FROM UN-COORDINATED TO EFFICIENT: A PROPOSAL FOR REGULATING GE PRODUCTS IN A WAY THAT MEETS THE NEEDS OF CONSUMERS, PRODUCERS, AND INNOVATORS

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Dinosaurs and man, two species separated by sixty-five million years of evolution have just been suddenly thrown back into the mix together. How can we possibly have the slightest idea what to expect? –Alan Grant[1]

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1. JURASSIC PARK (Universal Pictures 1993).

INTRODUCTION

Humans have been modifying plants and animals since the dawn of agriculture.[2] This was originally done through "selective breeding" or "artificial selection" and has since evolved into "genetic engineering" (GE).[3] Selective breeding has influenced everything from corn and wheat to hunting dogs.[4] Humans have not regulated the creation of organisms using this older method, other than through intellectual property rights.[5] However, when humans learned to manipulate mice DNA, scientists, the media, and governmental officials became concerned.[6] The Organizing Committee for the International Conference on Recombinant DNA Molecules (Recombinant DNA Committee) placed a moratorium on GE projects until the 1975 Asilomar Conference, when scientists created safety and containment regulations.[7] In 1980, the U.S. Supreme Court upheld the first patent for bacteria and in 1987, scientists tested the first genetically modified (GM) food crops.[8] In 2003, scientists produced the first commercial GM animal—a glowing fish—causing turmoil among watchdogs because the Food & Drug Administration (FDA) initially decided not to regulate the organism.[9]

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2. *See e.g.*, B. M. Chassy, *The History and Future of GMOs in Food and Agriculture*, 54 CEREAL FOODS WORLD 169, 169 (2007) (discussing domestication of plants and animals "to suit the needs of improved production, resistance to diseases and pests, and to serve human preferences").

3. Gabriel Rangel, *From Corgis to Corn: A Brief Look at the Long History of GMO Technology*, SCI. IN THE NEWS (August 9, 2015), http://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/.

4. *Id.*

5. *See* Morten Walløe Tvedt, *Patent Protection in the Field of Animal Breeding*, 57 ACTA AGRICULTURAE SCANDINAVICA 105, 106 (2007) (summarizing the history of patent regulation of selectively bred animals).

6. Rangel, *supra* note 3.

7. *Id.*

8. *Id.*

9. *See* Zhiyuan Gong et al., *Development of Transgenic Fish for Ornamental and Bioreactor by Strong Expression of Fluorescent Proteins in the Skeletal Muscle*, 308 BIOCHEMICAL & BIOPHYSICAL RES. COMM. 58, 58 (2003) (explaining the development of the glowing fish); *see also Statement Regarding Glofish*, U.S. FOOD & DRUG ADMIN., https://wayback.archive-it.org/7993/20170404230909/https:/www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm (last updated Sept. 9, 2014) (explaining the FDA did not elect to regulate genetically-engineered zebra danio fish because they posed no heightened threat to the environment); *see also CFS Sues FDA To Regulate Genetically Engineered Glofish*, CENTER FOR FOOD SAFETY (Jan. 14, 2004), http://www.centerforfoodsafety.org/press-releases/904/cfs-sues-fda-to-regulate-genetically-engineered-glofish (announcing CFS's decision to sue the FDA for its failure to regulate GloFish).

This paper discusses the history of genetically modified organisms (GMOs).[10] Part II evaluates the development of GE practices over time and the public outcry they have caused.[11] Part III elaborates on the rather intricate and somewhat confusing U.S. framework for evaluating and approving GM products.[12] Lastly, Part IV covers the issues caused by the current framework and possible solutions for addressing those issues. The solutions proposed herein suggest a simpler, more open process led and coordinated by the United States Department of Agriculture (USDA), with input as needed from the Environmental Protection Agency (EPA) and the FDA.[13]

I. HISTORY OF GMOS AND A DISCUSSION OF THE ISSUES

A. History

Humans began altering organisms as early as 32,000 years ago when they started domesticating wolves.[14] Since then, the human race has bred bananas,[15] carrots,[16] corn,[17] and wheat[18] into submission—just to name a few. Humans turned wild, unruly weeds into robust, nutritious crops, making them easier to grow and harvest.[19] Humans chose the most desirable members of each species and encouraged them to breed.[20]

As technology progressed, scientists found new ways to change plants and animals. In 1973, Herbert Boyer and Stanley Cohen discovered how to

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10. *Compare Genetically Modified Organism*, DICTIONARY.COM (3rd ed. 2005) *with Genetic Engineering*, MERRIAM WEBSTER DICTIONARY (2018) (comparing the difference in denotation between "genetic engineering," "genetic modification," and "genetically modified organism"—all refer pieces of the same puzzle, but genetic engineering is the field, genetically engineered or modified is the process, and genetically modified organisms are the result).

11. *See infra* Part II. History of GMO's and a Discussion of the Issues.

12. *See infra* Part III. Establishment of the Framework.

13. *See infra* Part IV. Proposed Changes to the Framework.

14. Carl Zimmer, *From Fearsome Predator to Man's Best Friend*, N.Y. TIMES (May 16, 2013), https://www.nytimes.com/2013/05/16/science/dogs-from-fearsome-predator-to-mans-best-friend.html?smid=pl-share.

15. *See* Tanya Lewis, *Here's What Your Food Would Look Like If it Weren't Genetically Modified Over Millennia*, BUS. INSIDER (Aug. 9, 2015), http://www.businessinsider.com/foods-before-genetic-modification-2015-8/#wild-carrot-7 (providing examples of foods that appear radically different now as compared to hundreds of years ago).

16. *Id.*

17. GENETIC SCIENCE LEARNING CENTER, EVOLUTION OF CORN, http://learn.genetics.utah.edu/content/selection/corn (last visited Oct. 9, 2018).

18. Michael Balter, *Farming was So Nice, It was Invented at Least Twice*, SCIENCE (July 4, 2013, 2:15 PM), http://www.sciencemag.org/news/2013/07/farming-was-so-nice-it-was-invented-least-twice.

19. Sean B. Carroll, *Tracking the Ancestry of Corn Back 9,000 Years,* N.Y. TIMES (May 24, 2010), https://www.nytimes.com/2010/05/25/science/25creature.html.

20. Chassy, *supra* note 2, at 169.

transfer DNA from one organism to another.[21] The researchers cut DNA from an antibiotic resistant strain of plasmid pSC101 and inserted it into Escherichia coli, transferring pSC101's tetracycline resistance to the bacteria.[22] The researchers found that the resistance was still present after reproduction and began experimenting further, eventually adding frog DNA to E. coli.[23] Just a year after the groundbreaking discovery, scientists called for a voluntary moratorium on GE projects, outlining potential hazards and the need for guidelines.[24] After the 1975 Asilomar Conference, the Recombinant DNA Committee agreed upon standards and containment procedures for use in GE projects.[25] Each experiment on an organism falls into a category (1, 2, 3, or 4), which corresponds to a containment measure.[26] For example, experiments on animal viruses (category 2) "should be performed only with vector–host systems having demonstrably restricted growth capabilities outside the laboratory and with moderate risk containment facilities."[27] In moderate-risk containment facilities "transfer operations should be carried out in biological safety cabinets (e.g., laminar flow hoods), gloves should be worn during the handling of infectious materials, vacuum lines must be protected by filters, and negative pressure should be maintained in the limited access laboratories."[28] With these new standards in place, scientists could continue their work, confident that their research would not harm society. The conference, still being written about today, instilled trust in the public and governments around the globe because scientists showed that they could effectively police themselves.[29]

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21. SCI. HISTORY INST., HERBERT W. BOYER & STANLEY N. COHEN, https://www.sciencehistory.org/historical-profile/herbert-w-boyer-and-stanley-n-cohen (last visited Sept. 23, 2018).

22. *Id.*

23. *Id.*

24. Paul Berg et al., Letter to the Editor, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE, no. 4148, July 26 1974, at 303,, http://science.sciencemag.org/content/185/4148/303 (explaining the Committee on Recombinant DNA Molecules' concerns about genetic engineering research).

25. Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. OF THE NAT'L ACAD. OF LIFE SCI. 1981 (1975), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC432675/pdf/pnas00049-0007.pdf.

26. NAT'L INST. OF HEALTH, GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES, § II-A-1 (Apr. 2016), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html (outlining the modern Risk Groups used in GE experiments).

27. Berg et al., *supra* note 25, at 1983.

28. *Id.* at 1982.

29. Rangel, *supra* note 3; Paul Berg*, Asilomar 1975: DNA Modification Secured,* 455 NATURE 290, 290 (2008), http://www.nature.com/nature/journal/v455/n7211/full/455290a.html; Ezekiel J. Emanuel, *Tinkers and Tailors: Three Books Look to the Biomedical Frontier*, N.Y. TIMES (Mar. 16, 2017), https://www.nytimes.com/2017/03/16/books/review/gene-machine-bonnie-rochman.html.

In 1980, the Supreme Court held that GE organisms are patentable.[30] This went completely against the previously held notion that living things were not patentable subject matter under 35 U.S.C. § 101.[31] Two years later, scientists introduced synthetic insulin to society and twelve years after that, the first GM food product (the Flavr Savr tomato) entered commercial production.[32] The public trust gained by the Asilomar Conference did not last, as the Flavr Savr tomato faced a massive amount of public scrutiny even after a seven-year testing and approval process.[33] Researchers engineered the tomato to stay firm longer after ripening, eliminating the need for artificial ripening through ethylene exposure.[34] They claimed its ability to ripen naturally also increased, as suggested by the name, its flavor.[35] In 1996, Zeneca released a tomato paste in the U.K. made from the Flavr Savr tomatoes.[36] While some articles suggest the tomato's demise was due to Monsanto[37] purchasing the Flavr Savr brand,[38] others suggest Dr. Pusztai's study on rats was responsible.[39] Both brands eventually died due to the

30. *See generally*, Diamond v. Chakrabarty, 477 US 303, 309–310 (1980) (holding that the human-made, genetically engineered, oil-eating bacterium qualified as patentable subject matter under 35 U.S.C. § 101 because it had "markedly different characteristics from any found in nature and … the potential for significant utility.").

31. 35 U.S.C. § 101 (2012).

. Lawrence K. Altman, *A New Insulin Given Approval For Use in U.S.*, N.Y. TIMES, Oct. 30, 1982, *available at* http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html; Michael Winerip, *You Call That a Tomato?*, N.Y. TIMES (June 24, 2013), https://www.nytimes.com/2013/06/24/booming/you-call-that-a-tomato.html?smid=pl-share.

33. *See e.g.*, G. Bruening & J.M. Lyons, *The Case of the FLAVR SAVR Tomato*, CAL. AGRIC., July-Aug. 2000, at 7, http://calag.ucanr.edu/Archive/?article=ca.v054n04p6 (explaining Sainsbury and Safeway's declaration against genetically engineered ingredients was in response to consumer concerns).

34. *Id.*

35. *See* Winerip, *supra* note 32 (describing typical complaints about the tomato's lack of flavor).

36. *See* Bruening & Lyons, *supra* note 33, at 7.

37. *See generally, About Monsanto Company,* MONSANTO, https://monsanto.com/company/ (last visited Sep. 28, 2018) (explaining Monsanto, recently acquired by Bayer, was a publicly traded, U.S.-based, agrochemical and agricultural biotechnology corporation).

38. Winerip, *supra* note 32 (suggesting that Monsanto's lack of transparency reduced public confidence in the Flavr Savr tomato).

