# GENE DRIVE: MODERN MIRACLE OR ENVIRONMENTAL DISASTER

*Kristen D. Brooks*[*]

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## I. INTRODUCTION

The field of biotechnology is rapidly expanding; to some, this represents opportunity for exciting scientific advancements in human health, agriculture, and environmental management. However, since its beginning, people have feared the potential risks associated with the developing technology. For

* J.D. Candidate, University of Illinois College of Law Class of 2020. I would like to thank my family for all their support throughout the years. I would also like to thank Professor Arden Rowell for her guidance and advice.

example, one early biotechnology case, *Foundation on Economic Trends v. Heckler*, decided by the Court of Appeals for the District of Columbia in 1985, centered around the potential environmental risks of genetically engineered organisms.[1] In this case, plaintiff environmental groups challenged the release of genetically engineered bacteria into the environment, claiming that the National Institutes of Health (NIH) failed to perform an adequate environmental risk assessment.[2]

Though the plaintiffs in the above case would argue the environmental constraints on biotechnology are insufficient to counter the serious risks involved, other commentators would claim the opposite.[3] A recent study conducted by the Pew Research Center found the general public is similarly conflicted as to their views of the proper use of biotechnology.[4] The study found that fifty-seven percent of those surveyed approved of genetically engineering animals to provide organs for human transplant, but only twenty-one percent approved of genetically engineering animals for entertainment purposes, such as the GloFish.[5] The study also found seventy percent of persons approved of genetically engineering mosquitoes as a means to control disease vectors, a surprising amount considering the negative response from Florida residents following the British company, Oxitec's, proposal to release its "friendly mosquitoes" in the Florida Keys.[6] The Pew Research Center cited two major concerns behind the public's negative response to biotechnology: a general fear of tampering with nature and concern regarding the potential environmental impacts.[7]

The concerns of the public may not be unfounded: biotechnology is a relatively new field, and its consequences are not yet well known.[8] For that reason, it is important for the U.S. government to have a strong and consistent method for regulating new technologies, which balances the public health and environmental concerns with the need to promote innovation in the field.

This Note seeks to demonstrate the inconsistent nature of the existing legal framework that regulates genetically engineered animals in the United States, as well as establish that the best way to overcome these challenges is to modify the

1. Found. of Econ. Trends v. Heckler, 756 F.2d 143, 145 (1985); Elie Gendloff, *Stauber v. Shalala: Are Environmental Challenges to Biotechnology Too Difficult?*, 4 WIS. ENV. L. J. 41, 55 (1997).

2. Heckler, 756 F.2d at 145–46.

3. *See, e.g.*, Gendloff, *supra* note 1 (discussing the view that environmental constraints hinder the development of new biotechnology).

4. Cary Funk & Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals That Benefits Human Health, but Many Oppose Other Uses*, PEW RES. CTR. (Aug. 16, 2018), http://www.pewresearch.org/science/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses/.

5. *Id.*

6. *Id.*; Lisa Palmer, *Genetically Modified Mosquito Sparks a Controversy in Florida*, YALE ENV'T 360 (June 4, 2015), https://e360.yale.edu/features/genetically_modified_mosquito_sparks_a_controversy_in_florida.

7. Funk & Hefferon, *supra* note 4.

8. *See, e.g.*, THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 73 (2016) [hereinafter GENE DRIVES] (discussing uncertainties involved with genetically engineering animals).

existing law governing the regulation of genetically engineered animals. The Note will begin with a background of the recent boom in the biotechnology industry which gave rise to the Coordinated Framework for the Regulation of Biotechnology, and it will include a description of engineered gene drive technology—one of the more recent developments in genetic engineering. In the Analysis, this Note will show how gene drive technology fits imperfectly into the old regulatory framework through case studies. The Analysis will also describe how the different regulatory agencies handle similar gene drive-like organisms inconsistently, and the inherent danger of this approach considering upcoming developments in the field. Finally, the Recommendation will outline actions that Congress, the courts, and agencies should take to avoid the serious pitfalls currently risked under the Coordinated Framework.

## II. BACKGROUND

The 1980s could easily be called the golden age of biotechnology, and surely the beginning of the field as we know it today.[9] In 1980, the Supreme Court decided a genetic organism could be afforded patent protection in the seminal case of *Diamond v. Chakrabarty*.[10] The expansion of the biotechnology field following this case was incredible. In 1981, the first gene-synthesizing machines and the first genetically engineered plant were created, and PCR—a process for repeated replication of genes and gene fragments—was invented shortly after, in 1983.[11]

The law, however, failed to advance as rapidly as the emerging scientific industry. The new biotechnology did not fit cleanly into any existing statutory constructs, and there was general confusion regarding how these technologies ought to be regulated.[12] Prior to the adoption of the Coordinated Framework, the NIH was responsible for regulating biotechnological research, an arrangement which was problematic in many respects.[13] The NIH simply lacked the power to provide the type of regulation necessary for these technologies: it was unable to reach institutions which were not funded by NIH grants, could not impose any sanctions beyond rescinding those grants, and the regulations it did enforce were in themselves inadequate.[14]

In 1984, the federal government recognized the serious human and environmental health risks posed by biotechnologies and acknowledged the need for more firm regulation in this area.[15] The Senate then held a hearing on the

9. *See* Brian Colwell, *Biotechnology Timeline: Humans Have Manipulated Genes Since the 'Dawn of Civilization,'* GENETIC LITERACY PROJECT (July 18, 2017), https://geneticliteracyproject.org/2017/07/18/biotechnology-timeline-humans-manipulating-genes-since-dawn-civilization/ (showing a comprehensive timeline of important biotechnology advancements and discoveries dating back to 7,000 BCE).

10. Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980).

11. Colwell, *supra* note 9.

12. *See* David L. Stepp, *The History of FDA Regulation of Biotechnology in The Twentieth Century*, FOOD & DRUG L. 1, 48–52 (1999) (discussing regulation of biotechnology prior to the introduction of the Coordinated framework, including the many pitfalls and uncertainties that existed).

13. *Id.* at 49.

14. *Id.* at 50–51.

15. *Id*. at 56.

potential consequences of genetic engineering, and it ultimately decided that existing statutes, although they required clarification as to how they apply to the new technologies, were sufficient and no new legislation was necessary.[16]

The Coordinated Framework for the Regulation of Biotechnology was published in 1986.[17] Rather than create new laws or regulatory bodies, this framework merely reiterates that existing laws are considered adequate and identifies the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and U.S. Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS) as the leading regulatory agencies for biotechnology.[18] The duties of regulation are split between the three agencies based on the particular use of a biotechnology product—the EPA regulates products with pesticide properties under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the FDA regulates genetically engineered animals as "new animal drugs" under the Federal Food, Drug, and Cosmetic Act (FDCA), and the USDA/APHIS regulates plant pests under the Plant Protection Act (PPA).[19]

Since 1986, the biotechnology field has shown no sign of slowing down, and new innovations are placing a strain upon the old laws that continue to be tortuously adapted to fit the changing landscape.[20] Jump forward to 2012, when scientists discovered the revolutionary gene-editing tool CRISPR.[21] CRISPR is notably unique for its remarkable precision and diverse application.[22] The technology can locate a particular target gene, cut that gene at precise locations, and simultaneously insert a new genetic sequence at the site far more efficiently and reliably than any previously existing technique.[23] Additionally, CRISPR's flexibility allows scientists to edit nearly any gene across a wide range of species, resulting in essentially boundless possibilities.[24]

One rising application of CRISPR Genome Editing is the creation of gene drive organisms.[25] A gene drive is a naturally occurring phenomenon in which a particular genetic allele (one version of the specified gene) does not follow the traditional pattern of Mendelian genetics.[26] That is, while the typical allele has a fifty percent chance of being inherited by each offspring, the chance of

16. NAT'L RES. COUNCIL COMM. ON SCI. EVALUATION OF THE INTRODUCTION OF GENETICALLY MODIFIED MICROORGANISMS & PLANTS INTO THE ENV'T, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 137 (Nat'l Academies Press 1989).

17. *Id.* at 138.

18. *Id*.

19. EXEC.OFFICE OF THE PRESIDENT, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 9 (Jan. 4, 2017) [hereinafter 2017 UPDATE], https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf.

20. *See, e.g.*, *id.* (detailing the 2017 update to the Coordinated Framework, which is more a clarification of the regulatory agencies preexisting roles rather than a substantial legal update).

21. Mark Shwartz, *Target, Delete, Repair: CRISPR is a Revolutionary Gene-Editing Tool, But It's Not Without Risk*, STANFORD MED. (2018).

22. *FAQs*, WYSS INST., https://wyss.harvard.edu/faqs-gene-drives/ (last visited Mar. 13, 2020).

23. *Id*.

24. *Id*.

25. *Id*.

