section8c-plan-reg-reform.pdf [https://perma.cc/NSH7-LB74].

[5] For shorthand, we adopt the term "synthetic conservation" to describe this heterogenous category of bioengineered animals and plants that will and indeed sometimes are designed to become part of ecosystems. Agencies have used a variety of terms to cover such biota, which arguably is suggestive of their lack of clarity about how to approach these organisms. *See* Sarah Copper, *Following the Framework: Intentional Genomic Alterations in Animals*, 18 J. FOOD L. & POL'Y 117, 137–38 (2022) (describing some of the terminology agencies have employed).

[6] Coordinated Framework, *supra* note 2, at 23302.

[7] *Id.*

the jurisdiction of one or more of these agencies.[8] It is important to note that the Coordinated Framework has never established any new legal authority for regulating biotechnology in its thirty-eight years of existence. Instead, FDA, EPA, and USDA are directed to regulate biotechnology only to the extent that their pre-existing statutory authority allows such regulation.[9]

For its part, EPA regulates biotechnology only to the extent that it can be characterized as a pesticide or a toxic product.[10] Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA regulates pesticides.[11] Under section 408 of the Federal Food, Drug, and Cosmetic Act (FDCA), EPA establishes the amount of pesticide chemical residues that may be present in food.[12] Under the Toxic Substances Control Act (TSCA) and implementing regulations, EPA currently regulates biotechnology products that are new microorganisms, with exclusions for microorganisms used as food or pesticides.[13]

The FDA is primarily charged with promoting public health through the regulation of food and drug products, possibly including biotechnology products, under the Food, Drug, and Cosmetic Act and the Public Health Service Act.[14] As interpreted by FDA, these laws require it to pursue the following goals with respect to biotechnology products: "[e]nsure human and animal food is safe, sanitary, and properly labeled"; "[e]nsure human and animal drugs are safe and effective"; and "[e]nsure the safety, purity, and potency of biological products."[15]

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[8] *Id.* at 23303 ("Where regulatory oversight or review for a particular product is to be performed by more than one agency, the policy establishes a lead agency, and consolidated or coordinated reviews.").

[9] *See* Carlene Dooley, Note, *Regulatory Silos: Assessing the United States' Regulation of Biotechnology in the Age of Gene Drives*, 30 GEO. ENV'T L. REV. 547, 556 (2018); ELIZABETH NELSON ET AL., U.S. DEP'T OF AGRIC., PROPOSAL TO PERMIT THE FIELD RELEASE OF GENETICALLY ENGINEERED DIAMONDBACK MOTH IN NEW YORK 6 (2016), https://www.aphis.usda.gov/sites/default/files/16_076101r_pea.pdf [https://perma.cc/9HL8-C5YW].

[10] *See* Coordinated Framework, *supra* note 2, at 23313.

[11] *See* 7 U.S.C. § 136a(a).

[12] *See* 21 U.S.C. § 346a.

[13] Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act, 62 Fed. Reg. 17910, 17911, 17922, 17924 (Apr. 11, 1997); *see also* Coordinated Framework, *supra* note 2, at 23313–14.

[14] *See* 21 U.S.C. § 393(b); 42 U.S.C. § 202.

[15] 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 9 tbl.1 (2017) [hereinafter UPDATE TO THE COORDINATED FRAMEWORK], https://www.fda.gov/media/102658/download?attachment [https://perma.cc/S9VP-8FHP]; *see also* Alison Peck, *Re-Framing Biotechnology Regulation*, 72 FOOD & DRUG L.J. 314, 320 (2017) ("FDA's authority is based primarily on the Federal Food, Drug and Cosmetic Act, a 1938 act that includes authorization for FDA to ensure food safety through regulation of food additives and misbranding." (footnotes omitted)).

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agricultural products from pests and diseases.[16] Under the Animal Health Protection Act (AHPA)[17] and the Plant Protection Act (PPA),[18] USDA has authority to regulate plants and animals (including biotechnology products) that pose a risk to agricultural plant and livestock health.[19] Under the Virus-Serum-Toxin Act,[20] USDA also oversees products in veterinary biologics and ensures these products are pure, safe, potent, and effective.[21]

The initial strategy for responding to emerging biotechnology products was finalized in 1986 by the White House Office of Science and Technology Policy (OSTP).[22] In its nearly four decades of existence, the Coordinated Framework has been subject to many assessments and critiques by industry, public interest organizations, scholars, the National Academy of Sciences, and regulators.[23] While many of these critiques have called into question the fundamental regulatory focus, structure, and process of the Coordinated Framework, changes to it have been relatively limited.[24]

In 2022, President Biden signed an Executive Order seeking to "coordinate a whole-of-government approach to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security."[25] While this necessarily implicated the Coordinated Framework, conspicuously, the Coordinated Framework is not specifically mentioned in the EO.[26] Instead, the EO calls on the Assistant to the President for National Security Affairs, in consultation with the Assistant to the President for Economic Policy and the Director of the Office of Science and Technology Policy, to coordinate implementation of the EO.[27] Moreover, though it states

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[16] Coordinated Framework, *supra* note 2, at 23304.

[17] 7 U.S.C. §§ 8301–8302.

[18] *Id.*§§ 7701–7702.

[19] USDA's authority stems primarily from a law that dates to the Federal Plant Pest Act of 1957, reorganized in the Plant Protection Act, which gave USDA jurisdiction. *See id.* §§ 7701–7786.

[20] 21 U.S.C. §§ 151–159.

[21] *Id.*§ 154a(3)(B).

[22] Coordinated Framework, *supra* note 2, at 23302. *See, e.g.*, Clarifying Current Roles and Responsibilities Described in the Coordinated Framework, 80 Fed. Reg. 60414, 60415 (Oct. 6, 2015).

[23] *See* Dooley, *supra* note 9, at 552, 555, 558; 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, 172 (2019).

[24] *See generally* UPDATE TO THE COORDINATED FRAMEWORK, *supra* note 15 (making limited updates to the Framework, purportedly to promote more scientifically sound decisions and to clarify agency roles and responsibilities).

[25] Exec. Order No. 14,081, 87 Fed. Reg. 56849 (Sept. 12, 2022).

[26] *Id.* at 56854.

[27] *Id.* at 56850.

that the EO's core policy is to promote a whole-of-government approach for addressing (among other things) environmental concerns, the EO only expressly involves the Departments of Health and Human Services, Agriculture, Commerce, and Energy to implement the EO and advance its goals.[28]

To its credit, the EO potentially opens the Coordinated Framework to meaningful consideration of ecological risks by centering "climate" and "climate change" in biotechnology regulatory review.[29] Indeed, anthropogenic climate change has threatened and will increasingly threaten biodiversity and ecological health.[30] Accordingly, nurturing biodiversity and ecological health is itself an essential measure for mitigating the effects of climate change.[31] For the EO to actually achieve what it sets forth as one of its primary goals, the EO thus can and must make biodiversity and ecological health a key goal of biotechnology regulation.

However, as detailed below, both the EO and the Coordinated Framework fail to serve that crucial goal. They leave untouched (and even unmentioned) the fact that none of the agencies with authority either under the Coordinated Framework or even under the EO has the appropriate expertise for assessing risks to biodiversity or advancing ecological conservation. Moreover, the Coordinated Framework and the EO, by narrowly defining biotechnology in product development terms, ensure that government oversight exclusively takes the form of market-access regulation, even in the synthetic conservation context.

III. BIOTECHNOLOGY DESIGNED TO INHABIT ECOSYSTEMS: GENETICALLY MODIFIED FISH AS DRUGS, ENGINEERED BUGS AS INSECTICIDES, AND WOOLLY MAMMOTHS AND OTHER GENETICALLY RESCUED ORGANISMS

The alteration of the genomes of species for human benefit is nothing new.[32] Genetic modification of mice for medical research is decades old, as is the genetic modification of seeds for crops for livestock and human consumption.[33]

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[28] *Id.* at 56851.

[29] *Id.* at 56851, 56858.

[30] *See* Sarah R. Weiskopf et al., *Climate Change Effects on Biodiversity, Ecosystems, Ecosystem Services, and Natural Resource Management in the United States*, SCI. TOTAL ENV'T, Sept. 1, 2020, Article No. 137782, at 1, 2, 10, https://doi.org/10.1016/j.scitotenv.2020.137782 [https://perma.cc/N82M-LPNP] (providing the most up-to-date assessment of anthropogenic climate change impacts on biodiversity, ecosystems, and ecosystem services in the United States).

[31] Alejandro E. Camacho, *De- and Re-Constructing Public Governance for Biodiversity Conservation*, 73 VAND. L. REV. 1585, 1628 (2020) [hereinafter Camacho, *De- and Re-Constructing Public Governance*].

[32] *See, e.g.*, Nina V. Fedoroff, *The Past, Present and Future of Crop Genetic Modification*, 27 NEW BIOTECH. 461, 462 (2010).