39. *See* Bruening & Lyons, *supra* note 33 (explaining that a U.K. House of Commons report credited the decline of tomato paste to Dr. Pusztai's research); SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, FIRST REPORT, 1998-9, HC 286, at ¶ 25 (UK); *see also*, Conan Milner, *Top Five GMO Failures*, EPOCH TIMES (Aug. 21, 2013), https://www.theepochtimes.com/top-5-gmo-failures_255547.html (relating the Flavr Savr tomato's demise to Dr. Pusztai's television interview). Dr. Pustzai's published research can be viewed at Stanley W.B. Ewen & Arpad Pusztai, *Effects of Diets Containing Genetically Modified Potatoes Expression* Galanthus nivalis *Lectin on Rat Small Intestine*, 354 THE LANCET 1353 (1999), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(98)05860-7/fulltext.

tomato's GMO designation, and Dr. Pusztai had a very large impact on the public opinion of GE as a whole.[40]

B. Shift in Public Opinion

In 1998, Dr. Pusztai did a television interview on "World in Action" about his research, before his study had been published or peer-reviewed.[41] During the interview, Dr. Pusztai suggested that rats he studied suffered from stunted growth and repressed immune systems resulting from their ingestion of GE potatoes.[42] Due to the incredible buzz caused by the interview, the Director of Dr. Pusztai's home research facility put a hold on Dr. Pusztai's work and inspected his records, finding them incredibly unorganized.[43] An official audit was performed and the committee concluded that Dr. Pusztai's results did not support the conclusion he touted on TV.[44] But the damage was already done.[45]

Today, those who are anti-GE see Dr. Pusztai as "a hero - the scientist who stood up to the establishment and, as a result, had his career squashed at the behest of shadowy forces in the GM industry and the government."[46] Professor Chris Leaver, a GM scientist at Oxford University, theorizes that although "the vast majority of people were somewhat neutral at the time," Dr. Pusztai's statements pushed them off the fence into anti-GE territory.[47] In 1999, the British Royal Society reviewed Dr. Pusztai's data again and reached the same conclusion as the internal audit committee.[48] Even with that conclusion, debate still exists over what Dr. Pusztai's research shows and just how he went wrong.[49]

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40. Bruening & Lyons, *supra* note 33, at 7 (showing that Dr. Pusztai's initial claims were incorrect, but Sainsbury and Safeway still discontinued sale of the Zeneca tomato paste brand); SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, *supra* note 38, at ¶ 22–27.

41. Dr. Nina V. Fedoroff, *Pusztai's Potatoes - is 'Genetic Modification' the Culprit?*, AGBIOWORLD, http://www.agbioworld.org/biotech-info/articles/biotech-art/pusztai-potatoes.html (last visited Sept. 23, 2018).

42. *Id.*

43. *Id.*

44. *Id.*

45. Jeffrey Smith, *Anniversary of a Whistleblowing Hero*, HUFFINGTON POST (Aug. 9, 2010), http://www.huffingtonpost.com/jeffrey-smith/anniversary-of-a-whistleb_b_675817.html (updated Dec. 6, 2017).

46. *Id.*; James Randerson, *Arpad Pusztai: Biological Divide*, THE GUARDIAN (Jan. 15, 2008), https://www.theguardian.com/education/2008/jan/15/academicexperts.highereducationprofile.

47. Randerson, *supra* note 45.

48. Fedoroff, *supra* note 40.

49. *See, e.g.*, Randerson, *supra* note 45 (stating that "newspaper stories generated confusion over the nature of the genetic modification. These articles refer to potatoes modified with a lectin gene from jackbean that is poisonous to mammals. But no one can agree on where this came from. The

C. Benefits

Since the beginning of GE technology, there have been no peer-reviewed studies proving GM products are inherently harmful.[50] Anti-GE advocates still use Dr. Pusztai's research, along with other flawed studies, like the Institute for Responsible Technology's gluten study or Seralini's tumor ridden rats, to call for a permanent moratorium on GE projects.[51] However, countless more studies show GM products are not harmful and can actually be quite beneficial.[52] Part III discusses potential hazards of GMOs in the

misinformation was formalised in a press release issued by the Rowett. James says Pusztai approved it. Pusztai says he was not aware of it until it was published. Either way, the jackbean experiments that never were have proved extremely damaging to Pusztai. Even now, GM scientists dismiss Pusztai's work on the grounds of a supposed schoolboy error: of course the rats suffered, they say, they were being fed potatoes that were genetically modified to produce a poison."); Fedoroff, *supra* note 40 ("The transgenic potato lines [used in the study] were different from each other, as well as from the parental potatoes. A later study on transgenic potatoes came to the same conclusion. Here Pusztai jumped to the conclusion that these differences must be attributable to the fact that the plants were transgenic – and he went public with his conclusion. What he probably didn't know – because he was neither a plant breeder nor a plant biologist – was that the very process through which the plants are put during the introduction of the transgene – culturing through a callus stage and then regeneration of the plant – can cause marked changes in both the structure and expression of genes."); AGRIC. BIOTECHNOLOGY COUNCIL OF AUSTL *Rats and Potatoes: Toxicity Studies and GM Foods* (2012), https://docslide.us/documents/issue-paper-1-rats-and-potatoes-toxicity-studies-and-gm-foods.html (explaining the doubts about Pusztai's research by independent reviewers); Steve Connor, *Science: Pusztai: The Verdict,* INDEPENDENT, (Feb. 19, 1999, 1:02 AM), http://www.independent.co.uk/arts-entertainment/science-pusztai-the-verdict-1071729.html.

50. THE NAT'L ACAD. PRESS, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 236 (2016), https://agbiotech.ces.ncsu.edu/wp-content/uploads/2016/05/NAS-Genetically-Engineered-Crops-Full-Report.pdf?fwd=no.

51. *See e.g.*, Ronnie Cummins, *Hazards of Genetically Engineered Foods and Crops: Why We Need a Global Moratorium*, IN MOTION (Aug. 24, 1999), http://www.inmotionmagazine.com/geff4.html ("A brief look at the already-proven and likely hazards of GE products provides a convincing argument for why we need a global moratorium on all GE foods and crops.").

52. Elizabeth Weise, *Academies of Science Finds GMOs Not Harmful to Human Health*, USA TODAY (May 17, 2016), http://www.usatoday.com/story/tech/2016/05/17/gmos-safe-academies-of-science-report-genetically-modified-food/84458872/; *see e.g.*, Layla Katiraee, *10 Studies Proving GMOs are Harmful? Not if Science Matters*, GENETIC LITERACY PROJECT (Nov. 13, 2015), https://www.geneticliteracyproject.org/2015/11/13/10-studies-proving-gmos-are-harmful-not-if-science-matters/ (stating that "current scientific consensus regarding GMOs remains unchanged: they are safe and do not pose a health risk to humans."); *see e.g.*, Megan L. Norris, *Will GMOs Hurt My Body? The Public's Concerns and How Scientists Have Addressed Them*, HARV. U.: THE GRADUATE SCHOOL OF ARTS AND SCI.: SCI. IN THE NEWS (Aug. 9, 2015), http://sitn.hms.harvard.edu/flash/2015/will-gmos-hurt-my-body/ (finding that GMOs exhibit no toxicity); *see also* Jon Entine, *The Debate About GMO Safety Is Over, Thanks To A New Trillion-Meal Study*, FORBES (Sept. 17, 2014), https://www.forbes.com/sites/jonentine/2014/09/17/the-debate-about-gmo-safety-is-over-thanks-to-a-new-trillion-meal-study/#7719d2d68a63 (explaining that over 2,000 studies document that biotechnology does not pose "an unusual threat to human health . . ."); *see also*, Mark Lynas, *GMO Safety Debate is Over*, CORNELL ALL. FOR SCI. BLOG (May 23, 2016), https://allianceforscience.cornell.edu/blog/2016/05/gmo-safety-debate-is-over/ (discussing the report by the National Academies of Science, Engineering, and Medicine which found no evidence that GE crops were less safe than non-GE crops); Steven Novella, *Séralini Fails Replication*, NEUROLOGICA BLOG

context of each agency's responsibilities in the certification process but, as with most new technologies, there are numerous benefits.[53] For example, about twenty years ago the Ringspot virus was decimating Hawaiian papaya, until a researcher at Cornell University genetically modified the plant using genes from the virus.[54] Golden Rice provides an even more potent example of GM's value because of its potential to solve Vitamin A Deficiency (VAD).[55]

The World Health Organization estimates that VAD affects 250 million preschool children, which can cause poor vision and even blindness.[56] Addressing VAD can reduce child mortality by 23% in the areas that suffer most.[57] This is why the Rockefeller Foundation created and distributed Golden Rice (GM vitamin A-rich rice), using a food product already common in VAD-affected areas to boost vitamin A consumption.[58] Scientists pulled genes from daffodils and a soil bacteria to increase the levels of beta-carotene in the rice, which the human body converts to vitamin A.[59] The Golden Rice project is essentially open source, with the private sector providing free licenses for intellectual property rights and multiple research institutions working together on the project.[60] Even though the project has proven effective and humanitarians such as Bill and Melinda Gates support the product, anti-GE groups such as Greenpeace still scrutinize Golden Rice.[61] Some opponents go so far as to destroy field trials in an effort to stop the plant's approval and production.[62] Golden Rice still awaits commercial

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(June 8, 2018), https://theness.com/neurologicablog/index.php/seralini-fails-replication/ (discussing the continued effect of Séralini's study).

53. *See infra* Part III. Establishment of the Framework (discussing the history of the Coordinated Framework for the Regulation of Biotechnology along with its benefits and drawbacks).

54. Dennis Gonsalves et al., *Transgenic Virus Resistant Papaya*: *From Hope to Reality for Controlling Papaya Ringspot Virus in Hawaii*, APSNET (July 2004), http://oregonstate.edu/instruct/bi430-fs430/Documents-2004/3B-BIOTECH%20METH/Gonsalves-papaya-story-AmPhytopSoc2004.pdf.

55. JORGE E. MAYER ET AL., THE GOLDEN RICE PROJECT 1 (June 17, 2006), http://www.goldenrice.org/PDFs/The_Golden_Rice_Project_Mayer_et_al_2006.pdf.

56. *Micronutrient Deficiencies*, WORLD HEALTH ORGANIZATION, http://www.who.int/nutrition/topics/vad/en/ (last visited Sept. 21, 2018).

57. *Id.*

58. Dan Charles, *In A Grain Of Golden Rice, A World Of Controversy Over GMO Foods*, NPR (Mar. 7, 2013), https://www.npr.org/sections/thesalt/2013/03/07/173611461/in-a-grain-of-golden-rice-a-world-of-controversy-over-gmo-foods.

59. MAYER ET AL., *supra* note 54, at 1–2.

60. *Id.* at 2; *see also* Laura Lloyd, *Golden Rice Still Struggling for Acceptance in Asia*, WORLD-GRAIN.COM (Aug. 30, 2016), https://www.world-grain.com/articles/6975-golden-rice-still-struggling-for-acceptance-in-asia (explaining the company that developed Golden Rice surrendered its intellectual property rights).

61. Amy Harmon, *Golden Rice: Lifesaver?*, N.Y. TIMES (Aug. 24, 2013), https://www.nytimes.com/2013/08/25/sunday-review/golden-rice-lifesaver.html.

62. *Id.*

approval in Asia, even though one bowl could provide up to 60% of a child's recommended daily value of vitamin A.[63] Despite the pushback from anti-GE groups, Golden Rice's benefits have inspired other GE crops, such as biofortified beans, cassava, sweet potatoes, and more, though some biofortified crops are being created through more traditional methods.[64]

GMOs may also be useful in fighting non-native diseases. For example, many scientists believe genetic modification is the only way to save the Florida Orange.[65] When the Asian citrus psyllid (an insect) was brought to the U.S., farmers began losing trees by the grove.[66] The insect causes citrus greening (officially named Huanglongbing), which presents as atrophy in the tree and fruit that never ripens.[67] Due to the differences in California and Florida oranges,[68] 90% of America's juice comes from Florida, and 87% of Florida's citrus is processed into juice concentrate.[69] If Florida oranges die off from greening without a substantial replacement, the U.S. will lose a significant portion of its orange production. The industry's decline has also impacted Florida's culture and economy.[70] Solving greening may not bring Florida's economy back to its previous state, but it could save hundreds of groves and an entire industry otherwise likely to die out.

GMOs can reduce disease in humans as well. Bill Gates has called for more GMOs by investing in projects like Target Malaria.[71] The project intends to GM mosquitoes to reduce fertility, thereby reducing the population

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63. *Id.*; *See* Lloyd, *supra* note 59 (describing that Golden Rice will not be available to farmers anywhere in the world for "at least a couple years"); *see History of the Golden Rice Project*, GOLDEN RICE PROJECT, http://www.goldenrice.org/Content1-Who/who2_history.php (last visited Oct. 9, 2018) (explaining the difficult approval process for Golden Rice).