26. *Id*.

inheriting a gene drive allele is significantly higher.[27] Also unique is the fact that gene drive alleles continue to be prevalent within a population even if they do not provide any selective advantage, whereas a traditionally inherited gene that is neutral or competitively disadvantageous would decrease in prevalence or disappear completely from the population.[28] With CRISPR, scientists are now able to take advantage of these "selfish genes" by inserting a desired sequence into the gene, resulting in rapid, reliable dissemination of the genotype within the population.[29]

There are several uses for engineered gene drives.[30] Synthesized gene elements could be driven into agricultural pest populations to make them more benign or less abundant.[31] Protective genes could be driven into endangered species, conveying resistance to biological or chemical stressors.[32] Gene drives could even be used to eradicate invasive species or devastating disease vectors.[33]

Although the potential for human and environmental benefit is great, so are the risks involved. Gene drives carry similar risks as some bio-controls already in production today, such as the Oxitec mosquito. Since these are living, free roaming organisms that are designed to be released into the wild, there is significant potential for damage, the possibilities of which have not been well studied and are not understood.[34] For example, gene drives and bio-controls designed for population suppression, such as would be used to decrease or entirely eradicate disease-causing pests, could unintentionally upset the ecosystem balance.[35]

However, due to the unique nature of gene drive organisms, their production and release may be particularly risky compared to other types of bio-controls.[36] The Oxitec mosquito is designed only to decrease wild populations.[37] The engineered trait causes approximately 25% of the insect's offspring to die, and approximately 25% of its offspring become carriers of the engineered

27. *Id.*

28. Zahra Meghani & Jennifer Kuzma, *Regulating Animals with Gene Drive Systems: Lessons from the Regulatory Assessment of a Genetically Engineered Mosquito*, 5 J. RESPONSIBLE INNOVATION 203, 203–04 (2017).

29. *See FAQs*, WYSS INST., https://wyss.harvard.edu/faqs-gene-drives/ (last visited Mar. 13, 2020) (describing briefly how CRISPR helps scientists utilize gene drives).

30. *See, e.g.*, Jennifer Kuzma & Lindsey Rawls, *Engineering the Wild: Gene Drives and Intergenerational Equity*, 56 JURIMETRICS J. 279, 280 (2016) (listing potential uses for engineered gene drives).

31. *Id.*

32. *Id.*

33. *See* Dorian Moro et al., *Identifying Knowledge Gaps for Gene Drive Research to Control Invasive Animal Species: The Next CRISPR Step*, 13 GLOBAL ECOLOGY AND CONSERVATION 1, 2 (2018) (discussing the use of engineered gene drives for invasive vertebrate species); *see also* Meghani & Kuzma, *supra* note 28, at 204 (indicating the importance of gene drive research to eliminate disease spreading mosquito populations).

34. *See supra* note 29 (describing potential to harm wild populations).

35. *See* James P. Collins, *Gene Drives in Our Future: Challenges of and Opportunities for Using A Self-Sustaining Technology in Pest and Vector Management*, 12 BMC PROCEEDINGS 38, 40 (2018) (stating that gene drive may have "irreversible" effects on the environment).

36. *See id.* (discussing some risks involved with gene drives).

37. *Oxitec to Apply New Generation of Self-Limiting Mosquito Technology to Malaria-Spreading Mosquitoes*, OXITEC (June 19, 2018), https://www.oxitec.com/en/news/oxitec-to-apply-new-generation-of-self-limiting-mosquito-technology-to-malaria-spreading-mosquitoes.

genetic insert.[38] After about ten generations, the engineered gene has dwindled from the population.[39] Conversely, when a gene drive is used, the engineered gene persists indefinitely and spreads rapidly.[40] To demonstrate, one recent study placed 150 mosquitoes carrying an engineered population suppressing gene drive into a population of 300 female and 150 male insects.[41] Within seven to eleven generations, all mosquitoes in the study carried the gene drive and, as a result, no eggs were laid.[42] An entire population was eradicated in as few as eight generations.[43]

Although no gene drive organism has yet reached the field testing stage, the National Academies of Sciences, Engineering, and Medicine has predicted this technology to be an area of significant growth over the next five to ten years,[44] and it is sure to present new, difficult challenges and risks which must be addressed by the regulating agencies.[45] The purpose of the Coordinated Framework was to provide regulation adequate to protect human and environmental health with a predictable, efficient, and transparent process for inventors to avoid impeding useful innovation.[46] In the Analysis below, this Note shall address whether the Coordinated Framework continues to uphold these purposes in the current state of biotechnological innovation.

## III. ANALYSIS

### *A. Introduction to the Oxitec Mosquito and FDA Regulation*

The case of the Oxitec "Friendly Mosquito" is a good place to start an investigation of the Coordinated Framework in action, as it is perhaps the best demonstration of the convoluted nature of the Coordinated Framework. The line of genetically engineered mosquitoes was developed by the British corporation, Oxitec, and was heralded as an important invention for the prevention of mosquito-transmitted disease.[47]

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38. *See* Megan Molteni, *How 'Self Limiting' Mosquitos Can Help Eradicate Malaria*, WIRED (June 21, 2018, 7:00am), https://www.wired.com/story/oxitec-gates-self-limiting-mosquitoes/ (explaining how Oxitec mosquitoes decrease wild populations).

39. *Id*.

40. Kyros Kyrou et al., *A CRISPR-Cas9 Gene Drive Targeting doublesex Causes Complete Population Suppression in Caged Anopheles gambiae Mosquitoes*, 36 NATURE BIOTECHNOLOGY 1062, 1065 (2018).

41. *Id*.

42. *Id*.

43. *See id.* (describing how the population was gone within seven to eleven generations).

44. THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 49 (2017) [hereinafter PREPARING FOR FUTURE PRODUCTS].

45. *See generally*, Meghani & Kuzma, *supra* note 28 (addressing the environmental concerns and uncertainties associated with gene drives and questioning the FDA's preparedness to handle these concerns); *see also supra* note 29 (acknowledging the need for case-by-case evaluation of gene drive systems and their unique risk to other organisms and the environment).

46. EMERGING TECHNOLOGIES INTERAGENCY POL'Y COORDINATION COMMITTEE'S BIOTECHNOLOGY WORKING GROUP, NATIONAL STRATEGY FOR MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS 4 (2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

47. Insung Hwang, *Change in Regulation is Necessary for Genetically Engineered Mosquitos*, 6 MICH. J. OF ENVTL. AND ADMIN. L. 285, 286 (2016).

The Oxitec mosquito is an engineered variant of the *Aedes aegypti* species, which is the species known to spread several human diseases such as Malaria, Dengue, and Zika.[48] These are devastating illnesses; in 2017 there were 435,000 reported deaths from Malaria alone.[49] The proposed technology is fairly straight forward—Oxitec developed a "self-limiting" sequence which is injected into the genome of male *Aedes aegypti* mosquitoes.[50] When these altered insects are released into the wild, they mate with wild females, and the engineered gene is passed to their offspring.[51] The self-limiting nature of the gene causes all female offspring that inherit the engineered sequence to die before reaching maturity.[52] Oxitec claims this method not only reduces instances of mosquito-transmitted illness, but also benefits the environment.[53] The release of the self-limiting mosquitoes mitigates the need for harmful chemical pesticides which can contaminate food and water, as well as injure wildlife.[54]

The mosquito was first released into the wild in Brazil.[55] The company began field trials in 2011; in Juazeiro, Bahia, Brazil, between 2011 and 2015, Oxitec's mosquitoes achieved a decrease of over ninety percent in the *Aedes aegypti* population.[56] Following these successes, Oxitec opened a production facility within Brazil, and mosquitoes have since been released in the City of Piracicaba, covering an area of 65,000 residents.[57] Perhaps it is surprising, considering the verified benefits of the releases in South America, that the mosquitoes have yet to be approved for release within the United States.[58] After all, mosquito-transmitted diseases have been a significant concern in the U.S. states and territories; the Zika virus alone, though currently declining, had over 1,000 cases reported in 2017.[59]

Opinions on the delay for approval are varied. Although the benefits of Oxitec's mosquito are clear and verifiable, the risks involved are not well understood.[60] This, combined with the public's general distrust of regulatory agencies' competency to evaluate those risks, resulted in public backlash

48. *Id.* at 287–88.

49. *Malaria*, WORLD HEALTH ORG. (Jan. 14, 2020), https://www.who.int/news-room/fact-sheets/detail/malaria.

50. *Our Technology*, OXITEC, https://www.oxitec.com/en/our-technology/ (last visited Mar. 12, 2020).

51. *Id.*

52. *Id.*

53. *Id.*

54. Carolyn P. Neuhaus & Arthur L. Caplan, *Ethical Lessons from A Tale of Two Genetically Modified Insects*, 35 NATURE BIOTECHNOLOGY 713, 714 (2017).

55. *Brazil*, OXITEC, https://www.oxitec.com/brazil/ (last visited Mar. 12, 2020).

56. *Id.*

57. *Id.*

58. *See EPA Opens Public Comment Period for Oxitec's Mosquito Technology Demonstration Project in Florida Keys*, OXITEC (Sept. 16, 2019), https://www.oxitec.com/en/news/epa-public-comment-announcement-2019 (stating that Oxitec expects to begin releasing mosquitoes in Florida in 2020 or 2021, contingent on the EPA's approval).