[33] *Id.*; *see also Science and History of GMOs and Other Food Modification Processes*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/agricultural-biotechnology/science-and-

In addition, genetically modified forms of domesticated livestock have been approved by agencies ostensibly operating within the Coordinated Framework.[34] Beyond the smaller changes to an organism's DNA through genome editing, the rapidly growing field of synthetic biology has emerged this century with scientists stitching together long stretches of DNA to be inserted into an organism's genome.[35]

Our focus here, however, is reliance on genetic engineering in the context of animal and plant species that are *intentionally* released into the broader environment to promote ecological or human health. Synthetic ecosystem management or conservation—for brevity, synthetic conservation—captures at least the parts of intentional genetic engineering that we believe are especially inapt under the Coordinated Framework. It also is increasingly salient considering the growing technological capacity, as well as mounting demand by at least some constituencies, for the employment of active biotechnological interventions to manage a range of stressors on ecological and human health.[36]

Synthetic conservation could employ a range of emerging technologies that might serve a range of purposes. For example, this might include the genetic manipulation of a species and its subsequent introduction into a new environment to fill an ecological niche and provide another ecosystem service, such as assisting cleanup.[37] It could also involve the genetic manipulation of microbes or other organisms for the purpose of altering nutrient cycles or introducing new substances into the environment for conservation purposes.[38] Or it might even include the use of xenobiology,[39] a technology to produce forms of life not found in nature (e.g., silicon-based life forms or a different information-carrying molecule other than DNA), perhaps to create new species

history-gmos-and-other-food-modification-processes [https://perma.cc/M58W-B64X] ("[By] 1940: Plant breeders [had] learn[ed] to use radiation or chemicals to randomly change an organism's DNA."). *See generally* 1 THE MOUSE IN BIOMEDICAL RESEARCH: HISTORY, WILD MICE, AND GENETICS (James G. Fox et al. eds., 2d ed. 2006).

[34] *See, e.g.*, Greg Cima, *Genetically Modified Cattle May Be Sold for Food in U.S.*, AM. VETERINARY MED. ASS'N: NEWS (Mar. 21, 2022), https://www.avma.org/news/genetically-modified-cattle-may-be-sold-food-us [https://perma.cc/7J57-RZMM] ("Cattle that are genome edited to grow short, slick hair are the first genetically modified cattle that U.S. authorities will allow to be raised for food.").

[35] INT'L CIV. SOC'Y WORKING GRP. ON SYNTHETIC BIOLOGY, A SUBMISSION TO THE CONVENTION ON BIOLOGICAL DIVERSITY'S SUBSIDIARY BODY ON SCIENTIFIC, TECHNICAL AND TECHNOLOGICAL ADVICE (SBSTTA) ON THE POTENTIAL IMPACTS OF SYNTHETIC BIOLOGY ON THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY 8–9 (2011), https://cbd.int/doc/emerging-issues/Int-Civil-Soc-WG-Synthetic-Biology-2011-013-en.pdf [https://perma.cc/ER7J-H3JP].

[36] *See* Kent H. Redford, William Adams, Rob Carlson, Georgina M. Mace & Bertina Ceccarelli, *Synthetic Biology and the Conservation of Biodiversity*, 48 ORYX 330, 333–34 (2014).

[37] *Id.* at 333.

[38] *See* INT'L CIV. SOC'Y WORKING GRP. ON SYNTHETIC BIOLOGY, *supra* note 35, at 4, 14.

[39] *Id.* at 22.

to fill ecological niches or to clean up pollution, such as a microbe that feeds upon carcinogenic toxins.

One of the most important and talked-about technological deployments involving genetic engineering designed for intentional releases into the environment are so-called gene drives.[40] In gene-drive interventions, a species is intentionally modified so that the genetic modification will be passed on to offspring.[41] Gene-drive technology can and has been used to create modified populations that are designed to die off in a single generation.[42] But gene-drive technology, in theory, could be used (and is planned to be used[43]) to create modified populations that will become dominant in the environment on an ongoing basis via successful reproduction.[44] To date, we only have fully realized examples of gene-drive modifications that are designed to create a population that dies off in a single generation, such as the genetically modified mosquitoes and diamondback moths, both of which were proposed for field releases and studies within the United States.[45] (Only the moth field study has occurred to date, however.[46])

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[40] *See* Dooley, *supra* note 9, at 548–49.

[41] *See generally* Ethan Bier, *Gene Drives Gaining Speed*, 23 NATURE REVS. GENETICS 5 (Aug. 6, 2022), https://doi.org/10.1038/s41576-021-00386-0 [https://perma.cc/Q3JB-PZ77]; N. Wedell, T. A. R. Price & A. K. Lindholm, *Gene Drive: Progress and Prospects*, PROC. ROYAL SOC'Y B, Dec. 18, 2019, Article No. 20192709, https://royalsocietypublishing.org/doi/epdf/10.1098/rspb.2019.2709 [https://perma.cc/8QGJ-MFT6].

[42] *See generally* Renaud Lacroix et al., *Open Field Release of Genetically Engineered Sterile Male* Aedes Aegypti *in Malaysia*, PLOS ONE, Aug. 27, 2012, Article No. e42771, at 1, https://doi.org/10.1371/journal.pone.0042771 [https://perma.cc/L9EB-U3WF] (detailing study in which authors released engineered adult male mosquitoes (OX513A) that are effectively sterile and die in a single generation into an uninhabited forested area of Malaysia and efficiently combatted *Aedes aegypti*, which vectors dengue).

[43] *See* Omar S. Akbari et al., *A Synthetic Gene Drive System for Local, Reversible Modification and Suppression of Insect Populations*, 23 CURRENT BIOLOGY 671, 676–77 (2013) (outlining a modified mosquito population that is intended to suppress and overtake local native, but not global, populations); *see also* John Godwin et al., *Rodent Gene Drives for Conservation: Opportunities and Data Needs*, PROC. ROYAL SOC'Y B, Nov. 6, 2019, Article No. 20191606, at 1, 2, https://royalsocietypublishing.org/doi/epdf/10.1098/rspb.2019.1606 [https://perma.cc/ZM7V-VS5K] (discussing the possibility and potential need for using naturally occurring and synthetically selfish genetic mechanisms for controlling problematic rodent populations).

[44] Indeed, researchers have raised alarm at the possibility of synthetically modified populations dominating or destroying naturally occurring populations. *See* Charleston Noble, Ben Adlam, George M. Church, Kevin M. Esvelt & Martin A. Nowak, *Current CRISPR Gene Drive Systems Are Likely to Be Highly Invasive in Wild Populations*, ELIFE, June 19, 2018, Article No. e33423, at 1, 7, https://elifesciences.org/articles/33423 [https://perma.cc/9AR4-TLTJ].

[45] *See* Lacroix et al., *supra* note 42, at 2; NELSON ET AL., *supra* note 9, at 1.

[46] Alejandro E. Camacho, *Going the Way of the Dodo: De-Extinction, Dualisms, and Reframing Conservation*, 92 WASH. U. L. REV. 849, 852–53 (2015) [hereinafter Camacho, *Going the Way of the Dodo*].

Another well-publicized category of genetic engineering designed for intentional release into the environment is the use of cloning and related technologies to create a facsimile of an extinct population using a closely related non-extinct species as part of the effort. Such efforts have been dubbed de-extinction or genetic rescue efforts.[47] These include grandiose, Jurassic Park-worthy but as-yet-unrealized plans for "de-extinction" of ancient species such as the woolly mammoth.[48] But they also may include less sensational efforts, such as developing and introducing recently diminished or extinct species.[49] One example of this sort is the American chestnut tree, which is not technically extinct and is currently being reviewed for broad environmental

[47] *See* Leslie Paul Thiele, *Nature 4.0: Assisted Evolution, De-Extinction, and Ecological Restoration Technologies*, GLOB. ENV'T POL., Aug. 2020, at 9, 16, 18 (describing innovations in de-extinction and genetic rescue efforts and the risks they carry).

[48] *See generally* Douglas J. McCauley, Molly Hardesty-Moore, Benjamin S. Halpern & Hillary S. Young, *A Mammoth Undertaking: Harnessing Insight from Functional Ecology to Shape De-Extinction Priority Setting*, 31 FUNCTIONAL ECOLOGY 1003 (2017) (providing an overview of current research attempts to genetically rescue the woolly mammoth and passenger pigeon); *Passenger Pigeon Project*, REVIVE & RESTORE, https://reviverestore.org/about-the-passenger-pigeon [https://perma.cc/UA9E-V964]; J. Folch et al., *First Birth of an Animal from an Extinct Subspecies (*Capra Pyrenaica Pyrenaica*) by Cloning*, 71 THERIOGENOLOGY 1026 (2009).

[49] Gabriel Popkin, *Can Genetic Engineering Bring Back the American Chestnut?*, N.Y. TIMES (Apr. 30, 2020), https://www.nytimes.com/2020/04/30/magazine/american-chestnut.html (explaining that the American chestnut almost disappeared because of fungal blight in the early twentieth century, and that genetic engineering based on vestiges of the tree population could produce a tree that would not succumb to blight and would flourish again). Whether the large-scale release of genetically engineered American chestnut trees would cause undue ecological disruption is an open question and one that will almost certainly not get the attention it deserves under the current Coordinated Framework, because an agency with limited ecological expertise and jurisdictional scope, USDA, is overseeing the regulatory review process. *See* Thomas Parker Redick, *Will Genetically Engineered Chestnuts Be Roasting on an Open Fire of Litigation?*, A.B.A. (Mar. 23, 2023), https://www.americanbar.org/groups/environment_energy_resources/publications/am/will-genetically-engineered-chestnuts (discussing possible legal issues); *see also* Erik Carlson, *The USDA's Approval of GE Chestnut Trees Would Be a Step Forward for Threatened Species Conservation*, HILL (Dec. 18, 2022), https://thehill.com/opinion/energy-environment/3766283-the-usdas-approval-of-ge-chestnut-trees-would-be-a-step-forward-for-threatened-species-conservation [https://perma.cc/V9UP-WUVG]; Kim C. Steiner et al., *Rescue of American Chestnut with Extraspecific Genes Following Its Destruction By a Naturalized Pathogen*, 48 NEW FORESTS 317, 318, 332 (2017) (discussing the continuing revival of the American Chestnut through genetic intervention after near-total extinction by pathogens); Kate Evans, *De-Extinction Company Aims to Resurrect the Tasmanian Tiger*, SCI. AM. (Aug. 16, 2022), https://www.scientificamerican.com/article/de-extinction-company-aims-to-resurrect-the-tasmanian-tiger [https://perma.cc/7MUL-2DB6]; David Henning, *The Quagga Project Part II: 35 Years on*, GETAWAY (Mar. 8, 2022), https://www.getaway.co.za/travel/travel-ideas/the-quagga-project-part-ii-35-years-on [https://perma.cc/HJ3N-D2CQ] (detailing efforts to bring back the quagga, a subspecies of the plains zebra, through de-extinction technologies).

release by USDA.[50] (That example also raises the "Wrong Regulators" point we make next.)

