Regulatory Silos: Assessing the United States' Regulation of Biotechnology in the Age of Gene Drives

CARLENE DOOLEY*

ABSTRACT

The advent of CRISPR gene editing technology has moved the use of gene drives, genetically engineering an organism to push a preferred gene through a target population, from the hypothetical to experimental stages. Gene drives have the potential for profound advances in human and environmental health, but also the risk of profound harms, if not properly researched and, if eventually appropriate, implemented. These gene drives test the regulatory abilities of the United States' current approach to regulating biotechnology, namely the Coordinated Framework for the Regulation of Biotechnology. This Note seeks to explore the question of how to build a regulatory framework in an area of scientific innovation that is flexible enough to respond to changes and ensures the necessary level of regulation without stifling innovation. It argues that the regulatory concerns and necessary regulatory protections for gene drives show that the United States' current method of regulation is not flexible enough to respond effectively to gene drive research. Focusing on the responsible environmental management of gene drives, this Note uses current research and potential implementations of gene drives to investigate how the United States can retool its current regulatory framework for regulating the development and introduction of genetically engineered products. To be effective in the face of technological developments and scientific uncertainty the United States regulatory system for biotechnology must be flexible, responsive to scientific discovery, transparent, and risk management focused. This Note argues that these goals can be met without new legislative action by creating a central coordinating committee within the Coordinated Framework that can quickly respond to regulatory concerns of new technology, ensure regulatory lines of authority are made clear and resolved, and highlight to lawmakers if there are unregulated products of concern.

* Georgetown Law, J.D. 2018; University of Minnesota, B.A and B.S. 2013. The author is immensely thankful to Professor Edith Brown Weiss and Professor Hope Babcock for their guidance and support.

TABLE OF CONTENTS

INTRODUCTION

Imagine a world where malaria, yellow fever, and Lyme disease are eradicated because their main carrier, for example mosquitoes, can no longer spread the disease. A world where invasive species can be eliminated from their non-native habitats in a dozen or so generations, and weeds are genetically engineered to be less resilient to pesticides. A world where humans can design the ecosystems around them by specifically editing the genes of wild organisms. How should the present generation determine when and where to release such monumental changes?

Genetic modification of organisms has sparked debate since its inception. In fact, in the 1970s, scientists themselves initially issued a voluntary moratorium on synthetic biology research, which is research into designing new, or redesigning existing, biological systems.[1] Once again, a powerful new gene editing tool, clustered regularly-interspaced short palindromic repeats ("CRISPR"), has come onto the scene, and expanded opportunities for genetic engineering. Along with opportunities, CRISPR has brought along debates about what should and should not be done through genetic engineering. One use of CRISPR/cas9 has been to pair the technology with gene drives.[2] A gene drive spreads a desired trait

1. *See* Paul Berg, *Meetings that Changed the World: Asilomar 1975: DNA Modification Secured*, 455 NATURE 290 (2008) (Experts agreed to continue research on recombinant DNA under strict guidelines at the International Congress on Recombinant DNA in 1975).

2. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 3 (2016) [hereinafter NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES].

throughout a wild population.[3] This is particularly revolutionary as it would allow the genetic modification of wild organism populations.[4]

However, the strength of this technology necessitates careful experimentation, community involvement, and risk analysis to determine if, where, and when a gene drive organism should be released. This investigation will need to be done on a case-by-case basis in order to accurately assess the impact of each different drive.[5]

The United States currently regulates biotechnology products through a Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework") which is a mechanism to increase cooperation and coordination between three agencies, the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the Department of Agriculture ("USDA").[6] This framework is a formulation of relationships between the relevant agencies and does not provide a central coordinating system for biotechnology regulation. Biotechnology products are divided into regulatory silos based on their ability to fit into existing statutes.[7] The potential release of gene drive organisms indicates that new technologies have the ability to push the bounds of this coordinated system and may not easily fit into one of the existing regulatory silos.

This Note argues that we should reconsider the policy of quickly dividing products of biotechnology based on use into different regulatory agencies in favor of a flexible and adaptive regulatory sharing program based on comprehensive, case-by-case analysis of genetic engineering research and products. A suggested mechanism for developing this regulatory sharing program is to create a tiered regulatory approach. This would involve a central coordinating committee that can flexibly adapt to new advances in scientific technology and community concerns. This committee could conduct a preliminary review of new technologies and recommend appropriate regulatory procedures for biotechnology products.

Section I of this Note lays out the technological background of gene drives. Section II identifies the regulatory issues presented by gene drives and key features of an appropriate regulatory regime. Section III diagrams the current regulatory system for biotechnology and identifies failures in this system when it comes to regulating gene drives. Finally, Section IV argues why a coordinating committee can adequately create the necessary flexibility for biotechnology regulation.

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3. *Id.* at 1–3.

4. *Id.*

5. *Id.* at 5–6 (listing some of the many factors that weigh in the cost-benefit analysis of gene modification).

6. *See*, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302 (Jun. 26, 1986) [hereinafter Coordinated Framework] (describing each federal agency's role in the regulation of biotechnology).

7. *Id.*

I. TECHNOLOGY BACKGROUND

The term gene drive generally refers to systems that create a preferential inheritance for a genetic trait when passed through sexual reproduction.[8] In a traditional Mendelian inheritance system, genes have a fifty-percent chance of being passed on in sexual reproduction, however, a gene drive involves a trait that will be passed on to greater than fifty-percent of offspring.[9] Gene drives occur in nature, and scientists have discussed the hypothetical use of gene drives by humans to "push" a desired genetic trait though a population for more than fifty years.[10] However, the recent advent of CRISPR/cas9 has moved the use of gene drives for targeted population changes from the hypothetical to the possible.[11]

The CRISPR/cas9 gene editing system is a revolutionary genetic engineering tool. CRISPR/cas9 allows scientists to make precise cuts to existing deoxyribonucleic acid ("DNA") sequences, which enables them to then remove or replace those sequences.[12] CRISPRs are ribonucleic acid ("RNA")-mediated defense systems used by bacteria that when paired with guide proteins, such as the cas9 protein, can precisely cut a DNA segment.[13] Researchers have shown that these systems can be engineered to make precise cuts in an organism's DNA.[14] CRISPR is also a simple and efficient tool compared to prior sequence-specific gene editing tools.[15]

Researchers may be able to use CRISPR/Cas9 to develop gene drives which spread a desired gene through nearly one hundred-percent of a target population.[16] Typically, when an organism which humans have genetically engineered to carry a specific gene drive, e.g. a "gene drive organism", and a wild organism reproduce, only one chromosome of the offspring carries the designed mutation. However, gene drives allow this mutation to copy itself into the partner chromosome so that both chromosomes carry the mutation and nearly all offspring will inherit the mutation.[17]

Possible uses of gene drives include: targeting disease vectors, eradicating invasive species, and aiding agricultural production. Proposed applications

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8. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 1–3.