59. *Zika Virus: 2017 Case Counts in the U.S.*, CTR. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/zika/reporting/2017-case-counts.html (last visited Mar.13, 2020).

60. *See infra* Part II (discussing the anticipated risks associated with wild-release gene drive mosquitoes).

against a Florida release, proposed in 2015.[61] The public's demonstrated lack of confidence in the current approach to regulating this type of technology under the Coordinated Framework is concerning and not unfounded.

In 2011, Oxitec first filed with the FDA for approval to release its Friendly Mosquito in Key Haven, Florida.[62] Under the Coordinated Framework, the FDA has regulatory jurisdiction over genetically engineered animals.[63] This power is purportedly granted to it by the Food, Drug and Cosmetic Act, although the Act never mentions genetically engineered animals (or biotechnology at all).[64] As previously discussed, the Coordinated Framework did not create new law to govern biotechnology, but merely attempted to clarify how emerging inventions would fit into pre-existing law.[65] Instead, the Framework repurposes the FDCA definition of "new animal drug" to cover genetically engineered animals.[66]

The FDCA defines a "new animal drug" as "any drug intended for use for animals other than man for which the safety and efficacy has not been sufficiently proven" and drug as "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[67] The reasoning that follows is that the genetic material used to modify the genetically engineered animal is a drug, under this definition.[68] Then, because this genetic insert is being used to modify the DNA of an animal, it is a new animal drug.[69]

Categorizing the engineered genetic insert as a new animal drug is not only a strained interpretation of the statutory language, but also fails to provide the regulation necessary for this type of technology. The Center for Veterinary Medicine (CVM) is the division of the FDA responsible for regulating new animal drugs.[70] The CVM states as its mission: to ensure new animal drugs are safe for animals and to make more animal drugs legally available.[71] This means the main objective of the FDA's regulatory assessment is to determine if the engineered genetic insert is safe for the mosquito itself and to facilitate these technologies entering the market.[72]

This is not to say the FDA entirely neglects environmental concerns when assessing a new animal drug. The National Environmental Policy Act (NEPA), implemented by the Council on Environmental Quality (CEQ), requires all federal agencies to consider the environmental impact of proposed major federal

61. Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitoes and The Coordinated Framework for Biotechnology*, 51 U.C. DAVIS L. REV. 205, 225 (2017).

62. Hwang, *supra* note 47, at 288.

63. Neuhaus & Caplan, *supra* note 54.

64. 2017 UPDATE, *supra* note 19, at 18.

65. Alison Peck, *Re-framing Biotechnology Regulation*, 72 FOOD & DRUG L. J. 314, 319 (2017).

66. 2017 UPDATE, *supra* note 19, at 18.

67. 21 U.S.C. § 321(v) (2018); 21 U.S.C. § 321 (g)(1) (2018).

68. Hwang, *supra* note 47, at 290–91.

69. *Id.*

70. *New Animal Drug Applications*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/NewAnimalDrugApplications/default.htm (last visited Nov. 28, 2018).

71. *About the Center for Veterinary Medicine (CVM)*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm (last visited Nov. 28, 2018).

72. *See id.* (listing the purposes behind CVM regulation of new animal drugs).

actions and, in most cases, compile an environmental assessment (EA).[73] The EA generally includes the need for the proposed action, evaluation of the alternative actions, environmental impacts of the proposed action and alternative actions, and a listing of the agencies and persons consulted.[74] This assessment is minimalistic in nature, but if it indicates the actions proposed are "major federal actions significantly affecting the quality of the human environment . . .", a more detailed, environmental impact statement (EIS) may be prepared.[75] With NEPA, Congress sought to compel federal agencies to consider the environmental risks of their actions and to "use all practicable means and measures" to protect environmental values.[76] Laudable as this legislation was, it has repeatedly missed the mark at achieving its policy goals.[77]

Although the general process for NEPA compliance is uniform among the various federal agencies, the requirements are inconsistently applied by those agencies. This is because NEPA and its implementing regulations require that each agency shall create its own procedures for environmental assessment, resulting in some agencies applying more lax requirements than others.[78] Scholars and scientists have found the FDA's approach to environmental assessments for genetically engineered animals particularly problematic.[79]

The FDA assessment begins with a New Animal Drug Application (NADA) submitted by the inventors seeking approval for their GE animal.[80] Along with the application, the inventor must either file an environmental assessment or a claim of categorical exclusion from the environmental assessment requirement.[81] If the environmental assessment indicates that an agency action may significantly affect the environment, a more thorough environmental impact statement is required, which states the purpose and need for the project and considers reasonable alternatives.[82] Alternatively, the FDA (or other agency) may interpret from the environmental assessment that there is no significant environmental impact from the action, in which case it releases a

73. Helen Leanne Serassio, *Legislative and Executive Efforts to Modernize NEPA and Create Efficiencies in Environmental Review*, 45 TEXAS ENV'T L. J. 317, 319 (2015).

74. 40 C.F.R. § 1508.9(b) (2018).

75. 42 U.S.C. § 4332(2)(C) (2018); Victor B. Flatt, *The "Worst Case" May be The Best: Rethinking NEPA Law to Avoid Future Environmental Disasters*, 6 ENVTL. & ENERGY L. & POL'Y J. 181, 184 (2011).

76. 42 U.S.C. § 4331; Flatt, *supra* note 75, at 184.

77. *See, e.g.*, Stepp, *supra* note 12 at 95 (describing the USDA approved field testing of a vaccine in swine without a NEPA environmental assessment. The developer of the vaccine claimed, among other things, that no such assessment was required because the field test did constitute an "environmental release").

78. *Compare*, 21 C.F.R. § 25 (2018) (codifying the FDA's regulations for environmental assessment to comply with NEPA), *with* 7 C.F.R. § 372 (2018) (codifying APHIS's regulations for environmental assessments).

79. *See, e.g.*, Gregory Gethard, *Suit Slams FDA for Approval of Genetically Modified Salmon*, 34 NO. 5 WESTLAW J. TOXIC TORTS 5 (2016). (recounting the troubling case claiming the FDA failed to adequately address environmental concerns when approving genetically engineered salmon).

80. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ENVIRONMENTAL ASSESSMENT OF HUMAN DRUG AND BIOLOGICS APPLICATIONS 1 (July 1998) [hereinafter GUIDANCE FOR INDUSTRY], https://www.fda.gov/downloads/Drugs/Guidances/ucm070561.pdf.

81. *Id.* at 3.

82. Western Watersheds Project v. Abbey, 719 F.3d 1035, 1045 (9th Cir. 2013).

finding of no significant impact (FONSI) statement and no environmental impact statement is prepared.[83]

Some scholars critique the FDA's approach to environmental assessment because the requirements for inventors lack thoroughness, causing some environmental risks to go unreported.[84] Some are even more skeptical regarding the role of inventors preparing and submitting the environmental assessments for their own technology, and fear this presents a chance to create a biased picture of their product.[85] The cases below further illustrate and explain some of the concerns involving the FDA's handling of genetically engineered animals and the shortcomings of the NEPA requirements.

### *1. The FDA, NEPA, and GloFish*

On December 9, 2003, the FDA released its "Statement Regarding GloFish."[86] The statement was a single paragraph long and merely stated that "[t]here is no evidence that these genetically engineered zebra danio fish pose any more threat to the environment than their unmodified counterparts . . . . In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish."[87] The International Center for Technology Assessment brought suit against the FDA, claiming its decision that the GloFish was of no more threat to the environment or public health than its unmodified counterparts was a clear error and failed to consider the potential for accidental or intentional releases of the fish into the wild.[88] Any wild release of a non-native organism is considered invasive and can have several ecological consequences including interbreeding and hybridization with wild species or outcompeting the native species.[89] The International Center for Technology Assessment also claimed a potential risk to human health: if wild fish, marketed for consumption, were to ingest the genetically engineered GloFish, it could cause introduction into the human food chain.[90]

Regardless of these concerns, the FDA did not conduct any environmental assessment and, according to the District Court of the District of Columbia, it was not required to do so under NEPA.[91] As stated above, NEPA applies to agency actions; declining to regulate a particular product, the court said, is not

83. 40 C.F.R. § 1508.13 (2018).

84. *See, e.g.*, Nathaniel Logar & Leslie K. Pollock, *Transgenic Fish: Is A New Policy Framework Necessary for A New Technology?*, ENVTL. SCIENCE & POLICY (2004) (stating that the scope of environmental assessments fails to provide a thorough assessment of reasonably foreseeable risks to the entire ecosystem); *See also*, Albert C. Lin, *supra* note 61 at 224 (pointing out the narrow focus of the environmental assessment for Oxitec mosquitoes).

85. Logar & Pollock, *supra* note 84.

86. *Statement Regarding Glofish*, U.S. FOOD & DRUG ADMIN. (Dec. 9, 2003), https://wayback.archive-it.org/7993/20170404230909/https:/www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm.

87. *Id.*

88. Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1, 4 (D.D.C. 2006).

89. Rekha K. Rao, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of Transgenic Glofish*, 57 ADMIN. L. R. 903, 913 (2005).

90. *Int'l Ctr. for Tech. Assessment*, 421 F. Supp. 2d at 4.