What unifies the current, planned, and potential future deployments of what we call synthetic conservation technology is that DNA is fabricated or intentionally manipulated—or in the case of xenobiology, even substituted with XNA[51]—with the purpose of intentional release into the environment, outside the confines of a laboratory or research breeding facility.[52] Because of the complexity and dynamic nature of ecological phenomena and the technologies being developed and the fact of intentional environmental release, deployments of synthetic conservation implicate great ecological uncertainty and great potential ecological harm, as well as, in some instances, potentially substantial ecological benefits.[53]

There are, to be sure, difficult line-drawing questions surrounding what should count as synthetic conservation (which, again, is characterized by ecological uncertainty and risk) and what should not. For example, salmon that have been genetically engineered to grow faster are currently marketed under the label AquAdvantage salmon.[54] With FDA approval, such salmon are cultivated in facilities where the goal is that the salmon never be released into the broader environment. However, these commercial AquAdvantage salmon facilities are not hermetically sealed, and releases into the broader environment, critics have argued, are perhaps inevitable.[55] It therefore may be sensible to characterize AquAdvantage salmon as implicating the level of ecological uncertainty and risk characteristic of, and definitional for, the synthetic conservation category. As we discuss in Part VI, there is an important task, yet to be even acknowledged by the federal government, in the development of criteria for deciding precisely what kinds of technological deployments now regulated under the Framework implicate the greatest ecological uncertainties and risks and thus warrant a profoundly reformed system of regulation and oversight. This Article, however, focuses on those strategies whose deliberate purpose is to intentionally enhance some component of the environment, and the existing legal framework's limited capacity to assess and manage the risks and benefits of such diverse strategies.

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[50] *See* Redick, *supra* note 49.

[51] *See generally* Markus Schmidt, *Xenobiology: A New Form of Life as the Ultimate Biosafety Tool*, 32 BIOESSAYS 322 (2010).

[52] *See* Redford et al., *supra* note 36, at 334.

[53] *See* INT'L CIV. SOC'Y WORKING GRP. ON SYNTHETIC BIOLOGY, *supra* note 35, at 18, 32.

[54] Kara M. Van Slyck, Note, *Salmon with a Side of Genetic Modification: The FDA's Approval of AquAdvantage Salmon and Why the Precautionary Principle is Essential for Biotechnology Regulation*, 41 SEATTLE U. L. REV. 311, 313 (2017).

[55] *Id.* at 318, 335.

IV. THE WRONG REGULATORS FOR ECOLOGICAL BENEFITS AND RISK

The Coordinated Framework for the Regulation of Biotechnology centers FDA, EPA, and USDA as the agencies for managing biotechnology.[56] As such, the Coordinated Framework's regulatory authority is inherently decentralized, fragmented horizontally among three federal agencies, each with piecemeal jurisdiction.[57] In each of its iterations, the Coordinated Framework has never created new jurisdiction; rather, it identifies existing fragmented authority lodged in these three agencies and seeks to coordinate the exercise of this jurisdiction.[58] There is no catch-all default for products that do not fall within the wheelhouse of one of the agencies.

This can lead to gaps in regulation in some circumstances, as well as overlapping regulatory authority in others.[59] With three agencies and domains that are somewhat unclear, even after various allegedly clarifying updates, each agency is free to shirk or delay action, which may result in either lack of regulatory oversight or, on the flip side, chilling of development and research.[60] Commentators argue that the definitional focus of the statutory scheme's definitional focus has caused a "silo effect," forcing rigid compartmentalization where it is often inappropriate.[61] Perhaps unsurprisingly, the mismatch between regulatory authority and the actual phenomena being regulated has led to irregular, perplexing characterizations, such as classifying genetically modified mosquitoes as animal drugs.[62]

But synthetic conservation raises a fundamentally new concern. These agencies, in particular FDA, have limited expertise for assessing the ecological risks and benefits of synthetic conservation strategies.[63] At the federal level, the

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[56] *See* Coordinated Framework, *supra* note 2, at 23302.

[57] Claire Althouse, *"Farming Out" Regulatory Responsibility: Private Parties in the Biotechnology Age*, 23 GEO. INT'L ENV'T L. REV. 421, 423 (2011).

[58] *See* Coordinated Framework, *supra* note 2, at 23302.

[59] *See* Deepti A. Kulkarni, *The Age of Innovation in Food: Is Our Regulatory System Ready?*, 80 MD. L. REV. ONLINE 41, 45 (2021), https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1072&context=endnotes/ [https://perma.cc/D3YJ-FK3P] (explaining that "there remains significant uncertainty or lack of clarity" regarding how the agencies can and will coordinate in dividing and sharing responsibilities under the Framework).

[60] *See* Peck, *supra* note 15, at 319, 323.

[61] Jordan Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 DICK. L. REV. 53, 63 (2012).

[62] *See* Joel F. Aldrich, *The Rise of the Mutants: Obtaining Regulatory Approval for the Release of Genetically Modified Mosquitoes*, 17 COLUM. SCI. & TECH. L. REV. 292, 309–11 (2016) (outlining and critiquing FDA's classification of modified mosquitoes as animal drugs).

[63] Albert C. Lin argues that "[a] better approach would empower regulatory agencies having relevant expertise to exercise oversight," but the thrust of his discussion seems to be that FDA, as compared to EPA, takes too cramped a view of ecological assessment. Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitoes and the Coordinated*

Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration's Marine Fisheries Service (NOAA Fisheries), and to a lesser extent the federal land agencies (including the National Park Service, United States Forest Service, and Bureau of Land Management) are agencies with varying expertise in ecological risks and benefits.[64] Yet, these agencies are not part of the Coordinated Framework. Nor are they expressly involved in President Biden's new EO,[65] or Reform Plan.[66]

As several commentators have noted, even though FDA may be well equipped to evaluate medicines developed through synthetic biology, there may be environmental risks the agency is not well placed to understand or do a meaningful risk analysis for.[67] For instance, a company that developed a genetically engineered (GE) salmon applied to FDA for approval to enter the market. However, FDA does not have the expertise to address environmental concerns, even though these appear to be the main risks introduced by the salmon.[68] Additionally, FDA failed to consult with federal agencies that did have environmental expertise and chose not to prepare an Environmental Impact Statement despite the fact that the Environmental Assessment prepared by the company does not appear to contain the information necessary for a Finding of No Significant Impact (FONSI).[69] Moreover, FDA does not have any clear

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Framework for Biotechnology, 51 U.C. DAVIS L. REV. 205, 232 (2017). Our view is that offices within EPA other than the pesticide-focused FIFRA office, as well as numerous agencies outside EPA, have significant expertise relevant for addressing the issues raised by synthetic conservation, yet they are routinely absent from regulatory review.

[64] *See* Coordinated Framework, *supra* note 2, at 23302.

[65] *See* Exec. Order No. 14,081, 87 Fed. Reg. 56849, 56855 (Sept. 12, 2022) (directing the "Secretary of Agriculture, the Administrator of the Environmental Protection Agency, and the Commissioner of Food and Drugs, in coordination with the Director of OMB, the ADPD, and the Director of OSTP" to carry out the commission); Paradise & Fitzpatrick, *supra* note 61, at 87–88 ("Perhaps most critical for the regulatory landscape for synthetic biology products is that environmental and containment safeguards, as with most FDA regulated products, are almost nonexistent.").

[66] *See* REFORM PLAN, *supra* note 4, at 3.

[67] *See* Paradise & Fitzpatrick, *supra* note 61, at 76; Kristen D. Brooks, Note, *Gene Drive: Modern Miracle or Environmental Disaster*, 2020 U. ILL. J.L. TECH. & POL'Y 201, 210 (addressing the same criticism).

[68] Michael Bennett Homer, Note, *Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83, 109 (2011).

[69] FDA received many criticisms that its review had been too narrow to justify the FONSI, but the agency has not sought additional data and has summarily rejected such criticisms while affirming its view that there is not a need for an Environmental Impact Statement nor consultation with FWS. *See AquAdvantage Salmon – Response to Public Comments on the Environmental Assessment*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/aquadvantage-salmon-response-public-comments-environmental-assessment [https://perma.cc/6TR3-RMUS].

statutory authority under the FDCA to deny approval of a New Animal Drug Application solely because approval would harm the environment.[70]

EPA has substantial expertise in toxic and pesticidal substances as well as water and air quality, but it has little to no expertise related to ecological conservation. EPA also has only limited, unclear regulatory authority over GE animals, and thus a limited, unclear role in the approval of products whose principal risks are environmental.[71] Moreover, it is questionable whether products of synthetic conservation can be regulated under TSCA because it is unclear whether they qualify as "chemical substances."[72]

Meanwhile, APHIS has some expertise in the management of invasive species, but the focus of its authority under the Coordinated Framework has always been exclusively on plant pests. Furthermore, it lacks expertise in the broad range of ecological benefits and risks raised by potential synthetic conservation strategies. The result of all of this is a very piecemeal structure that allocates authority to governmental institutions that lack the core expertise and regulatory authority to manage synthetic conservation strategies.