9. Press Release, Wyss Institute, Harvard, FAQs: Gene drives, 1, https://wyss.harvard.edu/staticfiles/newsroom/pressreleases/Gene%20drives%20FAQ%20FINAL.pdf (last visited April 21, 2018).

10. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 1–3.

11. Elizabeth Pennisi, *U.S. Academies Gives Cautious Go-ahead to Gene Drive*, SCI., 2 (Jun. 8, 2016), http://www.sciencemag.org/news/2016/06/us-academies-give-cautious-go-head-gene-drive.

12. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 12.

13. Martin Jinek et al., *A Programmable Dual-RNA – Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. 816, 816 (2012).

14. *Id.*

15. Maximilian Haeussler & Jean-Paul Concordet, *Genome Editing with CRISPR-cas9: Can It Get Any Better?*, 43 J. OF GENETICS AND GENOMICS 239, 239–50 (2016).

16. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 2.

17. Heidi Ledford, *CRISPR, The Disruptor*, 522 NATURE 20 (2015), http://www.nature.com/news/crispr-the-disruptor-1.17673.

include: eliminating the ability of a mosquito population to transmit malaria or suppress the mosquito population,[18] eliminating invasive species by spreading a genetic trait that will eradicate them,[19] and lowering pesticide and herbicide resistance in wild weeds.[20] These are just some potential uses of gene drives and the list will inevitably continue to grow. This wide range of proposed uses for gene drives shows both the vast potential benefits this technology holds, and how difficult it is to regulate gene drives based solely on their end use.

Researchers are currently conducting lab experiments with gene drives, but field release has not occurred.[21] For example, Kevin Esvelt has researched the possibility of engineering white-footed mice to be immune to Lyme disease and releasing them on Nantucket Island, with the goal of decreasing the high rates of human contraction of Lyme disease in the area.[22] There are limits to what gene drives can do; namely, they cannot affect species that reproduce only asexually, and gene drives "will typically take dozens of generations to affect a substantial portion of a target population."[23] Therefore, gene drives are most applicable in organisms that sexually reproduce and have short generation times.

With these high possible benefits comes significant risks and uncertainties. Unlike many other genetically engineered organisms, where risk mitigation has been managed by containment and the inability to reproduce, a gene drive seeks to actively transform the distribution of a wild species.[24] This raises serious questions about the impact of releasing gene drive organisms into a population. In terms of research on gene drives, there are concerns about the state of laboratory security and accidental releases.[25] When it comes to the potential release of a gene drive organism, there are major concerns as to the effects the organism will have on the ecosystem in which it is released,[26] and the possibility of a genetically engineered drive jumping a species barrier.[27] Another concern is designing a regulatory system to ensure that communities are involved in the decision of

18. Antonio Regalado, *The Extinction Invention*, MIT TECH. REV. (2016), https://www.technologyreview.com/s/601213/the-extinction-invention/; Andrew Hammond et al., *A CRISPR-Cas9 Gene Drive System Targeting Female Reproduction in the Malaria Mosquito Vector Anopheles Gambiae*, 34 NATURE BIOTECHNOLOGY 78, 78–81 (2015), http://www.nature.com/nbt/journal/v34/n1/full/nbt.3439.

19. Jason G. Goldman, *Harnessing the Power of Gene Drives to Save Wildlife*, SCI. AM. (Sept. 14, 2016), https://www.scientificamerican.com/article/harnessing-the-power-of-gene-drives-to-save-wildlife/.

20. Kenneth A. Oye et al., *Regulating Gene Drives*, 345 SCI. 626, 626 (2014).

21. Michael Specter, *Rewriting the Code of Life*, THE NEW YORKER (Jan. 2, 2017), http://www.newyorker.com/magazine/2017/01/02/rewriting-the-code-of-life.

22. *Id*.

23. Oye et al., *supra* note 20, at 626.

24. Jackson Champer et al., *Cheating Evolution: Engineering Gene Drives to Manipulate the Fate of Wild Populations*, 17 NATURE REVIEWS GENETICS 146 (2016).

25. *See* Ewen Callaway, *'Gene Drive' Moratorium Shot Down at UN Biodiversity Meeting*, NATURE NEWS (Dec. 21, 2016), http://www.nature.com/news/gene-drive-moratorium-shot-down-at-un-biodiversity-meeting-1.21216.

26. Regalado, *supra* note 18.

27. *Id*.

determining if a gene drive organism, which has the potential to alter their environment significantly, should be released.[28] Other issues include: who should have authority to authorize a release of an organism that will likely have transboundary effects across jurisdictions, and the effects of gene drive organisms from an intergenerational equity point of view.[29] There are also concerns about biosecurity, for example the possible use of gene drives to spread a harmful disease.[30]

At their heart, these concerns are based on a need for clear knowledge about the risks of given gene drives, and transparency in decision making about when and if they should be used.[31] These risks have led for some to call for a moratorium against gene drive research.[32] Kevin Esvelt, the first to propose using CRISPR gene drive organisms to alter wild populations, has called for "open discussion and safeguards" in gene drive research, and emphasized the risk of field trials.[33] He is currently working on "daisy drives" which are drives designed to gradually vanish over generations, these drives may limit the risk of a gene drive spreading outside the targeted area and allow communities to make decisions about their environments.[34]

The rapid development of gene drives and possibility of their release brings up key questions about the adequacy of the United States' current system of biotechnology regulation. Namely, is the current regulatory framework flexible enough to respond to revolutionary innovations and not stifle scientific innovation, while at the same time appropriately addressing and managing the potential risks from these new technologies? In order to evaluate the current U.S. regulatory system, it is necessary to look at what proper regulation of gene drives may look like.