91. *Id.* at 8.

an agency action and, thus, does not trigger NEPA requirements.[92] The court went on to say NEPA does not apply even if the agency's inaction may have environmental consequences because "[n]o agency could meet its NEPA obligations if it had to prepare an environmental impact statement every time the agency had power to act but did not do so . . . ."[93] Finally, the court struck down the International Center for Technology Assessment's attempt to challenge the FDA's inaction, declaring that an agency's decision not to regulate a product is within its jurisdiction.[94] This case demonstrates that the discretion given to federal agencies renders NEPA clearly insufficient to protect environmental values on its own.

However, the problems with NEPA are not limited to instances where the agency takes no regulatory action, as was later demonstrated when the FDA considered approval of the genetically engineered AquAdvantage salmon.

### *2. The Flawed Environmental Assessment of the AquAdvantage Salmon*

The AquAdvantage salmon is a transgenic fish created by the company Aqua Bounty.[95] Aqua Bounty injects Atlantic salmon eggs with a gene construct which contains an antifreeze gene from the ocean pout and a growth hormone from the larger Chinook salmon.[96] The result is an Atlantic salmon which is larger and reaches maturity more quickly than conventional salmon.[97]

The AquAdvantage salmon was the first genetically engineered animal intended for human consumption—a quality that brought with it several unique considerations and concerns that are beyond the scope of this Note.[98] However, one clear point of overlap between all GE animals assessed by the FDA is the preparation of an environmental assessment as required by NEPA.[99]

At first glance, this assessment appears to be a thorough review of the risks and asks the important questions: (1) the likelihood the animal will escape confinement, (2) likelihood of survival and dispersal upon escape, (3) likelihood of reproduction upon escape, and (4) likely environmental consequences of escape.[100] After reviewing these considerations, the agency released its finding of no significant impact, fielded questions from the public, and proceeded to approve the fish for consumption in the United States.[101]

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92. *Id.*

93. *Id.* (quoting Defenders of Wildlife v. Andrus, 627 F.2d 1238, 1243, 1246 (D.C.Cir.1980)).

94. *Id*. at 5.

95. Michael P. McEvilly, *Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon*, 11 DUKE L. & TECH. REV. 413, 414 (2013).

96. *Id.*

97. *Id.*

98. *See id.* (discussing many of the unique regulatory considerations for a genetically engineered animal intended for human consumption).

99. GUIDANCE FOR INDUSTRY, *supra* note 80 at 1.

100. U.S. FOOD & DRUG ADMIN., FINDING OF NO SIGNIFICANT IMPACT: AQUADVANTAGE SALMON 4 (2015), https://fda.gov/media/93823/download.

101. *Id.*

Despite the apparent thoroughness, legal scholars, scientists, and environmental groups alike voiced objections to the approval.[102] The legal community pointed out problems with the FDA's approval process, particularly a lack of transparency and opportunity for public comment before the genetically engineered animal was approved, while scientists and environmentalists critiqued whether the assessment truly was as thorough as it appeared.

One article points to the Veterinary Medicine Advisory Committee notes to demonstrate the serious problems with the FDA's approval process for the AquAdvantage salmon.[103] The committee expressed concerns regarding the adequacy of Aqua Bounty's research including small sample sizes, and the limited number of studies actually conducted.[104] Additionally, the committee noted that Aqua Bounty's studies were released only ten days before public comments were due, limiting the amount of time for the scientific community to comment on the adequacy of the research.[105]

Scientists acknowledge that the questions asked by the FDA's environmental assessment are important, but fail to cover the full range of risks associated with the new technology.[106] For example, the New Animal Drug Application neglects to address the environmental concerns associated with an increase in salmon farming, including increased pollution and pressure on wild fish stock to feed farm-raised fish.[107]

Environmental law group, EarthJustice, submitted a citizen petition on behalf of Ocean Conservancy in May 2011, claiming the decision to approve the AquAdvantage salmon is one that significantly affects the human environment and requires an environmental impact statement.[108] Like the Veterinary Medicine Advisory Committee, EarthJustice notes serious flaws in Aqua Bounty's environmental assessment which, it states, demands further study.[109] One such flaw is that Aqua Bounty claims its fish are sterile, meaning the risk of escape during transport from its Canadian facility to the Panamanian facility is negligible.[110] In actuality, the study submitted by Aqua Bounty demonstrates that as many as five percent of its fish may not be sterile.[111] Furthermore, Aqua Bounty did not submit any data demonstrating that its fish truly are sterile, and this fact was confirmed by the FDA.[112]

102. McEvilly, *supra* note 95.

103. McEvilly, *supra* note 95; U.S. FOOD & DRUG ADMIN., VETERINARY MED. ADVISORY COMM. MEETING: AQUADVANTAGE SALMON 352 (2010), https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-response-public-comments-environmental-assessment.

104. McEvilly, *supra* note 95, at 424–25.

105. *Id.* at 425.

106. Martin D. Smith et al., *Genetically Modified Salmon and Full Impact Assessment*, 330 SCIENCE 1052, 1053 (2010).

107. *Id.*

108. EARTHJUSTICE, CITIZEN PETITION FROM EARTHJUSTICE ON BEHALF OF OCEAN CONSERVANCY ET AL. 2 (May 25, 2011), http://www.centerforfoodsafety.org/files/final-ge-salmon-citizen-petition-52511.pdf.

109. *Id.*

110. *Id.* at 9.

111. *Id.*

112. *Id.*

NEPA is not the only environmental statute regulatory agencies must comply with; in some cases, the Endangered Species Act may apply. This came into play during the FDA's assessment of the AquAdvantage salmon.

As part of its environmental assessment, an administrative agency must also evaluate the impact of the biotechnology on endangered species under the Endangered Species Act.[113] If the agency finds its action may affect a listed species or critical habitat, the agency is then required to consult with the appropriate expert agency, either the Fish and Wildlife Service (FWS) or the National Marine Fisheries Service, before continuing.[114] Interestingly, the FDA did report to the Fish and Wildlife Service its determination that the GE salmon may affect a listed population of wild salmon.[115] However, rather than take the next step with the Fish and Wildlife Service to evaluate this perceived threat, the FWS merely suggested the FDA retract its "may affect" determination.[116] The Institute for Fisheries Resources brought suit against the agencies, and the court noted that it was unclear why the Fish and Wildlife Service would want to dissuade an action agency from its conclusion that the proposed action "may affect" a species.[117] This is because, the court says, the issue could have been just as easily dismissed by a written concurrence that the proposed action was unlikely to affect any listed species.[118] This demonstrates that, like NEPA was easily circumvented in the case of the GloFish, expert consultation under the ESA may also simply be avoided.

### *3. A Closer Look at FDA's Environmental Assessment for Oxitec Mosquitoes*

Although the FDA transferred regulation of the Oxitec mosquito to the EPA in 2017, there is no need to speculate as to how it would have regulated the GE insects had it maintained jurisdiction; the agency got so far as to release its environmental assessment and finding of no significant impact.[119] This means that, like the GloFish and the AquAdvantage salmon, the Oxitec mosquito overcame the several environmental risks recited by scientists and ecologists, negating the need for an environmental impact statement, and it was ultimately approved for limited wild release in Florida.[120]

Scientists were understandably dissatisfied with the FDA's decision to issue a finding of no significant impact based on Oxitec's environmental assessment, a decision which only further demonstrates the flawed nature of biotechnology assessments under the NEPA requirements.[121] One problem with

113. 50 C.F.R. § 402.14 (2020).
114. Inst. for Fisheries Res. V. Burwell, 2016 WL 4529517, at *1 (N.D. Cal. 2016).
115. *Id.*
116. *Id.*
117. *Id.* at *3.
118. *Id.*
119. CTR. VETERINARY MED., ENVIRONMENTAL ASSESSMENT FOR INVESTIGATIONAL USE OF AEDES AEGYPTI OX513A (Aug. 5, 2016); CTR. VETERINARY MED., FINDING OF NO SIGNIFICANT IMPACT (Aug. 5, 2016).
120. *See supra* Part II (discussing the risks involved with wild release of GE mosquitoes in detail).
121. *See* Meghani & Kuzma, *supra* note 33, at S203 (discussing the problems with the FDA's assessment of the Oxitec mosquito).

the assessment is that the FDA's focus for approving the field trials was to test the safety of the genetic modification for the mosquitoes involved and the efficacy of the treatment; that is, there was no description in Oxitec's assessment collecting data on potential impacts on the local ecosystems.[122] Secondly, the FDA does not appear to take seriously the amount of uncertainty involved with the field trials of the GE insects in its evaluation.[123] For example, the FDA states in its FONSI that the "[r]isk of establishment or spread has been determined to be negligible" due to the short duration of the investigational trial and the determination that "any unanticipated adverse effects are unlikely to be widespread or persistent in the environment."[124] This conclusion seemingly ignores several variables noted by Oxitec in its environmental assessment, including the survival probabilities of GE mosquitoes and the possibility that tetracycline may be present in the environment.[125] In fact, Oxitec discloses that as much as forty percent of GE mosquitoes may survive more than two days and as many as fifteen to twenty days even in the absence of tetracycline, with that number increasing if tetracycline is present.[126] The FDA's finding likewise ignores the possibility of spread from the trial site despite Oxitec's EA also identifying studies demonstrating that female mosquitoes can fly over 200 meters and have been dispersed passively by ships, trains, or cars, suggesting probability of migration is more than negligible.[127]