V. THE WRONG (PRODUCT) MODEL FOR BIOTECHNOLOGY DESIGNED TO INHABIT ECOSYSTEMS

Another fundamental problem with the Coordinated Framework, Biden's new EO, and its Reform Plan[73] is that they are fundamentally premised on market regulation of biotechnologies. This market-regulation regime focuses on

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[70] *See, e.g.*, OFF. OF SCI. & TECH. POL'Y, CASE STUDY NO. I: GROWTH-ENHANCED SALMON 14–15 (2001); Homer, *supra* note 68, at 112; *see Frequently Asked Questions About Animal Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/safety-health/frequently-asked-questions-about-animal-drugs#animaldrug [https://perma.cc/978Q-PWNW] (July 26, 2021).

[71] *See* Homer, *supra* note 68, at 112. In 2017, in response to confusion regarding the line between FDA and EPA jurisdiction over engineered mosquitoes, FDA issued Guidance for Industry No. 236, which states that mosquito-related products intended to function as pesticides are not "drugs" and hence will be regulated by EPA, but FDA will continue to have jurisdiction over mosquito-related products that are intended to prevent, treat, mitigate or cure a disease. *See generally* U.S. FOOD & DRUG ADMIN., FDA-2016-D-4482-0032, CLARIFICATION OF FDA AND EPA JURISDICTION OVER MOSQUITO-RELATED PRODUCTS: GUIDANCE FOR INDUSTRY NO. 236 (2017), https://www.fda.gov/media/102158/download?attachment [https://perma.cc/9SJZ-BCQ3].

[72] Gregory N. Mandel & Gary E. Marchant, *The Living Regulatory Challenges of Synthetic Biology*, 100 IOWA L. REV. 155, 175–76 (2014).

[73] The Reform Plan consistently uses the language of "products" to describe the subject matter of the Coordinated Framework. *See generally* REFORM PLAN, *supra* note 4. Indeed, the overriding theme of the Reform Plan is that the regulatory review under the Coordinated Framework needs to be streamlined to assist the expeditious introduction of "products" to market. *See id.* at 1–3, 5. While rapid regulatory review understandably is a goal of commercial interests, it is not necessarily consistent with the careful consideration of ecological impacts and adaptive management needs that we argue is appropriate.

limiting potential risks of products on human health, and secondarily, the environment.[74] The legal and regulatory frameworks implemented by each agency vary according to the type of product, but the underlying construct is that each area of oversight is characterized by a statutorily defined product. Even those who have called for sustainability-sensitive reforms in biotechnology governance fully embrace the product model and the overriding goal of facilitating the entry of products into the marketplace.[75] Among academic commentators, Monast is notable in acknowledging that the product model is a value choice;[76] we go a step further and argue that it is the obviously wrong value choice with respect to synthetic conservation.

A. *Product Regulation*

Each of the three agencies is charged only with regulating certain *products*. Under the Federal Food, Drug, and Cosmetic Act and related laws, FDA oversees three primary categories of GE products: (1) human drugs and medical products, (2) animal drugs, and (3) foods derived from plants.[77] These laws "generally require premarket approval of drugs, biological products, medical devices, food additives, and dietary supplements."[78]

The scope of APHIS jurisdiction is also limited to products. APHIS regulates release of a product under the PPA only if it is a pest of livestock or plants, meaning something deemed to potentially hurt livestock or plants.[79] The

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[74] *See supra* Part IV; REFORM PLAN, *supra* note 4, at 4 ("In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for Regulation of Biotechnology ('Coordinated Framework') in response to concerns about whether the 'regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques.' The Coordinated Framework outlined the federal regulatory policy for biotechnology products and federal agency oversight responsibilities to protect health and the environment while advancing innovation.").

[75] *See, e.g.*, Mary E. Maxon, *Racing to Be First to Be Second*, ISSUES SCI. & TECH., Spring 2023, at 64, 66 (calling for "updates to regulatory statutes" that will "tackle the complexities of the pre-commercialization phase, which require a delicate balance for regulators between transparent decisionmaking and confidentiality obligations").

[76] Federal Meat Inspection Act of 1906, Pub. L. No. 59-382, 34 Stat. 669, *amended by* Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967) (codified at 21 U.S.C. §§ 601–695); *see also* Jonas J. Monast, *Editing Nature: Reconceptualizing Biotechnology Governance*, 59 B.C. L. REV. 2377, 2412 (2018) ("The decision to prioritize development of biotechnology products through a product-based regulatory system is itself a value choice.").

[77] *Id.* at 2391.

[78] *Id.*

[79] *About APHIS*, ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/banner/aboutaphis [https://perma.cc/PH2X-TXXS] (Aug. 2, 2024); *Biotechnology Regulations*, ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.

AHPA gives APHIS authority to prohibit or restrict imports "or entry of any animal, article, or means of conveyance" into the United States if necessary to prevent the introduction or dissemination "of any pest or disease of livestock."[80] Under the PPA, a "plant pest" includes organisms "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[81] In addition, APHIS claims some, although not-entirely-clear, jurisdiction over the introduction of genetically engineered livestock products like hornless cattle under the Federal Meat Inspection Act and Poultry Products Inspection Act.[82]

Meanwhile, EPA regulates genetically engineered pesticides via its authority to regulate under the Federal Insecticide, Fungicide, and Rodenticide Act.[83] Under FIFRA, EPA evaluates the safety of pesticide, chemical, or microorganism products designed to kill pests before the pesticide product is allowed into the U.S. market.[84] EPA also regulates products under TSCA.[85] EPA also potentially regulates products under TSCA, but unlike FIFRA, TSCA only requires applicants to file a notice with EPA ninety days prior to the manufacture of the chemical and places the burden on EPA to find that the new chemical product is likely to present an unreasonable risk of injury to health or the environment.[86] Absent such a finding, the product may be released into the marketplace.[87]

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aphis.usda.gov/biotechnology/regulations [https://perma.cc/CY4N-YJ5P]. APHIS is mentioned throughout the literature, especially the Coordinated Framework itself, in lieu of USDA. *See* Coordinated Framework, *supra* note 2, at 23304.

[80] Animal Health Protection Act, 7 U.S.C. §§ 8301–8322.

[81] 7 C.F.R. § 340.3 (2024).

[82] Josh Long, *Ag Industry, Consumer Advocates Split over USDA Animal Biotech Proposal*, SUPPLYSIDE FOOD & BEVERAGE J. (Jan. 29, 2021), https://www.foodbeverageinsider.com/food-beverage-regulations/ag-industry-consumer-advocates-split-over-usda-animal-biotech-proposal [https://perma.cc/THA5-KB6B] (describing USDA's claimed jurisdiction under a 2021 Memorandum of Understanding between USDA and FDA).

[83] SARAH R. CARTER, MICHAEL RODEMEYER, MICHELE S. GARFINKEL & ROBERT M. FRIEDMAN, SYNTHETIC BIOLOGY AND THE U.S. BIOTECHNOLOGY REGULATORY SYSTEM: CHALLENGES AND OPTIONS 14, 28 (2014), http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf [https://perma.cc/V45U-FVET].

[84] 7 U.S.C. § 136a(a), (c)(5). Under FIFRA regulations, a pesticide product means a pesticide in the particular form in which the pesticide is, or is intended to be, distributed or sold. 40 C.F.R. § 152.3 (2024).

[85] 15 U.S.C. §§ 2601–2602; *Summary of the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act [https://perma.cc/FG8Q-D6AW].

[86] 15 U.S.C. § 2604(a)(1)(B)(i); Rogers Corp. v. EPA, 275 F.3d 1096, 1101 (D.C. Cir. 2002) ("Section 5 goes so far as to bar, with only limited exceptions, the manufacture of a new chemical substance or new use prior to notice to the Administrator who, upon finding that there is a reasonable basis to conclude such action presents or may present an unreasonable risk of injury to health or the environment, may prohibit or place restrictions on its manufacture, processing, or distribution.").

[87] 15 U.S.C. § 2604(a)(3)(C); *Rogers Corp.*, 275 F.3d at 1101.

B. *Narrow Risk Assessments at Market Approval Stage*

Beyond the common critique mentioned in Part IV, that the Coordinated Framework's focus on only certain products can lead to peculiar classifications[88]—or worse, gaps in oversight of potentially risky activities—the legally mandated assessments typically are much too narrow to capture the breadth of risks and advantages for synthetic conservation measures.

The FDA considers whether a genetically altered plant, animal, or other organism is a "safe" product to be marketed in the United States.[89] If an animal is genetically engineered for medical or therapeutic purposes, then FDA is the only agency with oversight responsibilities.[90] Though it has asserted broad authority over GE animals through creative interpretations of "food" or "drugs," FDA is only tangentially concerned with the risk to the environment from such proposed products.[91] A 2024 FDA guidance document provides that FDA has authority to regulate gene drives because they have a veterinary function; as such, gene-drive "products" are to be reviewed whether the proposed products are "safe and effective" for their "intended use."[92] As commentators have noted, this scope of review arguably is far too constrained to capture the wide-ranging,

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[88] *See* Aldrich, *supra* note 62, at 309–11 (outlining and critiquing FDA's classification of modified mosquitoes as animal drugs).

[89] Monast, *supra* note 76, at 2390; *Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/qa-fda-regulation-intentional-genomic-alterations-animals [https://perma.cc/TUY5-BZBG] ("Under the FD&C Act, food must be safe for consumption regardless of whether it is derived from plants or animals, or whether the genome of the plant or animal it is derived from has been intentionally altered.").

[90] UPDATE TO THE COORDINATED FRAMEWORK, *supra* note 15, at 19.