II. REGULATORY ISSUES AND GOALS REGARDING GENE DRIVES

In analyzing the ability of the Coordinated Framework to regulate gene drive organisms, it is useful to look at recommendations for what regulatory elements are needed for gene drives. Due to the complexity of regulating gene drives, and uncertainties in how regulation of gene drives will work, there have also been calls by the National Academies of the Sciences ("NAS") and other experts in the

28. J. Craig Venter Institute, *Policy and Regulatory Issues for Gene Drives in Insects: Workshop Report* 6 (Aug. 2016), https://s3.amazonaws.com/org.jcvi.s3-www-drupal/s3fs-public/assets/projects/policy-and-regulatory-issues-for-gene-drives-in-insects/report-complete.pdf.

29. Jennifer Kuzma & Lindsey Rawls, *Engineering the Wild: Gene Drives and Intergenerational Equity*, 56 JURIMETRICS J. 279, 285 (2016).

30. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 8.

31. Callaway, *supra* note 25.

32. *See id.*

33. SCULPTING EVOLUTION, http://www.sculptingevolution.org/kevin-m-esvelt (last visited Feb. 24, 2018); Carl Zimmer, *'Gene Drives' Are Too Risky for Field Trials, Scientists Say*, N.Y. TIMES (Nov. 16, 2017), https://www.nytimes.com/2017/11/16/science/gene-drives-crispr.html?mtrref=www.google.com.

34. *Daisy Drive Systems*, SCULPTING EVOLUTION, http://www.sculptingevolution.org/daisydrives (last visited Feb. 24, 2018).

field to clarify how the United States' framework will regulate gene drives.[35] Suggested regulatory elements include: phased testing pathways for gene drives, ecological risk assessments, community involvement, and transparency. There are regulatory concerns brought up by all drives, but the particular analysis of these concerns can be highly dependent on the specific drive. This is why experts have argued for a case-by-case analysis that focuses on the function of the gene drive.[36]

A recent report by the NAS, addressing gene drive regulation, proposed a phased testing pathway for engaging in gene drive research.[37] Phased testing is a useful response to researchers and policy-makers calling for cautious research into gene drives because it considers the risks at each step of development.[38] The NAS has advocated a phased testing pathway that is similar to the World Health Organization's guidelines for genetically modified mosquitos.[39] The NAS broke this pathway into five phases: research preparation, laboratory based research, field based research, staged environmental release, and post release surveillance.[40] At each stage, the relevant "risk assessment, public engagement, and governance" should take place and a determination is made as to whether the gene drive organism's development should continue.[41] This phased testing pathway exhibits that not only are regulatory concerns regarding gene drives different depending on the specific drive in question, they are also different depending on the drive's development stage.

In terms of environmental risks, NAS argues for the use of ecological risk assessments for potential gene drive organism releases.[42] The NAS defines ecological risk assessment as, "the study and use of probabilistic decision-making tools to evaluate the likely benefits and potential harms of a proposed activity on the wellbeing of humans and the environment, often under conditions of uncertainty."[43] The NAS report notes that environmental risk assessments and environmental impact statements, as required under the National Environmental Protection Act ("NEPA") do not require a "probabilistic assessment of potential risks" and are not sufficient for the kind of assessment needed for gene drives.[44] Furthermore, current EPA ecological risk assessment guidance "lags behind

35. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 142; J. Craig Venter Institute, *supra* note 28.

36. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 171; Oye et al., *supra* note 20, at 627.

37. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 5.

38. Callaway, *supra* note 25.

39. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 161.

40. *Id*. at 82.

41. *Id*. at 81.

42. *Id*. at 105.

43. *Id*.

44. *Id*. at 109.

advances in the field."[45] The NAS specifically criticizes the EPA's ecological risk assessment for failing to "adequately address the assessment of multiple stressors and endpoints," in other words they are designed to deal with one chemical, instead of interactions of multiple environmental stressors, and focus on the chemicals effects on "a limited set of specific endpoints."[46] Therefore, the report provides a suggested framework for ecological risk assessments. These assessments will compare alternative strategies, incorporate community concerns, and identify uncertainties, which are all vital elements in gene drive regulation.[47] Elements of a sufficient ecological risk assessment include: consideration of alternative strategies, incorporation of public opinion, identification of uncertainties, the ability to trace cause-and-effect outcomes, and quantifying the probability of these outcomes.[48]

There have also been calls to ensure gene drive research and regulatory approval is transparent, perhaps through public databases so that the community can be more involved in the decisions throughout the research, testing, and the possible release of an organism.[49] However, this brings up issues of proprietary of information and research data. Therefore, an adequate regulatory system for gene drives will need to find a way to balance between protecting proprietary information and ensuring adequate community knowledge. Community knowledge does not only mean the community where the initial release will take place, but also potentially affected communities if the gene drive spreads.

A key recommendation for regulating gene drives is that it should be done on a case-by-case basis as each drive may have different impacts depending on what gene is edited, what the drive's target population is, and other factors.[50] Moreover, some scholars have advocated for further research and development of reverse drives, drives that can "undo" the genetic modification of a drive in a local population, before any drive is released.[51]

Overall, the consensus seems to advocate for a cautious and incremental approach into gene drive research. The key, however, to successfully implementing a cautious regulatory approach is resolving current gaps in the United States' regulatory structure.

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45. *Id*.
46. *Id*. at 111.
47. *Id*. at 6.
48. *Id*.
49. Callaway, *supra* note 25; *see* Core Working Group on Guidance for Contained Field Trials, *Guidance for Contained Field Trials of Vector Mosquitoes Engineered to Contain a Gene Drive System: Recommendations of a Scientific Working Group*, 8 VECTOR-BORNE & ZOONOTIC DISEASES 127, 144 (2008), http://online.liebertpub.com/doi/pdf/10.1089/vbz.2007.0273.
50. Oye et al., *supra* note 20, at 627.
51. *Id*. at 627.

III. THE CURRENT REGULATORY LANDSCAPE

The new developments in gene drive technology reveal some inadequacies of the United States' current regulatory system for biotechnology. While the United States has experience regulating other genetically modified organisms ("GMO"), gene drives raise new risk factors because they are designed to spread through, and alter, wild populations.[52] Whereas GMO regulation often strives to limit the flow of genes between a GMO and wild populations, gene drive organisms specifically seek to spread a gene through distinct populations, potentially crossing legal and territorial boundaries.[53] Furthermore, the range of possible uses of gene drive organisms exhibits gaps in the Coordinated Framework where it is unclear how new gene drive organisms will be regulated. In order to understand the regulatory uncertainties within the Coordinated Framework, it is necessary to look at how the current system is likely to regulate gene drives. First, this section will examine regulation of laboratory research on gene drives.[54] Second, it will look at the structure of the Coordinated Framework, including a recent effort to update the framework, and examine the application of this framework to gene drive regulation. Finally, it will look at the use of executive working groups to design a system of regulation for biotechnology.