A third problem with the FDA's environmental assessment process is that it allows a qualitative rather than quantitative report of findings. Rather than using concrete data to model the prevalence of GE mosquitoes in and around the trial site over time, the FDA accepts statements that risks are "highly unlikely," "minor," or "marginal."[128] This language, utilized in Oxitec's environmental assessment, is vague and generally uninformative. Consider, for instance, Oxitec's statement that "[t]he potential likelihood (of the OX513A mosquito) . . . establish[ing] in the environment has a medium confidence of uncertainty, because it would require detailed information on . . . temperature, humidity, larval competition, predation, breeding site, container, vegetation etc."[129] Although this statement does list the various sources of uncertainty in Oxitec's determination, it does not provide any information regarding how or to what extent each variable might affect the GE mosquito's establishment in the environment.[130] Additionally, there is no definition for how much uncertainty is covered by a "medium confidence of uncertainty."[131] These examples

122. *Id.*
123. *Id.* at S210.
124. *Id.* at S213; FDA, PRELIMINARY FINDING OF NO SIGNIFICANT IMPACT IN SUPPORT OF AN INVESTIGATIONAL FIELD TRIAL OF OX 513A *AEDES AEGYPTI* MOSQUITOES (2016).
125. Meghani & Kuzma, *supra* note 33, at S213.
126. *Id.*
127. *Id.* at S214.
128. *Id.*
129. *Id.* at S215; OXITEC, DRAFT ENVIRONMENTAL ASSESSMENT FOR INVESTIGATIONAL USE OF AEDES AEGYPTI OX513A 118 (2016).
130. OXITEC, DRAFT ENVIRONMENTAL ASSESSMENT FOR INVESTIGATIONAL USE OF AEDES AEGYPTI OX513A 118 (2016).
131. *Id.*

highlight a couple of the qualitative approach's notable issues: it lacks transparency and downplays the uncertainties involved with a proposal.[132] Consider, as another example, Oxitec's statement that "[i]t is extremely unlikely that OX513A will survive longer than their short lifespan."[133] Compare this with the quantitative assessment, mentioned previously, that forty percent of OX513A mosquitoes survive more than two days, with twenty percent surviving more than fifteen to twenty days.[134] Notice not only how much more informative the quantitative assessment is, but also how misleading the first, qualitative statement appears in light of this additional data. It is surely not obvious or certain that twenty to forty percent would fall under every person's definition of the term "extremely unlikely", thus rendering this term essentially useless.[135]

With these considerations in mind, it becomes apparent why scientists were wary and concerned with the FDA's decision to conduct only an environmental assessment rather than the more rigorous environmental impact statement—a document which would have taken into greater consideration the potential ecological impacts of the action in comparison to alternatives. It may have been a result of this flawed assessment that proponents on both sides welcomed the move of the GE mosquito case to the EPA.[136]

### *B. EPA Regulation of the Oxitec Mosquito*

In October 2017, and FDA announced it would transfer regulation of the Oxitec mosquito to the EPA, making this the first GE animal to fall under the regulatory jurisdiction of the EPA.[137] The EPA has regulatory authority over the genetically engineered mosquitoes under the Federal Insecticide, Fungicide, and Rodenticide Act.[138] Similar to their categorization under the FDCA, the logic for this new placement is not intuitive. The EPA classifies the GE mosquitoes as a pesticide product due to their function of reducing or eliminating insect species.[139] This classification is problematic, however, because the statute is written with chemical pesticides in mind and does not account for the type of management involved with living organisms. This is evident because, for example, the test to determine whether an environmental or human health risk outweighs the benefit of the product requires the EPA to take into account the level of pesticide residues in food products.[140]

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132. Meghani & Kuzma, *supra* note 33, at S214.

133. OXITEX, DRAFT ENVIRONMENTAL ASSESSMENT FOR INVESTIGATIONAL USE OF AEDES AEGYPTI OX 513A 119 (2016).

134. Meghani & Kuzma, *supra* note 33, at S213.

135. *Id*.

136. Nancy Klingener, *In GMO Mosquito Debate, Both Sides Favor Switching Federal Agencies*, WLRN (Oct. 5, 2017), https://www.wlrn.org/post/gmo-mosquito-debate-both-sides-favor-switching-federal-agencies.

137. FOOD & DRUG ADMIN., CLARIFICATION OF FDA AND EPA JURISDICTION OVER MOSQUITO RELATED PRODUCTS 5 (2017), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf.

138. 2017 UPDATE, *supra* note 19, at 10.

139. FOOD & DRUG ADMIN., CLARIFICATION OF FDA AND EPA JURISDICTION OVER MOSQUITO RELATED PRODUCTS 5 (2017), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf.

140. 2017 UPDATE, *supra* note 19, at 10.

The classification is further problematic when considering how it will apply to the future of biotechnology, especially gene drives. Research is emerging regarding the use of gene drives to eradicate disease-spreading rats.[141] Like the mosquitoes, this genetically engineered animal would act as a pesticide (or rodenticide) which should place it within the jurisdiction of the EPA under the current logic.[142] The problem is that mammals have different considerations than invertebrates—for example society may be more concerned about the humane treatment of mammals than invertebrate insects.[143] Under the regulations instilled by the EPA, consideration is not afforded to the humane treatment of the pesticide or the health of the pesticide.[144]

The big question, however, is whether the EPA is better equipped to handle the environmental concerns which come with these wild-release biotechnology products than the FDA?

### *1. EPA Ecological Risk Assessment*

As should be expected from an agency which purpose is to protect the environment, the EPA's approach to environmental assessment is the most thorough of the three agencies in the Coordinated Framework.[145] This is mainly due to its extensive guidelines and three step process for conducting human health and ecological risk assessments.[146]

The EPA begins its assessment with a step called "problem formation."[147] This phase is dedicated to defining endpoints—the human or environmental health values important to the decision.[148] For example, an endpoint from an ecological risk assessment of the EPA-regulated *Wolbachia* mosquito would be the efficacy of mosquito management.[149] Next, the EPA creates conceptual models, which are written descriptions and visual representations of predicted relationships between ecological entities and potential stressors.[150] This step is important because the models provide a unique visual of what is known and not

141. Caroline M. Leitschuch et al., *Developing Gene Drive Technologies to Eradicate Invasive Rodents from Islands*, 5 J. OF RESPONSIBLE INNOVATION 121, 124 (2018).

142. 2017 UPDATE, *supra* note 19, at 10.

143. *See Animal Welfare Act*, U.S. DEP'T AGRIC., http://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_program_information (last visited Nov. 29, 2018) (stating that the AWA does not apply to invertebrates).

144. *See* 2017 UPDATE, *supra* note 19, at 10 (conveying the test the EPA uses to determine the safety of a pesticide, asking whether it poses unreasonable risk to man or the environment and assessing human dietary risks associated with pesticide use).

145. *See* ENVTL. PROT. AGENCY, GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT 40 (May 14, 1998), https://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf (detailing the EPA's risk assessment process).

146. *About Risk Assessment*, ENVTL. PROT. AGENCY, https://www.epa.gov/risk/about-risk-assessment (last visited Feb. 25, 2020).

147. GENE DRIVES, *supra* note 8, at 116.

148. *Id.*

149. DAMAYANTI BUCHORI ET AL., RISK ASSESSMENT ON THE RELEASE OF WOLBACHIA-INFECTED AEDES AEGYPTI 30 (2017), http://www.eliminatedengue.com/library/publication/document/yogyakarta/risk_assessment_on_the_release_of_wolbachia-infected_aedes_aegypti.pdf.

150. ENVTL. PROT. AGENCY, GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT 40 (May 14, 1998), https://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf.

known about the problem and aids the agency to plan further research into the problem.[151]

With the information from the planning stage in hand, the risk managers and assessors of the EPA are ready to conduct an analysis.[152] The purpose of the analysis phase is to determine the various effects of stressors on ecological entities and the level of exposure to those stressors.[153] Finally, the information from the analysis is synthesized into an estimate of risk, in a stage called "risk characterization."[154] "Risk" is the chance of harmful effects to human health or ecological systems, taking into account the probability of an event occurring (exposure) and the negative impact of that event (effect).[155]

The EPA's ecological risk assessment differs from the NEPA environmental assessment processes used by the FDA and USDA in several regards.[156] Perhaps most importantly, the EPA ecological risk assessment guidance promotes a probabilistic, quantitative approach as opposed to the deterministic, qualitative approach typically used in NEPA mandated EAs.[157] As discussed above, qualitative environmental assessments, such as those utilized in the FDA regulatory process, can be problematic. First, risks reported in this way, on a categorical high, medium, or low scale, cannot be adequately validated without quantitative definitions of these categories.[158] Additionally, qualitative assessments fail to sufficiently characterize and quantify the uncertainty associated with the assessed technology.[159] In contrast, the EPA's approach would portray uncertainty and variability for each parameter using probability distributions.[160] A quantitative approach is better for environmental risk assessments because it not only provides better information for the agency itself to aid in its decision-making, but also provides better quality information to the public who may review this information and participate in the regulatory process.