[91] The FDA says that it will comply with NEPA to the extent it requires the assessment of environmental effects associated with its decisions under the FDCA, but even so, NEPA does not require FDA to assign any weight to environmental effects in its standard regulatory review process. *Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, *supra* note 89 ("Any potential environmental issues would be a function of the traits introduced into those animals and the conditions under which those animals would be raised. For example, a biopharm animal intended to be kept in a contained environment poses a different set of risks from an animal with an IGA that is intended to be released into the environment. FDA will consider potential environmental effects on a case-by-case basis as required by the National Environmental Policy Act."). At most, FDA's inattention to environmental risks could subject it to suit under the Administrative Procedure Act if it could be shown that FDA acted arbitrarily and capriciously, which is a very deferential standard. 5 U.S.C. § 706(2)(A); *see, e.g.*, Dep't of Com. v. New York, 588 U.S. 752, 773 (2019) ("We review the Secretary's exercise of discretion under the deferential 'arbitrary and capricious' standard." (citation omitted)).

[92] U.S. FOOD & DRUG ADMIN., FDA-2008-D-0394-0458, HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS: RISK-BASED APPROACH, GUIDANCE FOR INDUSTRY NO. 187A, at 2–3 (2024), https://www.fda.gov/media/74614/download [https://perma.cc/YAP2-HN54].

ecosystem-wide effects of gene-drive deployments.[93] FDA's conceptualization of gene drives as a veterinary measure and regulatory focus on limiting harm to the host animal illustrates the Coordinated Framework's regulatory incongruity.

Similarly, APHIS "focuses on potential harm to agricultural plants and animals."[94] APHIS's required assessment of plant pests encompasses only the narrow meaning of whether or not a plant may physically damage other plants.[95] APHIS explains that its mission as to biotechnology generally is "[t]o protect plant health" and address risks of "certain organisms developed using genetic engineering that may pose a risk to plant health."[96]

On its face, this approach does not weigh the risks (or benefits) that new plants pose to human health or the environment more broadly. Similarly, APHIS's assessment of potential animal harm under the AHPA is also focused on risks to livestock,[97] not to broader ecological advantages and disadvantages.

Likewise, EPA's assessment remains narrow, particularly for assessing conservation strategies. "The EPA regulates new genetically-engineered products if they meet the definition of a pesticide or produce 'new chemical substances' that are not otherwise regulated by the FDA or USDA."[98] FIFRA does mandate an assessment of the risks and benefits of a pesticide product to human health and the environment,[99] but again, its focus is only on pesticides. Because FIFRA deals with chemicals, such as herbicides, EPA has limited jurisdiction over genetically modified crops.[100] The risk-benefit analysis mandated under FIFRA, however, is not designed to have EPA focus on risks to habitat or the potential for promoting ecological health.

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[93] *See, e.g.*, Kenneth A. Oye et al., *Regulating Gene Drives*, 345 SCIENCE 626, 628 (2014).

[94] Monast, *supra* note 76, at 2391.

[95] CARTER, RODEMEYER, GARFINKEL & FRIEDMAN, *supra* note 83, at 25.

[96] *Biotechnology Regulatory Services (BRS)*, U.S. DEP'T OF AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology [https://perma.cc/JS5G-JAMV].

[97] *Cf.* 7 U.S.C. § 8301(1)(C) ("[T]he prevention, detection, control, and eradication of diseases and pests of animals are essential to protect . . . the economic interests of the livestock and related industries of the United States.").

[98] Monast, *supra* note 76, at 2391.

[99] To obtain registration, an applicant must show that the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). "Unreasonable adverse effects on the environment" is defined as

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21 [the Federal Food, Drug, and Cosmetic Act].

7 U.S.C. § 136(bb).

[100] Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 834 (9th Cir. 2013). After a review of the 2017 Update to the Coordinated Framework, this statement holds true. *See generally* UPDATE TO THE COORDINATED FRAMEWORK, *supra* note 15.

> EPA's interpretation and implementation of FIFRA involves a balancing of the risks associated with the use of the pesticide against the social and economic benefits to society accruing from the use of the pesticide. Accordingly, the potential exists for a pesticide that poses high risks to threatened or endangered species to be registered under FIFRA, if that pesticide provides economic benefits that outweigh those risks.[101]

Moreover,

> [a] decision on whether to register or cancel a pesticide is made on a nationwide basis without any real consideration of specific geographic or temporal factors. For example, a particular pesticide may easily meet the cost-benefit registration standard because on a nationwide basis the benefits of the pesticide exceed the environmental or health costs.[102]

Meanwhile, TSCA requires only pre-manufacturing notices to EPA for substances being developed and produced for commercial purposes.[103] The pre-manufacturing risk assessment is limited to a review of existing information before manufacture and puts the burden on EPA to find an unreasonable risk.[104] Thus, while EPA's review under TSCA of a genetically engineered microorganism (GEM) does include "the potential for pathogenicity/toxicity to terrestrial and aquatic animals and plants" and potential "interactions of the GEM with other microorganisms in the environment and its effects on environmental processes such as biogeochemical cycling,"[105] EPA generally will lack the necessary information to assess these potential risks either before or after the product comes to market.

The agencies' review of synthetic conservation deployments—products, as the agencies conceive them—fails to include a comprehensive assessment of not only the ecological risks but also the potential ecological benefits. Synthetic

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[101] Mary Jane Angelo, *Discordant Environmental Laws: Using Statutory Flexibility and Multi-Objective Optimization to Reconcile Conflicting Laws*, 38 STAN. ENV'T L.J. 165, 179 (2019).

[102] *Id.* at 181.

[103] *See* 15 U.S.C. § 2604(a)(1)(B)(i) (prohibiting the manufacture of a new chemical substance unless the manufacturer "submits to the Administrator, at least 90 days before such manufacture or processing, a notice . . . of such person's intention to manufacture or process such substance and such person complies with any applicable requirement" of the TSCA); *id.* § 2604(i)(1) ("For the purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.").

[104] *Id.* § 2604(a)(2). EPA is empowered to prohibit the manufacture of a substance if "the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required" by the act. *Id.* § 2604(e)(1)(A)(i).

[105] GWENDOLYN MCCLUNG, U.S. ENV'T PROT. AGENCY, RISK ASSESSMENT OF GENETICALLY ENGINEERED AND SYNTHETIC BIOLOGY MICROORGANISMS BY EPA UNDER THE TOXIC SUBSTANCES CONTROL ACT 1 (2014), https://cns.asu.edu/sites/default/files/mcclungg_synbiopaper_2014.pdf [https://perma.cc/T354-2A7V].

biology strategies like gene drives have the potential to harm conservation goals as well: not only to harm ecological health,[106] but also possibly to compromise historical fidelity or concepts of wild or "natural" conservation.[107] Yet synthetic conservation strategies like gene drives also have the potential to promote conservation: to promote ecological health and maybe even historical fidelity (if clones), to protect and help recovery of endangered species, to reduce harmful disease vectors and invasive species, to promote effective and more efficient wildlife management, and to foster other ecosystem services.[108] None of these regimes provides anything close to a process for assessing these varied risks and benefits, which, ideally, is what is needed for informed decision-making. Unfortunately, the EO Reform Plan also avoids discussion of ecological risks and benefits.[109]

C. *Incongruity with Biotechnology for Conservation*

Relatedly, risk mitigation under the FDA, APHIS, and EPA regimes is focused on minimizing risk of release.[110] This makes little sense when introduction into the environment is intentional—indeed, *the purpose* of the strategy. A core characteristic of certain synthetic conservation techniques is

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[106] *See, e.g.*, Jesse L. Reynolds, *Engineering Biological Diversity: The International Governance of Synthetic Biology, Gene Drives, and De-Extinction for Conservation*, 49 CURRENT OP. ENV'T SUSTAINABILITY 1, 2 (2020) ("Genetic modification could affect the species in unexpected ways or spread beyond the target population or species, for example via horizontal gene flow or hybridization."); Kevin M. Esvelt & Neil J. Gemmell, *Conservation Demands Safe Gene Drive*, PLOS BIOLOGY, Nov. 16, 2017, Article No. e2003850, at 2, https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2003850 [https://perma.cc/8TVY-L35Y] ("[G]enetic population suppression would be extremely useful for conservation and, unlike traps and poisons, would not cause any animals to suffer. However, tackling cosmopolitan species such as rats with this strategy would likely have worldwide effects."); Mandel & Marchant, *supra* note 72, at 167–68, 170–72 (raising general concerns regarding harm from synthetic biology).

[107] *See* Camacho, *Going the Way of the Dodo*, *supra* note 46, at 859–60; Brooks, *supra* note 67, at 201–02, 205 (discussing environmental risks of biotechnology and gene drives including harm to native species).

[108] For an example of a positive assessment of the ecological benefits vis-à-vis the risks of a measured, careful deployment of synthetic conservation to "rescue" a subspecies from extinction, see Alexandra Pavlova et al., *Benefits of Genetic Rescue of a Critically Endangered Subspecies from Another Subspecies Outweigh Risks: Results of Captive Breeding Trials*, BIOLOGICAL CONSERVATION, July 29, 2023, Article No. 110203, at 9, https://doi.org/10.1016/j.biocon.2023.110203 [https://perma.cc/5RUK-XNNM]; *see also* Sarah Hartley, Riley Taitingfong & Pedro Fidelman, *The Principles Driving Gene Drives for Conservation*, 135 ENV'T SCI. & POL'Y 36, 36–37 (2022) (detailing the potential benefits for environmental conservation that gene-drive technology could provide).

[109] *See* REFORM PLAN, *supra* note 4, at 5–6 (failing to reference the risks and benefits, other than a brief mention of developing guidance on ecological risk-assessment data needs for "plant-incorporated protectants").

[110] *See supra* Part V.B.

that they are intended for deliberate introduction into natural environments. Gene drives, for instance, involve releasing organisms with engineered genes that then spread those engineered genes through the population—the intentional spread of a genetic trait through a population.[111] As such, they are some of the most interventionist techniques possible. Uncertainty is likely to be particularly confounding, and there are likely to be especially acute concerns regarding irreversibility and the ability to control the intervention.[112] Yet, the potential benefits in light of concerns regarding disease and ecological harm from climate change make at least a comprehensive assessment of the tradeoffs of such technologies vital. The existing Coordinated Framework's regime does not make this possible.