A. NATIONAL INSTITUTE OF HEALTH AND INSTITUTIONAL BIOSAFETY COMMITTEES

Currently, mainly the National Institute of Health ("NIH") and Institutional Biosafety Committees ("IBC") regulate laboratory experiments for gene drives.[55] NIH guidelines cover laboratory experiments, and are binding if a research program receives NIH funding.[56] Because the NIH can act as a single agency and need only propagate guidelines rather than full rulemakings, it can operate flexibly to respond to changes in biotechnology.[57] IBCs oversee, at an institutional level, research on genetic modification by assessing the risks of an experiment and recommending containment mechanisms.[58] Positive elements of this regulatory structure include case-by-case oversight, done at an institutional level, by assessing specific laboratory experiments.[59] Furthermore, not all researchers are bound by NIH guidelines, and the inexpensive nature and simplicity of gene editing through CRISPR opens up the potential types of researchers, and not all may be formal institutions governed by IBCs.[60]

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52. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 149.
53. *Id.*
54. This Note focuses mainly on the regulation of release of gene drive organisms and does not get into issues regarding appropriate regulation of laboratory contained experiments.
55. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 158.
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*

B. COORDINATED FRAMEWORK

Field experiments releasing a gene drive organism into a test environment, and eventual full release of gene drives, will likely fall under the regulatory purview of the Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework" or "CFRB").[61] However, there are significant uncertainties regarding how the agencies within the Coordinated Framework will regulate these gene drives, as the following discussion explains.

1. Background

In response to the rise in new genetic engineering processes, such as the use of recombinant DNA, the Regan Administration developed the Coordinated Framework in 1986 to ensure the safety of biotechnology products.[62] This framework was subsequently updated in 1992, and recently by the Obama administration in 2017.[63] The Coordinated Framework rests on the finding that "for the most part" current statutes are sufficient to regulate biotechnology products.[64] It seeks to provide a balance that ensures the protection of health and the environment, while reducing regulatory burdens, avoiding unjustifiable inhibitions to innovation, stigmatizing new technologies or creating trade barriers.[65] The Coordinated Framework mainly brought together three agencies deemed to have regulatory oversight for relevant existing statutes – the EPA, FDA, and USDA – and ensured coordination between the agencies.[66] Under this framework regulation is "product-based . . . presumes a low risk from genetic modification, and [bases] review of GM products under existing federal statutes."[67] Review is based on the intended use of the product, such as for food or pesticides.[68] Which means, in the case of gene drives, different agencies may end up regulating different gene drives under different statutory grants of regulatory authority depending on their ultimate purpose.

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61. *Id*. at 154.

62. Coordinated Framework, *supra* note 6, at 40; *see also* MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY (2017), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [hereinafter MODERNIZING].

63. Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992); *see also* MODERNIZING, *supra* note 62, at 5.

64. Coordinated Framework, *supra* note 6, at 3.

65. *See* MODERNIZING, *supra* note 62, at 7; *see generally* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23302–06 (discussing the Coordinated Framework).

66. *See* MODERNIZING, *supra* note 62, at 2–3.

67. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C.L. REV. 733, 733 (2003).

68. Coordinated Framework, *supra* note 6, at 20.

2. Updating the Coordinated Framework

The Coordinated Framework is intended to be flexible as well as updated in response to changes in technology.[69] In an effort to achieve these goals, the Obama Administration issued an executive office memorandum in 2015 directing the EPA, FDA, and USDA to modernize the biotechnology regulatory system while: "maintain[ing] high standards that are based on the best available science and that deliver appropriate health and environmental protection"; "establish[ing] transparent, coordinated, predictable, and efficient regulatory practices across agencies . . ."; and "promot[ing] public confidence . . . through clear and transparent public engagement."[70] This executive memorandum also established the Biotechnology Working Group under the auspices of the Emerging Technologies Interagency Policy Coordination Committee.[71]

The Executive Memorandum assigned three main tasks to the EPA, USDA, and FDA: to update the Coordinated Framework, to clarify the roles and responsibilities of each agency, to develop a long term strategy to ensure that future risks are assessed efficiently, and to commission a report on the future landscape of biotechnology.[72] The Biotechnology Working Group developed a National Strategy for Modernizing the Regulatory System for Biotechnology Products,[73] accompanied by a proposed Update to the Coordinated Framework,[74] and, in March of 2017, of the NAS released a study entitled *Preparing for Future Products of Biotechnology*.[75] The EPA, FDA, and USDA committed to releasing an annual report every year for five years detailing their progress towards the goals of "increasing transparency, increasing predictability and efficiency, and supporting the science that underpins the regulatory system."[76] Updating the Framework did not end with these changes to the Coordinated Framework. The FDA released new guidance and the USDA released a proposed rule, both of

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69. *See* MODERNIZING, *supra* note 62, at 8.

70. EMERGING TECHS. INTERAGENCY POLICY COORDINATION COMM., 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 [hereinafter EMERGING]; Memorandum from John P. Holdren, Assistant to the President of Sci. & Tech., Director, Office of Sci. & Tech. Policy et al., to Heads of Food & Drug Admin., Envtl. Prot. Agency & Dep't Agric. (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

71. Memorandum from John P. Holdren, *supra* note 70, at 3.

72. *Id*. at 3–4.

73. EMERGING, *supra* note 70, at 5.

74. *See* MODERNIZING, *supra* note 62, at 55.

75. NAT'L ACADS. OF SCIS., ENG'G, & MED., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY (2017), https://www.nap.edu/catalog/24605/preparing-for-future-products-of-biotechnology. These updates were released in January of 2017 right before the Obama Administration left office.