### *2. Application of EPA Risk Assessment to Gene Drive Organisms*

Some scholars posit that the EPA's approach to risk assessment is mostly well suited for regulating upcoming gene drive technologies, or at least better so

151. *Id.* at 41.
152. GENE DRIVES, *supra* note 8, at 116.
153. *Id.*
154. *Id.*
155. Anthony J. Conner et al., *The Release of Genetically Modified Crops into the Environment*, 33 THE PLANT J. 19, 21 (2002); *see also About Risk Assessment*, ENVTL. PROT. AGENCY, https://www.epa.gov/risk/about-risk-assessment (last visited Feb. 25, 2019) (giving the EPA's definition of risk).
156. GENE DRIVES, *supra* note 8, at 116.
157. *See* ENVTL. PROT. AGENCY, RISK ASSESSMENT FORUM WHITE PAPER: PROBABILISTIC RISK ASSESSMENT METHODS AND CASE STUDIES (2014) (describing the guidelines for the EPA's quantitative approach to ecological risk assessments); *see also* Keith R. Hayes et al., *Meeting the Challenge of Quantitative Risk Assessment for Genetic Control Techniques: A Framework and Some Methods Applied to the Common Carp (Cyprinus carpio) in Australia*, 16 BIOLOGICAL INVASIONS, 1273 (2014) (comparing the probabilistic risk assessment approach to the deterministic approach more prevalent across regulating bodies).
158. Hayes et al., *supra* note 157, at 1276.
159. *Id.*
160. Meghani & Kuzma, *supra* note 28, at S215.

than the FDA's environmental assessment.[161] Two strengths of the ecological risk assessment are the ability to create cause and effect models and to quantify the probability of specific outcomes.[162] Gene drives are likely to involve multiple stressors and cumulative effects which will require detailed models to understand and plan a thorough analysis.[163] Merely listing the various stressors will not be sufficient, as would be done in the typical environmental assessment. Examples of models which could be useful for categorizing gene drive risks include invasive species models which show movement of invasive species through an ecosystem and various environmental interactions, or proposed plans for genetically modified organisms which take into account survival and reproduction of the organisms, interactions between the organism and the environment, and genetic transfer, among other considerations.[164]

This is not to say that ecological risk assessments are perfect for evaluating gene drive technologies. One limitation is that the EPA's risk assessments have focused on individual stressors affecting only a few receptors over relatively small areas.[165] Additionally, assessments do not sufficiently account for variation in intensity of stressors by location and over time.[166] Thirdly, the EPA has typically conducted ecological risk assessments for chemicals rather than organisms, and some worry that the process will not adequately cover the concerns that are unique to releasing live animals.[167]

### *C. The Case of the Diamondback Moth*

The EPA's regulatory authority over the Oxitec mosquito demonstrates that if a biotechnology product both classifies as a genetically engineered animal and functions as a pesticide it falls under the regulatory jurisdiction of the EPA. The framework becomes even more complicated when the product in question is a genetically engineered animal, which is used as a pesticide, and the pest it is designed to eliminate is a plant pest; in that situation, jurisdiction would fall to the USDA.[168] The USDA/APHIS is currently the only U.S. agency to review and approve of a wild-release genetically engineered insect: a GE variant of the plant pest, the diamondback moth.[169]

The GE diamondback moth was also developed by Oxitec, and, like its GE mosquito, the moth also controls insect populations with self-limiting genes.[170]

161. *See* GENE DRIVES, *supra* note 8, at 114 (discussing EPA ecological risk assessments and how they would apply to gene drives).

162. *Id.* at 128.

163. *Id.*

164. *Id.* at 202, 205.

165. *Id.* at 203.

166. *Id.*

167. *Id.*

168. 2017 UPDATE, *supra* note 19, at 23–24.

169. Kristen V. Brown, *America's First Free-Roaming Genetically Engineered Insects are Coming to New York*, GIZMODO (July 7, 2017), https://gizmodo.com/the-us-just-greenlit-the-release-of-genetically-modifie-1796725343.

170. *Diamondback Moth Project at Cornell University FAQ*, CORNELL U. C. AGRIC. & LIFE SCI., https://shelton.entomology.cornell.edu/diamondbackmoth/diamondback-moth-project-at-cornell-university-faq/ (last updated Jan. 29, 2020).

In March 2016, Cornell University submitted an application to APHIS for permission for open release of its genetically engineered moths in New York, after already being approved in 2014 for caged releases of the insects.[171] The next year, in April 2017, APHIS released its EA, initiating the public comment period.[172] A month later, public comments closed with over 670 comments; compare that to the 2,600 comments the FDA received regarding the Oxitec mosquito in only three days.[173] Shortly after, APHIS released its finding of no significant impact for release of the GE diamondback moths.[174]

As its function is essentially the same as the GE mosquito, the GE moth carries all the same environmental risks that upset Florida citizens, yet the moth was approved relatively quickly by the USDA with little opposition. In fact, as with the AquAdvantage salmon and the Oxitec mosquito, the USDA conducted its environmental assessment and released a finding of no significant impact, again without completing any environmental impact statement.[175] However, unlike the salmon or the mosquito, critique of the USDA's decision is not prevalent.

The Northeast Organic Farming Association of New York spoke against the decision to forgo an environmental impact statement.[176] The organization's policy advisor stated that any release of a novel organism into the environment should be a significant issue and was skeptical about the USDA/APHIS's claim that the insects would only be released in a ten-acre area.[177]

The environmental assessment itself is interesting in that its focus is clearly on how the biotechnology affects or could affect agricultural practices.[178] For example, under a section for effects on wildlife, the assessment states the proposed "release of GE DBMs are not anticipated to change common agricultural activities related to preparing and maintaining agricultural fields that are currently occurring" and horizontal gene transfer to predators is also unlikely.[179] Like the FDA had a narrowed focus on the health of the GE animal and human health, the USDA has tailored its environmental assessment to focus on the effects of the GE insects on agricultural crops.[180]

171. U.S. DEP'T AGRIC., NATIONAL ENVIRONMENTAL POLICY ACT DECISION: FINDING OF NO SIGNIFICANT IMPACT FOR PERMIT TO FIELD RELEASE GENETICALLY ENGINEERED DIAMONDBACK MOTHS 1–2 (July 6, 2017), https://www.aphis.usda.gov/brs/aphisdocs/16_076101r_fonsi.pdf.

172. *Id.* at 4.

173. *Id.*; Neuhaus & Caplan, *supra* note 54.

174. U.S. DEP'T AGRIC., NATIONAL ENVIRONMENTAL POLICY ACT DECISION: FINDING OF NO SIGNIFICANT IMPACT FOR PERMIT TO FIELD RELEASE GENETICALLY ENGINEERED DIAMONDBACK MOTHS (July 6, 2017), https://www.aphis.usda.gov/brs/aphisdocs/16_076101r_fonsi.pdf.

175. *Id*.

176. Tiffany Stecker, *Genetically Engineered Moths Spark Debate over Biotech Bugs*, BLOOMBERG NEWS (Apr. 18, 2017), https://www.bna.com/geneticallyengineered-moths-spark-n57982086838/.

177. *Id.*

178. *See* U.S. DEP'T AGRIC., FINAL EA FOR PERMIT TO RELEASE GE DIAMONDBACK MOTH (June 2017), https://www.aphis.usda.gov/brs/aphisdocs/16_076101r_fea.pdf (describing the environmental assessment conducted for the field release of diamondback moths).

179. *Id*. at 36.

180. *See id.* (demonstrating that the USDA's focus throughout its environmental assessment of the diamondback moths is how it affects agriculture as compared to the alternative of doing nothing).

This may explain how the moth passed through the USDA's inspection process so quickly compared to how the similar mosquito fared with the FDA, and, more recently, the EPA. Cornell University states that the diamondback moth is the worst plant pest worldwide, costing farmers four to five billion dollars annually.[181] Noting that the USDA's purpose is to protect and promote agriculture, it only makes sense the agency would want to push through controls for this pest. Furthermore, its environmental assessment states that the GE moth actually benefits the environment by lessening the need for the harmful pesticides currently used in agriculture to kill these pests.[182]

## IV. RECOMMENDATION

The problem of how to regulate biotechnology isn't new, and many scholars are well aware that the current regulatory framework within the U.S. is convoluted, inconsistent, and fails to adequately address the problems at hand.[183] The Coordinated Framework was explicitly meant to be adapted as technology changed, and, although there has been some modification, nothing significant has changed since its adoption in 1986.[184] The most recent update in 2017 only acts as a guide to aid innovators through the approval process by merely detailing which agency is responsible for various types of biotechnology and providing hypotheticals to illustrate how the categorization works in practice.[185] In fact, the update itself states that the existing framework already adequately covered human health and environmental concerns, and only lacked clarification, transparency, and predictability for inventors.[186]

Several scholars have claimed the problem with the Coordinated Framework is that it is confusing to navigate, and inventors cannot be certain which agency will regulate their technology or how to apply.[187] However, as demonstrated in the Analysis above, this is not the greatest danger associated with the current regulatory system. Each agency works for its own agenda, each has its own method of evaluating new technologies, and each conduct different types of assessments to determine environmental impact. As demonstrated in the Analysis of this Note, the inconsistencies in the environmental assessments are particularly problematic, especially where products with identical methods of action and substantially similar risks are treated differently merely due to differences in how they are applied.