64. WORLD HEALTH ORG., BIOFORTIFICATION OF STAPLE CROPS, http://www.who.int/elena/titles/biofortification/en/ (last updated Oct. 4, 2018); XiaoZhi Lim, *Biofortification: Is it the Next 'Green Revolution' For More Nutritious Food?*, GENETIC LITERACY PROJECT (June 2, 2017), https://geneticliteracyproject.org/2017/06/02/biofortification-next-green-revolution-nutritious-food/.

65. Paul Voosen, *Can Genetic Engineering Save the Florida Orange?*, NAT'L GEOGRAPHIC (Sept. 13, 2014), http://news.nationalgeographic.com/news/2014/09/140914-florida-orange-citrus-greening-gmo-environment-science.

66. *Id.*

67. *Id.*; *Citrus Greening (Huanglongbing)*, UNIV. OF FLA. CITRUS EXTENSION, http://www.crec.ifas.ufl.edu/extension/greening/index.shtml (last visited Oct. 9, 2018).

68. *California vs Florida Oranges, What's the Difference?*, DAVIDSON BROTHERS (Nov. 26, 2013), http://blog.davidsonbros.com/2013/11/california-vs-florida-oranges-whats.html.

69. *Facts About Florida Oranges & Citrus*, VISIT FLORIDA, http://www.visitflorida.com/en-us/eat-drink/facts-about-florida-citrus-oranges.html (last visited Sept. 25, 2018).

70. Alana Samuels, *Florida Without Oranges*, THE ATLANTIC (Jan. 27, 2015), https://www.theatlantic.com/business/archive/2015/01/florida-without-oranges/384774 (stating that the Florida citrus industry generated one billion dollars less each year between 2007 and 2013).

71. Antonio Regalado, *Bill Gates Doubles His Bet on Wiping Out Mosquitoes with Gene Editing*, MIT TECH. REV. (Sept. 6, 2016), https://www.technology review.com/602304/bill-gates-doubles-his-bet-on-wiping-out-mosquitoes-with-gene-editing/.

of mosquitoes that carry and transmit the disease.[72] GMOs are also known for higher yields and fewer inputs.[73] They can reduce erosion and help feed the growing population.[74] With population estimates reaching nine billion by 2050, something will need to be done to ensure food needs are met worldwide.[75] A solution may come in the form of increased yields or decreased waste but will likely include both.[76]

D. Current Climate

Those who intend to introduce new GM crops are still facing an uphill battle. Anti-GE proponents are so ardent that even after the devastating earthquake in 2010, which killed more than 300,000 people and left over one million homeless, they burned corn and vegetable seeds donated by Monsanto.[77] Protestors questioned the seeds and Monsanto's motives, even though Monsanto claimed to have worked closely with the Haitian Ministry of Agriculture.[78] The Ministry stated that the same seeds and the fungicide coating, meant to protect the seeds during the germination process, were already in use in Haiti.[79] The most outspoken advocates of burning the seeds

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72. *See* Joe F. Aldrich, *The Rise of The Mutants: Obtaining Regulatory Approval for the Release of Genetically Modified Mosquitoes*, 17 COLUM. SCI. & TECH. L. REV. 292, 296 (2016).

73. *U.S. Farmers: GMO Crops Help Reduce Inputs and Enhance Conservation*, THE FOOD DIALOGUES (Dec. 15, 2016), http://www.fooddialogues.com/article/u-s-farmers-gmo-crops-help-reduce-inputs-enhance-conservation/ (discussing farmers' positive experiences with GM crops); U.S. Farmers & Ranchers Alliance, *What are the Benefits of GMOs, Both Today and in the Future?*, THE FOOD DIALOGUES, http://www.fooddialogues.com/article/benefits-gmos-today-future (last visited Oct. 9, 2018).

74. U.S. Farmers & Ranchers Alliance, *supra* note 72.; *see* Anastasia Bondar, *The Promise of GMOs: Conservation Tillage*, BIOLOGY FORTIFIED, (Feb. 19, 2014), https://www.biofortified.org/2014/02/conservation-tillage/ (discussing the benefits of conservation tillage for GMO soybeans).

75. *Benefits of Food & Ag Biotechnology*, COALITION FOR SAFE & AFFORDABLE FOOD, http://coalitionforsafeaffordablefood.org/benefits-of-biotechnology (last visited Sept. 22, 2018); Jonathan Foley, *The Future of Food*, NAT'L GEOGRAPHIC, http://www.nationalgeographic.com/foodfeatures/feeding-9-billion (last visited Sept. 30, 2018).

76. H. Charles J. Godfray et. al., *Food Security: The Challenge of Feeding 9 Billion People*, 327 SCIENCE 812, 813, 815-16 (2010).

77. Gary Dunion, *Aftershock in Haiti*, RED PEPPER (Dec. 28, 2010), https://www.redpepper.org.uk/aftershock-in-haiti/.

78. *Id.*; Beverly Bell, *Haitian Farmers Commit to Burning Monsanto Hybrid Seeds*, THE WORLD POST, http://www.huffingtonpost.com/beverly-bell/haitian-farmers-commit-to_b_578807.html (last updated May 25, 2011).

79. Mica Veihman, *Five Answers on Monsanto's Haiti Seed Donation*, MONSANTO BLOG (May 20, 2010), https://web.archive.org/web/20100924082925/http://monsantoblog.com/2010.05.20.five-answers-monsanto-haiti.

claimed accepting the seeds would irrevocably associate Haitian farmers with multinational corporations.[80]

In fact, the hatred towards GM crops, and Monsanto's association with them, has given rise to groups like March Against Monsanto.[81] These groups use fearmongering and sensationalism to oppose GE projects.[82] This has even led to personal attacks on GE scientists. Dr. Kevin Folta, a researcher at the University of Florida, was verbally flayed in a front-page article for The New York Times.[83] Because of the article and additional harassment, Dr. Folta had to take a hiatus from the public eye.[84] In 2008, the FBI named eco-terrorists and animal rights extremists "one of the most serious domestic terrorism threats in the U.S."[85] Reaching a consensus on anything is difficult when a large portion of stakeholders are waving torches and pitchforks.[86]

Anti-GE activists, which often includes organic farmers, claim that corporations who own GM crop technology will use it to harass farmers through contamination suits.[87] Part of this argument is based on misinformation surrounding a Canadian farmer who sprayed his field to isolate the Roundup Ready Canola that had blown into it.[88] The farmer, Percy

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80. Steve Baragona, *Hungry Haitian Farmers Urged to Burn Donated US Seeds,* VOA NEWS (June 07, 2010 8:00 PM), http://www.voanews.com/a/hungry-haitian-farmers-urged-to-burn-donated-seed-95860699/163933.html.

81. *See* MARCH AGAINST MONSANTO, https://www.march-against-monsanto.com/ (last visited Dec. 9, 2018).

82. Karl Haro von Mogel, Kavin Senapathy, & David Sutherland, *Call For Action: It's Time to March Against the March Against Monsanto*, GENETIC LITERACY PROJECT (Feb. 2, 2015), https://geneticliteracyproject.org/2015/02/02/call-for-action-its-time-to-march-against-the-march-against-monsanto/; *See also Why I'm Joining the March Against Monsanto*, THE RISK-MONGER (May 20, 2016), https://risk-monger.com/2016/05/20/why-im-joining-the-march-against-monsanto (describing tactics used by March Against Monsanto to rally supporters).

83. *Compare* Eric Lipton, *Food Industry Enlisted Academics in G.M.O. Lobbying War, Emails Show*, N.Y. TIMES (Sept. 5. 2015), https://nyti.ms/2kqbjA4, *with* David Kroll, *What the New York Times Missed on Kevin Folta and Monsanto's Cultivation of Academic Scientists*, FORBES (Sept. 10, 2015), https://www.forbes.com/sites/davidkroll/2015/09/10/what-the-new-york-times-missed-on-kevin-folta-and-monsantos-cultivation-of-academic-scientists/#6c25489a619a (arguing against the NY Times article and that Folta's only "crime is that he works and speaks about GMOs.").

84 . Kevin M. Folta, FACEBOOK (Nov. 4, 2015), https://www.facebook.com/kmfolta/posts/899781960100117. "Additional harassment" includes threats of violence to his family and his laboratory. Kroll, *supra* note 82.

85. *Putting Intel to Work*, FEDERAL BUREAU OF INVESTIGATION (June 30, 2008), https://archives.fbi.gov/archives/news/stories/2008/june/ecoterror_063008.

86. Figuratively, of course.

87. Dan Charles, *Top Five Myths of Genetically Modified Seeds, Busted*, NPR (Oct. 18, 2012), http://www.npr.org/sections/thesalt/2012/10/18/163034053/top-five-myths-of-genetically-modified-seeds-busted; *See e.g.* Carey Gillam, *Organic Growers Lose Decision in Suit Versus Monsanto Over Seeds*, REUTERS (June 10, 2013: 2:46 PM),https://www.reuters.com/article/us-monsanto-organic-lawsuit/organic-growers-lose-decision-in-suit-versus-monsanto-over-seeds-idUSBRE9590ZD20130610 (describing farmers' efforts to stop Monsanto from filing contamination suits).

88. Charles, *supra* note 86.

Schmeiser, later harvested those plants for the next year's seed.[89] Schmeiser planted a patented seed without paying the licensing fees and used contamination as an excuse to evade responsibility.[90] Though Monsanto has been heavy-handed in going after patent law violators, the stories about the corporation are generally significantly exaggerated.[91]

The misinformation spread about GMOs is a large reason for the opposition by farmers and legislators of GMO labeling.[92] As seen with the Flavr Savr tomato, GMO labeling issues have the potential to destroy a product.[93] The hazards of GMO labeling are also supported by companies seeing success from removing GM products from their lineup and publicizing it.[94] Both sides of the dispute have taken the position that consumers cannot listen to reason and only respond to sensationalism, which has resulted in more sensationalism from anti-GE groups and little communication from pro-GE groups.[95]

Public opinion polls, however, show that the public is mostly ambivalent towards GMOs.[96] Most members of the public lack knowledge about the science behind GMOs and are concerned about its "unnaturalness," but they accept there is inherent risk in everything and would like more honest appraisals of the risks in GMO products.[97] Groups like the Coalition for Safe Affordable Food are working toward a middle ground. They propose a label that allows consumers to learn more about the source of their food but avoids the stigma of having a GM label.[98] The approval process for GM products

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89. *Id.*

90. *Id.*

91. *See* Gillam, *supra* note 86 (describing Monsanto's "reputation for zealously defending [its] patents").

92. *See e.g.*, Jeff Apthorp, *Why We Don't Feed Our Animals GMO Feed – Part 3*, SEVEN SONS FARM, https://sevensons.net/blog/why-we-don-t-feed-our-animals-gmo-feed-part 3?fb_comment_id=1108110275878623_1165280126828304#f5107588f27c3c (last visited Sep. 29, 2018) (citing Séralini's study as one of the reasons the farm does not use GMO feed); Rangel, *supra* note 3.

93. *See supra* Section II.b, *Shift in Public Opinion*; *see also* Chassy, *supra* note 2, at 171 (explaining McDonald's pulled GM potatoes for fear of consumer rejection).

94. Weise, *supra* note 51; *see e.g.*, *Chipotle (CMG) Eliminates Additives from its U.S. Food Menu*, ZACKS (Mar. 29, 2017), https://www.zacks.com/stock/news/254543/chipotle-cmg-eliminates-additives-from-its-us-food-menu (describing how Chipolte no longer uses GMO ingredients or additives and how their stock price is recovering); Maggie Hennessy, *Why Restaurants are Still Saying No to GMO*, QSR (Jan. 2017), https://www.qsrmagazine.com/health-wellness/why-restaurants-are-still-saying-no-gmo.

95. Cyrus Martin, *The Psychology of GMO*, 23 CURRENT BIOLOGY (SPECIAL ISSUE), no. 9, 2008, at R356, R356.

96. Claire Marris, *Public views on GMOs: Deconstructing the Myths*, 2 EMBO REP. 545, 545 (2001); HOLLY RHODES & KEEGAN SAWYER, PUBLIC ENGAGEMENT ON GENETICALLY MODIFIED ORGANISMS 6 (2015).