76. Sam Rothbloom, *Administration's Biotechnology Working Group Updates Coordinated Framework & Unveils National Strategy*, CONSUMER PRODUCT MATTERS (Sept. 21, 2016), https://www.consumerproductmatters.com/2016/09/administrations-biotechnology-working-group-updates-coordinated-framework-unveils-national-strategy/.

these actions sought to clarify the roles of the respective agencies in the apparent attempt to capture future developments in biotechnology regulation.[77] These efforts demonstrate how difficult it can be to coordinate three agencies and accurately predict all regulatory needs.

A recent report from the Interagency Task Force on Agricultural and Rural Prosperity, created by the Trump Administration, advocates for reaffirming "strong support of the Coordinated Framework for the Regulation of Biotechnology, and the corresponding National Strategy for Modernizing the Regulatory System for Biotechnology Products."[78] This report advocates continued work to modify the regulatory system that is focused on developing a "streamlined, science-based regulatory policy."[79] It also includes recommendations for interagency coordination through the White House Office of Science and Technology Policy, and expediting the "commercialization of biotechnology products."[80]

The process of updating the Coordinated Framework also shows that, while it is somewhat flexible, there is a large investment of time and energy that each agency, either working independently or collaboratively, must expend in order to adequately respond to changes in technology. The questions raised by gene drive organisms also show that updates to the Framework can never fully identify all the possible questions that new technologies can raise.

3. Coordinated Framework and Regulatory Jurisdiction

Under the Coordinated Framework, the EPA regulates biotechnology products pursuant to grants of regulatory authority in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the Toxic Substance Control Act ("TSCA"). The FDA regulates biotechnology products that qualify for regulation under the FDCA and the Public Health Service Act ("PSH"). The USDA regulates biotechnology products that qualify for regulation under the Animal Health Protection Act ("AHPA"), Plant Protection Act ("PPA"), Federal Meat Inspection Act ("FMIA"), Poultry Products Inspection Act ("PPIA"), Egg Products Inspection Act ("EPIA"), and Virus-Serum-Toxin Act ("VSTA").[81]

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77. Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability, 82 Fed. Reg. 6561 (Jan. 19, 2017); U.S. Dep't. Agric., 2017 Proposed Biotechnology Regulations (Apr. 12, 2018), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/2016-340-rule/2016-340-home.

78. TASK FORCE ON AGRICULTURE AND RURAL PROSPERITY, REPORT TO THE PRESIDENT OF THE UNITED STATES FROM THE TASK FORCE ON AGRICULTURAL AND RURAL PROSPERITY 34 (2017), https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf.

79. *Id*.

80. *Id*.

81. MODERNIZING, *supra* note 62, at 9.

Many of these statutes may be applicable to gene drive organisms. For example, the EPA may be able to regulate some gene drives under their pesticide regulatory authority in FIFRA.[82] The FDA regulates a wide variety of products, but key provisions that may apply to gene drives include the new animal drug provisions under the FDCA.[83] The key question for FDA approval is if the drug is "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[84] Finally, the USDA has authority to regulate "plant pests" and uses this to regulate biotechnology that is released both in contained and open areas.[85] They also have authority to regulate "noxious weed[s]."[86] Overall, the Coordinated Framework is designed so that "the specific regulatory path . . . of any biotechnology product, is dependent on the nature and characteristics of the product and its application."[87] However, because there is no central coordinating board determining the relevant regulatory path for new biotechnology products, there are regulatory uncertainties when new technologies arise.

This regulatory uncertainty is particularly evidenced when one examines who would regulate the potential release of gene drive organisms. The NAS provided a good depiction of this by analyzing different case studies of gene drive organisms and finding that in each case, "how gene-drive modified organisms fit within the regulatory jurisdiction of FDA, USDA, and EPA is unclear, and their processes for assessing risks may differ from one another."[88] Overall, there are significant uncertainties about how these agencies will regulate potential gene drives. For example, the FDA may be able to regulate a mosquito designed to eliminate the spread of a virus as a "new animal drug."[89] The USDA, FDA or EPA may regulate a mouse designed to reduce or eliminate an invasive species depending on if the agencies classify the mouse as a plant pest ("USDA"), a new animal drug ("FDA"), or a pesticide ("EPA").[90] There are also questions about how other agencies, such as the U.S. Fish and Wildlife Service ("FWS"), would be engaged in each different gene drive.[91] State and local environmental laws and notification requirements for the release of genetically modified organisms are also at play

82. 7 U.S.C. § 136(u) (2012); *see also* NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 159.

83. 21 U.S.C. § 321(v); *see also* EXECUTIVE 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 16 (2017), https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf [hereinafter 2017 REGULATORY UPDATE]; NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 145.

84. 21 U.S.C. § 321.

85. 7 U.S.C. § 711; *see also* 2017 REGULATORY UPDATE, *supra* note 83, at 22–23.

86. 7 U.S.C. § 711.

87. MODERNIZING, *supra* note 62, at 8.

88. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 158.

89. *Id*. at 145.

90. *Id*.

91. *Id*. at 147.

here, especially because gene drives will likely spread across state and local borders.[92]

The recent update to the Coordinated Framework laid out coordination mechanisms that the EPA, FDA, and USDA already utilize. These mechanisms include Formal and Ad Hoc Interagency Working Groups and Memoranda of Understanding.[93] Interagency working groups and interagency communication also helps to bring in expertise from other relevant agencies.[94]

C. EXECUTIVE WORKING GROUPS

There have been a number of temporary working groups to advise and develop the Coordinated Framework.[95] These groups illustrate the usefulness of having coordinating committees by virtue of the work they did both developing and updating the Coordinated Framework. Their experiences and expertise will be vital to developing a standing coordinating committee. President Obama's 2015 Memorandum created the Biotechnology Working Group within the Emerging Technologies Interagency Policy Coordination Committee and tasked the group with increasing the "transparency, coordination, predictability, and efficiency of the regulatory system for products of biotechnology."[96] President Obama also issued Executive Order 13521 which established the Presidential Commission for the Study of Bioethical Issues.[97] This Commission was designed to advise the President on "bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology."[98] The commission's membership is comprised of people from the fields of "bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social scientists."[99]

The implementation of a central coordinating committee would likely help create the necessary regulatory flexibility for proper regulation of emerging technologies including gene drives. Currently, responses to new technologies take place on an agency by agency basis or through a process of updating the Coordinated Framework. This means there is a significant amount of time where interested actors, such as scientists, industry, and regulators themselves, are unsure how the EPA, USDA, and FDA will regulate a new technology. Having a central

92. *Id*. at 152.
93. MODERNIZING, *supra* note 62, at 36–37.
94. *See id*. at 36.
95. Coordinated Framework, *supra* note 6 (the Biotechnology Science Coordinating Committee helped initially develop the Coordinated Framework).
96. EMERGING, *supra* note 70, at 1.
97. Establishing the Presidential Commission for the Study of Bioethical Issues, 74 Fed. Reg. 62671 (Nov. 30, 2009).
98. *Id*.
99. *Id*.

coordinating committee can help give structure and clarity to this ad hoc method of dealing with new technologies.