Unfortunately, the existing statutory regimes used by FDA, APHIS, and EPA are not only narrow and thus deficient at the time of the initial, market-entry evaluation, but they also largely ignore the need for ongoing risk monitoring, the value of contingency planning, and the need for adaptive management. For instance, once APHIS grants a petition for nonregulated status for a transgenic plant, it no longer has any authority over the plant or its progeny, including even the monitoring of such plants for unexpected impacts.[113] This remains true even after the recent revisions to the Framework.[114] While examples used in earlier updates do help to clarify where some new technologies fit in, the basic framework relying upon preexisting statutes not optimized for synthetic biology remains the same.[115] Indeed, the EO Reform Plan for revising

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[111] Dooley, *supra* note 9, at 548–49.

[112] *See* Lin, *supra* note 63, at 225 (critiquing the inattention of biotechnology regulation to ecological uncertainty).

[113] As noted more than twenty years ago, it is not known whether APHIS's permitting of transgenic plants causes ecological harm because there is no or insufficient monitoring of ecological effects. *See* COMM. ON ENV'T IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, NAT'L RSCH. COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 168, 183 (2002). From its public announcements and policy statements, it does not appear that APHIS has attempted to make monitoring of ecological effects part of its permit conditions; indeed, much more attention has been paid to revising regulations to broaden exemptions from permitting requirements altogether. *See Biotechnology Permits*, U.S. DEP'T OF AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/permits/permits [https://perma.cc/UA8X-2GFY]; *see also* Emily Montgomery, *Genetically Modified Plants and Regulatory Loopholes and Weaknesses Under the Plant Protection Act*, 37 VT. L. REV. 351, 368 (2012) ("Once a plant is deregulated, the PPA no longer provides authority for any continued monitoring of genetically modified plants to watch for, or respond to, unanticipated environmental impacts or to limit the volume or location of plantings where there may be environmental risk.").

[114] *See* Movement of Certain Genetically Engineered Organisms, 84 Fed. Reg. 26514, 26516–18 (proposed Jun. 6, 2019) (to be codified at 7 C.F.R. pts. 340, 372) (making no changes to APHIS monitoring practices).

[115] *See, e.g.*, *id.* at 26518 (discussing the regulation of plants that produce plant-made industrials and pharmaceuticals under the FDCA and the TSCA).

the Coordinated Framework continues to ignore the need for ongoing monitoring and adaptive management.[116]

D. *Ignoring the Ethical Tradeoffs Introduced by Biotechnology for Conservation*

More broadly, synthetic conservation measures raise concerns about the ethical tradeoffs and goals of such strategies (and the regulatory framework), which the Coordinated Framework (and indeed, most other federal laws and processes) largely ignores. In synthetic conservation in particular, the "product" is not the focus or end goal of the engineering process. The product is at most a means to the end of restoring an ecosystem, improving human health or the health of an endangered species, or some other indicia of ecological health.[117] In such a case, not only should the process be evaluated for the attendant risks, but it should probably be balanced against the value of the end goal.

Unfortunately, there is at best a cursory discussion in both the Coordinated Framework as well as the relevant scholarly literature of broader ethical issues; the emphasis instead is more on technical concerns.[118] In none of the Coordinated Framework's regimes is there an attempt to consider whether a potential strategy promotes ecological integrity or health. EPA, the agency allegedly assigned authority over environmental harm, is tasked only with regulating biotechnological innovations via TSCA and FIFRA, neither of which is designed to evaluate the introduction of species into new habitats to promote conservation.[119]

Despite the Coordinated Framework's ostensible attempt to create a comprehensive regulatory framework for coordinating the management of biotechnology, the Coordinated Framework fails to integrate many laws that reflect broader ecological values.[120] The Coordinated Framework fails to integrate many laws governing intentional introduction of biotechnologies, including federal endangered and invasive species management laws, other federal wildlife management laws, and federal land laws, let alone state wildlife

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116 *See generally* REFORM PLAN, *supra* note 4 (failing to address conservation goals or efforts).

117 *See* Christopher Hunter Lean, *Synthetic Biology and the Goals of Conservation*, 27 ETHICS, POL'Y & ENV'T 250, 260 (2024).

118 *See generally, e.g.*, Rina Singh, Editor's Note, *Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology*, 19 INDUS. BIOTECH. 79, 79–81 (2023).

119 *See* Coordinated Framework, *supra* note 2, at 23324–32.

120 *See, e.g.*, Endangered Species Act of 1973, Pub. L. No. 92-205, 87 Stat. 884 (codified as amended at 16 U.S.C. §§ 1531–1544); Wilderness Act of 1964, Pub. L. No. 88-577, 78 Stat. 890 (codified at 16 U.S.C. §§ 1131–1136); National Wildlife Refuge System Improvement Act of 1997, Pub. L. No. 105-57, 111 Stat. 1252 (codified as amended at 16 U.S.C. §§ 668dd–668ee); National Forest Management Act of 1976, Pub. L. No. 94-588, 90 Stat. 2949 (codified at 16 U.S.C. §§ 1600–1687).

and public and private land laws.[121] Moreover, even the presumptions or standards that these conservation laws impose for introductions of new organisms vary depending not only on the type of species but also on the type of lands targeted for introduction.[122] There are thus many gaps and oddities in how even these laws manage release.

Just focusing on species conservation and public land laws, the existing regime is a patchwork of local, state, federal, and international regulations that reflect a variety of goals, some of which are inconsistent with releasing organisms with engineered genes. This patchwork reflects a variety of different goals and approaches. Some regulatory provisions focus on *historical preservation*, promoting historical fidelity or minimizing change.[123] Some such laws allow or promote native species, while these and others seek to minimize or eradicate nonnative exotic invasive species.[124]

Other regulatory regimes or specific legal provisions focus on *natural preservation*.[125] Some of these laws thus focus on minimizing human intervention and protecting "natural" species, communities, or ecosystems.[126]

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[121] For example, the Coordinated Framework does not include 16 U.S.C. § 1539(j), which allows for the limited introduction of experimental populations into an ecosystem.

[122] For example, the Wilderness Act of 1964 applies exclusively to specific tracts of federal land. The Act includes the following definition for "wilderness":

> An area of wilderness is further defined to mean in this chapter an area of undeveloped Federal land retaining its primeval character and influence, without permanent improvements or human habitation, which is protected and managed so as to preserve its natural conditions and which (1) generally appears to have been affected primarily by the forces of nature, with the imprint of man's work substantially unnoticeable; (2) has outstanding opportunities for solitude or a primitive and unconfined type of recreation; (3) has at least five thousand acres of land or is of sufficient size as to make practicable its preservation and use in an unimpaired condition; and (4) may also contain ecological, geological, or other features of scientific, educational, scenic, or historical value.

16 U.S.C. § 1131(c).

[123] Alejandro E. Camacho, *In the Anthropocene: Adaptive Law, Ecological Health, and Biotechnologies*, 15 L., INNOVATION & TECH. 280, 282 (2023). [hereinafter Camacho, *In the Anthropocene*].

[124] Exec. Order No. 13,112, 64 Fed. Reg. 6183, 6184 (Feb. 8, 1999).

[125] Robin Kundis Craig, *"Stationarity Is Dead"—Long Live Transformation: Five Principles for Climate Change Adaptation Law*, 34 HARV. ENV'T L. REV. 9, 31–33 (2010) (discussing current regulations relating to the environment, which are predicated on a conception of "natural" and current laws that seek either to preserve or restore an environment to this natural state).

[126] *See* Camacho, *Going the Way of the Dodo*, *supra* note 46, at 878 ("The goal of such legal provisions is to avoid or minimize human involvement in species movement or the progression of reserved ecological areas. Such reserved lands and biota are explicitly or implicitly considered valuable in large part because they are deemed wild or natural, separate from humans, and not artificial or an artifact of human activity."); *see also* Holly Doremus,

Relatedly, some laws seek to restrict "introduced" species.[127] Some legal provisions expressly seek to isolate introduced species from "natural" biota, in some cases providing fewer regulatory protections to the artifacts of human action as compared to those that lack direct human intervention.[128] Others subject manmade or artificial activities to more review.[129]

Yet a third type of resource law regime focuses on promoting *sustained yield*.[130] These regimes have often been tied to more consumptive uses like silviculture or fishing and typically have focused on maximizing the yield of a particular favored resource, akin to agriculture.[131] Few such regimes or provisions emphasize promoting ecological health.

This patchwork of resource laws did not contemplate and therefore is not designed to manage the introduction of products of genomic technologies.[132] Some resist or disfavor any introduction, either of an organism or gene.[133] For some conservation laws that allow certain introductions, the focus is to strictly isolate and contain introduced populations from "natural" or "native"

The Endangered Species Act: Static Law Meets Dynamic World, 32 WASH. U. J.L. & POL'Y 175, 205–06 (2010) (highlighting that traditional conservation strategies assume "that what nature needs most is for people to leave it alone").

[127] *See* Camacho, *De- and Re-Constructing Public Governance*, *supra* note 31, at 1600; *see also* 16 U.S.C. § 701; Plant Protection Act, Pub. L. No. 106-224, 114 Stat. 438 (codified at 7 U.S.C. §§ 7701–7786); Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, 16 U.S.C. § 4701(a)(2) ("[W]hen environmental conditions are favorable, nonindigenous species become established, may compete with or prey upon native species of plants, fish, and wildlife, may carry diseases or parasites that affect native species . . . .").