97. *Id.*

98. COAL. FOR SAFE & AFFORDABLE FOOD, National Biotech Disclosure Law, http://coalitionforsafeaffordablefood.org/common-sense-solution (last visited Oct. 9, 2018).

should provide the same benefits. It should allow concerned citizens to be involved in, or at least kept abreast of, the process while providing an honest, easy to digest assessment of a product's risks as compared to the current options. Part III of this paper proposes a new framework to meet the needs of consumers, producers, and innovators.

II. ESTABLISHMENT OF THE FRAMEWORK

The Coordinated Framework for Regulation of Biotechnology (Coordinated Framework or the framework), established under President Reagan in 1986, was meant to be a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."[99] The result, however, has been less than desirable. John Charles Kunich, currently a lecturer in the Department of Political Science and Public Administration at the University of North Carolina at Charlotte, explained:

> the environmental risks posed by genetically engineered organisms are not addressed in a coherent manner. There is no single federal statute that governs the subject matter. The regulatory regime that does exist only confronts a few aspects of the issue, and then only in a piecemeal, haphazard fashion. And there is no federal agency with overarching responsibility for the topic; rather, multiple agencies are charged with monitoring disparate portions of it, with no effective means for ensuring comprehensive and consistent coverage. Consequently, there are sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment. Additionally, proponents of new and potentially important genetically engineered "products" are forced to navigate a confusing maze of agencies and statutes, with resulting inefficiency and needlessly steep economic and opportunity costs and delays for industry and the general public.[100]

Professor Kunich later accepted this disorder due to the relative newness of GE,[101] but more than 15 years have passed since Professor Kunich's paper,

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99. Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302(proposed June 26, 1986).

100. John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823 (2001).

101. *Id.*

and the chaos that is the Coordinated Framework should no longer be acceptable.

When the Coordinated Framework was originally introduced, it was expected that the process would evolve as technology did. However, the working group that created the framework concluded that the current laws covered most of the regulatory basis necessary at the time.[102] The 1992 Update to the Coordinated Framework emphasized that new products should not be segregated based on the technology used to produce them, but that they should be evaluated based on their individual characteristics and corresponding potential hazards.[103] In reality, each product's intended use determines its approval process.[104] Despite stated intentions, we have essentially segregated GE products because non-GE products generally do not require government approval to be marketed and sold.[105]

The last update to the framework occurred after the Executive Office of the President released a memorandum in July 2015.[106] The memorandum directed the appropriate agencies to clarify their roles and develop a long-term strategy for future GE products.[107] The improvements were meant to:

- maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and

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102. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23302-23303.

103. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6,753 (Feb. 24, 1992).

104. *Id* at 6,757; *but see* MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 277 (1st ed. 2009) (asserting that GE products in the EU are regulated based on the technology used to produce them and not their characteristics).

105. *Cf.* GARY RUSKIN, SEEDY BUSINESS: WHAT BIG FOOD IS HIDING WITH ITS SLICK PR CAMPAIGN ON GMOS 15-16 (Jan. 2015), https://www.usrtk.org/seedybusiness.pdf (discussing the approval of GMO food products).

106. Exec. Office of the President, Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products 3–4 (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf [hereinafter *July 2015 EOP Memorandum*].

107. *Id.* at 4.

- promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.[108]

The memorandum also stated that the Obama Administration "sought regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers."[109] The Update to the Coordinated Framework,[110] published in 2017, contains no real changes or "updates." It is simply a guidance document.[111] The Update provides examples, so innovators can see who will review their products and consumers know what products each agency must review.[112] Furthermore, the third-party study on the future of biotechnology, conducted as a requirement of the President's memorandum, only covers GE crops.[113] However, the FDA had already assessed several GE animals by the time of the President's memorandum.[114]

Virtually every legal article written on the framework agrees it is confusing, unacceptably slow, and inadequate to address future technologies.[115] The Coordinated Framework will need a major overhaul to

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108. *Id.* at 3.

109. *Id.* at 2.

110. MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY (Jan. 4, 2017), https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf [hereinafter 2017 UPDATE] (explaining the purpose of and distribution of agency regulation over biotechnology).

111. Roger R. Martella, Jr., *Agency Regulation Through Guidance Documents*, SIDLEY AUSTIN LLP (last visited Sept. 21, 2018), http://masonlec.org/site/rte_uploads/files/AGENCY%20REGULATION%20THROUGH%20GUIDANCE%20DOCUMENTS.pdf (explaining that agency guidance documents, though not legally binding, are a powerful compliance tool because of an agency's enforcement power, as they "set standards for agency implementation and thus can function as de facto regulations.").

112. 2017 UPDATE, *supra* note 109, at 9, tbl. 1.

113. July 2015 EOP Memorandum, *supra* note 105, at 5; THE NAT'L ACAD. PRESS, *supra* note 49, at xiii.

114. *See infra* notes 118–19 and accompanying text.

115. E.g., Michael P. McEvilly, Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon, 11 DUKE L. & TECH. REV. 413 (2012); Michael Bennet Homer, Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology, 45 COLUM. J.L. & SOC. PROBS. 91, 99-101 (2011); Lars Noah, Whatever Happened to the "Frankenfish"?: The FDA's Foot-Dragging on Transgenic Salmon, 65 ME. L. REV. 606, 607, (2013); Maria R. Lee-Muramoto, Reforming the "Uncoordinated" Framework for Regulation of Biotechnology, 17 DRAKE J. AGRIC. L. 311, 343-44 (2012); Dorothy W. Bisbee, Note, Preparing For a Blue Revolution: Regulating The Environmental Release of Transgenic Fish, 12 VA. ENVTL. L.J. 625, 656 (1993); Holly Beth Frompovicz, Comment, A Growing Controversy: Genetic Engineering in Agriculture, 17 VILL.

align with current technologies and stakeholder expectations. However, we must first understand how the framework currently works and what each piece is meant to accomplish. This section will discuss each agency's part in the framework as well as each agency's statutory territory, what it does well, and what it could do better.

A. FDA

The FDA's Plant Biotechnology Consultation Program evaluates GM crops only on a voluntary basis.[116] Though "industry considers consultation with the FDA to be a mandatory process" and the FDA has reviewed over 150 varieties through the program, it remains a voluntary resource for interested developers.[117] In creating the program, the FDA concluded that GM crops are not materially different from conventional crops and "companies developing new ingredients, new versions of established ingredients, or new processes for producing a food or food ingredient must make a judgment about whether the resulting food substance is a food additive requiring premarket approval by FDA."[118]

The FDA also declined to regulate the first GM animal available in the United States, the GloFish, because it was not intended to enter the food supply.[119] The first GM animal to go through the formal approval process was a goat in 2009.[120] The goat was engineered to create an anticoagulant, ATryn, in its milk.[121] Since then, the FDA has approved applications for a

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ENVTL. L.J. 265, 277-78 (2006); Gregory Jaffe, Symposium: Remarks on Regulating Genetically Modified Foods in the United States, 10 RICH. J.L. & TECH. 8 (2003).

116. *How FDA Regulates Food from Genetically Engineered Plants*, U.S. FOOD &. DRUG ADMIN, https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm461831.htm (last visited Sep. 28, 2018).

117. *Id.*; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 71 (2004); 2017 UPDATE, *supra* note 109, at 17 ("[T]o the best of FDA's knowledge, all GE food crops intended for marketing have been the subject of a consultation or other relevant premarket processes prior to marketing.").

118. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992).

119. *Statement Regarding Glofish*, *supra* note 9 (explaining the F.D.A. has no reason to regulate aquarium fish because the fish are not used as food and pose no risk to the environment).

120. *Genetically Engineered Animals: General Q&A*, U.S. FOOD & DRUG ADMIN (archived 2017), https://wayback.archive-it.org/7993/20170111175109/http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm [hereinafter *F.D.A. General Q&A*].

121. *Id.*; FOOD AND DRUG ADMINISTRATION, US PACKAGE INSERT, ANTITHROMBIN (RECOMBINANT) ATRYN FOR INJECTION (2009).

faster-growing GM salmon and a chicken that lays eggs containing an enzyme used for treating lysosomal acid lipase deficiency.[122]
The application for AquAdvantage salmon was filed in 1995, and though it has technically been approved, the process still is not over.[123] In November 2015, the FDA determined that AquAdvantage salmon are safe to eat.[124] However, AquaBounty Technologies, owner of AquAdvantage salmon, cannot import their fish into the United States until the FDA finalizes its labeling requirements as required by Congress.[125]

The FDA gets its statutory authority from the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA).[126] The FDA classifies GM animals as "new animal drugs" under the FDCA, asserting that an "rDNA construct in a GE animal that is intended to affect the structure or function of the animal, regardless of the intended use of products that may be produced by the GE animal, meets the [FDCA] drug definition."[127] These provisions were added to the FDCA in 1938, well

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122. *F.D.A. General Q&A*, *supra* note 119; *FDA Update: FDA Approves First Drug to Treat Rare Enzyme Disorder in Infants, Children*, AM. ACAD. OF PEDIATRICS (Feb. 10, 2016), http://www.aappublications.org/news/2016/02/10/FDAUpdate021016.

123. AQUABOUNTY TECHNOLOGIES, *Chronology of AquAdvantage® Salmon and AquaBounty Technologies* (last visited Sept. 21, 2018), https://www.aquabounty.com/wp-content/uploads/2014/01/Chronology-of-AquAdvantage-Salmon-F1.pdf.; Brady Dennis, *FDA Bans Imports of Genetically Engineered Salmon — for Now*, WASH. POST (Jan. 29, 2016), https://www.washingtonpost.com/news/to-your-health/wp/2016/01/29/fda-bans-imports-of-genetically-engineered-salmon-for-now/?utm_term=.ca4ec73624d2; *Import Alert 99-40: Genetically Engineered (GE) Salmon*, U.S. FOOD & DRUG ADMIN (Apr. 30, 2016), https://www.accessdata.fda.gov/cms_ia/importalert_1152.html; *AquAdvantage Salmon Approval Letter and Appendix*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm466214.htm (last updated Dec. 1, 2017) [hereinafter *Approval Letter*].

124. *FDA Has Determined That the AquAdvantage Salmon is as Safe to Eat as Non-GE Salmon*, U.S. FOOD & DRUG ADMIN., https://wayback.archive-it.org/7993/20180423201237/https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm (last updated Dec. 13, 2017); Dennis, *supra* note 122; *see* Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry, 80 Fed. Reg. 73193, 73194 (Nov. 24, 2015) (providing guidance on whether foods derived from GE plants require labeling by the FDA). Just before this article's publication, the FDA deactivated its import alert against the AquAdvantage salmon, which means "AquAdvantage salmon eggs can now be imported to the company's contained grow-out facility in Indiana to be raised into salmon for food." *Statement from FDA Commissioner Scott Gottlieb, M.D., on continued efforts to advance safe biotechnology innovations, and the deactivation of an import alert on genetically engineered salmon*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632952.htm (last updated Mar. 10, 2019).

125. *Id.*

126. 21 U.S.C. § 393 (2012); 42 U.S.C. § 262(k)(5)(B) (2012).

127. The FDCA defines drug as:

> "The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or

before the invention of the technology the act currently regulates.[128] Nevertheless, the FDA is empowered by: (1) its ability to remove dangerous food from market; and (2) its responsibility to evaluate food additives for pre-market approval.[129] "[A] substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) for the intended use or is otherwise excluded (e.g., a pesticide, the safety of which is overseen by EPA, or a new animal drug, the safety of which is addressed by the new animal drug approval provisions of the [FDCA])."[130] Food additives are subject to the National Environmental Policy Act (NEPA), which requires environmental impact studies (EIS) and toxicological studies.[131]

GM animals must go through the New Animal Drug Application (NADA) process before they are marketed.[132] The FDA's Center for Veterinary Medicine (CVM) conducts the approval process, evaluating "the safety of any food derived from the GE animal, … the safety of the article to the target animal," and "whether the claims made by the sponsor are valid."[133] Under the FDCA, the FDA has 180 days to approve or disapprove a NADA, unless they have agreed to a different time period with the applicant.[134] As discussed later in this section, the FDA does not follow this rule for most GMO applications. Once approved, the FDA posts a notice to the Federal Register as well as the agency's website.[135] Post-approval, sponsors have record-keeping duties and the FDA has monitoring

> official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."