IV. SUGGESTED RESPONSE TO UNCERTAIN REGULATORY LANDSCAPE

As discussed above, the rapid development of new technologies can, and likely will, strain the strict regulatory silos of the Coordinated Framework. However, there are significant drawbacks and difficulties to enacting new legislation. Therefore, in order to ensure regulatory uncertainties can be quickly resolved and concerns about security continuously addressed, this Note proposes the adoption of a tiered regulatory approach where a coordinating committee reviews new technologies and recommends the proper regulatory procedure. This approach encompasses suggestions made by policy makers and scholars to create a central coordinating committee for biotechnology regulation.[100] However, unlike calls for a new operating statute,[101] this committee would work within the current Framework. Similar to President Obama's creation of the Biotechnology Working Group, President Trump may be able to form this committee to operate on a more permanent basis, with designated seats for interested agencies and experts in the field. This committee would review new biotechnologies and determine their regulatory pathway, as was suggested by a recent policy workshop report.[102] This committee would facilitate a prompt review of how emerging technologies fit into the regulatory scheme, compared to the current options which entails waiting for all three agencies to update guidelines and rulemakings in light of new technologies or for the President to order an overhaul of the Coordinated Framework.

In order to encourage communication and collaboration between agencies and stakeholders, this committee should include representatives from relevant federal agencies and experts in the field. The committee should also include relevant technology and industry experts, community representatives, and local government representatives when useful for evaluating specific technologies, such as how a direct release of a gene drive would be regulated. This committee can also serve as a point of contact for agencies to clarify their regulatory roles without needing an executive order to update the Coordinated Framework. The committee could evaluate any new regulatory concerns created by new technologies, for example the need for high community involvement and ecological risk assessments in certain gene drives and ensure that the agencies are addressing the concerns as the Coordinated Framework originally intended.[103] This coordinating

100. Heather Hosmer, *Outgrowing Agency Oversight: Genetically Modified Crops and the Regulatory Commons Theory*, 25 GEO. INT'L ENVTL. L. REV. 647, 669 (2013); J. Craig Venter Institute, *supra* note 28.

101. Hosmer, *supra* note 100, at 669.

102. J. Craig Venter Institute, *supra* note 28.

103. Coordinated Framework, *supra* note 6, at 4 ("[T]wo basic principles: (1) Agencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review to the extent

committee can also provide resources for stakeholders to reach out regarding questions on the regulation of biotechnology. Finally, this committee will ideally be able to quickly alert lawmakers if there is a concerning technology that escapes regulation under the current system.

To analyze how this coordinating committee can resolve the questions raised by gene drives without the need for a new operating legislation this Note will: (A) look at the difficulties of a new operating legislation, (B) discuss why this approach accurately handles the process-product debate for regulating biotechnology, (C) look into how this approach solves regulatory uncertainty issues, and (D) review how this approach will address key concerns in the regulation of gene drives.

A. DIFFICULTIES OF NEW LEGISLATION

The political will required for new legislation can be massive, and new operating statutes with new agencies or delegating new responsibilities to current agencies requires significant political capital and economic investment. Beyond these difficulties, new legislation or new agency authority that would cover biotechnology, or specifically genetically engineered organisms, is not necessary, nor ideal, for the reasons discussed below.

A new operating agency would be unnecessary as existing agencies have extensive experience and expertise regulating biotechnology products.[104] As one scholar pointed out back in 1988 "a number of government agencies" are well suited for regulating the risks of genetically modified organisms.[105] The EPA, USDA, and FDA have expertise in regulating biotechnology products, and many of these products fit well into the regulatory purview of these agencies. Moreover, because regulation of innovative technology requires a rapid response to changing risks and knowledge, incorporating more elements of adaptive regulation, without losing expertise and regulatory tools of the current system, would aid in responding effectively to technological developments.[106] Having a coordinating board review and direct biotechnology products would enable this flexible and rapid response.

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permitted by their respective statutory authorities; and, (2) agencies should utilize scientific reviews of comparable rigor.").

104. Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 205 (1987); 2017 REGULATORY UPDATE, *supra* note 83, at 36.

105. Mark W. Lauroesch, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 126 (1998). Mark Lauroesch advocated in 1988 for basing the regulatory system of biotechnology on existing statutes due to the delay in monitoring that a new operating statute would entail and noted that statutes providing broad regulatory authority may govern products of new technology that were never envisioned when the statute was enacted. *Id.* at 128–29 (citing Diamond v. Chakrabarty, 447 U.S. 303, 215 (1980)). He noted that building a regulatory structure on existing agency expertise can address these concerns. *Id.* at 126.

106. Karinne Ludlow et al., *Regulating Emerging and Future Technologies in the Present*, 9 NANOETHICS 151, 153 (2015).

The Coordinated Framework has been regulating biotechnology products since the 1980s, and there have been no massive failures in the system causing societal distrust. This would seem to indicate that, on the whole, things have been going well. A primary concern raised by maintaining past regulatory schemes in the face of emerging technologies is that a "cookie-cutter approach" may be used and the intricacies of new technologies may not be fully evaluated.[107] However, a regulatory status quo can "provide the capacity for policy makers and safety regulators to use existing tools and instruments to regulate emerging technology products in a way that differentiates them from their conventional counterparts."[108] Furthermore, it is still necessary to ensure that the regulatory agencies which have been delegated authority have the necessary capacity and expertise to regulate.