[128] *See* 16 U.S.C. § 4701(a)(2).

[129] *See* Camacho, *Going the Way of the Dodo*, *supra* note 46, at 878–79.

[130] *See* Camacho, *De- and Re-Constructing Public Governance*, *supra* note 31, at 1612; 16 U.S.C. § 531 ("'Sustained yield of the several products and services' means the achievement and maintenance in perpetuity of a high-level annual or regular periodic output of the various renewable resources of the national forests without impairment of the productivity of the land.").

[131] *See, e.g.*, Multiple-Use Sustained-Yield Act of 1960, Pub. L. No. 86-517, 74 Stat. 215 (codified as amended at 16 U.S.C. § 528–531); Magnuson-Stevens Act, Pub. L. No. 94-265, § 2(b)(1), 90 Stat. 331, 332 (codified at 16 U.S.C. § 1801(b)(1)) (offering as objectives both conserving and managing "fishery resources found off the coasts of the United States"); Sustained Yield Plan, CAL. CODE REGS. tit. 14, § 1091.1 (2024).

[132] *See* Camacho, *De- and Re-Constructing Public Governance*, *supra* note 31, at 1599–600. For example, the Lacey Act, which regulates the importation of wildlife into the United States, was enacted in 1981 and last amended in 2008. *Lacey Act*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/law/lacey-act [https://perma.cc/GM3M-K6UK]. Likewise, the Nonindigenous Aquatic Nuisance Prevention and Control Act was enacted in 1990 and later amended in 1996. 16 U.S.C. § 4701(a)(2); *Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/law/nonindigenous-aquatic-nuisance-prevention-and-control-act-1990 [https://perma.cc/DB6C-69HQ].

[133] *See* Camacho, *De- and Re-Constructing Public Governance*, *supra* note 31, at 1599–600.

populations,[134] so they do not allow (and actually resist) the introduction of genes. And some laws allow introduction but focus on promoting historical fidelity rather than attempting to advance likely future compatibility or ecological benefits.

Encouragingly, the National Academy of Sciences has sought to promote a more ecological approach to risk assessment.[135] But nonetheless, even this progressive approach does not meaningfully attend to the fundamental underlying value judgments related to the appropriate goals of strategies like introductions of genetically modified organisms for conservation.

VI. THE EXECUTIVE ORDER AS A LAUNCHING PAD?

The Coordinated Framework is a problematic way to address potential ecological interventions associated with genetically engineered plants and wildlife (like the AquAdvantage salmon), gene-drive species populations (like mosquitoes and moths), and "genetically rescued" species like (conceivably) the facsimile woolly mammoth, as we have explained. What to do about those problems is less clear, particularly given the reality that (1) as noted, the "energy" in public discourse and policy regarding biotechnology has been almost exclusively about bringing products to market more expeditiously, and (2) we have something close to legislative deadlock in Congress on a wide range of social and economic issues.[136]

In the absence of Congressional action, the Biden EO itself, however, points to a potentially productive first step—another executive order that would build on and add to the prior order. The Biden EO referenced climate change and sustainability and, as we have noted, implied ecological health and well-being were important goals of any biotechnology development and regulatory regime.[137] In a follow-up executive order, an administration could acknowledge that advancing ecological health must be central to synthetic conservation

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[134] Camacho, *Going the Way of the Dodo*, *supra* note 46, at 871 ("Section 10(j) allows 'experimental population' introductions 'only when, and at such times as, the population is wholly separate geographically from nonexperimental populations of the same species.'" (quoting 16 U.S.C. § 1539(j))). *See generally* S. M. Mussmann et al., *Genetic Rescue, the Greater Prairie Chicken and the Problem of Conservation Reliance in the Anthropocene*, ROYAL SOC'Y OPEN SCI., Feb. 22, 2017, Article No. 160736 (discussing legal protection for the genetically rescued greater prairie chicken and other conservation-reliant species under the Endangered Species Act, which could exacerbate political and economic concerns on species management).

[135] COMM. ON IMPROVING RISK ANALYSIS APPROACHES USED BY THE U.S., NAT'L RSCH. COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT, at ix (2009), https://nap.nationalacademies.org/read/12209/chapter/1 [https://perma.cc/GGY2-AV8K].

[136] SARAH BINDER, BROOKINGS, POLARIZED WE GOVERN? 17–18 (2014), https://www.brookings.edu/articles/polarized-we-govern [https://perma.cc/8ZN4-4UP7] (finding that levels of legislative gridlock have steadily risen over the past half-century and discussing impacts on Congress's ability to legislate).

[137] Exec. Order No. 14,081, 87 Fed. Reg. 56849, 56851 (Sept. 15, 2022).

governance, as well as the possibility that the current product-approval-for-commercialization model will not necessarily serve that goal, particularly in the context of synthetic conservation. The subsequent order should also acknowledge that defining synthetic conservation (or whatever term is used) and drawing lines between categories of greater and lesser ecological concern is difficult and invariably contextual. Then the subsequent order could direct the creation of a task force to consider how exactly to define the categories of greatest concern, and to address how long-term ecological health can be safeguarded through regulatory oversight with respect to those categories.

A good deal of the commentary and suggested reforms regarding regulation of synthetic conservation have focused on the Endangered Species Act (ESA).[138] The ESA is the principal federal law aimed at the protection of rare and vulnerable species and, to a limited extent, the habitats upon which these species depend.[139] However, despite the successes of the ESA in preventing the extinction of hundreds of species listed as endangered and threatened by direct human development,[140] the law's limitations as a comprehensive framework for promoting long-term ecological protection are well documented.[141] Indeed, the ESA does not unambiguously protect newly created or genetically rescued species.[142] As such, the charge of a synthetic conservation task force specifically should not be limited to considering how the ESA might be better employed to manage synthetic conservation.[143] It would need to develop substantive guidelines for assessing the broader ecological risks and benefits of particular strategies. It should also require the development of procedures for ensuring meaningful participation by interested parties in the assessment of such

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[138] *See, e.g.*, Jonas J. Monast, *Governing Extinction in the Era of Gene Editing*, 97 N.C. L. REV. 1329, 1356 (2019) (suggesting that ESA regulations be clarified as to how the statute applies to genetically modified organisms); Monast, *supra* note 76, at 2409; Trevor J. Cooper, *Managing the Anthropocene: Genetic Engineering, De-Extinction, and the Uncertain Future of Ecosystem Management*, 75 RUTGERS U. L. REV. 705, 733 (2023).

[139] 16 U.S.C. §§ 1531–1544; Doremus, *supra* note 126, at 177–79.

[140] *See* Daniel J. Rohlf, *The Endangered Species Act at Forty: The Good, the Bad, and the Ugly*, 20 ANIMAL L. 251, 255 (2014).

[141] *Id.* at 268 (detailing the pitfalls of the ESA, particularly federal actions that can continue to adversely affect a species' critical habitat as long as they do not "go *too* far"); Kalyani Robbins, *Missing the Link: The Importance of Keeping Ecosystems Intact and What the Endangered Species Act Suggests We Do About It*, 37 ENV'T L. 573, 585–86, 589–90 (2007) (proposing alterations to the current regulatory framework under the ESA to better protect the ecosystems in which endangered species live).

[142] *See* Norman F. Carlin, Ilan Wurman & Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction,"* 33 STAN. ENV'T L.J. 3, 18 (2014); *see also* Babcock, *supra* note 23, at 185; Cooper, *supra* note 138, at 733.

[143] As Hope Babcock notes, it seems implausible that Congress would constructively amend the Endangered Species Act to address the inadequacies of the Coordinated Framework as to ecological risk from synthetic biology. Babcock, *supra* note 23, at 185; *see also* Cooper, *supra* note 138, at 723.

tradeoffs in particular cases, as well as active monitoring and contingency planning to adjust strategies to account for change and/or new information.

Because they have the greatest relevant expertise and focus, the task force should consist of relevant offices at EPA and the U.S. Department of the Interior, along with NOAA in the Department of Commerce. The task force should be required to solicit public comment before finalizing the report and should be charged with producing a report and recommendations for the public, President, and Congress.[144]

Even if a President in the future could be convinced to take this first step, one might argue that it would be futile because current statutory authority for relevant agencies simply does not allow them to do what should be done—new legislation is needed. But we disagree. While each of us has argued that environmental governance could and should be better fashioned to manage the complexity and uncertainty from ecological change and emerging technologies,[145] there are nonetheless a wide range of current statutes that might be tapped to provide some relevant regulatory authority, and regulatory creativity is simply an unavoidable necessity in an era of legislative deadlock.[146]

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[144] As both Albert C. Lin and Jonas Monast suggest, greater public participation regarding specific releases of modified animal populations is needed. *See* Lin, *supra* note 63, at 227; Monast, *supra* note 76, at 2426–27. We agree. However, it is also important that the public be directly engaged regarding the larger philosophical, political, and empirical questions raised by synthetic conservation generally. The Biden Executive Order certainly did not achieve that objective, as only a few of the public comments addressed ecological well-being at all and there was no response from government decision-makers to the comments that were received. *See* Press Release, The White House, Fact Sheet: Biden-Harris Administration Announces New Bold Goals and Priorities to Advance American Biotechnology and Biomanufacturing (Mar. 22, 2023), https://www.whitehouse.gov/ostp/news-updates/2023/03/22/fact-sheet-biden-harris-administration-announces-new-bold-goals-and-priorities-to-advance-american-biotechnology-and-biomanufacturing [https://perma.cc/C3TG-WV4T].

[145] Camacho, *In the Anthropocene*, *supra* note 123, at 281–82; David A. Dana, *Can the Law Track Scientific Risk and Technological Innovation?* 3 (Nw. Univ. Sch. of L., Faculty Working Paper No. 113, 2010).