21 U.S.C. § 321(g)(1) (2012). (supporting that GM animals fall under provision C); F.D.A., GUIDANCE FOR INDUSTRY 187, REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 4–5 (Sept. 18, 2008), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052463.pdf.

128. 21 U.S.C. § 360b; FDA New Animal Drugs, 21 C.F.R. §§ 510, 514 (1976).

129. 21 U.S.C. §§ 348(c), 350h(d), 350*l*(a) (2012).

130. 2017 UPDATE, *supra* note 109, at 16 (citing 21 U.S.C. 321(s)).

131. *Id.*; The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. §§ 4321-4370 (2012); Margaret Rosso Grossman, *Genetically Engineered Animals in the United States: The AquAdvantage Salmon*, 11 EUR. FOOD & FEED L. REV. 190, 192 (2016).

132. *See e.g.*, *AquAdvantage Salmon - Response to Public Comments on the Environmental Assessment*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm466220.htm. (last updated Nov. 27, 2018) (responding to comments submitted on the EA of the AquAdvantage Salmon's NADA).

133. 2017 UPDATE, *supra* note 109, at 19.

134. 21 U.S.C. § 360b(c).

135. 21 U.S.C. § 360b(i); 2017 UPDATE, *supra* note 109, at 19-20.

responsibilities.[136] Medical products produced by GM animals fall under the PHSA and go through the same process as most other drugs and medical devices.[137]

During the evaluation process, the FDA looks at: (1) the description of the GM animal; (2) the genomic alteration and how it is created; (3) how the genomic alteration is passed from one generation to another; (4) phenotypic characteristics of the GM animal; (5) whether the genomic alteration is stable across generations; (6) any environmental impacts and the safety of foods derived from GM animals; and (7) a demonstration of the claimed GE animal.[138] Though the FDCA does not explicitly call for FDA review of environmental effects, NADA requires an environmental assessment (EA) that is conducted by the applicant.[139] In the case of AquAdvantage salmon, environmental concerns included the likelihood of escape, likelihood of survival after escape, possibility of reproduction after escape, and consequences to the environment of a potential escape.[140] However, there was low likelihood of escape or reproduction because the modification rendered only female salmon infertile and AquaBounty grew the salmon in landlocked pens. Therefore, the FDA made a finding of no significant impact (FONSI).[141]

Applicants are also required to submit reports of all clinical studies, including the individual data sets.[142] Test results for GE animal products include information on toxicity and any changes in the genomic alteration over generations or its phenotypic expression over time.[143] Post-approval, applicants are required to submit any information that may indicate their approval should be suspended or withdrawn.[144]

While the FDA has statutory authority to regulate foods and pull hazardous products from market, it does not have statutory authority over

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136. 2017 UPDATE, *supra* note 109, at 20.

137. *Id.*

138. *Id.* at 19.

139. New Animal Drug Applications, 21 C.F.R. § 514.1(b)(14) ((1976); 21 C.F.R. § 25.40(b) (2016); *AquAdvantage Salmon*, *supra* note 130 ("NEPA requires that FDA consider the environmental impacts of any "major federal action" that it takes. 42 U.S.C. § 4332(c). Approval of a new animal drug application is a 'major federal action.' ").

140. *Questions and Answers on FDA's Approval of AquAdvantage Salmon*, U.S. FOOD & DRUG ADMIN., https://web.archive.org/web/20170506025118/https://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm473237.htm (last updated Dec. 21, 2015).

141. *Id.*

142. Federal Food, Drug, and Cosmetic Act § 512(b), *as codified* 21 U.S.C. § 360b(b).

143. F.D.A. GUIDANCE FOR INDUSTRY, *supra* note 125, at 19–23.

144. 21 C.F.R. §§ 510.300(b), 514.80 (1976); FDA GUIDANCE FOR INDUSTRY, *supra* note 125, at 24–25.

meat and poultry.[145] The USDA is the agency responsible for ensuring the safety of meat and poultry, leaving milk and in-shell eggs the only animal food products under FDA purview.[146] The FDA relies on the section of the FDCA which reads, "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[147] However, the approval process examines the product of the modification (the animal) not the "article" performing the modification (the GE process).[148] So the FDA arguably stretched the definition of an animal drug in order to gain oversight, which is interesting given the FDA's program for regulating GM crops is voluntary, but not all that surprising given the FDA has a "history of creatively interpreting its statutory authority to regulate novel technologies."[149] Lars Noah argues the transgenic salmon gene to animal drug analogy is not implausible, but other scholars recognize the hypocritical nature of the FDA's decisions in regulating GE products.[150] The FDA also elected to evaluate the environmental effects of GM animals, even though the EPA is supposed to be an integral part of the framework and have statutory authority over the AquAdvantage salmon's approval.[151]

The FDA effectively made themselves the go-to agency for approving GM animals, even though the EPA and USDA also have jurisdiction.[152] A cursory Google search for "USDA AquAdvantage salmon" or "EPA AquAdvantage salmon" brings up reports from only the FDA. Additionally, the only animal example of the eight used in the Update to the Coordinated

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145. 21 U.S.C. § 393 (2012) (listing the duties of the FDA); MOU Between FDA and FSIS Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in Production of Meat and Poultry Products, 65 Fed. Reg. 33,330, 33,3331 (May 23, 2000) (effective Jan. 31, 2000).

146. 21 U.S.C. § 451 (2012); 21 U.S.C. § 679 (a), (2012); Egg Products Inspection Act, 21 U.S.C. § 1031 (2012); *See What FDA Does and Does Not Regulate*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm374203.htm#Milk__Eggs__Meat__and_Poultry_ (last updated Oct. 19, 2017) (explaining the distribution of regulatory authority of milk, eggs, meat, and poultry).

147. 21 U.S.C. § 321 (g) (1) (c) (2012).

148. 21 U.S.C. § 360 (b) (2012).

149. Noah, *supra* note 114, at 611–12.

150. *Id.* at 612; *See generally* Lee-Muramoto, *supra* note 114, at 321 (describing instances where the FDA decided to either waive or execute its statutory authority).

151. *See* U.S. FOOD & DRUG ADMIN., AQUADVANTAGE® ENVIRONMENTAL ASSESSMENT (2015), https://www.fda.gov/downloads/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm466218.pdf; *See infra* Part III(c). Establishment of a Framework: EPA.

152. *See* 2017 UPDATE, *supra* note 109, at 3 (designating the EPA, USDA, and FDA as the primary regulatory agencies); *See* 2017 UPDATE, *supra* note 104, at 8 (indicating that the regulating agencies should operate in "an integrated and coordinated fashion" when regulating GM animals); *See* 2017 UPDATE, *supra* note 104, at 18 ("FDA regulates GE animals under the new animal drug provisions of the FD&C Act and the FDA's implementing regulations.").

Framework is a hypothetical rabbit that produces insulin.[153] This chosen example is firmly within the FDA's jurisdiction due to its medical product purpose. Under "II. Which agencies have oversight and why", the only agency mentioned is the FDA.[154] However, the USDA has a statutory duty to ensure animal health, and logically the EPA is the best agency to evaluate the possible environmental effects from the animal's production or its possible escape from containment.[155] The entire purpose of this update seems to be clarification, yet it lacks an example catering to GM food animals. This is extremely disappointing given the agency taking charge of biotechnology regulation just underwent the review process for a GM food animal and knows more are on the way.[156] Most of the other examples used in the update are GM crops, which are only voluntarily regulated under the FDA.[157] Maybe this is a sign that the FDA is not certain how to go about the GM animal approval process, but that means it is the perfect time to reorganize.

1. Problems and Abilities

As noted above, the approval process for AquAdvantage salmon took a very long time.[158] Some have argued the delay was due to politics, pointing out that the FDA issued a positive draft EA in 2010 and virtually the same draft EA two years later, before finally approving the application in 2015.[159] No matter the reason, the extensive amount of time needed to get an application approved has severe consequences, and violates the rule set out in the FDCA requiring that the Secretary of Health and Human Services review applications within 180 days.[160] The AquAdvantage salmon was stuck in the middle of confusing bureaucracy for more than two decades.[161] Despite AquaBounty's optimism, its losses continue to grow and a large portion of the losses can be accredited to legal fees related to the FDA's

153. 2017 UPDATE, *supra* note 109, at 49 (explaining that the insulin purified from GE rabbit milk is regulated as a human drug under the FDA Center for Drug Evaluation and Research).

154. *Id.*

155. *See infra* Part III (b). Establishment of a Framework: USDA.

156. *Genetically Engineered Animals: General Q&A*, *supra* note 119 (noting that "[m]any kinds of GE animals are in development.").

157. 2017 Update, *supra* note 105, at 39–51 (providing hypothetical case studies for corn, a plum, a canola, a rose, a two microbial pesticides, and algae).

158. *See* AQUABOUNTY TECHNOLOGIES, *supra* note 122 (discussing the chronology of AquAdvantage Salmon approval).

159. Noah, *supra* note 14, at 606–607; *see* Entine, *supra* note 50 (explaining public perception over GMO foods remains poor even though over 2,000 studies documented that biotechnology does not pose an unusual threat to human health).

160. 21 U.S.C. § 360b(c) (2012).

161. *See AQUABOUNTY* TECHNOLOGIES, *supra* note 122 (explaining the approval process from 1989-2013).

approval.[162] Additionally, AquaBounty's patent on the AquAdvantage salmon (issued August 13, 1996) expired well before the FDA published its incomplete approval.[163] Patent law provides for the extension of a patent if the product is kept off the market by a regulatory review during the patent's valid life, but the AquaBounty patent did not receive this privilege.[164] AquaBounty may not have known about the statute or they may have decided not to submit an extension application. Even still, patents can only be extended once and for no more than 14 years or half the time between the submission of a NADA and the beginning of an EA, whichever is less.[165] The statute governing patent extension assumes the product in question completed the approval process and is on the market. In the case of the AquAdvantage salmon, an extension would have been virtually useless. Our patent system cannot "promote the Progress of Science" if an innovator's entire term of exclusivity is eaten up by a flawed approval process.[166]

The approval process also receives complaints for lack of transparency. The Trade Secrets Act prohibits the FDA from disclosing information during the NADA process.[167] The FDA cannot even disclose that an application has been filed, unless the company has already told the public.[168] Though the FDA should always be required to protect a company's intellectual property, the NADA regulations were implemented in 1975 and therefore were not meant to encapsulate GE plants and animals.[169] The FDA did update the NADA provisions,[170] but the AquAdvantage application process demonstrates that the NADA approval process is not adequate to address all interests.[171]

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162. *Optimism despite mounting losses for GM salmon firm*, THE FISH SITE (Mar. 16, 2017), http://www.thefishsite.com/fishnews/28938/optimism-despite-mounting-losses-for-gm-salmon-firm; *AquaBounty's losses widen as uncertainty remains over getting product to market*, UNDERCURRENT NEWS (Mar. 17, 2017), https://www.undercurrentnews.com/2017/03/17/aquabountys-losses-widen-as-uncertainty-remains-over-getting-product-to-market.

163 . *Compare* 35 U.S.C. § 154 (a) (2) (2012) (indicating patent terms end 20 years from the filing date) *with* U.S. Patent No. 5,545,808 (filed Mar. 10, 1994), *and* APPROVAL LETTER, *supra* note 122 (explaining that because the patent was filed March 10, 1994, it expired on March 10, 2014, which was a year before the FDA approved AquAdvantage Salmon).

164. 35 U.S.C. § 156 (a) (2012); *see* APPROVAL LETTER, *supra* note 122 (approving AquAdvantage Salmon a year after the patent expired, and failing to discuss 35 U.S.C. § 156(a) privilege).

165. 35 U.S.C. § 156(c) (2012).

166. U.S. CONST. art. I, § 8, cl. 8.

167. 21 U.S.C. § 331(j) (2012); 18 U.S.C. § 1905 (2012); 21 C.F.R. § 514.11.

168. 21 U.S.C. § 331.

169. 21 C.F.R. § 510; Animal Drug Procedure: Reorganization and Republication, 40 Fed. Reg. 13,802 (Mar. 27, 1975).

170. *See generally* New Animal Drug Applications, 74 Fed. Reg. 54,749, 54,751 (Oct. 23, 2009).