The flexibility of the Coordinated Framework, when increased by having a standing coordinating committee acting as a focal point for facilitation, allows regulators to benefit from regulatory experience without limiting solutions by classifying new technologies into inapplicable and strict regulatory categories.[109] By allowing early proactive review of new technologies, this system will ensure that truly unique regulatory issues receive their appropriate focus and issues that are well suited to established regulatory methods can benefit from the developed expertise.[110] This committee benefits from the flexibility and rapid response of the Governance Coordinating Committee model advocated by Marchant and Wallach .[111] They argue that Committees can work with stakeholders across spectrums and ensure "monitoring evaluating, and balancing competing interests."[112]

B. BASIS OF REGULATION

An examination of the ideal regulatory basis for genetically engineered products supports the decision to move away from a new operating legislation and towards continuing the Framework and increasing its flexibility with a standing committee. There is an ongoing debate about the most effective way to regulate genetically engineered products: should the process used to create the organism or the ultimate product created from the technology provide the basis for regulating these products? This question encompasses a debate between process-based or product-based regulation of biotechnology products. However, a binary focus on process or product obscures a more flexible case-by-case analysis of the new

107. *Id.*
108. *Id.*
109. *Id.*
110. *Id.*
111. *Id.* at 155.
112. *Id.*

product.[113] This is because a pure focus on the process, as would likely be involved in new legislation, does not have the benefit of ensuring similar products made by different technologies or mechanisms, but with similar effects or goals, are regulated similarly.[114] Conversely, the United States' regulatory system resembles more of a product focus, where there is no initial review before genetically engineered organisms are separated by use.[115] However, gene drive organisms show that use-based separation may cause regulatory concerns that are technology specific. For example, the ecological concerns of gene drives would likely have to be handled differently by different regulatory entities. In the case of gene drives, many of the potential risks are relevant regardless of the ultimate purpose of the drive, and the level of risk will likely depend more on the type of drive, altered genetic trait, and release environment.[116]

The binary discussion of genetically engineered organisms does not translate well when one is looking at gene drive organisms that are released in a target environment in order to change it. Kenneth Oye has suggested a function-based regulation for gene drives where risk is examined by "the ability to influence any key biological component the loss of which would be sufficient to cause harm to humans or other species of interest," and regulatory authority is given to the agency with the expertise to evaluate the specific application in question for each gene drive.[117] This is close to a product-based approach because it focuses on the risks of a specific use of the gene drive, but it also incorporates the case-by-case analysis that is key to accurately assessing risks imposed by releasing a given gene drive.[118] Moreover, having a coordinating committee that can review proposed gene drives will ensure that risk can be properly evaluated and the best fitting agency is given regulatory authority.

Furthermore, these process-product debates focus strongly on a scientific understanding of the effects and risks of the products of gene drives and may ignore the value of community opinions.[119] Gene drive organisms are designed to change wild populations, potentially having significant ecosystem effects. Therefore, a key consideration for any risk analysis must be the community's, defined broadly enough to include all possible spreads of the gene drive, desire for the given ecosystem change. Jennifer Kuzma, argues that instead of looking

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113. Margaret A. Hamburg, *Innovation, Regulation, and the FDA*, 363 NEW ENG. J. MED 2228, 2231 (2010) (arguing that there must be a "new set of flexible regulatory standards for product review for the 21st century through the emerging field of regulatory science.").

114. Coordinated Framework, *supra* note 6, at 3.

115. Alan McHughen, *A Critical Assessment of Regulatory Triggers for Products of Biotechnology: Product vs. Process*, 7 GM CROPS & FOOD 125 (2016).

116. Oye et al., *supra* note 20, at 628.

117. *Id.*

118. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 142.

119. Douglas A. Kysar, *Preferences for Process: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525; Andy Stirling et al., *Perspective: Regulating Genetic Engineering: The Limits and Politics of Knowledge*, 31 ISSUES IN SCI. & TECH. 23 (2015).

strictly at process-product or science-values divisions as the guiding forces in risk regulation for genetically modified organisms, there should be a "governance system that is both informed by the science and guided by the concerns and values of citizens."[120] She points out that process-product distinctions often focus on the appropriate level of genetic modification, instead of realizing that both, the genetic modification used and the product that is developed, can have risks that may need to be explored.[121] What these different approaches - whether process-, product-, function- or hybrid-focused - have in common is a preference for looking at each proposed genetically engineered product on a case-by-case basis.

The current United States regulatory system of biotechnology regulation is a piecemeal assembly of different statutes that requires regulatory statutes and the early separation of gene drive regulation based on a given drives desired utility outcome, rather than its function as a drive.[122] Retooling the regulatory methods to ensure that a preliminary review of the organism as an entity onto itself takes place before dividing regulation based on use, will allow for a comprehensive assessment of the full range of regulatory issues presented in a new technology and ensure the agencies are aware of relevant issues with similar technologies.[123] In this vein, a central coordinating committee could review new biotechnology products and funnel them into the proper regulating entity, ensuring a comprehensive analysis of the new products takes place before the products are placed into an existing regulatory regime.

C. REGULATORY UNCERTAINTY

A coordinating committee will also help resolve regulatory uncertainty regarding new technologies faster and more efficiently than the current Framework. Regulatory uncertainty can, at times, be a positive force, but given the nature of biotechnology, as well as the risks and suggested regulatory steps raised by gene drives, gene drives are not a case where regulatory uncertainty is beneficial. Having a well-established central coordinating committee could provide early review of new and developing technologies, a communication platform for interested parties, advice to agencies of their potential regulatory roles, and advice about new regulatory steps that may need to be taken. This could help resolve regulatory uncertainty and lower regulatory costs of emerging biotechnology products. This coordinating committee could help address regulatory uncertainty in three main ways.

First, the Coordinated Framework rests on cooperation between multiple possible regulators, namely the–EPA, FDA, and USDA–as well as the ability to reach

120. Jennifer Kuzma, *Policy: Reboot the Debate on Genetic Engineering*, 531 NATURE 165 (2016), http://www.nature.com/news/policy-reboot-the-debate-on-genetic-engineering-1.19506.

121. *Id.*

122. McHughen, *supra* note 115, at 125.

123. Oye et al., *supra* note 20, at 626.

out to other relevant agencies. This system, with numerous potential regulators, is therefore very susceptible to the regulatory commons issues described by Professor William Buzbee.[124] Namely, the existence of multiple regulators provides incentives for agencies to fail to address issues that should be regulated.[125] As other scholars have pointed out, a coordinating committee can be useful in providing a remedy to this regulatory commons issue.[126] The coordinating committee proposed by this Note is particularly important as its main operation will be to review new technology, particularly when there is uncertainty about the optimal regulatory response. Indeed, in the case of new technologies, scholars have observed that agencies fail to regulate new risks from emerging technologies because of the high cost of engaging in the initial regulation, but then face difficulties regulating later because of entrenched industry interests.[127] The flexible adaptive case-by-case mechanisms of an initial board review for emerging biotechnology products will allow a chance for flexible regulation that does not entrench regulatory responses that are either over or under regulatory for relevant risk.