[146] For example, agencies could use the National Environmental Policy Act (NEPA) and regulations promulgated thereunder to provide for some of the sort of meaningful ecological reviews we advocate. NEPA has a very broad, expansive purpose. *See What Is the National Environmental Policy Act?*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/nepa/what-national-environmental-policy-act [https://perma.cc/MMP2-7ZK2] (Sept. 4, 2024) ("Title I of NEPA contains a Declaration of National Environmental Policy. This policy requires the federal government to use all practicable means to create and maintain conditions under which man and nature can exist in productive harmony."). The NEPA review process allows for interagency consultation and certainly does not prohibit it. *See generally id.* ("A federal, state, tribal or local agency having special expertise with respect to an environmental issue . . . may be a cooperating agency. A cooperating agency has the responsibility to . . . develop information and prepare environmental analysis that the agency has special expertise in [and] make staff support available.").

Of course, if this proposed executive order actually leads to new regulations, those regulations might be challenged and struck down as exceeding the agencies' delegated statutory authority.[147] However, it is possible that relevant stakeholders, like synthetic biology researchers and companies, might welcome a new, more comprehensive and considered regulatory framework, even if it entailed more upfront and continuing regulatory management. After all, efforts to deploy specific "products" of synthetic conservation, like disease-reducing mosquitoes proposed for release in Florida, have resulted in substantial public outcry and backlash, derailing proposed deployment.[148] The public might have greater trust in a thorough, transparent public regulatory process, and that trust, ultimately, could benefit companies and academic researchers working in synthetic conservation.[149] A push for new regulations also could encourage self-governance by industry and non-industry researchers.[150] As of now, there appears to be no meaningful efforts at self-governance in the form of, for example, voluntary guidelines or statements of best practice.

Moreover, one item that the executive order could place on the task force's agenda is recommendations regarding discretionary federal funding for research. At least some of the researchers and entities involved in synthetic conservation receive direct federal funding or are part of institutions receiving

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[147] Expansive regulatory action under the Coordinated Framework is open to challenge for lack of statutory basis in part because there is no specific federal statute specifically delegating to agencies the power to establish and implement the Framework. Moreover, recent Supreme Court decisions limit the authority of any agency to act without clear statutory authorization. *See* West Virginia v. EPA, 597 U.S. 697, 723 (2022) (holding that with respect to major questions, an agency requires a plain statutory statement of its authority to act, based on "both separation of powers principles and a practical understanding of legislative intent"); *see generally* Loper Bright Enters., Inc. v. Raimondo, 603 U.S. 369 (2024) (expressly overruling the *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* precedent that afforded deference to agencies with respect to the interpretation of ambiguous statutory delegations of authority).

[148] Sandee LaMotte, *750 Million Genetically Engineered Mosquitoes Approved for Release in Florida Keys*, CNN (Aug. 20, 2020), https://www.cnn.com/2020/08/19/health/gmo-mosquitoes-approved-florida-scn-wellness/index.html [https://perma.cc/69WP-U38V] (discussing the immediate public backlash to the project in Florida and concerns from local advocates and environmental groups).

[149] *Cf.* Libby Maman, Yuval Feldman & David Levi-Faur, *Varieties of Regulatory Regimes and Their Effect on Public Trust in Market Actors* 27–28 (Bar Ilan Univ. Fac. of L. Rsch. Paper No. 4055285, 2022), https://ssrn.com/abstract=4055285 [https://perma.cc/L2AB-TXVS] (finding a significant increase in public trust of market actors who are subject to state regulation rather than self-regulation).

[150] *Cf.* Babcock, *supra* note 23, at 171 (proposing that "participants in the field of de-extinction undertake traditional governmental functions, including setting, implementing, and enforcing performance standards, until external regulations are developed," and suggesting that "pressure from the application of social norms, like those pertaining to the environment and human health, and a motivated, educated public might encourage participants in the field of de-extinction to self-regulate" (footnote omitted)).

such funding.[151] Federal funding could be used as a lever to require transparency regarding the research and an agreement to follow certain procedures, even those that otherwise could not be imposed because of a lack of statutory authority. While Congress ultimately has control over the agencies such as the National Science Foundation and National Institutes of Health spend their budgets, the agencies can influence the budget allocation via the detailed budget proposals they provide annually to Congress.[152]

Of course, it is possible that there will be insufficient interest in doing anything at the federal level: we acknowledge that the overall framework for biotechnology has received hardly any legislative or regulatory attention, despite widespread acknowledgement that it needs improvement as a general matter.[153] One possibility is that a state or states could address this federal regulatory failure by developing a state statute and/or regulation regarding synthetic conservation. Such state initiatives, particularly those by California, have been important prods to the federal government to act in several environmental contexts,[154] and that could be true in this context as well.

Another possible forum is international law. The United States is one of only two nations that is not a party to the only comprehensive treaty on biodiversity to date, the Convention on Biological Diversity (CBD).[155] But every other nation with a substantial economy and research sector is a party to the CBD, the United States participates in CBD meetings and talks despite its

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[151] Academic researchers at major universities that receive federal funding are at the forefront of gene-drive research, for example. *See, e.g.*, Mario Aguilera, *Synthetic SPECIES Developed for Use as a Confinable Gene Drive*, U.C. SAN DIEGO TODAY (June 2, 2021), https://biology.ucsd.edu/about/news/2021/article_060721.html [https://perma.cc/23QK-HQFY].

[152] *See generally, e.g.*, U.S. NAT'L SCI. FOUND., FY 2025 BUDGET REQUEST TO CONGRESS, https://nsf-gov-resources.nsf.gov/files/2025-Budget-Rollout-Fact-Sheet.pdf?VersionId=cwLYpwAXTQ_IoQffOAMg7AxpdGnBYsV [https://perma.cc/W6Z2-D7YH] (summarizing National Science Foundation's proposed 2025 budget to Congress); MONICA M. BERTAGNOLLI, NAT'L INST. HEALTH, OVERVIEW OF FY 2025 PRESIDENT'S BUDGET, https://officeofbudget.od.nih.gov/pdfs/FY25/br/Overview%20of%20FY%202025%20Presidents%20Budget.pdf [https://perma.cc/7QS7-4EPQ] (giving an overview of National Institutes of Health's proposed 2025 budget to Congress).

[153] *See, e.g.*, Al Gore, *Planning a New Biotechnology Policy*, 5 HARV. J.L. & TECH., 19, 27–28 (1991).

[154] Krista Yee, "*A Period of Consequences": Global Warming Legislation, Cooperative Federalism, and the Fight Between the EPA and the State of California*, 32 ENVIRONS: ENV'T L. & POL'Y J. 183, 191–213 (2008); Albert C. Lin & Michael Burger, *State Public Nuisance Claims and Climate Change Adaptation*, 36 PACE ENV'T L. REV. 49, 51 (2018) (arguing that lawsuits filed against oil companies in California could spur federal action).

[155] Catrin Einhorn, *Nearly Every Country Signs on to a Sweeping Deal to Protect Nature*, N.Y. TIMES, https://www.nytimes.com/2022/12/19/climate/biodiversity-cop15-montreal-30x30.html (Dec. 20, 2022).

nonmembership,[156] and it seems highly plausible that action by the parties to the CBD on synthetic conservation would gain some attention from industry, researchers, and lawmakers within the United States. The conference of the parties to the CBD, in fact, has broadly called for a precautionary approach to synthetic biology and is in the process of creating an ad hoc technical expert group on synthetic biology to keep the parties informed about developments in synthetic biology.[157] If the parties to the CBD could be persuaded to adopt more specific language and recommendations regarding synthetic biology and its regulatory evaluation by governments, that could have an impact on the relevant stakeholders within the United States.

In sum, none of the paths to bringing a climate-change-informed realism to U.S. regulation regarding synthetic conservation—a realism that centers ecological well-being over time as a key goal and counters the hegemony of the current "product," market-entry-for-products model—is necessarily easy. But the Biden Executive Order could, conceivably, be the jumping-off point for efforts to achieve the needed reforms to address current and emerging alterations of wildlife and the ecosystem they inhabit and will inhabit.

VII. CONCLUSION

The Biden Administration Executive Order acknowledged that biotechnology regulation needs to center sustainability as an objective, but none of its details follow up on that important acknowledgement. The Coordinated Framework that the Executive Order leaves unchanged is particularly deficient with respect to synthetic conservation strategies that involve the engineering of animal organisms for intentional release into the environment. Such strategies already exist, many more are under research development, and they inherently entail great ecological uncertainty and risk. What is needed for the regulation of such strategies is a substantial departure from the current Coordinated Framework model—a model that has remained substantially inert through seven presidential administrations. Efforts such as those offered by the Biden administration in 2024 through its Reform Plan for the Coordinated Framework are incremental and insufficient. The original Coordinated Framework and subsequent modifications have consistently given short shrift to ecological uncertainty and risks but also to benefits. What is needed is a much more thoughtful federal, state, and/or international regulatory regime that envisions synthetic conservation as not involving "products" like cars or toothpaste but fundamental alterations of the environment that, while potentially beneficial,

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[156] *See, e.g.*, Press Release, U.S. Dep't of State, U.S. Delegation to the Convention on Biological Diversity Conference of Parties in Montreal (Dec. 9, 2022), https://www.state.gov/u-s-delegation-to-the-convention-on-biological-diversity-conference-of-parties-in-montreal [https://perma.cc/BP92-LRWT]; *see also* Einhorn, *supra* note 155.

[157] *Synthetic Biology*, CONVENTION ON BIOLOGICAL DIVERSITY (Mar. 3, 2023), https://www.cbd.int/synbio [https://perma.cc/47Q2-MHN5].

also pose potential costs that must be carefully assessed both upfront and on an ongoing, adaptive basis.