171. *See* Chris D'Angelo, *FDA Sued Over Approval of Genetically Engineered Salmon*, HUFF POST (Mar. 31, 2016), http://www.huffingtonpost.com/entry/fda-sued-over-genetically-engineered-

Under the Coordinated Framework, the FDA is supposed to work with other agencies to conduct its review.[172] In fact, the FDA is required by law to consult with the National Marine Fisheries Service (NMFS) "to produce a report on any environmental risks associated with genetically engineered seafood products."[173] The FDA also must consult with the Fish and Wildlife Service (FWS) if an application's approval may affect an endangered species.[174] Though many believed the FDA failed its duty to consult the NMFS during the AquAdvantage approval process,[175] the FDA claims it "consulted with FWS and the [NMFS] and shared its 'no effect' determination with them."[176] The FDA eventually "met with NMFS, answered its questions, and, consequently, neither agency objected to FDA's 'no effect' determination."[177] However, this hardly qualifies as consulting with the NMFS to create a report. The FDA created a report and asked the NMFS to rubber-stamp it. While the FDA may have conducted an adequate environmental review, a true consultation would go a lot further to assuage public fear.

Arguably, the FDA also lacks the expertise to consistently conduct comprehensive evaluations of GE animal applications. Before the introduction of GM animals the FDA regularly reviewed animal drugs, but "conventional animal drugs do not cause animals to have permanent, inheritable genetic alterations."[178] Also, the FDA generally managed the growth of animals in a laboratory environment, whether for testing, drug production, or medical device purposes.[179] While the USDA has regulated domestic livestock since its inception, the regulation of livestock grown in

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salmon_us_56fd75f7e4b083f5c60730bc (reporting over a dozen fishing and environmental groups are suing the FDA to block the approval of genetically modified salmon).

172. 2017 UPDATE, *supra* note 109, at 36 (explaining that the Coordinated Framework tasks the FDA, EPA and USDA with ensuring the safety of biotechnology products).

173. 21 U.S.C. § 2106 (2012).

174. 16 U.S.C. § 1536(a)(2) (2012).

175. Homer, *supra* note 114 at 115; Complaint for Declaratory & Injunctive Relief at 3, Inst. For Fisheries Res. v. Burwell, No. 3:16-cv-01574-VC (N.D. Cal. Mar. 30, 2016).

176. *AquAdvantage Salmon – Response to Public Comments on the Environmental Assessment*, FDA (Jan. 26, 2018, 1:05pm), https://wayback.archive-it.org/...rinary/DevelopmentApprovalProcess/GeneticEngineering/%20GeneticallyEngineeredAnimals/ucm466220.htm; FDA, *supra* note 142 at 156-57.

177. FDA, *supra* note 164.

178. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 116 at 120.

179. *See Why are Animals Used for Testing Medical Products?, About FDA, Transparency*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/aboutfda/transparency/basics/ucm194932.htm (last updated Aug. 22, 2018); *Product Classification: Medicinal Leeches*, *Medical Devices, Databases*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=nrn (last updated Dec. 10, 2018).

traditional livestock facilities is new to the FDA.[180] Even a former FDA official felt that, in reference to a mosquito application, "[w]ithout relevant expertise, not surprisingly the FDA has been ill-equipped to review the application expeditiously, and especially to fulfill the requirements of the National Environmental Policy Act, which mandates that such approvals take into consideration possible environmental impacts."[181] His concern is shared by many, including the National Research Council.[182] The FDA has shown that it is unwilling to fully incorporate other agencies in the review process. Not only is this dangerous, as important factors in the evaluation may be missed, but it goes against the intent behind the creation of the framework.[183]

Although the FDA has many faults and the Coordinated Framework is incredibly confusing, the FDA is attempting to help applicants navigate the process. However, this is limited to just the FDA's requirements, so applicants are virtually on their own in attempting to meet other agencies' requirements. To assist applicants, the FDA assigns one project manager to each applicant.[184] The project manager is available to answer questions about the process and assist the applicant in setting a schedule for submissions.[185] It is important to note though that there is no mention of assigned project managers in the 2017 Update to the Coordinated Framework. Innovators would likely be more comfortable with the process if they knew the FDA

. *See History of APHIS*, U.S. DEP'T. OF AGRIC., https://www.aphis.usda.gov/aphis/banner/aboutaphis/SA_APHIS_History (last updated Aug. 3, 2015); Christopher Doering, *FDA Issues Rules for Genetically Modified Animals*, REUTERS (Sept. 18, 2008 3:12 PM) https://www.reuters.com/article/us-food-modified-fda/fda-issues-rules-for-genetically-modified-animals-idUSN1839524720080918 (discussing the FDA's authority to regulate GE animals under the FDCA).

181. John J. Cohrssen & Henry I. Miller, *We Can Beat Zika and Malaria--If the FDA Allows*, FORBES (Jan. 29, 2016) https://web.archive.org/web/20160215112834/http://www.forbes.com/sites/henrymiller/2016/01/29/eliminating-zika-and-malaria-will-require-real-leadership-and-more-responsive-regulation/amp.

182. NATN'L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 114 (2002); PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 116 at 121, 142; Letter from Congressman Peter DeFazio, et al. to Margaret Hamburg, M.D., Comm'r of the Fed. Drug Admin., (Sept. 28, 2010), *available at* http://defazio.house.gov/media-center/press-releases/house-urges-fda-to-protect-american-consumers-and-the-environment-from.

183. *See generally* Homer, *supra* note 107 at 100.

184. Alia Albrecht, Leader of Project Management Team, U.S. Food & Drug Admin, ONADE Project Managers, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CVM/WhatWeDo/UCM398005.pdf (last visited Sept. 21, 2018); *Office of New Animal Drug Evaluation*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/AboutFDA/CentersOffices/%20OfficeofFoods/CVM/WhatWeDo/ucm077923.htm (last visited Apr. 30, 2017); Angela K. S. Clarke, DVM, U.S. Food & Drug Admin., Commc'ns with ONADE 4, http://c.ymcdn.com/sites/www.aavpt.org/resource/resmgr/imported/10Clarke.pdf (last visited Oct. 9, 2018).

185. Clarke, *supra* note 172, at 5.

assigns a point-of-contact to help each applicant with all of their FDA applications.

B. USDA

The USDA has statutory authority under the Animal Health Protection Act (AHPA) and the Plant Protection Act (PPA) to regulate GM products which may, as the names suggest, have an effect on plant or animal health.[186] Specifically, the USDA may regulate anything that is a pest to, or may cause diseases in, livestock and anything considered a plant pest or noxious weed.[187] The Animal and Plant Health Inspection Service (APHIS) requires developers to submit petitions for nonregulated status to APHIS before transporting or releasing GMOs.[188] In the case of non-animal applications, APHIS may make a finding for nonregulated status, in which there are no post-approval requirements, or it may provide a permit and place marketing and release requirements on the organism.[189]

During the application process, APHIS is required to evaluate environmental impacts and provide comment opportunities similar to the FDA; comments are accepted from the public after a draft EA has been published in the Federal Register.[190] In 2012, APHIS updated its commenting opportunities, providing the public a chance to comment on completed petitions before APHIS begins the EA process.[191] Along with the publication of a draft EA, APHIS sometimes includes notices of public meetings where concerned citizens can voice their thoughts in person.[192] If public comments raise sufficient concern, APHIS will prepare an EIS, which is more detailed than an EA, and the public may have up to three more chances to comment.[193] The APHIS website provides a listing of applications and guidance for developers.[194] APHIS also provides an "Am I Regulated?" service, which allows developers to determine whether their products fall under APHIS's authority.[195] In 2017, APHIS published a proposed rule expanding the list of exempted products, but "plants with traits that [have not] already been

186. 7 U.S.C. §§ 8301-22; 7 U.S.C. §§ 7701-86.
187. 2017 UPDATE, *supra* note 104, at 23.
188. *Id.* at 22-3.
189. *Id.* at 24.
190. *Id.* at 23.
191. *Id.* at 25.
192. *Id.*
193. *Id.*
194. *Id.* at 23-4; *Biotechnology Regulatory Services*, U.S. DEP'T OF AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology (last visited Apr. 30, 2017).
195. *Id.* at 24.; *Am I Regulated Under 7 CFR Part 340?*, U.S. FOOD & DRUG ADMIN., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated (last modified Sep. 12, 2018).

evaluated by APHIS for risk as a plant pest or noxious weed" will still be subject to approval.[196]

Additionally, the USDA has jurisdiction under the Virus-Serum-Toxin Act (VSTA) to regulate GMOs in veterinary biologics and the USDA's Food Safety and Inspection Service (FSIS) regulates meat, poultry, eggs, and fish under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act respectively.[197] Veterinary biologics always have post-approval requirements and are required to immediately report any data concerning the "purity, safety, potency, or efficacy of a product."[198] The FSIS is supposed to inform the public and stakeholders of any decisions involving GE animals.[199] In the 2017 Update, FSIS stated that it "will utilize ask FSIS, a Web-based computer application, designed to help more effectively respond to technical and policy-related questions, including determinations regarding GE product[s], from inspection program personnel, industry, consumers, other stakeholders, and the public."[200]

The USDA's programs provide plenty of opportunities for feedback and the agencies under it have made efforts to provide guidance to developers.[201] The USDA made real efforts to modernize its rules and the application process through the 2017 Update. Though the USDA has a level of statutory authority over GM animals, the FDA does not appear to have involved them in a significant way when evaluating the AquAdvantage salmon. Involving the USDA more in the process may, at the very least, emphasize the importance of process transparency and stakeholder investment. Recognizing the vast capital investment required to bring a new GM product through the approval process may bring internal attention to the fact that the FDA's foot-dragging, if continued, will chase away developers.

In the past, however, there have been concerns that the USDA is too motivated by stakeholder investment. Scholars have argued the USDA was at one time, and maybe even still, controlled by the lumber and agribusiness industries.[202] They argue this control resulted in producer friendly policies

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196. Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 7,008, 7,016 (Jan. 19, 2017) (to be codified at 7 C.F.R. pt. 340); Kelly Servick, *Proposed U.S. Biotech Rules Raise Industry Hopes and Anxieties*, SCIENCE (Jan. 27, 2017, 1:30 PM), http://www.sciencemag.org/news/2017/01/proposed-us-biotech-rules-raise-industry-hopes-and-anxieties.

197. *See generally* 21 U.S.C. §§ 151-9 (2018) (regulating veterinary products for domestic animals); *See* 21 U.S.C. §§ 601-95 (2012); 21 U.S.C. § 451 (2012); Egg Product Inspection, 21 U.S.C. §§ 1032.

198. 2017 UPDATE, *supra* note 107, at 25.

199. *Id.* at 26-7.

200. *Id.* at 27.

201. 2017 UPDATE, *supra* note 107, at 5.

202. Jason Waanders, *Growing A Greener Future: USDA and Natural Resource Conservation*, 29 ENVTL. L. 235, 275 (1999).

while conservationists were left by the wayside.[203] The potential conflict of interest between assisting producers and setting dietary guidelines has long been a point of concern for many members of the public.[204] Most notable are the concerns over the USDA's promotion of dairy products, which some argue are linked to many health risks and should not be promoted so heavily by a department of the United States.[205] The USDA has also been the subject of several discrimination lawsuits. One such batch was over the servicing of farm loans for Hispanic and woman growers.[206] These lawsuits and concerns over special interests may serve to cancel out any goodwill that would come from the USDA's feedback policies in review processes. If the public does not trust the agency to be unbiased, even a transparent review process may not engender confidence on the safety of new technologies that get approved. The public already has a skeptical view of GMOs, a poor public opinion of the reviewing agency would not help anything, but the USDA has been working to be more inclusive and unbiased.

The 2008 Farm Bill created the Office of Advocacy and Outreach (OAO) within the USDA.[207] In 2015, the USDA announced $8.4 million in grants to "provide training, outreach and technical assistance for socially disadvantaged, tribal and veteran farmers and ranchers."[208] The Farm Service Agency, which manages loans for new farmers, has an additional pot of money set aside specifically for minority and women farmers and ranchers.[209] The agency also has a Student Diversity Program which teaches

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203. *Id.*

204. Green, *Not Milk: The USDA, Monsanto, and the U.S. Dairy Industry*, ALTERNET (July 8, 2002, 7:00 pm), http://www.alternet.org/story/13557/not_milk%3A__the_usda%2C_monsanto%2C_and_the_u.s._dairy_industry; Evelyn Theiss, *Should the USDA make Dietary Guidelines while it promotes meat and dairy industry?*, CLEVELAND.COM, (March 8, 2011 9:24 AM), http://www.cleveland.com/healthfit/index.ssf/2011/03/should_the_usda_make_dietary_g.html.