Second, regulatory uncertainty can hamper investment and research into emerging technologies.[128] Gene drive technology is currently in the research stage. If society wants to realize the potential positive outcomes from this technology, there will likely need to be research and development investments in order to move it from the research stage into reality. Furthermore, CRISPR is a relatively easy-to-use and inexpensive technology. In fact, undergraduates at the University of Minnesota recently came close to developing a reversal drive for an international synthetic biology competition.[129] Therefore, it cannot be assumed that all parties working on gene drives have the sophistication or knowledge to know what regulatory procedures they need to abide by. Regulatory uncertainty could discourage these actors engaging in research or lead to inadequate regulation of the products of their research.

Third, both the potential risks of gene drives and the likelihood of community concern for the possible effects of gene drives make it imperative that there be adequate review before release and that individuals have confidence in that review.[130] Regulatory uncertainty harms this system by creating gaps that gene drive organisms may fall through which, in turn, would harm public confidence

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124. William W. Buzbee, *Recognizing the Regulatory Commons: A Theory of Regulatory Gaps*, 89 IOWA L. REV. 1, 13–14 (2003).

125. *Id.*

126. Hosmer, *supra* note 100, at 669.

127. *See* Matthew T. Wansley, *Regulation of Emerging Risks*, 69 VAND. L. REV. 401, 403–04 (2016).

128. *See* Amy L. Stein, *Reconsidering Regulatory Uncertainty: Making a Claim for Energy Storage*, 41 FLA. ST. U. L. REV. 697, 732 (2014).

129. Ike Swetlitz, *College Students Almost Engineer Controversial Gene Drive*, PBS (Dec. 5, 2016), http://www.pbs.org/newshour/rundown/watchful-eyes-students-come-close-engineering-gene-drive/.

130. *Cf.* Gregory N. Mandel, *Regulating Emerging Technologies*, TEMP. U., Research Paper No. 2009-18, 2 (April 8, 2009), http://ssrn.com/abstract=1355674.

in the regulatory system. Fortunately, these concerns could provide impetus for stakeholders to work with the coordinating committee. As Gregory N. Mandel notes, these "mutual concerns about uncertainty" can provide a groundwork for stakeholders to work together.[131] The coordinating committee, in addition to the Coordinated Framework, will allow stakeholders the opportunity to discuss the risks and benefits of new technologies openly and make suggestions of the proper route for regulation.

Under the current framework, the regulatory lift required to comprehensively regulate a new technology like gene drives requires three different agencies to evaluate their respective regulatory authority and may require new guidelines or regulations. This regulatory burden can take years to overcome and does not provide a good format for flexible, responsive regulation.[132] An important aspect of designing a system that regulates biotechnology products is ensuring that unknown future developments in technology will be regulated. Doing this through flexibility in the legal regime has the advantage of allowing for regulatory responses that can rapidly react to new conditions.[133] The Coordinated Framework strives to input some flexibility into biotechnology regulation by allowing for updates to the Framework and encouraging coordination among the agencies.[134] However, by failing to provide a forum for early review of biotechnology products before it enters a regulatory agency silo, the framework requires each agency to review and determine which new biotechnologies fall under their regulatory authority.[135]

D. KEY CONCERNS IN THE REGULATION OF GENE DRIVES

Beyond providing a platform to efficiently and optimally resolve uncertainties about the regulation of gene drives, this coordinating committee can also utilize tools in the Coordinated Framework to address the issues of environmental review, transparency, and community involvement in relation to gene drives.

First, by providing an initial review of the necessary regulatory questions, this coordinating committee may be able to highlight the need for an ecological risk assessment for gene drives. The NAS has pointed out that current ecological risk assessments by the EPA and environmental impact statements by the USDA and FDA do not constitute rigorous enough ecological risk assessments.[136] Having a centralized coordinating committee emphasize the need for these assessments could provide a platform to highlight this insufficiency and

131. *Id*. at 4.

132. *See* Wilson R. Huhn, *Three Legal Frameworks for Regulating Genetic Technology*, 19 J. CONTEMP. HEALTH L. & POL'Y 1, 4 (2003).

133. *See* Justin R. Pidot, *Governance and Uncertainty*, 37 CARDOZO L. REV. 113, 116 (2015).

134. Coordinated Framework, *supra* note 6, at 40.

135. *See* Pidot, *supra* note 133.

136. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES, *supra* note 2, at 111.

encourage interagency cooperation to address the need for long term ecosystem analysis of gene drives.

Second, as discussed above, there is a need for transparency and community involvement in regulating gene drives. However, this can be difficult due to the propriety nature of the research. Mark Lauroesch suggested a useful response to this problem that could be operationalized in the context of gene drives by the coordinating committee.[137] He proposed community review boards, similar to institutional review boards at universities, which would consist of representatives of areas where release experiments are planned and representatives from the appropriate regulatory agencies.[138] These boards would not release information publicly, but would still provide public representation in the initial planning stages before disclosure is appropriate.[139]

CONCLUSION

Like so many new technologies, the potential for gene drive organisms brings new challenges to the existing regulatory structure for biotechnology. The ability to genetically engineer wild populations brings unique ethical and practical regulatory questions. Recognizing the need for a careful case-by-case analysis of these technologies and the existing expertise of the agencies involved in the Coordinated Framework helps inform ways to make this structure more flexible and adaptive while minimizing regulatory uncertainty.

Ultimately, the introduction of a standing coordinating committee to conduct preliminary review of both gene drive organisms and other new biotechnology products that strain the Framework's traditional regulatory silos, allows for flexibility and appropriate regulation while still maintaining the benefits of the current Coordinated Framework. This standing committee can also provide recommendations for agencies of the new risks posed by emerging technologies and new regulatory techniques or requirements that these technologies might require. By providing a consistent forum for interested parties, the committee can help decrease regulatory uncertainty and ensure the proper regulation of new gene drive technologies.

137. Lauroesch, *supra* note 105, at 132.
138. *Id.*
139. *Id.*