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181. *Diamondback Moth Project at Cornell University FAQ*, CORNELL U. C. AGRIC. & LIFE SCI., https://shelton.entomology.cornell.edu/diamondbackmoth/diamondback-moth-project-at-cornell-university-faq (last updated Jan. 25, 2019).

182. U.S. DEP'T AGRIC., FINAL EA FOR PERMIT TO RELEASE GE DIAMONDBACK MOTH (June 2017), https://www.aphis.usda.gov/brs/aphisdocs/16_076101r_fea.pdf.

183. *See, e.g.*, Alison Peck, *Re-framing Biotechnology Regulation*, 72 FOOD & DRUG L. J. 314 (2017) (discussing the need to rework the Coordinated Framework).

184. *Id.*

185. 2017 UPDATE, *supra* note 19.

186. *Id.*

187. *See, e.g.*, 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, 311–12 (2016).

The future of genetically engineered animals promises to be vast with a great variety of different applications. One example, as mentioned in the Analysis, is the development of GE rats to lower populations of disease-carrying rodents.[188] Other ideas for gene drive technology include eradicating populations of invasive species, modifying disease vectors to hinder disease transmission, or altering pesticide-resistant pests to render them susceptible.[189] These applications will present a new range of never-before-seen risks that will require careful consideration and evaluation by regulatory agencies, and under the current regulatory framework, many of these GE animals are likely to fall under the jurisdiction of the FDA as new animal drugs.[190] Given the weaknesses of the FDA's previous GE animal assessments, if biotechnology continues on its current trajectory, it will be necessary for the FDA to conduct more thorough environmental assessments.

This section begins by discussing potential legislative and regulatory solutions to ensure consistency and promote environmental health and safety in the age of biotechnology, including the creation of entirely new legislation specifically directed at biotechnology products. Alternatively, the CEQ could promulgate new regulations to provide equal environmental protection across agencies. Next, this section addresses how courts could ensure stricter agency compliance with NEPA requirements. Finally, this Note addresses how the agencies themselves could adopt better guidelines for assessing the risks associated with future biotechnology.

### *A. New Biotechnology-Specific Legislation*

New legislation could be written to replace the Coordinated Framework in order to ensure consistency and thoroughness of environmental assessments for biotechnology products. This could be achieved either by designating a new agency dedicated to the regulation of biotechnology or by simply specifying which existing agency should handle this area of innovation.[191]

Creating an entirely new agency would be a major endeavor and is unlikely to be a viable solution to the problem.[192] However, another potential solution could be to write new biotechnology-specific legislation which directs all genetically engineered animals to the EPA. This may be an intuitive placement for the animals; the National Research Council has previously stated that the greatest concerns associated with animal biotechnology are environmental impacts.[193] This designation would resolve confusion over which agency regulates the animals, provide consistency by regulating all animals under the

188. Megan Scudellari, *Self-Destructing Mosquitoes and Sterilized Rodents: The Promise of Gene Drives*, 571 Nature 160, 160 (2019).

189. JACQUE KEELE, BUREAU OF RECLAMATION, USING GENETIC MANIPULATION TO CONTROL INVASIVE SPECIES (2017); Kevin M. Esvelt et al., *Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations*, ELIFE, https://elifesciences.org/articles/03401.pdf.

190. *New Animal Drug Applications*, *supra* note 70.

191. Carlene Dooley, *Regulatory Silos: Assessing the United States' Regulation of Biotechnology in the Age of Gene Drives*, 30 GEO. ENVTL. L. REV. 547, 562 (2018).

192. *Id*.

193. NATIONAL RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 9 (2002).

same agency, and circumvent the problematic environmental assessments conducted by the FDA and USDA. This proposal does have some problems, however. First, directing all GE animals to the EPA could require the agency to work outside of its area of expertise.[194] An example would be the AquAdvantage salmon; although the EPA may be best situated to perform a thorough ecological risk assessment, it does not have as much experience regulating products for human consumption beyond evaluating safe amounts of pesticide residue.[195] In such cases, the FDA may actually be the best regulatory body to evaluate and regulate the product, provided the agency conducts more thorough assessments to ensure environmental safety. A second problem with this proposal is that the EPA may become overwhelmed with the influx of GE animals and be forced to conduct less thorough risk assessments as a result.

### *B. Reworking NEPA: Legislative Solutions*

Other than changing the Coordinated Framework itself, consistency of environmental assessments across agencies could be achieved by amending the National Environmental Policy Act to provide more decisive and encompassing requirements for environmental reviews. As it is currently written, NEPA provides little direction for agencies.[196] In what is probably its most relevant section, NEPA only says that all agencies of the federal government shall include in every recommendation or report on major federal actions significantly affecting the quality of the human environment, a detailed statement on the environmental impact of the proposed action.[197] The broad language of this provision allows significant agency discretion to determine when an environmental impact statement is necessary. For example, the FDA's interpretation is than an EIS is only required when there is an "unacceptable risk."[198] This has allowed the FDA to avoid completing environmental impact statements for either the AquAdvantage salmon or the Oxitec mosquito, even though scientists voiced concerns that significant environmental impact was certainly possible.[199]

Congress could address this inconsistency by rewriting this section of NEPA in more decisive language. An example of new language could be: "an environmental impact statement shall be compiled when an agency action is found to have any impact on the environment." This change cuts the "significant

194. *See* Gregory M. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in The Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2239 (2004) (discussing the inexperience of the Coordinated Framework agencies at regulating certain genetically modified organisms).

195. *Setting Tolerances for Pesticide Residues in Food*, ENVTL. PROTECTION AGENCY, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety (last visited Mar. 12, 2020).

196. 42 U.S.C. § 4332(c) (2018).

197. *Id*.

198. *Environmental Impact Evaluation Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm314401.htm (last visited Jan. 31, 2019).

199. *See, e.g.*, Elizabeth M. P. Madin, *Genetically Engineered Salmon Pose Environmental Risks that Must be Considered*, 61 BIOSCIENCE 6, 6 (2011) (discussing briefly some of the serious ecological risks associated with genetically modified salmon). *See also*, Meghani & Kuzma, *supra* note 28 (highlighting some environmental risks of GE mosquitoes).

risk" language, which agencies tend to read as a high threshold, allowing them to prepare the environmental impact statement only in the most extreme cases.

### *C. Reworking NEPA: Administrative Solutions*

Another method to ensure consistent, higher quality risk assessments across agencies would be through administrative rulemaking. The Council on Environmental Quality (CEQ) is the agency responsible for implementing NEPA.[200] Through its various regulations it has played a significant role in defining requirements for environmental impact statements, and it created the environmental assessment as a means for agencies to determine whether an action is likely to have a "significant" impact so as to require preparation of an EIS.[201] However, as demonstrated in the Analysis above, the large amount of discretion afforded to agencies to decide whether to complete an EIS results in many decisions to forgo the more thorough assessment, even in instances where an environmental assessment suggests significant environmental impact is possible. For that reason, a potential change to the NEPA regulations would be to eliminate the environmental assessment/environmental impact statement distinction entirely and, instead, adopt the EPA's ecological risk assessment.

As discussed above, the EPA risk assessment is much more thorough than the current NEPA environmental assessment requirements and may be a better fit for the future of gene drive and other biotechnologies that may fall under agencies other than the EPA. The CEQ could promulgate rules making the EPA's three stage risk assessment procedure the standard for all NEPA environmental assessments. This decision would ensure the FDA, USDA, and EPA all review environmental risks equally and with appropriate thoroughness and transparency.

### *D. Judicial Solutions*

Though a legislative change may be an ideal solution to ensure improved environmental assessments for biotechnology, the legislative process is undoubtedly long and arduous. Gene drives may reach regulators in as little as three years, and there needs to be some assurance in place that these technologies will be assessed for environmental risks thoroughly and appropriately.[202] One alternative method for improving assessments across agencies could be enforcement of NEPA requirements in the court system.

Although it is well established that NEPA does not require agencies to conduct any particular risk assessment,[203] some courts, particularly in the Ninth

200. 42 U.S.C. § 4342 (2018).

201. Albert C. Lin, *Revamping our Approach to Emerging Technologies*, 76 BROOK. L. REV.1309, 1348 (2011); Jamison E. Colburn, *Administering the National Environmental Policy Act*, 45 ENVT'L. L. REP. NEWS & ANALYSIS 10287, 10316 (2015).

202. Megan Scudellari, *Self-Destructing Mosquitoes and Sterilized Rodents: The Promise of Gene Drives*, 571 NATURE 160, 160 (2019).