205. Michael Moss, *While Warning About Fat, U.S. Pushes Cheese Sales,* N.Y. TIMES (Nov. 6, 2010), https://www.nytimes.com/2010/11/07/us/07fat.html.

206 . Stephen Carpenter, *The USDA Discrimination Cases: Pigford, InRe Black Farmers, Keepseagle, Garcia, and Love*, 17 DRAKE J. AGRIC. L. 1, 33 (2012); Associated Press, *Lawmakers Urge U.S.D.A. to Discuss Bias Complaints*, N.Y. TIMES (Dec. 26, 2015), https://www.nytimes.com/2015/12/27/us/lawmakers-urge-usda-to-discuss-bias-complaints.html?_r=0; Kari Lyderson, *Native American Farmers and Ranchers Press USDA on Bias Complaints*, WASHINGTON POST (July 30, 2010), http://www.washingtonpost.com/wp-dyn/content/article/2010/07/29/AR2010072905738.html.

207. U.S. DEPT. OF AGRIC., *About the Office of Advocacy and Outreach*, https://www.outreach.usda.gov/aboutus.htm (last visited Sept. 22, 2018).

208. Press Release, U.S. Dept. of Agric., USDA Announces $8.8 Million to Support a Diverse Next Generation of Farmers and Ranchers (Sept. 28, 2015), available at https://www.usda.gov/media/press-releases/2015/09/28/usda-announces-88-million-support-diverse-next-generation-farmers.

209. FARM SERV. AGENCY, MINORITY AND WOMEN FARMERS AND RANCHERS, https://www.fsa.usda.gov/programs-andservices/farm-loan-programs/minority-andwomen-farmers-and-ranchers/index (last visited Sep. 27, 2018).

students about current issues in agriculture.[210] In 2016, the USDA won the Federal Agency of the Year award from the League of United Latin American Citizens.[211] Under the direction of Tom Vilsack, the USDA made major strides in their diversity efforts, improving the discrimination complaint process and establishing official policies to prevent discrimination based on age and English proficiency.[212] With the number of farmers in the United States continuing to plummet, the USDA saw a 21 percent increase in Hispanic farmers and a 12 percent increase in black farmers between 2007 and 2012.[213] Despite its poor history, the USDA is working to increase its diversity and get rid of any cultural biases that may exist in the agency.[214] The USDA's efforts to repair its relationship with minority groups should give some confidence to anyone who doubts the agency's neutrality. As the head of any GMO review framework, they are liable to receive negative feedback based on previous mistakes. However, the USDA's transparent review process policies are much better than those of the FDA and would help the public begin to understand and embrace GMOs.

C. EPA

The EPA has authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to regulate "the sale, distribution, and use of all pesticides, including those produced through genetic engineering."[215] The EPA will approve a product for use if the adverse effect on the environment is not unreasonable.[216] The EPA is supposed to balance the economic, social, and environmental costs of using the product.[217] The EPA is also in charge of evaluating any human dietary risks that may arise from residues of pesticides.[218] "FIFRA provides EPA broad authority to establish or modify data needs and timing for registrations to achieve program and statutory objectives"[219] and "the Agency can issue data waivers, accept additional data

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210. OFFICE OF THE CHIEF ECONOMIST, STUDENT DIVERSITY PROGRAM, https://www.usda.gov/oce/forum/diversity/diversity_program.htm (last visited Sep. 27, 2018).

211. Tom Vilsak, *The People's Department: A New Era for Civil Rights at USDA*, MEDIUM (Aug. 2, 2016), https://medium.com/usda-results/https-medium-com-usda-results-chapter-8-b57f91b64d49.

212. *Id.*

213. *Id.*

214. *See generally Id.* (describing steps the USDA took to eliminate discrimination and increase diversity).

215. 2017 UPDATE, *supra* note 104, at 10 (citing 7 U.S.C. § 136a(a)).

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.*

or accept alternative approaches as appropriate."[220] For any experimental testing covering more than 10 acres, developers must receive an Environmental Use Permit. This permit allows the EPA to set acre limits and other protective conditions on a product's use while developers collect data to support their applications.[221] Following approval, developers are required to pay maintenance fees on their product registration and, much like the other agencies, submit any negative findings immediately.[222]

The EPA also has jurisdiction over dietary risks through the FDCA.[223] Developers must gain a "tolerance" or "tolerance exemption" from the EPA before marketing foods for humans or animals.[224] Tolerances or exemptions may be temporary and may be modified or revoked at any time.[225] Tolerances set by the EPA are enforced by the FDA.[226]

Through the Toxic Substances Control Act (TSCA), the EPA also has jurisdiction over new and existing chemical substances, including those produced using biotechnology.[227] Other statutes cover food, food additives, drugs, cosmetics, medical devices, pesticides, tobacco, nuclear material, and firearms.[228] Similar to the FIFRA process, the EPA evaluates the potential environmental and health risks associated with a particular new chemical before allowing it to be manufactured and distributed.[229] The EPA publishes a notice when it approves a new chemical substance.[230]

While the EPA may not provide the mid-application commenting opportunities of the USDA, in the 2017 Update, the EPA claims to have an online tool for developers to determine their regulatory status.[231] In actuality, the EPA is steering developers towards the same online comment form any concerned citizen would use.[232] This is likely a very busy communication channel for the EPA and does not seem like the best method for such a specific need. A cursory search does not provide any more information on

220. *Id.* at 11.
221. *Id.*
222. *Id.*
223. 21 U.S.C. § 346a(b)(2)(i) (2012).
224. 2017 UPDATE, *supra* note 104, at 12.
225. *Id*. at 13.
226. *Id.*
227. 15 U.S.C. § 2601-97 (2012).
228. 2017 UPDATE, *supra* note 104, at 13 (citing 15 U.S.C. § 2601-97 (2012).
229. *Id.* at 14.
230. *Id.*
231. *Id.*
232. ENVTL. PROT. AGENCY, CONTACT US ABOUT THE REGULATION OF BIOTECHNOLOGY UNDER TSCA AND FIFRA, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/forms/contact-us-about-regulation-biotechnology-under (last visited Oct. 9, 2018).

the possibility of a "pre-notice consultation," though the EPA's section of the 2017 Update makes it sound like this is a normal, common tool.[233]

Compared to the FDA and USDA, the EPA's regulatory jurisdiction is limited. Therefore, even though they are the "Environmental" Protection Agency, their expertise in evaluating environmental concerns from biotechnology may also be somewhat limited. In 1998, the EPA approved StarLink corn.[234] The EPA determined that the Bt toxin engineered into the corn may be allergenic if consumed by humans but approved it for use in animal feed.[235]

> Because of the biology of corn and the nature of the U.S. crop-handling system, however, segregating StarLink corn from the food supply proved to be extremely difficult. In September 2000, genes from StarLink corn were detected in taco shells and other corn products intended for human consumption, a clear violation of its registration. This discovery resulted in huge recalls of food products containing the genetically engineered corn.[236]

When reports of StarLink contamination in products intended for humans started coming in, the EPA asked the FDA to intercede and remove StarLink from the market.[237] The EPA issued a formal recall and everyone thought the product was gone until it reappeared in Saudi Arabia in 2013.[238] Though most GMOs are relatively safe, StarLink is an example of how difficult it can be to contain a product and how far contamination can spread.[239] It will be very important, as the number of GMOs grow, to ensure that products are both safe and able to be separated in the pipeline if necessary.

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233. 2017 UPDATE, *supra* note 104, at 14.

234. FEDERATION OF AMERICAN SCIENTISTS, INTRODUCTION TO THE AGRICULTURAL BIOSECURITY CASE STUDIES, *Agricultural Biotechnology: Safety, Security and Ethical Considerations, StarLink Corn: A Cautionary Tale*, https://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html (last visited Jan. 16, 2018).

235. *Id*.

236. *Id.*

237. Letter from Joseph A. Levitt, Center for Food Safety Director, to Steve Johnson, U.S. Envtl. Prot. Agency Acting Assistant Administrator (Jun. 12, 2001), https://archive.epa.gov/scipoly/sap/meetings/web/pdf/letter.pdf.

238. *StarLink Resurfaces: GM Corn Banned Decade Ago Found in Saudi Arabia*, RT NEWS (Aug. 27, 2013), https://www.rt.com/news/banned-gm-resurfaces-saudi-arabia-074/.

239. *StarLink Corn: A Cautionary Tale*, FED'N OF AM. SCI., https://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html. (last visited Sept. 26, 3018); *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG. (May 2014), www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/.

The EPA is an official part of the Coordinated Framework and should be actively involved in the approval of GM products. The FDA's failure with the review and monitoring of StarLink are proof that the entirety of the Framework should be responsible for reviewing GMOs. This is especially true since the EPA has so many monitoring programs tracking the status of environmental conditions like air quality, water quality, and erosion.[240] The EPA also works closely with local agencies to ensure that states meet drinking water and air quality standards.[241] Therefore, the EPA is an important resource for evaluating the potential environmental effects of new GMOs, which will be vital to avoid the issues that come with a lack of biodiversity.

Genetic engineering can create disease- and pest-resistant crops, but can also result in species becoming extremely similar—even to the point of danger. A particular example of this issue is the banana.[242] Because they were planted or exported by United Fruit in the late 1800s, most banana trees across the world are genetically similar.[243] Most of the plants were created through a form of cloning.[244] This created a banana—the Gros Michel—that was ideal for consumers and shippers, but every Gros Michel tree was resistant or susceptible to the same diseases.[245] In the early 1900s, a Panamanian disease appeared in Guatemala, where most bananas were grown.[246] The Gros Michel banana variety was quite susceptible to the disease, and because the trees were clones, the disease spread easily.[247] As Gros Michel banana trees started dying off, United Fruit began replacing them with Cavendish bananas.[248] Now, the Cavendish variety is even more dominant than the Gros Michel was at the time of the blight.[249] Consequently, the next foreign disease to come through will likely wipe out almost all

240. EPA, MONITORING PROGRAMS, https://www.epa.gov/measurements/monitoring-programs (last visited Sept. 24, 2018).

241. EPA, REGULATORY INFORMATION BY TOPIC: WATER, https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-water#drinking (last visited Sep. 27, 2018); EPA, PUB. NO. EPA-456/K-07-0013, THE PLAIN ENGLISH GUIDE TO THE CLEAN AIR ACT 3 (2007), https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-air (last visited Oct. 9, 2018).

242. Rob Dunn, *Humans Made the Banana Perfect – But Soon, It'll Be Gone*, WIRED (Mar. 14, 2017), https://www.wired.com/2017/03/humans-made-banana-perfect-soon-itll-gone/?mbid=nl_31417_p2&CNDID=.

243. *Id.*

244. *Id.*

245. Nathaniel Scharping, *The Banana As We Know It Is Dying…Again*, DISCOVER (Dec. 27, 2017), http://blogs.discovermagazine.com/crux/2017/12/27/banana-fungus-panama-disease/#.WlwlMqhKuhc.

246. *Id.*

247. *Id.*

248. *Id.*

249. *Id.*

commercially produced bananas grown today. This situation is similar to that of the Florida Orange, and while GE can help us fight diseases, over commitment to GE may do more harm than good.[250] It will be important to have all hands on deck as we continue to review GMOs especially if the Coordinated Framework's goal is to complete comprehensive evaluations.