203. Jamison E. Colburn, *The Risk in Discretion: Substantive NEPA's Significance*, 41 COLUM. J. L. 1, 37 (2016).

Circuit, have found that agencies' decisions not to prepare any EIS violated NEPA.[204] In the ninth circuit, an agency must prepare an EIS if the environmental effects of a proposed agency action are highly uncertain or if the federal action is controversial.[205]

Consider how this approach could influence, for example, the FDA's approval of the AquAdvantage salmon; upon publication of its draft EA, the FDA received thousands of comments, as well as letters from public interest groups, the Fish and Wildlife Service, and the U.S. Senate all expressing concern that the assessment inadequately evaluated the risk associated with the GE technology.[206] Under Ninth Circuit precedent, this would likely be enough evidence to demonstrate the controversial nature of the federal action, and, thus, the FDA would be required to prepare a full EIS for the GE fish.[207]

If all courts interpreted NEPA in this way, more environmentally risky agency actions would be evaluated under the more comprehensive EISs rather than an EA only. This is not, however, a perfect solution for the regulation of gene drives and other biotechnology. First, this does not solve the GloFish problem; if an agency takes no action at all, its decision simply is not governed by NEPA and no environmental assessment is required.[208] Second, the judicial process is not quick. Petitioners must first exhaust all administrative remedies before even reaching the district court.[209] This could be particularly problematic if the FDA is, in the meantime, allowed to proceed with its approval.[210] Considering how rapidly a gene drive could spread through a population, the delays involved with administrative petitions and adjudication could be

204. *See, e.g.*, Ocean Advocates v. U.S. Army Corps of Eng'rs, 402 F.3d 846, 865 (9th Cir. 2005) (explaining that the Army Corps of Engineers violated NEPA by failing to provide a convincing statement of reasons why its action would have an insignificant effect on the environment); *see also*, Nat'l Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722 (9th Cir. 2001) (demonstrating how a court evaluates if an agency's decision not to complete an EIS as required by NEPA is arbitrary and capricious).

205. Nat'l Parks & Conservation Ass'n, 241 F.3d at 731.

206. *AquAdvantage Salmon—Response to Public Comments on the Environmental Assessment*, U.S. FOOD & DRUG ADMIN. (Sept. 14, 2018), https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-response-public-comments-environmental-assessment; EarthJustice & Center for Food Safety, Comment on Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon (Apr. 26, 2013), http://www.centerforfoodsafety.org/files/42613-final-cfs-and-earthjustice-comment_49553.pdf; Letter from Fish and Wildlife Service, U.S. DEPT. OF THE INTERIOR, to the Veterinary Medicine Advisory Committee, U.S. Food & Drug Admin. (Sept. 30, 2010) (on file at https://www.regulations.gov/document?D=FDA-2011-P-0448-0001); Letter from U.S. Senate, to Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, U.S. Food & Drug Admin. (Sept. 28, 2010) (on file at https://www.regulations.gov/document?D=FDA-2011-P-0448-0001).

207. *See* Nat'l Parks & Conservation Ass'n, 241 F.3d at 736 (determining that 85% of 450 comments was more than enough negative feedback on the action to constitute an "outpouring of public protest").

208. Int'l Ctr. for Tech. Assessment, 421 F.Supp.2d, at 8.

209. Ctr. For Food Safety v. Hamburg, 142 F.Supp.3d 898, 904 (N.D. Cal. 2015) (quoting Save Strawberry Canyon v. U.S. Dept. of Energy, 80 F.Supp.2d 737, 745 (N.D. Cal. 2011)), *vacated*, 696 Fed. Appx. 302 (9th Cir. 2017).

210. *See* Ctr. for Food Safety, 142 F.Supp.3d at 906 (claiming that the APA's "inoperative" exception to the exhaustion requirement only applies to optional administrative remedies and not to the FDA's mandatory citizen petition requirement), *vacated*, 696 Fed. Appx. 302 (9th Cir. 2017). *But see* Darby v. Cisneros, 509 U.S. 137 (1993) (stating that "an appeal to 'superior agency authority' is a prerequisite to judicial review . . . when the agency requires an appeal 'by rule and provides that the [administrative] action is . . . inoperative' pending that review" (quoting 5 U.S.C. § 704)).

seriously detrimental.[211] Lastly, judicial enforcement of NEPA requirements may only compel agencies to prepare an EIS, but does not dictate how agencies assess risks.[212]

### *E. Agency Guidance Documents*

The recommendations described above assume that agencies involved in the regulation of biotechnology will require some outside influence compelling them to conduct adequate assessments of the environmental risks posed by new biotechnologies, whether that be Congress or the judiciary. A different approach would be for the regulating agencies to take on the responsibility of evaluating these risks themselves through the formulation of risk assessment guidelines.

For some of the previously identified issues, administrative guidance may actually be the best solution. One particular problem which has not been addressed in this section is the FDA's GloFish review: scientists and environmental groups claimed that the GloFish had the potential to impact ecological systems, but the FDA was able to choose not to conduct even the least stringent environmental assessment on the basis that a decision not to regulate is not a "federal action" under NEPA.[213] Though this issue could possibly be addressed by Congress by amending NEPA to apply also to agency inactions, this would result in overbroad and burdensome requirements.[214] CEQ rulemaking is also unlikely to be much help; even if the agency were to promulgate a rule providing more guidance as to when an environmental assessment is required, agency inaction would not be within the scope of NEPA for it to apply.[215]

However, the CEQ could write guidelines explicitly directed at the FDA's process for reviewing biotechnology, instructing the agency to conduct, at a minimum, an environmental assessment for all biotechnology or all genetically engineered animals which it reviews, regardless of whether it ultimately chooses to regulate these technologies.[216] Such guidelines would not be as binding on the agency as a rule, but there is evidence that some courts take CEQ guidance documents into consideration when evaluating agencies' NEPA procedures.[217] This would be more consistent with the policy of NEPA, that federal agencies

211. Tina Hesman Saey, *In Lab Tests, This Gene Drive Wiped Out a Population of Mosquitoes*, SCIENCENEWS (Sept. 24, 2018), https://www.sciencenews.org/article/lab-tests-gene-drive-wiped-out-population-mosquitoes (discussing a scientific study in which a population of 450 wild mosquitoes was wiped out within seven generations by 150 gene drive mosquitoes).

212. Colburn, *supra* note 203.

213. *Statement Regarding Glofish*, U.S. FOOD & DRUG ADMIN. (Dec. 9, 2003), https://wayback.archive-it.org/7993/20170404230909/https:/www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm.

214. Int'l Ctr. for Tech. Assessment, 421 F. Supp. 2d at 8.

215. *Id.*

216. *Id.*

217. Jamison E. Colburn, *Administering the National Environmental Policy Act*, 45 ENVTL. L. REP. NEWS & ANALYSIS 10287, 10309 (2015).

consider the environmental consequences of their decisions, and that the public remains informed of these processes.[218]

The FDA, USDA, and EPA could also create their own guidance documents to ensure more consistent and thorough risk assessments across the Coordinated Framework agencies. FDA and USDA could adopt the EPA's ecological risk assessment guidelines for evaluating genetically engineered animals intended for wild release. As discussed in the Analysis, the EPA's ecological risk assessment guidelines, though not perfect, are the most comprehensive of the three Coordinated Framework agencies and the best suited for evaluating gene drive organisms. The National Academies of Sciences, Medicine, and Engineering has definitively concluded that the EA and EIS prepared by the FDA and USDA, though in compliance with the minimum requirements of NEPA, are ultimately insufficient to address the concerns raised by engineered gene drive organisms.[219] Therefore, at a minimum, the FDA and USDA should adopt a similar probabilistic, quantitative approach to risk assessment for biotechnology. This approach would ensure more consistent and thorough assessments of GE animals across the three agencies without requiring any major legislative overhauls of the current system.

## V. CONCLUSION

Biotechnology is a rapidly expanding field with an unbelievable amount of potential for the future. Genetically engineered animals could be incredibly beneficial in a number of areas including human health, environmental management, and agriculture. However, this new technology, especially that of gene drive organisms, comes with several serious environmental risks; careful and consistent regulation from the FDA, EPA, and USDA will be necessary to promote the expansion of the biotechnology field while preventing the environmental pitfalls which could occur. Because GE animals are generally categorized as new animal drugs under the FDCA, many of these new developments will fall under the jurisdiction of the FDA, which is problematic considering the agency's past short-comings and inadequate environmental assessments. Ideally, to address this problem and ensure all three of the agencies are applying adequate assessments for the ecological risks involved, Congress should create new legislation specifically directed at biotechnology, or, alternatively, the CEQ should promulgate new rules with the goal of promoting consistent ecological risk assessments across all agencies tasked with reviewing new biotechnologies. In the meantime, these issues should be addressed by the agencies themselves by adopting guidelines for more thorough, probabilistic ecological risk assessments.

218. 42 U.S.C. § 4331 (2018); Flatt, *supra* note 75.
219. PREPARING FOR FUTURE PRODUCTS, *supra* note 44, at 152.