III. PROPOSED CHANGES TO THE FRAMEWORK

The Pew Initiative on Food and Biotechnology, after a study on the Coordinated Framework, noted that one of the main arguments against changing the system was that "[t]here is no scientific justification for changing the regulatory system."[251] Another argument claims the following:

> The concerns about inadequate or uncertain authority in the current system and coverage of future genetically engineered plants and animals are not significant. Agencies have sufficient flexibility in their laws to reach all biotechnology products that might raise concerns. Uncertainty and possible duplication can be clarified through agency policy guidance. While agencies may have to creatively and expansively interpret their legal authority to reach some biotechnology products, the risk that these interpretations will be successfully challenged—and that some products might go unregulated—is actually very low. As a practical matter, technology developers are unlikely to challenge an agency's questionable assertion of jurisdiction over its GE products, out of concern that the marketplace will reject a product if an agency claims that the developer has evaded a review or approval process.[252]

While there may be no scientific justification, agencies should not be "creatively interpreting" their legal authority. One argument, gathered by the Pew Initiative, in favor of changing the system focuses on the fact that the Coordinated Framework is behind current technology:

> The regulatory system needs to be improved in order to catch up with the technology, and a failure to do so could not only pose human health and environmental risks, but undermine public trust in the regulatory system and jeopardize market

250. *Id.*
251. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 109 at 19.
252. *Id.*

> acceptance of agricultural biotechnology. The gaps and inadequacies in the current system are becoming increasingly apparent with the development of new biotechnology products that do not fit into the system.[253]

Several others note that "[t]rust in government regulators is a critical component to build market acceptance of a new technology" and "stretching an agency's authority through creative legal interpretations can strain credibility and trust in the system."[254] For the public to believe in the safety of GMO crops, the Coordinated Framework needs to change.

While change is necessary, it is unlikely that Congress will create an entirely new agency to handle the regulation of biotechnology. The Coordinated Framework could be simpler if developers of the products covered by multiple agencies could merely submit a single application to one agency which then coordinates with all the others. Given the effort the USDA has put into answering developers' questions, providing comment opportunities to the public, and updating its regulations to more closely match the state of biotechnology, this single application process should flow through the USDA. As shown in Part III(b) above, the USDA has regulatory authority over GM plants, animals, and other organisms. Consequently, all of the overlapping products should only have to go through one application and approval process; products like drugs and miscellaneous chemicals would only go through the singular agency responsible for their approval. A singular agency could reduce the massive amount of paperwork and coordination required to get a new GM product approved. The current process not only chases large companies away but severely limits the abilities of small developers to get their product to market. Although one overarching agency would vastly simplify the process, GM animal developers will have to get used to navigating the agencies already in place.

To truly promote innovation, the program needs to be reasonably navigable for the average developer. Comments to the 2017 Update identified this as an issue:

> Referring to the 1986 Coordinated Framework, which identified a "lead agency" for products requiring regulatory oversight and/or review from multiple agencies, one commenter pointed out that the Proposed Update to the Coordinated Framework does not mention "lead agencies" and noted that identification of a lead agency would make it

253. *Id.* at 20.
254. *Id.* at 18.

> clear to a potential applicant which agency to approach for an initial consultation. Another commenter asked for APHIS to be clearly identified as having the lead role and primary responsibility for regulatory assessments.[255]

Additionally, the USDA regularly coordinates with other agencies. For example, the Huanglongbing Multi-Agency Coordination framework, established in December, 2013 by the USDA, included "representatives from the California, Florida, and Texas citrus industry; Arizona, California, Florida, and Texas State departments of agriculture; USDA's Agricultural Research Service, Animal and Plant Health Inspection Service, and National Institute of Food and Agriculture; and the [EPA]."[256] The group solicited applications for and funded 31 projects across the southeastern United States and California.[257] The EPA also regularly coordinates with other agencies, which is why it is so disappointing that the FDA seemingly failed to meaningfully involve the other agencies in the Coordinated Framework. Comments given in the process of updating the Coordinated Framework addressed this issue:

> Several responses expressed the need for better coordination among regulatory agencies, including on risk assessments and data collection on unintended consequences. One response suggested the creation of a "review" board consisting of representatives from all three regulatory agencies to review all new genetically engineered and non-genetically engineered crops. Another response suggested establishing a group of experts under the National Academy of Sciences (with representation from each regulatory agency) to determine whether a product is exempt from review and creating and publishing decision trees for developers to determine whether and which products are exempt. . . . Another response requested coordination among relevant agencies such that burden on industry with respect to obtaining multiple permits for conducting trials could be

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255. 2017 UPDATE, *supra* note 104, at 59.

256. USDA, *Huanglongbing (HLB) Multi-Agency Coordination Updates* (Jul. 12, 2017), https://web.archive.org/web/20170712105533/https://www.usda.gov/topics/disaster/multi-agency-response-devastating-citrus-disease/huanglongbing-hlb-multi-agency.

257. *Id.*; *HLB-MAC Funded Research*, U.S. DEP'T OF AGRIC. (Jul 12, 2017), https://www.usda.gov/sites/default/files/documents/2016-hlb-mac-funded-projects.pdf, [https://web.archive.org/web/20170520203600/https://www.usda.gov/sites/default/files/documents/2016-hlb-mac-funded-projects.pdf].

> reduced. Some responses also identified specific case studies to highlight these concerns.[258]

Several other comments recommended adding even more agencies to the Coordinated Framework, such as the U.S. Fish and Wildlife Service for environmental assessments.[259] The Fish and Wildlife Service is particularly abreast of issues involving migratory and invasive species. Contamination possibilities for GM animals will likely be much worse than those with plants, since animals have the ability to move on their own. The United States is already fighting many invasive species all over the country. For example, pythons, once kept as pets, often get released by owners who are overwhelmed with the size of the snakes as they grow.[260] As a powerful predator unusual to the region, pythons are thriving in the Everglades, and now researchers are worried that pythons are passing a dangerous lung disease onto native snakes in the area.[261] As GM animals grow in number, the characteristics of GM species could become much different from native species. This could result in the GM species being uniquely suited to survive in their given environment, possibly resulting in invasive-species-like issues. The U.S. Fish and Wildlife Service would be quite valuable in evaluating the possible environmental or ecological effects of new modified species.

Other commenters identified the Department of Defense, Department of Health & Safety, Department of Commerce, and Department of State as agencies which should be involved in the review process.[262] Many of these agencies may be involved in enforcement and regulation after products are approved, so involving them on the front-end would likely be useful. At least, agencies in the Coordinated Framework need to work with other agencies as needed to ensure the products going through the review process are evaluated fully and impartially. The FDA is not currently doing a very good job of coordination, but if the USDA were the lead agency for the Coordinated Framework, consumers would likely see much more collaboration and communication.

Furthermore, the statutes and rules surrounding the application process should be updated to adapt to new technologies, with some forethought to the technologies yet to be developed. Some companies, like Recombinetics,

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258. 2017 UPDATE, *supra* note 104, at 54.

259. *Id.* at 59.

260. FLA. FISH & WILDLIFE CONSERVATION COMM'N, *Nonnatives-Burmese Python*, http://myfwc.com/wildlifehabitats/nonnatives/reptiles/burmese-python/ (last visited Sep. 27, 2018).

261. Jenny Staletovich, *Florida's latest python problem: They may spread disease to other snakes, study shows*, MIAMI HERALD (Dec. 21, 2017), http://www.miamiherald.com/news/local/environment/article190898924.html.

262. 2017 UPDATE, *supra* note 104, at 59.

believe their method of GE does not fall under the current statutes.[263] Recombinetics uses Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), which allows developers to find and edit specific genes.[264] The USDA has determined that plants created with the CRISPR technology will not be regulated, as they do not "contain foreign DNA from plant pests such as viruses or bacteria."[265] Allowing new technologies, such as CRISPR, to go unregulated will not sit well with the average consumer. As a result, the public's attitude toward GMOs is unlikely to change significantly any time soon.

Regulating products by their individual characteristics rather than by the technology used to create them is a nice story to deflect developers' concerns about technological bias; but, it is just a story. The Coordinated Framework already regulates every GM product in some way, and developers are already voluntarily sending applications to the FDA for each new GM crop. Navigating the system would be much easier if developers could presume that all new GM products are regulated through the single system. Agencies could then exclude products as the federal government gains a better understanding of the particular technologies used to create GMOs and their resulting characteristics. The USDA did exactly this with its 2017 updated rulemaking.[266]

Updated rules should also create more transparency to benefit consumers. The USDA provides at least two opportunities for public comment, one of which may be a live discussion. This process begins as soon as a complete application is filed.[267] The FDA's ability to match this process is limited by the laws surrounding drug applications.[268] Updating the laws to take GM animals out of the NADA process would allow agencies the opportunity, at the very least, to announce that a new application had been filed. Hiding the application for the evaluation of new GM products does not improve the public's opinion of GMOs. To overcome the stigma, the public must feel involved in the evaluation process and see the incredible benefits and low risks of properly-regulated GMOs.

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263. Heidi Ledford, *Salmon Approval Heralds Rethink of Transgenic Animals*, NATURE (Nov. 23, 2015), https://www.nature.com/news/salmon-approval-heralds-rethink-of-transgenic-animals-1.18867.

264. *What are genome editing and CRISPR-Cas9?*, U.S. NATIONAL LIBRARY OF MEDICINE (AUG. 2017), https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting.

265. Emily Waltz, *Gene-edited CRISPR mushroom excapes US regulation*, 532 NATURE 293, 293 (2016) (internal quotations omitted); Press Release, USDA, Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (2018) https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation.

266. 2017 UPDATE, *supra* note 104, at 2.

267. *See supra* text accompanying notes 159-62.

268. 21 U.S.C. § 360b(c) (2012).

At the same time, it will be important to ensure that applicants' vulnerable intellectual property is protected throughout the process. Agencies in the Coordinated Framework will need to develop policies to protect the trade secrets associated with products under review. Thomas Corriher has argued that "[a]pproving genetically engineered salmon as a veterinary drug allows for research data to be conveniently hidden from the public, under the guise of trade secrets."[269] It may be that no amount of change to the current process will appease those who believe the FDA is hiding behind intellectual property concerns. However, the USDA's experience communicating with skeptical consumers should be sufficient to increase the transparency while protecting developers.

CONCLUSION

Centering the GM product application process under the USDA will facilitate better communication with developers and consumers. It will also result in more coordination among the relevant agencies and likely make the evaluation process timelier. Increasing transparency in the application process is vital to securing the support of the public. If the United States wants to attract the business of GMO developers, it must make the approval process more expedient. GE technology has incredible potential and as new organisms are developed, the Coordinated Framework must be able to comprehensively evaluate each one.

Researchers are already working on several new GM animals. Researchers at Recombinetics have been working on developing hornless dairy cows.[270] Dairy cows generally have their horns removed at a young age to protect workers at the dairy.[271] Some cattle breeds are naturally hornless, but most cattle breeds are not.[272] Recombinetics's development would eliminate the need to dehorn cows.[273] Hornless cows already exist naturally, so the change should not cause any harmful environmental effects. The GM dairy cows would be very useful to producers, but it is likely that they would get caught up in the review process for a very long time if no change happens, just like AquAdvantage salmon. The current review process of the

269. Thomas Corriher, *The F.D.A. is Using a Unique G.M.O. Salmon Approval Process to Bypass U.S. Regulations*, THE HEALTH WYZE REPORT (Sept. 30, 2009), https://healthwyze.org/reports/499-the-fda-is-using-a-unique-gmo-salmon-approval-process-to-bypass-us-regulations.

270. Servick, *supra* note 185.

271. *Id.*

272. Laine J. Misch, et. al., *An Investigation into the Practices of Dairy Producers and Veterinarians in Dehorning Dairy Calves in Ontario*, 48 CAN. VETERINARY J. 1249 (2007).

273. Servick, *supra* note 185.

Coordinated Framework is detrimental to the development of new GM products. It may also turn out to be detrimental to species that are currently in trouble. The North American honeybee has been dying off in massive quantities for some time now.[274] Every year, 30-40% of America's bee colonies die off and are not replaced.[275] Honeybees have been fighting disease, climate change, lack of food, and parasites.[276] Honeybees are a necessary part of our environment and food supply. They keep other pests at bay and fertilize our crops.[277] Genetic engineering may be able to help them, but if new developments are stuck in review for several decades, we may be unable to save the honeybee. The Coordinated Framework needs to change, and soon.

274. Sean Rossman, *A Third of the Nation's Honeybee Colonies Died Last Year. Why You Should Care*, USA TODAY (May 26, 2017), https://www.usatoday.com/story/news/nation-now/2017/05/26/third-nations-honeybee-colonies-died-last-year-why-you-should-care/348418001.

275. *Id.*

276. *Id.*

277. *Id.*.